

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.

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SHPI

SAFETY ENSURES TOMORROW®

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THOMSON  
FINANCIAL

March 31, 2003

Dear Shareholders,

2002 was a pivotal year for SHPI, as we made significant progress in our transition from a development stage enterprise to a successful operating company. This progress is reflected in our product portfolio advancement, establishment of a manufacturing base, new technology development, and financial performance.

**Product Portfolio**

In 2002 and January 2003, the first four product lines based upon our proprietary safety needle technologies were introduced into the U.S. market. In addition, we completed a development and license agreement for the next product line we expect to be launched. These innovative new products include the following:

- **Monoject Magellan™** (safety syringe needle): Introduced in the second quarter of 2002 by Kendall, a business unit of Tyco Healthcare, Monoject Magellan™ became the first safety needle product line to be launched based upon our patented FlexLoc® technology. Kendall manufactures and markets Monoject Magellan™ under a license agreement with SHPI. Kendall's sales and marketing efforts have been productive, already converting several major accounts and signing important new GPO contracts in the \$260 million U.S. safety syringe needle market.
- **LiftLoc® Safety Infusion Set** (safety Huber needle): The September 2002 launch of our LiftLoc® product line was significant, since LiftLoc® is the first product to be manufactured under our authority and marketed under our own SHPI label. Bard Access Systems, Inc. initiated its private label launch of the complete LiftLoc® product line in December 2002. We supply finished product to Bard, the leader in the field of implanted ports, under a supply and distribution agreement for the acute care market. SHPI branded product is sold through first-tier distributors, including Cardinal Health, Medline and PSS, with a strong presence in the important alternate site markets of oncology and chronic hematology. To support our distributors' efforts we have hired a highly experienced Vice President, Sales & Marketing, put in place four Regional Sales Managers, and established full-time customer service support.
- **Majestik™ Shielded Needle** (safety angiographic introducer needle): In November 2002, Merit Medical Systems, Inc., a leader in the field of proprietary disposable products used in cardiology and radiology procedures, introduced Majestik™ Shielded Needle into the U.S. market. Majestik™ is a safety angiography needle based upon our FlexLoc® technology. Merit manufactures and markets Majestik™ under a license agreement with SHPI.
- **LuproLoc™** (pre-filled syringe safety needle): In January 2003, TAP Pharmaceutical Products Inc. initiated the U.S. market launch of Lupron Depot® with LuproLoc™. Under the terms of a license agreement with SHPI, TAP is attaching our proprietary safety needle device to pre-filled syringes of its blockbuster drug Lupron Depot® (leuprolide acetate for depot suspension), the first pharmaceutical product available with our pre-filled syringe safety needle device and the first product in its class to offer an integral safety needle device on pre-filled syringes. TAP has branded this integral safety needle device LuproLoc™.

	<h1>SHPI</h1>	<a href="http://www.shpi.com">WWW.SHPI.COM</a>
	<small>SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.</small>	
<small>585 WEST 500 SOUTH BOUNTIFUL, UT 84010</small>		<small>T: 801.298.3360 F: 801.298.1759</small>

- **Safety Blood Collection Products:** In May 2002, we announced the completion of a second development and license agreement with Kendall pertaining to our safety blood collection devices. By combining our proprietary integral safety needle device with a one-piece injection molded barrel to prevent cross-contamination, this innovative product line will help protect both the healthcare worker and patient. These products are a natural extension of the Monoject Magellan™ safety syringe product line introduced by Kendall in 2002. Since FDA 510(k) clearance has already been received for this device, we are working with Kendall to rapidly complete commercialization in preparation for product launch.

### **New Technology Development**

To date, our commercialization efforts have been focused on developing product applications based upon FlexLoc®, our first safety needle platform technology. FlexLoc® technology can be characterized as an integral, extensible plastic sheath that is activated with a simple, one-step process to encase the needle after use.

A notable accomplishment in 2002 was the filing of three new patent applications related to SecureLoc™, our second major platform technology. SecureLoc™ technology can be described as an integral safety capsule that automatically senses the end of the needle as it slides down the needle shaft and instantly locks out to encapsulate the needle tip. Activation of a SecureLoc™ device can be active or passive depending upon the product application and/or clinician preference. SecureLoc™ technology can be applied to a wide range of safety medical needles, many currently without a viable safety solution. Our initial product applications of this new platform technology are focused in two major market areas, long specialty needles and safety catheter introducers.

We have a significant program underway for developing safety long specialty needles based upon our SecureLoc™ technology. These needles are used across a variety of medical disciplines, including anesthesiology, oncology, radiology, urology, and cardiology. Initial markets of interest include epidural, spinal, introducer needles, soft tissue and bone biopsy, and others. Together long specialty needles represent a combined market opportunity in excess of \$200 million annually in the U.S.

We have also been making rapid progress in the development of passive safety catheter introducers based upon the SecureLoc™ technology. The intuitive design of our initial product applications would not require clinicians to modify their current technique. Our devices would also minimize the issue of blood splatter or loss of control, as could be the case with some of the existing technologies. The IV catheter market in the U.S. alone represents a \$255 million market opportunity.

### **Financial Performance**

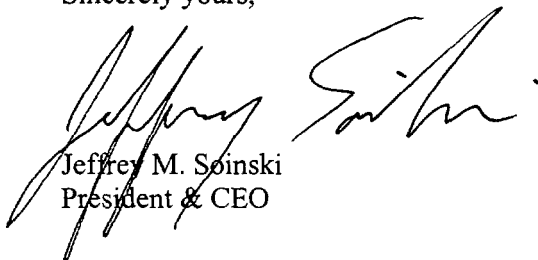
Our financial performance in 2002 reflects our initial strides in making the transition to an operating company environment. Even though three of the four products discussed above were not launched until the fourth quarter of 2002 or January 2003, we did begin to develop positive trends in our financial results. For the year ended December 31, 2002, operating revenues totaled \$1.63 million, more than three times those of 2001. Importantly, 30% of revenues in 2002 were

related to product sales and royalties versus 0% in 2001. Our Gross Profit Margin for 2002 was 82%, an improvement of 22 percentage points versus 2001. Even with these increased revenues and significant product development and commercialization activities, we were able to maintain total Operating Expenses for the year ended December 31, 2002 at \$3.98 million, only a 1% increase versus 2001. We also reallocated our Operating Expenses to the most productive areas in 2002, General & Administrative expenses decreased by 39%, Research & Development increased by 36%, and Sales & Marketing increased by 27% versus 2001. Increased revenues combined with relatively flat operating expenses resulted in an Operating Loss of \$2.65 million for the calendar year ended December 31, 2002, an improvement of \$960 thousand or 27% versus 2001.

We ended 2002 in a strong financial position with sufficient resources to execute our business plan in 2003. Current assets at December 31, 2002 were \$6.4 million, including cash and cash equivalents of \$5.5 million.

The growth of our marketed product portfolio combined with the establishment of an important new platform technology positions our company well for 2003 and beyond. We expect 2003 to be another year with dramatically improved operating results, bringing us closer to our goal of becoming a successful operating company with sustainable revenue and earnings growth based upon multiple product lines and strategic relationships. We believe that this strategy will result in building enduring value for our shareholders.

Sincerely yours,



Jeffrey M. Soinski  
President & CEO

*This letter contains forward-looking statements within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, as amended. Such statements are subject to risks and uncertainties that could cause actual results to vary materially from those projected in the forward-looking statements. The Company may experience significant fluctuations in future operating results due to a number of economic conditions, risks in product and technology development, the effect of the Company's accounting policies and other risk factors detailed in the Company's SEC filings. These factors and others could cause operating results to vary significantly from those in prior periods and those projected in forward-looking statements. Additional information with respect to these and other factors, which could materially affect the Company and its operations, are included on certain forms the Company files with the Securities and Exchange Commission.*



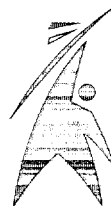
PATIENT # 2357 - JW

HOSPITAL RECORDS

NO. 882357

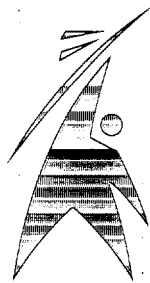
ATTENTION:

Healthcare workers suffer an  
estimated 800,000 injuries from  
accidental needlesticks annually.  
That's why we're here.



**SHPI**

SAFETY ENSURES TOMORROW™



Distinguished by a herald's staff with two white ribbons, the Greek messenger of the gods Hermes was an inventive genius at birth. Because he often flew on winged shoes to help others escape from harm, he became known for his helpfulness to mankind. Over the centuries, his staff evolved into the caduceus, the universal medical symbol of the staff with two intertwined snakes.



**Our safety needles allow medical professionals  
to help others while protecting themselves.**

## AN ACCIDENTAL NEEDLESTICK CAN HURT FOR A LIFETIME.

Healthcare is one of the largest industries in the world and grows larger each year. Healthcare worker safety is and will remain a high priority, high profile issue. Healthcare workers in the U.S. use about 6 billion needles and suffer an estimated 800,000 injuries from accidental needlesticks and other sharps annually.<sup>1</sup>

Diseases that can be acquired from such accidents include HIV/AIDS, HBV (Hepatitis B virus), HCV (Hepatitis C virus), diphtheria, gonorrhea, typhus, herpes simplex virus, malaria, syphilis and tuberculosis.

According to the American Hospital Association, a single case of serious blood-borne pathogen infection can cost more than \$1 million in expenses for follow-up testing, lost work time and disability payments. \$750 million to \$1 billion is spent in the U.S. annually on the testing and treatment of accidental needlestick injuries.<sup>2</sup>

With numbers this tragic and costly, it's easy to see why state and federal legislation have mandated the use of safety medical needles, culminating in the U.S. Needlestick Safety and Prevention Act, effective since April 2001.

While such government regulations are expected to dramatically increase conversions to safety products, the greatest obstacle to conversion may be adequate supply and availability of well-designed and cost-efficient safety products.

<sup>1</sup> Centers for Disease Control and Prevention, *MMWR* 46(2): 21-25

<sup>2</sup> Based upon data in U.S. General Accounting Office Report GAO-01-60R



ESTIMATES INDICATE  
HEALTHCARE WORKERS  
SUFFER 800,000 ACCIDENTAL  
NEEDLESTICKS ANNUALLY.

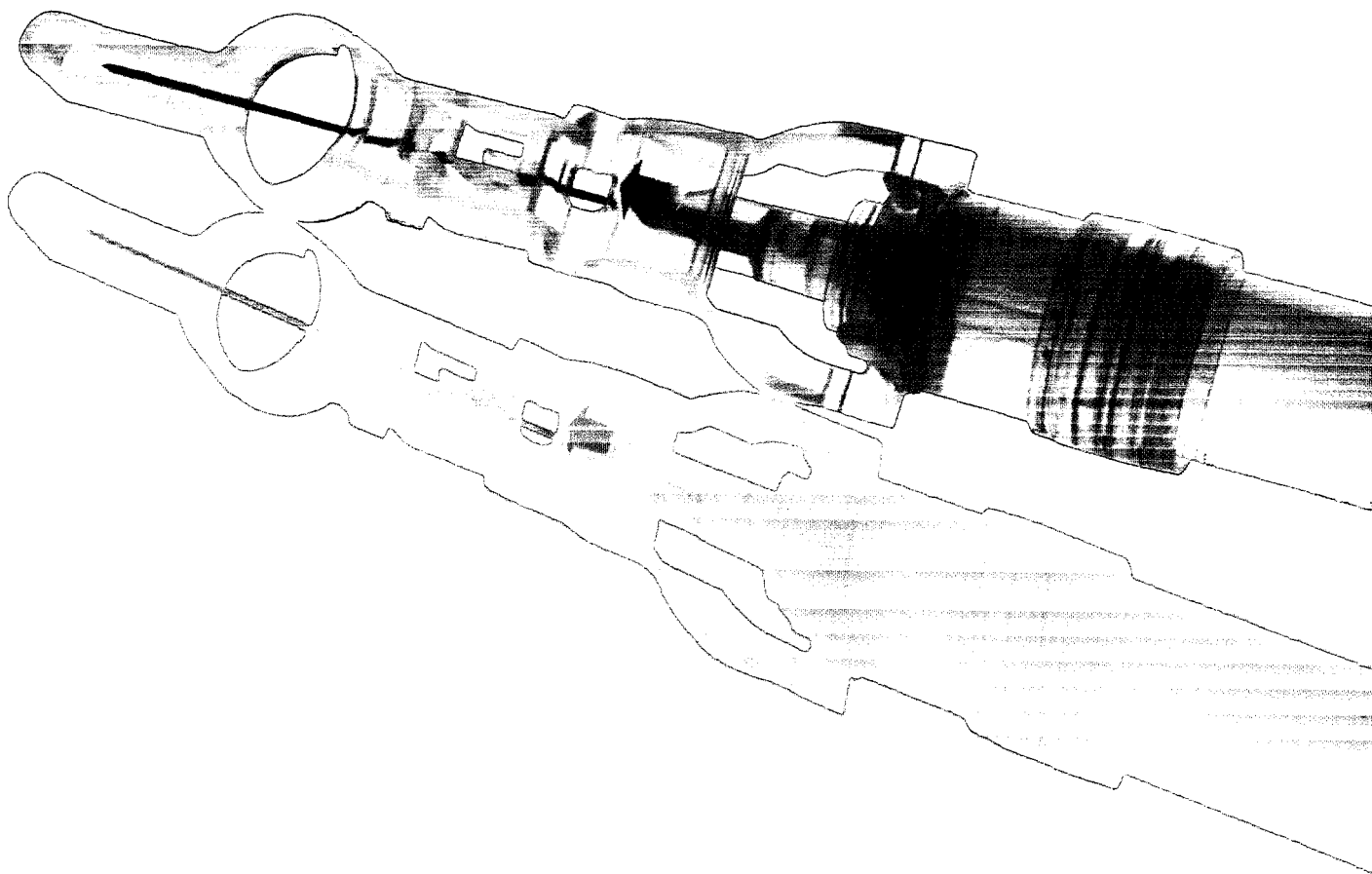


ACCIDENTAL NEEDLESTICKS  
ACCOUNT FOR 86% OF ALL  
OCCUPATIONALLY ACQUIRED  
CASES OF HIV/AIDS.

Source: Centers for Disease Control and Prevention,  
*HIV/AIDS Surveillance Report 8(2): Atlanta, GA 1996*



The U.S. Needlestick Safety and Prevention Act requires healthcare employers to review new safety needle products and mandates their usage by employees.

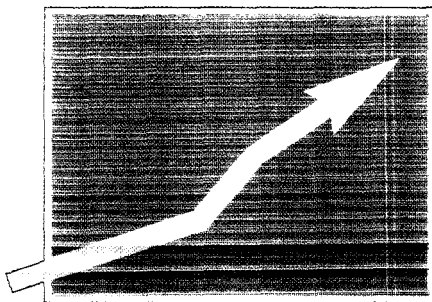


# *Our Vision:* EVERY NEEDLE A SAFE NEEDLE.



CDC REPORTS THAT MORE THAN 80% OF NEEDLESTICK INJURIES CAN BE PREVENTED BY USING SAFETY NEEDLE DEVICES.

Source: U.S. General Accounting Office Report GAO-01-60R



THE DISPOSABLE NEEDLE MARKET IS ESTIMATED TO BE WELL OVER \$1 BILLION A YEAR AND GROWING.

Source: Industry Estimates

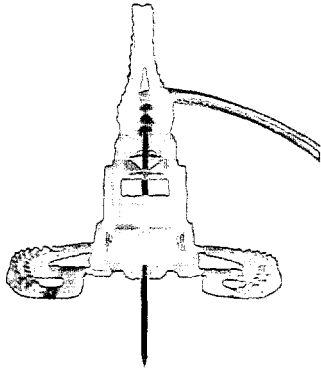
We design and develop cost-effective, innovative safety healthcare products that minimize the risk of accidental needlesticks, which are a leading cause of the spread of blood-borne diseases.

We have 20 highly differentiated, patented safety needle technologies that apply to virtually all medical needles used today. These proprietary technologies are protected by 22 U.S. patents and over 90 U.S. and international patent applications pending.

We manufacture and market certain products under our own label. Other products are supplied to third parties on an OEM basis or licensed to leading manufacturers and marketers in the disposable medical products industry.

There is a significant and growing market opportunity for our innovative and patent-protected safety needle products. The current U.S. market for disposable medical needles is well in excess of \$1 billion and growing.

# *Our Mission:* LEADERSHIP

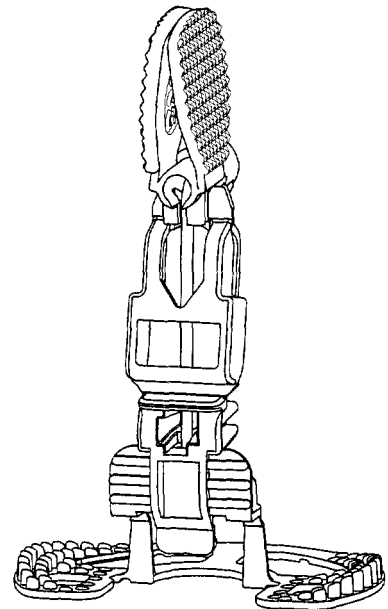


Our mission is to be the leader and innovator in disposable medical safety sharps products, with an initial focus on safety medical needles.

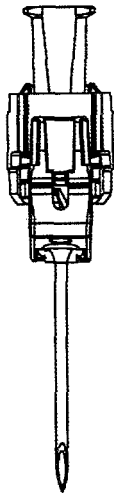
Our strategy to achieve this mission involves: 1) capturing significant market share of targeted product segments, 2) broadening existing product lines, and 3) developing new products and seeking additional market opportunities.

*We specialize in products that provide the following features and benefits:*

- Excellent functionality for the intended medical use.
- Similar or enhanced clinical technique versus conventional products.
- Comparable, improved or additional ancillary clinician or patient benefits (*e.g.*, comfort or convenience).
- Efficient/low cost manufacturability to provide attractive margins at a reasonable price.
- Superior safety technology to prevent accidental exposure to blood borne pathogens.



# Our Business Model: PARTNERSHIP



**Kendall (Tyco)**

**Bard**

**Merit**

**TAP (Takeda-Abbott)**

MANY OF OUR PRODUCTS GO TO MARKET UNDER THE NAMES OF INDUSTRY-LEADING PARTNERS.

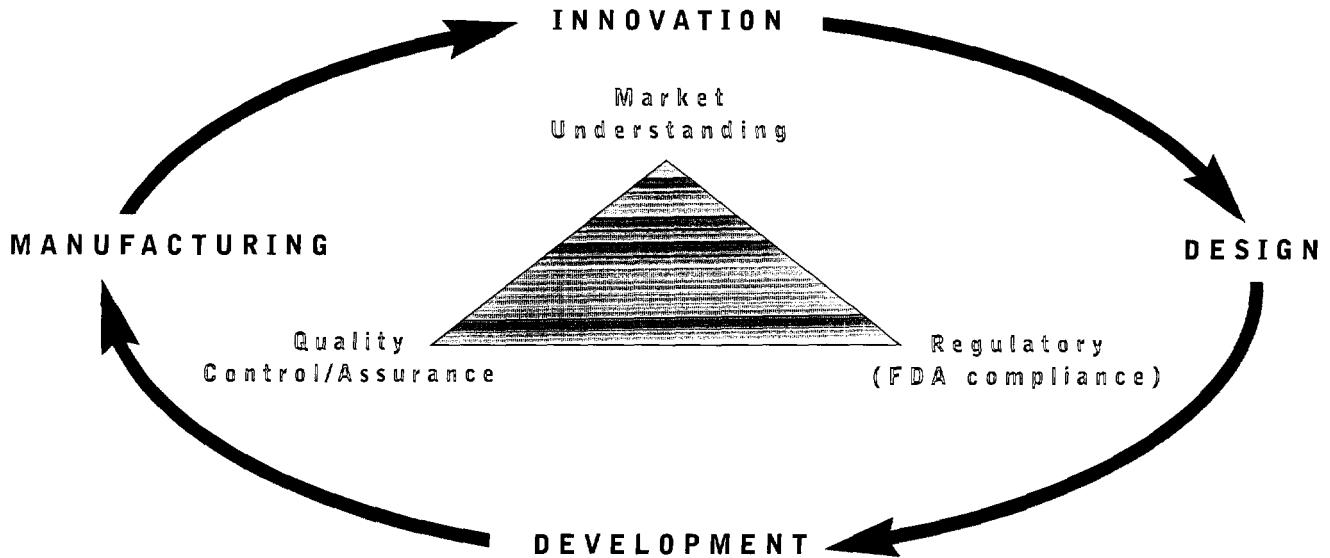
Our business model is to enter into licensing, OEM supply, or distribution agreements for our products, rather than engage in direct sales of products to end-users.

We operate under product agreements relating to specific technologies and product lines with Kendall, a business unit of Tyco Healthcare, TAP Pharmaceutical Products Inc., Merit Medical Systems, Inc. and Bard Access Systems, Inc., a subsidiary of C.R. Bard, Inc.

We have distribution agreements in place with Cardinal Health, Medline Industries, Inc., and Physician Sales and Service, Inc. ("PSS") for products marketed under our own SHPI label. Additional discussions are ongoing with potential partners for other applications of our proprietary technologies.

OEM supply or distribution arrangements are our preferred business relationship for targeted specialty products. Out-licensing opportunities are pursued for high volume product opportunities where efficient and low cost manufacturing is unfeasible at a contract manufacturer, or when a large capital investment is required to scale-up manufacturing.

# *Our Capabilities:* **COMPREHENSIVE**

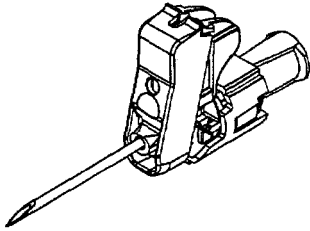


From concept to market, we are fully-equipped to imagine, design, develop and manufacture medical safety products. It all begins with market understanding. Before R&D begins, our world-class specialists interview clinicians, observe their techniques, and develop an intricate understanding of their safety device requirements. This understanding then drives product concept and design.

During the design process, our deep background in regulatory issues, including FDA compliance, ensures that products are ready for market as early as possible. This expertise, along with extensive experience in quality control and assurance, also impacts our efficiency in manufacturing and delivering a quality product from our manufacturing partners.

Once a product is ready to launch, our dedicated sales, marketing and customer service staff stand ready to assist our distributors and strategic partners in their marketing efforts.

# Our Products: PATENTED AND EXCLUSIVE



## SHPI SAFETY NEEDLE SOLUTIONS

SYRINGE

HUBER

BLOOD COLLECTION

PRE-FILLED SYRINGE

GUIDEWIRE INTRODUCER NEEDLES

IV CATHETER

PICC INTRODUCER NEEDLES

WINGED NEEDLE SETS

EPIDURAL

SPINAL

BIOPSY

PLASMA APHAERESIS SETS

DIALYSIS SETS

OTHER SPECIALTY NEEDLES

Our patent-protected safety needle technologies are the basis for a wide range of safety needle products. These products apply to virtually all medical needles used today.

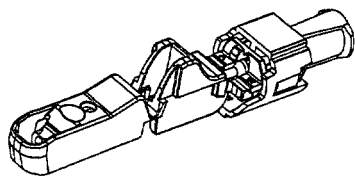
Ongoing research and development are intended to maintain and expand our leadership position in safety needle technologies. The following pages offer a detailed description of our initial safety needle products.

**22** U.S. PATENTS

**90** U.S. AND INTERNATIONAL  
PATENTS PENDING

## SAFETY SYRINGE NEEDLES

# 1



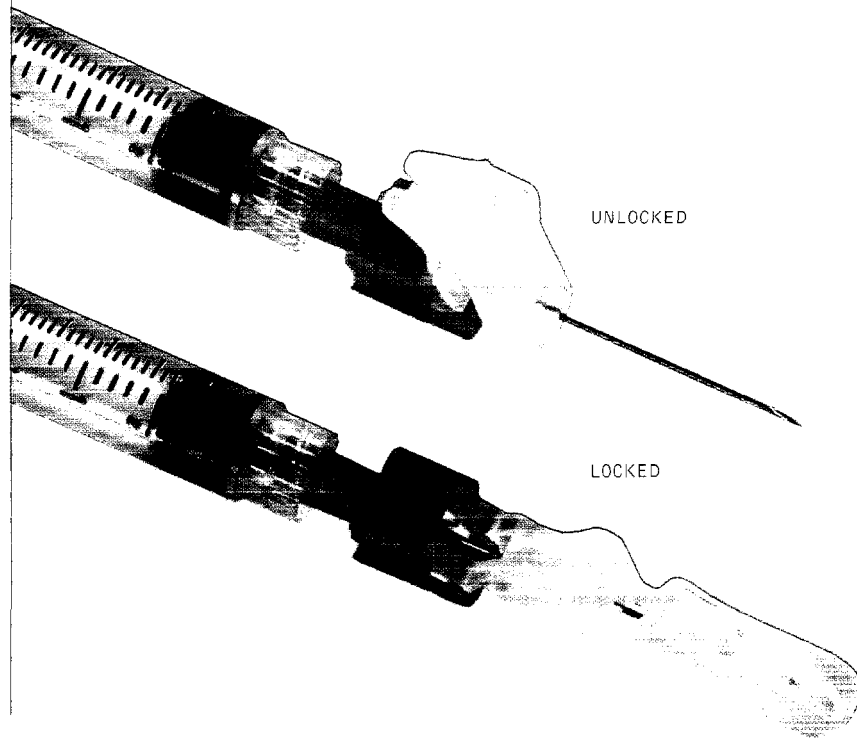
THERE IS SIGNIFICANT RISK  
OF ACCIDENTAL NEEDLESTICKS  
DURING SYRINGE NEEDLE USE.

**M**onoject Magellan™ is a single use, disposable safety syringe needle. This innovative product features engineering controls designed to provide a high level of safety, while conforming to user technique. It is low-cost, intuitive and easy-to-use. The integral safety mechanism is activated by a simple press with the thumb or finger, or by pressing the device against a solid surface such as a counter or tabletop. Monoject Magellan™ is packaged in a sterile, easy-to-open peel pack.

### Monoject Magellan™ features include:

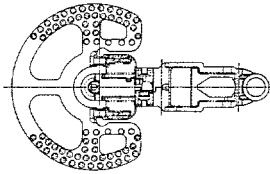
- Easy one-handed activation
  - Minimizes training and in-service
- Needle based engineering control
  - Promotes clinical flexibility
- Robust safety shield covers entire needle
  - Maximizes protection from sharps injury
- Complete 15 SKU product line in a variety of needle lengths and gauges
  - Simplifies standardization to safety

*Monoject Magellan™ is manufactured and marketed by Kendall, a business unit of Tyco Healthcare and a leading marketer of syringe needles. The Monoject Magellan™ product line competes in the \$260 million U.S. safety needle and syringe market.*



# LIFTLOC® SAFETY HUBER NEEDLES

# 2



A MAJOR CAUSE OF ACCIDENTAL NEEDLE STICK INJURIES FROM HUBER NEEDLES IS DUE TO THE "REBOUND EFFECT."

LiftLoc® Safety Infusion Set incorporates a Huber type needle into an integral safety needle device. Huber needles are used to access surgically implanted, subcutaneous vascular access ports on a repeated basis. As such, they are hollow-bore and potentially blood-contaminated at the time of removal, with a significant need for an effective safety solution. An estimated 47% of accidental needlestick injuries from Huber needles is due to the "rebound effect,"<sup>1</sup> which occurs during needle withdrawal from the implanted port.

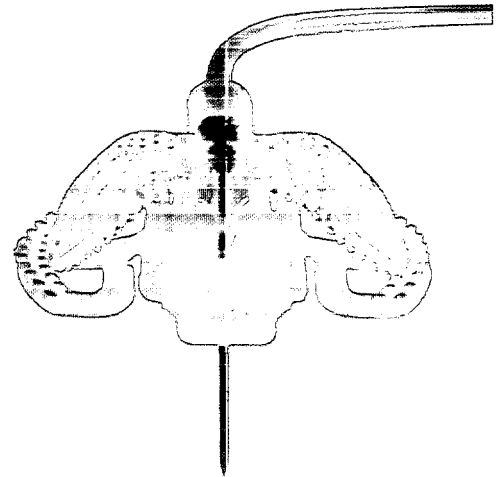
LiftLoc® features a robust safety shield that is deployed as the needle is withdrawn from the port, effectively reducing the risk of accidental needlesticks, including rebound injuries. A unique Patient Comfort Pad™ is packaged with each LiftLoc® set. The Patient Comfort Pad™ is made of breathable felted foam that creates a soft uniform barrier between the Huber needle's wings and the patient's skin. Its use is optional.

LiftLoc® Safety Infusion Set is the first product to be manufactured under our authority and supervision. And, the first product to be marketed under the SHPI brand.

*LiftLoc® Safety Infusion Set is distributed in the hospital market on a private label basis by Bard Access Systems, Inc., a leader in the field of implanted ports. The product line is distributed under the SHPI label by Cardinal Health, Medline Industries, Inc., and Physician Sales and Service, Inc. ("PSS"). LiftLoc® Safety Infusion Set competes in the \$46 million U.S. Huber needle market.*

#### LiftLoc® Safety Infusion Set features include:

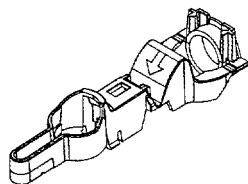
- Conforms to current user technique
- Reduces the risk of accidental needlestick injuries
- Non-coring Huber needle
- Capped "Y" site for needleless access
- Low profile, easy-to-dress
- Latex free



<sup>1</sup> Janine Jagger, MPH, PhD, *Avoiding rebound injuries from Huber needles.* (nursing precautions), Nursing, April 1999



## PRE-FILLED SYRINGE SAFETY NEEDLE DEVICE



PRE-FILLED SYRINGES ARE A SIGNIFICANT DRUG DELIVERY MODALITY, WITH A STRONG NEED FOR AN EFFECTIVE, COST-EFFICIENT SAFETY NEEDLE SOLUTION.

A wide range of drugs, from high volume vaccines to many of today's newer drugs are delivered via pre-filled syringes. Prefilled syringes are used to deliver drugs in a variety of forms, including liquids, gels, lyophilized (freeze-dried) drugs, or a combination of liquid and dry in a multiple chamber syringe.

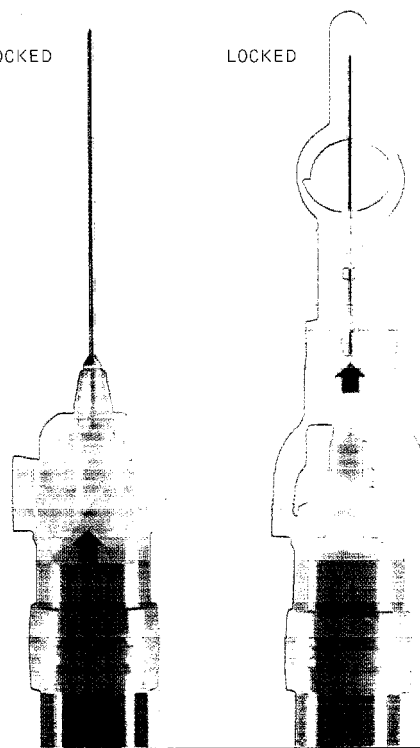
We have developed a proprietary safety needle device that is adaptable to a wide variety of pre-filled syringes. This device provides intuitive, one-handed activation. Additionally, the device is designed for easy integration into pharmaceutical manufacturing. Our device can be applied to the pre-filled syringe after filling and before final packaging. This minimizes capital investment and speeds integration.

Lupron Depot® (leuprolide acetate for depot suspension), marketed by TAP Pharmaceutical Products, is the first pharmaceutical product available with our pre-filled syringe safety needle device and the first product in its class to offer an integral safety needle device on pre-filled syringes.

*TAP Pharmaceutical Products Inc. (Takeda-Abbott) is the first major pharmaceutical company to attach our innovative safety needle device to its pre-filled syringes. The U.S. market for pre-filled syringes is estimated to be in excess of \$100 million annually.*

UNLOCKED

LOCKED



## SAFETY BLOOD COLLECTION DEVICES

## 4

COMBINING A PROPRIETARY SAFETY NEEDLE DEVICE WITH AN INTEGRAL BARREL HELPS PROTECT BOTH THE HEALTHCARE WORKER AND PATIENT.

The present method for drawing blood from patients for blood tests involves insertion of a needle, which is attached to a barrel, into a blood vessel. Blood is then obtained by way of vacuum pressure, most often into a small evacuated tube-like container inserted into the barrel. After blood is drawn, the needle is manually removed from the patient. At this point, the collection tube, barrel and needle are often set aside on a tray or table. Then the needle is usually unscrewed from the barrel and discarded into a sharps container, while the barrel is often used again with another patient (increasing the risk of cross-contamination).

We have developed a family of safety blood collection (phlebotomy) products that have a unique, one-piece injection molded barrel with an integral safety needlestick prevention feature. Since the blood collection barrel is integral to the needle assembly, our safety phlebotomy device ensures that a new barrel is used for each patient. Our product offers easy one-handed activation and has been highly rated in market acceptance studies. The FDA has already granted 510(k) clearance for marketing this device.

*The safety blood collection product line will be manufactured and marketed by Kendall, a business unit of Tyco Healthcare. It will compete in the \$130 million U.S. blood collection needle market.*



## SAFETY ANGIOGRAPHIC NEEDLES

5

SAFETY AND INTUITIVE OPERATION FOR THE MILLIONS OF ANGIOGRAPHY PROCEDURES PERFORMED ANNUALLY.

The Majestik™ Shielded Needle is a proprietary safety angiographic needle. Angiographic needles are used to provide vascular access for the introduction of guidewires or other devices during diagnostic or therapeutic procedures, primarily in the fields of cardiology and radiology.

The Majestik™ Shielded Needle is intuitive and easy-to-use. After using the needle, the clinician simply presses a button to mechanically extend a safety shield over the needle. Once the device is locked around the needle, the entire unit is then discarded into an approved sharps container.

The Majestik™ Shielded Needle features include:

- Simple, one-step activation
- 18 gauge 7cm needle
- Top or right orientation
- Normal or ribbed hub
- Integral safety device covers entire needle
- Fits in standard sharps container

*Majestik™ Shielded Needle is manufactured and marketed by Merit Medical Systems, Inc., a leading manufacturer and marketer of proprietary disposable products used in cardiology and radiology procedures. Approximately 10 million angiography procedures are performed each year worldwide.*



## NEW TECHNOLOGY

# 6

SECURELOC™ TECHNOLOGY ADDS SAFETY TO A WIDE RANGE OF MEDICAL NEEDLES, MANY CURRENTLY WITHOUT A VIABLE SAFETY SOLUTION.

SecureLoc™ technology is an integral safety capsule that automatically senses the end of the needle as it slides down the needle shaft and instantly locks out to encapsulate the needle tip. Activation of a SecureLoc™ device can be active or passive depending upon the product application and/or clinician preference. Our initial product applications of this new platform technology are focused in two major market areas, long specialty needles and safety catheter introducers.

### **Safety Long Specialty Needles**

**There is no integral safety alternative available for most long specialty needles.**

We have a significant program underway for developing safety long specialty needles based upon the SecureLoc™ technology. These needles are used across a variety of medical disciplines, including anesthesiology, oncology, radiology, urology, and cardiology. Initial markets of interest include epidural, spinal, introducer needles, soft tissue and bone biopsy, and others. Together long specialty needles represent a combined market opportunity in excess of \$200 million annually in the U.S.

Due to their length, these specialty needles present unique challenges for developing an effective safety system that does not interfere with clinical technique. SecureLoc™ effectively addresses these problems. In

addition, SecureLoc™ can be efficiently manufactured and installed onto existing long specialty needles.

### **Safety Catheter Introducers**

**The IV catheter market in the U.S. alone represents a \$255 million market opportunity.**

Catheter introducers are devices that insert catheters into veins or other areas of the body using a catheter insertion needle to allow blood or other fluids to be removed from or delivered into the patient's body. Peripheral IV catheter use presents a risk for clinician exposure to blood-borne pathogens similar to those faced in drawing blood. Inserting a catheter involves a percutaneous (*i.e.*, through the skin) needlestick followed by threading the catheter over the needle into a patient's vein or artery.

We have developed proprietary safety needle products for catheter insertion based upon our SecureLoc™ technology. These products provide passive needle protection in an intuitive design that is integral to the catheter introducer. Clinicians would be able to use our passive safety catheter introducers without modification to their current technique and still have effective protection. Our products also minimize the issue of blood splatter or loss of control as is the case with some of the existing safety catheter introducers.

## EXPERIENCED LEADERSHIP




Left to right: Paul Evans, Jeff Soinski, Guy Jordan, Donald Solomon


Our leadership team is highly experienced in both the healthcare and medical safety product sectors. Their brief biographies show we have the entrepreneurial leadership, strategic guidance and industry experience necessary to efficiently realize our full market potential.

 **Jeffrey Soinski** *President and CEO*


Mr. Soinski brings 20 years of general management, business development and marketing experience to SHPI, including several years as the President and CEO of ViroTex Corporation (“ViroTex”), a venture-backed pharmaceutical company focused on the development and commercialization of proprietary drug delivery systems. Mr. Soinski merged ViroTex into Atrix Laboratories, Inc. (Nasdaq: ATRX) in 1998. Prior to joining SHPI, he was the Managing Partner and CEO of Mad Dogs & Englishmen, a marketing communications firm with offices in New York and San Francisco. Mr. Soinski has a BA degree from Dartmouth College.

 **Guy Jordan** *Ph.D., Chairman of the Board*


Dr. Jordan brings a wealth of senior management healthcare experience to SHPI, with a strong focus in the areas of vascular disease and oncology. Dr. Jordan recently retired as Group President for C.R. Bard, Inc. with global operating responsibility for their oncology businesses, geographic responsibility for Canada, Australia, Latin America and Asia Pacific, and functional responsibility for all of Bard’s research and development. Prior to joining C.R. Bard in 1986, Dr. Jordan held senior product development positions at American Cyanamid. Dr. Jordan has a Ph.D. degree from Georgetown University and an MBA from Fairleigh Dickinson University.

 **Donald Solomon** *Ph.D., COO, CTO, VP, Director*

Dr. Solomon has over 23 years of medical product experience in research, product development, engineering and manufacturing. Prior to joining SHPI, Dr. Solomon was the Vice President of Research and Development at Johnson & Johnson Medical – Vascular Access. Prior to that he spent 14 years at Becton Dickinson (“BD”), and held positions as Worldwide Director of R&D for BD Pharmaceutical Systems Division based in France, and Director of R&D for Biocompatible Polymer Development at the BD Infusion Therapy Division. Dr. Solomon holds 38 patents and is the author of 52 scientific publications. He received Masters and Ph.D. degrees from Case Institute of Technology at Case Western Reserve University.

 **Paul Evans** *VP, Business Development, General Counsel and Secretary*

Mr. Evans brings a wide range of intellectual property and corporate legal experience to SHPI, having previously served as Vice President, General Counsel for an R&D company, and as a patent attorney with the law firm of Snow, Christensen & Martineau. In addition, Mr. Evans leads the company's business development efforts. Prior to earning his law degree, Mr. Evans worked as a Project/Design Engineer for Morton International (now Autoliv). He holds BS and JD degrees from the University of Utah.

 **Larry Sheldon** *VP, Sales and Marketing*


Mr. Sheldon brings over 24 years of relevant healthcare experience to SHPI, including domestic and international management of sales, marketing, national accounts, and customer service. Most of Mr. Sheldon's experience is from Johnson & Johnson, where he was Vice President, Corporate Distributor Business, responsible for managing distributor relationships for medical/surgical products with annual sales of \$1.7 billion. At Johnson & Johnson, Mr. Sheldon held several senior sales management positions in both the Patient Care and Hospital Services divisions. Immediately prior to joining SHPI, Mr. Sheldon was the Sr. VP, Sales & Marketing at Tillotson Healthcare Corporation, a domestic medical and non-medical glove manufacturer. He has a BS degree from Fairleigh Dickinson University.

 **David Jahns** *Director*


Mr. Jahns is a General Partner and principal of Galen Partners. Since joining Galen in 1993, Mr. Jahns has been responsible for making and managing successful investments in several of the firm's portfolio companies. He is an experienced board member and currently serves on the boards of DAOU Systems, Inc. and several of Galen's privately held portfolio companies. Prior to joining Galen, Mr. Jahns worked in the Corporate Finance Division at Smith Barney. Mr. Jahns has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BA degree from Colgate University.

 **Stuart Randle** *Director*

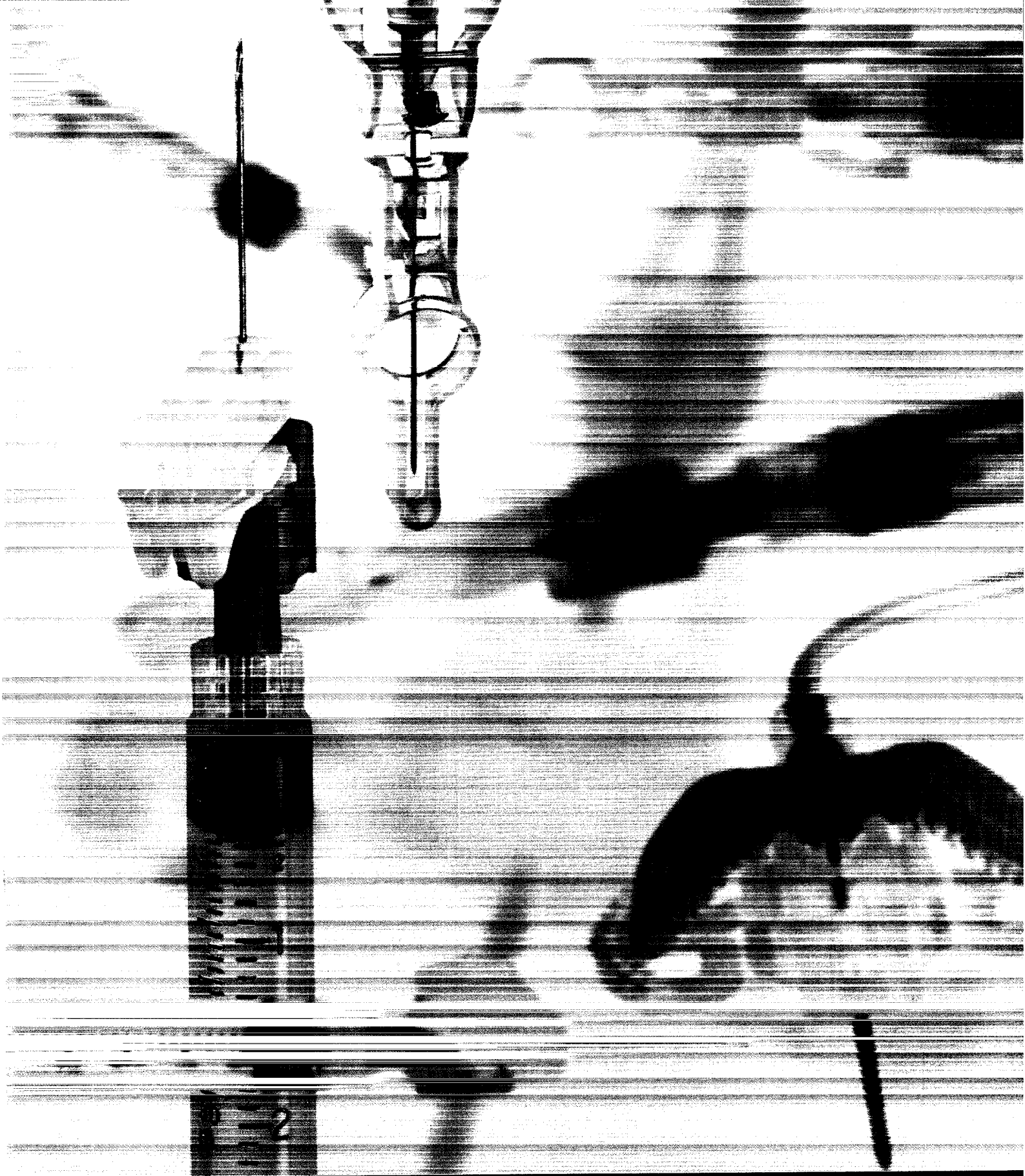
Mr. Randle is the past President and CEO of ACT Medical, Inc., a leading company providing outsourcing services to the medical device, biotech and diagnostic industries. He merged ACT Medical with MedSource Technologies in 2001. Prior to ACT Medical, Mr. Randle was President, Northeast Region, for Allegiance Corporation, a \$5 billion medical products distribution and manufacturing company. He is also the past President, New England Region, for Baxter Healthcare Corporation. Mr. Randle has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BS degree from Cornell University.

 **Stephen Shapiro** *Director*

Mr. Shapiro has over 30 years of relevant medical device and equipment industry experience, including executive positions at Union Carbide and Becton Dickinson. In 1982, he joined The Wilkerson Group, a leading management consultancy to the healthcare industry. Mr. Shapiro was Managing Director of The Wilkerson Group at the time of its acquisition by IBM. In 1999, Mr. Shapiro left The Wilkerson Group to focus on sourcing and evaluating investments for two premier healthcare venture capital firms, including Galen Partners. Mr. Shapiro has a BS degree from MIT and an MS degree in biomedical engineering from the University of California, Berkeley.

 **Robert Walker** *Director*

Mr. Walker is the past President of the IHC Affiliated Services Division of Intermountain Healthcare, a regional hospital company. He is also former Chairman of the Board of AmeriNet, Inc., a national group purchasing organization for hospitals, clinics, detox/drug centers, emergency, nursing homes, and other healthcare institutions. Mr. Walker is a member of the American Hospital Association and the Hospital Financial Management Association. He has a BS degree in Business Administration from the University of Utah.





**SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.**

**585 WEST 500 SOUTH • BOUNTIFUL, UT 84010**

**T: 801.298.3360 • F: 801.298.1759 • WWW.SHPI.COM**

**NASDAQ OTCBB: SHPI**



SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

Annual Report Pursuant  
to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

For the fiscal year ended  
December 31, 2002

Commission file number  
0-26694

**SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation)

**93-0945003**  
(IRS Employer Identification No.)

**585 West 500 South, Bountiful, Utah 84010**  
(Address of principal executive offices)

**(801) 298-3360**  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(g) of the Act:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$.02 Par Value	None

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

The issuer's revenue for its most recent fiscal year was \$1,630,948

The aggregate market value of the common stock held by non-affiliates (*i.e.*, does not include directors, executive officers or ten percent stockholders identified in Item 11 hereof) of the issuer as of March 14, 2003 was approximately \$12,532,000.

As of March 14, 2003, the Company had 17,921,479 shares of common stock outstanding.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.

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## Forward-Looking Statements

When used in this Form 10-KSB, in our filings with the Securities and Exchange Commission ("SEC"), in our press releases or other public or stockholder communications, or in oral statements made with the approval of an authorized executive officer, the words or phrases "would be," "will allow," "intends to," "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," or similar expressions are intended to identify "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements specifically include, but are not limited to, launch dates for licensed products; dates upon which we will receive royalty payments, the generation of royalty revenues from our licensees; acceptance of safety products by health care professionals; plans to rely on our joint venture partners to pursue commercialization of licensed products; expectations regarding the ability of our products to compete with the products of our competitors; acceptance of our products by the marketplace as cost-effective; factors affecting the ability of licensees to sell licensed products; sufficiency and timing of available resources to fund operations; plans regarding the raising of capital; the size of the market for safety products; plans regarding sales and marketing; strategic business initiatives; intentions regarding dividends and the launch dates of our licensed products.

We caution readers not to place undue reliance on any forward-looking statements, which speak only as of the date made, are based on certain assumptions and expectations which may or may not be valid or actually occur, and which involve various risks and uncertainties, including but not limited to risk of a lack of demand or low demand for our products or for safety products generally, a determination of one or more licensees to focus their marketing efforts on products other than those licensed from us; the inability to license or enter into joint venture or similar arrangements relating to products that are not being commercialized, competitive products and pricing, delays in introduction of products licensed by us due to manufacturing difficulties or other factors; difficulties in product development, commercialization and technology, changes in the regulation of safety healthcare products, a failure to timely obtain Food and Drug Administration ("FDA") or other necessary approval to sell future products and other risks set forth in Item 6 "Risk Factors" and elsewhere herein. If and when product sales commence, sales may not reach the levels anticipated. As a result, our actual results for future periods could differ materially from those anticipated or projected.

Unless otherwise required by applicable law, we do not undertake, and specifically disclaim any obligation, to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

## PART I

### Item 1. Description of Business

#### Overview

We design, develop, manufacture, and license cost-effective, innovative safety healthcare products that minimize the risk of accidental needle sticks, which are a leading cause of the spread of blood-borne diseases such as human immunodeficiency virus and autoimmune deficiency syndrome ("HIV/AIDS") and hepatitis B virus ("HBV") and hepatitis C virus ("HCV"). We have 20 highly differentiated, patented safety needle technologies. These technologies apply to virtually all medical needles used today including: syringe, pre-filled syringe, IV catheter, guidewire introducer, PICC introducer, winged needle sets, blood collection, epidural, spinal, plasma aphaeresis sets, dialysis sets, Huber, biopsy, and other specialty needles.

Our business model is to enter into licensing, original equipment manufacturing ("OEM") supply, or distribution agreements for our products, rather than engage in direct sales of products to end-users on our own. We have entered into product agreements relating to specific technologies and product lines with The Kendall Company ("Kendall"), a division of Tyco Healthcare Group LP, Bard Access Systems, Inc. ("Bard"), TAP Pharmaceutical Products Inc. ("TAP") and Merit Medical Systems, Inc. ("Merit"). We have distribution agreements in place with Cardinal Health ("Cardinal", formerly Allegiance), Medline

Medline"), and Physician Sales and Service, Inc. ("PSS") for products marketed under our "PSS" label. Additional ongoing with potential partners for several other product applications of our proprietary technology. Our primary objective is to be the leader and innovator in disposable medical safety sharps with an initial focus on safety medical needles. We will seek to commercialize products providing the following features and benefits:

- Excellent functionality for the intended medical use;
- Similar or enhanced clinical technique versus conventional product offerings;
- Comparable, improved or additional ancillary patient benefits (e.g., comfort, convenience, etc.);
- Efficient/low cost manufacturability to provide attractive margins at a reasonable price; and
- Superior safety technology to prevent accidental exposure to blood-borne pathogens.

In 2002 and January 2003, the first four product lines based upon our proprietary safety needle technologies were introduced into the U.S. market. These products are discussed in detail in the *Our Products* section below and include the following:

- Monject Magellan™ -- safety syringe needle (Kendall)
- Liftloc® Safety Infusion Set -- safety Huber needle (Bard private label and SHPI branded)
- Majestik™ Shielded Needle -- safety angiographic introducer needle (Merit)
- LuproLoc™ -- pre-filled syringe safety needle (TAP)

We see a significant and growing market opportunity for our medical safety needle products. The current U.S. market for disposable medical needles is well in excess of \$1 billion. Most of this market is directly impacted by recent state and federal safety legislation, culminating in the Needlestick Safety and Prevention Act, which was signed into federal law in November 2000, and became effective in April 2001. This law requires healthcare employers to review new safety needle products and mandates their usage by employees. As various government agencies increase their efforts to monitor compliance and better designed safety products become available at reasonable pricing, we anticipate that conversion to safety products will continue to accelerate.

While foreign safety needle legislation lags behind that of the U.S., certain countries, such as France, have already demonstrated an interest in increasing efforts to protect their healthcare workers in a similar manner. As these efforts continue, we expect foreign demand for medical safety needle products to expand.

**Our Products**

We have 20 highly differentiated, patented safety needle technologies that are the basis for a wide range of safety needle products. These proprietary technologies are protected by 22 U.S. patents and over 90 U.S. patents and international patent applications pending. Our primary research and development, business development and marketing efforts are focused on the following product lines:

*Safety Syringe Needles*

There is significant risk of accidental needlesticks during syringe needle use. Generally, the use of a needle for a medical procedure involves removing a needle cap just prior to performing the procedure. In the past, medical personnel attempted to achieve protection from accidental needlesticks by replacing the needle cap after performing a procedure, but a high number of accidental needlesticks related to needle cap replacement resulted in such practices being prohibited by the Centers for Disease Control ("CDC"). Some medical personnel began using needles and syringes having sheaths that could be extended over the exposed needle after a procedure.

Our safety syringe needle eliminates the need to perform dangerous recapping techniques with an integral safety device that covers the needle after use. This innovative product features engineering controls designed to provide a high level of safety while conforming to current user technique. It is low-cost, intuitive, and easy-to-use. The integral safety mechanism is activated by a simple press with the thumb or finger, or by pressing the device against a solid surface such as a counter or tabletop.

A robust product line based upon this proprietary safety syringe needle technology is being manufactured and marketed by Kendall, a division of Tyco Healthcare Group LP and the second leading marketer of syringe needles. In November 1999, we entered into a Development and License Agreement (the "Kendall Agreement") with Kendall relating to the production of a line of safety medical needle products, including six syringe products and five other safety needle products. The Kendall Agreement became effective in March 2000. In April 2000, we received \$1,464,956 under the Kendall Agreement. We received an additional \$1,000,000 in November 2002 in exchange for our assigning to Kendall the FlexLoc® and ReLoc™ trademarks and two related U.S. patents and their progeny for a technology. The assignment of the patent rights to Kendall provides for our retention of an exclusive, royalty-free worldwide license in a number of strategic product areas. The Kendall Agreement also provides for us to receive development fees and ongoing royalties, including a \$500,000 advance royalty payment also received in November 2002.

Kendall initiated its U.S. market launch of a proprietary line of safety syringe needles based upon this technology in the second calendar quarter of 2002, subsequent to receiving 510(k) clearance from the FDA in 2001. Kendall is marketing the product line under the brand name Monoject Magellan™. The Monoject Magellan™ product line includes 15 stock-keeping units ("SKUs") in a variety of needle lengths and gauges, and competes in the \$260 million U.S. safety needle and syringe market.

#### *Safety Huber Needle Devices*

Our LiftLoc® Safety Infusion Set incorporates a Huber type needle into an integral safety needle device. This product is designed for use with a vascular access infusion system (used to infuse fluids, drugs, or for blood sampling) and is specifically designed to access surgically implanted, subcutaneous vascular ports on a repeated basis. Patients with implanted ports require access by Huber needles frequently over six months to a year. A major cause of accidental needlestick injuries to healthcare workers from Huber needles is due to the "rebound effect," which occurs during needle withdrawal from the implanted port. This needle presents a high risk for transmission of blood-borne pathogens, since it is hollow-bore and potentially blood-contaminated at the time of removal.

Our LiftLoc® Safety Infusion Set conforms to current user technique and reduces the risk of accidental needlesticks, including rebound injuries, by locking the needle into a protective sheath as the needle is withdrawn from the port. Each LiftLoc® set is packaged with a unique Patient Comfort Pad™ accessory product. The Patient Comfort Pad™ is made of breathable felted foam that creates a soft uniform barrier between the Huber needle's wings and the patient's skin. Its use is optional.

The LiftLoc® Safety Infusion Set product line is distributed in the hospital market by Bard Access Systems, Inc., a division of C. R. Bard, Inc., a leading multinational developer, manufacturer and marketer of healthcare products in the field of implanted ports that are accessed using Huber needles. In September 2001, we entered into a Distribution Agreement (the "Bard Agreement") with Bard whereby Bard acquired the non-exclusive right to promote, market, distribute and sell the LiftLoc® Safety Infusion Set, which we manufacture, to hospitals and group purchasing organizations. The Bard Agreement excludes alternate site locations, such as homecare services, nursing homes, oncology centers, infusion centers, same day surgery centers, physician offices and clinics, non-hospital pharmacies and pain clinics. Under the terms of the agreement, we sell finished product to Bard for marketing under Bard's private label. Bard is subject to minimum purchase requirements. The Bard Agreement is for a two-year period from the initial date of product launch, and automatically renews for successive one-year terms unless terminated by Bard in writing not less than 180 days prior to the expiration of the initial term or any renewal term.

In the third calendar quarter of 2002, we entered into distribution agreements with Allegiance Healthcare (now named Cardinal Health), Medline and PSS, leading distributors with a strong presence in the oncology, chronic hematology, and long-term intravenous nutritional markets, for distribution of LiftLoc® Safety Infusion Set under the SHPI label. Under the terms of the distribution agreements, LiftLoc® distributors purchase product from us for resale to their end-user customers. The Allegiance agreement shall continue until 90 days after written notice of termination is received by either party. The PSS and Medline agreements are for a one-year period, and automatically renew for successive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

We received 510(k) clearance from the FDA for LiftLoc® Safety infusion Set in 2001, and initiated the U.S. market launch of the product line under our SHPI label in September 2002. Bard initiated its U.S. market launch of LiftLoc® Safety Infusion Set under the Bard label in December 2002. The LiftLoc® Safety Infusion Set product line includes 19 SKUs in a variety of needle lengths and gauges. It competes in the \$46 million U.S. Huber needle market.

#### *Pre-filled Syringe Safety Needle Device*

Pre-filled syringes are a significant drug delivery modality, with a strong need for an effective, cost-efficient safety needle solution. A wide range of drugs, from high volume vaccines to many of today's newer drugs, are delivered via pre-filled syringes. Typically, the pre-filled syringe is made of glass to ensure appropriate shelf life and inertness to the drug. Pre-filled syringes are used to deliver drugs in a variety of forms, including liquids, gels, lyophilized (freeze-dried) drugs, or a combination of liquid and dry in a multiple chamber syringe.

We have developed a proprietary safety needle device that is adaptable to a wide variety of pre-filled syringes. This device provides intuitive, one-handed activation. Additionally, the device is designed for easy integration into pharmaceutical manufacturing. Our device can be applied to the pre-filled syringe after filling and before final packaging. This minimizes capital investment and speeds integration.

In July 2002, we entered into a Development and License Agreement (the "TAP Agreement") with TAP Pharmaceutical Products Inc. (a joint venture between Abbott Laboratories and Takeda Chemical Industries, Ltd.), whereby TAP acquired the right to attach our proprietary safety needle device to their pre-filled syringes. The TAP Agreement has an effective date of January 1, 2002. Under the TAP Agreement, we have and will receive reimbursement for research and development expenses, payments related to the achievement of certain development and regulatory milestones, and on-going royalty payments based upon the number of pre-filled syringes manufactured with our proprietary safety needle device. The TAP Agreement is for a minimum period of three years.

TAP is attaching our proprietary safety needle device to pre-filled syringes of Lupron Depot® (leuprolide acetate for depot suspension), the first pharmaceutical product available with our pre-filled syringe safety needle device and the first product in its class to offer an integral safety needle device on pre-filled syringes. TAP has branded this integral safety needle device LuproLoc™. TAP initiated the U.S. market launch of Lupron Depot® with LuproLoc™ in January 2003, after receiving FDA approval as the result of filings with both the FDA's Center for Drug Evaluation and Research ("CDER") and its Center for Devices and Radiological Health ("CDRH"). Pharmaceutical products sold in pre-filled syringes represent a multi-billion dollar worldwide market. The total U.S. market for pre-filled syringe needles is estimated to be in excess of \$100 million annually.

#### *Safety Blood Collection (Phlebotomy) Devices*

The present method for drawing large amounts of blood from patients for blood tests involves insertion of a needle, which is attached to a barrel, into a blood vessel. Blood is then obtained by way of vacuum pressure, most often into a small evacuated tube-like container inserted into the barrel. After blood is drawn, the needle is manually removed from the patient. While the healthcare worker continues attending to the patient, the collection tube, barrel and needle are often placed on a tray, table or otherwise set aside.



Afterward, the needle is usually unscrewed from the barrel and discarded into a sharps container, while the barrel is often used again with another patient (increasing the risk of cross contamination).

We have developed a family of safety blood collection products that combine a unique, one-piece injection molded barrel with an integral safety needle device. Since the blood collection barrel is integral to the needle assembly, our safety phlebotomy device ensures that a new barrel is used for each patient. Our product offers easy, one-handed activation and has been highly rated in market acceptance studies.

Our safety blood collection product line will be manufactured and marketed by Kendall, a business unit of Tyco Healthcare. In April 2002, we entered into a Second Development and License Agreement with Kendall (the "2<sup>nd</sup> Kendall Agreement") relating to blood collection needles and blood collection needle/holder combinations. Under the terms of the agreement, we will receive reimbursement for research and development expenses, payments related to the achievement of certain regulatory and sales milestones, and on-going royalty payments on all product sales.

The FDA has already granted 510(k) clearance for marketing this proprietary safety blood collection device. It will compete in the \$130 million U.S. blood collection needle market.

#### *Safety Angiographic Needles*

Angiographic needles are used to provide vascular access for the introduction of guidewires or other devices during diagnostic or therapeutic procedures, primarily in the fields of cardiology and radiology. Approximately 10 million angiography procedures are performed each year worldwide.

We have entered into a License Agreement (the "Merit Agreement") with Merit Medical Systems, Inc. relating to the manufacture and marketing of safety needle devices for angiographic guidewire introducers. Merit is a leading manufacturer and marketer of proprietary disposable products used in cardiology and radiology procedures. We received an upfront license fee payment of \$100,000 in January 2001, which is being recognized ratably by us over the estimated five-year life of the Merit Agreement. Under the terms of the Merit Agreement, we will receive ongoing royalties on net product sales and began receiving minimum royalty payments in 2002.

Merit initiated its U.S. market launch of a safety angiographic needle based upon our proprietary safety needle technology in November 2002. Merit designed and developed the product, and is marketing it under the Majestik™ Shielded Needle brand name. The Majestik™ Shielded Needle is intuitive and easy-to-use. After using the introducer needle, the clinician simply presses a button to mechanically extend a safety shield over the needle. After the safety device is locked around the needle, the entire unit is then discarded into an approved sharps container. The Majestik™ Shielded Needle competes in the estimated \$17 million U.S. introducer needle market.

#### *Safety Long Specialty Needles*

We have a significant program underway for developing safety long specialty needles based upon our SecureLoc™ technology. These needles are used across a wide range of medical disciplines, including anesthesiology, oncology, radiology, urology, and cardiology. Initial markets of interest include epidural, spinal, introducer needles, soft tissue and bone biopsy, and others. Together long specialty needles represent a combined market opportunity in excess of \$200 million annually in the U.S.

Due to their length, these specialty needles present unique challenges for developing an effective safety system that does not interfere with clinical technique. We have developed and filed patents for SecureLoc™, an innovative safety needle technology that we believe effectively addresses these problems. SecureLoc™ can be efficiently manufactured and installed onto existing long specialty needles. We are currently engaged in active discussions with potential corporate partners for several specialty long needle product applications of the SecureLoc™ technology.

### *Safety Catheter Introducers*

Catheter introducers are devices that insert catheters into veins or other areas of the body using a catheter insertion needle to allow blood or other fluids to be removed from or delivered into the patient's body. Peripheral IV catheter use has problems similar to those faced in drawing blood. Inserting a catheter involves a percutaneous (*i.e.*, through the skin) needlestick followed by threading the catheter over the needle into a patient's vein or artery. This method can be unsafe in two respects. First, when the needle is pulled out of the catheter, there is often a discharge of blood that could contaminate the healthcare worker. Second, inadvertent needlesticks can occur when the needle is withdrawn from the catheter, because, in some instances, the needle is temporarily left exposed while the healthcare worker tends to the patient.

We have developed proprietary safety needle products for catheter insertion, which provide passive needle protection in an intuitive design that is integral to the catheter introducer. These products are also based upon our SecureLoc™ technology. Clinicians would be able to use our passive safety catheter introducers without modification to their current technique and still have effective protection. Our device also minimizes the issue of blood splatter or loss of control as is the case with some of the existing technologies. This device will compete in the \$255 million U.S. IV catheter market. We are currently engaged in active licensing discussions on this product line.

## **Industry**

### *Market*

Healthcare is one of the largest industries in the world and grows larger each year. Healthcare worker safety is and will remain a high priority, high profile issue. Healthcare workers in the U.S. use about 6 billion needles and suffer an estimated 800,000 injuries from accidental needlesticks and other sharps annually. Diseases that can be acquired from such accidents include HIV/AIDS, HBV, HCV, diphtheria, gonorrhea, typhus, herpes simplex virus, malaria, syphilis and tuberculosis. Recent federal and state legislation in conjunction with increased awareness of these statistics is projected to spur significant growth in the safety needle and syringe market, as sales are converted from the traditional disposable needle and syringe market. The current U.S. market for disposable medical needles is well in excess of \$1 billion and growing.

User efficiency and cost effective solutions are being sought with increasing demand. Our products target this market segment. Non-safety products today compete primarily on price. Although our strategy includes being priced competitively with other safety devices, we also seek to compete on the basis of healthcare worker safety, ease of use, reduced cost of disposal, patient comfort, and compliance with Occupational Safety and Health Administration ("OSHA") regulations. We believe that when all indirect costs (needle disposal, testing, labor savings and costs, treatment and workers compensation expense) are considered, our products will compete effectively both with "traditional" products and with the safety products of our competitors.

### *Accidental Needlestick Injuries*

Needles for hypodermic syringes, phlebotomy sets, intravenous catheters, safety steel needles and specialty medical needles are necessary to inject drugs and other fluids into the body and for drawing blood and other fluids from the body. Hypodermic needles are used for the injection of drugs. Phlebotomy sets are used for the drawing of blood. Catheters, butterfly needles and specialty needles are used for access to patient vessels. There is an increasing awareness of the potential danger of infections and illnesses to healthcare workers that result from accidental needlesticks and of the need for safer needle devices to reduce the number of such accidents.

It is estimated that at least 1,000 healthcare workers annually contract serious infections from accidental needlestick and sharps injuries in the U.S. Estimates also suggest that safety needle devices may prevent more than 80% of all needlestick injuries. Testing and treatment of needlestick injuries costs the U.S. healthcare system between \$750 million and \$1 billion each year. The average cost of treating a needlestick injury not resulting in the transmission of a disease is between \$450 and \$800 per incident, which only considers the direct costs associated with HBV, HCV and HIV screens and employee health time. According to the American Hospital Association, a single case of serious blood-borne pathogen infection can cost more than \$1 million in expenses for follow-up testing, lost work time and disability payments. Even if no infection occurs as a result of the injury, the average cost of treating a high-risk exposure is estimated to be about \$3,000 per needlestick. According to the CDC, the 1998 infection rate following a single needlestick injury with a contaminated needle or other sharp was between 6% and 30% for HBV, 0.5% and 2% for HCV, and about 0.3% for HIV. 85% of the healthcare workers infected with HCV become chronic carriers of the virus. Treatment of HCV is very expensive, averaging \$1,700 per month. Treatment for HIV is also expensive, with costs averaging up to \$6,000 per month. Accidental needlesticks are the cause of 86% of all occupationally acquired cases of HIV/AIDS.

While we expect recent government regulations to dramatically increase conversions to safety products in the future, the greatest obstacle to conversion may be adequate supply and availability of well-designed and cost-efficient safety products. We believe that pressure is increasing from the government and private sectors for the healthcare industry to develop medical devices that will provide a safer working environment for healthcare and related workers and patients. Our products are intended to address the demand for medical devices that reduce the risk of accidental exposure to blood-borne diseases.

#### *Legislative Response*

National safety regulations have highlighted the demand for safety medical devices. The Needlestick Safety and Prevention Act was signed into federal law in November 2000, and became effective in April 2001. Twenty-six U.S. states have passed safety legislation requiring the use of safety needle products. OSHA also issued a national directive in November 1999 requiring use of safety medical devices, then revised the order in November of 2000 to comply with the Needlestick Safety and Prevention Act. This order requires healthcare employers to review new safety products and mandates their use by employees. Various government agencies now monitor hospitals and clinics for compliance. We believe these developments will positively affect our ability to commercialize our products.

#### **Our Strategy**

Our primary objective is to be the leader and innovator in disposable medical safety sharps products, with an initial focus on safety medical needles. We are seeking to accomplish this objective by capturing significant market share of targeted product segments, broadening existing product lines, developing new products and seeking additional market opportunities.

Our business model is to enter into licensing, OEM supply, or distribution agreements for our products, rather than engage in direct sales of products to end-users on our own. OEM supply or distribution arrangements are our preferred business relationship for targeted specialty products. Out-licensing agreements are pursued for high volume product opportunities where efficient and low cost manufacturing is unfeasible at a contract manufacturer, or when a large capital investment is required to scale-up manufacturing.

#### **Marketing and Sales**

Because we focus on the design, development, manufacture, OEM supply and license of cost-effective, innovative safety healthcare products, we are not engaged in the sale of our products directly to end-users. For our licensed products, our current marketing efforts primarily focus upon identifying market leaders in the pharmaceutical and medical device industries who are highly qualified to sell and distribute

our products after manufacture, incorporate our safety applications in their existing products, or some combination of the foregoing.

For products that we supply on an OEM private label basis or market under our own SHPI label, such as LiftLoc® Safety Infusion Set, we provide significant sales and marketing support to our corporate partners and qualified distributors. This support includes development and supply of marketing materials, active lead generation through participation in trade shows, outbound telemarketing and sales presentations, in-service participation and customer service support. We significantly expanded our sales and marketing capabilities in 2002, by hiring a highly experienced Vice President of Sales & Marketing and establishing full-time customer service support. In addition, we have put in place four geographically dispersed Regional Sales Managers to train our distributors' representatives and guide and support their efforts in the field.

### **Manufacturing and Facilities**

Products being developed under OEM supply or distribution agreements are manufactured under our authority and supervision by a qualified contract manufacturer. In 2002, we began producing our LiftLoc® Safety Infusion Set and Patient Comfort Pad™ at an ISO 9002 qualified contract manufacturer. Products subject to licensing agreements are manufactured by our corporate partners. The materials used to produce our products are generally widely available. We do not anticipate difficulty in obtaining such materials.

Our facilities include 15,574 square feet of leased space. Our primary use of the space is for offices. However, our facility also includes designated laboratory space for the development and testing of product prototypes, and a dedicated machine shop to support our product development activities. In 2002, we established a controlled warehouse, customer service and pick, pack and ship operation at our facility to support sales of LiftLoc® Safety Infusion Set.

### **Patents and Proprietary Rights**

Our policy is to seek patent protection for all developments, inventions and improvements that are patentable and which have potential value to us and to protect as trade secrets other confidential and proprietary information. We intend to vigorously defend our intellectual property rights to the extent our resources permit.

We have 22 U.S. patents relating to our safety medical needle technologies. We have over 90 U.S. and international patents and patent applications pending. The patents referred to above first begin to expire in 2013. We filed 10 U.S. utility patent applications during 2002.

Our future success may depend upon the strength of our intellectual property. We believe that our patents and patent applications are or will be valid and enforceable. There is no assurance, however, that if such patents are challenged this belief will prove correct. In addition, patent applications filed in foreign countries and patents granted in such countries are subject to laws, rules and procedures, which differ from those in the U.S. Patent protection in such countries may be different from patent protection provided by U.S. laws and may not be as favorable to us.

We are not aware of any patent infringement claims against us directly. In December 2002, Becton, Dickinson and Company ("BD") filed a lawsuit against Tyco Healthcare Group LP ("Tyco Healthcare"), asserting that the Monoject Magellan™ safety products infringe upon a BD patent. See Item 3. "Legal Proceedings." Litigation to enforce patents, to protect proprietary information, or to defend us against alleged infringement of the rights of others may occur. Such litigation would be costly, could divert our resources from other planned activities, and could have a material adverse effect on our results of operations and financial condition.

## Research and Development

We have devoted a substantial portion of our efforts to designing and developing healthcare products. To date, research and development expenditures have resulted in our ownership of, or right to, in excess of 100 patents and patent applications worldwide and the creation of 20 highly differentiated, patented safety needle technologies. These technologies apply to virtually all medical needles used today including: syringe, pre-filled syringe, IV catheter, guidewire introducer, PICC introducer, winged needle sets, blood collection, epidural, spinal, plasma aphaeresis sets, dialysis sets, Huber, biopsy, and other specialty needles. We spent \$2,468,347 in 2002 and \$1,815,082 in 2001 on research and development activities. Customer sponsored research activities relating to the development of new products, services or techniques or the improvement of existing products, services or techniques for which we earned revenues were \$636,425 in 2002 and \$202,615 in 2001. We plan to continue research and development on our current products under development and new products. There is no assurance that our ongoing research and development activities will prove effective.

## Government Regulation

### *Product Approvals*

We are regulated by the FDA, pursuant to various statutes, including the (Federal Food, Drug and Cosmetic Act) ("FD&C") Act, as amended and supplemented by the Medical Device Amendments of 1976 (the "1976 Amendments") and the Safe Medical Devices Act of 1990. Although our focus in the past has been on the design and development of devices, we anticipate that as we engage in more OEM manufacturing, we will become increasingly active in pursuing regulatory approvals. We have submitted and received FDA clearance for our LiftLoc® Safety Infusion Set. In addition, our strategic partners have received FDA clearances for Monoject Magellan™ Safety Syringe Needle, Safety Blood Collection Device, LuproLoc™ Pre-filled Syringe Safety Needle, and Majestik™ Shielded Angiographic Needle. We plan to submit an additional 510(k) application for one or more safety needle devices based upon the SecureLoc™ technology during 2003.

Pursuant to the 1976 Amendments, the FDA classifies medical devices intended for use with humans into three classes, Class I, Class II and Class III. The controls applied to the different classifications are those the FDA believes are necessary to provide reasonable assurance that a device is safe and effective. Many Class I devices have been exempted from pre-market notification requirements by the FDA. These products can be adequately regulated by the same types of controls the FDA has used on devices since the passage of the FD&C Act in 1938. These "general controls" include provisions related to labeling, producer registration, defect notification, records and reports and good manufacturing practices ("GMP"). The GMP regulation has been recently replaced by a more comprehensive Quality System Regulation ("QSR"). QSRs include implementation of quality assurance programs, formalized product development procedures, written manufacturing specifications and processing procedures, written distribution procedures and record keeping requirements. Class II devices are products for which the general controls of Class I devices are deemed not sufficient to assure the safety and effectiveness of the device and thus require special controls. Special controls for Class II devices include performance standards, post-market surveillance, patient registries and the use of FDA guidelines. Standards may include both design and performance requirements. Class III devices have the most restrictive controls and require pre-market approval by the FDA. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices. None of our currently proposed products are believed to be to be Class III products. The FDA has further established three tiers or levels of scientific review – Tier 1, Tier 2, and Tier 3 within each class. Submissions for Tier 1 devices receive limited review while submissions for Tier 2 and 3 devices receive more comprehensive reviews.

Section 510(k) of the FD&C Act requires individuals or companies manufacturing medical devices intended for use with humans to file a notice with the FDA at least 90 days before introducing a product not exempted from notification requirements into the marketplace. The notice (a "510(k)

Notification”) must state the class in which the device is classified and the actions taken to comply with performance standards or pre-market approval which may be needed if the device is a Class II or Class III device, respectively. If a company states the device is unclassified, it must explain the basis for that determination.

In some cases obtaining pre-market approval for Class III devices can take several years. Product clearance pursuant to a 510(k) Notification can be obtained in much less time. The average time for 510(k) clearance for safety devices is currently 90 days. In general, clearance of a 510(k) Notification for a Class II device may be obtained if we can establish that the new device is “substantially equivalent” to another device of that Class already on the market. This requires the new device to have the same intended use as a legally marketed predicate device and have the same technological characteristics as the predicate device. If the technological characteristics are different, the new device can still be found to be “substantially equivalent” if information submitted by the applicant (including clinical data if requested) supports a finding that the new device is as safe and effective and does not raise questions of safety or efficacy that are different from the predicate device.

We expect our safety medical needle products to be categorized as Class II devices. We also expect that these products will not require pre-market approval applications but will be eligible for marketing clearance through the 510(k) Notification procedure based upon their substantial equivalence to previously marketed devices.

Although the 510(k) Notification clearance process is ordinarily simpler and faster than the pre-market approval application process, there can be no assurance that we will obtain 510(k) Notification clearance to market our products, that our products will be classified as set forth above, or that, in order to obtain 510(k) Notification clearance, we will not be required to submit additional data or meet additional FDA requirements which could substantially delay sales and add to our expenses. Moreover, any 510(k) Notification clearance, if obtained, may be subject to conditions on the marketing or manufacturing of the related products, which could impede our ability to market or manufacture such products.

In addition to the requirements described above, the FD&C Act requires that all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices that they distribute commercially. The FD&C Act also requires that all manufacturers of medical devices comply with labeling requirements and manufacture devices in accordance with QSRs. QSRs require that companies manufacture their products and maintain their documents in a prescribed manner with respect to manufacturing, testing, and quality control. The FDA’s Medical Device Reporting regulation requires that companies provide information to the FDA on death or serious injuries alleged to have been associated with the use of their products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. The FDA further requires that certain medical devices not cleared with the FDA for marketing in the U.S. meet specific requirements before they are exported. We are registered as a manufacturer with the FDA.

The FDA inspects medical device manufacturers and distributors, and has broad authority to order recalls of medical devices, to seize non-complying medical devices, to enjoin and/or impose civil penalties on manufacturers and distributors marketing non-complying medical devices, and to criminally prosecute violators. Noncompliance with FDA regulations could have a material adverse effect on our company.

In addition to the laws and regulations described above, we are subject to government regulations applicable to all businesses, including, among others, regulations related to occupational health and safety, workers’ benefits and environmental protection.

#### *Safety Product Mandates*

\* Safety regulations and legislation have also increased the demand for and exposure of safety medical devices. The Needlestick Safety and Prevention Act became effective in April 2001 and orders specific revisions to OSHA’s blood-borne pathogens standard. This legislation requires healthcare

employers to review new safety products and mandates their use by employees. The revised standard directs all healthcare facilities and employers to select safety needle devices as they become available.

Twenty-six U.S. states have passed safety legislation requiring use of safety needle products. OSHA also issued a national directive in November 1999 requiring use of safety medical devices. In November 2000, the CDC and OSHA issued safety alerts urging healthcare workers to use safety devices having engineered controls.

#### *Foreign Regulation*

Distribution and sales of our products in countries other than the U.S. is subject to regulations in those countries. In December of 2002, SHPI received a medical device license and approval to sell our LiftLoc® Safety Infusion Set in Canada. There can be no assurance that we will be able to obtain the approvals necessary to market our products in other countries outside the U.S.

#### **Competition**

The healthcare products market is highly competitive. Many of our competitors have longer operating histories, are substantially larger and are better financed and better situated in the market than we are. Our major competitors are identified below.

The leading suppliers of syringe needles and syringes with needles are Becton, Dickinson and Company and Kendall. Terumo Medical Corporation ("Terumo") holds a minor U.S. market share. B. Braun Medical is a leader in Europe and Asia, while Terumo is a leader in Japan and the Pacific Rim. In addition to the major companies mentioned above, other developers of safety medical needles include Med-Design Corporation, ICU Medical, Inc., Now Medical Technologies, Retractable Technologies, Inc., Medi-Hut Co., Inc., Medisys Technologies, Inc., and Portex, Inc.

Competitive suppliers of safety Huber needle products with an integral safety feature or mechanism include Now Medical, Horizon Medical Products, Inc., Churchill Medical Ltd., and Portex, Inc. We also anticipate that B. Braun will soon enter the U.S. market with a competitive safety Huber needle product. We believe our LiftLoc® Safety Infusion Set provides significant advantages versus competitive safety Huber needle products on the market.

Leading suppliers in the blood collection (phlebotomy) needle market are BD, Kendall and Terumo.

The specialty needle market includes a wide variety of needles including Huber, spinal, epidural, biopsy, dental, dialysis, plasma aphaeresis, blood donor collection sets, guidewire introducer, PICC introducer, Veress and ophthalmic needles. Numerous companies compete within the various markets associated with each of these needles. These companies include Cardinal Health, Arrow, Bard, B. Braun Medical, Kendall, Cook, Inc., BD, Horizon Medical Products, Boston Scientific, Guidant, ICU Medical, Inc., Merit, Medtronic, Manan Medical Products, Hart Enterprises, Baxter International, Inc., Johnson & Johnson, Medamicus, Needle Tech, Terumo, Daum, U.S. Biopsy, Ballard and Abbott Laboratories.

The leading suppliers in the IV catheter market are BD and Johnson & Johnson. Other suppliers of IV catheters with minor positions in this market include B. Braun Medical and Terumo.

Conventional needle products have competed primarily on the basis of price. However, we believe the safety needle market offers substantial opportunities for premium priced products. We expect to compete on the basis of healthcare worker safety, ease of use, patient comfort, added product features and compliance with state, federal and OSHA regulations. We believe our products will perform well based on product design features and provide attractive margins for our partners and us at a reasonable cost to the end user.

## **Company Background**

Specialized Health Products, Inc. ("SHP"), a Utah corporation, was incorporated in November 1993. On July 28, 1995, SHP became a wholly owned subsidiary of SHPI, a Delaware corporation, through a merger with a subsidiary of SHPI (the "Acquisition"). On that date SHP changed its name to "Specialized Health Products International, Inc ("SHPI)." The persons serving as officers and directors of SHP immediately prior to the consummation of the Acquisition were elected to the same offices with SHPI and retained their positions as directors and officers of SHP. In addition, the outstanding securities of SHP became outstanding securities of SHPI.

We restructured our management team and board of directors in November 2001 following a private placement of preferred stock to Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen Partners") and other accredited investors. In conjunction with the investment, we recruited a new president and CEO and appointed five new members to our board of directors. Our leadership team is highly experienced in both the healthcare and medical safety product sectors. See Item 9 "Directors, Executive Officers, Promoters and Control Persons."

## **Seasonality of Business**

Sales of our products are not subject to seasonal variations.

## **Backlog**

There is no backlog of unfilled orders of our products.

## **Employees**

As of March 14, 2003, we employed 27 people, 14 of which are engineers. All but four of our employees are actively engaged in our research, product development, or sales and marketing efforts. We have four Regional Sales Managers reporting to our Vice President, Sales & Marketing, and employ a full-time customer service representative to provide product support and ordering assistance.

Our employees are not represented by any labor union, and we believe our relations with employees are good.

## **Item 2. Description of Property**

Our principal offices are located at 585 West 500 South, Bountiful, Utah, under the terms of a lease with an unaffiliated lessor, which expires on May 31, 2006, subject to our right to extend the lease term for an additional three years. The offices and laboratories comprise 15,574 square feet of space. We believe that our current office space will be adequate to meet the needs of current and expected growth for the foreseeable future. We may, however, require additional warehousing or manufacturing facilities in the future depending upon the volume of products sold and the manufacturing arrangements we develop.

## **Item 3. Legal Proceedings**

In December 2002, BD filed a lawsuit against Tyco Healthcare in the United States Court of the District of Delaware, asserting that Tyco Healthcare's Monoject Magellan™ safety products infringe upon BD's U.S. Patent No. 5,348,544 ('544 Patent), titled "Single-Handedly Actuable Safety Shield for Needles." BD is seeking injunctive relief as well as damages, including attorneys' fees and costs, in an unspecified amount. Tyco Healthcare responded in court filings that the Monoject Magellan™ safety products do not infringe the '544 Patent. Moreover, Tyco Healthcare asserted in court filings that the '544 patent is invalid and unenforceable.



Under a Development and License Agreement executed between Tyco Healthcare and us related to the Monoject Magellan™ safety products, Tyco Healthcare has the right to withhold up to fifty percent (50%) of royalties due as an offset against litigation expenses related to charges of infringement by a third party for the manufacture, use or sale of licensed product. This right continues during the period in which such litigation is pending. If, as a result of judgment in the litigation or settlement with BD, Tyco Healthcare is required to pay royalty and/or other monies to BD, Tyco Healthcare may thereafter deduct from the amount of royalties due us on unit sales of products alleged to infringe, an amount which is the lesser of all royalties and/or other monies paid by Tyco Healthcare to BD, or fifty percent (50%) of all royalty payments otherwise payable to us.

**Item 4. Submission of Matters to a Vote of Security Holders**

None

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## PART II

### Item 5. Market for Common Equity and Related Stockholder Matters

#### Dividend Policy

The holders of our Series A Preferred Stock are entitled to receive dividends at the rate of eight percent per share per annum, payable semi-annually, when, if and as declared by the board of directors, out of any assets legally available therefore. The right to dividends on the Series A Preferred Stock is not cumulative, and the holders of Series A Preferred Stock have no right to any accrued or future dividend payment by reason of the fact that dividends on such shares are not declared or paid in any prior year.

To date, we have not paid dividends on our common stock. The payment of dividends on the common stock, if any, is at the discretion of the board and will depend upon our earnings, if any, our capital requirements and financial condition, and other relevant factors. See Item 6. "Management's Discussion and Analysis or Plan of Operation." Moreover, we are prohibited from paying a dividend on our common stock unless a dividend is also concurrently declared and paid on the Series A Preferred Stock. In addition, no dividend paid on the common stock may exceed the dividend paid on the Series A Preferred Stock. We do not intend to declare any dividends in the foreseeable future, but instead intend to retain all earnings, if any, for use in our operations.

#### Share Price History

Our common stock is traded in the over-the-counter market in what is commonly referred to as the "Electronic" or "OTC Bulletin Board" or the "OTCBB" under the trading symbol "SHPI." The following table sets forth the high and low bid information of our common stock for the periods indicated. The price information contained in the table was obtained from America Online ("AOL") and its information suppliers. Note that the over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and that the quotations may not necessarily represent actual transactions in the common stock.

<u>Quarter Ended</u>	<u>High</u>	<u>Low</u>
<u>2001</u>		
March 31 .....	\$1.18	\$0.81
June 30 .....	\$0.95	\$0.31
September 30 .....	\$0.83	\$0.62
December 31 .....	\$1.90	\$0.70
<u>2002</u>		
March 31 .....	\$1.73	\$1.25
June 30 .....	\$1.43	\$1.05
September 30 .....	\$1.05	\$0.60
December 31 .....	\$1.03	\$0.65

#### Holders of Record

At March 14, 2003, there were approximately 320 holders of record of our common stock. The number of holders of record was calculated by reference to our stock transfer agent's books.

#### Issuance of Securities

The Series A Preferred Stock Purchase Agreement (the "Series A Agreement") entered into in November 2001 provided that the investors had the right, but not the obligation to acquire additional shares

of Series A Preferred Stock at \$.458 per share (\$5,000,000 total) during the 12 months following the initial closing date of November 7, 2001. In September 2002, Galen Partners exercised their option to purchase the additional shares to which they held rights. Under the terms of the Series A Agreement, the options to purchase held by the remaining qualified investors would expire in thirty days if not exercised. All of those holding options to purchase exercised some or all of their rights, purchasing an additional 10,944,339 shares of Series A Preferred stock. We realized net proceeds of \$5,002,957 from the transaction. A non-cash beneficial conversion charge of \$3,281,564 was recognized related to this transaction. This amount has been treated as a preferred stock dividend in the 2002 financial statements.

The issuance of the securities described above was exempt from registration pursuant to Sections 4(2) and 4(6) of the Securities Act of 1933 and pursuant to Regulation D as promulgated under the Securities Act of 1933. We did not use an underwriter in connection with these transactions.

## **Item 6. Management's Discussion and Analysis or Plan of Operation**

The following discussion and analysis provides information which management believes is relevant to an assessment and understanding of our consolidated results of operations and financial condition. The discussion should be read in conjunction with the consolidated financial statements and notes thereto.

### **Overview**

We design, develop, manufacture, and license cost-effective, innovative safety healthcare products that minimize the risk of accidental needle sticks, which are a leading cause of the spread of blood-borne diseases such as human immunodeficiency virus and autoimmunodeficiency syndrome ("HIV/AIDS") and hepatitis B virus ("HBV") and hepatitis C virus ("HCV"). We have 20 highly differentiated, patented safety needle technologies. These technologies apply to virtually all medical needles used today including: syringe, pre-filled syringe, IV catheter, guidewire introducer, PICC introducer, winged needle sets, blood collection, epidural, spinal, plasma aphaeresis sets, dialysis sets, Huber, biopsy, and other specialty needles.

### **Financial Position**

We had \$5,507,580 in cash as of December 31, 2002, an increase of \$2,136,173 from December 31, 2001. Working capital as of December 31, 2002 was \$4,719,110 as compared to \$2,317,175 at December 31, 2001. These increases were primarily due to the \$5 million investment by Galen Partners and other accredited investors in September and November 2002.

### **Product Agreements**

In November 1999, we entered into a Development and License Agreement (the "Kendall Agreement") with Kendall relating to the production of a line of safety medical needle products, including six syringe products and five other safety needle products. The Kendall Agreement became effective in March 2000. In April 2000, we received \$1,464,956 under the Kendall Agreement. We received an additional \$1,000,000 in November 2002 in exchange for our assigning to Kendall the FlexLoc® and ReLoc™ trademarks and two related U.S. patents and their progeny for a technology. Both of these payments are being recognized ratably over the life of the Kendall Agreement. The assignment of the patent rights to Kendall provides for our retention of an exclusive, royalty-free worldwide license in a number of strategic product areas. The Kendall Agreement also provides for us to receive development fees and ongoing royalties, including a \$500,000 advance royalty payment also received in November 2002. Kendall initiated its U.S. market launch of a proprietary line of safety syringe needles based upon this technology in the second calendar quarter of 2002. Kendall is marketing the product line under the brand name Monoject Magellan™. The Monoject Magellan™ product line includes 15 stock-keeping units ("SKUs") in a variety of needle lengths and gauges, and competes in the \$260 million U.S. safety needle and syringe market.

In January 2001, we entered into a License Agreement (the "Merit Agreement") with Merit Medical Systems, Inc. relating to the manufacture and marketing of safety needle devices for angiographic guidewire introducers. Merit is a leading manufacturer and marketer of proprietary disposable products used in cardiology and radiology procedures. We received an upfront license fee payment of \$100,000 in January 2001, which is being recognized ratably by us over the estimated five-year life of the Merit Agreement. Under the terms of the Merit Agreement, we will receive ongoing royalties on net product sales and began receiving minimum royalty payments in 2002. Merit initiated its U.S. market launch of a safety angiographic needle based upon our proprietary safety needle technology in November 2002. Merit is marketing this product under the Majestik™ Shielded Needle brand name. It competes in the estimated \$17 million U.S. introducer needle market.

In September 2001, we entered into a Distribution Agreement (the "Bard Agreement") with Bard whereby Bard acquired the non-exclusive right to promote, market, distribute and sell the LiftLoc® Safety Infusion Set, which we manufacture, to hospitals and group purchasing organizations. The Bard Agreement excludes alternate site locations, such as homecare services, nursing homes, oncology centers, infusion centers, same day surgery centers, physician offices and clinics, non-hospital pharmacies and pain clinics. Under the terms of the agreement, we sell finished product to Bard for marketing under Bard's private label. Bard is subject to minimum purchase requirements. The Bard Agreement is for a two-year period from the initial date of product launch, and automatically renews for successive one-year terms unless terminated by Bard in writing not less than 180 days prior to the expiration of the initial term or any renewal term. Bard initiated its U.S market launch of LiftLoc® Safety Infusion Set under the Bard label in December 2002. The LiftLoc® Safety Infusion Set product line includes 19 SKUs in a variety of needle lengths and gauges. It competes in the \$46 million U.S. Huber needle market.

In July 2002, we entered into a Development and License Agreement (the "TAP Agreement") with TAP Pharmaceutical Products Inc. (a joint venture between Abbott Laboratories and Takeda Chemical Industries, Ltd.), whereby TAP acquired the right to attach our proprietary safety needle device to their pre-filled syringes. The TAP Agreement has an effective date of January 1, 2002. Under the TAP Agreement, we have and will receive reimbursement for research and development expenses, payments related to the achievement of certain development and regulatory milestones, and on-going royalty payments based upon the number of pre-filled syringes manufactured with our proprietary safety needle device. The TAP Agreement is for a minimum period of three years. TAP is attaching our proprietary safety needle device to pre-filled syringes of Lupron Depot® (leuprolide acetate for depot suspension), the first pharmaceutical product available with our pre-filled syringe safety needle device and the first product in its class to offer an integral safety needle device on pre-filled syringes. TAP has branded this integral safety needle device LuproLoc™. TAP initiated the U.S. market launch of Lupron Depot® with LuproLoc™ in January 2003.

In April 2002, the Company entered into a Second Development and License Agreement with Kendall (the "2<sup>nd</sup> Kendall Agreement") relating to blood collection needles and blood collection needle/holder combinations. Under the terms of the agreement, SHPI will receive reimbursement for research and development expenses, payments related to the achievement of certain regulatory and sales milestones, and on-going royalty payments on all product sales. The FDA has already granted 510(k) clearance for marketing this proprietary safety blood collection device. It will compete in the \$130 million U.S. blood collection needle market.

In July 2002, we entered into a Distribution Agreement (the "PSS Agreement") with Physician Sales and Service, Inc. ("PSS") whereby PSS acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, PSS purchases SHPI branded product from us for resale to their end-user customers. The PSS Agreement is for a one-year period, which automatically renews for successive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

In August 2002, we entered into a Distribution Agreement (the "Medline Agreement") with Medline Industries, Inc. whereby Medline acquired the non-exclusive right to distribute and sell the LiftLoc® Safety Infusion Set. Under the terms of the agreement, Medline purchases SHPI branded product

from us for resale to their end-user customers. The Medline Agreement is for a one-year period, which automatically renews for successive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

In August 2002, the Company entered into a Distribution Agreement (the "Allegiance Agreement") with Allegiance Healthcare Corporation, now named Cardinal Health, whereby Allegiance acquired the non-exclusive right to distribute and sell the LiftLoc® Safety Infusion Set. Under the terms of the agreement, Allegiance purchases SHPI branded product from us for resale to their end-user customers. The Allegiance Agreement shall continue until 90 days after written notice of termination is received by either party.

In connection with these product agreements, all product introductions are scheduled and controlled by our distribution and license partners. There is no assurance that products will be launched as anticipated, that effective sales and marketing efforts will be maintained, or that we will realize future revenues in excess of any minimum purchase/royalty commitment from these agreements.

We plan to focus our research and development activities on the further development of additional products based upon our intellectual property portfolio and unique safety needle technologies. We plan to focus our business development efforts on continuing discussions and negotiations with third parties to generate revenues through additional OEM manufacturing, distribution and product licensing relationships.

### **Critical Accounting Policies**

#### *Revenue Recognition*

Pursuant to Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements," we recognize license revenue when the following criteria have been met: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectibility is reasonably assured.

We have received upfront fees totaling \$2,500,000 from Tyco Healthcare and \$100,000 from Merit. These upfront payments are being recognized ratably over the life of the respective agreements.

Product revenues are recognized upon the shipment of the product.

Royalty revenue is recognized when the related products are sold or upon our fulfillment of any future obligation under the related agreements. Revenue from development agreements is recognized as the services are performed in accordance with the stated terms of the agreements.

#### *Long-Lived Assets*

We review long-lived assets for impairment when events or changes in circumstances indicate that the book value of an asset may not be recoverable. We evaluate, at each balance sheet date, whether events and circumstances have occurred that indicate possible impairment. We use an estimate of future undiscounted net cash flows of the related asset or group of assets over the remaining life in measuring whether the assets are recoverable. As of December 31, 2002, management did not consider any of our long-lived assets to be impaired.

### **Years Ended December 31, 2002 and 2001**

During the year ended December 31, 2002, we had total operating revenue of \$1,630,948, compared with total operating revenue of \$520,074 for the year ended December 31, 2001. During 2002, we recognized \$636,425 in development fee revenue, \$506,900 in technology and licensing fee revenue, \$225,804 from product sales and \$261,819 in royalty revenue. Cost of goods sold combined with costs

incurred to generate development fee revenue in 2002 was \$295,921. During 2001, we recognized \$202,615 in development fee revenue and \$317,459 in technology and licensing fee revenue. Costs incurred to generate development fee revenue in 2001 were \$206,974. We will look to our product agreements, sales of our own branded products through distributors, and additional development and strategic arrangements for future revenue growth.

Research and development ("R&D") expenses in 2002 were \$2,468,347 compared to \$1,815,082 in 2001. The increase was primarily due to costs incurred in bringing the LiftLoc® Safety Infusion Set product line to market and hiring additional R&D personnel.

Sales and marketing ("S&M") expenses in 2002 were \$437,256 compared to \$342,803 in 2001. A significant amount of the increase results from sales and marketing expenses related to the market introduction of LiftLoc® Safety Infusion Set, including hiring a Vice President, Sales & Marketing, and establishing an internal customer service department.

General and administrative ("G&A") expenses in 2002 were \$1,079,927 compared to \$1,766,423 in 2001, a reduction of \$686,496. G&A expenses in 2001 included \$316,974 in one-time severance expenses related to contractual obligations to the former CEO. A concerted effort continues to minimize G&A expenses as a percentage of our total operating expenses.

Total operating expenses in 2002 were \$3,985,530 compared to \$3,924,308 in 2001, relatively flat on a year-to-year basis.

Other income (expense) was \$36,112 in 2002 compared to (\$64,714) in 2001. The change was primarily due to \$4,897 in interest expenses and finance charges paid in 2002 compared to \$79,040 in 2001. The decrease was due to the retirement of bridge loan financing entered into in 2001 prior to the capitalization concluded with Galen Partners and other accredited investors in November 2001.

Our net loss (not including preferred stock dividends) in 2002 was \$2,614,391, compared to \$3,675,922 in 2001. The primary factor contributing to the reduced loss in 2002 was our ability to generate a significant increase in revenue, while holding total operating expenses at the prior year level.

The Series A Preferred Stock Purchase Agreement (the "Series A Agreement") entered into in November 2001 provided that the investors had the right, but not the obligation to acquire additional shares of Series A Preferred Stock at \$.458 per share (\$5,000,000 total) during the 12 months following the initial closing date of November 7, 2001. In September 2002, Galen Partners exercised their option to purchase the additional shares to which they held rights. Under the terms of the Series A Agreement, the options to purchase held by the remaining qualified investors would expire in thirty days if not exercised. All of those holding options to purchase exercised some or all of their rights, purchasing an additional 10,944,339 shares of Series A Preferred stock. We realized net proceeds of \$5,002,957 from the transaction. A non-cash beneficial conversion charge of \$3,281,564 was recognized related to this transaction. This amount has been treated as a preferred stock dividend in the 2002 financial statements.

### **Liquidity and Capital Resources**

To date, we have financed our operations principally through private placements of equity securities, the sale of technology and patents, advanced royalties, development fees, technology and license fees and proceeds from the exercise of common stock rights. We used net cash for operating activities of \$2,568,832 during 2002, compared to net cash used of \$2,889,601 for 2001. In addition, during 2002, \$279,952 was used for the purchases of capital property and equipment, compared to \$53,112 during 2001. Net cash provided from financing activities in 2002 was \$5,002,957, all coming from the placement of preferred stock. In 2001, net cash of \$6,303,525 was provided through the sale of both preferred and common stock. As of December 31, 2002, our working capital was \$4,719,110 and our current liabilities were \$1,718,310.

Our working capital requirements for the foreseeable future will vary based upon a number of factors, including the costs to complete development work, the cost of bringing safety medical needle technologies and other products to commercial viability, the timing of the market launches of new safety needle products and the level of sales of our current products. As of December 31, 2002, we had accounts payable and accrued liabilities totaling \$515,972. We also had current deferred revenue of \$1,202,338, which will not require the use of cash. At December 31, 2002, we had cash of \$2,007,580, with an additional \$3,500,000 invested in certificates of deposit. This cash, along with cash generated from the sale of products, development fees and royalties, is expected to provide sufficient cash for us to execute our business plan in 2003. If we are not able to reduce our operating losses, our liquidity will be adversely affected and we may be required to seek additional sources of financing to fund operations. We may not be able to obtain adequate financing when needed or obtain it on terms which are satisfactory. Failure to raise capital when needed could prevent us from achieving our business objectives.

As of March 14, 2003, we had granted stock options that were exercisable for 6,657,500 shares of common stock at exercise prices ranging from \$1.00 to \$2.00 per share and issued warrants that are exercisable for 800,000 shares of common stock at exercise prices of \$1.25 and \$2.00 per share. The exercise of all such stock options and warrants would result in an equity infusion of \$9,760,169. All of these stock options and warrants are out of the money and there can be no assurance that any of the stock options or warrants will be exercised.

#### **Recent Accounting Pronouncements**

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 141, "Business Combinations", and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired outside of a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives will not be amortized, but rather will be tested at least annually for impairment. The adoption of SFAS No. 141 and No. 142 on January 1, 2002, did not have a material impact on our financial position or results of operations.

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." Under SFAS No. 143, the fair value of a liability for an asset retirement obligation must be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002. The adoption of SFAS No. 143 is not expected to have a material impact on our financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets." SFAS No. 144 supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of", and addresses financial accounting and reporting for the impairment or disposal of long-lived assets. The statement is effective for fiscal years beginning after December 15, 2001. The adoption of SFAS No. 144 on January 1, 2002, did not have a material impact on our financial position or results of operations.

In April 2002, the FASB issued SFAS No. 145, "Rescission of SFAS No. 4, 44, and 64, Amendment of SFAS No. 13, and Technical Corrections." SFAS No. 145, which is effective for fiscal years beginning after May 15, 2002, among other things, eliminates the requirement that gains and losses from the extinguishments of debt be classified as extraordinary items. We do not believe the adoption of SFAS No. 145 will have a significant effect on our financial position and results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," which is effective for exit or disposal activities that are initiated after December 31, 2002. SFAS No. 146 addresses significant issues related to the recognition, measurement, and reporting of costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." We do not believe that the adoption of SFAS No. 146 will have a significant effect on our financial position and results of operations.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure - an amendment of FASB Statement No. 123." SFAS No. 148 is effective for years ending after December 15, 2002, provides alternative methods for a voluntary change to the fair value based method of accounting for stock-based employee compensation and required prominent disclosure about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The adoption of SFAS No. 148 did not have a significant effect on our financial position and results of operations.

In November 2002, the FASB issued FASB Interpretation Number, or FIN. 45 "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others (an interpretation of SFAS No. 5, 57, and 107 and rescission of FIN 34)." FIN 45 clarifies the requirements of SFAS No. 5, "Accounting for Contingencies," relating to a guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. The adoption of FIN 45 did not have a significant effect on our financial position and results of operations.

In January 2003, the FASB issued FIN 46, "Consolidation of Variable Interest Entities, and interpretation of ARB 51." The primary objectives of FIN 46 are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights ("variable interest entities" or "VIE's") and how to determine when and which business enterprise should consolidate the VIE (the "primary beneficiary"). This new model for consolidation applies to an entity in which either (1) the equity investors (if any) do not have a controlling financial interest or (2) the equity investment at risk is insufficient to finance that entity's activities without receiving additional subordinated financial support from other parties. In addition, FIN 46 requires that both the primary beneficiary and all other enterprises with a significant variable interest in a VIE make additional disclosures. We do not believe that the adoption of FIN 46 will have a significant effect on our financial position and results of operations.

### Contractual Obligations

Our contractual obligations as of December 31, 2002 were as follows:

Obligation	Total	Payments Due by Year		
		2003	2004	Thereafter
Operating leases	\$ 866,627	\$ 244,823	\$ 253,908	\$ 367,896

We lease office space under a non-cancellable operating lease.

### Recent Financing Activities

The Series A Preferred Stock Purchase Agreement (the "Series A Agreement") entered into in November 2001 provided that the investors had the right, but not the obligation to acquire additional shares of Series A Preferred Stock at \$.458 per share (\$5,000,000 total) during the 12 months following the initial closing date of November 7, 2001. In September 2002, Galen Partners exercised their option to purchase the additional shares to which they held rights. Under terms of the Series A Agreement, the options to purchase held by the remaining qualified investors would expire in thirty days if not exercised. All of those holding options to purchase exercised some or all of their rights, purchasing an additional 10,944,339 shares of Series A Preferred stock. We realized net proceeds of \$5,002,957 from the transaction. A non-



cash beneficial conversion charge of \$3,281,564 was recognized related to this transaction. This amount has been treated as a preferred stock dividend in the 2002 financial statements.

### **Inflation**

We do not expect the impact of inflation on operations to be significant.

### **Risk Factors**

In addition to the risks set forth above, we are subject to certain other risk factors due to the industry in which we compete and the nature of our operations. These risk factors include the following:

***We have a history of losses and may never become profitable.***

We have incurred total net losses of \$25,507,638 since inception in November 1993. With the exception of the second quarter of 1999, all quarters have had operating losses. Among other things, our ability to achieve profitability is dependent on:

- Successful marketing of our products by our distribution partners and licensees;
- For products that are not subject to distribution or license arrangements, our ability to enter into OEM manufacturing or license arrangements on commercially advantageous terms; and
- Our ability to develop additional safety medical products.

There can be no assurance that we will become profitable.

***Our success is dependent on sales generated by our distribution and licensing partners.***

We have entered into licensing arrangements with Kendall, TAP and Merit. In addition, we have entered into a private label distribution agreement with Bard, and distribution agreements for our branded products with Cardinal Health, Medline and PSS. You should consider the following in assessing the value of these agreements and our financial prospects:

- We are reliant on our business partners for substantially all of our product revenues;
- Our product revenues will depend, in part, on the marketing ability, marketing plans and credit-worthiness of our business partners;
- The ability of our business partners to sell our products will depend on competitive factors and the resources such parties commit to the sale of our products. The extent to which our partners commit their resources to the sale of our products is entirely within their control. In addition, our partners are not obligated to pursue the development and commercialization of our products;
- We are dependent on our business partners with respect to release dates for the products under contract;
- Our licensed products and products subject to private label distribution agreements will be marketed under our business partners' labels and goodwill associated with use of the products may inure to the benefit of our business partners rather than to us;
- We have limited sales and marketing capabilities, and those resources are deployed in support of our distributors' efforts. At this time, we do not intend to build a direct sales and marketing infrastructure for commercial sales of products;

- Our distribution and licensing arrangements provide us with only limited protection from changes in manufacturing costs and raw materials costs;
- We may be limited in our ability to negotiate with new business partners upon any renewals of agreements;
- The Kendall Agreement can be terminated upon 15 days written notice;
- BD has filed a lawsuit against Tyco Healthcare asserting that the Monoject Magellan™ safety products infringe upon a BD patent. BD is seeking injunctive relief as well as damages, including attorneys' fees and costs, in an unspecified amount. Under a Development and License Agreement Tyco Healthcare has the right to withhold up to fifty percent (50%) of royalties due us as an offset against litigation expenses related to charges of infringement by a third party for the manufacture, use or sale of licensed product. This right continues during the period in which such litigation is pending. If, as a result of judgment in the litigation or settlement with BD, Tyco Healthcare is required to pay royalty and/or other monies to BD, Tyco Healthcare may thereafter deduct from the amount of royalties due us on unit sales of products alleged to infringe, an amount which is the lesser of all royalties and/or other monies paid by Tyco Healthcare to BD, or fifty percent (50%) of all royalty payments otherwise payable to us;
- Because our licensing arrangements are generally expected to provide our business partners with exclusivity with respect to the products to be marketed by those partners, our success will be highly dependent on the results obtained by our partners and the diligence with which our partners seek to develop, market and sell our products; and
- Our distribution and licensing arrangements do not provide for substantial minimum product royalties in the event our partners do not seek to develop, market or sell our products.

If our distribution and licensing partners are not successful in their efforts to develop, market and sell our products, it may result in the discontinuance of our business due to lack of revenue.

***We are dependent upon our licensing partners or contract manufacturers to manufacture our products.***

Under our licensing arrangements, we are primarily relying on licensees to arrange for the commercial manufacture of products. LiftLoc™ Safety Infusion Set is manufactured at a contract manufacturer under our authority and supervision. Contracting with third parties or relying on licensees to manufacture products presents the following risks:

- Delays in the manufacture of products could have a material adverse effect on the marketing of the products;
- The manufacturers may not comply with requirements imposed by the FDA or other governmental agencies;
- We may have to share intellectual property rights to improvements in the manufacturing processes or new manufacturing processes for products;
- In those instances where we may seek third-party manufacturers for new products, we may not be able to locate acceptable manufacturers or enter into favorable long-term agreements with them; and
- We may not be able to find substitute manufacturers, if necessary.

Any of these factors could delay commercialization of products and adversely affect the sale of the products and license or joint venture revenues.

***Our medical devices must be cleared or approved by the FDA before they can be sold in the U.S.***

Our ability to receive revenue from our products is subject to obtaining proper regulatory approvals. Moreover, obtaining FDA approval or clearance to market a product can be a lengthy and costly process, which, in some cases, involves extensive clinical studies. While we or our partners have received FDA clearance for our safety syringe needle, safety Huber needle products, safety angiographic needle, pre-filled syringe safety needle, and blood collection devices, we or our distribution partners or licensees may not be able to obtain the necessary FDA authorizations to allow marketing of our other products in a timely fashion, or at all.

Once the necessary FDA approvals or clearances are obtained, later problems with the product could cause the FDA to suspend or revoke the approvals or clearances. Also, once the FDA provides clearance to market our products, our distribution partners or licensees are subject to continuing requirements governing, among other things, the claims that can be made with respect to the products and manufacturing processes. Failing to comply with the FDA's requirements can result in issuance of FDA Warning Letters, FDA refusal to approve or clear products, revocation or withdrawal of approvals previously granted, product seizures, injunctions, recalls, operating restrictions, limitations on continued marketing and civil and criminal penalties.

Our manufacturing activities require us to comply with ongoing FDA requirements for submission of post market information. In addition, we are required to adhere to requirements pertaining to the FDA's current QSR. The current QSR requirements govern the methods, facilities and controls used for the manufacture, testing, design, packaging, labeling and storage of medical devices.

Our failure or the failure of our distribution partners or licensees to comply with the FDA and other applicable regulations could cause our business to be harmed significantly.

***There are negative pricing pressures on safety products.***

Prices for our safety products may be higher than for competing conventional products that are not designed to provide the safety protection afforded by our products. Our prices, however, are expected to be competitive with those of competing safety products. Continuing pressure from third-party payers to reduce costs in the healthcare industry, as well as increasing competition from safety products made by other companies, could adversely affect our selling prices. Reductions in selling prices could adversely affect our operating margins if we cannot achieve corresponding reductions in manufacturing costs.

***Our business could be adversely affected by changes in safety medical product technology.***

Our products are in various stages of production, pre-production, development and research. There is no assurance that development of superior products by competitors or changes in technology will not eliminate the need for our products. The introduction of competing products using different technology could adversely affect our attempts to develop and market our products.

***Our products may not be accepted by the market.***

The use of safety medical products, including our products, is relatively new. The market may not accept our products. Their acceptance will depend in large part on our ability to demonstrate the operational advantages, safety, efficacy, and cost-effectiveness of our products in comparison with competing products and our ability to distribute our products through major medical products companies or distributors. Our products may not achieve market acceptance and major medical products companies or distributors may not sell our products.

***Our long-term success is dependent on the success of our research and development efforts.***

Many of our safety medical needle technologies and products are still in various stages of pre-production, development and research. We are also exploring additional product applications for our technologies. The continued development of our products and development of additional applications and

new products is important to our long-term success. There can be no assurance that our technologies or products will be developed or, if developed, that they will be successful.

***Our success is dependent on our patents and proprietary rights.***

Our future success depends in part on our ability to protect our intellectual property and maintain the proprietary nature of our technologies through a combination of patents and other intellectual property arrangements. The protection provided by our patents and patent applications, if issued, may not be broad enough to prevent competitors from introducing similar products. In addition, our patents, if challenged, may not be upheld by the courts of any jurisdiction. Patent infringement litigation, either to enforce our patents or to defend us from infringement suits, would be expensive and, if it occurs, could divert our resources from other planned uses. Any adverse outcome in such litigation could have a material adverse effect on our ability to market, sell or license the related products. Patent applications filed in foreign countries and patents in such countries are subject to laws and procedures that differ from those in the U.S. Patent protection in such countries may be different from patent protection under U.S. laws and may not be as favorable to us. Some of our international patent prosecution efforts are funded by third parties. The failure of the funding parties to pay for the international patent prosecution costs would materially affect our ability to prosecute these patents. We also attempt to protect our proprietary information through the use of confidentiality agreements and by limiting access to our facilities. There can be no assurance that our program of patents, confidentiality agreements and restricted access to our facilities will be sufficient to protect our proprietary technology.

***We may not have adequate resources to manage anticipated growth.***

We may not be equipped to successfully manage any future periods of rapid growth or expansion, which could be expected to place a significant strain on our managerial, operating, financial and other resources. Our future performance will depend, in part, on our ability to manage growth effectively, which will require us to

- Improve existing and implement management information systems, operating, administrative, financial and accounting systems and controls;
- Maintain close coordination among engineering, accounting, finance, marketing, sales and operations; and
- Retain and train additional management, technical and marketing personnel.

There is intense competition for management, technical and marketing personnel in our business. Our failure to attract and retain additional key employees could have a material adverse effect on our ability to continue as a going concern.

***We are dependent on Management and Technical Personnel.***

Our success depends upon the skills, experience and efforts of our management, and technical personnel (the "working team"). Should the services of one or more members of our present working team become unavailable for any reason, our business could be adversely affected. The employment agreements that we have in place with the working team allow members of the working team to terminate their employment at any time. There is no assurance that we will be able to retain the existing working team or attract new employees of the caliber needed to achieve our objectives.

***Because we are significantly smaller than the majority of our competitors, we may lack the resources needed to capture market share.***

We are engaged in a highly competitive business and will compete directly with companies that have longer operating histories, more experience, substantially greater financial resources, greater size, more substantial research and development and marketing organizations, established distribution channels and are better situated in the market than us. Our competitors and potential competitors include Arrow, Baxter International, B. Braun, Becton, Dickinson and Company, Boston Scientific, Churchill Medical

Ltd., Cook, Inc., Horizon Medical Products, ICU Medical, Inc., Johnson & Johnson, Kendall, Manan Medical Products, Medamicus, Med-Design Corporation, Medi-Hut Co., Inc., Medisys Technologies, Inc., NMT Group PLC, Now Medical Technologies, Portex, Inc., Retractable Technologies, Inc., Terumo, and several others identified in Item 1 "Description of Business-Competition". Our competitors may use their economic strength to influence the market to continue to buy their existing products. Our competitors may also be potential strategic partners with respect to various products as are, for example, Kendall, Bard and Merit. We do not have an established customer base and are likely to encounter a high degree of competition in developing a customer base. One or more of these competitors could use their resources to improve their current products or develop new products that may compete more effectively with our products. New competitors may emerge and may develop products that compete with our products. No assurance can be given that we will be successful in competing in this industry.

***Potential product liability relating to failure of our safety products.***

The sale of safety medical devices entails an inherent risk of liability in the event of product failure or claim of harm caused by product operation. There can be no assurance that we will not be subject to such claims, that any claim will be successfully defended or, if we are found liable, that the claim will not exceed the limits of our insurance. Our current insurance coverage is in the amount of \$1 million per occurrence and \$2 million in aggregate. We also have an umbrella policy in the amount of \$4 million. In some cases, we have indemnification arrangements in place with strategic partners who are selling our products under their label or distributing our branded products. There is no assurance that we will maintain product liability insurance in the future, that such insurance will be available, or that we will not be subject to product liability claims in excess of our insurance coverage.

***Uncertainties in the healthcare industry create uncertainties regarding medical safety products.***

The healthcare industry is subject to changing political, economic and regulatory influences that may affect the procurement practices and operations of healthcare facilities. During the past several years, the healthcare industry has been subject to increased government regulation of reimbursement rates and capital expenditures. Among other things, third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and reimbursement levels for healthcare products and procedures. Because prices of our products may exceed the price of conventional products, the cost control policies of third-party payers, including government agencies, may adversely affect use of our products.

***Limitations on director liability.***

Our Certificate of Incorporation provides, as permitted by Delaware law, that our directors are not personally liable to the company or its stockholders for monetary damages for any action or failure to take any action, with specified exceptions. These provisions may discourage stockholders from bringing suit against a director for breach of duty and may reduce the likelihood of derivative litigation brought by stockholders on behalf of the company against a director. In addition, our Certificate of Incorporation and Bylaws provide for mandatory indemnification of directors and officers to the fullest extent permitted by Delaware law and we have entered into contracts with our directors and officers providing for such indemnification.

***Anti-takeover provisions of certificate of incorporation and bylaws may discourage non-negotiated takeover of our company.***

Our Certificate of Incorporation provides for the division of the board of directors into three classes substantially equal in number. At each annual meeting of stockholders one class of directors is to be elected for a three-year term. Amendments to this provision must be approved by a two-thirds vote of all the outstanding stock entitled to vote; the number of directors may be changed by a majority of the entire board of directors or by a two-thirds vote of the outstanding stock entitled to vote. Meetings of stockholders may be called only by the board of directors, our CEO or our president. Stockholder action may not be taken by written consent. These provisions could have the effect of (i) discouraging attempts at non-negotiated takeovers that may provide for stockholders to receive a premium price for their stock, or (ii) delaying or preventing a change of control, which some stockholders may believe is in their interest.

***Our common stock price may continue to be volatile.***

Market prices of securities of medical technology companies are highly volatile from time to time. The trading price of our common stock may be significantly affected by factors such as the announcement of new product or technical innovations by us or our competitors, proposed changes in the regulatory environment, or by other factors that may or may not relate directly to us. Sales of substantial amounts of common stock (including stock which may be issued upon exercise of warrants or stock options or upon conversion of the Series A Preferred Stock), or the perception that such sales may occur, could adversely affect the trading price of our common stock.

***We do not anticipate paying dividends in the foreseeable future.***

We have never paid dividends on our common stock. The payment of dividends, if any, on the common stock in the future is at the discretion of the board of directors and will depend upon our earnings, if any, capital requirements, financial condition and other relevant factors. The board of directors does not intend to declare any dividends on our common stock in the foreseeable future.

***Our common stock is subject to dilution.***

As of December 31, 2002, there were 17,921,479 shares of our common stock issued and outstanding. On this date we also had outstanding 21,861,369 shares of Series A Preferred Stock which is convertible into the same number of shares of common stock. The conversion rate of the Series A Preferred Stock can be adjusted upon the happening of certain triggering events. In addition, an aggregate of 7,347,500 additional shares of our common stock are issuable pursuant to stock options granted under our stock option plans and warrant agreements.

***No assurance of a liquid public market for our common stock.***

There can be no assurance as to the depth or liquidity of any market for our common stock or the prices at which holders may be able to sell their shares. As a result, an investment in our common stock may not be totally liquid, and investors may not be able to liquidate their investment readily or at all when they need or desire to sell.

***Applicability of low priced stock risk disclosure requirements may adversely affect the prices at which our common stock trades.***

Our common stock may be considered a low priced security under rules promulgated under the Securities Exchange Act of 1934. Under these rules, broker-dealers participating in transactions in low priced securities must first deliver a risk disclosure document which describes the risks associated with such stocks, the broker-dealer's duties, the customer's rights and remedies, and certain market and other information, and make a suitability determination approving the customer for low priced stock transactions based on the customer's financial situation, investment experience and objectives. Broker-dealers must also disclose these restrictions in writing to the customer, obtain specific written consent of the customer, and provide monthly account statements to the customer. With these restrictions, the likely effect of designation as a low priced stock will be to decrease the willingness of broker-dealers to make a market for the stock, to decrease the liquidity of the stock and to increase the transaction cost of sales and purchases of such stock compared to other securities.

**Item 7. Financial Statements**

See index to consolidated financial statements and consolidated financial statement schedules beginning on page F-1 hereof.

**Item 8. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure**

None.

### PART III

#### Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance With Section 16(a) of the Exchange Act

Set forth below is certain information concerning each of our directors and executive officers as of March 15, 2003.

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>With the Company Since</u>
Jeffrey M. Soinski	41	President, Chief Executive Officer and Director	2001
Guy J. Jordan, Ph.D. (1)(2)	54	Chairman of the Board	2001
Donald D. Solomon, Ph.D.	52	Vice President, Chief Operating Officer, Chief Technical Officer and Director	2000
Paul S. Evans	40	Vice President, Business Development, General Counsel and Secretary	2000
Larry D. Sheldon	52	Vice President, Sales and Marketing	2002
Keith L. Merrell	57	Controller, Acting Chief Financial Officer and Treasurer	2000
David W. Jahns (2)	37	Director, Chairman of Compensation Committee	2001
Stuart A. Randle (1)	43	Director	2001
Stephen I. Shapiro (2)	58	Director	2001
Robert R. Walker (1)	72	Director, Chairman of Audit Committee	1994

(1) Member of Audit Committee.

(2) Member of Compensation Committee.

*Jeffrey M. Soinski.* Mr. Soinski is our President, Chief Executive Officer and a director. His term as a director expires at the 2005 annual meeting of stockholders. Mr. Soinski brings 20 years of general management, business development and marketing experience to our company, including several years as the President and Chief Executive Officer of ViroTex Corporation ("ViroTex"), a venture-backed pharmaceutical company focused on the development and commercialization of proprietary drug delivery systems. Mr. Soinski was with ViroTex from 1992 through 1999. He merged ViroTex into Atrix Laboratories, Inc. (Nasdaq: ATRX) in 1998, and continued working with Atrix on a transitional basis through 1999. From 2000 through 2001, Mr. Soinski was the Managing Partner and Chief Executive Officer of Mad Dogs & Englishmen, a marketing communications firm with offices in New York and San Francisco. Mr. Soinski has a BA degree from Dartmouth College.

*Guy J. Jordan, Ph.D.* Dr. Jordan is our Chairman of the board. His term as a director expires at the 2005 annual meeting of stockholders. Dr. Jordan brings a wealth of senior management healthcare experience to our company, with a strong focus in the areas of vascular disease and oncology. Dr. Jordan recently retired as Group President for C.R. Bard, Inc. with global operating responsibility for their oncology businesses, geographic responsibility for Canada, Australia, Latin America and Asia Pacific, and functional responsibility for all of Bard's research and development. Prior to joining C.R. Bard in 1986, Dr. Jordan held senior product development positions at American Cyanamid. Dr. Jordan has a Ph.D. degree from Georgetown University and an MBA from Fairleigh Dickinson University.

*Donald D. Solomon, Ph.D.* Dr. Solomon is Chief Operating Officer, Chief Technology Officer, a Vice President and a director. His term as a director expires at the 2005 annual meeting of stockholders. Dr. Solomon joined us in October 2000 and has served as a director since March 2001. He has over 23 years of medical product experience in research, product development, engineering and manufacturing. Prior to joining our company, Dr. Solomon was the Vice President of Research and Development at Johnson & Johnson Medical – Vascular Access from 1997 to 2000. Prior to that Dr. Solomon spent 14 years at Becton Dickinson (“BD”), and held positions as Worldwide Director of R&D for BD Pharmaceutical Systems Division based in France, and Director of R&D for Biocompatible Polymer Development at the BD Infusion Therapy Division. Dr. Solomon holds 38 patents and is the author of 52 scientific publications. He received Masters and Ph.D. degrees from Case-Institute of Technology at Case Western Reserve University.

*Paul S. Evans.* Mr. Evans is our Vice President, Business Development, General Counsel and corporate Secretary. He joined us in June 2000. Mr. Evans manages our intellectual property portfolio and corporate legal matters, and is extensively involved in business development efforts. Mr. Evans brings a wide range of intellectual property and corporate legal experience to us, having previously served as Vice President, General Counsel for a R&D company (1994 to 2000), and as a patent attorney with the law firm of Snow, Christensen & Martineau. Prior to earning his law degree, Mr. Evans worked as a Project/Design Engineer for Morton International (now Autoliv). He holds BS and JD degrees from the University of Utah.

*Larry D. Sheldon.* Mr. Sheldon is our Vice President, Sales and Marketing. He joined us in November 2002. Mr. Sheldon brings over 24 years of relevant healthcare experience to our company, including domestic and international management of sales, marketing, national accounts, and customer service. Most of his experience is from Johnson & Johnson (“J&J”), where he was employed from 1978 to 1997. While at J&J, Mr. Sheldon served as Vice President, Corporate Distributor Business, responsible for managing distributor relationships for medical/surgical products with annual sales of \$1.7 billion. Mr. Sheldon also held several senior sales management positions at J&J in both the Patient Care and Hospital Services divisions. From 1998 to 2000, Mr. Sheldon was Senior Vice President, Sales and Marketing, for Paper Pak Products, Inc. From 2000 until joining our company in 2002, Mr. Sheldon was Senior Vice President, Sales and Marketing, at Tillotson Healthcare Corporation, a domestic medical and non-medical glove manufacturer. He has a BS degree from Fairleigh Dickinson University.

*Keith L. Merrell.* Mr. Merrell is our Controller, Acting Chief Financial Officer and Treasurer. He joined us in July 2000. Mr. Merrell draws on 28 years of accounting experience to manage all of our accounting functions and to interface with our independent public accountants. He spent two years in the field of public accounting, and served as Chief Financial Officer or Controller of four companies prior to his joining us. His business career also includes extensive experience in management, sales and marketing, and consulting. He served as Vice President – Western Operations for Michelex, an injection molding company with corporate headquarters in New York, from 1998 to 2000. From 1991 to 1998 he served as Director of Finance for The Duplication Group, planning, implementing and bringing online the first CD manufacturing facility in the intermountain area. He graduated from Arizona State University with a BS degree in Accounting.

*David W. Jahns.* Mr. Jahns serves as one of our directors. His term as a director expires at the 2003 annual meeting of stockholders. Mr. Jahns is a General Partner and principal of Galen Partners. Since joining Galen in 1993, Mr. Jahns has been responsible for making and managing investments in several of the firm’s portfolio companies. He is an experienced board member and currently serves on the boards of DAOU Systems, Inc. and several of Galen’s privately held portfolio companies. Prior to joining Galen, Mr. Jahns worked in the Corporate Finance Division at Smith Barney, where he worked on a variety of corporate finance and merger and acquisition related transactions, and assisted in the marketing of public offerings. Mr. Jahns has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BA degree from Colgate University.



*Stuart A. Randle.* Mr. Randle serves as one of our directors. His term as a director expires at the 2004 annual meeting of stockholders. Mr. Randle is a highly experienced healthcare executive with over 20 years of operating successes. From 1998 to 2001, Mr. Randle was the President and CEO of ACT Medical, Inc., a leading company providing outsourcing services to the medical device, biotech and diagnostic industries. He merged ACT Medical, Inc. with MedSource Technologies in 2001. From 1996 through 1998, Mr. Randle was President, Northeast Region, for Allegiance Corporation, a \$5 billion medical products distribution and manufacturing company. He is also the past President, New England Region, for Baxter Healthcare Corporation. Mr. Randle has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BS degree from Cornell University.

*Stephen I. Shapiro.* Mr. Shapiro serves as one of our directors. His term as a director expires at the 2004 annual meeting of stockholders. Mr. Shapiro has over 30 years of relevant medical device and equipment industry experience, with special expertise in a wide variety of healthcare markets, particularly high-volume sterile disposables, critical care instruments and cardiovascular devices. Mr. Shapiro began his career at Union Carbide Clinical Diagnostics and Becton Dickinson, where he was Director of Advanced R&D and New Business Development. In 1982, he joined The Wilkerson Group, a leading management consultancy to pharmaceutical, medical device, and diagnostic companies. Mr. Shapiro was Managing Director and a principal of The Wilkerson Group at the time of its acquisition by IBM in 1996. In 1999, Mr. Shapiro left The Wilkerson Group (now IBM Healthcare Consulting) to focus on sourcing and evaluating investments for two premier healthcare venture capital firms, including Galen Partners. He currently serves on the board of Noveste Corporation. Mr. Shapiro has a BS degree from the Massachusetts Institute of Technology and an MS degree in biomedical engineering from the University of California, Berkeley.

*Robert R. Walker.* Mr. Walker serves as one of our directors. His term as a director expires at the 2003 annual meeting of stockholders. Since 1992, Mr. Walker has been principally self-employed as a consultant in the healthcare industry primarily in the area of start-up medical device companies. From 1976 to 1992, Mr. Walker was employed by IHC Affiliated Services Division of Intermountain Healthcare, a regional hospital company. He retired as President of IHC Affiliated Services in 1992. He is also a former Chairman of the board of AmeriNet, Inc., a national group purchasing organization for hospitals, clinics, detox/drug centers, emergency, nursing homes, private laboratories, psychiatric centers, rehabilitation facilities, surgical centers and other institutions. Mr. Walker is a member of the American Hospital Association and the Hospital Financial Management Association. He has a BS degree in Business Administration from the University of Utah.

Our executive officers are elected by the board on an annual basis and serve at the discretion of the board.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers, directors and persons who beneficially own more than 10% of our common stock to file initial reports of ownership and reports of changes in ownership with the SEC. Such persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms filed by such persons.

Based solely on our review of forms furnished to us and representations from reporting persons, we believe that all filing requirements applicable to our executive officers, directors and more than 10% stockholders were complied with during 2002.

#### **Item 10. Executive Compensation**

The tables below set forth certain information concerning compensation paid by us to our Chief Executive Officer and all other executive officers with annual compensation in excess of \$100,000 (determined for the year ended December 31, 2002) (the "Named Executive Officers"). The tables include information related to stock options granted to the Named Executive Officers.

*Summary Compensation Table.* The following table provides certain information regarding compensation paid by us to the Named Executive Officers.

**SUMMARY COMPENSATION TABLE**

Name and Principal Position	Year	Annual Compensation			Awards		Payouts	All Other Compensation (\$)
		Salary (\$)	Bonus (\$)	Other Annual Compensation\$(1)	Restricted Stock Awards (\$)	Stock Options/ SAR(#)	LTIP Payouts(\$)	
Jeffrey M. Soinski (2), President, CEO & director	2001	14,615	---	---	---	2,500,000	---	---
	2002	240,000	43,200(6)	---	---	---	---	610(4)
Donald D. Solomon, Ph.D. (3), VP, CTO, COO & director	2000	31,942	---	1,375	---	100,000	---	---
	2001	165,000	---	8,250	---	600,000	---	273(4)
	2002	190,000	34,200(6)	9,500	---	---	---	1,081(4)
Paul S. Evans (3), VP, Business Development, General Counsel & Secretary	2000	86,798	---	2,406	28,125	100,000	---	268(4)
	2001	165,000	---	7,219	---	400,000	---	460(4)
	2002	175,000	31,500(6)	---	---	---	---	579(4)
Larry D. Sheldon (5) VP, Sales and Marketing	2002	21,923	---	---	---	500,000	---	---
Keith L. Merrell (3) Acting CFO, Controller & Treasurer	2000	41,250	---	2,062	---	50,000	---	179(4)
	2001	90,000	---	4,500	---	55,000	---	410(4)
	2002	102,000	3,000	5,100	---	---	---	456(4)

- (1) These amounts represent payments by us into our 401(k) retirement plan for the benefit of the Named Executive Officer.
- (2) Mr. Soinski joined SHPI in November 2001. Salary represents partial year from the date of his employment.
- (3) Dr. Solomon and Messrs. Evans and Merrell joined SHPI in 2000. Salaries for 2000 represent partial year from the date of their employment
- (4) Represents amounts paid by us for life insurance on the lives of Mr. Soinski, Dr. Solomon, Mr. Evans and Mr. Merrell with insurance proceeds payable to the beneficiary designated by them.
- (5) Mr. Sheldon joined SHPI in November 2002. Salary represents partial year from the date of his employment.
- (6) Bonuses accrued and expensed in 2002; paid out in 2003.

*Option Grants in Fiscal Year 2002.* The following table sets forth certain information with respect to stock options grants during the year ended December 31, 2002 to Named Executive Officers.

**OPTION/SAR GRANTS IN LAST FISCAL YEAR  
(Individual Grants)**

Name	Number of Securities Underlying Options/SAR Granted (#) (1)	Percent of Total Options/SAR Granted to Employees in Fiscal Year	Exercise or Base Price (\$/Share)	Expiration Date
Larry D. Sheldon	500,000	100%	\$1.00	12/30/2012

- (1) These options were granted pursuant to our 2000 Stock Option Plan.

## Compensation of Directors

No cash fees or other consideration were paid to our employee directors for service on the board during 2002. We did not provide cash compensation to non-employee directors in 2002 and do not plan to do so in 2003. Prior to 2002 we granted stock options, which vest over a three year period, to our non-employee directors as compensation for service on the board. We have made no other agreements regarding compensation of non-employee directors. All directors are entitled to reimbursement for reasonable out-of-pocket travel related expenses incurred in the performance of their duties as board members.

## Employment and Indemnity Agreements

We have entered into an employment agreement with Mr. Jeffrey Soinski. The employment agreement provides that (i) Mr. Soinski receive a beginning base salary of \$240,000 per year in addition to performance based bonuses; (ii) Mr. Soinski receive stock options to acquire 2.5 million shares of our common stock at market value on the date of grant which stock options vest over a four-year period; (iii) Mr. Soinski is entitled to vacation pay, health insurance and life insurance; (iv) Mr. Soinski's employment contract may be terminated at any time by us; (v) if the employment of Mr. Soinski is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Mr. Soinski is terminated for reasons other than disability, death or for cause, then Mr. Soinski's salary and medical benefits will continue for a period of 18 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Donald Solomon, Ph.D. The employment agreement provides that (i) Dr. Solomon receive a beginning base salary of \$190,000 per year in addition to performance based bonuses; (ii) Dr. Solomon receive stock options to acquire 600,000 shares of our common stock at market value on the date of grant which stock options vest over a four-year period; (iii) Dr. Solomon is entitled to vacation pay, health insurance and life insurance; (iv) Dr. Solomon's employment contract may be terminated at any time by us; (v) if the employment of Dr. Solomon is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Dr. Solomon is terminated for reasons other than disability, death or for cause, then Dr. Solomon's salary and medical benefits will continue for a period of 12 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Mr. Paul Evans. The employment agreement provides that (i) Mr. Evans receive a beginning base salary of \$175,000 per year in addition to performance based bonuses; (ii) Mr. Evans receive stock options to acquire 400,000 shares of our common stock at market value on the date of grant which stock options vest over a four-year period; (iii) Mr. Evans is entitled to vacation pay, health insurance and life insurance; (iv) Mr. Evans' employment contract may be terminated at any time by us; (v) if the employment of Mr. Evans is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Mr. Evans is terminated for reasons other than disability, death or for cause, then Mr. Evans' salary and medical benefits will continue for a period of 12 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Mr. Keith Merrell. The employment agreement provides that (i) Mr. Merrell receive a beginning base salary of \$102,000 per year in addition to performance based bonuses; (ii) Mr. Merrell receive stock options to acquire 55,000 shares of our common stock at market value on the date of grant which stock options vest over a four-year period; (iii) Mr. Merrell is entitled to vacation pay and health insurance; (iv) Mr. Merrell's employment contract may be terminated at any time by us; (v) if the employment of Mr. Merrell is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Mr. Merrell is terminated for reasons other than disability, death or for cause, then Mr.

Merrell's salary and medical benefits will continue for a period of 3 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Mr. Larry D. Sheldon. Mr. Sheldon's employment agreement provides that (i) Mr. Sheldon receive a beginning base salary of \$180,000 per year; (ii) Mr. Sheldon's current employment agreement terminates on November 30, 2004 should he fail to relocate to Salt Lake City by that date; (iii) Mr. Sheldon receive stock options to acquire 500,000 shares of our common stock at a price of one dollar per share which stock options vest over a four-year period; (iv) Mr. Sheldon is entitled to vacation pay, health insurance and life insurance; (v) Mr. Sheldon's employment contract may be terminated at any time by us; (vi) if the employment of Mr. Sheldon is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vii) if Mr. Sheldon is terminated for reasons other than disability, death or for cause, then Mr. Sheldon's salary and medical benefits will continue for a period of 6 months from the date of termination and his other benefits will cease as of the date of termination. However, in the event Mr. Sheldon is not employed at the end of the 6-month period following termination, Mr. Sheldon shall be entitled to salary and medical benefits for up to an additional 6 months.

In January 2003, we approved a 2003 Executive Officer Bonus Plan. Under the plan executive officers eligible for bonuses during 2003 include the CEO, COO, VP of Sales and Marketing and VP of Business Development and General Counsel. Plan participants will earn 20% of their annual salary based upon 100% achievement of the overall revenue goal outlined in our approved budget plan. Also, plan participants will be eligible to receive incremental bonus payments for performing beyond the budget plan. The amount of incremental payments, if earned, will be based upon the recommendation of the Compensation Committee and approved by the board of directors. The maximum base bonus that could be paid under this plan is \$160,200. In connection with this plan, we also adopted an Employee Bonus Plan for employees other than the Named Executive Officers to reward specific individual or team achievements during 2003.

We have entered into indemnity agreements (the "Indemnity Agreements") with each of our executive officers and directors pursuant to which we have agreed to indemnify the officers and directors to the fullest extent permitted by law for any event or occurrence related to the service of the indemnitee for us as an officer or director that takes place prior to or after the execution of the Indemnity Agreement. The Indemnity Agreements obligate us to reimburse or advance expenses relating to any proceeding arising out of an indemnifiable event. Under the Indemnity Agreements, our officers and directors are presumed to have met the relevant standards of conduct required by Delaware law for indemnification. Should the Indemnity Agreements be held to be unenforceable, indemnification of these officers and directors may be provided by us in certain cases at our discretion.

#### **401(k) Retirement Plan**

Effective in 1996, we adopted a 401(k) retirement plan whereby we contribute up to five percent of payroll compensation to the plan, matching employee contributions to the plan on a dollar for dollar basis up to the maximum five percent contribution.

#### **Accrued Vacation Pay**

Our current policy allows all employs to carry over maximum days of vacation pay from year to year equivalent to a one-year accrual at the rate earned.

#### **Indemnification for Securities Act Liabilities**

Delaware law authorizes, and our Bylaws and Indemnity Agreements provide for, indemnification of our directors and officers against claims, liabilities, amounts paid in settlement and expenses in a variety of circumstances. Indemnification for liabilities arising under the Act may be permitted for our directors,

officers and controlling persons pursuant to the foregoing or otherwise. However, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Exchange Act of 1934 and is, therefore, unenforceable.

### Stock Options and Warrants

In November 2001, our stockholders approved the adoption of the Specialized Health Products International, Inc. 2001 Stock Option Plan (the "2001 Option Plan"). The 2001 Option Plan permits us to grant "non-qualified stock options" and "incentive stock options" to acquire our common stock. The total number of shares authorized for the Option Plan may be allocated by the board between the non-qualified stock options and the incentive stock options from time to time, subject to certain requirements of the Internal Revenue Code of 1986, as amended. The option exercise price per share under the Option Plan may not be less than the fair market value of a share of common stock on the date on which the option is granted. A total of 5,000,000 shares are allocated to the Option Plan. As of December 31, 2002, options to acquire an aggregate of 4,984,690 shares of common stock at exercise prices ranging from \$1.00 to \$2.00 were outstanding under the Option Plan.

We have also issued stock options under stock options plans that preceded the 2001 Option Plan ("Prior Plans"). As of December 31, 2002, options to acquire an aggregate of 1,562,810 shares of common stock at exercise prices ranging from \$1.00 to \$2.00 were outstanding under Prior Plans.

In addition to the stock options detailed above, we have outstanding warrants to buy 800,000 shares of common stock at exercise prices of \$1.25 to \$2.00.

### Compensation Committee Interlocks and Insider Participation

None of our executive officers serve on our Compensation Committee or in a like capacity in any other entity.

### Item 11. Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 14, 2003, for: (i) each person who is known by us to beneficially own more than five percent of our common stock, (ii) each of our directors, (iii) each of our Named Executive Officers, and (iv) all directors and executive officers as a group.

<u>Name and Address of Beneficial Owner(1)</u>	<u>Shares Beneficially Owned(2)</u>	<u>Percentage of Total(2)</u>	<u>Position</u>
Jeffrey M. Soinski (3)	892,354	4.74	President, CEO and Director
Guy J. Jordan, Ph.D. (4)	188,555	1.04	Chairman of the Board
Donald D. Solomon, Ph.D. (5)	422,541	2.30	Vice President, COO, CTO and Director
Paul S. Evans (6)	327,309	1.79	Vice President, Business Development, General Counsel, and Secretary
Larry D. Sheldon(7)	3,132	*	Vice President, Sales and Marketing
Keith L. Merrell (8)	152,214	*	Controller, Acting CFO and Treasurer
David W. Jahns (9)	47,218	*	Director

<u>Name and Address of Beneficial Owner(1)</u>	<u>Shares Beneficially Owned(2)</u>	<u>Percentage of Total(2)</u>	<u>Position</u>
Stuart A. Randle (10)	44,441	*	Director
Stephen I. Shapiro (11)	112,721	*	Director
Robert R. Walker (12)	184,218	1.02	Director
Executive Officers and Directors as a Group (10 persons)	2,370,388	5.6%	
Galen Partners III, L.P. and affiliates (13)	15,256,413	38.3%	

\* Less than 1%.

- (1) Except where otherwise indicated, the address of the beneficial owner is deemed to be the same address as the company.
- (2) Beneficial ownership is determined in accordance with SEC rules and generally includes holding voting and investment power with respect to the securities. Shares of common stock subject to options or warrants currently exercisable, or exercisable within 60 days, are deemed outstanding for computing the percentage of the total number of shares beneficially owned by the designated person, but are not deemed outstanding for computing the percentage for any other person.
- (3) Includes 6,911 shares of common stock purchased through our 401(k) plan and options to acquire 885,410 shares of common stock. Does not include options to acquire 1,614,590 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (4) Includes options to acquire 188,555 shares of common stock. Does not include options to acquire 211,445 shares of common stock that vest 60 days beyond March 14. Those options vest, in cumulative fashion, in equal monthly installments ending on the four-year anniversary of the date of grant.
- (5) Includes 10,000 shares of common stock, 65,666 shares of Series A Preferred Stock that is immediately convertible into the same number of shares of common stock, 44,380 shares of common stock purchased through our 401(k) plan and options to acquire 312,495 shares of common stock. Does not include options to acquire 278,646 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (6) Includes 61,000 shares of common stock, 24,649 shares of common stock purchased through our 401(k) plan and options to acquire 241,660 shares of common stock. Does not include options to acquire 258,340 shares of common stock that vest 60 days beyond March 14. Those options vest, in cumulative fashion, in equal monthly installments ending on the four-year anniversary of the date of grant.
- (7) Includes 3,132 shares of common stock purchased through our 401(k) plan.
- (8) Includes 36,000 shares of common stock, 26,284 shares of common stock purchased through our 401(k) plan and options to acquire 50,000 shares of common stock. Does not include options to acquire 15,070 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (9) Includes options to acquire 47,218 shares of common stock. Does not include options to acquire 52,782 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006. Does not include shares held by Galen Partners III, L.P. David Jahns is a member of Claudius, L.L.C., a Delaware limited liability company, and a general partner of Galen Partners III, L.P. and Galen Partners International III, L.P. See note (13) below.

- (10) Includes options to acquire 44,441 shares of common stock. Does not include options to acquire 55,559 shares of common stock that vest in equal monthly installments between May 27, 2003 and December 27, 2006.
- (11) Includes 65,503 shares of Series A Preferred Stock that is immediately convertible into the same number of shares of common stock and options to acquire 47,218 shares of common stock. Does not include options to acquire 52,782 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (12) Includes stock options to purchase 121,218 shares of common stock and 63,000 shares of common stock that Mr. Walker is deemed to beneficially own through a trust. Does not include options to acquire 52,782 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (13) Information regarding Galen Partners III, L.P. and its affiliates is derived from the Form 4 filed by Galen Partners III, L.P. with the Securities and Exchange Commission on September 9 and September 26, 2002. Shares owned represent 13,937,735 shares of Series A Preferred Stock held of record by Galen Partners III, L.P., 1,261,605 shares of Series A Preferred Stock held of record by Galen Partners International III, L.P., and 57,073 shares of Series A Preferred Stock held of record by Galen Employee Fund III, L.P. William R. Grant, Bruce F. Wesson, L. John Wilkerson, David W. Jahns, Srinj Conjeevaram, and Zubeen Shroff are all natural persons and are the members of Claudius, L.L.C., a Delaware limited liability company, the general partner of Galen Partners III, L.P. and Galen Partners International III, L.P. Bruce F. Wesson is the President of Wesson Enterprises, Inc., a Delaware corporation, which is the general partner of Galen Employee Fund III, L.P.

#### Series A Preferred Stock

The Company currently has issued and outstanding 21,861,369 shares of Series A Preferred Stock which is convertible into the same number of shares of common stock. The conversion rate of the Series A Preferred Stock can be adjusted upon the happening of certain triggering events. Galen Partners III, L.P. and affiliates own 15,256,413 of these shares as described in the above table, which comprises 69.78% of the outstanding Series A Preferred Stock. No other stockholder owns more than 5% of the outstanding Series A Preferred Stock.

#### Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information with respect to the Company's equity compensation plans approved by security holders and plans not approved by security holders for the year ended December 31, 2002.

#### Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	7,347,500	\$1.31	952,500
Equity compensation plans not approved by security holders	0		0
<b>Total</b>	<b>7,347,500</b>	<b>\$1.31</b>	<b>952,500</b>

## **Item 12. Certain Relationships and Related Transactions**

On November 7, 2001, our stockholders approved the issuance to Galen Partners and other accredited and sophisticated investors of a total of 10,917,030 shares of Series A Preferred Stock for an aggregate purchase price of \$5 million, or \$.458 per share. Galen Partners purchased their shares for \$3,500,000 and the other investors purchased their shares in exchange for the cancellation of \$1,500,000 of debt.

In September and November 2002, Galen Partners and other accredited and sophisticated investors exercised rights to acquire an additional 10,944,339 shares of Series A Preferred Stock for an aggregate net purchase price of \$5,002,957, or \$.458 per share. The Series A Preferred Stock is immediately convertible into the same number of shares of our common stock and the conversion rate is subject to adjustment if we issue additional shares of common stock for an amount less than the then current conversion price and upon the happening of certain other events.

## **Item 13. Exhibits and Reports on Form 8-K**

### **Exhibits**

Listed on page 43 hereof.

### **Reports on Form 8-K**

None

## **Item 14. Controls and Procedures**

Within the 90 days prior to this report, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including our consolidated subsidiaries) required to be included in our periodic SEC filings. There have been no significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation.

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## SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**SPECIALIZED HEALTH PRODUCTS  
INTERNATIONAL, INC.**  
(Registrant)

Date: March 14, 2003

By /s/ Jeffrey M. Soinski  
Jeffrey M. Soinski  
President, Chief Executive Officer and Director

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Jeffrey M. Soinski</u> Jeffrey M. Soinski	President, Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2003
<u>/s/ Keith L. Merrell</u> Keith L. Merrell	Controller, Acting Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 14, 2003
<u>/s/ Guy J. Jordan, Ph.D.</u> Guy J. Jordan, Ph.D.	Chairman of the Board	March 14, 2003
<u>/s/ Donald D. Solomon, Ph.D.</u> Donald D. Solomon, Ph.D.	Director, Vice President, COO and CTO	March 14, 2003
<u>/s/ David W. Jahns</u> David W. Jahns	Director	March 14, 2003
<u>/s/ Stuart A. Randle</u> Stuart A. Randle	Director	March 14, 2003
<u>/s/ Stephen I. Shapiro</u> Steve I. Shapiro	Director	March 14, 2003
<u>/s/ Robert R. Walker</u> Robert R. Walker	Director	March 14, 2003

## CERTIFICATIONS

### CEO Certification

I, Jeffrey M. Soinski, as Chief Executive Officer of the Company, certify that:

1. I have reviewed this annual report on Form 10-KSB of Specialized Health Products International, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 14, 2003

/s/ Jeffrey M. Soinski

Jeffrey M. Soinski

President, Chief Executive Officer, Director

CFO Certification

I, Keith L. Merrell, as acting Chief Financial Officer of the Company, certify that:

1. I have reviewed this annual report on Form 10-KSB of Specialized Health Products International, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - d. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - e. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 14, 2003

/s/ Keith L. Merrell

Keith L. Merrell

Acting Chief Financial Officer

## EXHIBIT INDEX

<u>EXHIBIT NO.</u>	<u>DESCRIPTION OF EXHIBIT</u>
3(i).1	Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3(i).1 of the Company's Form 10-QSB, dated September 30, 2001).
3(i).2	Certificate of Designations, Preferences and Limitations of Series A Preferred Stock, dated November 6, 2001 (Incorporated by reference to Exhibit 3(i).2 of the Company's Form 10-QSB, dated September 30, 2001).
3(i).3	Articles of Incorporation of Specialized Health Products, Inc. ("SHP") (Incorporated by reference to Exhibit 3(i).2 of the Company's Registration Statement on Form S-1 filed December 11, 1995 (File No. 33-901014)).
3(i).4	Articles of Amendment of SHP (Incorporated by reference to Exhibit 3(i).3 of the Company's Registration Statement on Form S-1 filed December 11, 1995 (File No. 33-901014)).
3(ii).1	Second Amended and Restated Bylaws of the Company.
3(ii).2	Bylaws of SHP (Incorporated by reference to Exhibit 3(ii).2 of the Company's Registration Statement on Form S-1 filed December 11, 1995 (File No. 33-901014)).
10.1	Employment Agreement with Jeffrey M. Soinski, dated November 8, 2001 (Incorporated by reference to Exhibit 10.1 of the Company's Form 10-QSB, dated September 30, 2001).
10.2	Employment Agreement with Donald D. Solomon, Ph.D. (Incorporated by reference to Exhibit 10.2 of the Company's Form 10-KSB, dated December 31, 2001).
10.3	Employment Agreement with Mr. Paul S. Evans. (Incorporated by reference to Exhibit 10.2 of the Company's Form 10-KSB, dated December 31, 2001).
10.4	Form of Indemnity Agreement with Executive Officers and Directors (Incorporated by reference to Exhibit 10.4 of the Company's Form 10-KSB, dated December 31, 2000).
10.5	Employment Agreement with Mr. Larry Sheldon.
10.6	Development and License Agreement, effective date of March 29, 2000, by and among Safety Syringe Corporation, a wholly owned subsidiary of the Company and The Kendall Company (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, dated March 29, 2000).
10.7	License Agreement by and among Merit Medical Systems, Inc. and Safety Syringe Corporation (Incorporated by reference to Exhibit 10.7 of the Company's Form 10-KSB, dated December 31, 2000).
10.8	Specialized Health Products International, Inc. 1998 Stock Option Plan (Incorporated by reference to Appendix A to the Company's Amended Proxy Statement filed October 1, 1998).
10.9	Specialized Health Products International, Inc. 2000 Stock Option Plan (Incorporated by reference to Exhibit 10.7 of the Company's Quarterly Report on Form 10-QSB, dated June 30, 2000).
10.10	Specialized Health Products International, Inc. 2001 Stock Option Plan (Incorporated by reference to Exhibit 10.9 of the Company's Quarterly Report on Form 10-QSB, dated September 30, 2001).
10.11	Series A Stock Purchase Agreement, dated October 5, 2001, by and between the Company and the investors identified therein (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, dated November 7, 2001).
10.12	Investors' Rights Agreement, dated October 5, 2001, by and between the Company and the

## Exhibit 99.2

In connection with the Annual Report of Specialized Health Products International, Inc. (the "Company") on Form 10-KSB for the period ending December 31, 2002, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keith L. Merrell, acting Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Keith L. Merrell  
Acting Chief Financial Officer  
March 14, 2003

**SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.**  
585 West 500 South  
Bountiful, Utah 84010

**NOTICE OF ANNUAL MEETING OF STOCKHOLDERS**  
May 29, 2003

NOTICE is hereby given that the Annual Meeting of Stockholders of Specialized Health Products International, Inc. (the "Company") will be held at the Little America Hotel located at 500 South Main Street, Salt Lake City, Utah 84101, at 9:00 a.m. MDT on May 29, 2003, for the following purposes:

1. To elect two members of the Board of Directors; and
2. To transact such other business as may properly come before such meeting or any adjournments thereof.

The record date for the meeting is the close of business on April 15, 2003 and only the holders of voting securities of the Company on that date will be entitled to vote at such meeting or any adjournment thereof.

By order of the Board of Directors

/s/ Paul S. Evans  
Secretary

April 15, 2003

*Please Return Your Signed Proxy*

**PLEASE COMPLETE AND PROMPTLY RETURN YOUR PROXY IN THE ENCLOSED ENVELOPE. THIS WILL NOT PREVENT YOU FROM VOTING IN PERSON AT THE MEETING. IT WILL, HOWEVER, HELP ASSURE A QUORUM AND AVOID ADDED PROXY SOLICITATION COSTS.**

## PROXY STATEMENT

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**SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.**  
585 West 500 South  
Bountiful, Utah 84010

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### ANNUAL MEETING OF STOCKHOLDERS

To Be Held May 29, 2003

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### INTRODUCTION

This Proxy Statement is being furnished to holders of Specialized Health Products International, Inc. (the "Company") common stock (the "Common Stock"), par value \$0.02 per share, and Series A Preferred Stock (the "Preferred Shares"), par value \$.001 per share, in connection with the solicitation of proxies by the Company for use at the Annual Meeting of Stockholders of the Company (the "Annual Meeting") to be held at the Little America Hotel located at 500 South Main Street, Salt Lake City, Utah 84101, at 9:00 a.m. MDT on May 29, 2003, and at any adjournment(s) or postponement(s) thereof. The Company's Common Stock and Preferred Shares are sometimes hereinafter referred to jointly as the "Shares." This Proxy Statement, the enclosed Notice and the enclosed form of proxy are being first mailed to stockholders of the Company on or about April 15, 2003.

### VOTING AT THE ANNUAL MEETING

The Board of Directors of the Company (the "Board") has fixed the close of business on April 15, 2003, as the record date (the "Record Date") for the determination of stockholders entitled to notice of and to vote at the Annual Meeting. As of the Record Date, there were outstanding 17,921,479 shares of Common Stock held by approximately 320 holders of record and 21,861,369 Preferred Shares held by approximately 29 holders of record. On the Record Date there were no Shares of the Company's stock held as treasury stock by the Company. Holders of record of the Company's Shares on the Record Date are entitled to cast one vote per Share, exercisable in person or by properly executed proxy, with respect to each matter to be considered by them at the Annual Meeting. The presence, in person or by properly executed proxy, of the holders of a majority of the outstanding Shares is necessary to constitute a quorum at the Annual Meeting.

The Shares will be voted in accordance with the instructions indicated in a properly executed proxy. If no instructions are indicated, such Shares will be voted as recommended by the Board. If any other matters are properly presented to the Annual Meeting for action, the person(s) named in the enclosed form(s) of proxy and acting thereunder will have discretion to vote on such matters in accordance with their best judgment. Broker non-votes and abstentions are not treated as votes cast for purposes of any of the matters to be voted on at the meeting. A stockholder who has given a proxy may revoke it by voting in person at the meeting, or by giving written notice of revocation or a later-dated proxy to the Secretary of the Company at any time before the closing of the polls at the meeting. Any written notice revoking a proxy should be sent to Specialized Health Products International, Inc., 585 West 500 South, Bountiful, Utah 84010, Attention: Mr. Paul S. Evans, Secretary.

At the Company's annual meeting, stockholders will act upon the matters outlined in the accompanying notice of meeting, including the election of one director (the "Common Director") by the holders of Common Stock and the election of one director (the "Series A Preferred Director") by the holders of Preferred Stock. The affirmative vote of a plurality of the votes cast at the meeting by the holders of the Common Stock is required to elect the Common Director. The affirmative vote of a plurality of the votes cast at the meeting by the holders of the Preferred Stock is required to elect the Series A Preferred Director. The Board recommends that holders of the Shares vote FOR the approval of election of the directors proposed by the Board.

## MATTERS TO BE CONSIDERED AT THE ANNUAL MEETING

### 1. Election of Directors

#### Board of Directors

The Company's Board is divided into three classes. One class of directors is elected at each annual meeting of stockholders for a three-year term. Holders of the Common Stock are entitled to elect five of the seven Board members and holders of the Preferred Stock are entitled to elect two of the seven Board members. Each year a different class of directors is elected on a rotating basis. The terms of David W. Jahns and Robert W. Walker expire in 2003. The terms of Stephen I. Shapiro and Stuart A. Randle expire in 2004. The terms of Jeffrey M. Soinski, Guy J. Jordan and Donald D. Solomon expire in 2005. David W. Jahns and Stephen I. Shapiro are Series A Preferred Directors and the other five directors are Common Directors. No other person has acted as a director of the Company during 2002. The number of directors comprising the Board of Directors is seven.

At this meeting two directors have been nominated by the Board for election to the class whose term expires at the 2006 annual meeting. David W. Jahns has been nominated as the Series A Preferred Director and Robert R. Walker has been nominated as the Common Director.

Unless otherwise specified, proxy votes will be cast for the election of the nominee as a director. If the nominee should be unavailable for election, the Board may designate a substitute nominee. It is intended that proxy votes will be cast for the election of such substitute nominee. Stockholder nominations of persons for election as directors are subject to the notice requirements described under the caption "Other Matters" appearing later in this proxy statement. The affirmative vote of a plurality of the votes cast at the meeting by the holders of the Preferred Shares is required to elect the Series A Preferred Director. The affirmative vote of a plurality of the votes cast at the meeting by the holders of the Common Stock is required to elect the Common Director.

The following pages contain information concerning the nominee and the directors whose terms of office will continue after the meeting. Unless the context otherwise requires, all references in this Proxy to the "Company" shall mean Specialized Health Products International, Inc. ("SHPI") and its subsidiaries, Specialized Health Products, Inc. and its other subsidiaries, on a consolidated basis and, where the context so requires, shall include its predecessors.

THE BOARD RECOMMENDS A VOTE FOR THE ELECTION AS DIRECTOR OF THE NOMINEES NAMED HEREIN.

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Set forth below is certain information concerning each of our directors and executive officers as of March 15, 2003.

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>With the Company Since</u>
Jeffrey M. Soinski	41	President, Chief Executive Officer and Director	2001
Guy J. Jordan, Ph.D. (1)(2)	54	Chairman of the Board	2001
Donald D. Solomon, Ph.D.	52	Vice President, Chief Operating Officer, Chief Technical Officer and Director	2000
Paul S. Evans	40	Vice President, Business Development, General Counsel and Secretary	2000
Larry D. Sheldon	52	Vice President, Sales and Marketing	2002
Keith L. Merrell	57	Controller, Acting Chief Financial Officer and Treasurer	2000
David W. Jahns (2)	37	Director, Chairman of Compensation Committee	2001
Stuart A. Randle (1)	43	Director	2001
Stephen I. Shapiro (2)	58	Director	2001
Robert R. Walker (1)	72	Director, Chairman of Audit Committee	1994

(1) Member of Audit Committee.

(2) Member of Compensation Committee.

*Jeffrey M. Soinski.* Mr. Soinski is our President, Chief Executive Officer and a director. His term as a director expires at the 2005 annual meeting of stockholders. Mr. Soinski brings 20 years of general management, business development and marketing experience to our company, including several years as the President and Chief Executive Officer of ViroTex Corporation ("ViroTex"), a venture-backed pharmaceutical company focused on the development and commercialization of proprietary drug delivery systems. Mr. Soinski was with ViroTex from 1992 through 1999. He merged ViroTex into Atrix Laboratories, Inc. (Nasdaq: ATRX) in 1998, and continued working with Atrix on a transitional basis through 1999. From 2000 through 2001, Mr. Soinski was the Managing Partner and Chief Executive Officer of Mad Dogs & Englishmen, a marketing communications firm with offices in New York and San Francisco. Mr. Soinski has a BA degree from Dartmouth College.

*Guy J. Jordan, Ph.D.* Dr. Jordan is our Chairman of the board. His term as a director expires at the 2005 annual meeting of stockholders. Dr. Jordan brings a wealth of senior management healthcare experience to our company, with a strong focus in the areas of vascular disease and oncology. Dr. Jordan recently retired as Group President for C.R. Bard, Inc. with global operating responsibility for their oncology businesses, geographic responsibility for Canada, Australia, Latin America and Asia Pacific, and functional responsibility for all of Bard's research and development. Prior to joining C.R. Bard in 1986, Dr. Jordan held senior product development positions at American Cyanamid. Dr. Jordan has a Ph.D. degree from Georgetown University and an MBA from Fairleigh Dickinson University.

*Donald D. Solomon, Ph.D.* Dr. Solomon is Chief Operating Officer, Chief Technology Officer, a Vice President and a director. His term as a director expires at the 2005 annual meeting of stockholders. Dr. Solomon joined us in October 2000 and has served as a director since March 2001. He has over 23 years of medical product experience in research, product development, engineering and manufacturing. Prior to joining our company, Dr. Solomon was the Vice President of Research and Development at Johnson & Johnson Medical - Vascular Access from 1997 to 2000. Prior to that Dr. Solomon spent 14 years at Becton Dickinson ("BD"), and held positions as Worldwide Director of R&D for BD Pharmaceutical Systems Division based in France, and Director of R&D for Biocompatible Polymer Development at the BD Infusion Therapy Division. Dr. Solomon holds 38 patents and is the

author of 52 scientific publications. He received Masters and Ph.D. degrees from Case Institute of Technology at Case Western Reserve University.

*Paul S. Evans.* Mr. Evans is our Vice President, Business Development, General Counsel and corporate Secretary. He joined us in June 2000. Mr. Evans manages our intellectual property portfolio and corporate legal matters, and is extensively involved in business development efforts. Mr. Evans brings a wide range of intellectual property and corporate legal experience to us, having previously served as Vice President, General Counsel for a R&D company (1994 to 2000), and as a patent attorney with the law firm of Snow, Christensen & Martineau. Prior to earning his law degree, Mr. Evans worked as a Project/Design Engineer for Morton International (now Autoliv). He holds BS and JD degrees from the University of Utah.

*Larry D. Sheldon.* Mr. Sheldon is our Vice President, Sales and Marketing. He joined us in November 2002. Mr. Sheldon brings over 24 years of relevant healthcare experience to our company, including domestic and international management of sales, marketing, national accounts, and customer service. Most of his experience is from Johnson & Johnson ("J&J"), where he was employed from 1978 to 1997. While at J&J, Mr. Sheldon served as Vice President, Corporate Distributor Business, responsible for managing distributor relationships for medical/surgical products with annual sales of \$1.7 billion. Mr. Sheldon also held several senior sales management positions at J&J in both the Patient Care and Hospital Services divisions. From 1998 to 2000, Mr. Sheldon was Senior Vice President, Sales and Marketing, for Paper Pak Products, Inc. From 2000 until joining our company in 2002, Mr. Sheldon was Senior Vice President, Sales and Marketing, at Tillotson Healthcare Corporation, a domestic medical and non-medical glove manufacturer. He has a BS degree from Fairleigh Dickinson University.

*Keith L. Merrell.* Mr. Merrell is our Controller, Acting Chief Financial Officer and Treasurer. He joined us in July 2000. Mr. Merrell draws on 28 years of accounting experience to manage all of our accounting functions and to interface with our independent public accountants. He spent two years in the field of public accounting, and served as Chief Financial Officer or Controller of four companies prior to his joining us. His business career also includes extensive experience in management, sales and marketing, and consulting. He served as Vice President – Western Operations for Michelex, an injection molding company with corporate headquarters in New York, from 1998 to 2000. From 1991 to 1998 he served as Director of Finance for The Duplication Group, planning, implementing and bringing online the first CD manufacturing facility in the intermountain area. He graduated from Arizona State University with a BS degree in Accounting.

*David W. Jahns.* Mr. Jahns serves as one of our directors. His term as a director expires at the 2003 annual meeting of stockholders. Mr. Jahns is a General Partner and principal of Galen Partners. Since joining Galen in 1993, Mr. Jahns has been responsible for making and managing investments in several of the firm's portfolio companies. He is an experienced board member and currently serves on the boards of DAOU Systems, Inc. and several of Galen's privately held portfolio companies. Prior to joining Galen, Mr. Jahns worked in the Corporate Finance Division at Smith Barney, where he worked on a variety of corporate finance and merger and acquisition related transactions, and assisted in the marketing of public offerings. Mr. Jahns has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BA degree from Colgate University.

*Stuart A. Randle.* Mr. Randle serves as one of our directors. His term as a director expires at the 2004 annual meeting of stockholders. Mr. Randle is a highly experienced healthcare executive with over 20 years of operating successes. From 1998 to 2001, Mr. Randle was the President and CEO of ACT Medical, Inc., a leading company providing outsourcing services to the medical device, biotech and diagnostic industries. He merged ACT Medical, Inc. with MedSource Technologies in 2001. From 1996 through 1998, Mr. Randle was President, Northeast Region, for Allegiance Corporation, a \$5 billion medical products distribution and manufacturing company. He is also the past President, New England Region, for Baxter Healthcare Corporation. Mr. Randle has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BS degree from Cornell University.

*Stephen I. Shapiro.* Mr. Shapiro serves as one of our directors. His term as a director expires at the 2004 annual meeting of stockholders. Mr. Shapiro has over 30 years of relevant medical device and equipment industry experience, with special expertise in a wide variety of healthcare markets, particularly high-volume sterile disposables, critical care instruments and cardiovascular devices. Mr. Shapiro began his career at Union Carbide Clinical Diagnostics and Becton Dickinson, where he was Director of Advanced R&D and New Business

Development. In 1982, he joined The Wilkerson Group, a leading management consultancy to pharmaceutical, medical device, and diagnostic companies. Mr. Shapiro was Managing Director and a principal of The Wilkerson Group at the time of its acquisition by IBM in 1996. In 1999, Mr. Shapiro left The Wilkerson Group (now IBM Healthcare Consulting) to focus on sourcing and evaluating investments for two premier healthcare venture capital firms, including Galen Partners. He currently serves on the board of Noveste Corporation. Mr. Shapiro has a BS degree from the Massachusetts Institute of Technology and an MS degree in biomedical engineering from the University of California, Berkley.

*Robert R. Walker.* Mr. Walker serves as one of our directors. His term as a director expires at the 2003 annual meeting of stockholders. Since 1992, Mr. Walker has been principally self-employed as a consultant in the healthcare industry primarily in the area of start-up medical device companies. From 1976 to 1992, Mr. Walker was employed by IHC Affiliated Services Division of Intermountain Healthcare, a regional hospital company. He retired as President of IHC Affiliated Services in 1992. He is also a former Chairman of the board of AmeriNet, Inc., a national group purchasing organization for hospitals, clinics, detox/drug centers, emergency, nursing homes, private laboratories, psychiatric centers, rehabilitation facilities, surgical centers and other institutions. Mr. Walker is a member of the American Hospital Association and the Hospital Financial Management Association. He has a BS degree in Business Administration from the University of Utah.

Our executive officers are elected by the Board on an annual basis and serve at the discretion of the Board.

#### **Board Committees**

The Board has an Audit Committee and Compensation Committee. The Board does not have a Nominating Committee.

The Company's Audit Committee held three meetings during 2002. The function of the Audit Committee as detailed in the Audit Committee Charter is to provide assistance to the Board in fulfilling their responsibility to the stockholders, potential shareholders, and investment community relating to corporate accounting, reporting practices of the Company and the quality and integrity of the financial reports of the Company. In so doing, it is the responsibility of the Audit Committee to maintain free and open means of communication between the directors, the independent auditors and Company management. The members of the Audit Committee are Guy J. Jordan, Stuart A. Randle and Robert R. Walker. The Company believes that the members of the Audit Committee are independent as defined by Rule 4200(a) of NASD's listing standards.

The Company's Compensation Committee held one meeting during 2002. The Compensation Committee administers the Company's stock option plan, establishes a general compensation policy for the Company and, except as prohibited by applicable law, may take any and all actions that the Board could take relating to the compensation of employees, directors and other parties. The members of the Compensation Committee are David W. Jahns and Stephen I. Shapiro.

#### **Board Meetings and Directors' Attendance**

The Board held six meetings during 2002. There were no actions taken by unanimous consent during 2002. No incumbent director attended fewer than 75 percent of the Board meetings held or fewer than 75 percent of the committee meetings held by committees on which an incumbent director served during 2002.

#### **Certain Relationships And Related Transactions**

On November 7, 2001, our stockholders approved the issuance to Galen Partners and other accredited and sophisticated investors of a total of 10,917,030 shares of Series A Preferred Stock for an aggregate purchase price of \$5 million, or \$.458 per share. Galen Partners purchased their shares for \$3,500,000 and the other investors purchased their shares in exchange for the cancellation of \$1,500,000 of debt.

In September and November 2002, Galen Partners and other accredited and sophisticated investors exercised rights to acquire an additional 10,944,339 shares of Series A Preferred Stock for an aggregate net purchase price of \$5,002,957, or \$.458 per share. The Series A Preferred Stock is immediately convertible into the same

number of shares of our common stock and the conversion rate is subject to adjustment if we issue additional shares of common stock for an amount less than the then current conversion price and upon the happening of certain other events.

### Security Ownership of Management and Certain Beneficial Owners

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 14, 2003, for: (i) each person who is known by us to beneficially own more than five percent of our Common Stock, (ii) each of our directors, (iii) each of our Named Executive Officers, and (iv) all directors and executive officers as a group. On March 14, 2003 the Company had 17,921,479 shares of Common Stock outstanding.

<u>Name and Address of Beneficial Owner(1)</u>	<u>Shares Beneficially Owned(2)</u>	<u>Percentage of Total(2)</u>	<u>Position</u>
Jeffrey M. Soinski (3)	892,354	4.74	President, CEO and Director
Guy J. Jordan, Ph.D. (4)	188,555	1.04	Chairman of the Board
Donald D. Solomon, Ph.D. (5)	422,541	2.30	Vice President, COO, CTO and Director
Paul S. Evans (6)	327,309	1.79	Vice President, Business Development, General Counsel, and Secretary
Larry D. Sheldon(7)	3,132	*	Vice President, Sales and Marketing
Keith L. Merrell (8)	152,214	*	Controller, Acting CFO and Treasurer
David W. Jahns (9)	47,218	*	Director
Stuart A. Randle (10)	44,441	*	Director
Stephen I. Shapiro (11)	112,721	*	Director
Robert R. Walker (12)	184,218	1.02	Director
Executive Officers and Directors as a Group (10 persons)	2,370,388	5.6%	
Galen Partners III, L.P. and affiliates (13)	15,256,413	38.3%	

\* Less than 1%.

- (1) Except where otherwise indicated, the address of the beneficial owner is deemed to be the same address as the company.
- (2) Beneficial ownership is determined in accordance with SEC rules and generally includes holding voting and investment power with respect to the securities. Shares of common stock subject to options or warrants currently exercisable, or exercisable within 60 days, are deemed outstanding for computing the percentage of the total number of shares beneficially owned by the designated person, but are not deemed outstanding for computing the percentage for any other person.

- (3) Includes 6,911 shares of common stock purchased through our 401(k) plan and options to acquire 885,410 shares of common stock. Does not include options to acquire 1,614,590 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (4) Includes options to acquire 188,555 shares of common stock. Does not include options to acquire 211,445 shares of common stock that vest 60 days beyond March 14. Those options vest, in cumulative fashion, in equal monthly installments ending on the four-year anniversary of the date of grant.
- (5) Includes 10,000 shares of common stock, 65,666 shares of Series A Preferred Stock that is immediately convertible into the same number of shares of common stock, 44,380 shares of common stock purchased through our 401(k) plan and options to acquire 312,495 shares of common stock. Does not include options to acquire 278,646 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (6) Includes 61,000 shares of common stock, 24,649 shares of common stock purchased through our 401(k) plan and options to acquire 241,660 shares of common stock. Does not include options to acquire 258,340 shares of common stock that vest 60 days beyond March 14. Those options vest, in cumulative fashion, in equal monthly installments ending on the four-year anniversary of the date of grant.
- (7) Includes 3,132 shares of common stock purchased through our 401(k) plan.
- (8) Includes 36,000 shares of common stock, 26,284 shares of common stock purchased through our 401(k) plan and options to acquire 50,000 shares of common stock. Does not include options to acquire 15,070 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (9) Includes options to acquire 47,218 shares of common stock. Does not include options to acquire 52,782 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006. Does not include shares held by Galen Partners III, L.P. David Jahns is a member of Claudius, L.L.C., a Delaware limited liability company, and a general partner of Galen Partners III, L.P. and Galen Partners International III, L.P. See note (13) below.
- (10) Includes options to acquire 44,441 shares of common stock. Does not include options to acquire 55,559 shares of common stock that vest in equal monthly installments between May 27, 2003 and December 27, 2006.
- (11) Includes 65,503 shares of Series A Preferred Stock that is immediately convertible into the same number of shares of common stock and options to acquire 47,218 shares of common stock. Does not include options to acquire 52,782 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (12) Includes stock options to purchase 121,218 shares of common stock and 63,000 shares of common stock that Mr. Walker is deemed to beneficially own through a trust. Does not include options to acquire 52,782 shares of common stock that vest in equal monthly installments between May 14, 2003 and November 14, 2006.
- (13) Information regarding Galen Partners III, L.P. and its affiliates is derived from the Form 4 filed by Galen Partners III, L.P. with the Securities and Exchange Commission on September 9 and September 26, 2002. Shares owned represent 13,937,735 shares of Series A Preferred Stock held of record by Galen Partners III, L.P., 1,261,605 shares of Series A Preferred Stock held of record by Galen Partners International III, L.P., and 57,073 shares of Series A Preferred Stock held of record by Galen Employee Fund III, L.P. William R. Grant, Bruce F. Wesson, L. John Wilkerson, David W. Jahns, Srinu Conjeevaram, and Zubeen Shroff are all natural persons and are the members of Claudius, L.L.C., a Delaware limited liability company, the general partner of Galen Partners III, L.P. and Galen Partners International III, L.P. Bruce F. Wesson is the President of Wesson Enterprises, Inc., a Delaware corporation, which is the general partner of Galen Employee Fund III, L.P.

### Series A Preferred Stock

The Company currently has issued and outstanding 21,861,369 shares of Series A Preferred Stock which is convertible into the same number of shares of common stock. The conversion rate of the Series A Preferred Stock can be adjusted upon the happening of certain triggering events. Galen Partners III, L.P. and affiliates own 15,256,413 of these shares as described in the above table, which comprises 69.78% of the outstanding Series A Preferred Stock. No other stockholder owns more than 5% of the outstanding Series A Preferred Stock.

### Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information with respect to the Company's equity compensation plans approved by security holders and plans not approved by security holders for the year ended December 31, 2002.

## EQUITY COMPENSATION PLAN INFORMATION

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance</u>
Equity compensation plans approved by security holders	7,347,500	\$1.31	952,500
Equity compensation plans not approved by security holders	0		0
<b>Total</b>	<b>7,347,500</b>	<b>\$1.31</b>	<b>952,500</b>

### Section 16(a) Beneficial Ownership Reporting Compliance

The members of the Board, the executive officers of the Company and persons who hold more than ten percent of the Company's Common Stock are subject to reporting requirements of Section 16(a) of the Securities Exchange Act of 1934, which require them to file reports with respect to their ownership of and transaction in the Company's securities, and furnish the Company copies of all such reports they file. Based upon the copies of those reports furnished to the Company, and written representations that no other reports were required to be filed, the Company believes that all reporting requirements under Section 16(a) for the fiscal year ended December 31, 2002, were met in a timely manner by its executive officers, Board members and greater than ten percent stockholders.

### Executive Compensation

The tables below set forth certain information concerning compensation paid by us to our Chief Executive Officer and all other executive officers with annual compensation in excess of \$100,000 (determined for the year ended December 31, 2002) (the "Named Executive Officers"). The tables include information related to stock options granted to the Named Executive Officers.

*Summary Compensation Table.* The following table provides certain information regarding compensation paid by us to the Named Executive Officers.

### SUMMARY COMPENSATION TABLE

Name and <u>Principal Position</u>	Year	<u>Annual Compensation</u>			<u>Awards</u>		<u>Payouts</u>	All Other Compensation ( <u>\$</u> )
		<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Other Annual Compensation(\$)(1)</u>	<u>Restricted Stock Awards (\$)</u>	<u>Stock Options/ SAR(#)</u>	<u>LTIP Payouts(\$)</u>	
Jeffrey M. Soinski (2), President, CEO & director	2001	14,615	---	---	---	2,500,000	---	---
	2002	240,000	43,200(6)	---	---	---	---	610(4)
Donald D. Solomon, Ph.D. (3), VP, CTO, COO & director	2000	31,942	---	1,375	---	100,000	---	---
	2001	165,000	---	8,250	---	600,000	---	273(4)
	2002	190,000	34,200(6)	9,500	---	---	---	1,081(4)
Paul S. Evans (3), VP, Business Development, General Counsel & Secretary	2000	86,798	---	2,406	28,125	100,000	---	268(4)
	2001	165,000	---	7,219	---	400,000	---	460(4)
	2002	175,000	31,500(6)	---	---	---	---	579(4)
Larry D. Sheldon (5) VP, Sales and Marketing	2002	21,923	---	---	---	500,000	---	---
Keith L. Merrell (3) Acting CFO, Controller &	2000	41,250	---	2,062	---	50,000	---	179(4)
	2001	90,000	---	4,500	---	55,000	---	410(4)

Name and Principal Position	Year	Annual Compensation			Awards		Payouts	All Other Compensation (\$)
		Salary (\$)	Bonus (\$)	Other Annual Compensation(\$)(1)	Restricted Stock Awards (\$)	Stock Options/ SAR(#)	LTIP Payouts(\$)	
Treasurer	2002	102,000	3,000	5,100	---	---	---	456(4)

- (1) These amounts represent payments by us into our 401(k) retirement plan for the benefit of the Named Executive Officer.
- (2) Mr. Soinski joined SHPI in November 2001. Salary represents partial year from the date of his employment.
- (3) Dr. Solomon and Messrs. Evans and Merrell joined SHPI in 2000. Salaries for 2000 represent partial year from the date of their employment.
- (4) Represents amounts paid by us for life insurance on the lives of Mr. Soinski, Dr. Solomon, Mr. Evans and Mr. Merrell with insurance proceeds payable to the beneficiary designated by them.
- (5) Mr. Sheldon joined SHPI in November 2002. Salary represents partial year from the date of his employment.
- (6) Bonuses accrued and expensed in 2002; paid out in 2003.

**Option Grants in Fiscal Year 2002.** The following table sets forth certain information with respect to stock options grants during the year ended December 31, 2002 to Named Executive Officers.

**OPTION/SAR GRANTS IN LAST FISCAL YEAR  
(Individual Grants)**

Name	Number of Securities Underlying Options/SAR Granted (#) (1)	Percent of Total Options/SAR Granted to Employees in Fiscal Year	Exercise or Base Price (\$/Share)	Expiration Date
Larry D. Sheldon	500,000	100%	\$1.00	12/30/2012

- (1) These options were granted pursuant to our 2000 Stock Option Plan.

**Compensation of Directors**

No cash fees or other consideration were paid to our employee directors for service on the board during 2002. We did not provide cash compensation to non-employee directors in 2002 and do not plan to do so in 2003. Prior to 2002 we granted stock options, which vest over a three year period, to our non-employee directors as compensation for service on the board. We have made no other agreements regarding compensation of non-employee directors. All directors are entitled to reimbursement for reasonable out-of-pocket travel related expenses incurred in the performance of their duties as board members.

**Employment and Indemnity Agreements**

We have entered into an employment agreement with Mr. Jeffrey Soinski. The employment agreement provides that (i) Mr. Soinski receive a beginning base salary of \$240,000 per year in addition to performance based bonuses; (ii) Mr. Soinski receive stock options to acquire 2.5 million shares of our common stock at market value on the date of grant which stock options vest over a four-year period; (iii) Mr. Soinski is entitled to vacation pay, health insurance and life insurance; (iv) Mr. Soinski's employment contract may be terminated at any time by us; (v) if the employment of Mr. Soinski is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Mr. Soinski is terminated for reasons other than disability, death or for cause, then Mr. Soinski's salary and medical benefits will continue for a period of 18 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Donald Solomon, Ph.D. The employment agreement provides that (i) Dr. Solomon receive a beginning base salary of \$190,000 per year in addition to performance based

bonuses; (ii) Dr. Solomon receive stock options to acquire 600,000 shares of our common stock at market value on the date of grant which stock options vest over a four-year period; (iii) Dr. Solomon is entitled to vacation pay, health insurance and life insurance; (iv) Dr. Solomon's employment contract may be terminated at any time by us; (v) if the employment of Dr. Solomon is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Dr. Solomon is terminated for reasons other than disability, death or for cause, then Dr. Solomon's salary and medical benefits will continue for a period of 12 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Mr. Paul Evans. The employment agreement provides that (i) Mr. Evans receive a beginning base salary of \$175,000 per year in addition to performance based bonuses; (ii) Mr. Evans receive stock options to acquire 400,000 shares of our common stock at market value on the date of grant which stock options vest over a four-year period; (iii) Mr. Evans is entitled to vacation pay, health insurance and life insurance; (iv) Mr. Evans' employment contract may be terminated at any time by us; (v) if the employment of Mr. Evans is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Mr. Evans is terminated for reasons other than disability, death or for cause, then Mr. Evans' salary and medical benefits will continue for a period of 12 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Mr. Keith Merrell. The employment agreement provides that (i) Mr. Merrell receive a beginning base salary of \$102,000 per year in addition to performance based bonuses; (ii) Mr. Merrell receive stock options to acquire 55,000 shares of our common stock at market value on the date of grant which stock options vest over a four-year period; (iii) Mr. Merrell is entitled to vacation pay and health insurance; (iv) Mr. Merrell's employment contract may be terminated at any time by us; (v) if the employment of Mr. Merrell is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Mr. Merrell is terminated for reasons other than disability, death or for cause, then Mr. Merrell's salary and medical benefits will continue for a period of 3 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Mr. Larry D. Sheldon. Mr. Sheldon's employment agreement provides that (i) Mr. Sheldon receive a beginning base salary of \$180,000 per year; (ii) Mr. Sheldon's current employment agreement terminates on November 30, 2004 should he fail to relocate to Salt Lake City by that date; (iii) Mr. Sheldon receive stock options to acquire 500,000 shares of our common stock at a price of one dollar per share which stock options vest over a four-year period; (iv) Mr. Sheldon is entitled to vacation pay, health insurance and life insurance; (v) Mr. Sheldon's employment contract may be terminated at any time by us; (vi) if the employment of Mr. Sheldon is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vii) if Mr. Sheldon is terminated for reasons other than disability, death or for cause, then Mr. Sheldon's salary and medical benefits will continue for a period of 6 months from the date of termination and his other benefits will cease as of the date of termination. However, in the event Mr. Sheldon is not employed at the end of the 6-month period following termination, Mr. Sheldon shall be entitled to salary and medical benefits for up to an additional 6 months.

In January 2003, we approved a 2003 Executive Officer Bonus Plan. Under the plan executive officers eligible for bonuses during 2003 include the CEO, COO, VP of Sales and Marketing and VP of Business Development and General Counsel. Plan participants will earn 20% of their annual salary based upon 100% achievement of the overall revenue goal outlined in our approved budget plan. Also, plan participants will be eligible to receive incremental bonus payments for performing beyond the budget plan. The amount of incremental payments, if earned, will be based upon the recommendation of the Compensation Committee and approved by the board of directors. The maximum base bonus that could be paid under this plan is \$160,200. In connection with this plan, we also adopted an Employee Bonus Plan for employees other than the Named Executive Officers to reward specific individual or team achievements during 2003.

We have entered into indemnity agreements (the "Indemnity Agreements") with each of our executive officers and directors pursuant to which we have agreed to indemnify the officers and directors to the fullest extent permitted by law for any event or occurrence related to the service of the indemnitee for us as an officer or director that takes place prior to or after the execution of the Indemnity Agreement. The Indemnity Agreements obligate us



to reimburse or advance expenses relating to any proceeding arising out of an indemnifiable event. Under the Indemnity Agreements, our officers and directors are presumed to have met the relevant standards of conduct required by Delaware law for indemnification. Should the Indemnity Agreements be held to be unenforceable, indemnification of these officers and directors may be provided by us in certain cases at our discretion.

#### **401(k) Retirement Plan**

Effective in 1996, we adopted a 401(k) retirement plan whereby we contribute up to five percent of payroll compensation to the plan, matching employee contributions to the plan on a dollar for dollar basis up to the maximum five percent contribution.

#### **Accrued Vacation Pay**

Our current policy allows all employes to carry over maximum days of vacation pay from year to year equivalent to a one-year accrual at the rate earned.

#### **Indemnification for Securities Act Liabilities**

Delaware law authorizes, and our Bylaws and Indemnity Agreements provide for, indemnification of our directors and officers against claims, liabilities, amounts paid in settlement and expenses in a variety of circumstances. Indemnification for liabilities arising under the Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing or otherwise. However, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Exchange Act of 1934 and is, therefore, unenforceable.

#### **Stock Options and Warrants**

In November 2001, our stockholders approved the adoption of the Specialized Health Products International, Inc. 2001 Stock Option Plan (the "2001 Option Plan"). The 2001 Option Plan permits us to grant "non-qualified stock options" and "incentive stock options" to acquire our common stock. The total number of shares authorized for the Option Plan may be allocated by the board between the non-qualified stock options and the incentive stock options from time to time, subject to certain requirements of the Internal Revenue Code of 1986, as amended. The option exercise price per share under the Option Plan may not be less than the fair market value of a share of common stock on the date on which the option is granted. A total of 5,000,000 shares are allocated to the Option Plan. As of December 31, 2002, options to acquire an aggregate of 4,984,690 shares of common stock at exercise prices ranging from \$1.00 to \$2.00 were outstanding under the Option Plan.

We have also issued stock options under stock options plans that preceded the 2001 Option Plan ("Prior Plans"). As of December 31, 2002, options to acquire an aggregate of 1,562,810 shares of common stock at exercise prices ranging from \$1.00 to \$2.00 were outstanding under Prior Plans.

In addition to the stock options detailed above, we have outstanding warrants to buy 800,000 shares of common stock at exercise prices of \$1.25 to \$2.00.

#### **Compensation Committee Interlocks and Insider Participation**

None of our executive officers serve on our Compensation Committee or in a like capacity in any other entity.

## **2. Other Matters**

#### **Discretionary Authority**

At the time of mailing of this proxy statement, the Board was not aware of any other matters which might be presented at the meeting. If any matter not described in this Proxy Statement should properly be presented, the persons named in the accompanying proxy form will vote such proxy in accordance with their judgment.

### **Independent Public Accountants**

The Company retained PricewaterhouseCoopers LLP ("PWC") as its independent auditor for the current year. PWC has acted as the Company's independent auditor since 2002. The Company expects representatives of PWC to be present at the Company's 2003 Annual Meeting of Stockholders. PWC will have the opportunity to make a statement at the annual meeting if it desires to do so and it is expected that representatives of PWC will be available to respond to appropriate questions if called upon to do so.

### **Report of the Audit Committee of the Board Of Directors**

The Company's Board has adopted a written charter for the Audit Committee, which is included as Annex A hereto.

The Audit Committee hereby reports as follows:

1. The Audit Committee has reviewed and discussed the audited financial statements with the Company's management.

2. The Audit Committee has discussed with PWC, the Company's independent accountants, the matters required to be discussed by SAS 61 (Communication with Audit Committees).

3. The Audit Committee has received the written disclosures and the letter from PWC required by Independence Standards Board Standard No. 1 (Independence Discussions with Audit Committees), and has discussed with PWC their independence.

4. Based on the review and discussion referred to in paragraphs (1) through (3) above, the Audit Committee recommended to the Board, and the Board has approved, that the audited financial statements be included in the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, for filing with the Securities and Exchange Commission.

Guy J. Jordan  
Stuart A. Randle  
Robert R. Walker

### **Changes in Accountants**

In July 2002, the Company retained PWC as its independent auditor. Prior to the engagement of PWC, Arthur Andersen LLP ("AA") had acted as the Company's independent auditor. The Company's Board of Directors made the decision to change auditors due to the cessation of business by AA.

The reports on the financial statements of the Company for each of the two past fiscal years did not contain any adverse opinion or disclaimer of opinion and were not modified as to uncertainty, audit scope, or accounting principles.

During the Company's two most recent fiscal years, there were no disagreements with AA on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements(s), if not resolved to the satisfaction of AA, would have caused AA to make a reference to the subject matter of the disagreements(s) in connection with its report; nor has AA ever presented a written report, or otherwise communicated in writing to the Company or its Board of Directors the existence of any "disagreement" or "reportable event" within the meaning of Item 304 of Regulation S-B.

**Audit Fees**

The aggregate fees billed for professional services rendered for the audit of the Company's annual financial statements for 2002 and the reviews of the financial statements included in the Company's Forms 10-QSB for that fiscal year were \$74,070.

**Financial Information Systems Design and Implementation Fees**

No fees were incurred for professional services rendered in connection with Company's financial information system and related design and implementation in 2002.

**All Other Fees**

Auditors billed the Company approximately \$9,500 for other services for the fiscal year ended December 31, 2002, all of which were domestic tax services related to consulting on federal, state and local tax matters. The Audit Committee of the Board has considered whether the provision of non-audit services is compatible with maintaining auditor's independence.

**Notice Requirements**

Any stockholder who desires to have a proposal included in the Company's proxy soliciting material relating to the Company's 2004 annual meeting of stockholders should send to the Secretary of the Company a signed notice of intent. This notice, including the text of the proposal, must be received no later than February 15, 2004.

**Annual Report**

This Proxy Statement has been preceded or accompanied by an Annual Report. Stockholders are referred to such reports for financial and other information about the activities of the Company, but such report is not to be deemed a part of the proxy soliciting material.

**Expenses and Methods of Solicitation**

The expenses of soliciting proxies will be paid by the Company. In addition to the use of the mails, proxies may be solicited personally, or by telephone or other means of communications, by directors, officers and employees of the Company and its subsidiaries, who will not receive additional compensation therefor. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries for the forwarding of proxy solicitation material to certain beneficial owners of the Company's Common Stock, and the Company will reimburse such forwarding parties for reasonable expenses incurred by them.

By order of the Board of Directors,

By /s/ Paul S. Evans  
Paul S. Evans, Secretary

## APPENDIX A

### SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.

#### AUDIT COMMITTEE CHARTER

##### ORGANIZATION

There shall be a committee of the board of directors of Specialized Health Products International, Inc. (the "Company") to be known as the Audit Committee. The Audit Committee shall be composed of directors who are independent of the management of the Company and are free of any relationship that, in the opinion of the board of directors (the "Board"), would interfere with their exercise of independent judgment as a committee member.

##### STATEMENT OF POLICY

The Audit Committee shall provide assistance to the board of directors in fulfilling their responsibility to the shareholders, potential shareholders, creditors and other stakeholders relating to corporate accounting, reporting practices of the Company and the quality and integrity of the financial reports of the Company. In so doing, it is the responsibility of the Audit Committee to maintain free and open means of communication between the directors, the independent auditors and Company management.

##### COMPOSITION

The Audit Committee shall be comprised of three or more directors as determined by the Board, each of whom shall be independent directors. All members of the Audit Committee shall have a working familiarity with basic finance and accounting practices, and at least one member of the Audit Committee shall have accounting or related financial management expertise.

The members of the Audit Committee shall be appointed by the Board at the annual organizational meeting of the Board or until their successors shall be duly qualified and appointed. Unless a chair is appointed by the full Board, the members of the Audit Committee may designate a chair by majority vote of the full Audit Committee membership.

##### MEETINGS

The Audit Committee shall meet at least two times annually, or more frequently as circumstances dictate. As part of its responsibility to foster open communication, the Audit Committee or its members are expected to meet for discussions with Company management frequently. There will be at least two formal meetings with Company management in the presence of the independent auditors. The Audit Committee will hold separate executive sessions to discuss any matters that the Audit Committee believes should be discussed privately.

##### RESPONSIBILITIES

In carrying out its responsibilities, the Audit Committee's policies and procedures will remain flexible, in order to best react to changing conditions and to ensure that the corporate accounting and reporting practices of the Company are in accordance with all requirements and are of the highest quality.

In carrying out these responsibilities, the Audit Committee will:

1. Develop an effective Audit Committee charter approved by the Board. Update this charter at least annually or as business developments may dictate.
2. Influence the overall Company "tone" for quality financial reporting, sound business risk controls, and ethical behavior.

3. Review and recommend to the Board the Audit Committee's choice of independent auditors and the level of fees for audits of the financial statements of the Company. Recommend dismissal when necessary. Maintain an active dialog with the independent auditors to identify and disclose any relationship or services that may impact the objectivity and independence of the auditors.
4. Meet with the independent auditors and financial management of the Company to review the scope of the proposed audit for the current year and the audit procedures to be utilized, and at the conclusion thereof review the results of such audit, including any comments or recommendations of the independent auditors.
5. Emphasize the adequacy of internal controls to identify any payments, transactions, or procedures that might be deemed illegal or otherwise improper. Review the Company's policy statements to enforce adherence to its code of conduct.
6. Monitor the integrity and quality of annual and interim financial reporting to shareholders with management and the independent auditors to determine that the independent auditors are satisfied with the disclosure and content of the financial statements to be presented to the shareholders. Review changes in accounting principles and concur as to their appropriateness.

The Audit Committee on a regular basis should also monitor the integrity and quality of internal financial and operating information used by management in its decision making processes.

7. Provide sufficient opportunity for the independent auditors to meet with the members of the Audit Committee without members of management present. Among the items to be discussed in these meetings are the independent auditors' evaluation of the Company's financial and accounting personnel, and the cooperation that the independent auditors received during the course of the audit.
8. Consider and review with the independent auditors:
  - (a) Any significant findings in the independent auditors SAS 71 interim financial statement review prior to the Company's filing of its Form 10-QSB.
  - (b) The adequacy of the Company's internal controls including computerized information system controls and security.
  - (c) Any significant findings and recommendations of the independent auditors together with management's responses thereto.
9. Monitor compliance with the Company code of conduct and regulatory requirements, and review and assess conflicts of interest and related-party transactions.
10. Evaluate and make recommendations regarding management initiatives affecting the financing of the Company and related matters.
11. Assess independent auditor performance.
12. Assess Audit Committee performance.
13. Review and approve required stock exchange certifications, if any, and proxy statement disclosure.
14. Provide a report of the Audit Committee's findings that result from its financial reporting oversight responsibilities including representation that the Audit Committee has:
  - a. discussed with the independent auditors the matters required to be discussed by Statement on Auditing Standards No. 61, Communication with Audit Committees, as amended,

- b. received and reviewed the written disclosures and the letter from the independent auditors required by Independence Discussions with Audit Committees, as amended, by the Independence Standards Board,
- c. discussed with the auditors the auditors' independence.

This report from the Audit Committee is to be included in proxy statements filed by the Company.

- 15. Conduct an annual quality discussion with the independent auditors wherein the independent auditors discuss their judgment about the quality, not just the acceptability, of the Company's accounting principles as applied in its financial reporting.
- 16. Ensure that the independent auditors review interim financial statements and conduct a quality discussion with the independent auditors before the Company files its Form 10-Q or 10-QSB.

APPENDIX B

PROXY CARD FOR ANNUAL MEETING OF STOCKHOLDERS OF  
SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC

**This Proxy is Solicited on Behalf of the Board Of Directors.** The undersigned hereby appoints Jeffrey M. Soinski as Proxy, with the power to appoint his substitute and hereby authorize them to represent and to vote, as designated below, all voting shares of stock of Specialized Health Products International, Inc. held of record by the undersigned on April 15, 2003, at the annual meeting of stockholders to be held on May 29, 2003, or any adjournment thereof.

**1. Election of Nominee Director – Holders of the Common Stock Voting as a Separate Class**

FOR Robert R. Walker                       WITHHOLD AUTHORITY to vote for Robert R. Walker

**2. Election of Nominee Director – Holders of the Series A Preferred Stock Voting as a Separate Class**

FOR David W. Jahns                       WITHHOLD AUTHORITY to vote for David W. Jahns

**3. In their discretion, the Proxy is authorized to vote upon such other business as may properly come before the meeting.**

**This proxy when properly executed will be voted in the manner directed herein by the undersigned stockholder(s). If no directions are made, this proxy will be voted for the above Proposals.**

Please sign below. When shares are held by joint tenants, both should sign. When signing as attorney, executor, administrator, trustee or guardian, please give full title as such. If a corporation, please sign in full corporation name by President or other authorized officer. If a partnership, please sign in partnership name by authorized person.

Dated: \_\_\_\_\_, 2003

\_\_\_\_\_  
(signature)

\_\_\_\_\_  
(signature if held jointly)

Please mark, sign, date and return the proxy card promptly using the enclosed envelope or proxy cards may be sent by facsimile to Colonial Stock Transfer at (801) 355-6505 or directly to the Company at (801) 298-1759.

\_\_\_\_\_  
(print name of stockholder(s))

**SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.**  
**PROXY CARD FOR ANNUAL MEETING OF STOCKHOLDERS OF**  
**SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC**

This Proxy is Solicited on Behalf of the Board Of Directors. The undersigned hereby appoints Jeffrey M. Soinski as Proxy, with the power to appoint his substitute and hereby authorize them to represent and to vote, as designated below, all voting shares of stock of Specialized Health Products International, Inc. held of record by the undersigned on April 15, 2003, at the annual meeting of stockholders to be held on May 29, 2003, or any adjournment thereof.

**This proxy when properly executed will be voted in the manner directed herein by the undersigned stockholder(s). If no directions are made, this proxy will be voted for the above Proposals.**

(Continued, and to be marked, dated and signed, on other side)

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▲ FOLD AND DETACH HERE ▲





1. Election of Nominee Director – Holders of the Common Stock Voting as a Separate Class

FOR Robert R. Walker	WITHHOLD AUTHORITY to vote for Robert R. Walker
<input type="checkbox"/>	<input type="checkbox"/>

2. Election of Nominee Director – Holders of the Series A Preferred Stock Voting as a Separate Class

FOR David W. Jahns	WITHHOLD AUTHORITY to vote for David W. Jahns
<input type="checkbox"/>	<input type="checkbox"/>

3. In their discretion, the Proxy is authorized to vote upon such other business as may properly come before the meeting.

Please mark, sign, date and return the proxy card promptly using the enclosed envelope or proxy cards may be sent by facsimile to Colonial Stock Transfer at (801) 355-6505 or directly to the Company at (801) 298-1759.

Dated: \_\_\_\_\_, 2003

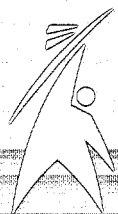
\_\_\_\_\_  
(signature)

\_\_\_\_\_  
(signature if held jointly)

\_\_\_\_\_  
(print name of stockholder(s))

Please sign below. When shares are held by joint tenants, both should sign. When signing as attorney, executor, administrator, trustee or guardian, please give full title as such. If a corporation, please sign in full corporation name by President or other authorized officer. If a partnership, please sign in partnership name by authorized person.

▲ FOLD AND DETACH HERE ▲



**SHPI**

**SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.**

**585 WEST 500 SOUTH • BOUNTIFUL, UT 84010**

**T: 801.298.3360 • F: 801.298.1759 • WWW.SHPI.COM**

**NASDAQ OTCBB: SHPI**