Good things come in small plastic packs

Specialized Health Products, Inc. gets to the heart of the matter: clinician safety and patient comfort.

"Huber" is the generic name for the needle used to administer chemotherapy drugs and other such intravenous fluids to cancer and chronic hematology patients. A Huber needle is inserted into a surgically implanted, subcutaneous port. This port allows access to chemotherapy drugs, for example, on a repeated basis, over an extended period. Configured at a right angle, the needle might be in a patient's implanted port anywhere from three hours to seven days. When a clinician removes the needle from a port, there is always a danger of what is referred to as a "rebound effect," where the port's retentive forces "hold" onto the needle. Then, when the needle releases, it can rebound and result in the clinician receiving a needlestick injury. Because it is a hollow-bore needle, it could be filled with the patient's blood or fluids, leading to the spread of blood-born diseases such as HIV/AIDs or hepatitis B or C, should an accidental needlestick occur. Approximately 47 percent of accidental needlestick injuries arising from the use of Huber needles are attributed to this rebound effect.

It's estimated that U.S. healthcare workers suffer 800,000 injuries from accidental needlesticks and other sharps annually. This leads to an estimated $750 million to $1 billion spent each year in the testing and treatment of needlestick injuries, to which the U.S. Congress responded by enacting the Needlestick Safety and Prevention Act, effective in April 2001.

This is where Specialized Health Products, Inc. (SHPI), Bountiful, UT, comes in as a leading developer and manufacturer of safety medical needle products. Its mission is to minimize the risk of accidental needlesticks. Founded in 1993, the company's first entry into the safety Huber needle market was the high-selling LiftLoc® safety infusion set. MiniLoc™ is its newest technology in the rapidly growing, $60-million U.S. safety Huber needle market. "We've designed our MiniLoc safety infusion set with the comfort of the patient and the convenience of the oncology nurses in mind," says Dr. Don Solomon, chief operations officer and chief technology officer for SHPI.

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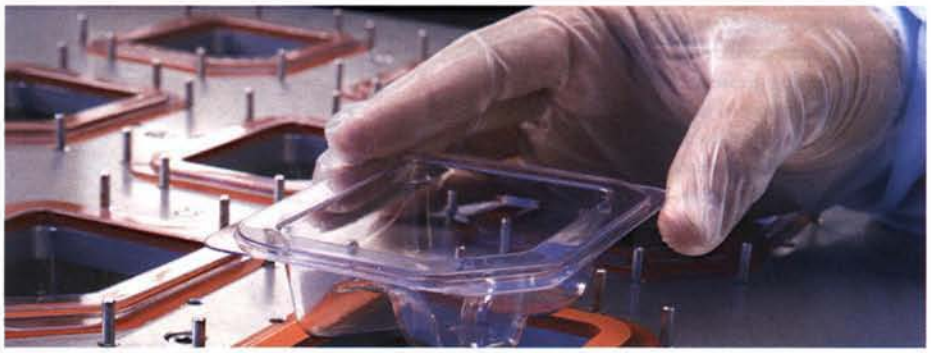
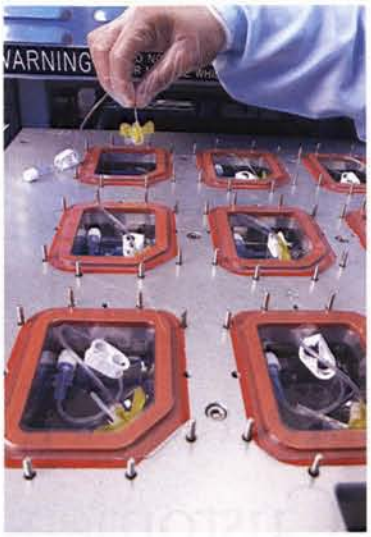
A packaging challenge, the thermoformed tray, above and below, has a narrow cavity to accept the right-angle needle and 8 in. of tubing in its infusion set.



"We've spoken to numerous oncology nurses and other clinicians since launching LiftLoc®," says Dr. Solomon, "and they are looking for a safety needle even more like the conventional nonsafety needles they used before the law came into effect." With that in mind, SHPI has designed and developed the next-generation MiniLoc. It has a smaller footprint, a lower height with a smooth, comfortable base that's designed for patient comfort, and a safety mechanism that's easy to use and does not impact the clinician's technique. In addition, SHPI has added a proprietary lubricant to the needle to reduce needle-penetration force.

As for the clinician's technique, the MiniLoc's proprietary design provides familiar wings that meet to provide an extremely stable grip during the insertion procedure (and deaccess procedure) due to the tab insert on the wings. The smaller design (or footprint) allows the clinician to dress the device with a transparent medical dressing and have the MiniLoc lay flat to the skin. The proprietary safety mechanism enables controlled, easy engagement of the safety mechanism.

The MiniLoc's small footprint and right-angle needle presented a significant packaging challenge. This fell to SHPI's packaging engineer, Shawn Horner, and by extension to **Flexpak Corp. (www.flexpakcorp.com)**, which manufactures the product's thermoformed tray. The primary challenge was the narrow cavity necessary to accommodate the needle's right angle. In addition, it was necessary to consider the positioning of the eight inches of tubing connected to the infusion set.



The tubing coils neatly, with no kinks, in a recess. More important, the needle can be removed the same way, each and every time.

Says Horner, "We wanted the tubing to coil neatly in a recess with no kinks. But more important, we wanted to design a package that allowed the wings to retain their shape so that they wouldn't become 'set' in the wrong position."

This thinking, according to Solomon, goes back to clinicians' convenience. "We want them to be able to take the needle out of the package in the same way each and every time," he says. "That means the wings must be secured in the same position in the package."

So the people at SHPI and Flexpak went to work. With the narrow, right-angle cavity, Flexpak needed to ensure consistent material distribution along the bottom of the thermoformed tray to prevent thin spots—not acceptable in medical packaging due to the threat of contamination from possible punctures.

For that reason, the rigid, vinyl film used for the thermoform trays was sourced from **Klöckner Pentaplast of America, Inc. (www.kpfilms.com).**

States Ed Berger of Flexpak, "We use them for most medical packaging because they're top-notch. For this project, we proposed two different types of their film to SHPI: Pentamed® rigid vinyl and polyethylene terephthalate glycol films. SHPI chose the rigid, vinyl film. For what they needed, Klöckner Pentaplast film offered excellent performance at a cost-effective price. We were glad to be able to offer such an economical choice."

Klöckner Pentaplast business manager for Medical Device Films Richard Ryder says, "We manufacture a full range of specially formulated films for a wide variety of medical packaging applications. The vinyl film that SHPI specified is ETO-[ethylene oxide] sterilizable in compliance with FDA [U.S. Food & Drug Administration] regulations, does the job and doesn't break the bank."

At SHPI, Horner admits that the

The narrow thermoforming cavity maintains material distribution to the bottom with a 'rib' along one wall that supports the product.

precision he was looking for was not typical of a standard retail tray, and he praises Flexpak's ingenuity. "I believe in letting vendors work for you," he says, "and Flexpak came through after only a couple of design interactions. They managed to ensure even material distribution into the cavity while maintaining material thickness at the sealing flange. The Klöckner Pentaplast film that Flexpak used had a lot to do with the quality of their work."

That wasn't the half of it, admits Berger. "The geometry used to hold the product's wings was somewhat difficult because of the change in angles along the vertical wall of the part," he says. "It had the potential to produce thin spots in the material that could negatively impact the sterilization process. That's why we always turn to Klöckner Pentaplast. Their film is consistently high-quality."

What Flexpak devised to secure the wings with a proper fit was a "brace." Explains Berger, "The thermoformed cavity for the needle is narrow and deep. In order to maintain sufficient material distribution to the bottom of the cavity, we could not make it any narrower. The solution was the addition of a 'rib' feature along an adjacent wall that provides sufficient product support." The rib innovation actually eliminates an extra part otherwise necessary to hold the wings in place, thus reducing material usage.

In the end, the entire footprint measures 3.34 in. wide by 3.9 in. long and 1.16 in. high, and is thermoformed at Flexpak on a **Sencorp (www.sencorp-inc.com)** 2500 machine. "It has been a great relationship" says Solomon of Flexpak. The same footprint is used for all 29 MiniLoc stockkeeping units in a variety of lengths and product configurations, and in 19, 20 or 22 needle gauges.

But SHPI thought even further than the thermoform tray in terms of clinicians' convenience. They considered the limited shelf space in a hospital supply closet. SHPI decided to develop an innovative new shelf box for MiniLoc, and the novel idea to store MiniLoc sets in a "fridge pack" was born. At least a fridge pack is what most people would recognize as the shelf box that **RD Packaging** developed under SHPI's direction. The shelf box—or dispenser box—makes it easy for a clinician to reach in and grab a MiniLoc set. Because it sits on the shelf sideways, the whole box takes up less space, and the four-sided graphics are easily visible as to what is contained therein and how to use the needle.

Along with the other raw materials, the shelf boxes are shipped to **Integra Biotechnical (www.integrabio.com)** in Tijuana, Mexico. Raw materials also include: needles, injected-molded plas needle parts (safety mechanism, base and wings), thermoform trays, Tyvek® lidding, label ribbon and corrugated cases. The MiniLoc safety infusion set thus assembled is then placed in the thermoform tray. The tray and lidding are then ready to enter the medical he sealer, a Standard BM 2020 from **Belc Packaging Systems (www.belcopackaging.com)**. In the fir tally, there are 20 MiniLoc sets in an

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end-loaded shelf case. And there are eight boxes in a corrugated case, making a total of 160 units or needles. The cases are then shrink-wrapped on large pallets and sent to California to be ETO-sterilized. From there, they are sent to the warehouse for distribution.

Read about how Star Scientific packs 'cigaletts' smokeless tobacco in **CHILD-RESISTANT BLISTER-PACKS** at **www.packagingdigest.com/info/starscientific**

Hard to believe, but it took only two months, approximately, for the packaging design to come together. The project landed on Horner's desk March 1, 2005, and he had the finished prototype packaging in hand by the end of April. That doesn't include the nine months that MiniLoc was in project development. Then came two to three months of biocompatibility testing to reach the high standards set for implantable devices such as Huber needles. To meet FDA standards, 500 activations were performed in a simulated use study in which the MiniLoc could not fail even once. It didn't, and it ultimately received FDA's 510(k) clearance. And in September 2005, the first MiniLoc safety infusion set hit the shelves.

According to Solomon, "Clinicians are clamoring for our MiniLoc." SHPI is focused on the design, development and manufacture of innovative safety medical devices. SHPI manufactures certain products under its own label. Other products are supplied to large corporate customers, such as Bard Access Systems, on a private-label, OEM basis. In those cases where the product will be manufactured in the hundreds of million of units, SHPI licenses products to leading manufacturers in the global disposable medical product industry, receiving royalty payments. Examples of other disposable medical products based upon SHPI's technologies are safety epidural and spinal needles, bone biopsy needles and blood-collection devices. SHPI has more than 125 issued or pending patents for safety needle technologies that apply to virtually all medical needles used today.

The geometry holding the product's wings changes angles along the vertical wall of the part. The vinyl compensates for changes.

The SHPI sales team will work with distributors to oncology departments at hospitals and clinics across the country to present MiniLoc to clinicians. In the future, SHPI plans to market to economically developed countries in Europe, Asia and Japan where safety is more of a concern. It shouldn't be a difficult sales pitch. With the MiniLoc safety needle, SHPI has created a friendly safety needle with a low activation force that does not interfere with the clinician's technique. The MiniLoc safety infusion set locks out so clinicians cannot accidentally stick themselves, thereby avoiding exposure to blood-borne pathogens.

Sums up Solomon, "We appreciate the development help, responsiveness and sensitivity to cost that we received from Flexpak. They met the challenge in providing a cost-effective solution using Klöckner Pentaplast vinyl film."

More information is available:

Belco Packaging Systems, 800/833-1833. **www.belcopackaging.com.**
Flexpak Corp., 602/353-4102. **www.flexpakcorp.com.**
Integra Biotechnical, 760/682-1670. **www.integrabio.com.**
Klöckner Pentaplast of America, 540/832-1426. **www.kpfilms.com.**
RD Packaging, 858/205-0647.
Sencorp, 508/771-9400. **www.sencorp-inc.com.**
Specialized Health Products, 801/298-3360. **www.shpi.com.**