



Title: **Safety Needle Manufacturer Points to Higher Yields with Precision Air-Free Adhesives Dispenser**

By: Scott Beebe, President of Fishman Corporation

Specialized Health Products, Inc. (SHPI), based in Bountiful, Utah, is a developer, manufacturer and marketer of proprietary safety medical devices, designed to minimize the risk of accidental needlesticks – often referred to as Safety Needles. SHPI has developed multiple safety needle products based upon two primary technology platforms, which apply to virtually all medical needles used today.

More than six billion syringe needles are used annually by healthcare workers in the U.S. As a result, some 800,000 injuries occur due to accidents with needles, often after medicine has been administered or blood has been drawn from a patient. The risk of transmitting HIV/AIDS, hepatitis B and C and other diseases between patient and healthcare worker has thus been high; and with more than \$1 billion being spent annually on testing and treatment of accidental needlestick injuries, state and federal legislation has been enacted, mandating the use of medical safety needles.

For SHPI, the industry-wide emphasis on needle safety has resulted in a phenomenal demand for the company's products... but success has bred challenge. Mark Ferguson, Director of Product Development and Engineering for SHPI, explains: "We do business two ways, one of which is licensing and contracted development. We license our proprietary technology to other manufacturers, and often contract to engineers and develop the product for our licensed partner. SHPI is a full service product development

firm. Tyco Healthcare's Monoject Magellan™ line of safety needle products is a good example of this business model. The second way we do business is by developing and manufacturing our own proprietary products. These products are available for sale to distributors as SHPI branded products, and are also provided on an OEM basis to many of the major medical manufacturers such as Bard Access Systems, Tyco Healthcare, and Merit Medical. In some cases, our two business models are blended – by that, I mean in certain cases, we are manufacturing products which were specifically developed for, and are licensed exclusively, to an OEM. Since these are medical products, quality is a primary concern for us, and the products we ship meet rigid quality assurance standards.”

He adds, “Despite our tight production schedules and high shipping volumes, the possibility of a defective product being delivered to a customer is simply unacceptable.”

SHPI needles are produced at the Tijuana, Mexico facility of Integra Biotechnical LLC, a medical device contract manufacturer. SHPI designed, developed and controls eight assembly lines currently running at Integra. Lines are comprised of assembly cells, or stations, that vary from manual to fully automated, depending on the requirements of a given assembly step. (See Figure 1.) All cells or stations are manually fed. The current combined capacity of the installed lines is about five million devices annually.

SHPI currently manufactures four series of disposable medical needles for OEM customers: the LiftLoc® Safety Infusion Set, the MiniLoc™ Safety Infusion Set, the SecureLoc™ Safety Introducer Needle, and the Monoject Magellan Bone Biopsy Needle. In all cases, a stainless steel needle and associated tubing (depending on the product) are secured in a plastic housing with an adhesive. Figure 2 shows dispensing of Loctite UV-cured adhesive in assembly of a MiniLoc™ Safety Infusion Set. “The process sounds simple,” says Ferguson, “but these adhesive volumes are small, and precision in adhesive dispensing is vital to the performance of our products. With some of the systems we evaluated, we had a problem consistently dispensing precise amounts of the adhesives we use.”



Figure 1. Assembly Cells at Tijuana Facility for Manufacturing SHPI Needle Assemblies



Figure 2. Dispensing of Adhesive in Assembly of MiniLoc™ Safety Infusion Set

Take the needle used in one of the products, for example. Securing the stainless steel tubing in the hub requires a precise amount of adhesive to be dispensed at the needle joint. “We evaluated a hydraulic positive displacement system, but the repeatability we needed was just not there,” recalls Ferguson. “It was too unreliable. One control unit kept crashing. A different version was stable, but leaking occurred in the hydraulic line between the drive motor in the controller and the dispensing gun, resulting in a loss of dispense precision. ”

“Clearly,” he said, “a more reliable system with sufficient accuracy and repeatability was required. We started looking around for a better solution.”

Ultimately, SHPI turned to a dispensing system developed by Fishman Corporation: the LDS9000¹. Unlike the other types of dispensing products on the market, the Fishman dispenser is somewhat unique, in that movement of the piston in the syringe (or barrel) — which forces material out of the tip — does not depend on pressure provided by either air or hydraulic fluid. Instead, a flexible electrical cable assembly connects the microprocessor control unit with a linear actuator in the dispense gun, which provides a highly controllable positive displacement force on the piston.

As can be seen from the cutaway illustration of the gun (Figure 3), a stepper motor and a mechanical lead screw are employed to extend or retract a piston attached to the end of the screw. The stepper motor rotates a nut between electrically charged poles. Though the nut turns, its axial position does not change. The lead screw, threaded through the nut (and secured from turning itself), thus moves up and down on command from the control unit.

¹LDS = Linear Drive System

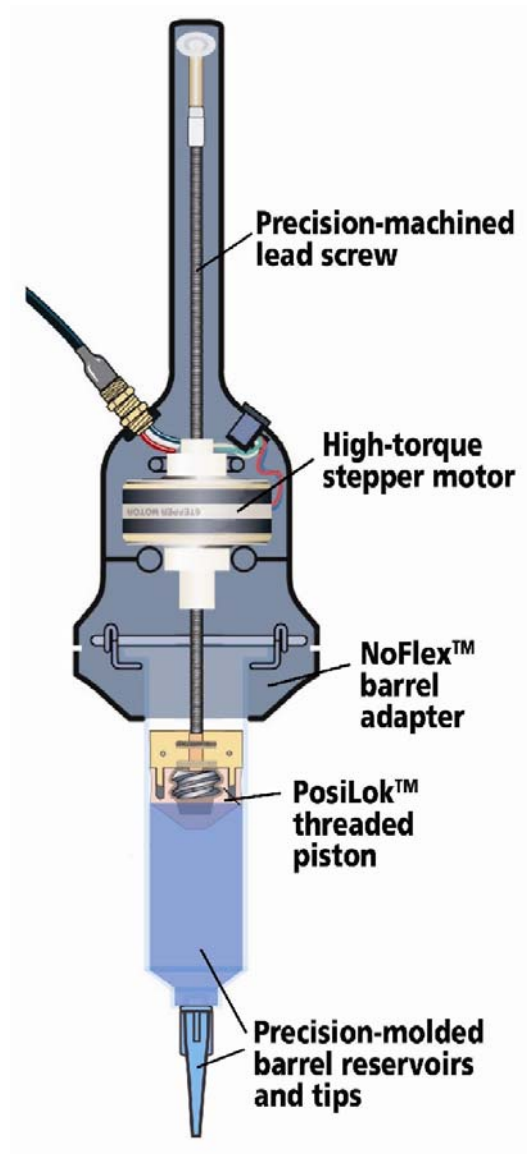


Figure 3. Cutaway View of LDS9000 Dispensing Gun

As a result of the precisely controlled rotation of the lead screw, the piston pushes exact and repeatable amounts of adhesive through the syringe and dispensing tip. To accomplish this, key data are programmed and stored in the control unit: the specific

syringe dimensions (inner diameter and length), dispense volume, dispense rate, drawback, and drawback delay. With these parameters entered, the software calculates the exact movement of the piston in the barrel to dispense the required amount. Neither the viscosity of the material nor the amount left in the syringe has any impact on dispense volume; and simply activating the control, either manually or automatically, ensures high repeatability in delivering the desired amount. After a dot of adhesive is dispensed, a programmable pullback of the piston prevents fluid ooze.

“Frankly, Ferguson points out, “we liked the idea of an electrical cable connecting the controller and the gun, as opposed to a hydraulic link. That way, leakage wouldn’t be a concern. We figured if we were able to get the accuracy and repeatability we needed, then the choice was easy.”

Fishman dispensers can be hand-hand, mounted in bench-top stands, or even ganged in fixtures and programmed for automated operation. When mounted in automated equipment, the equipment controller signals the dispense action through the footswitch connector on the Fishman controller. For the manually operated stations, the dispenser is generally fixtured (see Figures 1 and 2) and is actuated through the foot switch included with the dispenser. In all cases, the amount dispensed is automatically determined as programmed by the control unit.

SHPI is currently running 20 Model SDAV LDS9000’s at the Tijuana facility”²
“The Fishman dispensers are enabling us to meet both our production schedules and our quality goals,” says Ferguson. “We’re satisfied.

³The Fishman SDAV is capable of consistent dispense volumes as small as 0.00023cc, significantly less than SHPI requirements.