

Improvements in Sharps Safety in the Operating Room

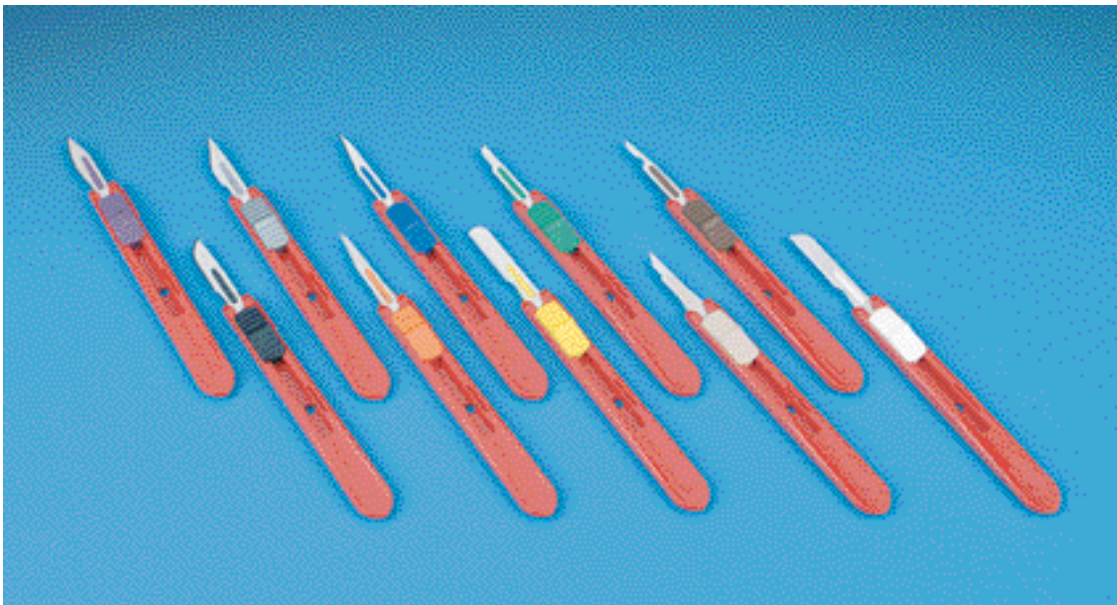
by Ron Stoker

Since the passage of the Needlestick Safety and Prevention Act of 2000, we are seeing the implementation of the use of safety-engineered devices throughout many parts of the hospital. Not all departments of the hospital have been compliant with the requirements of law. From all indications, the cardiology, radiology and anesthesiology departments have all been slow to comply with the requirements of the law. It would appear the implementation of safety products in the operating room (OR) has also lagged behind. This noncompliance has often been seen as a lack of concern about sharps safety by physicians. One study illustrated this apparent lack of concern by documenting the number of percutaneous injuries that occurred at various hospitals in the United States between 1993 and 2002. During this time period, a 38.1 percent reduction in injuries was seen in patient rooms, compared with only a 5.7 percent drop in the OR. The study, conducted by the International Healthcare Worker Safety Center, found that injury rates from hollow-bore needles declined by almost 33 percent between 1993 and 2002. Injury rates from suture needles increased by 26.8 percent over that same period.

Sharps injuries in the OR are not a minor problem! Were you aware that accidental cuts or needlestick injuries occur in 1 to 15 percent of all operations? The most common cause of suture needle injury is suturing fascia, during which 59 percent of all suture needle injuries occur.

This data indicates there have been very few changes made in the OR to reduce these sharps injuries in recent years. OSHA has not totally ignored this lack of compliance with the Needlestick Safety and Prevention Act of 2000. In fact, OSHA has stepped up the number of citations to healthcare facilities that are not using safety-engineered medical devices with sharps injury prevention features. These fines for noncompliance can be rather significant, particularly if it can be shown by OSHA that the lack of use of safety products is a willful violation of the OSHA Bloodborne Pathogen Standard.

Figure 1. DeRoyal Safety Scalpel with retractable blade



Safety Products That Can Be Used in the Operating Room

Every hospital has the assignment to comply with OSHA standards. It is important that hospitals evaluate safety devices on a regular basis. It is recommended that each hospital have a number of committees responsible for evaluating new safety products. Staff members who are directly responsible for patient care should be involved in the identification and selection process of new safety devices.

Safety Scalpels

During the past five years a number of safety scalpels have been introduced to the market. With conventional scalpels, injuries can occur when passing instruments to other surgical team members, when removing the contaminated blade from the handle, or when the blade is left uncovered on the instrument tray.

Safety scalpels come either as shielded scalpels or as a retractable scalpel. Shielded scalpels have a stationary blade that is covered by a shield when not in use. The protective safety shield over the scalpel blade is designed to protect surgical personnel from accidental percutaneous injuries. The safety shield can be extended and retracted using one hand that can minimize the potential for percutaneous injury. At the end of the procedure the blade does not have to be removed from the handle before disposal. This enhances safety by decreasing the

risk of percutaneous injuries. The retractable blade scalpel is a functional blade that's retracted so the blade is covered by the body of the scalpel when not in use. One example is the Safety Scalpel produced by DeRoyal (see Figure 1 on page 14).

Neutral Zone

Another good technique for reducing accidental sharps injuries in the operating room is the use of a neutral zone or no-hands passing zone. A number of devices have been used in conjunction with the no-hands passing zone, including trays, basins and hand instrument stands. Some of these have been more effective than others. One choice that has been used frequently is the kidney basin, which is found in almost every healthcare institution room in the country. This is an extremely dangerous method of passing sharps. The kidney shape requires the fingers to be inserted next to the sharp. In addition, the kidney basin tends to tip sharps so that sometimes the sharp end is up.

The best device that should be selected for a no-hands passing zone should be large enough to contain the sharps used, not easily tipped over, and easily mobile. One such product that is used for transferring sharps in the OR as described is the ScrubSafe™ manufactured by DeRoyal. The ScrubSafe is a safety-engineered device that is used to transfer and pass a wide range of sharp instruments between members of the scrub team during any surgical procedure (see Figure 2).

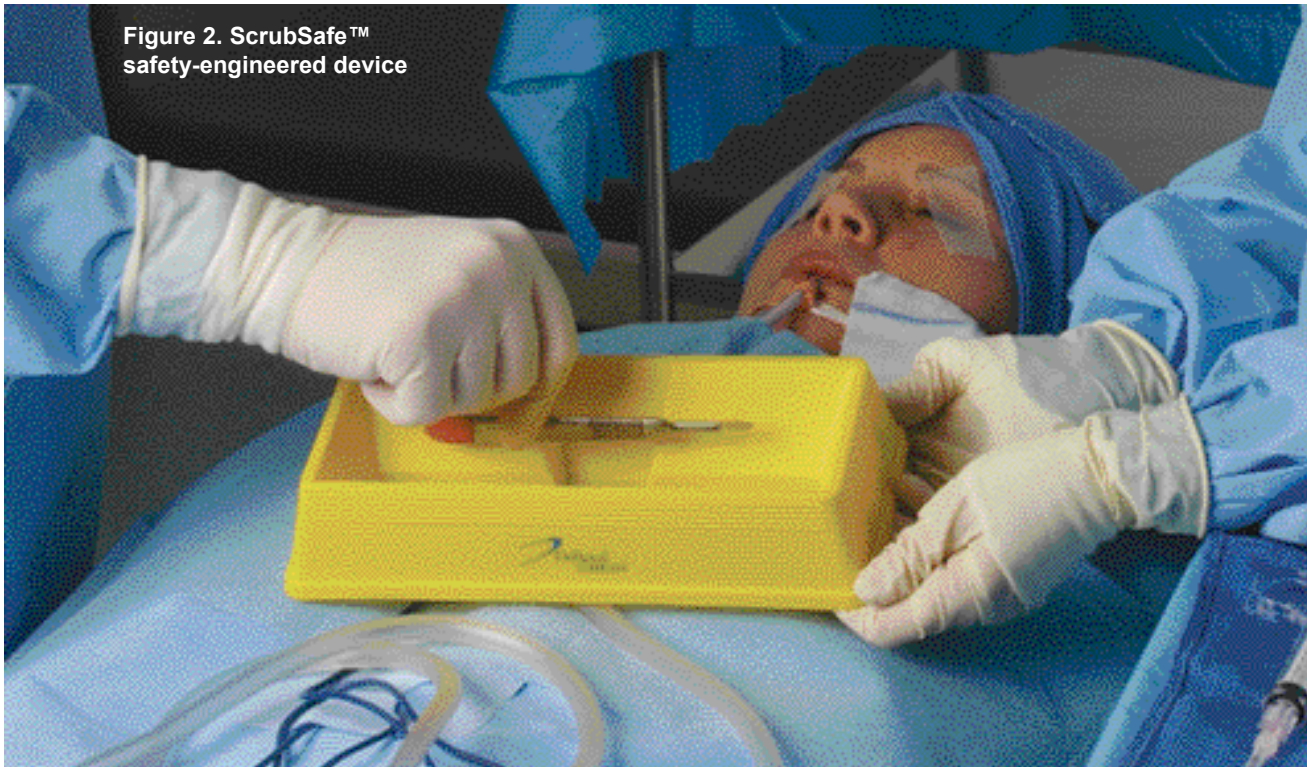


Figure 2. ScrubSafe™ safety-engineered device

Safety Fascia Suturing

One area, however, that has previously not been addressed has been the sharps injuries caused by suture needle injuries when suturing fascia, the underlying layer below the skin, that must be closed at the conclusion of most major surgical procedures. According to a statement from the American College of Surgeons, the most common cause of suture needle injury is suturing fascia, during which 59 percent of all suture needle injuries occur. This is not a minor problem, as there are more than 5 million fascia closures performed each year in the United States alone!

One company that is trying to make a difference in this area is SutureTek Inc., a privately held medical device company specializing in safe-suturing devices. It has introduced a new product, the SutureTek 360° Fascia Closure Device, which reduces the possibility of needlestick injuries during fascia closing. The SutureTek 360° Fascia Closure Device is intended for the approximation of soft tissue in general surgical procedures. The device is designed to reduce needlestick injuries during suturing procedures in the OR. The needle is contained within a cartridge, thus avoiding exposed “sharps” that may injure the surgeon, other OR staff or the patient.

Figure 3. SutureTek 360° Fascia Closure Device



This device is specifically designed to protect surgeons, nurses and OR staff against potentially deadly suture needlestick injuries during fascia closure by ensuring that the sharp point of the suture needle—which is contained within a sterile, disposable suture cartridge at all times—is never exposed.

The SutureTek 360° Degree Fascia Closure Device consists of a patented, ergonomic, reusable suturing device that uses patented disposable suture cartridges. The device is faster, easier and safer for surgeons than tedious and difficult hand suturing. SutureTek suture cartridges use standard taper-point fascia closure needles, and all types of standard absorbable or nonabsorbable sutures. Hands and fingers are not exposed to the sharp point of the needle before, during or after the procedure. This is critically important because a recent study from Johns Hopkins reported that almost 40 percent of urban

surgery patients are infected with deadly diseases such as hepatitis or HIV/AIDS.

The device places a stitch by driving the curved needle in a complete 360-degree circular arc (CCW). The device handle is fully squeezed and released twice to place each stitch. The first squeeze and release of the handle drives the needle 180-degrees. The second squeeze and release of the handle drives the needle 180-degrees again. To place a stitch, the surgeon squeezes and releases the handle trigger completely—until an audible “click” is heard and the trigger comes to a full stop. At this point the needle is now driven through the tissue located within the opening (aperture) at the front end of the device. This action is repeated again, with the surgeon squeezing and releasing the handle trigger a second time. An audible click is heard when this is completed. The body of the needle (and the suture) will now completely pass through the tissue, and the needle returns to its original position, thus completing the stitch.

The SutureTek 360° Degree Fascia Closure Device has been used extensively in a wide variety of surgical procedures in the United States and Europe, including many types of major abdominal surgeries, caesarian deliveries, abdominal hysterectomies, hip and knee replacements, and spinal surgery.

Many surgeons who have used this device speak highly about it. According to Elias Arous, MD, FACS, chief of surgery at UMass Memorial Hospital, University of Massachusetts in Worcester, Mass., it has made a big difference in his ORs. “As the first hospital to purchase this device, we immediately realized its potential to reduce suture needlesticks to all operating room personnel, as well as its added benefits of making wound closure faster and easier for surgeons across all surgical specialty areas,” he states.

Dr. Timothy Pitchford, MD, bariatric surgeon at Sacred Heart Hospital in Eau Claire, Wis., indicates: “The biggest benefit to this device is that there is no

needle exposure to the surgeon and operating room staff.” Dr. Pitchford’s concerns are of particular importance in areas with high infection rates for hepatitis C and HIV.

Michael Q. Durry, MD, FACS, chairman, department of surgery at Bon Secours Baltimore Health System in Baltimore, Md., indicates: “I serve a patient population with a high rate of hepatitis C and HIV, so zero percent needlesticks are our goal. SutureTek’s 360° Fascia Closure Device takes me a long way toward that goal.”

In addition to the protection of healthcare workers, the SutureTek product can also protect the interest of patients. “Safeguarding our employees during surgery is very important, but there are also significant benefits to patients because SutureTek can reduce the time a patient is under anesthesia in the operating room. The instrument is usually faster than hand suturing, and provides consistent

high-quality stitches. It is cost effective because rather than being disposable, it is reesterilized,” states Dennis Schoff, Center for Surgical Care director, Sacred Heart Hospital, Eau Claire, Wis.

The surgeon retains complete control of the placement, depth and spacing of each stitch. The needle always follows the arc of its own curve, minimizing trauma to the tissue. The result is a series of consistent, high-quality stitches.

The SutureTek 360° Fascia Closure Device uses all standard types and sizes of sutures, and a standard curved fascia closure needle, enabling placement of all types of continuous or interrupted stitches. It precisely replicates traditional hand suturing techniques. A single SutureTek 360° Fascia Closure Device disposable suture cartridge will enable a surgeon to place as least as many stitches than surgeons can now place using a conventional fascia closure suture. No extra length of suture is used up when suturing with the device, as compared to hand-suturing with standard fascia closure sutures.

The device prevents accidental needlesticks by containing the sharp point of the needle in a protective cartridge when not in use. It also reduces trauma to the tissue by assuring the needle always follows its own arc. For surgeons, it speeds up the procedure and reduces the tedium of hand suturing—simply squeeze the handle to place a stitch. The device can be used with equal ease in either hand. †

Author’s note: The SutureTek 360° Fascia Closure Device was developed by SutureTek Inc. (North Chelmsford, Mass.). SutureTek was commercially launched in the United States at the end of 2005, following U.S. Food and Drug Administration (FDA) approval. According to the manufacturer, the SutureTek 360° Fascia Closure Device is often supplied at no charge to hospitals that purchase the disposable suture cartridges. The cartridges cost approximately \$300 (U.S.) per box of 12. To really understand the product you must see it in action. Please turn your Internet browser to www.suturetek.com/suturetek_content/video/SutureTek_FasciaClosure_Device_500k_1.wmv. It will knock your socks off! For more information on this product please contact the author at info@ISIPS.org or contact the manufacturer at 978.251.8088.

Ron Stoker is the founder and executive director of ISIPS, the International Sharps Injury Prevention Society, and is a frequent contributor to Managing Infection Control magazine. He speaks frequently at national and international meetings on sharps safety, hand hygiene and infection control issues. He is coauthor of the “Compendium of Infection Control Technologies.” For more information on the Compendium go to www.medicalsafetybook.com.