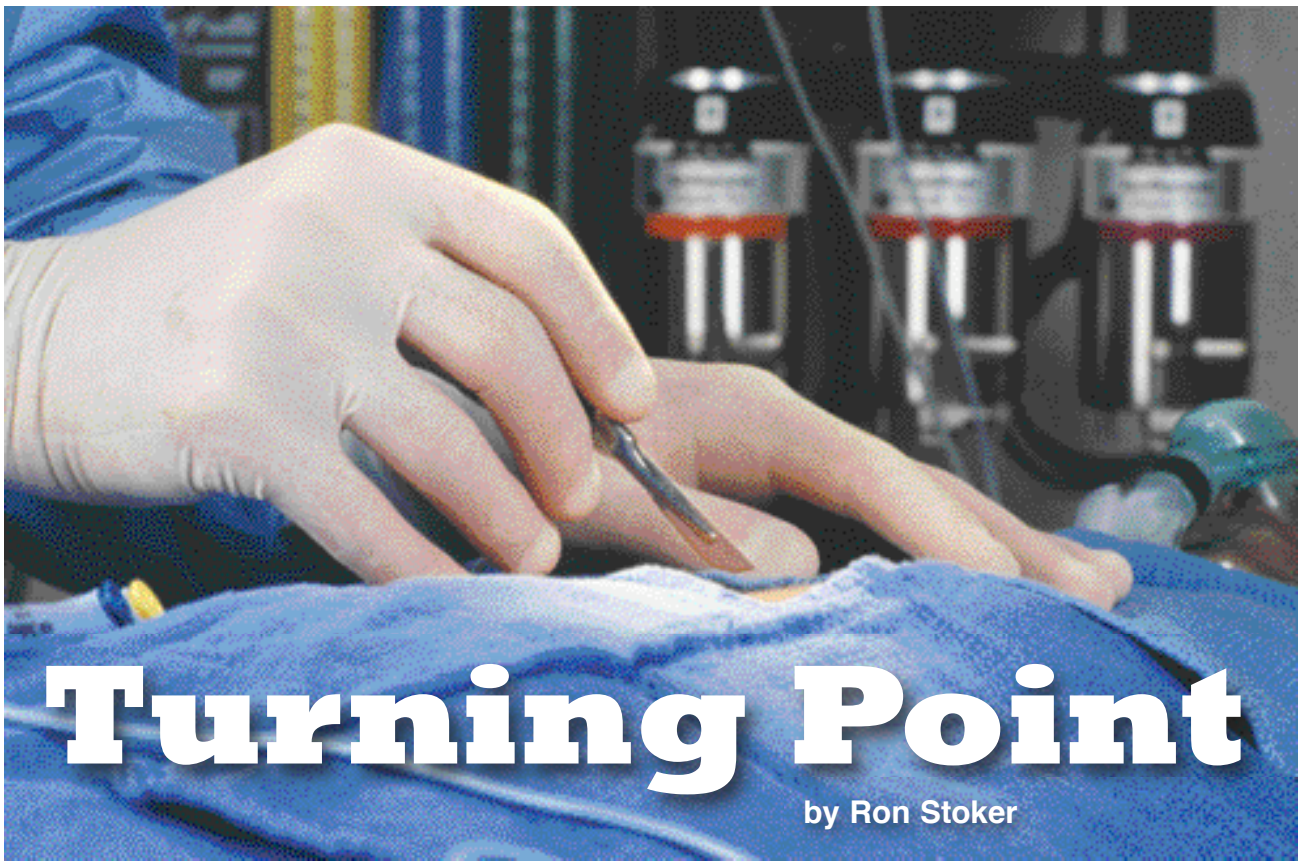


Turning Point

by Ron Stoker

New safety scalpel handle system provides safety features and familiar feel

During the last four months the author has reviewed a variety of issues that have been expressed concerning sharps safety in the operating room. During the course of our discussions we have looked at the requirements of the law concerning safety products in the operating room. In addition, we have reviewed the "state of the market" concerning safety scalpels. We have reviewed their features and benefits. In addition to looking at safety scalpels, we have reviewed alternate methods for the removal of scalpel blades from their handles without getting cut, as well as the importance of neutral zones and passing transfer trays.

Sharps safety in the operating room is not a new concept. With the existing level of legislation, regulations and protocols issued through governmental agencies, the topic of sharps injuries should either be infrequent or non-existent. Unfortunately, this is not the case in today's surgical environment. Although medical facilities have taken precautions to prevent sharps injuries, a point of discontent has been the use of safety scalpels.

Almost all surgeons and their teams were trained to routinely use a traditional stainless steel blade handle (i.e., a standard No.3 handle). Along with this traditional design comes a variety of positive features and benefits for the surgical team, except one—safety. In today's environment, an exposed blade routinely passed between medical professionals is simply unacceptable.

In an interpretation[1] letter issued by Richard E. Fairfax, director, Directorate of Enforcement Programs of OSHA, the question was asked, "Do healthcare facilities need to use reengineered safety scalpels to be in compliance with the bloodborne pathogens regulations, or can they simply evaluate?" In the letter, Dr. Fairfax indicated that employers are required to evaluate safer medical devices to eliminate or minimize employee exposure to blood or other potentially infectious materials (OPIM). Employers must solicit input from non-managerial employees in the selection process. Engineering controls, including safety scalpels, must be implemented where their use is feasible.

A second question asked, "Under what circumstances may they choose not to employ safety scalpels?" The reply, "OSHA recognizes that no one medical device is appropriate for use in all circumstances and that it is important to safeguard both patients and employees during medical and surgical

procedures. If the use of a particular engineering control, in this case a safety scalpel, compromises patient safety, its use would not be considered feasible. The employer, therefore, must determine what engineering and work practice controls effectively minimize hazards without unduly interfering with medical procedures. The standard also recognizes that market availability is another limiting factor in implementing the use of engineering controls and must be considered in both your choice of an engineering control and our enforcement of their use. However, please be aware, where exposures have been determined and where engineering controls are commercially available and feasible, they must be used."

The bloodborne pathogens standard requires that employers "document annually [their] consideration and implementation of appropriate commercially available and effective safer medical devices …" OSHA compliance officers have issued citations to employers at facilities where the exposure control plan (ECP) did not contain such documentation. It is required, therefore, that a site choosing not to employ safety scalpels, specifically address the non-use of a safety scalpel in its ECP.

The ability for the surgical team to effectively meet safety standards while not compromising surgical procedures is paramount.

Since that time, numerous citations have been issued to facilities that have not been in compliance. Given the current regulatory and legal environment, the decision to address safety may no longer be optional. In addition, the level of inspections and heightened awareness demonstrates that the surgical arena is no longer exempt. The ability for the surgical team to effectively meet safety standards while not compromising surgical procedures is paramount.

Every facility aims to keep staff members protected from sharps injuries and consistently looks for cutting-edge technology which will empower them to do so. In the realm of safety scalpels, product resistance has primarily arisen from the product design. In surveys of surgeons, safety scalpels are often met with the challenges of blade preference, concerns about puncturability, obstructed visibility, and the "lack of feel" as compared to traditional handles. Although the majority of medical professionals are willing to implement safety within their procedures, it cannot be done by placing surgeons at a disadvantage during their surgical procedure. Unfortunately, the fact that 38 percent of all surgical scalpel injuries are inflicted by the user on the assistant (as illustrated by the Centers for Disease Control and Prevention) simply can't be over looked. Therefore, the necessity for a product that addresses safety and conventional preferences is apparent.

I recently had an opportunity of looking at a new safety product from Sandel Medical Industries. Recognizing both the challenges of current product designs and the requirements of modern surgical teams, Sandel has engineered a product that has changed the preconceived model of sharps safety. They have developed a product, the Change-A-Blade™—a safety

Figure 1

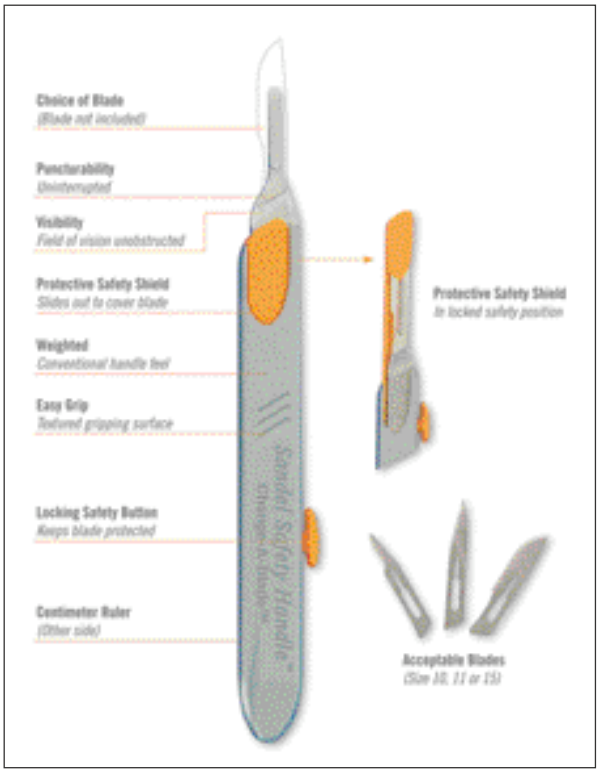


Figure 2

scalpel handle, that is similar to a standard scalpel except that it provides safety features. The Change-A-Blade design has mimicked the esthetics of a traditional scalpel handle. By addressing weight, feel and dimensions, the Change-A-Blade reacts very similar in the hands of a surgeon. So how was this done? The engineers at Sandel Medical visualized the traditional scalpel handle within a safety shield. In its bare form, the Change-A-Blade is a traditional scalpel handle with the benefit of staff protection (see Figure 1).

Just like a traditional scalpel handle, Sandel's Change-A-Blade features the distinct capability for surgeons to retain their preferred blade of choice. The Change-A-Blade is capable of accepting any standard No.10, No.11 or No.15 blade regardless of manufacturer. In one sense, this fundamental distinction places Change-A-Blade in a new product category. Rather than being a safety scalpel, it is really a safety scalpel handle.

Some clinicians have complained that some safety scalpels compromise blade disability and penetrability. In procedures requiring a deep incision, some surgeons have indicated that safety scalpels handicap them due to the safety design. By creating a fully retractable safety shield, the Change-A-Blade removes the preceding doubts held by surgical teams. The Change-A-Blade allows the blade to exist independently for an un-obscured line of sight—just like a traditional scalpel handle (see Figure 2).

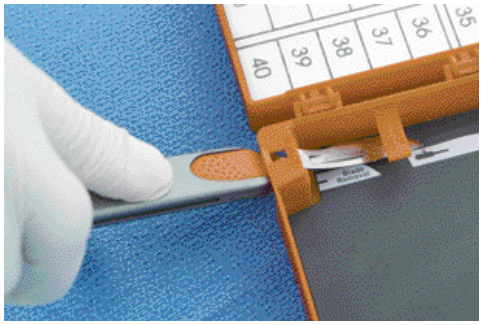
The Change-A-Blade reusable scalpel handle is easy to use. The clinician first removes the "time out" sleeve prior to use. The button is then pressed down and the safety shield is slid into a loading position. The scalpel blade is then loaded onto the scalpel. The handle will accept any standard No.10, No.11 or No.15 blade regardless of manufacturer. After the blade is securely loaded onto the handle, the button is slid forward until the safety shield is locked into place. In order to use the scalpel, the clinician simply disengages the safety shield. When the clinician is through using the scalpel, he simply presses the button down and slides the safety shield forward until he hears a distinct "click" which indicates the safety shield is fully engaged. The Change-A-Blade safety scalpel handle can have as many scalpel blade replacements as necessary. To remove the blade, the clinician will use the Sandel Scalpel Disarmer. The blade is inserted under the guard and the guard is snapped with a sharp edge towards the inside wall of the box (see Figure 3).

Figure 3

Press downward with index finger on orange shield at front of scalpel. The handle is pulled backwards. The blade may then be

placed on the magnetic pad at a desired location using the scalpel handle (see Figure 4).

Figure 4



The Change-A-Blade safety scalpel handle has a similar weight and size to conventional scalpels and is well balanced. It has been designed to minimize the risk of blade and scalpel injuries throughout healthcare environments with a current focus on the operating room.

Would you like more information on this safety product? Contact Sandel Medical industries at 866.SMIDEAS (764.3327) or visit their Web site at www.sandelmedical.com. ✛

Reference

1. 09/01/2004, Limiting factors for implementing the use of engineering controls, i.e., safety scalpels, under the Bloodborne Pathogens standard. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=25090

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. Mr. Stoker is providing a number of webinars focusing on a variety of sharps injury prevention safety products. For more information on the webinars, go to www.isips.org/seminars.html. For the latest list of safety medical devices go to www.isips.org/safetyproductlist.php. Do you know of any new safety products that should be added to this list? Send an e-mail to info@isips.org.