

Sandel Weighted Safety Scalpel™ (10/05)

Question: I recently saw an advertisement for a disposable safety scalpel that reportedly has a weight comparable to a conventional scalpel. Does DECS have any information about this scalpel from Sandel Medical Industries?

Answer: The scalpel blade is a type of sharp that has been implicated in percutaneous injuries. With a conventional scalpel, injuries can occur when passing the instrument to other dental team members; when removing the contaminated blade from the handle; or when the blade is left uncovered on the instrument tray. The Sandel Weighted Safety Scalpel™ has a protective safety shield over the scalpel blade designed to protect dental health-care personnel (DHCP) from accidental percutaneous injuries associated with conventional sterilizable scalpel handles and disposable blades. The safety shield can be extended and retracted using one hand which can minimize the potential for percutaneous injury. Also, the blade does not have to be removed from the handle before disposal further enhancing safety by decreasing the risk of percutaneous injury.

DECS recently completed a limited clinical evaluation of the Sandel Weighted Safety Scalpel™. During this clinical evaluation, five evaluators (general dentists, periodontists, and oral surgeons) used the disposable scalpel for a total of 151

incisions. All evaluators agreed that the instructions were easy to understand, the packaging was convenient, and that it was easy to remove the scalpel aseptically from the package. All evaluators agreed that the weight and size of the device was acceptable and well balanced. Additionally, all agreed that the blade was sharp for the initial incision. Most evaluators (3/5) were

neutral with respect to blade sharpness after the initial incision. The evaluators found the safety feature easy to use and recognize, and reported that it functioned as intended during the evaluation. The main disadvantages noted were the flexibility of the handle/blade connection and size. Several evaluators commented that they would prefer a device with a more rigid handle and blade connection design. Several evaluators commented that they would prefer a slimmer handle design to make the disposable scalpel less bulky and possibly improve access in patients with a small mouth. There were no reported percutaneous injuries during the evaluation period. When the evaluators were asked to comment whether they thought that the device was safer than a conventional scalpel and blade, four evaluators agreed that it was safer and one evaluator was undecided. The five evaluators agreed that the device was safe for clinical use.



Evaluating safety devices is challenging and several factors can impact the outcome of the product evaluation. With the introduction of any new device or technique a period of adjustment and relearning of technique is necessary. The short duration of this clinical evaluation; staff experience and preference for conventional devices; and perceived needs for devices with safety features are factors which can affect safety device evaluation. It's also important to consider that when presented with a device that has a significantly different design than a traditional device, decisions regarding preference and future use can be dependent upon the individual practitioner's style and technique. All of these factors can affect the evaluation of safety devices and could account for the variety of opinions obtained during this evaluation. This illustrates the importance of having staff members responsible for patient care involved in the identification and selection process when considering and evaluating new safety devices.

While it is not presently mandatory to use safety scalpels, OSHA requires annual consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure. The Sandel Weighted Safety Scalpel™ was found to be

safe for clinical use during this limited DECS evaluation, and is an example of a device that could be evaluated in USAF dental clinics to fulfill the OSHA evaluation requirement.

Manufacturer	Sandel Medical Industries, LLC 9540 De Soto Ave Chatsworth, CA 91311 (866) 764-3327 (818) 534-2500 (818) 534-2510 FAX www.sandelmedical.com
Price	Suggested Retail Price: \$170.88 Case of 96 Weighted Safety Scalpels™ (silver scalpel) (\$1.85 each) Government Price: \$160.63 Case of 96 Weighted Safety Scalpels™ (silver scalpel) (\$1.67 each)
Available Blade Sizes	#s 10, 11, 15
Summary of Safety Feature	Protective safety shield safety shield covers the blade (activated via locking/unlocking button) during periods of nonuse.
Advantages¹	+ Potentially safer because it may minimize risk for percutaneous injuries + Potentially safer for patients and staff because the protective safety shield covers the blade until needed + Weight comparable to conventional sterilizable scalpel + Conveniently packaged + Safety feature is easy to recognize and use + Safety feature can be activated with one hand + TIME OUT™ removable sleeve is a reminder to comply with JCAHO's Universal Protocol + Enhances infection control and safety because of its disposability
Disadvantages¹	- Blade/handle connection somewhat more flexible than a conventional device; may make the device feel unstable during use - Handle is thicker than traditional scalpel handle; may make access difficult to all areas of the mouth

¹Information compiled from limited DECS clinical evaluations.