

BD Bard-Parker™ Protected Blade System (3/06)

Question: I recently saw an advertisement for a safety scalpel that has an autoclavable metal handle and disposable blades with protective coverings. Does DECS have any information about this safety scalpel?

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 BD Bard-Parker™ Protected Blade System consists of an autoclavable metal scalpel handle designed with the weight and feel comparable to a traditional scalpel. Disposable Protected Blade System Cartridges are attached to the metal handle before use. The cartridge has a protective safety shield over the scalpel blade designed to protect users from accidental percutaneous injuries associated with conventional blades. The safety shield can be extended and retracted using one hand, which can minimize the potential for percutaneous injury. Also, the blade can remain covered during both assembly and disposal to help prevent accidental contact with the blade. The disposable Protected Blade System Cartridges are currently available in a variety of blade sizes (see table below).

DECS recently completed a limited clinical evaluation of the BD Bard-Parker™ Protected Blade System. Ten evaluators (two oral surgeons, four general dentists, and four dental assistants) participated in the clinical evaluation. All evaluators reported that it was easy to remove the device aseptically from the package. The evaluators found the safety feature easy to use and recognize, and reported that it functioned as intended during the evaluation. All evaluators agreed that the weight and size of the device was acceptable, well balanced, and stable during use. None of the evaluators reported that they changed their technique when using the device. All evaluators agreed that they had good access to all areas of the oral cavity with only one evaluator commenting that the extra material on the cartridge containing the blade made it more difficult to see around. All agreed that the BD Bard-Parker™ Protected Blade System was safer than a conventional scalpel and that the device could be considered to be interchangeable with a conventional scalpel. There were no reported percutaneous injuries during the evaluation period. Dental assistants appreciated the protective cover over the blade, which made injury less likely and they offered positive comments about the ease of assembly and blade removal from the scalpel handle. Overall the BD Bard-Parker™ Protected Blade System received high ratings during this limited clinical evaluation from both the dentists and the dental assistants.



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 that can affect safety device evaluation. Furthermore, the individual practitioner's style and technique must also be considered when evaluating and choosing devices with a significantly different design than a conventional device. 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 BD Bard-Parker™ Protected Blade System was found to be safe for clinical use during this limited evaluation, and is an example of a device that could be evaluated in USAF dental clinics to fulfill the OSHA evaluation requirement.

Manufacturer/Distributor	<p>Manufacturer: Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 (888) 237-2762 (201) 847-6800 (800) 847-2220 FAX www.bd.com</p> <p>Distributor: Crosstex International 10 Ranick Road Hauppauge, NY 11788-4209 (888) 276-7783 (631) 582-6777 (631) 582-1726 FAX www.crosstex.com</p>
Price	<p>Suggested Retail Price: \$175.50 Box of 5 Protected Blade System Handles Size 3* \$175.50 Box of 5 Protected Blade System Handles Size 4† \$268.50 Case of 150 Protected Blade System Cartridges§ \$298.50 Case of 150 Protected Blade System Cartridges Size 12 \$463.50 Box of 50 Protected Blade System Cartridges Size 12B</p> <p>Government Price¶: \$135.45 Box of 5 Protected Blade System Handles Size 3* \$135.45 Box of 5 Protected Blade System Handles Size 4† \$185.76 Case of 150 Protected Blade System Cartridges§ \$185.76 Case of 150 Protected Blade System Cartridges Size 12 \$140.30 Box of 50 Protected Blade System Cartridges Size 12B</p> <hr/> <p>* For use with blade sizes 10, 11, 15, 10A, 15C † For use with blade sizes 12, 12B, 20-25 § Pricing for frequently used blade sizes 10, 11, and 15 ¶ Crosstex International pricing</p>
Available Blade Sizes	#s 10, 11, 12, 15, 20, 21, 22, 23, 10A, 12B, 15C
Summary of Safety Feature	Autoclavable stainless steel handle with disposable Protected Blade System Cartridges. The cartridge has a protective safety shield over the scalpel blade designed to protect users from accidental percutaneous injuries associated with conventional blades. The safety shield can be extended and retracted using one hand.
Advantages¹	<ul style="list-style-type: none"> + 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 and upon blade removal + Stainless-steel, autoclavable handle with conventional weight and feel + Easier blade assembly compared to a conventional scalpel + Easier blade removal compared to a conventional scalpel + Safety feature can be activated with one hand + Safety feature is easy to recognize and use + Protected Blade System Cartridges conveniently packaged + Provides audible and tactile confirmation of safety feature lock
Disadvantages¹	- Handles are not compatible with all blade sizes

¹Information compiled from limited DECS clinical evaluations.