

C. R. Bard GmbH
Wachhausstrasse 6
76227 Karlsruhe
Deutschland



Attention: Risk Management

Account No.: «Customer_Number__SoldTo_»

«Customer_Name»

[Date]

«Address_Line_1»

«City», «State» «Zip»

Urgent Field Safety Notice

Potential for scalpel cut/stick injury caused by improper use of safety scalpel

Dear Customer:

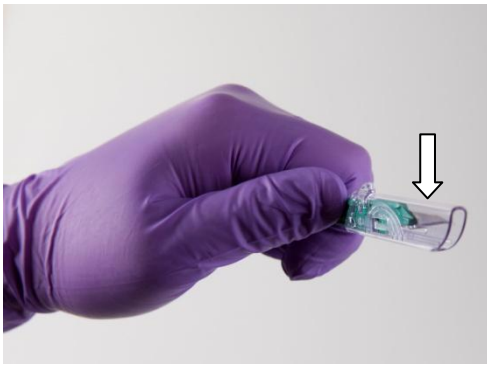
This is to inform you of a potential for an inadvertent scalpel stick injury involving the safety scalpel in some Bard Peripherally Inserted Central Catheter (PICC) kits.

Bard Access Systems recently replaced the Bard-Parker® Safety Scalpels manufactured by Becton, Dickinson (BD) with Safe-Cut® Safety Scalpels manufactured by Spectra Medical (Wilmington, MA). Although both blades have the push-slide safety mechanisms for exposing the blade, the usable sharp blade in the Safe-Cut® scalpel is pushed forward from within the handle. For those accustomed to the previous scalpel, two important differences are critical:

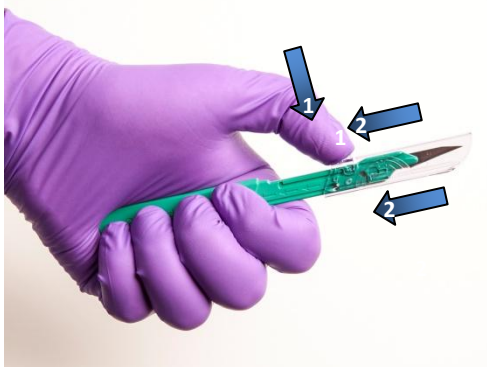
- Care should be taken that the open ended, diagonal end of the scalpel is pointed away from the hand/body whenever extending the blade.
- The blade has a lock in both the fully open and fully closed position—after use, ensure that the blade “clicks” into the fully closed position.

The instructions below are intended to assist you in understanding the differences in operation between the safety scalpel products provided in Bard’s PICC Insertion Kits.

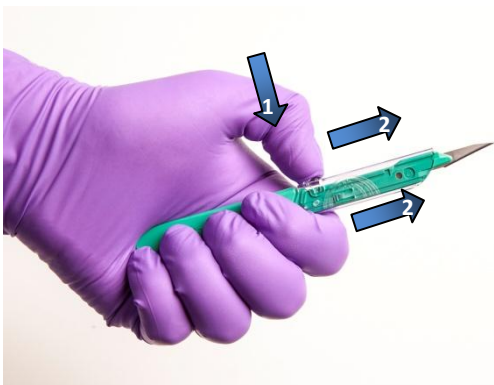
BD BARD-PARKER™ Safety Scalpel



Step 1: Check Blade Orientation - Examine the device ensuring that the blade is pointed away from you.

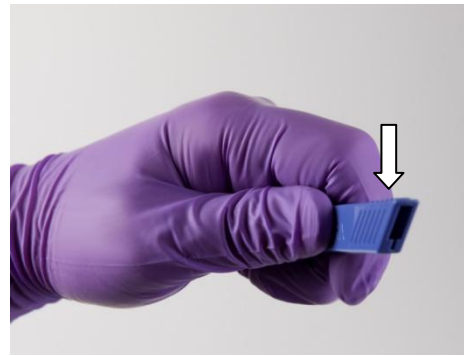


Step 2: Expose the Blade - Depress the top button on the clear protective shield and **retract** the protective shield to the rear locked position to fully uncover the blade.

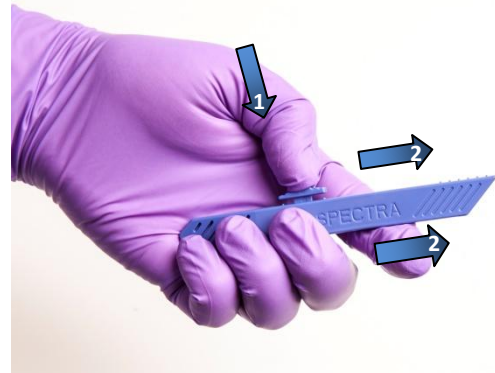


Step 3: Safety the Blade - Depress the top button on the clear protective shield and **advance** the protective shield to the forward locked position.

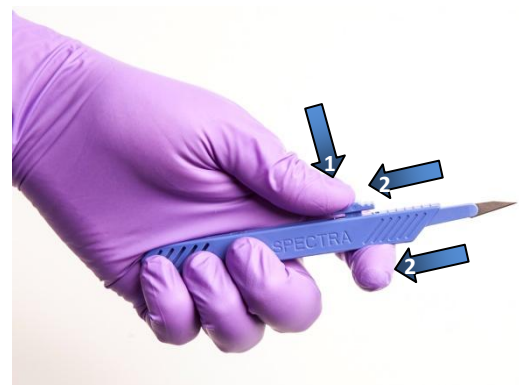
SPECTRA SAFE-CUT™ Safety Scalpel



Step 1: Check Blade Orientation - Examine the device ensuring that the blade channel is pointed away from you.



Step 2: Expose the Blade - Press down and forward on the safety release and **advance** the blade until it locks and you hear or feel a "click". This is the Use Position.



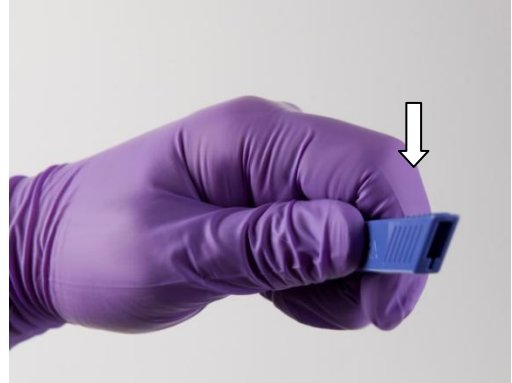
Step 3: Safety the Blade - Press down and backward on the safety release and **retract** the blade into the safety housing until it locks in the safe position.

BD BARD-PARKER™ Safety Scalpel



Step 4: Verify Safety - Examine the device ensuring that the clear protective shield is fully engaged over the blade.

SPECTRA SAFE-CUT™ Safety Scalpel



Step 4: Verify Safety - Examine the device ensuring that the blade is fully retracted into the safety housing.



Step 5: Disposal - The device is now in the safety position. Always dispose of used blades in an appropriate container.



Bard began shipping catheter units with the Safe-Cut scalpel on March 26, 2014, and our records indicate that you have received some of these units.

Please immediately provide this information to all clinical personnel involved with the use of Bard PICC-kits. In addition, if you have further distributed this product, please identify your customers and notify them at once of this notification. You may include a copy of this letter in your notification to your customers.

Both scalpel products function as intended and the purpose of this notification is to clarify the differences between the two types. Bard Access Systems has decided to provide all future Peripherally Inserted Central Catheter (PICC) kits with the BD Bard-Parker™ Safety Scalpel.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action. Should you have any questions or require assistance in this matter, please contact your local sales specialist or local Bard Customer Service Representative on +49 (0)721 9445-124.

Yours faithfully.

For and on behalf of C. R. Bard, Inc.

[Signature]

Enclosures: Reply Effectiveness Check Form

REFERENCE: **FA2014-17**

REPLY EFFECTIVENESS CHECK FORM

Potential for scalpel cut/stick injury caused by improper use of safety scalpel

By completing the below information you confirm that the Field Safety Notice Reference Number FA2014-17 has been received by your Healthcare Facility or Organisation and that all required actions are complete

Please PRINT Your Contact Information and fill form out completely	
Name	
Title	
Name of Account / Hospital	[Pre-populated field]
Contact Phone Number	
Date	

Please return completed form to:

RA/QA Specialist Deutschland, Österreich, Schweiz
C. R. Bard GmbH, Wachhausstrasse 6, 76227 Karlsruhe, Deutschland
Tel: +49 (0)721 9445-██████████ Fax: +49 (0) 721 9445-██████████
E-Mail: ██████████@crbard.com