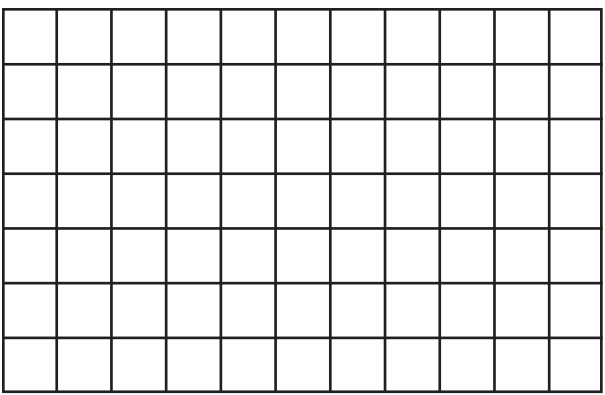
Bard Access Systems

Repair Kits For

Hickman*, Leonard* and Broviac* Central Venous Catheters



Instructions For Use

BARD

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Introduction

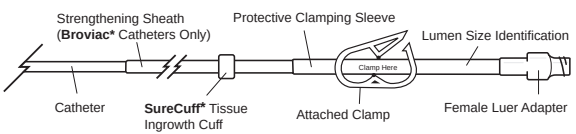
Indications For Use:

Hickman*, **Leonard*** and **Broviac*** catheter repair kits are designed for repair of the damaged external portion of the the indicated catheter. Repair of the catheter body segment requires at least 5 cm of undamaged catheter remaining external to the skin exit site. Repair of the adapter leg of multi lumen catheters requires at least 2.5 cm of undamaged adapter leg remaining proximal to the bifurcation or trifurcation.

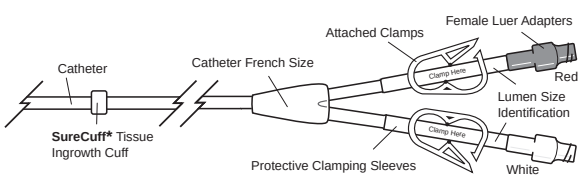
The catheter should be clamped with an atraumatic clamp between the catheter exit site and the damaged area when damage occurs and **must remain clamped during repair**.

Schematics

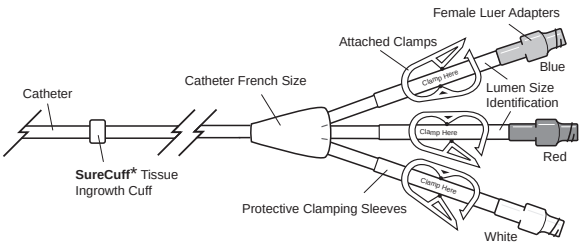
Hickman* and **Broviac*** Single Lumen Catheters



Hickman* and **Leonard*** Dual Lumen Catheters



Hickman* Triple Lumen Catheters



Additional Supplies Needed:

- Antiseptic (Povidone-Iodine is recommended)
- Atraumatic Clamp
- Gauze Sponges, 4 in. x 4 in. (10 cm x 10 cm)
- Heparin (Volume and Concentration per Hospital Policy)
- Isopropyl 70% Alcohol
- Scalpel
- Sterile Drapes
- Sterile Gloves
- Surgical Mask and Cap
- Syringe
- Tape
- Tongue Blade or Application Sticks

Warnings, Cautions and Precautions

Warnings:

- Intended for **Single Patient Use. DO NOT REUSE.** **Bard Access Systems** products are single use devices and should never be reimplanted. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Resterilization of incompletely cleaned devices may not be effective. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Cautions:

- Carefully read and follow all instructions prior to use.
- Only qualified healthcare practitioners should insert, manipulate and remove these devices.

Precautions:

- **Follow Universal Precautions when repairing the catheter.**
- **Follow all contraindications, warnings, cautions, precautions and instructions for all infusates as specified by its manufacturer.**
- **Use aseptic techniques** whenever the catheter lumen is opened or connected to other devices. Povidone-iodine is the suggested antiseptic to use with this device and components. Acetone and tincture of iodine should not be used because they could adversely affect the performance of the catheter and connectors. 10% acetone/70% isopropyl alcohol swabsticks used for dressing changes should not adversely affect the catheter.

I. Prior to repairing the catheter, do the following:

- Examine package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a double sterile package and is non-pyrogenic. **Do not use if package is damaged, opened or the expiration date has passed.** Sterilized by ethylene oxide. **Do not Resterilize.**
- Inspect kit for inclusion of all components.
- The repair kits are indicated for repair of external portion of catheter only.
- Silicone plugs may form in the opening of the tube of medical adhesive. These plugs should be removed before using the adhesive.
- The replacement segment, splicing sleeve, and stents will repair only the catheter and size for which the repair kit is indicated.

II. To avert device damage and/or patient injury during repair:

- **Avoid accidental device contact with sharp instruments and mechanical damage** to the catheter material. Use only smooth-edged atraumatic clamps or forceps.
- When cutting the damaged external catheter segment, a sufficient length of the external catheter segment must remain to permit repair and prevent catheter retraction under the skin line.

III. After repair, observe the following precautions to avoid device damage and/or patient injury:

- Infusion pressure greater than 25 psi (172 kPa) may damage blood vessels and viscus and is not recommended. **DO NOT USE A SYRINGE SMALLER THAN 10 ml!**

Catheter Repair Procedure

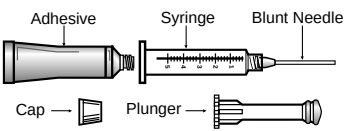
Catheter Preparation (For all catheter repairs)

Note: Stent(s) have been pre-mounted into the replacement segment to facilitate catheter repair.

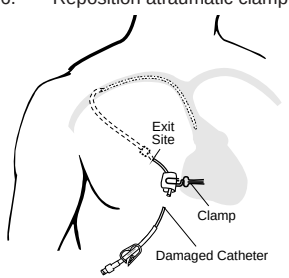
1. Assemble supplies.
2. Clean the external segment of the catheter with antiseptic and gauze and place cleaned segment on a sterile drape.

Using Sterile Technique:

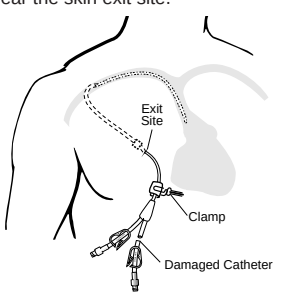
3. Wash hands thoroughly. Put on sterile gloves. If using powdered gloves, wipe powder from gloves with alcohol and 4 in. x 4 in. (10 cm x 10 cm) gauze.
4. Create a sterile field with drapes.
5. Remove plunger from syringe barrel, inject medical adhesive into syringe barrel, insert plunger, and attach blunt needle.



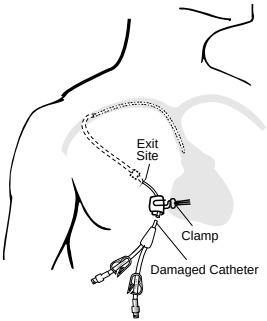
6. Reposition atraumatic clamp near the skin exit site.



Single Lumen Repair



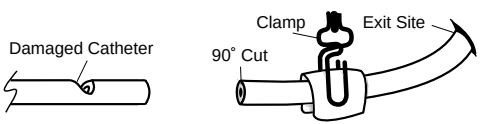
Multi-Lumen Adapter Leg Repair



Multi-Lumen
External
Segment
Repair

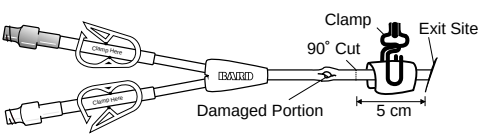
7. Cut the external portion of the damaged catheter at a 90° angle just distal to the damaged area.

Single Lumen



or

Multiple Lumen

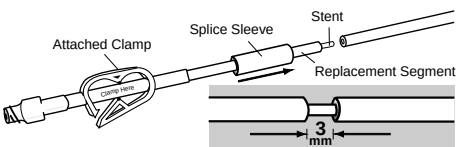


Warning: The length of the remaining external segment must be sufficient to permit catheter repair and prevent catheter retraction under the skin line.

Hickman* and Leonard* Adaptor Leg and External Segment Attachment

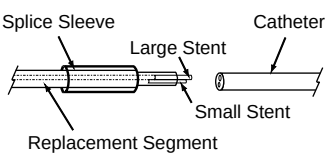
1. Insert the stent attached to the replacement catheter segment into the catheter lumen until the end of the replacement catheter tubing is 3 mm from the cut end of the catheter.

Single Lumen



or

Multiple Lumen



Note: For all catheters, do not remove the splice sleeve that is loose-mounted on the replacement catheter segment.

Note: If the replacement segment is to be cut to desired length, the splice connector stent can be removed and reinserted.

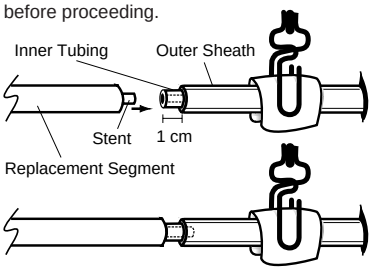
2. Dry space between catheter ends with a sterile 4 in. x 4 in. (10 cm x 10 cm) gauze pad. Fill the 3 mm space with adhesive and push the catheter ends together.

Broviac* External Segment Attachment

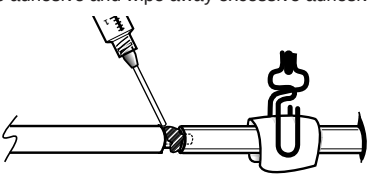
Warning: The length of the remaining external segment must be sufficient to permit catheter repair and prevent catheter retraction under the skin line.

Note: If the inner lumen of the catheter retracts inside the outer sheath, the outer sheath should be cut off flush with the inner lumen.

1. Pull inner tubing from outer sheath 1 cm with atraumatic forceps. Insert the splice connector stent into the inner lumen until catheter segments are together. Lubricate with Isopropyl 70% alcohol if necessary, but be sure the alcohol is removed or evaporated before proceeding.



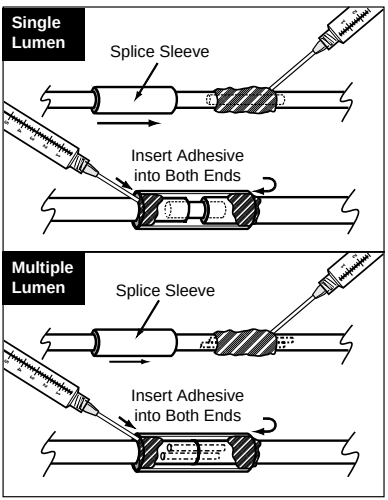
2. Use syringe to apply adhesive onto the exposed inner lumen and ease outer sheath over it. Roll between fingers to evenly distribute the adhesive and wipe away excessive adhesive.



Splice Sleeve Securement (For all catheter repairs)

1. Use syringe to apply adhesive onto the outside of the catheter around the spliced joint, covering an area about 2.5 cm overall

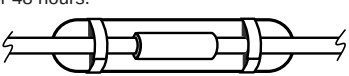
length. Slide the splice sleeve down and center it over the joint. Inject adhesive underneath each end of the splice sleeve. Roll the splice sleeve between fingers to distribute and extrude excess adhesive. Wipe away excess adhesive.



Sterile Field Is No Longer Required

2. Remove clamp. Aspirate the air in the replacement segment. GENTLY fill catheter with heparin and reclamp the catheter. **Caution:** Excessive pressure may rupture joint.

3. Fasten catheter repair joint to splint (application sticks or tongue blade) with tape. Avoid contact of the adhesive with the patient's skin for 48 hours.



Note: If necessary, the catheter may be used for infusion after four hours. The joint will not achieve full mechanical strength for 48 hours. The splint may be removed at that time.

Bard Access Systems

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact **Bard Access Systems** to see if additional product information is available.

Revised date: February 2007

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BARD

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