



Valve Assembly / Repair Kit

Product Description:

The Valve Assembly attaches to the Aspira* Drainage Catheter to prevent fluid or air exchange through the catheter when not in use.

The repair kit enables a patient with a damaged valve or catheter to retain the catheter and have it repaired rather than removed or replaced.

Indications For Use:

The Valve Assembly attaches to the Aspira* Drainage Catheter.

The Repair Kit is for repair of the Aspira* Drainage Catheter and replacement of the Aspira* Valve Assembly.

Contraindications:

- None known when used with the Aspira* Drainage system.

Warnings:

- Intended for single use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- Do not use excessive force on the valve or catheter. Excessive force or incorrect usage may damage the device.
- Dispose of used product in accordance with accepted medical practice and applicable local, state and federal regulations. Used product may present a potential biohazard.
- Do not attempt to place a wire, needle or other device through the valve.

Precautions:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Carefully read and follow instructions prior to using this device.
- Use this device only if you are a qualified health professional.
- Follow aseptic techniques when repairing the catheter and valve.
- Check the repair kit package for damage before opening.
- Sterilized using ethylene oxide. Do not resterilize.
- Ensure that the expiration date has not passed.
- Carefully follow the catheter valve connection technique described in these instructions to ensure proper connection and avoid catheter damage.
- Do not attempt to repair the catheter if damage has occurred within 5 cm of the exit site.
- Use only the Aspira* Drainage Valve Assembly to repair the Aspira* Drainage Catheter.
- Be careful not to dislodge the catheter when removing or assembling the valve.

Possible Complications:

Repair of the catheter may result in the following complications:

- Accidental catheter dislodgement, breakage or removal
- Exposure to bodily fluids
- Infection
- Leakage
- Occlusion

Use Instructions:

Valve Assembly instructions:

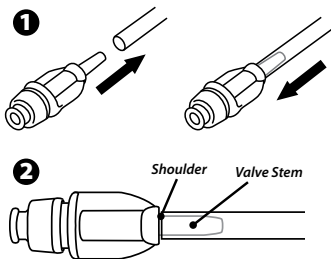
NOTE: Before beginning this procedure, read the "Contraindications," "Warnings," "Precautions" and "Possible Complications" sections of these instructions for use.

NOTE: Once the catheter has been inserted, make sure it is clamped at least 5 cm distal to the external catheter tip to prevent fluid flow prior to assembling the valve.

1. Make sure the catheter is clamped at least 5 cm distal to the external catheter tip.
2. Advance the catheter over the valve stem past the shoulder. ① ②

NOTE: If catheter and valve are connected and then disconnected, trim proximal end of the catheter and attach a new valve to ensure a secure connection.

3. Remove slide clamp from catheter.
4. Place a new cap over the catheter valve.



Repair Instructions:

NOTE: The catheter should be clamped between the damage and the exit site. Ensure that the catheter is clamped and remains clamped throughout the repair procedure.

1. Inspect the damaged catheter to determine where it needs to be cut off. Do not cut at this time.

NOTE: Be sure to retain as much of the external catheter length as possible.

2. Make sure the catheter is clamped at least 5 cm distal to the cut off point.
3. Clean the catheter with alcohol and/or povidone iodine wipes, where it will be cut off.
4. Using sterile scissors, cut the catheter at a 90° angle distal to the damaged section.
5. Follow the steps 1-4 above for assembling the valve.

CAUTION: Be careful not to dislodge the catheter when removing or assembling the valve.

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

Revised Date: October 2010

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