

## Valve Assembly / Repair Kit

### INSTRUCTIONS FOR USE

#### PRODUCT DESCRIPTION

The Valve Assembly attaches to the 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 Aspira Valve Assembly is indicated for use with Aspira, Asept®, PleurX® and Rocket® catheters.

#### CONTRAINDICATIONS

None known when used with the Aspira Valve Assembly.

#### WARNINGS

- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may 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, or cause accidental catheter dislodgement.
- 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 pass a wire, needle or other device through the valve.

#### PRECAUTIONS

- **⚠ ONLY** Caution - Federal law (USA) restricts this device to sale by or on the order of a physician.
- Use this device only if you are a qualified health professional.
- Follow aseptic techniques when repairing the catheter and valve.
- 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.
- Be careful not to dislodge the catheter when removing or assembling the valve.

#### POTENTIAL 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

## REPAIR INSTRUCTIONS

**NOTE:** Before beginning this procedure, read the “Contraindications”, “Warnings”, “Precautions” and “Potential Complications” sections of these instructions for use.

**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.

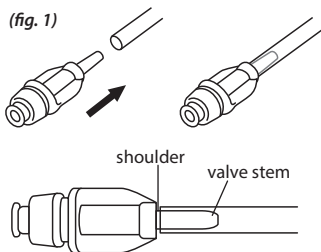
4. Using sterile scissors, cut the catheter at a 90° angle distal to the damaged section.

5. Advance the catheter over the valve stem until it is past the shoulder. (fig. 1)
















**NOTE:** Once the catheter and valve assembly are connected, they cannot be removed and reused. To replace the valve assembly, trim catheter below the valve assembly and attach a new valve assembly to ensure a secure connection.

6. Remove slide clamp from the catheter.

7. Place a new cap over the catheter valve.



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

SYMBOL	DESIGNATION
	Use By: YYYY-MM-DD
	Lot Number
	Catalog Number
	Do Not Re-sterilize
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single Use
	Caution
	Sterilized Using Ethylene Oxide
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Medical Device
	Unique Device Identifier
	Single Sterile Barrier
	Consult Instructions for Use For electronic copy scan QR code, or go to <a href="http://www.merit.com/ifu">www.merit.com/ifu</a> and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
	Authorized Representative in European Community
	Manufacturer

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