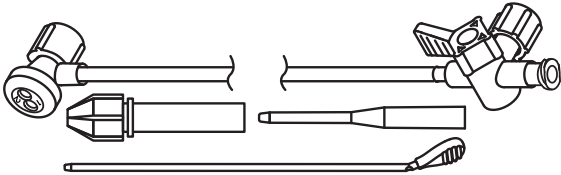


Universal Hemostasis Valve Adapter

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION:

The Merit Prelude Choice™ Universal Hemostasis Valve Adapter hub has two openings for devices/catheters and a hemostasis valve. The device has side arm tubing with stopcock. An insertion tool is included. The Merit Prelude Choice Universal Hemostasis Valve Adapter is used to minimize blood loss during the introduction of catheters or devices into the vasculature, and provide a side arm and three-way stopcock to facilitate aspiration or infusion.



INTENDED USE

The Merit Prelude Choice Universal Hemostasis Valve Adapter is intended to facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures. The device has a side arm tubing and a three-way stopcock to facilitate aspiration or infusion of fluids.

CONTRAINDICATIONS:

None.

WARNINGS

Do not use device with power injector.

CAUTIONS

- Do not alter device.
- This device should only be used by physicians thoroughly trained in the technique of angiography.
- The closing force of the hemostasis valves may alter or impair the function of some catheters.
- The insertion tool should always be used when placing guide wires through the Prelude Choice. The insertion tool should be used with devices 3.5F or smaller.
- Damage to the valve may occur if inner catheter is withdrawn rapidly.
- The Prelude Choice hemostasis valve adapter may be used with a Prelude sheath introducer that is 8F or smaller.
- The catheters, wires, devices, etc. that are used with the Prelude Choice must have a total outer diameter equal to or less than the internal diameter of the sheath introducer being used.
- Prior to use, ensure that the catheters/devices to be used are the appropriate size for the Prelude Choice and Prelude sheath introducer being used. Test compatibility prior to use.

Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution: Consult accompanying documents. Read instructions prior to use.
	Single Use.
	Do not resterilize.
	Non-pyrogenic.
	Do not use if package is damaged.
STERILE EO	EtO sterilized.

REUSE PRECAUTION STATEMENT

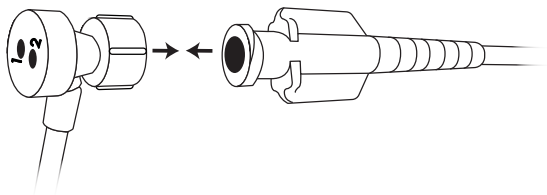
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also 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.

INSTRUCTIONS FOR USE

1. Flush the Prelude Choice prior to use.

NOTE: Prior to use, ensure that the catheters/devices to be used are the appropriate size for the Prelude Choice and Catheter/Guide being used. Test compatibility prior to use.

2. After the Catheter/Guide is placed into the appropriate site, attach the Prelude Choice onto the hub of the Catheter/Guide.

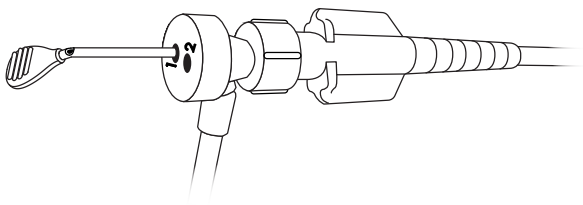


3. Follow manufacturer's recommendations for the catheter or device being introduced via the hemostasis valve adapter.

4. The insertion tool may be used to position the device/catheter through one of the openings in the Prelude Choice, through the hemostasis valve.

a. Place the device/catheter through the insertion tool to the distal end of the tool.

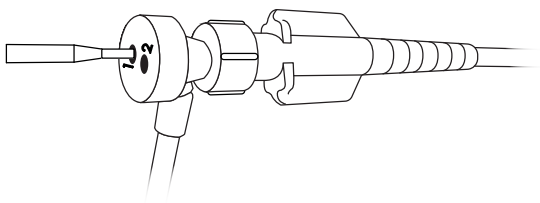
b. Insert the insertion tool/device/catheter through the cap of the Prelude Choice into the hemostasis valve.



c. Once the insertion tool/device/catheter are through the valve, remove the insertion tool by grasping the blue tab and firmly peeling it away from the device/catheter.

NOTE: The insertion tool should always be used when placing guide wires through the Prelude Choice. The insertion tool should be used with devices 3.5F or smaller.

5. The "J" straightener wire introducer tool may be used to position a "J" wire (or other) through one of the openings in the Prelude Choice, through the hemostasis valve.



CE 2797
www.merit.com



Manufacturer:

Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748



Authorized Representative:

Merit Medical Ireland Ltd,
Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22