HEMOSTASIS VALVE

DESCRIPTION
This device is a y-connector hemostasis valve with a rotating bar lock, a side port, and a rotating hemostasis valve by pushing the valve open or closed. The hemostasis valve is fully opened to its maximum diameter by pushing the valve opener distally. Pulling the valve opener proximally closes the hemostasis valve around the inserted interventional/ diagnostic device. With the valve in the closed position, devices can be advanced or pulled back as needed without adjustment of the hemostasis valve.

INDICATIONS
The hemostasis valve is intended to maintain hemostasis during the introduction, use, and withdrawal of interventional and diagnostic devices that have an outer diameter of 7 French or smaller.

WARNINGS
This device is intended for single use only. Do NOT resterilize and/or reuse. Do not use if package is opened or damaged.

This device is only to be used by experienced physicians trained in endovascular procedures.

THE device is not intended for use with pressure injections > 8 ATM/BAR. Power injection at pressure greater than 8 ATM/BAR could result in leakage.

Devices inserted across the hemostasis valve are not secure.

Devices inserted across the hemostasis valve prior to inserting or withdrawing a diagnostic/interventional device could cause damage to the device.

INSTRUCTIONS FOR USE
1. Attach the manifold to the side port of the device.
2. Connect the distal end of the device to the proximal end of the guiding catheter.
3. Flush with normal saline to remove air bubbles. To flush the valve segment, open the hemostasis valve by pushing the valve opener and continue to fill the assembly. To close the valve, pull the valve opener back to original position.
4. Attach the pressure/infusion device to the manifold, if applicable. Check that all connections are secure to avoid air aspiration during the procedure.
5. Introduce the guiding catheter into the device, together with the diagnostic/interventional catheter. When inserting the guide wire by itself, use a guide wire insertion tool to protect the distal tip of the guide wire.
6. Perform the rest of the procedure following the recommendations of the respective device manufacturers.

STORAGE REQUIREMENTS
Use before the expiration date indicated on the label.

Store at room temperature below 86°F (30°C), in a dry place, protected from light.

Specifications
- Inner diameter (narrowest portion): 7.2F / 2.4 mm / 0.094"
- Maximum diameter of device to be inserted: 7F / 2.33 mm / 0.092"
- Maximum pressure resistance with guide wire and diagnostic/ interventional catheter: 8 ATM/BAR (with maximum 35 drops over 30 second period)
- Maximum pressure resistance without device: 30 ATM/BAR

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

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