HONOR®

HEMOSTASIS VALVE

CAUTION
US Federal Law restricts this device to sale by or on the order of a physician.

DESCRIPTION
This device is a y-connector hemostasis valve with a rotating luer lock, a side port, and a push-pull hemostasis valve opener on the proximal end. 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 devices. 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 diagnostic and interventional 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.

The device should only 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.

Do not inject any fluid if air bubbles are visible within the device.

Any aspiration through the side port of the device should be made slowly and carefully to avoid the creation of a void at the proximal part of the connector. Failure could cause leakage.

Failure to open the hemostasis valve prior to inserting or withdrawing a diagnostic/interventional device could cause damage to the device.
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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 its 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 following the procedure recommended by the guiding catheter manufacturer.
6. Insert the guide wire, or guide wire and diagnostic/interventional catheter together, into the device. When inserting the guide wire by itself, use a guide wire insertion tool to protect the distal tip of the guide wire.
7. 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

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