FLO50™

English

Hemostasis Valve

INSTRUCTIONS FOR USE

DESCRIPTION
The FLO50™ Hemostasis Valve is a small Y-body valve with a clear female luer side arm and male luer rotator

INDICATIONS AND USAGE
The Merit FLO50 Hemostasis Valve is intended to maintain hemostasis with interventional devices with outside diameters up to 9Fr providing a fluid-tight seal around interventional devices with little or no blood loss during clinical procedures.

PRECAUTIONS
- Inspect the FLO50 hemostasis valve prior to use for any damage. Do not use if packaging is opened, damaged, or broken.
- Do not inject any fluid if air bubbles are visible within the valve
- The hemostasis valve must be completely closed during aspiration or injection. The narrowest portion of the hemostasis valve has an inner diameter of 0.118 inches (3.00mm, approximately 9Fr).
- Read manufacturer's instructions for the use of catheters, guide wires, and introducers prior to use.

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. Connect the sideport of the hemostasis valve to a flush system. With the valve OPEN, flush and fill the assembly with saline. To fill the valve section, open the valve, place one finger over the luer fitting and continue to fill the assembly.
2. Connect the male luer rotator of the hemostasis valve to the catheter. Ensure the connection is airless. Aspirate the valve to remove any trapped air and flush thoroughly with saline. Purge blood by opening the valve while continuing to flush the assembly. Close the valve when the blood has been purged. Inspect carefully for air bubbles and reflush if necessary.
3. Open the hemostasis valve and insert the guidewire or catheter. (If desired, insert the guidewire introducer and advance it through the valve). Advance the guidewire or catheter an appropriate distance into the vasculature. Close the valve around the shaft of the guidewire, catheter or introducer. This forms a fluid-tight seal, yet does not inhibit movement of the guidewire, catheter or introducer.

   WARNING: It is important that the valve be closed tight enough to prevent blood leakage, yet not so tight as to restrict function.
4. Read and follow the manufacturers IFU for devices to be used with the FLO50.
5. Withdraw the device to the point that the distal tip remains 10 to 20cm inside the vasculature. Open the valve and withdraw the device completely.
6. Disconnect the hemostasis valve from the catheter.

ADVERSE EFFECTS
Potential adverse effects (in alphabetical order) that may be associated with the FLO50 include, but are not limited to, the following:
- Blood loss
- Embolism
- Thrombosis

℞ 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
	Non-pyrogenic
	Do not use if package is damaged
STERILE EO	Sterilized using Ethylene Oxide

MERIT MEDICAL®

CE 2797
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