English

FLO40™ *HEMOSTASIS VALVE*

INSTRUCTIONS FOR USE

DESCRIPTION: FLO 40 and FLO 40X Hemostasis Valve

INDICATIONS AND USAGE: The FLO 40 and FLO 40X hemostasis valve is indicated for maintaining a seal around diagnostic/interventional devices with an outside diameter of <0.120"(0.305cm, approximately 9 Fr).

CAUTION: ℞ **Only** Read instructions prior to use. Read manufacturer's instructions for the use of diagnostic/interventional devices.

WARNING:
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: Inspect the device prior to use to verify that no damage has occurred during shipping. Do not use if package is damaged.

1. Connect the sideport of the FLO40/FLO40X Hemostasis Valve to the manifold assembly. Flush and fill the assembly with saline. To fill the valve section, open the valve, place one finger over the male luer fitting and continue to fill the assembly.

2. Connect the FLO40/FLO40X Hemostasis Valve to the guiding catheter. 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 valve and insert the diagnostic/interventional device an appropriate distance into the vasculature. Close the valve around the shaft of the device. This forms a fluid tight seal.

WARNING:
It is important that the valve be closed tight enough to prevent blood leakage, yet not so tight as to restrict function.

4. Open the valve and withdraw the diagnostic/interventional device completely.
5. Disconnect the hemostasis valve from the guiding catheter.

PRECAUTIONS: Do not inject any fluid if air bubbles are visible within the valve. First aspirate the valve to remove the air, then flush the valve as described above. The hemostasis valve must be completely closed during aspiration and injection. The narrowest rigid portion of the FLO40/FLO40X Hemostasis Valve has an inner diameter of 0.120 inches (0.305 cm, approximately 9 Fr).

Non-pyrogenic

℞ **Only**

MERIT MEDICAL®

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