ACCESSPLUS™ / ACCESS-9™ English

LARGE BORE HEMOSTASIS VALVE

INSTRUCTIONS FOR USE

DESCRIPTION:
Adjustable Merit AccessPLUS™ / Merit Access-9™ Hemostasis Valve.

INDICATIONS AND USAGE:
The AccessPLUS/Access-9 Hemostasis Valve is recommended for maintaining a fluid-tight seal around percutaneous transluminal angioplasty catheters and guidewires.

CONTRAINDICATIONS: None known

CAUTION:
- Rx Only: Federal (U.S.A.) law restricts this device to use by or on the order of a physician.
- Read manufacturer's instructions for the use of catheters, guidewires and introducers.
- After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
- In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

INSTRUCTIONS FOR USE:
Inspect the device prior to use to verify that no damage has occurred during shipping.

1. Connect the sideport of the hemostasis valve to the Merit manifold assembly. 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 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 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. Refer to the dilatation catheter labeling for intended use, contraindications and potential complications associated with the use of dilatation catheters in PTCA and/or PTA procedure.
5. Withdraw the catheter to the point that the distal tip remains 10 to 20 cm inside the vasculature. Open the valve and withdraw the catheter completely. During insertion and removal through the valve, the balloon must be completely deflated to safely and easily traverse the valve.
6. 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 or injection. The narrowest portion of the hemostasis valve has an inner diameter of 0.120 inches (0.305 cm) (approximately 9Fr).

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.

SYMBOL	DESIGNATION
REF	Catalog Number
LOT	Lot Number
	Caution
	Consult Instructions for Use. For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U. Customer Service
STERILE EO	Sterilized using Ethylene Oxide
	Do not use if package is damaged.
2	Single Use
	Use By
2 STERILIZE	Do Not Resterilze
	Non-pyrogenic
	Single sterile barrier system
	Manufacturer
EC REP	Authorized Representative in European Community
MD	Medical Device
	Date of Manufacture
UDI	Unique Device Identifier

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