English

# 10Fore™

Hemostasis Valve

## INSTRUCTIONS FOR USE

### DESCRIPTION
The 10Fore™ Hemostasis Valve has a 0.131" (3.33 mm) inside diameter. This device has two seals that operate independently: a primary seal and a compression seal. The primary seal is a diaphragm seal that forms around diagnostic and interventional devices as they move into and out of the vasculature. This seal provides minimal fluid loss without restricting device movement. The primary seal is open when the blue introducer is depressed and closed when released. An open primary seal permits air to be purged from the device and allows insertion and withdrawal of diagnostic and interventional devices.

The compression seal can be opened or closed by rotating the thumbwheel. Closing the compression seal allows for pressure injections up to 500 psi and secures the diagnostic or interventional device in position within the vasculature.

### INTENDED USE
The 10Fore Hemostasis Valve is intended to maintain hemostasis during the introduction, use, and withdrawal of diagnostic and interventional devices.

### INDICATIONS FOR USE
The 10Fore Hemostasis Valve is indicated for maintaining a seal around diagnostic and interventional devices with an outside diameter up to 0.131" (3.33 mm) during diagnostic and interventional procedures.

### CLINICAL BENEFITS
The 10Fore Hemostasis Valve provides an indirect clinical benefit to the patient by preventing or controlling blood loss during the introduction, use, and withdrawal of diagnostic and interventional devices.

### POTENTIAL COMPLICATIONS
- Infection
- Inflammation

### INTENDED USERS
**Physicians:** The 10Fore Hemostasis Valve is intended for use by physicians trained in diagnostic and interventional vascular procedures.
**Patients:** The 10Fore Hemostasis Valve is intended for use in patients undergoing diagnostic and interventional vascular procedures.

### CONTRAINDICATIONS
None known.

℞ **ONLY CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician trained in angiography and percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

### PRECAUTIONS
- Read manufacturer's instructions for the use of catheters, guide wires, and introducers prior to use.
- Inspect the 10Fore Hemostasis Valve prior to use for any damage. Do not use if packaging is open, damaged, or broken.
- Follow local guidelines and practices regulating the disposal of the 10Fore Hemostasis Valve after use.
- Contents are sterile (via ethylene oxide) and non-pyrogenic.

### REUSE PRECAUTION STATEMENT
For single patient use only. Do not reuse, reprocess, or resterilize. Reusing, 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. Reusing, 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.

### WARNING
- Do not inject any fluid if air bubbles are visible within the 10Fore Hemostasis Valve.
- To prevent damage to a balloon, it must be completely deflated during advancement/withdrawal through the 10Fore Hemostasis Valve.
- Failure to depress the blue introducer prior to inserting a guide wire introducer could cause seal damage, resulting in leakage and/or particulate embolization.
- Failure to open the primary seal and compression seal prior to inserting or withdrawing a diagnostic/interventional device could cause damage to the device.
- Care should be taken to avoid overtightening of the compression seal, as this may compromise the integrity of the diagnostic/interventional device lumen.
- Power injection at pressures greater than 500 psi could result in leakage or detachment of components.
- 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.

### STORAGE CONDITIONS
Room temperature, ventilation, away from direct sunlight.

### TRANSPORTATION CONDITIONS
Do not expose to excessive heat and/or humidity.

### INSTRUCTIONS FOR USE
1. Connect the side port of the 10Fore Hemostasis Valve to the manifold assembly. With the compression valve open, flush and fill the assembly with saline. To fill the valve section, ensure the primary seal is open by pushing down on the blue introducer. The primary seal can also be locked into an open position and unlocked by rotating the blue introducer a quarter turn clockwise and counterclockwise. Place one finger over the male Luer fitting and continue to fill the assembly until completely purged of air. Gently release the blue introducer to close the primary seal.
2. Connect the rotating male Luer adapter of the 10Fore Hemostasis Valve to the guiding catheter. Ensure the connection is airless.
3. To open the 10Fore Hemostasis Valve for diagnostic/interventional device insertion, depress the blue introducer to open the primary seal. The 10Fore Hemostasis Valve is now ready to accept any diagnostic/interventional device.
4. Insert the diagnostic/interventional device through the open primary seal and the open compression seal.

   **CAUTION:** The 10Fore Hemostasis Valve will be fully open and allow for blood loss when the primary seal is open and/or the blue introducer is depressed and rotated a quarter turn into the lock-open position.
5. Advance the diagnostic/interventional device through the open compression seal. A fluid-tight seal, providing little to no blood loss, will form around the diagnostic or interventional device while not restricting movement of the device.
6. Once the diagnostic/interventional device is in place, if desired, close the compression seal to allow for pressure injections of up to 500 psi and/or secure the diagnostic/interventional device in position.
7. Remove the diagnostic/interventional device through the open compression seal. If resistance is felt, open the primary seal as well.

Non-pyrogenic. Sterile if package is unopened and undamaged. Made in the USA.

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|  | Caution |
|  | Do not use if package is damaged and consult instruction for use |
| REF | Catalog number |
| LOT | Batch code |
| MD | Medical Device |
| UDI | Unique Device Identifier |
|  | Single use |
|  | Do not resterilize |

| | |
|---|---|
|  | Consult Instructions for Use<br>For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within seven calendar days, call U.S.A. or EU Customer Service. |
|  | Sterilized using ethylene oxide |
|  | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. |
|  | Single sterile barrier system |
|  | Use by date: YYYY-MM-DD |
|  | Date of manufacture: YYYY-MM-DD |
|  | Manufacturer |
|  | Authorized Representative in European Community |
|  | Keep away from sunlight |
|  | Keep dry |
|  | Non-pyrogenic |

Basic UDI-DI: 0884450BUDI791QP


CE 2797

www.merit.com

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