

Caution

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Do not alter this device in any way.

Description

The HEMOSTEER™ 9F Hemostatic Y Adapter contains a hemostasis valve with a secondary locking seal, a rotating luer lock, and a sideport. The primary hemostasis seal is opened by depressing the cap thereby enabling valve flushing, and a conduit for introduction and withdrawal of diagnostic/interventional devices. When the cap is not depressed, the seal returns to the closed position to allow device positioning with minimal fluid loss.

The secondary locking seal can be adjusted when the internal threads are engaged, by rotating the cap clockwise while slightly depressing it until the threads catch. Clockwise turns of the cap thereafter will close the locking seal. Rotating counterclockwise will open the locking seal. Closing the locking seal will secure the position of the inserted diagnostic/interventional device and/or permit pressure injections up to 450 psi (30.6 Atm.)

Indications & Intended Use

The HEMOSTEER™ 9F Hemostatic Y Adapter is to be used for maintaining a hemostatic seal around inserted devices with an outside diameter up to 0.118" (2.99mm) during the use of diagnostic/interventional devices for transluminal procedures.

How Supplied

- Contents are sterile if package is unopened and without damage. Sterilized with Ethylene Oxide gas. Non-pyrogenic.
- Contents One (1) HEMOSTEER™ 9F Hemostatic Y Adapter, 0.118" (2.99mm)

Warnings

- This device is intended for one time use only. DO NOT sterilize and/or reuse.
- Do not use if packaging is opened or damaged.
- Flush HEMOSTEER™ to remove air bubbles before use. DO NOT inject any fluid if air bubbles are visible.
- The HEMOSTEER™ is not intended for injection pressures greater than 450 psi (30.6 Atm.) Injection pressures greater than 450 psi (30.6 Atm.) could result in leakage or component damage.
- Failure to depress the cap prior to inserting a guide wire introducer could cause seal damage resulting in leakage and/or particulate embolism.

- Failure to open both seals prior to inserting or withdrawing a diagnostic/interventional device could result in damage to the diagnostic/interventional device or the seals.
- Balloon devices must be completely deflated during advancement/withdrawal through the HEMOSTEER™ to prevent damage to balloon.

Storage Requirements

- Use before the expiration date indicated on the label.
- Store in a cool, dark, dry place.

Precaution

- Prior to use, inspect the HEMOSTEER™ for any damage. Do not use a damaged HEMOSTEER™.
- DO NOT over tighten the locking seal, as this may compromise the lumen of the diagnostic/interventional device.
- DO NOT over tighten the locking seal with no inserted device. Overtightening can damage the locking seal.

Use Sterile Technique – a suggested procedure:

1. Peel open package and place contents on sterile field.
2. Attach a manifold system with connecting tubing to the sidearm of the HEMOSTEER™.
3. Depress cap to open primary seal and place finger over luer fitting opening. Flush with saline.
4. Connect the HEMOSTEER™ to the catheter.
5. Aspirate the system to remove any trapped air.
6. Prepare diagnostic/interventional devices according to manufacturer's instructions.
7. Insert the guide wire or guide wire and diagnostic/interventional combination into the HEMOSTEER™ through both opened seals (The cap must be depressed to open the primary seal). When introducing the guide wire alone, use a guide wire introducer.
8. Once the diagnostic/interventional device is in position, if desired, tighten the locking seal to secure device position and/or to allow injection pressures up to 450 psi (30.6 Atm.)
9. Perform remainder of procedure following recommendations of the respective device manufacturer(s).
10. When removing diagnostic/interventional device through an open locking seal, open the primary hemostasis seal by depressing the cap.

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DISTRIBUTED BY

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HEMOSTEER™

9F Hemostatic Valve

Hemostatic Y Adapter, 0.118" (2.99mm)