Boston Scientific

90981811-01

2014-08
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ACUITY® Pro

7F Guide Catheter

for use with
ACUITY® Pro Lead Delivery System

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℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

Contents

One (1) 7F ACUITY Pro guide catheter

User Information

Intended users of the ACUITY Pro guide catheter are those physicians trained in the implantation of cardiac resynchronization therapy (CRT) devices for the treatment of heart failure.

There are no additional training requirements for the intended users of the ACUITY Pro guide catheter to ensure safe and effective use.

The 7F ACUITY Pro guide catheter is designed for venous use to aid in the selective placement of Boston Scientific or Guidant left ventricular pacing leads in the cardiac vasculature. When used in conjunction with the 9F ACUITY Pro in a telescoping manner, it serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads introduced into the coronary venous system. The catheter is designed with a flexible distal segment and a soft tip to atraumatically enter the main coronary sinus (CS) and branch veins.

The 7F ACUITY Pro guide catheter includes a hub with an integrated hemostasis valve and luer lock flush port (Figure 1.0). The user cuts the hub and valve with the ACUITY™ Universal Cutter.

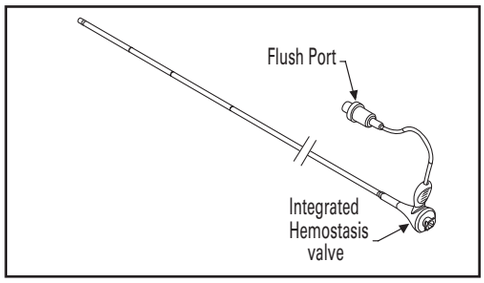

Figure 1.0 – Image of flush port and integrated valve

INTENDED USE / INDICATIONS FOR USE

The ACUITY Pro Lead Delivery System is intended to access the coronary venous system and may be used alone (9F) or in dual catheter delivery (9F with 7F). The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

CONTRAINDICATIONS

None known.

WARNINGS

- Do not alter any of the system devices, except as described in this document.
- The user should not place side holes in the shaft of the guide catheter. Puncturing the shaft of the guide catheter with hospital instruments may lead to thrombogenesis or failure of shaft integrity.
- When this guide catheter is in the body, it should be manipulated while under high-quality fluoroscopic observations.
- When this guide catheter is in the body, care should be taken to prevent air embolism by maintaining a closed hemostasis valve or plugging the lumen.
- Do not apply excessive torque, tension or force when manipulating the guide catheter or advancing devices through the catheter as damage/injury could result.
- Severe reactions may occur in response to contrast agents in some patients who either had unknown contrast allergies or who were not adequately premedicated.

PRECAUTIONS

- It is recommended that the guide catheter be advanced using a guidewire technique.
- It is recommended that a finishing wire be used for removal of guide catheter from lead.
- Guide catheters should be used only by physicians thoroughly trained in their intended use.
- Prior to the procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
- Remove the guide catheter carefully from the tray to reduce the possibility of damage.
- It is recommended to secure the outer guide catheter when removing the inner guide catheter if no hemostatic introducer was used for venous access.

ADVERSE EVENTS

Vessel trauma may result from the improper use of this device. Follow the enclosed directions carefully. Other potential adverse reactions that may result from the improper use of this device include, but are not limited to:

- air embolism
- hematoma at the puncture site
- hemorrhage
- infection
- vascular thrombosis
- vessel dissection
- vessel perforation
- vessel spasm

HOW SUPPLIED

This product is non-pyrogenic.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Use the device prior to the "Use By" date noted on the product label.

Handling and Storage

Store in a cool, dry, dark place.

PREPARATION FOR USE

Guide Catheter

1. Carefully remove components from the sterile packaging and place on sterile flat surface.
2. Attach a syringe filled with sterile heparinized normal saline to the flush port and flush until fluid exits tip of guide catheter.
3. Attach a syringe filled with sterile heparinized normal saline to the hub luer connector and flush until fluid exits tip of guide catheter.

DIRECTIONS FOR USE

The following information includes, but is not limited to, methods for using the lead delivery system.

Guide Catheter

1. Insert the 7F ACUITY Pro guide catheter through the hemostasis valve of the 9F ACUITY Pro guide catheter.
2. Advance the 7F guide catheter to the vascular site. Obtain a stable position with the guide catheter. If a contrast injection is desired, attach a contrast filled syringe to the flush port or luer connector on hub.
3. Insert the trans valve introducer (TVI) tool when introducing any device to open the hemostasis valve. Insert the desired device(s) into the guide catheter through the hub of the catheter. Remove the TVI tool once the device has passed through the hub.
4. If no lead is being delivered through the 7F guide catheter, follow these steps to remove the 7F guide catheter:

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a. Remove the 7F guide catheter by backing the guide catheter out while securing the 9F guide catheter hub in one hand.

5. If a lead has been delivered through the 7F guide catheter, follow these steps to remove the 7F guide catheter.
   a. If a finishing wire is utilized, first remove guidewire and then insert finishing wire prior to removing the guide catheter.
   b. It is recommended to pull back the guide catheter(s) from sub-selected branch vein into CS while maintaining stable position of the lead.
   c. Cut guide catheter per ACUITY™ Universal Cutter directions for use included with the 9F ACUITY® Pro guide catheter.
   d. Remove the cutter from the lead and set aside.
   e. Remove the 9F guide catheter per directions included with the 9F ACUITY Pro guide catheter.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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