



ACUITY® Pro

9F Guide Catheter

for use with
ACUITY® Pro Lead Delivery System

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Rx 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.

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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) 9F ACUITY Pro guide catheter, one (1) ACUITY™ Universal Cutter, one (1) guidewire introducer, one (1) torque device, two (2) trans valve introducer (TVI) tools, and one (1) dilator.

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 9F ACUITY Pro guide catheter is designed for venous use to provide a pathway through which contrast or devices, including Boston Scientific or Guidant left ventricular pacing leads, can be introduced into the coronary venous system. It is designed to provide access to the coronary venous system, and may be used in conjunction with smaller, appropriately sized catheters in a telescoping manner to improve the access and delivery capabilities of the system. The catheter is designed with a flexible distal segment and soft tip to atraumatically enter the main coronary sinus (CS) and branch veins.

The 9F 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.

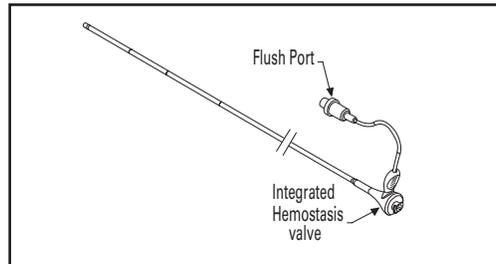


Figure 1.0 – Image of flush port and integrated valve

The transvalve introducer (TVI) (Figure 2.0) is a tool to aid insertion of devices through the guide catheter hub hemostasis valve.

The guidewire introducer (Figure 3.0) is a guidewire insertion tool with a plastic hub tapering down to the inside of a longer stainless steel tube.

The torque device (Figure 4.0) employs a plastic body and cap to tighten a metal collet onto a guidewire.

The dilator (Figure 5.0) is a tool that allows access into the venous vasculature without the use of a hemostatic introducer.

The ACUITY Universal Cutter (Figure 6.0) is a tool used to cut-away guide catheters following implantation of left ventricle (LV) leads in the coronary venous vasculature.

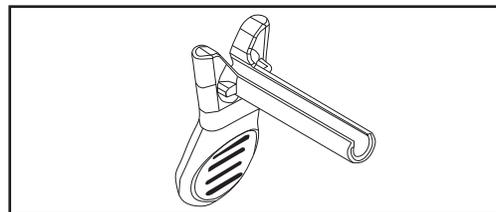


Figure 2.0 – Image of TVI tool

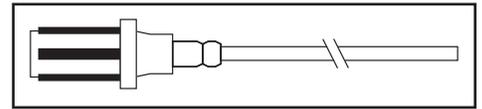


Figure 3.0 – Image of guidewire introducer

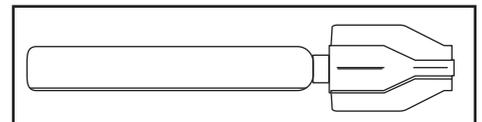


Figure 4.0 – Image of torque device

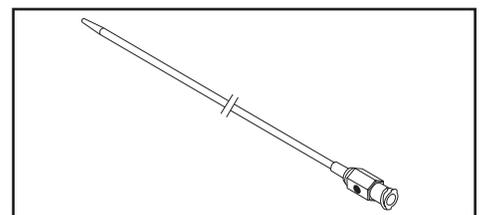


Figure 5.0 – Image of dilator

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 (7F with 9F). 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.

The TVI tool is recommended for use during insertion of devices through the hemostasis valve of guide catheter hub.

The guidewire introducer is recommended for use during vascular procedures to assist with the introduction of the guidewire into the left ventricular lead delivery system.

The torque device is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (including left ventricular lead delivery systems) to facilitate steering of the guidewire within the vascular anatomy.

The dilator is recommended to provide support for venous access, while inserted into a 9F outer catheter, with or without the use of a hemostatic introducer.

The ACUITY Universal Cutter is intended to facilitate Boston Scientific or Guidant guide catheter removal after the Boston Scientific or Guidant coronary venous lead is positioned.

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.
- The dilator is designed for venous access. It is not recommended for CS cannulation.
- 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

Dilator (if used)

1. Remove from package.
2. Attach a syringe filled with sterile heparinized normal saline to hub and flush until fluid exits distal tip of dilator.

Guide Catheter

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

Dilator (if used)

1. Insert dilator into flushed 9F guide catheter and insert over 0.035 inch guidewire to access venous vasculature.
2. Remove dilator and continue advancing the 9F guide catheter into right atrium to access CS ostium.

Guidewire Introducer

1. Insert the guidewire introducer, shaft end first, into the proximal opening of the hub.
2. Carefully insert the distal tip of the guidewire through the guidewire introducer and into the guide catheter.
3. After the guidewire has been positioned at the desired location, the guidewire introducer should be removed.

Torque Device

1. Loosen the cap of the torque device.
2. Insert the proximal end of the guidewire into the funnel-shaped hole on the distal end of the torque device cap. Once positioned at the desired location, tighten the cap to secure the torque device to the guidewire.
3. Rotate and advance the torque device to steer the guidewire to the desired position.
4. To move the torque device to a new position, loosen the cap, slide the device along the guidewire to the desired position, and tighten the cap.
5. Remove torque device prior to loading additional devices over the guidewire.

Guide Catheter (with dilator)

1. Insert the 9F ACUITY® Pro guide catheter into an introducer sheath or directly into the venous vasculature.
2. Remove dilator from 9F guide catheter.
3. Advance the guide catheter into the CS. 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.
4. Insert the TVI tool 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.
5. Once a satisfactory lead position has been achieved, prepare the guide catheter for removal.
6. If a finishing wire is utilized, first remove guidewire or stylet and then insert finishing wire prior to removing the guide catheter.
7. It is recommended to pull back the guide catheter from sub-selected branch vein into CS while maintaining stable position of the lead.
8. Cut guide catheter per ACUITY™ Universal Cutter directions for use below.

Guide Catheter (without dilator)

1. Insert the guide catheter into an introducer sheath.
2. Advance the guide catheter into the CS. 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 TVI tool 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. Once a satisfactory lead position has been achieved, prepare the guide catheter for removal.
5. If a finishing wire is utilized, first remove guidewire or stylet and then insert finishing wire prior to removing the guide catheter.
6. It is recommended to pull back the guide catheter from sub-selected branch vein into CS while maintaining stable position of the lead.
7. Cut guide catheter per ACUITY Universal Cutter directions for use below.

ACUITY Universal Cutter

1. Attach the cutter to the proximal lead body by snapping it into the distal lead management groove. Attach the lead to the proximal lead management hook of the cutter by rolling the lead into the hook. (See Figure 6.0 for cutter attachment)

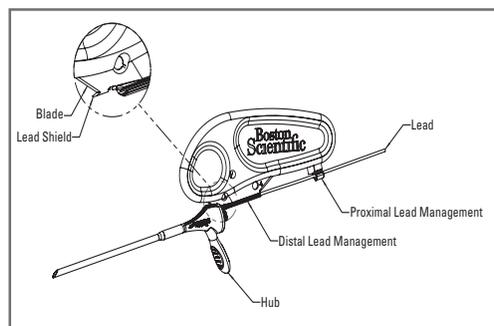


Figure 6.0 – Image of cutter engagement

2. Hold the cutter securely with one hand while resting that hand on a stable surface. Grasp the thumb tab portion of the guide catheter hub with the other hand.
3. Pull the guide catheter back to the cutter and engage the tip of the lead shield into the proximal end of the catheter hub.

4. Pull the hub and guide catheter across the cutter blade and away from the lead until the guide catheter is completely cut.
5. Once the lead is visualized and the guide catheter has been completely removed, set the guide catheter aside.
6. While maintaining a secure hold on the lead distal to the cutter, carefully remove the cutter from the lead.
7. While observing under fluoroscopy, carefully remove the finishing wire or guidewire, verifying final lead position. If removing a 7F guide catheter first, do not remove the finishing wire until all guide catheters have been removed.
8. If removing a 7F guide catheter first, ensure that the 9F guide catheter is secured prior to removing the 7F 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.**

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