Radux StandTall Instructions for Use
Sheath Extender and Securement Clasp

USA Caution
Federal (USA) law restricts this device to be sold by or on the order of a health care professional.

Caution
The Radux StandTall Sheath Extender and Securement Clasp should be used by a health care professional with adequate training in the use of the device.

Device Description
The StandTall is a sterile, disposable device that is used during the introduction of catheters and other devices into the vasculature. It is designed to hold an introducer sheath or other interventional devices in the desired, secured position and to facilitate alignment and introduction of interventional devices during percutaneous procedures. It consists of a sheath extender adapter and a securement clasp.

StandTall Sheath Extender is comprised of a:

- Sheath hub adapter,
- Malleable, lubricious, intermediary sheath, and
- A proximal hemostasis valve having side-arm flush tubing with a three-way stopcock for aspiration or infusion.

The Sheath Extender is offered in multiple lengths as follows and shown in Figure 1.

Part Number	Nominal Working Length (DIM A)	Nominal Flexible Length (DIM B)
ST0025L	25 cm	20 cm
ST0015L	15 cm	10 cm
ST0010L	10 cm	5 cm

The sheath extender is 8.3 Fr internal diameter (2.7mm ID). It is designed to connect to 5-8 FR introducer sheaths through the use of the universal hub adapter. Following attachment of the sheath extender to a previously placed introducer sheath, the sheath extender is attached to the securement clasp, which is then attached via its adhesive strip to the patient's skin, a drape, or another object associated with the patient.

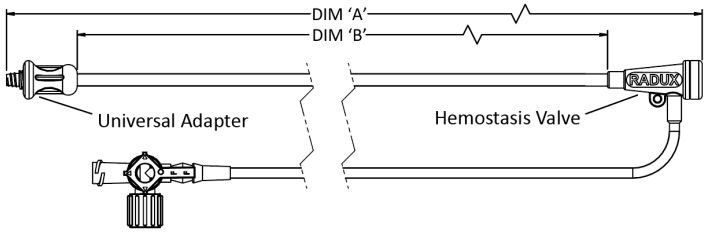
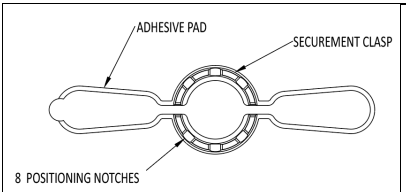


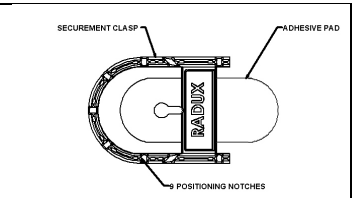
Figure 1. StandTall Sheath Extender

StandTall Securement Clasp is designed to hold the sheath extender or other interventional devices in the desired, secured position. There are two version as shown in Figure 2. The Securement Clasp is a plastic base with a medical grade adhesive pad used to secure the plastic base to the patient, drape, or another object associated with the patient. The securement clasp has positioning notches (Figure 3) that allow for positioning and securement by friction fitting the sheath

extender or interventional devices into the positioning notches. The notches are 0.13 inches wide and 0.14 inches deep, and therefore the Securement Clasp is compatible with devices of approximately 9 Fr (3 mm) outer diameter.

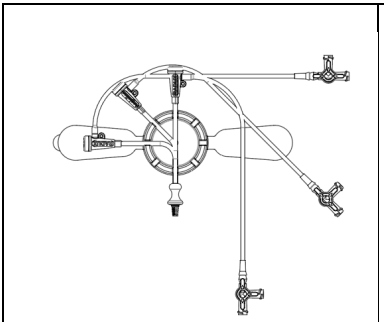


For use with 10 and 15 cm sheath extender



For use with 25 cm sheath extender

Figure 2. Securement Clasp Options



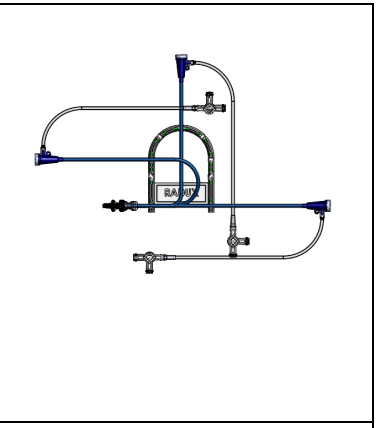


Figure 3. StandTall Showing Adjustable Positioning

Not Made with Rubber Latex
Complies with ISO 10993 limits as appropriate for the nature and duration of contact for the device.

Indication for Use

The StandTall is intended for use during the introduction of catheters or devices into the vasculature, and provides a side arm and three-way stopcock to facilitate aspiration or infusion.

Contraindications

None known.

Warnings and Precautions

- Product is sterilized by ethylene oxide in an unopened, undamaged package. If package is damaged, DO NOT USE. Discard and open another package.
- Do not alter device in any way.
- Single use only. DO NOT RESTERILIZE. DO NOT REUSE.
- Do not use if the device is bent, kinked, or damaged in any way.
- Do not use with a power injector.
- Over manipulation, torque, bending of Sheath Extender shaft or excessive pressure through the inner lumen can cause separation of the Sheath Extender from the introducer sheath.
- The StandTall Sheath Extender has been tested with the following 5-8Fr introducer and guiding sheaths: Terumo, Medtronic, Boston Scientific, Cordis, and 8Fr Cook. Do not use with non-compatible introducer sheaths.
- The maximum diameter of the instrument or catheter to be introduced should be determined to ensure its passage. All instruments or catheters should move freely through the valve and extender sheath.
- Before inserting or removing a catheter through the extender sheath, aspirate blood from the 3-way stopcock and flush with heparinized saline.

- Do not expose to organic solvents, e.g., alcohol. These solutions may affect the properties of the plastic resulting in degradation of the device.
- When inserting, manipulating or withdrawing a catheter from the sheath, always hold the sheath in place. If significant resistance is met, remove the devices together as a unit.
- Damage to the hemostasis valve assembly may occur under the following circumstances:
  - Catheter in valve system for extended periods.
  - Catheter is withdrawn too rapidly.

Potential Complications

The potential adverse events or complications related to the use of the StandTall may include, but are not limited to the following:

- Bleeding
- Thrombus or embolus formation
- Infection
- Device fracture and distal embolization

Directions for Use

The following instructions provide technical direction but do not obviate the need for training on the use of the device and are not intended as a substitute for the physician's experience and judgment in treating a specific patient.

1. Using sterile technique, peel open the vascular access introducer package and place contents on the sterile field. Inspect introducer and accessories for defects. Do not use any defective devices.

2. Prepare and place a standard introducer sheath into the desired location according to the manufacturer's instructions using sterile technique.
3. Aspirate and then flush, the 3-way stopcock of the introducer sheath, with sterile saline or heparinized saline. Remove all air, blood, and thrombus.

   Note: This should be repeated prior to and after each attachment or detachment of the StandTall sheath extender.
4. Connect a syringe to the 3-way, luer-lock, stopcock of the flush tubing and fill the sheath extender completely with saline /heparinized saline, removing all air.
5. Insert the sheath extender adapter into the hub of the introducer sheath and turn clockwise until secure.

Figure 4a. Insert universal adapter

Figure 4b. Turn clockwise until secure.

6. Attach the securement clasp using the adhesive pad to the surgical drape or patient in the desired position.

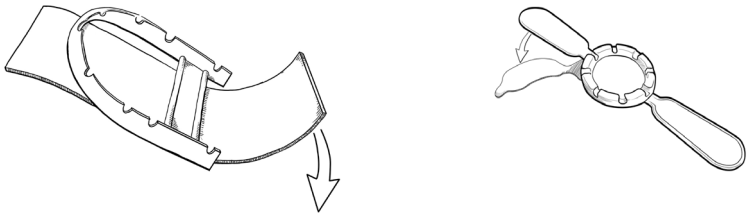


Figure 5. Remove Protective Cover from Adhesive Pad and Secure.

NOTE: The securement clasp may be repositioned and re-attached as needed.

7. Attach the sheath extender to the securement clasp and lock in the desired position using the positioning notches, while maintaining the stability of the introducer sheath.

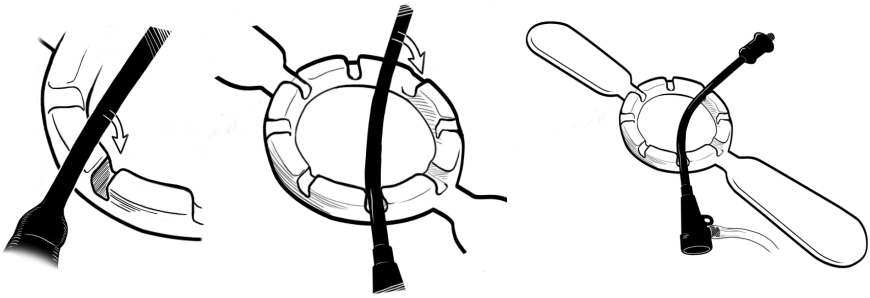


Figure 6. Attach and lock into desired position.

8. StandTall position can be adjusted by simply removing the distal attachment of the sheath extender from the securement clasp and reattaching in a different positioning notch. The securement clasp can also be repositioned.
9. Introduce the selected catheter or other device into the sheath using the instructions provided by the manufacturer of the catheter or other device, and standard hospital practice.
10. To change catheters, slowly withdraw the catheter from the vessel using instructions provided by the manufacturer of the catheter or other device, and standard hospital practice and repeat the insertion procedure.

    CAUTION: When removing the catheter, aspirate via the side port extension to collect blood products that may have been deposited at the tip of the sheath, the sheath hub junction or extender shaft

11. To detach StandTall from introducer sheath, detach the StandTall from the securement clasp and unscrew StandTall by firmly grabbing the universal adapter and rotating counterclockwise while pulling gently and maintaining stability of introducer sheath.
12. Always aspirate and flush introducer sheath and sheath extender after exchanging catheters and wires as well as after removing the StandTall and prior to its next use.

Packaging and Storage

The StandTall device has been sterilized with ethylene oxide. Keep dry and store in a cool, dry place.

Limited Warranty

Radux warrants that the StandTall is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of the product, which has been found by Radux to be defective in workmanship or materials. Radux shall not be liable for any incidental, special, or consequential damages arising from use of the product. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty. No employee, agent, or distributor has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Radux.

Symbols Legend

Symbol	Definition	Title and Designation # of Standard	Reference #
	Catalog Number	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.6
	Internal diameter of the device in French	N/A	N/A
	Internal diameter of the device in mm	ISO 11070:1998 Sterile single-use intravascular catheter introducers	7.2
	Number of devices included in the package	N/A	N/A
	Batch Code	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.5
	Sterilized using ethylene oxide	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.2.3
	Prescription Use Only	21 CFR 801.109	N/A

Symbol	Definition	Title and Designation # of Standard	Reference #
	Consult instructions for use	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.4.3
	Keep dry	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.4
	Keep away from sunlight	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.2
	Use by date	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.4
	Do not use if packaging is damaged	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.2.8
	Do not reuse	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.4.2

Symbol	Definition	Title and Designation # of Standard	Reference #
	Do not resterilize	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.2.6
 Not Made with Natural Rubber Latex	Not made with natural rubber latex	N/A	N/A
	Manufacturer	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.1

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