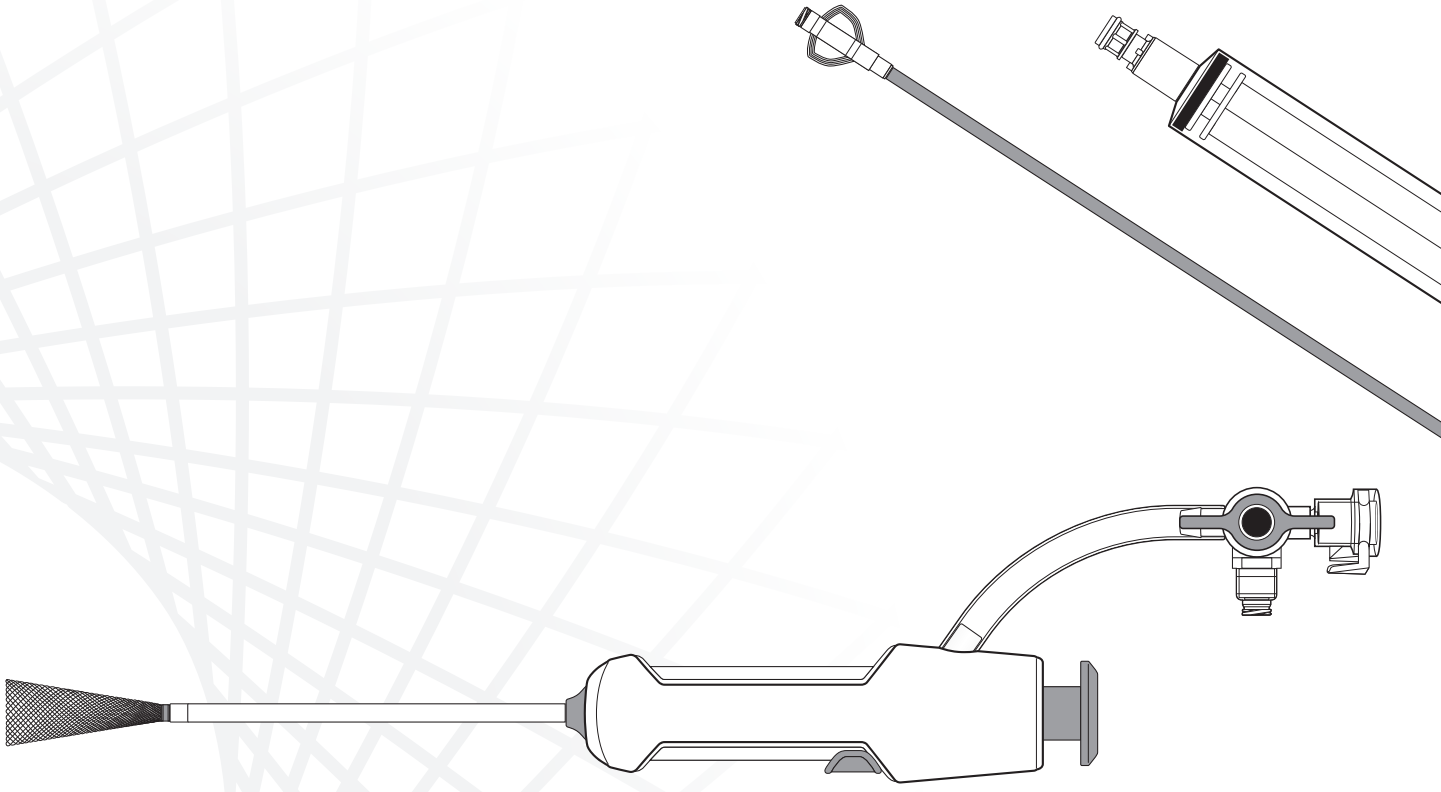
SURMODICS

Pounce™ SHEATH

Surmodics Pounce™ Sheath

INSTRUCTIONS FOR USE



CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Explanation of possible symbols on product labeling:

Contents: One (1) Pounce Sheath Assembly

Sterilized Using EO

Ref Catalogue Number

Do Not Reuse

Non-pyrogenic

Caution, Consult Accompanying Documents

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Use by Date

Keep Dry

Do Not Use if Package is Damaged

Manufacturer

Medical Device

Keep Away From Sunlight / Heat

Lot Number

Date of manufacture

Do Not Re-Sterilize

Consult Instructions for Use

Recommended Guidewire

Country of manufacture

Peel Here

DEVICE DESCRIPTION:

The Pounce™ Sheath is a single-use, sterile introducer sheath intended for the introduction of therapeutic or diagnostic devices within the vasculature. The Pounce™ Sheath includes the following features:

- Braided nitinol, self-expanding funnel at the sheath's distal end
- Handle assembly with slider button to actuate the funnel's deployment
- Hub and hemostasis valve assembly to allow for device introduction and removal
- Aspiration assembly to include tubing, a stopcock, and connection for a 60 cc syringe

Additional components provided within the packaging include:

- 0.035" guidewire compatible dilator designed for atraumatic introduction of the sheath
- 60 cc locking syringe, compatible with the sheath's aspiration assembly

A radiopaque marker band is located at the distal tip of the sheath during introduction and removal, when the funnel is sheathed. When the funnel is unsheathed, the radiopaque marker band is located proximally to the funnel. The funnel is sheathed and unsheathed with the actuation of a slider button located on the handle assembly.

The hemostasis valve can be actively defeated (opened), prior to device introduction or removal, by pressing down on the base of the surrounding hub. This action is designed to minimize device contact across the hemostatic valve during the introduction or removal of devices.

The aspiration assembly also aids in the delivery of contrast or saline.

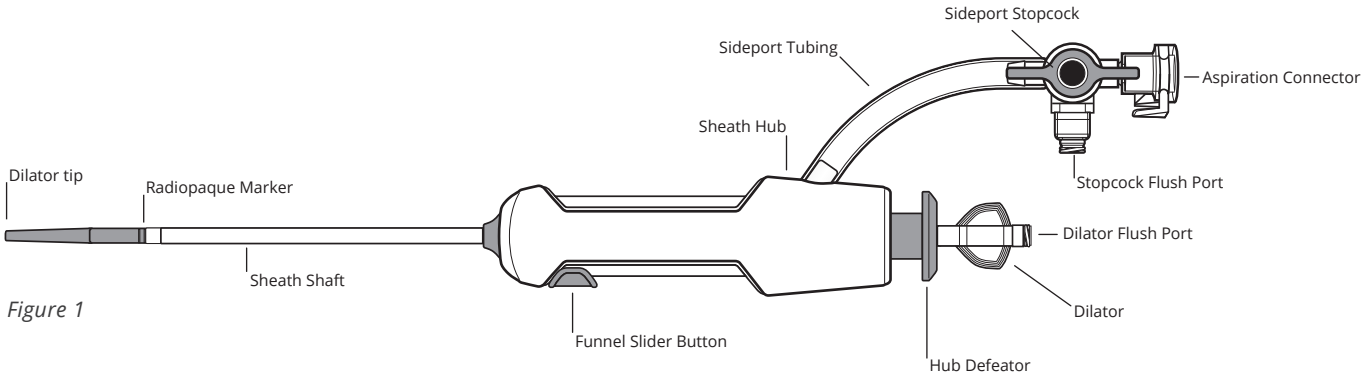


Figure 1

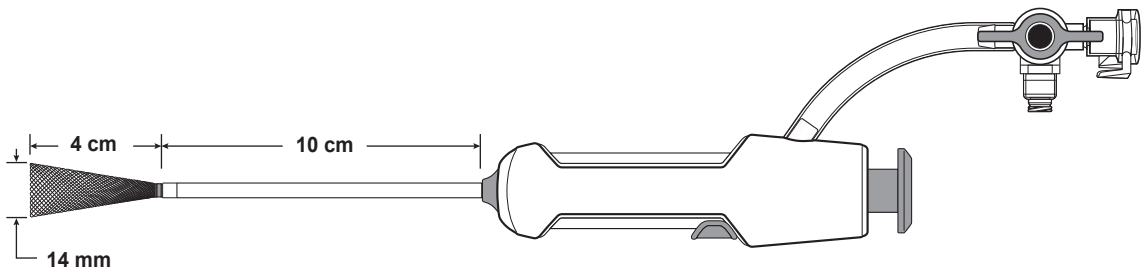


Figure 2

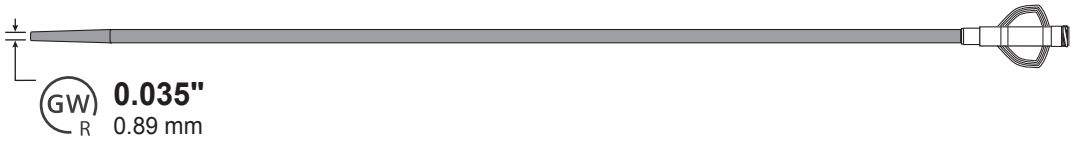


Figure 3

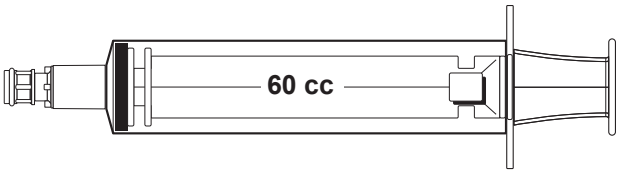


Figure 4

DEVICE SPECIFICATIONS

Model Number	Sheath ID	Guidewire Compatibility	Effective Length	Funnel Diameter
PFS-0035-12F14	12 Fr (4.0 mm)	0.035" (0.89 mm)	14 cm	14 mm

INDICATIONS FOR USE

The Pounce™ Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature.

CONTRAINDICATIONS

The Pounce™ Sheath is contraindicated for coronary and neurovascular use.

WARNINGS

- For single use only. Do not reuse, reprocess, or re-sterilize. Re-use, reprocessing, or re-sterilization of the device may compromise the structural integrity, leading to patient injury and/or patient infection.
- Should be used in conjunction with fluoroscopic guidance and proper anticoagulation agents
- Keep the sheath as straight as possible during use to avoid kinking.
- Do not advance the Pounce™ Sheath while the funnel is unsheathed in the vessel.
- The Pounce™ Sheath accepts devices up to 12 French (4.0 mm). All catheters and instruments used with this introducer should move freely through the valve and sheath. Damage to the sheath may result when the fit is tight.
- Avoid using excessive force to advance or retract the sheath against resistance.
- This device has not been evaluated for funnel deployment in vessels <6 mm diameter.
- This device has not been evaluated at pressures generated via power injection. Use of power injection may comprise the structural integrity, leading to patient injury.
- Presence of stent or obstruction in funnel deployment zone may cause difficulty in device removal.

PRECAUTIONS

- Do not use if the package or product is damaged or altered in anyway. A damaged package could indicate a breach of sterility or device damage.
- This product is intended for use by physicians trained and experienced in diagnostic and therapeutic techniques. Standard techniques for placement of vascular sheaths should be employed.
- Verify size compatibility of concomitant devices prior to use, do not attempt to advance concomitant devices through the sheath if resistance is felt.
- When inserting, manipulating, or withdrawing a concomitant device through the sheath always maintain sheath position.
- Ensure funnel is unsheathed before the removal of concomitant devices.
- Flush sheath and dilator with sterile saline to purge air from the shafts prior to use.

ADVERSE EVENTS

Potential adverse events which may be associated with use of Pounce™ Funnel Sheath include, but are not limited to:

- Bleeding
- Extravasation
- Hematoma
- Vessel laceration
- Vessel perforation
- Local inflammation
- Local pain
- Access site infection
- Distal embolization
- Air embolization
- Vasospasm

HOW SUPPLIED

- One (1) Pounce Sheath Assembly.
- Store in a cool dry place away from direct sunlight.

ADDITIONAL ITEMS REQUIRED (NOT PROVIDED)

Required Accessories:

- 0.035" guidewire
- Sterile saline
- Sterile syringe

INSTRUCTIONS FOR USE

PACKAGING REMOVAL

1. Remove pouch from carton box. Inspect pouch for any signs of damage.
2. Open pouch and transfer the device tray from pouch to sterile field.
3. Remove all three components from tray to include the sheath, 60cc syringe and dilator.
4. Inspect components for damage.

Note: If any components are damaged, do not use. Replace with a new device.

SHEATH FLUSHING

Using sterile saline, purge air from the sheath (flush) by taking the following steps:

1. Flush the dilator lumen.
2. Close the sheath's sideport stopcock and flush the sheath with sterile saline through the stopcock flush port to remove air.

SHEATH INTRODUCTION

1. Insert the dilator into the sheath until the hub of the dilator snaps into the proximal hub of the sheath.

Note: Ensure dilator is secured into the proximal sheath hub. If it is not secure, the sheath may advance without the dilator during insertion causing damage to the sheath tip or to the vessel.

2. Confirm the dilator is extended past the catheter shaft tip and free of damage.
3. Confirm a guidewire is placed within the targeted vessel and extends at least 10 cm past distal landing zone of the Pounce™ Sheath.
4. Under imaging, advance the Pounce™ Sheath over the previously placed guidewire.
5. When sheath is placed at targeted location, remove the dilator from the sheath.
6. To actuate the funnel, slide the button on the handle backwards, towards the hub of the sheath until the button is locked in place.

Note: At least 5 cm of the sheath must reside within the targeted vessel for appropriate deployment of the funnel.

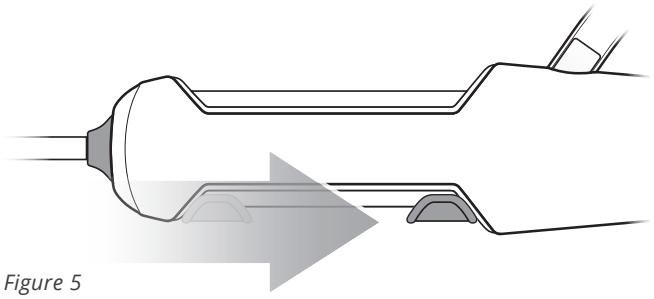


Figure 5

7. Confirm with imaging funnel is fully deployed.

SHEATH REPOSITIONING (AS NEEDED)

1. To advance the sheath forward, slide the button on the handle assembly forward towards the distal tip of the sheath until the button is locked in place.

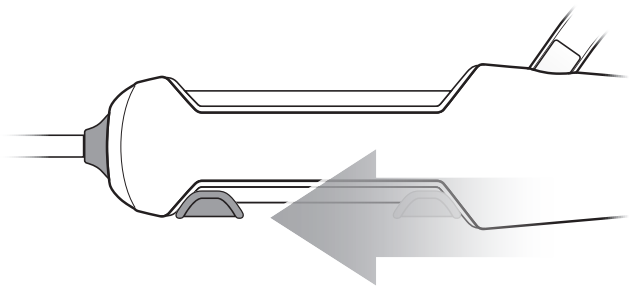


Figure 6

2. Insert the flushed dilator over the wire into the sheath and snap the dilator hub into the sheath hub.
3. Once the sheath is repositioned as desired, remove the dilator from the sheath.
4. To actuate the funnel, slide the button on the handle backwards, towards the hub of the sheath until the button is locked in place (See Figure 5).
5. Confirm with imaging funnel is fully deployed.

Note: If the Pounce™ Sheath needs to be removed or retracted backwards in the vessel, it can be done so without sheathing the funnel. Caution should be taken as to prevent vessel damage.

TRANSPORTATION OF DEVICES THROUGH THE SHEATH

1. Introduce and remove devices through the hub assembly.
2. The sheath allows for two methods to pass devices across the hemostasis valve:
   a. Insert appropriately sized device through the hemostasis valve.
   b. Press and hold the hub defeater to actively defeat the hemostasis valve (See Figure 7):
      i. Actively defeating the hemostasis valve will minimize device contact with hemostasis valve during introduction and removal of devices.
      ii. To minimize blood loss, immediately release the hemostasis defeater to close the valve.

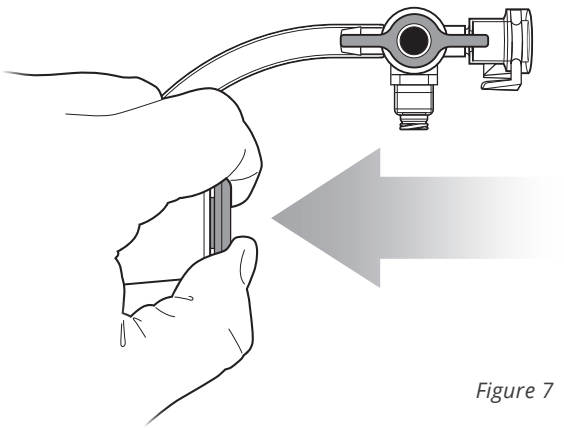


Figure 7

Note: If abnormal resistance is encountered during the introduction or removal of devices through the sheath, stop and determine the cause of resistance before proceeding.

SHEATH FLUID MANAGEMENT

1. Locate the flush port on the stopcock (Figure 1) to inject physician selected fluids using a sterile syringe.

Note: The stopcock must be in the closed position for injection through the flush port.

2. For aspiration:
    a. Close the stopcock.
    b. Attach the 60 cc syringe to the aspiration connection port (Figure 1).
    c. Pullback on the 60 cc syringe plunger and twist to place in locked configuration.
    d. Open the stopcock to aspirate.
    e. When aspiration is complete, close the stopcock and remove the 60 cc syringe from the aspiration connector. Dispose of collected extract according to facility protocols.
    f. If additional aspiration is required, repeat steps 2b-2e.

SHEATH REMOVAL

1. Under fluoroscopic guidance, assess if thrombus is on or near the unsheathed funnel. If thrombus is present, aspirate by following steps 2a-2f (under Sheath Fluid Management).
2. Once any remaining residual thrombus has been cleared, sheath the funnel by sliding the button on the handle assembly forward, towards the leading end of the sheath (Figure 6).
3. Confirm placement of a guidewire at least 10 cm past the end of the sheath.
4. Insert the flushed dilator over the wire into the sheath and snap the dilator hub into the sheath hub.
5. Withdraw the sheath and dilator as an assembly.

Note: If the Pounce™ Sheath needs to be removed or retracted backwards in the vessel, it can be done so without sheathing the funnel. Caution should be taken as to prevent vessel damage.

DISPOSAL

Dispose of the Pounce™ Sheath in accordance with applicable hospital, administrative and/or government policies.

REPORTING

Report any complications or device failures as soon as possible to the manufacturer, per the contact information provided on the device label.

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