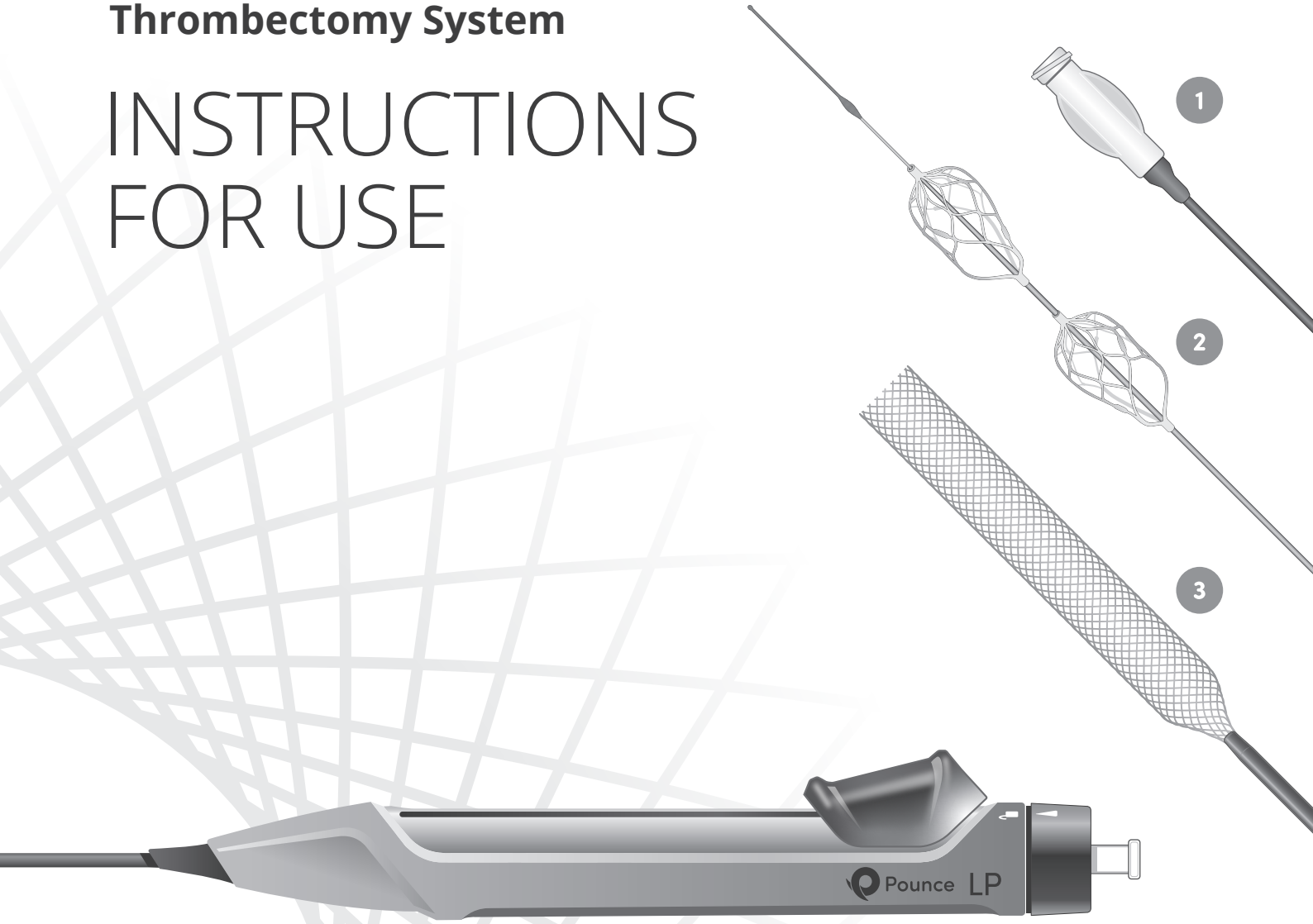
SURMODICS

Pounce™ LP Thrombectomy

Surmodics™ Pounce™ LP Thrombectomy System

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) Thrombectomy System

Sterilized Using Ethylene Oxide

Catalogue Number


Do Not Re-use


Non-pyrogenic


Caution

℞ only

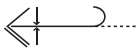
Caution: U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).


Use-by Date


Keep Dry


Do Not Use if Package is Damaged and consult instructions for use


Manufacturer


Maximum Guidewire Diameter


Keep Away From Sunlight/Heat

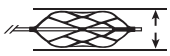
Lot Number


Date of Manufacture

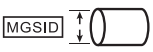
Do Not Re-Sterilize


Peel-away


Consult Instructions for Use


Basket Diameter


Funnel Diameter



Minimum Guide Sheath Inner Diameter


Effective Length


Single Sterile Barrier System with protective packaging inside

Medical Device

Country of Manufacture

DESCRIPTION

Device

The Surmodics™ Pounce™ Thrombectomy System is a percutaneous catheter system designed to facilitate mechanical thrombus removal in the peripheral arterial vasculature. The system is comprised of three separate components: a delivery catheter, a basket wire and a funnel catheter. The system also includes a basket loading tool accessory for loading the basket wire into the delivery catheter. The system contains the necessary radiopaque components to conduct the procedure and the system should be introduced through a minimum 7 Fr guide sheath. Not made with natural rubber latex.

Accessories

The system includes an optional accessories kit which is comprised of additional basket loading tools (2) and syringe tips (5) to aid in removing debris between passes.

INDICATION FOR USE / INTENDED USE

The Pounce™ Thrombectomy System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature.

The Pounce™ LP Thrombectomy System is indicated for use in vessels ranging from 2 mm to 4 mm in diameter.

COMPONENT DESCRIPTION

Refer to product labeling for appropriate system components. The system components dimensions are listed within the tables.

Table 1. Pounce Thrombectomy Compatibility Specifications

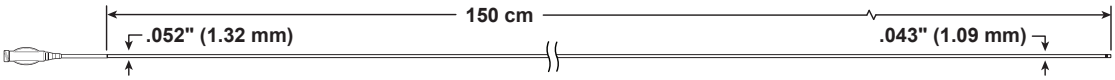
Model Number	Model Description	Guide Sheath French Size	Maximum Guide Wire Diameter (inches)	Maximum Guide Wire Diameter (mm)	Minimum Vessel Diameter (mm)	Maximum Vessel Diameter (mm)
PTS-0407-7F150	Pounce™ LP Thrombectomy System	≥ 7 FR	0.018″	0.457 mm	2 mm	4 mm

All components that enter blood vessels have radiopaque markers.

1

Delivery Catheter

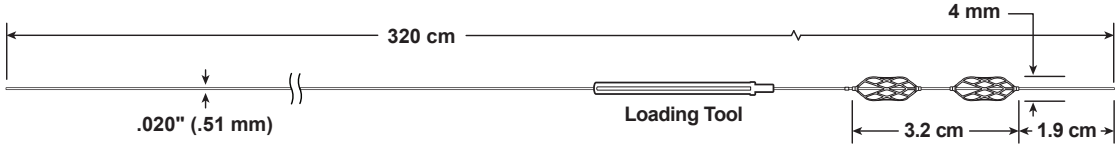
The delivery catheter is designed to deliver the basket wire to the location of the thrombus. Incorporated in the catheter is a radiopaque marker band located on the distal tip. The distal 42 cm of the catheter is hydrophilic coated.



2

Basket Wire

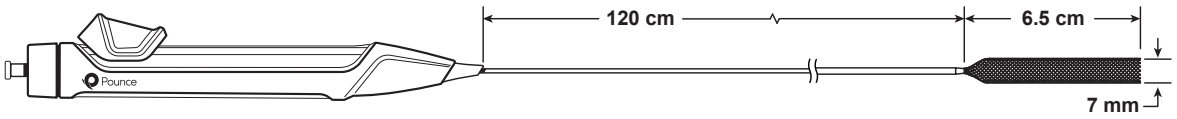
The basket wire is comprised of two distal nitinol self-expanding baskets mounted in series on a nitinol core wire for capturing thrombus. The core wire is tapered on the distal end with a safety coil for atraumatic delivery. The distal capture baskets have integral radiopaque markers mounted on the struts of the basket. The basket wire also comes with a basket loading tool for easy loading into the delivery catheter.



3

Funnel Catheter

The funnel catheter is used for thrombus collection and retrieval. The funnel catheter is made of an inner funnel catheter and an outer catheter. The two catheters work together to allow unsheathing and sheathing of the funnel using the slider button on the integrated handle. The funnel is made of a soft self-expanding nitinol that has integrated radiopaque wires for enhanced visualization. Additionally, a wire lock knob is located on the proximal end of the integrated handle.



CONTRAINDICATIONS

- The device is not intended for venous applications.
- The device is not intended for peripheral vasculature dilatation.
- The device is not for coronary or neurovascular use.
- The device is contraindicated for use in patients who cannot receive recommended intravenous anticoagulant therapy.
- The safety and effectiveness of the device has not been established in pediatric patients (<18 years of age).
- The device is not intended to be deployed in vessels with previously implanted devices.

COMPLICATIONS/POTENTIAL ADVERSE EVENTS

Possible complications associated with catheterization include, but are not limited to, the following:

- Allergic reaction
- Bleeding complications
- Blood vessel spasm
- Distal embolization
- Hematoma
- Infection
- Intra-vessel thrombosis, occlusion
- Pain at puncture site
- Vessel perforation, rupture, aneurysm, pseudoaneurysm, or dissection
- High blood pressure
- Hyperglycemia

Potential complications or adverse event risks should be communicated to the patient prior to the procedure.

WARNINGS

- Prior to use, read all package insert warnings, precautions and instructions. Failure to do so may result in severe patient injury or death.
- This product is intended for use by physicians trained in peripheral vascular percutaneous interventional procedures.
- Intended for one clinical use; do not deploy more than 3 times in a clinical procedure.
- Pre-clinical testing with this device showed the potential for clot formation in the absence of anticoagulation. Appropriate anticoagulation therapy should be administered to reduce the potential for thrombus formation on the device.
- 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.

- Do not use after the Expiration Date.
- 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.
- Do not use agents containing organic solvents.
- Do not wipe the surface with chemical solution such as alcohol.
- Before inserting the device into the body, flush with heparinized saline. Prior to re-insertion, aspirate through all devices to clear any residual thrombus, then flush with heparinized saline.
- The entire procedure, from skin incision to device removal, must be carried out aseptically within a sterile environment.
- Do not use a power injector with any device components.
- The basket wire is not intended to be torqued or advanced without the delivery catheter. This may cause vessel damage or compromised device functionality.
- This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this device. Prior to device use, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.
- Use of the Pounce Thrombectomy System in conjunction with other thrombolytic therapies, other thrombectomy devices, or other therapeutic devices in the same procedure or following treatment has not been evaluated.
- Device is not MRI compatible.
- Inspect all package seals prior to aseptic transfer.

INSTRUCTIONS FOR USE

Preparation

This procedure requires the patient to be anti-coagulated. Dosage and frequency at the discretion of the physician. Prepare vascular access site according to standard practice.

Gain Vascular Access

Deliver the guidewire past the clot (see Figure 1). Insert 7 Fr or greater guide sheath into access site. Place the distal end of the guide sheath approximately 15 cm proximal to the clot.

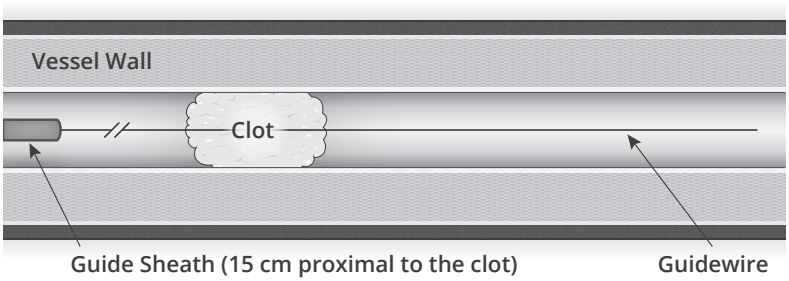


Figure 1

Note: Greater than 7 Fr guide sheath should be considered for high-volume clot burden to optimize clot retrieval.

Basket Wire Introduction

1. Unpackage the device tray from the pouch and retrieve the delivery catheter from its protective hoop within the tray, taking care not to kink or damage the component. Soak the delivery catheter prior to use in heparinized saline to lubricate the surface. Keep the surface of the delivery catheter wet during use. Once the clot has been crossed with a guidewire and using a guide sheath (7 Fr minimum) for introduction of the system, flush the delivery catheter. Then, back-load the delivery catheter over the guidewire until the distal tip is past the clot, or at the most distal site that is within the intended vessel diameter (see Figure 2).

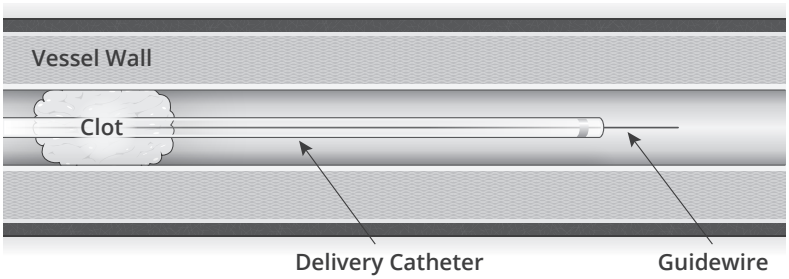


Figure 2

2. While maintaining distal position of the delivery catheter, remove the guidewire.

3. Retrieve the basket wire from its protective hoop within the tray. Advance the preloaded basket loading tool over the baskets, to completely collapse and constrain both the baskets (see Figure 3).

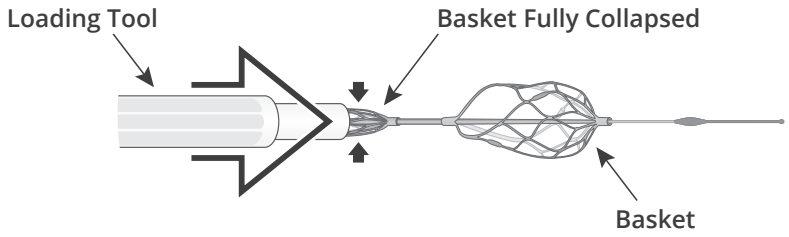


Figure 3

4. Insert the tapered tip of the basket loading tool into the proximal hub of the delivery catheter (see Figure 4).

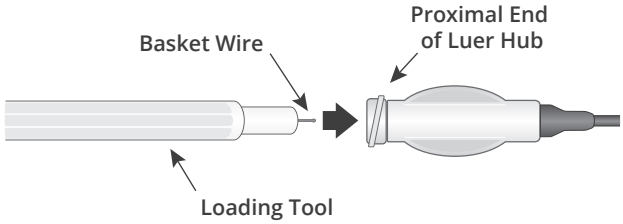


Figure 4

Note: If the basket loading tool is misplaced, retrieve an additional loading tool in the accessory kit.

5. Advance the basket wire through the delivery catheter until the tip of the basket wire exits the delivery catheter but the distal basket remains within the catheter at its tip (see Figure 5). Confirm placement under fluoroscopy.

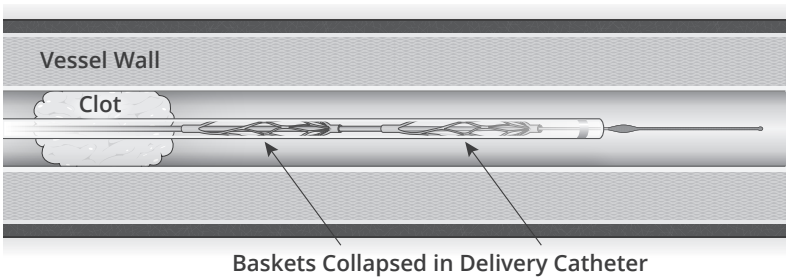
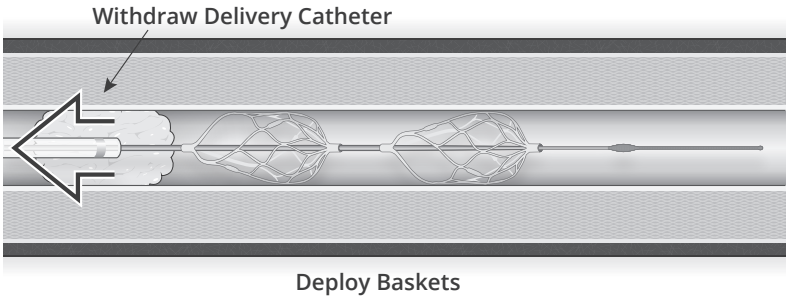


Figure 5

6. Deploy the two baskets by withdrawing the delivery catheter while stabilizing the basket wire (see Figure 6). Confirm placement under fluoroscopy.



Note: If unable to deploy the baskets distal to the clot due to vessel sizing, they may be deployed within the clot.

Figure 6

Funnel Catheter Introduction

7. Remove the funnel catheter from the tray. Then flush both luer connectors on the funnel catheter handle (see Figure 7).

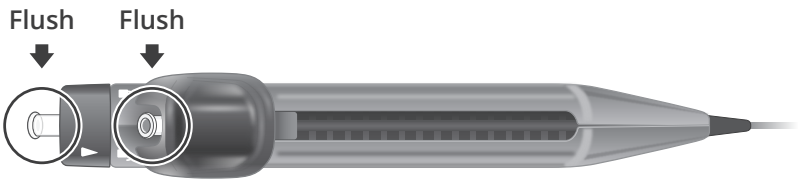


Figure 7

8. Manually prolapse/invert the funnel and back load proximal end of basket wire into the funnel catheter inner lumen (see Figure 8). Confirm that the basket wire has entered the inner lumen and has not interwoven within the funnel braid.

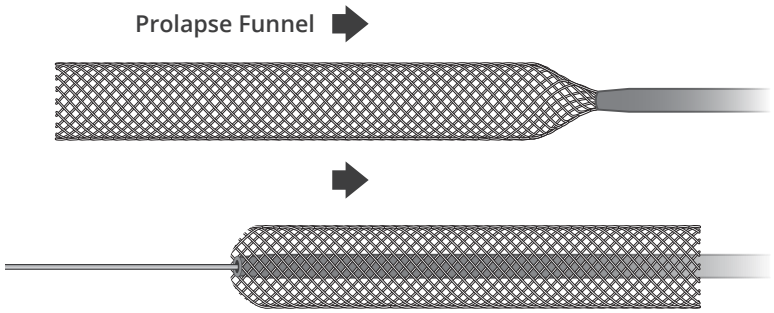


Figure 8

9. Straighten out the funnel and continue to advance the funnel catheter over wire until the wire exits the proximal luer of the funnel catheter handle.

10. Depress slider button and advance to most distal position to completely sheath the funnel (see Figure 9).

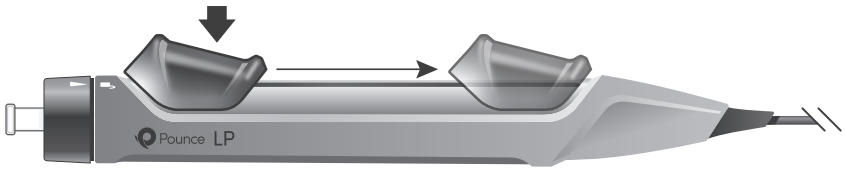


Figure 9

11. Continue to advance the funnel catheter over the basket wire and into the guide sheath. Position the tip of the funnel catheter outside of the guide sheath and proximal to the clot. Avoid deploying the funnel in the clot (see Figure 10). Confirm placement under fluoroscopy.

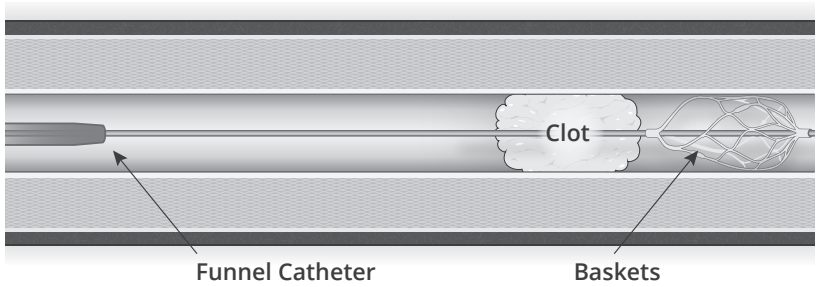
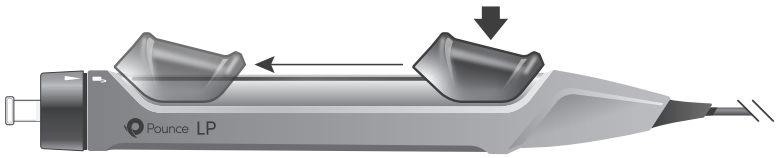


Figure 10

12. Straighten the funnel catheter shaft until there is no slack in the catheter.

13. To unsheathe the funnel, depress slider button and retract to the most proximal position (see Figure 11).



Note: If unable to deploy the baskets distal to the clot due to vessel sizing, they may be deployed within the clot.

Figure 11

Clot Retrieval

14. With the two baskets distal to, or within the clot, slowly pull back on the basket wire and clot until the distal-most basket tip is just inside the funnel (see Figure 12). Confirm placement under fluoroscopy.

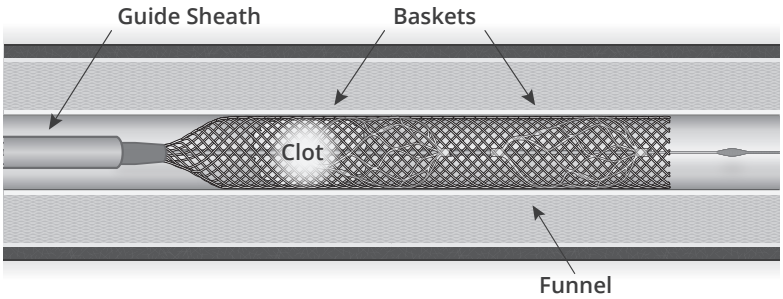


Figure 12

15. Rotate the wire lock on the proximal end of the handle to the locked position to lock the basket wire and funnel catheter together (Figure 13a). Holding the funnel catheter handle, pull back to capture the basket wire and funnel catheter completely into the guide sheath (see Figure 13b).

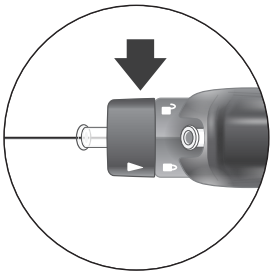


Figure 13a

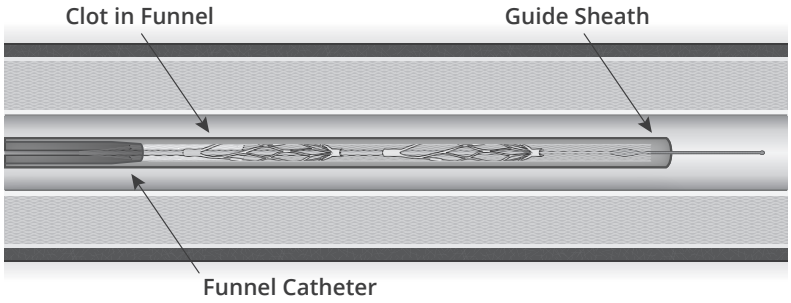


Figure 13b

Troubleshooting clot retrieval: If volume of clot cannot be retracted into the guide sheath, follow the below steps to upsize your guide sheath. If clot retrieval was successful, move to Step 16.

15a. If volume of clot cannot be retracted into guide sheath, rotate the wire lock on the proximal end of the handle to the unlocked position to unlock the basket wire.

15b. Slowly advance the basket wire distally to dislodge it from within the funnel.

15c. Depress slider button on the funnel catheter handle and advance it to the most distal position to completely sheath the funnel.

15d. While maintaining basket wire position, withdraw the funnel catheter completely out of the guide sheath.

15e. Withdraw the guide sheath until it is completely out of the vasculature.

15f. Backload a larger guide sheath onto the proximal end of the basket wire and advance it into the vasculature. Place the distal end of the guide sheath approximately 15 cm proximal to the clot.

15g. Reinsert funnel catheter by starting with Step 7 of the IFU. Once funnel catheter tip is in position, repeat Step 15 to re-attempt clot retrieval.

16. Holding the funnel catheter handle, continue withdrawing the funnel catheter and basket wire through the guide sheath until it is completely removed from the guide sheath.

17. Aspirate guide sheath to remove any residual clot.

18. Under fluoroscopy, confirm clot removal.

19. Rotate the wire lock on the proximal end of the handle to the unlock position (Figure 14) and push the basket wire distally to remove it from the funnel.

    Note: Do not pull the basket wire through the funnel cathether handle to remove it from the funnel.

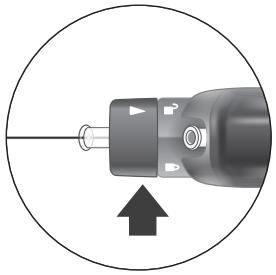


Figure 14

20. If reinsertion for additional clot removal is needed, the system should be clean of residual clot. Use heparinized saline to remove clot from the funnel and basket wire if needed.

    For additional assistance in removing debris from components, locate syringe tip in the accessories kit. Connect syringe tip to a syringe and eject heparinized saline directly at components.

    Utilize standard practices to ensure the hemostasis valve is free from debris prior to repeating the procedure.

    Confirm all components are cleaned and undamaged prior to reuse.

    Repeat the procedure starting at step 1.

21. If no reinsertion is needed, remove guide sheath and proceed with standard closure techniques.

Post Procedure:
The appropriate duration of post-procedure anticoagulant therapy for each patient is at the discretion of the physician.

After use, remove and discard product. The Pounce Thrombectomy System may be a potential biohazard. Handle and dispose the product in accordance with acceptable medical practices and applicable local, state, and federal laws and regulations.

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

How Supplied
Supplied sterilized by Ethylene Oxide gas in a kitted procedure tray within a peel-open pouch. Intended for single patient use. Do not reuse. Do not re-sterilize. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether it is sterile or not. Store in a cool, and dry place. Upon removal from package, inspect the product to ensure no damage has occurred.

Expiration Date
The expiration date is indicated on the label of the product package.

Contents
One (1) product per package.

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www.surmodics.com

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

www.surmodics.com/patents

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