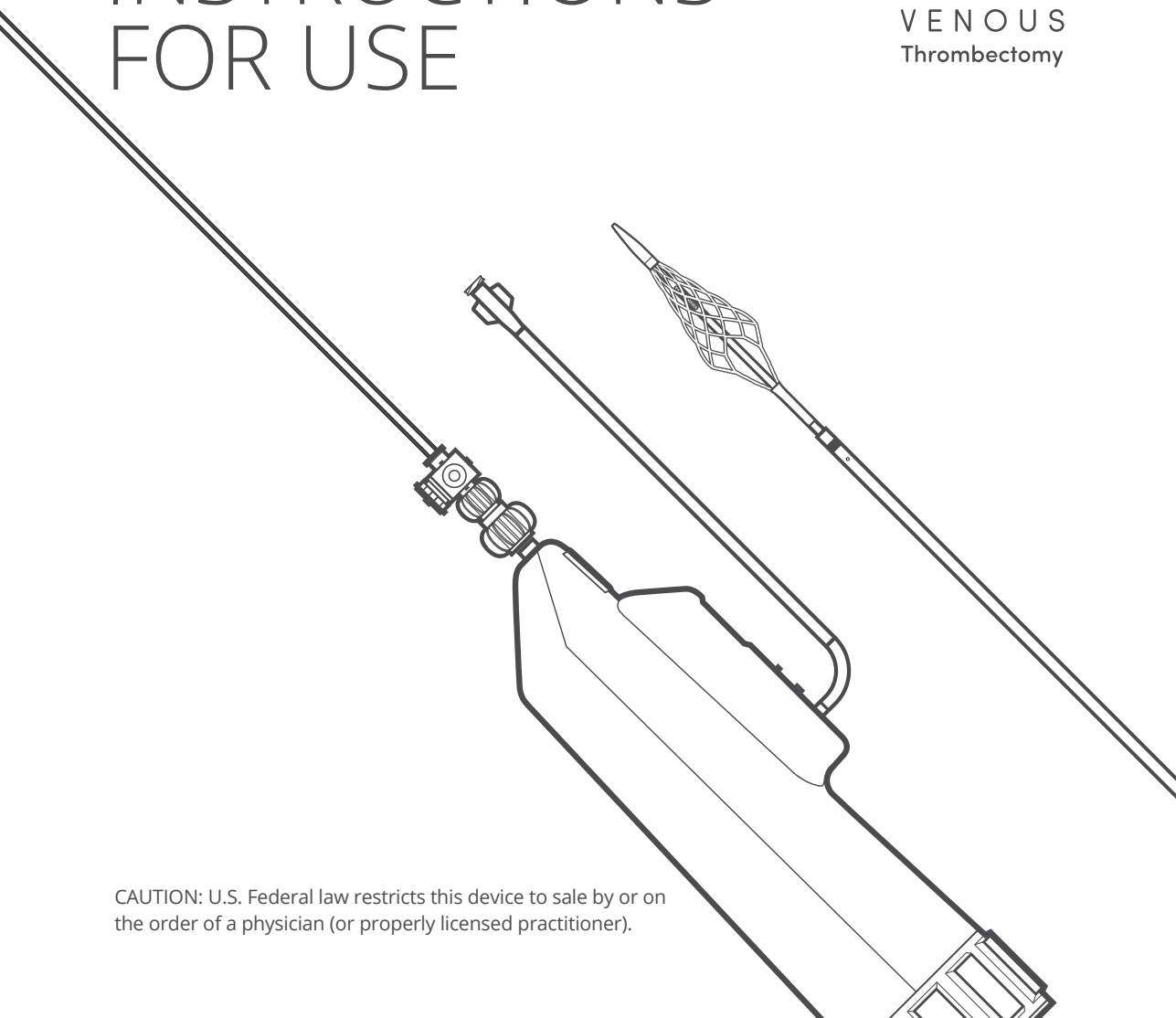
SURMODICS

Pounce™ Venous Thrombectomy System

Pounce™
VENOUS
Thrombectomy

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).

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

WARNING: 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.

1 DEVICE DESCRIPTION

The Pounce™ Venous Thrombectomy System is a venous thrombus extraction system for the treatment of vessels greater than 6mm diameter. The device is designed to be used in a medical catheter laboratory and allows for optional infusion of thrombolytic agents for patients in whom no contraindications exist.

The device is compatible with a 10Fr introducer and includes a wire-braided cobalt chromium basket for thrombus disruption. A rotational thrombus-extractor, consisting of a helical coil housed inside a metal tube, is powered by an internal DC motor and batteries. The extractor runs the length of the catheter, and when activated, the coil rotates and is designed to macerate and transport thrombus from the basket to a collection container outside the body.

The main features of the Pounce Venous Thrombectomy System are:

- The thrombus disruption basket
- The rotational thrombus extractor
- The device handle

The device is sterilized by ethylene oxide and is for single use only. It does not require servicing and there are no special installation requirements.

2 INTENDED USE

The intended use of the Pounce Venous Thrombectomy System is mechanical de-clotting and controlled and selective infusion of physician specified fluids, including thrombolytics, in the peripheral vasculature.

3 INDICATIONS FOR USE

The device is indicated for mechanical de-clotting and controlled and selective infusion of physician specified fluids, including thrombolytics, in the peripheral vasculature.

4 CONTRAINDICATIONS

Pounce Venous Thrombectomy System is contraindicated in the following:

- Patients contraindicated for endovascular procedures
- Patients who cannot tolerate contrast media
- Patients in whom the lesion cannot be accessed with the guide wire
- Veins less than 6mm diameter

5 GENERAL WARNINGS & PRECAUTIONS

- Pounce Venous Thrombectomy System should only be used by physicians trained in interventional procedures.
- Where possible avoid sources of other RF emitter such as known sources of electro-magnetic disturbance including diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, and metal detectors.
- Prior to use, read all contents of the package.
- Do not use if package is damaged or open.
- Pounce Venous Thrombectomy System has been evaluated for use in the peripheral vasculature only. It is not indicated for use in the central circulatory system.
- Do not use in patients who have a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or haemorrhage.
- Device must be removed prior to defibrillation.
- Always confirm basket has been fully collapsed prior to sheathing device.
- The basket must be in the collapsed and sheathed configuration prior to advancement to the initial start position or for any subsequent movement in the cephalad direction.
- The basket must be in the fully collapsed configuration prior to removal.
- Always confirm the rotating stopcock on the outer sheath is in the closed position prior to activating the motor.
- Do not push or pull the catheter against abnormal resistance. If high resistance is experienced, the basket diameter may be adjusted using the device handle.
- Should the extraction mechanism cease to function during use, turn off the switch, collapse the basket, and remove from the patient. The device should then be replaced with a new device.

- During the procedure heparin should be administered to maintain an appropriate Activated Clotting Time (ACT).
- The potential for pulmonary thromboembolism should be carefully considered when the device is used to break up and remove peripheral venous thrombus.

WARNING: No modification of this equipment is allowed.

6 POTENTIAL ADVERSE EVENTS

Potential adverse events which may be associated with use of Pounce Venous Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:

- abrupt closure of treated vessel
- acute myocardial infarction
- acute renal failure
- amputation
- bleeding from access site
- cerebrovascular accident
- death
- dissection
- embolization, proximal or distal
- hematoma
- hemolysis
- hemorrhage, requiring transfusion
- hypotension/hypertension
- infection at the access site
- pain
- pancreatitis
- perforation
- pseudoaneurysm
- reactions to contrast medium
- thrombosis/occlusion
- total occlusion of treated vessel
- vascular aneurysm
- vascular spasm
- vessel wall or valve damage

7 DIRECTIONS FOR USE

Required Procedural Accessories:

- Introducer Sheath
- 0.018" Guidewire
- Thrombus Collection Container

Packaging Removal:

1. Remove the Pounce Venous Thrombectomy System from carton. Inspect pouch for any signs of damage. If any damage is noted, do not use device. Replace with another device.

2. Remove the tray/device from the Tyvek pouch using standard sterile techniques.
3. Transfer tray/device to sterile field.
4. Remove blister tray cover.
5. To collapse basket during removal of the device from the tray, push the rear slide inward.
   Note: Do not attempt to tightly coil or bend the catheter shaft.
6. Inspect device visually for any damage. If any damage is noted, do not use device. Replace with another device.

Patient Preparation:

1. Prepare and drape the puncture site(s) as required.
2. Using standard clinical practice, access the lower peripheral vein.
3. Insert an introducer per instructions provided with device.
4. Using an 0.018" guidewire, advance past treatment location.
   Note: Ensure standard endovascular practices are utilized during the procedure, e. g., guidewire and introducer sheath management.

Device Preparation:

1. Sheathe the device in preparation for insertion:
   a. Collapse the basket by fully rotating dial clockwise, when viewed from behind the handle.
   b. Loosen the rotating valve on the outer sheath.
   c. Sheathe the basket by advancing the outer sheath forward, in a controlled manner, to the basket collar.
      Note: Always confirm basket has been fully collapsed prior to sheathing device.
   d. Tighten the rotating valve on the outer sheath.
2. Using sterile physiological saline and a sterile syringe flush:
   a. The outer sheath lumen and close the stopcock thereafter
   b. The extraction lumen
   c. The guidewire lumen
3. Attach thrombus collection container to the extraction lumen port.

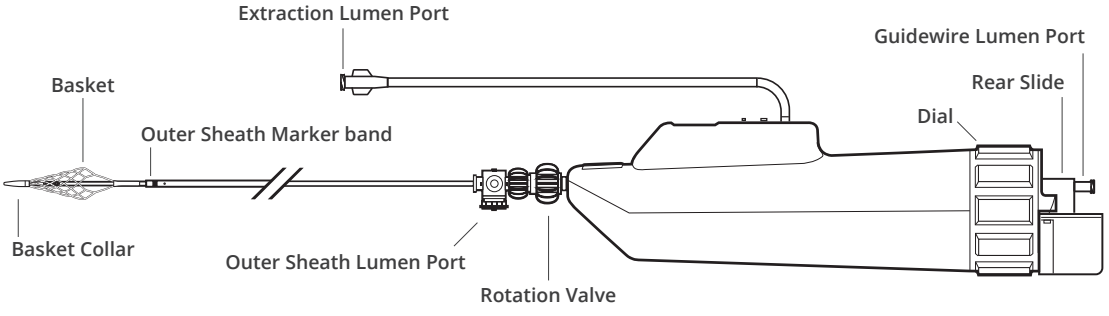


Figure 1: Schematic of the Pounce™ Venous Thrombectomy System

Thrombectomy Procedure:

Note: The outer sheath lumen port may be used to infuse physician specified fluids.

1. Perform the thrombectomy procedure under continuous fluoroscopy.
2. Load Pounce Venous Thrombectomy System onto the previously inserted guidewire, maintaining proper guidewire position past the treatment location.
3. Under fluoroscopy, using the marker band as a guide, advance the system past the treatment site.
4. Unsheathe the device in the following steps:
    a. Loosen the rotating valve on the outer sheath.
    b. Retract the outer sheath to the handle.
    c. Tighten the rotating valve on the outer sheath.
5. Expand the basket by fully rotating the dial counterclockwise, when viewed from behind the handle.
6. Confirm the basket has been deployed appropriately. If required, increase the basket diameter by gently sliding the extraction tube back towards the handle dial.
7. Switch on extraction system using the on/off switch located in the handle.
   Note: Once the extraction system is activated, monitor the extract being removed by the thrombectomy device. If extraction is not functional during the procedure;
    i. Switch off and re-activate the switch

   If the extraction system is still not functional;
    i. Switch off device
    ii. Remove (following steps 10-11) and replace the device

8. Slowly withdraw the system through the treatment site, in a retrograde direction.
   Note: Do not push or pull the catheter against abnormal resistance. If high resistance is experienced (tactile/visual/audio), the basket diameter may be decreased by rotating the handle dial clockwise or pushing the rear slide inward.
9. Once the system has been withdrawn through the treatment site, switch off the extraction system.
10. Collapse the basket by fully rotating the handle dial clockwise, when viewed from behind the handle.
11. Withdraw the system through the introducer sheath.
12. Prepare device for re-deployment (optional):
    a. Expand the basket by fully rotating the dial counterclockwise when viewed from behind the handle.
    b. Carefully remove thrombus in and around the basket.
    c. Prepare the device per the device preparation section.
       Note: A total of 3 deployments can be performed. The volume of extract removed from the patient should be considered.
    d. Following one or more passes per the above instructions, the extraction system may be intermittently turned off to minimize blood loss.
13. If appropriate, per clinical standard practice perform adjunctive procedures including aspiration, thrombolytic therapy, angioplasty, and/or stenting.

8 SPECIFICATIONS

Catheter shaft diameter	10Fr
Working Length	90cm
Overall length	128cm
Power source	2 x Alkaline batteries (non-replaceable)
Operating Voltage	9 Volts
Typical Operating Environment	Catheter Laboratory, 15–40°C

9 STORAGE

Store in a cool dry place away from direct sunlight.

10 DISPOSAL

Dispose of the Pounce Venous Thrombectomy System in accordance with the Waste Electrical and Electronic Equipment Directive (WEEED) and according to the standard institutional procedures for medical waste including single-use, blood contacting devices.

11 WARRANTY AND LIMITATION OF LIABILITY

Vetex Medical Limited warrants that the Pounce Venous Thrombectomy System will be free from defects in workmanship and materials. Vetex Medical Limited's sole liability for breach of this warranty shall be to replace or, at its discretion, refund the purchase price of the Pounce Venous Thrombectomy System. Save as aforesaid, there is no express or implied warranty, including without limitation, an implied warranty of merchantability or fitness for a particular purpose, given in respect of the Pounce Venous Thrombectomy System and all implied terms and warranties are hereby excluded to the extent permitted by law. Under no circumstances shall Vetex Medical Limited be liable for any direct, indirect, incidental, special or consequential damages other than as expressly provided by specific law and to the extent that same may not be excluded. No person has the authority to bind Vetex Medical Limited to any representation or warranty except as specifically set forth herein.

Descriptions or specifications in Vetex Medical Limited printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties as to their correctness, accuracy, reliability or otherwise.

Vetex Medical Limited will not be responsible under any circumstances, for any damage caused by the use of the Pounce Venous Thrombectomy System in a manner other than in accordance with these Instructions for Use including, without limitation any attempt to reuse, repair, re-sterilize, alter or modify of Pounce Venous Thrombectomy System.

SYMBOLS GLOSSARY

Symbol	Explanation
	Recommended Vessel Size
	Recommended Guidewire
	Catalogue or reference number
	Batch code
	Use-By date
	Sterilized using Ethylene Oxide
	Consult instructions for use
	Do not re-use

Symbol	Explanation
	Do not resterilize
	Keep away from sunlight
	Keep Dry
	Non-Pyrogenic
	Do not use if package is damaged and consult instructions for use
℞ only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Manufacturer
	Date of Manufacture
	This product contains electronics and should not be disposed of with household waste
MD	Medical Device
	Caution
	Fragile, Handle with Care
	Contents: One (1) Thrombectomy System
OTW	Over the Wire
	Type BF Applied Part
	Country of manufacture
	Single Sterile barrier system with protective packaging inside

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