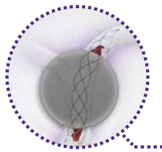

## Trevo® XP ProVue Retriever

| Reference Number | Description |
|---|---|
| 93068 | **2-part Kit:** Trevo XP ProVue Retriever 6x25mm + Excelsior® XT-27® Microcatheter |
| 90186 | Trevo XP ProVue Retriever 6x25mm |

## Excelsior® XT-27® Microcatheter

| Reference Number | Outer Diameter Proximal/Distal | Inner Diameter | Effective Length |
|---|---|---|---|
| XT275081 | 2.9F/2.7F | 0.027in (0.69mm) | 150cm |

**Trevo® XP ProVue Retriever (6x25mm)**

**See package insert for complete indications, complications, warnings, and instructions for use.**

**INDICATIONS FOR USE**

The Trevo Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

**COMPLICATIONS**

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with possible complications which may occur during or after the procedure. Possible complications include, but are not limited to, the following: air embolism; hematoma or hemorrhage at puncture site; infection; distal embolization; vessel spasm, pain/headache, thrombosis, dissection, or perforation; emboli; acute occlusion; ischemia; intracranial hemorrhage; false aneurysm formation; neurological deficits including stroke; and death.

**COMPATIBILITY**

6x25mm Retrievers are compatible with Excelsior® XT-27® Microcatheters (150cm x 6cm straight REF 275081). Compatibility of the Retriever with other microcatheters has not been established. Performance of the Retriever device may be impacted if a different microcatheter is used.

Balloon Guide Catheters (such as Merci® Balloon Guide Catheter and FlowGate® Balloon Guide Catheter) are recommended for use during thrombus removal procedures.

Retrievers are compatible with the Abbott Vascular DOC® Guide Wire Extension (REF 22260).

Retrievers are compatible with Boston Scientific RHV (Ref 421242).

**WARNINGS**

- Content, supplied STERILE using an ethylene oxide (EO) process. Nonpyrogenic.
- To reduce risk of vessel damage, adhere to the following recommendations:
  - Take care to appropriately size Retriever to vessel diameter at intended site of deployment.
  - Do not perform more than six (6) retrieval attempts in same vessel using Retriever devices.
  - Maintain Retriever position in vessel when removing or exchanging Microcatheter.
- To reduce risk of kinking/fracture, adhere to the following recommendations:
  - Immediately after unsheathing Retriever, position Microcatheter tip marker just proximal to shaped section. Maintain Microcatheter tip marker just proximal to shaped section of Retriever during manipulation and withdrawal.
  - Do not rotate or torque Retriever.
  - Use caution when passing Retriever through stented arteries.
- Do not resterilize and reuse. Structural integrity and/or function may be impaired by reuse or cleaning.
- The Retriever is a delicate instrument and should be handled carefully. Before use and when possible during procedure, inspect device carefully for damage. Do not use a device that shows signs of damage. Damage may prevent device from functioning and may cause complications.
- Do not advance or withdraw Retriever against resistance or significant vasospasm. Moving or torquing device against resistance or significant vasospasm may result in damage to vessel or device. Assess cause of resistance using fluoroscopy and if needed resheath the device to withdraw.
- If Retriever is difficult to withdraw from the vessel, do not torque Retriever. Advance Microcatheter distally, gently pull Retriever back into Microcatheter, and remove Retriever and Microcatheter as a unit. If undue resistance is met when withdrawing the Retriever into the Microcatheter, consider extending the Retriever using the Abbott Vascular DOC guidewire extension (REF 22260) so that the Microcatheter can be exchanged for a larger diameter catheter such as a DAC® catheter. Gently withdraw the Retriever into the larger diameter catheter.
- Administer anti-coagulation and anti-platelet medications per standard institutional guidelines.

**PRECAUTIONS**

- Prescription only-device restricted to use by or on order of a physician.
- Store in cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Do not expose Retriever to solvents.
- Use Retriever in conjunction with fluoroscopic visualization and proper anti-coagulation agents.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution between guide catheter and Microcatheter and between Microcatheter and Retriever or guidewire.
- Do not attach a torque device to the shaped proximal end of DOC® Compatible Retriever. Damage may occur, preventing ability to attach DOC® Guide Wire Extension.

**Excelsior® XT-27® Microcatheter**

**See package insert for complete indications, complications, warnings, and instructions for use.**

**INTENDED USE / INDICATIONS FOR USE**

Stryker Neurovascular Excelsior XT-27 Microcatheter is intended to assist in the delivery of diagnostic agents (such as contrast media), therapeutic agents, and non-liquid interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.

**CONTRAINDICATIONS**

None known.

**POTENTIAL ADVERSE EVENTS**

Potential adverse events associated with the use of microcatheters or with the endovascular procedures include, but are not limited to: access site complications, allergic reaction, aneurysm perforation, aneurysm rupture, death, embolism (air, foreign body, plaque, thrombus), hematoma, hemorrhage, infection, ischemia, neurological deficits, pseudoaneurysm, stroke, transient ischemic attack, vasospasm, vessel dissection, vessel occlusion, vessel perforation, vessel rupture, vessel thrombosis.

**WARNINGS**

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular 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. 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.

These devices should only be used by physicians who have received appropriate training in interventional neuroradiology.

Limited testing has been performed with solutions such as contrast media, interventional devices such as stents, and therapeutic agents such as PVA particles. The use of these catheters for delivery of products other than the types that have been tested for compatibility is not recommended.

Do not use catheter with glue, glue mixture or non-adhesive liquid embolic agent.

The accessories are not intended for use inside the human body.

Carefully inspect all devices prior to use. Verify shape, size and condition are suitable for the specific procedure.

Exchange microcatheters frequently during lengthy procedures that require extensive guidewire manipulation or multiple guidewire exchanges.

Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance could dislodge a clot, perforate a vessel wall, or damage microcatheter and guidewire. In severe cases, tip separation of the microcatheter or guidewire may occur.

Inspect product before use for any bends, kinks or damage. Do not use a microcatheter that has been damaged. Damaged microcatheters may rupture causing vessel trauma or tip detachment during steering maneuvers.

Shaping mandrel is not intended for use inside the human body.

Discontinue use of microcatheter for infusion if increased resistance is noted. Resistance indicates possible blockage. Remove and replace blocked microcatheter immediately.

DO NOT attempt to clear blockage by over-pressurization. Doing so may cause the microcatheter to rupture, resulting in vascular damage or patient injury.
Do not exceed 2,070 kPa (300 psi) infusion pressure. Excessive pressure could dislodge a clot, causing thromboemboli, or could result in a ruptured microcatheter or severed tip, causing vessel injury.

**CAUTIONS / PRECAUTIONS**

Federal Law (USA) restricts this device to sale by or on the order of a physician.

To facilitate microcatheter handling, the proximal portion of the microcatheter does not have the hydrophilic surface. Greater resistance may be encountered when this section of the microcatheter is advanced into the RHV.

Exercise care in handling of the microcatheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.

To control the proper introduction, movement, positioning and removal of the microcatheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.

Use the product prior to the "Use By" date printed on the label.

Flush dispenser coil of hydrophilically coated microcatheters prior to removal from dispenser coil. Once the microcatheter has been wetted, do not allow to dry. Do not reinsert the microcatheter into dispenser coil.

Check that all fittings are secure so that air is not introduced into guide catheter or microcatheter during continuous flush.

In order to achieve optimal performance of Stryker Neurovascular Microcatheters and to maintain the lubricity of the Hydrolene® Coating surface, it is critical that a continuous flow of appropriate flush solution be maintained between the Stryker Neurovascular Microcatheter and guide catheter, and the microcatheter and any intraluminal device. In addition, flushing aids in preventing contrast crystal formation and/or clotting on both the intraluminal device and inside the guide catheter and/or the microcatheter lumen.

Do not position microcatheter tip closer than 2.54 cm (1 in) from the steam source. Damage to the microcatheter tip may result.

Excessive tightening of a hemostatic valve onto the microcatheter shaft may result in damage to the microcatheter. Removing the peel-away introducer sheath without a guidewire inserted in the microcatheter lumen might result in damage to the microcatheter shaft.


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Date of Release: APR/2015

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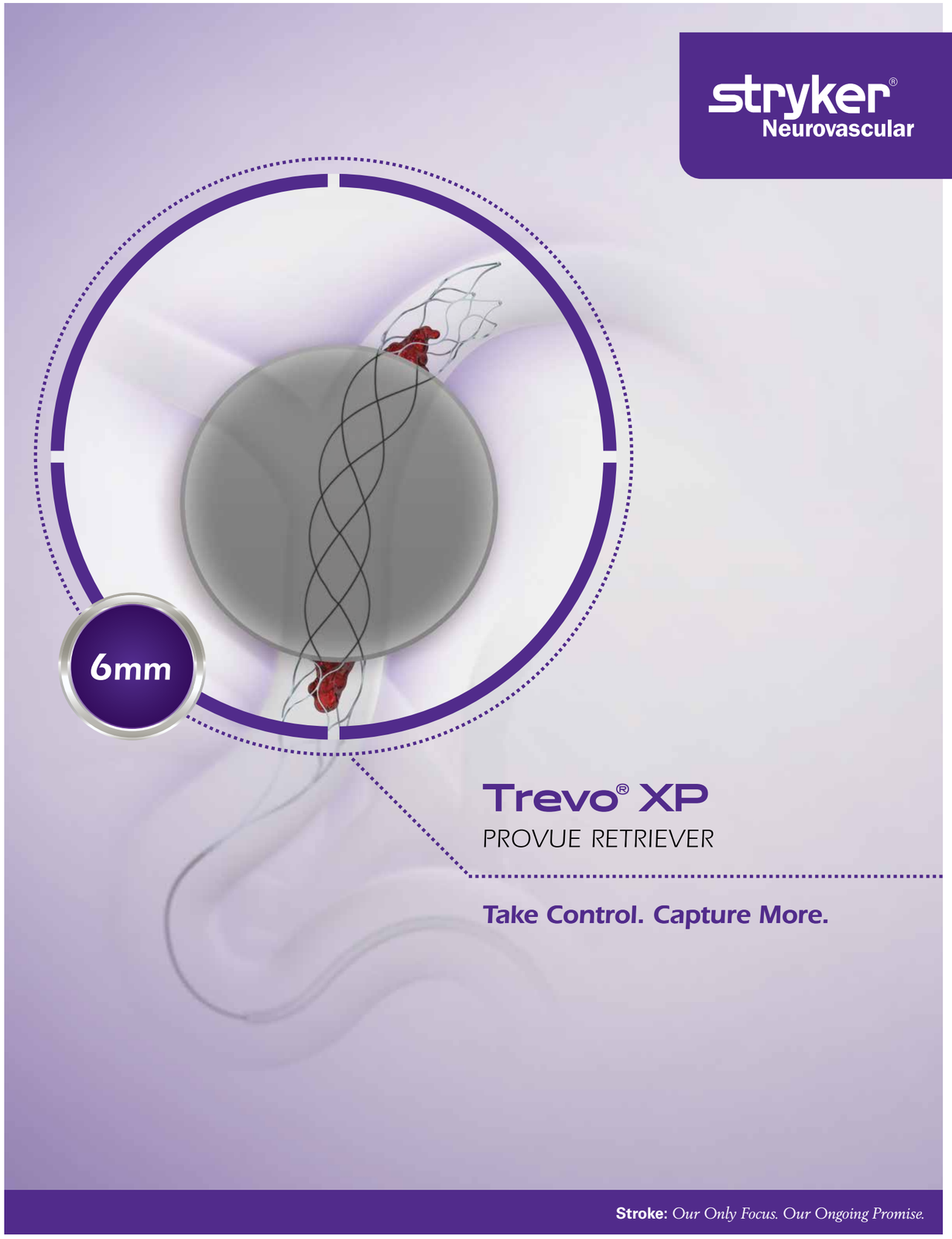



stryker® Neurovascular

# Trevo® XP
PROVUE RETRIEVER

**Take Control. Capture More.**

**Stroke:** *Our Only Focus. Our Ongoing Promise.*

# Trevo® XP ProVue Retriever 6mm

## Easy to See

Fully visible 6mm retriever for precise deployment and interactive retrieval

Solitaire 2 6x30mm  Trevo XP ProVue Retriever 6x25mm

## Easy to Access and Deliver

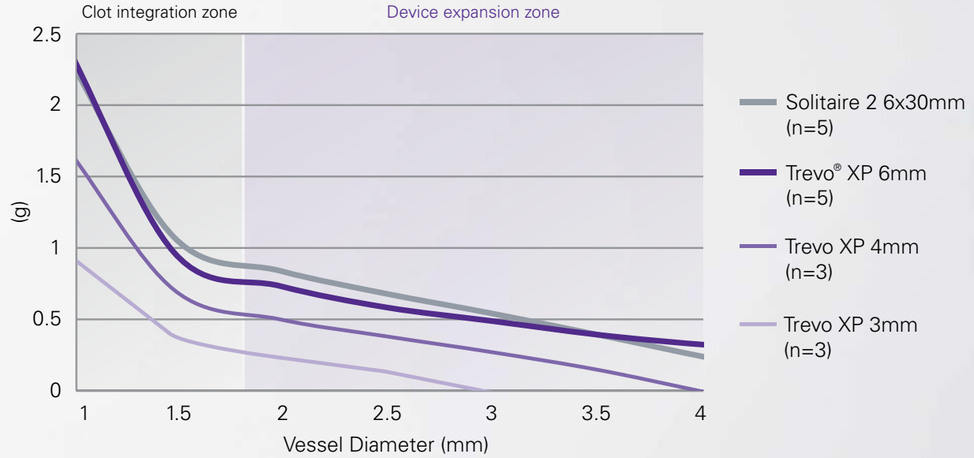
Excelsior® XT-27® Microcatheter Compatibility enables easy access to treatment site

**2x**
**less delivery force**
than Solitaire 2 6mm in a Marksman Microcatheter*

*Trevo XP ProVue Retriever 6mm delivery force in the Excelsior XT-27 Microcatheter was 98.2g (n=5); the Solitaire 2 6mm delivery force in the Marksman Microcatheter was 196.8g (n=5).
All photographs taken by Stryker Neurovascular.
Bench test results. Bench test results may not necessarily be indicative of clinical performance.
Testing performed by Stryker Neurovascular. Data are on file at Stryker Neurovascular and will be made available upon request.

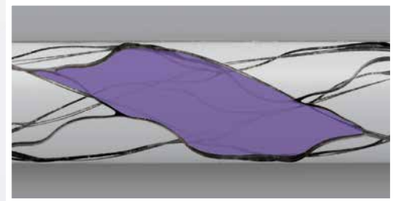
# Maximize Clot Retrieval

## High Overall Radial Force

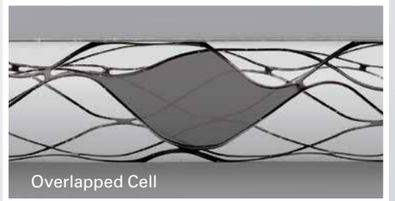



## Larger Cell Size to penetrate clot

Trevo XP ProVue Retriever 6x25mm



Solitaire 2 6x30mm




Devices photographed in a 3mm simulated vessel.

## 30mm Non-tapered Stent Length with Longer Clot Capture Zone