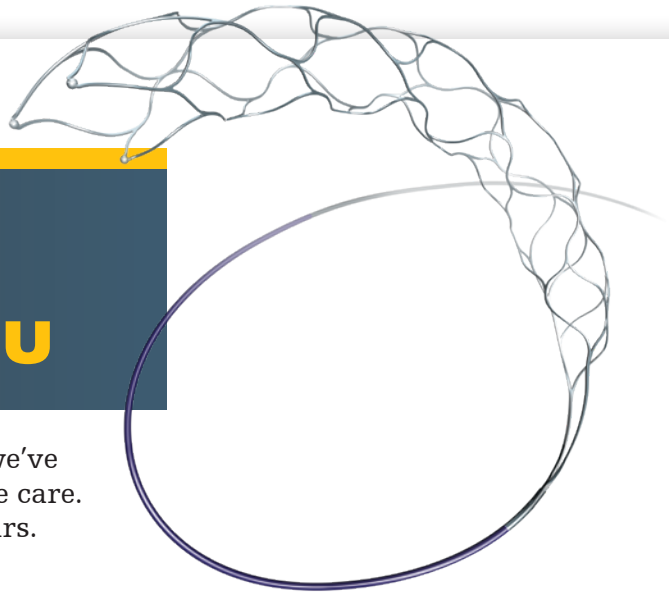
stryker

Trevo® Retrievers



10 years of advancing with you

Since launching Trevo Retrievers globally 10 years ago, we've been honored to be part of your journey to improve stroke care. You can count on us to be by your side for the next 10 years. We're with you all the way.

Advancing clinical knowledge

From **DAWN** to **Trevo 2000** to **ASSIST**, Trevo Retriever has continuously proven its safety and efficacy in clinical trials and registries.

2012	2014	2015	2017	2022
TREVO Trial **TREVO 2** Trial	**MR. CLEAN** Trial	**Trevo TRAK** Registry	**DAWN** Trial **Trevo 2000** Registry	**ASSIST** Registry

Advancing possibilities

The Trevo Retriever was the 1st stent retriever designed for acute ischemic stroke. With your feedback we've continued to design for the evolution of stroke treatment across four iterations of Trevo Retrievers.

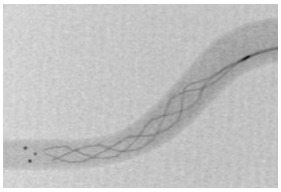
1st

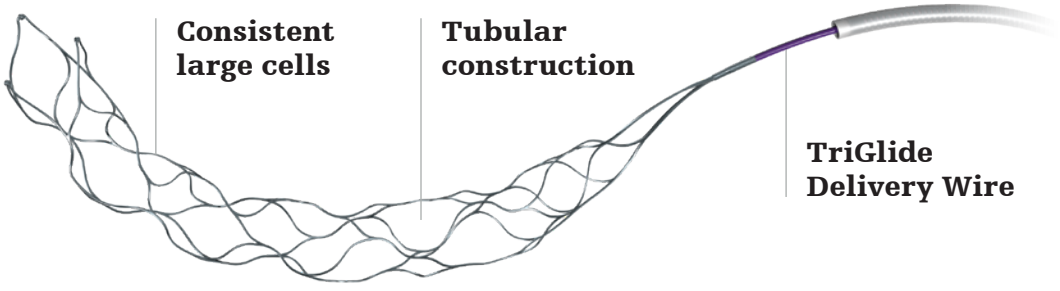
- designed for AIS
- fully visible
- proven to reduce disability for the treatment of AIS patients
- 3mm device
- FDA-cleared to reduce disability in patients up to 24 hours from symptom onset

Advancing your practice

Your goal is excellent clinical and procedural outcomes. Our goal is to give you a consistent, efficient stent retriever that can help you reach that goal.

Full length radiopacity





Trevo NXT ProVue Retriever

UPN	Description
90312	Trevo NXT ProVue Retriever 3x32
90313	Trevo NXT ProVue Retriever 4x28
90314	Trevo NXT ProVue Retriever 4x41
90315	Trevo NXT ProVue Retriever 6x37

Stroke Fast Pack (if available in region)*

UPN	Description
91312	Trevo NXT ProVue Retriever 3x32 + Trevo Trak 21 Microcatheter
91316	Trevo NXT ProVue Retriever 3x32 + Trevo Pro 14 Microcatheter
91313	Trevo NXT ProVue Retriever 4x28 + Trevo Trak 21 Microcatheter
91314	Trevo NXT ProVue Retriever 4x41 + Trevo Trak 21 Microcatheter
91315	Trevo NXT ProVue Retriever 6x37 + Trevo Trak 21 Microcatheter
91317	Trevo NXT ProVue Retriever 6x37 + Excelsior XT-27 Microcatheter

*Please contact your Stryker representative.

Trevo NXT ProVue Retriever

RX ONLY

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

Intended use/indications for use

1. The Trevo Retriever is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should start within 6 hours of symptom onset.
2. 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.
3. The Trevo Retriever is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (0-50 cc for age <80 years, 0-20 cc for age ≥80 years). Endovascular therapy with the device should start within 6-24 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.

Contraindications

None known.

Adverse events

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
- pain/headache
- vessel spasm
- thrombosis
- dissection
- perforation
- emboli
- acute occlusion
- ischemia
- intracranial hemorrhage
- false aneurysm formation
- neurological deficits including stroke
- death

Use of device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure. Possible risks include, but are not limited to, the following:

- alopecia,
- burns ranging in severity from skin reddening to ulcers,
- cataracts,
- delayed neoplasia

Adverse Event Reporting

Please notify your Stryker Neurovascular representative immediately if a device malfunctions or patient complication or injury is experienced or suspected. Please make every attempt to retain any suspect device, its associated components and their packaging for return to Stryker Neurovascular.

Warnings

Specific warnings for indication 1

- The safety and effectiveness of the Trevo Retrievers in reducing disability has not been established in patients with large core infarcts (i.e., ASPECTS ≤7). There may be increased risks, such as intracerebral hemorrhage, in these patients.
- The safety and effectiveness of the Trevo Retrievers in reducing disability has not been established or evaluated in patients with occlusions in the posterior circulation (e.g., basilar or vertebral arteries) or for more distal occlusions in the anterior circulation.

Specific warnings for indication 2

- To reduce risk of vessel damage, take care to appropriately size Retriever to vessel diameter at intended site of deployment.

Specific warnings for indication 3

- The safety and effectiveness of the Trevo Retrievers in reducing disability has not been established in patients with large core infarcts (i.e., ASPECTS ≤7). There may be increased risks, such as intracerebral hemorrhage, in these patients.
- The safety and effectiveness of the Trevo Retrievers in reducing disability has not been established or evaluated in patients with occlusions in the posterior circulation (e.g., basilar or vertebral arteries) or for more distal occlusions in the anterior circulation.
- Users should validate their imaging software analysis techniques to ensure robust and consistent results for assessing core infarct size.

General warnings applied to all indications

- Administration of IV t-PA should be within the currently approved window.
- To reduce risk of vessel damage, adhere to the following recommendations:
  - 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 or Aspiration Catheter tip marker over the proximal section of the Retriever. Maintain this position during manipulation and withdrawal.
  - Do not rotate or torque Retriever.
  - Use caution when passing Retriever through stented arteries.
- 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 or Aspiration Catheter over the Retriever and remove devices as a unit. If undue resistance is met when withdrawing the Retriever into the Microcatheter, consider exchanging for a larger diameter Aspiration Catheter. Gently withdraw the Retriever and larger diameter catheter as a unit.
- Administer anti-coagulation and anti-platelet medications per standard institutional guidelines.
- Do not use open or damaged packages.
- Do not expose Retriever to organic solvents.

Precautions

- Store in cool, dry, dark place.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- 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 through all catheter lumens.
- Users should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.

How supplied

Stryker Neurovascular products are sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and storage

Store in a cool, dry, dark place.

Trevo Trak 21 Microcatheter

RX ONLY

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

Intended use/indications for use

The Microcatheter is indicated for use in the selective placement of devices and/or fluids, such as contrast media, into the peripheral, coronary, and neuro vasculature during diagnostic and/or therapeutic procedures.

Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Possible complications include, but are not limited to the following: death, emboli, hematoma at the puncture site, hemorrhage, ischemia, neurological deficits including stroke, vasospasm, vessel perforation.

Use of device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure. Possible risks include, but are not limited to, the following: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, delayed neoplasia.

Compatibility

Refer to product label for device dimensions. Refer to labeling provided with other medical technologies to determine compatibility.

- Minimum recommended guide catheter inner diameter: 0.058in (1.47mm)
- Maximum recommended guide wire outer diameter: 0.018in (0.46mm)

Warnings

- Contents supplied STERILE using an ethylene oxide (EO) process. Nonpyrogenic.
- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance catheter against resistance without careful assessment of cause using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- Do not use device that has been damaged in any way. Damaged device may cause complications.
- Do not exceed maximum recommended infusion pressure. Excess pressure may result in catheter rupture or tip severance.

Catheter	Maximum Infusion Pressure
Trevo Trak 21 MC	1034 kPa (150 psi)

- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter.

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.
- Upon removal from package, inspect device to ensure it is not damaged.
- Do not expose device to organic solvents.
- Use device with fluoroscopic visualization and proper anti-coagulation agents.
- Hydrate microcatheter with saline for 2 minutes minimum before use. Once hydrated, do not allow it to dry.
- To maintain hydrophilic coating lubricity, provide continuous flow of appropriate solution between microcatheter and guide catheter.
- Hemostatic side-arm adapters may be used to provide seal around guidewire and microcatheter.
- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.
- Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.

How supplied

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Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and storage

Store in a cool, dry, dark place.

This document is intended solely for the use of healthcare professionals.

A physician must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that physicians be trained in the use of any particular product before using it in a procedure. The information presented is intended to demonstrate the breadth of Stryker product offerings. A physician must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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