

NEW Indication for Trevo Retrievers

Product bulletin

Stryker's Trevo[®] Retriever is the First Therapy in 20 Years to be Declared a Front-Line Treatment to Reduce Disability in Ischemic Stroke

Kalamazoo, Michigan, USA – Sept. 6, 2016 – The Food and Drug Administration (FDA) expanded on Sept. 2 the indication for Stryker's Trevo Retriever as front-line treatment to reduce disability in patients experiencing acute ischemic stroke. Trevo is the first and only thrombectomy device to receive this expanded indication, which has the potential to help the hundreds of thousands of Americans who experience ischemic strokes—or brain attacks—each year.

People suffering from stroke commonly experience devastating disabilities and loss of independence due to impaired movement, paralysis, loss of speech and memory. Randomized clinical data using the Trevo retriever alongside IV t-PA shows that patients are almost twice as likely to be functionally independent at 90 days after a stroke compared to medical management alone.¹ The strength of this data resulted in Trevo receiving the first and only FDA clearance for a thrombectomy device to significantly reduce disability in patients with ischemic stroke. This clearance for front-line use expands the treatment with Trevo to a broader group of patients.

"This new and unique indication for Trevo, as initial therapy for acute ischemic stroke with large vessel occlusions, has the potential to help hundreds of thousands of stroke patients," said Amrou Sarraj, MD, assistant professor of Neurology and Vascular Neurology Fellowship Program Director at the University of Texas Health Science Center at Houston. "These patients now have a significantly better chance for an independent life without disability."

Mari, an elementary school teacher and mother of twin boys, suffered an ischemic stroke in June of 2015. She received treatment with the Trevo Retriever at the Stroke and Neurovascular Center of Central California in Santa Barbara, Calif., within hours of her symptoms starting. She recalls, "I couldn't speak and I was quickly losing feeling on one side of my body. If there hadn't been a treatment option like Trevo, the blood clot might still be blocking the artery in my brain and I wouldn't be capable of living the active lifestyle I have today."

"This expanded indication for Trevo is a significant milestone in the treatment of patients who are suffering from this catastrophic disease and is an example of the strength of evidence for the Trevo device coming from randomized clinical trials," said Mark H. Paul, president of Stryker's Neurovascular division."

"So many patients with major ischemic stroke due to large vessel occlusions still go untreated today, largely ending up with a devastating long term disability," said Dr. Sarraj. "The FDA clearance of the Trevo Retriever as a front-line treatment to reduce disability reinforces the importance that all caregivers in the stroke pathway – from EMS to emergency room physicians to Neurologists to interventionalists – continue to come together to deliver fast and efficient treatment of stroke."

Based on the depth of clinical evidence, the Trevo Retriever is also included in the recent American Heart Association's 2015 stroke care guideline update where stent retrievers are now recommended as the standard of care for stroke patients experiencing a large artery blockage.²

About the FDA Indication

[FDA Announcements](#)

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-tPA). Endovascular therapy with the device should start within 6 hours of symptom onset.

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

About the Trevo Retriever

The Trevo Retriever is a tiny stent-shaped medical device that is attached to a thin wire. In a minimally invasive procedure that utilizes X-ray, the physician navigates the retriever from the femoral artery, which is located in the upper leg, to the blocked blood artery in the brain. The retriever is designed to ensnare the blood clot and remove it from the body. Originally cleared by the FDA in 2012 for the revascularization in patients experiencing ischemic stroke, the Trevo Retriever has been used in thousands of patients worldwide. An animation of Stryker's Trevo Retriever is available here: <https://youtu.be/PxcERzyl67I>

About Ischemic Stroke

An ischemic stroke occurs when an artery in the brain becomes blocked by a blood clot or other substance such as plaque, a fatty material. Blood vessels carry blood, oxygen and nutrients throughout the body and to the brain. When the brain is deprived of blood and oxygen, it fails to work properly. Depending on the severity of the stroke and the area of the brain affected, loss of brain function or death may occur. Ischemic stroke affects nearly 795,000 Americans annually and is the number five cause of death.³

About Stryker

Stryker is one of the world's leading medical technology companies and, together with our customers, we are driven to make healthcare better. The Company offers a diverse array of innovative products and services in Orthopaedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes. Stryker is active in over 100 countries around the world. Please contact us for more information at www.stryker.com.

Media Contact

Potomac Communications Group

Kelly Cousineau, kcousineau@pcgpr.com, 805-335-0152

1. aOR 1.88, p=0.014.
2. 2015 AHA/ASA Focused Update: Guidelines for the Early Management of Patients with Acute Ischemic Stroke.
3. 2016 Heart Disease and Stroke Statistics Update.

Trevo® XP ProVue Retrievers Directions For Use

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

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; pain/headache; vessel spasm, thrombosis, dissection, or perforation; emboli; acute occlusion; ischemia; intracranial hemorrhage; false aneurysm formation; neurological deficits including stroke; and death.

COMPATIBILITY

3x20mm retrievers are compatible with Trevo® Pro 14 Microcatheters (REF 90231) and Trevo® Pro 18 Microcatheters (REF 90238). 4x20mm retrievers are compatible with Trevo® Pro 18 Microcatheters (REF 90238). 4x30mm retrievers are compatible with Excelsior® XT-27® Microcatheters (150cm x 6cm straight REF 275081) and Trevo® Pro 18 Microcatheters (REF 90238). 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).

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 \leq 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.

WARNINGS APPLIED TO BOTH INDICATIONS

- Administration of IV t-PA should be within the FDA-approved window (within 3 hours of stroke symptom onset).
- Contents 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.

DOC is a trademark of Abbott Laboratories.