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.

Contraindications

The Trevo Trak 21 Microcatheter is contraindicated for delivery of liquid embolic agents, including those containing dimethyl sulfoxide (DMSO) or n-butyl cyanoacrylate (n-BCA).

Adverse events

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

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.

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: 0.046in (1.17mm)
- 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.
- Limited testing has been performed with solutions such as contrast media, and saline. The use of these microcatheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.

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

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.