

Excelsior Reach™ Microcatheter

RX ONLY

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

Intended use / indications for use

The Excelsior Reach Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils, into the peripheral, coronary, and neurovasculature. The Excelsior Reach Microcatheter is also intended to assist in the delivery of embolization materials into the peripheral and neurovasculature.

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, infraction, 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 patient 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. Used product and any associated used materials should be handled and processed as biohazardous material.
- These devices are intended for use only by physicians trained in performing endovascular procedures.
- Use only therapeutic devices, diagnostic agents, and embolization materials that have been cleared or approved for use in the intended target anatomy. The accessories are not intended for use inside the human body.
- Diagnostic agents, therapeutic devices, and embolization materials should be used in accordance with information provided by their respective manufacturer and labeling.
- Excelsior Reach Microcatheter is not recommended and has not been tested for use with stent-retrievers.
- Carefully inspect all devices prior to use. Verify shape, size and condition are suitable for the specific procedure.
- Exchange Excelsior Reach Microcatheters frequently during lengthy procedures that require extensive guidewire manipulation or multiple guidewire exchanges. Device may lose shape after repeated use.
- 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 the microcatheter and guidewire. In severe cases, tip separation of the microcatheter or guidewire may occur.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device, as this may
- cause unpredictable changes in the hydrophilic coating.
- Avoid wiping the device with dry gauze or excessive wiping of the coated device, as this may damage the hydrophilic coating.
- Infusion pressure should not exceed 700 psi to avoid potential rupture of Microcatheter.

Precautions

- Exercise care in handling of the Excelsior Reach Microcatheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.
- To reduce the probability of coating damage in tortuous vasculature, use a guide catheter with a minimum internal diameter that is ≥ 1.17 mm (0.046 in) and is recommended for use with Stryker Neurovascular hydrophilic coated microcatheters.
- To control the proper introduction, movement, posi-

tioning and removal of the Excelsior Reach Microcatheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.

- Use caution when manipulating, advancing, or withdrawing the device through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels, as this may result in destruction or separation of the outer coating, leading to adverse events requiring additional intervention.
- Greater resistance may be encountered when inserting the proximal portion of the microcatheter into the RHV.
- Use the product prior to the "Use By" date printed on the label.
- 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.