

AXS Catalyst Distal Access Catheter

RX ONLY

See Directions For Use for complete indications, contraindications, warnings and directions for use.

NOTE: This Catheter has two separate indications for use. Read the Directions For Use carefully.

Indication for use as a conduit

The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.

Indication for use as a revascularization device

The AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA are candidates for treatment.

Device description

The AXS Catalyst Distal Access Catheter is a single lumen, variable stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into the peripheral and neurovascular system. The catheter shaft has a hydrophilic coating to reduce friction during use. The catheter includes a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end allowing attachments for flushing and aspiration. It is packaged with a Rotating Hemostasis Valve (RHV) and Tuohy Borst valve with sideport for flushing, insertion of catheters and aspiration. The peel away introducer sheaths are designed to protect the distal tip of the catheter during insertion into the RHV or Tuohy Borst.

Additional device description when used as a revascularization device

The AXS Universal Aspiration System is composed of the following components:

- AXS Catalyst Distal Access Catheter
- AXS Universal Aspiration Tubing
- Medela Dominant Flex Pump
- AXS Universal Liner Set

The AXS Universal Aspiration System is designed to remove thrombus from the neurovasculature using continuous aspiration.

The AXS Catalyst Distal Access Catheter delivers aspiration from the Medela Dominant Flex Pump directly to the site of the occlusion to remove the clot. The AXS Catalyst Distal Access Catheter is the only component of the AXS Universal Aspiration System that is used intravascularly.

The AXS Universal Aspiration Tubing serves as a conduit to supply vacuum from the Medela Dominant Flex Pump to the distal tip of the AXS Catalyst Distal Access Catheter. The AXS Universal Aspiration Tubing provides a connection between the sterile and non-sterile environments. The proximal end of the AXS Universal Aspiration Tubing is connected to the AXS Universal Liner Set (outside of the sterile environment) while the distal end of the AXS Universal Aspiration Tubing is connected to the AXS Catalyst Distal Access Catheter (inside the sterile environment). The AXS Universal Liner Set is connected to the Medela Dominant Flex Pump (also outside of the sterile environment).

The Medela Dominant Flex Pump is designed to generate vacuum for the AXS Universal Aspiration System. When used as part of the AXS Universal Aspiration System, the AXS Catalyst Distal Access Catheter requires a minimum vacuum pressure of -68 kPa [-20.08 in Hg] from the Medela Dominant Flex Pump. The Medela Dominant Flex Pump is reusable, non-sterile, and intended to be utilized outside of the sterile environment.

The AXS Universal Liner Set is provided non-sterile and consists of an individually packaged canister liner and a ClotFinder specimen cup. The AXS Universal Liner Set is offered with and without a desiccant. The AXS Universal Liner Set is single-use and the repository for aspirated material.

Contraindications

None known.

Potential adverse events

Potential adverse events associated with the use of catheters 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

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

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. The AXS Catalyst Distal Access Catheter is 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.
- Limited testing has been performed with solutions such as contrast media, and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.
- Not intended for use with power injectors.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace catheter.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could dislodge a clot, perforate a vessel wall, or damage the device.

Additional warning for revascularization indication only

- Excessive aspiration may cause patient complications.

Precautions

- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Ensure the catheter's labeled outer diameter is smaller than the treatment vessel diameter. Do not use a device that has been damaged in any way. Damaged device may cause complications.
- To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- 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.

- Use the product prior to the "Use By" date printed on the label.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.
- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.

Additional precaution for conduit indication only

- Limit use of the AXS Catalyst Distal Access Catheters with retrievers to three (3) retriever attempts per catheter.