stryker®
Neurovascular

AXS Catalyst™

Distal Access Catheter

Stryker Neurovascular (DFU Template 8in x 8in EN), DFU, AXS Catalyst, EN, NV00012025-01B

AXS Catalyst™

Distal Access Catheter

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

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 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.

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 neuro vascular 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 Hemostastic 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.

User Information

The AXS Catalyst Distal Access Catheter should only be used by physicians trained in interventional endovascular procedures.

Contents

One (1) AXS Catalyst Distal Access Catheter

One (1) Rotating Hemostatic Valve (RHV)

One (1) Tuohy Borst Valve with sideport

Two (2) Peel-away introducer sheaths

Table 1. Compatibility Information

Catheter	Inner Diameter mm (in)	Outer Diameter F (mm) [in]	Effective length (cm)	Overall length (cm)
AXS Catalyst 5	1.47 (0.058)	Prox: 5.6F (1.86) [0.073] Dist: 5.3F (1.76) [0.069]	115, 132	120, 137
AXS Catalyst 6	1.52 (0.060)	Prox: 6.0F (2.01) [0.079] Dist: 5.4F (1.81) [0.071]	132	137

Accessory	Length
RHV	7cm
Tuohy Borst with Sideport	3.5cm

INTENDED USE/INDICATIONS FOR USE

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.

CONTRAINDICATIONS

None known.

WARNINGS

- 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.

PRECAUTIONS

- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. 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.
- 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.

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

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.

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.

OPERATIONAL INSTRUCTIONS

Required Additional Items

- Continuous flush set up

PREPARATIONS FOR USE

1. Set-up continuous flush through sheath or guide catheter lumen.
2. Select an appropriately sized catheter based on intended procedure and anatomy.
3. Gently remove contents from pouch using standard sterile technique

Caution: Flush the packaging hoop prior to removal of product to activate the hydrophilic coating of the catheter. Once hydrated, do not allow to dry.

4. Gently remove the catheter and accessories from the hoop and inspect prior to use to verify that they are undamaged. If any damage, replace with a new device.
5. Attach compatible RHV or Tuohy Borst valve based on intended procedure and associated devices, then flush RHV/Tuohy Borst valve and catheter lumen.
6. Set up continuous flush through catheter.

DIRECTIONS FOR USE

1. Gently insert catheter tip through a compatible sheath or guide catheter and over an appropriately sized guidewire.

   (Optional) Use the peel-away introducer sheath to assist in insertion of the catheter tip into the sheath/guide catheter valve. Once the catheter is inserted, retract and remove the peel-away introducer sheath.
2. Under fluoroscopic guidance, advance the catheter through the vasculature to the desired location.

Recommended Aspiration Procedure

1. Tighten the RHV/Tuohy Borst valve to prevent backflow.
2. Attach a partially filled 60mL syringe or aspiration system to catheter.
3. Apply aspiration to the catheter during withdrawal of the retrieval device.
4. 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 catheter under aspiration and flush catheter outside of patient. If flush is unsuccessful, replace catheter.
5. Continue aspirating until retriever and microcatheter are withdrawn from the catheter.

Note: If withdrawal of the retrieval device is difficult, simultaneously withdraw the catheter, microcatheter and retriever as a unit into the sheath/guide catheter under continuous aspiration. Remove sheath/guide catheter if necessary.

Table 2. Flow rate

Media (100%)	Size	Approximate Average Flow Rate at 43.5 psi (300 kPa), (ml/min)
Saline	0.058 x 115	438
	0.058 x 132	405
	0.060 x 132	445
Omnipaque®-300 (Non-Ionic Contrast)	0.058 x 115	158
	0.058 x 132	141
	0.060 x 132	156
MD-76R (Ionic Contrast)	0.058 x 115	103
	0.058 x 132	91
	0.060 x 132	102

WARRANTY

Stryker Neurovascular warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Stryker Neurovascular's control directly affect the instrument and the results obtained from its use. Stryker Neurovascular's obligation under this warranty is limited to the repair or replacement of this instrument and Stryker Neurovascular shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Stryker Neurovascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Stryker Neurovascular assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.

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Do not use if package is damaged.

Recyclable Package

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