

AXS Offset™ Delivery Assist Catheter
RX ONLY

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

Intended use / indications for use

The AXS Offset Delivery Assist Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature.

Contraindications

None known.

Potential adverse events

Potential adverse events associated with the use of Delivery Assist Catheters or with the endovascular procedures include, but are not limited to:

- Access site complications
- Allergic reaction
- Aneurysm perforation
- Aneurysm rupture
- CNS Tissue Inflammation
- 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

Warnings

This device is intended for use only by physicians trained in performing endovascular procedures.

- Limited testing has been performed with saline. The use of this catheter for delivery of solutions (such as contrast media) is not recommended.
- Not intended for use with power injectors.
- Do not exceed pressures greater than 43.5 psi (300kPa) during clinical use of the device. Excessive pressures could result in a ruptured catheter or severed tip, causing vessel injury.
- Do not use catheter with stents, retrievers, occlusion coils, glue, glue mixture or non-adhesive liquid embolic agent.
- Carefully inspect all devices prior to use. Verify shape, size and condition are suitable for the specific procedure.
- Exchange catheters frequently during lengthy procedures that require extensive guidewire manipulation or multiple guidewire exchanges.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance could dislodge a clot, perforate a vessel wall, or damage catheter and guidewire. In severe cases, tip separation of the catheter or guidewire may occur.

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

Table 1. Compatibility information

Delivery Assist Catheter	Effective length	Outside Diameter in (mm) [F]	Delivery Assist Catheter ID in (mm)	Max Guidewire Dia. in (mm)
AXS Offset	150	0.050 (1.3) [3.8]	0.021 (0.5)	0.018 (0.46)

Cautions / precautions

- To reduce the probability of coating damage in tortuous vasculature, use a Distal Access Catheter with a minimum internal diameter as specified in Table 1 above.
- 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.
- To facilitate catheter handling, the proximal portion of the catheter does not have the hydrophilic surface. Greater resistance may be encountered when this section of the catheter is advanced into the RHV.
- Exercise care in handling of the catheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.
- Use the product prior to the “Use By” date printed on the label.