stryker®
Neurovascular

AXS Offset™

Delivery Assist Catheter

Stryker Neurovascular (DFU Template 8in x 8in Global), DFU, AXS Offset, EN, NV00024324-01A

AXS Offset™

Delivery Assist 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

Stryker Neurovascular AXS Offset Delivery Assist Catheter is a single lumen device designed to aid the physician in accessing distal vasculature when used with a distal access catheter and steerable guidewire. Graded shaft stiffness ranging from a highly flexible tip to a semi-rigid proximal section aids the physician in tracking over selectively placed guidewires. A luer fitting located on the catheter hub is used for the attachment of accessories. A radiopaque tip facilitates fluoroscopic visualization.

Stryker Neurovascular AXS Offset Delivery Assist Catheter is hydrophilically coated on the distal 80cm of the outer surface to reduce friction during manipulation in the vessel.

User Information

This device should only be used by physicians who have received appropriate training in interventional neuroradiology or interventional radiology and preclinical training on the use of this device as established by Stryker Neurovascular.

Contents:

One (1) Delivery Assist Catheter

Table 1. Compatibility Information

Delivery Assist Catheter	Effective Length (cm)	Outside Diameter in (mm) [F]	Delivery Assist Catheter ID in (mm)	Max Guidewire Dia. in (mm)	Min Distal Access Catheter Lumen Dia. in (mm)
AXS Offset	150	0.050 (1.3) [3.8]	0.021 (0.5)	0.018 (0.46)	0.058 (1.5)

AXS Offset Delivery Assist Catheter has been tested with Stryker Neurovascular's AXS Catalyst distal access catheters.

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.

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.

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.

ADVERSE EVENT INFORMATION

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

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 setup

Preparations For Use

Warning: Inspect product before use for any bends, kinks or damage. Do not use a Delivery Assist Catheter that has been damaged. Damaged catheters may rupture causing vessel trauma or tip detachment during steering maneuvers.

Caution: Flush dispenser coil and hydrophilically coated outer shaft of the Delivery Assist Catheter with saline prior to removal from packaging tray. Once the Delivery Assist Catheter has been wetted, do not allow to dry.

1. Set up continuous flush through an appropriately sized Distal Access Catheter.
2. Gently remove the catheter from pouch using standard sterile technique.
3. Gently remove the catheter from the dispenser coil and inspect the catheter prior to use to verify that it is undamaged.
4. Attach compatible RHV or Tuohy Borst valve based on intended procedure and associated devices, then flush RHV/Tuohy Borst valve and catheter lumen.
5. Set up continous flush through catheter.

Caution: Check that all fittings are secure so that air is not introduced into the Distal Access Catheter and Delivery Assist Catheter during continuous flush.

Caution: In order to achieve optimal performance of Stryker Neurovascular's delivery assist catheter and to maintain the lubricity of the Hydrolene® Coating surface, it is critical that a continuous flow of appropriate flush solution be maintained between the Stryker Neurovascular delivery assist catheter and distal access catheter, and the delivery assist catheter and any steerable guidewire. In addition, flushing aids in preventing contrast crystal formation and/or clotting on both the steerable guidewire and inside the distal access catheter and/or the delivery assist catheter lumen.

Caution: Do not extend the Delivery Assist Catheter tip more than 30cm from the Distal Access Catheter tip.

Directions For Use

1. Gently insert Delivery Assist Catheter tip through a compatible Distal Access Catheter over an appropriately sized guidewire.
2. Under fluoroscopic guidance, advance the Delivery Assist Catheter and Distal Access Catheter through the vasculature to the desired location.
3. Remove Delivery Assist Catheter.

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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