## Important Safety Information.

# AXS Lift
# Intracranial Base Catheter

**RX ONLY**

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

### Intended use/indications for use

The AXS Lift Intracranial Base Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

### Contraindications

Patients with a known allergy or intolerance to device materials of bovine origin.

### 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 (Hematoma or Hemorrhage at the puncture site, sterile Inflammation or Granulomas)
- Acute Vessel Occlusion
- Additional Surgical Intervention
- Air Embolism
- Allergic reactions to bovine derived materials
- Cerebral Embolism and Infarct
- Death
- Distal Embolization
- Emboli
- False Aneurysm Formation
- Infection
- Intracranial Hemorrhage
- Ischemia
- Neurological Deficit including Stroke, TIA
- Pulmonary Embolism and Infarct
- Tissue Necrosis, Transient or Long-lasting
- Vessel Spasm, Thrombosis, Dissection or Perforation

Use of the 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

### 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.

### Warnings

- Compatibility has been established for the delivery of saline, heparin solution, and non-ionic contrast with these catheters. The use of solutions other than those tested is not recommended.
- Not intended for use with power injectors.
- If flow through the catheter becomes restricted, do not attempt to clear the catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace the catheter.
- Do not advance or withdraw the Intracranial device against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device.
- The device is coated with a hydrophilic coating at the distal end of the device for a length of 17.5 cm. Please refer to the Instructions for Use section for further information on how to prepare and use this device to ensure it performs as intended.
- Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

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. Used product and any associated used materials should be handled and processed as biohazardous material.

### 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.
- Vasospasm may occur while the device is within the artery. Manipulations of the device may increase the risk of vasospasm.
- 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.
- Movement of the device against resistance could dislodge an embolus, perforate a vessel wall, or damage the device.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
- 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.
- The safety and effectiveness of the coated device has not been established, or is unknown, in vascular regions other than those specifically indicated.

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