

AXS Infinity LS™ Long Sheath

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

INTENDED USE/INDICATIONS FOR USE

The AXS Infinity LS Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

ADVERSE EVENTS

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

- Acute Vessel Occlusion
- Air Embolism
- Death
- Distal Embolization
- Emboli
- False Aneurysm Formation
- Hematoma or Hemorrhage at the puncture site
- Infection
- Intracranial Hemorrhage
- Ischemia
- Neurological Deficit including Stroke
- Vessel Spasm, Thrombosis, Dissection or Perforation

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.

WARNINGS

When the AXS Infinity LS Long Sheath is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the AXS Infinity LS Long Sheath if resistance is met during manipulation, determine the cause of the resistance before proceeding.

PRECAUTIONS

1. Do not use kinked, damaged, or open devices.
2. Use the AXS Infinity LS Long Sheath prior to the "Use By" date specified on the package.
3. Exposure to temperatures above 54°C (130°F) may damage device. Do not autoclave.
4. Torquing or moving the device against resistance may result in damage to the vessel or device.
5. Maintain a constant infusion of appropriate flush solution.
6. If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
7. Examine the AXS Infinity LS Long Sheath to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
8. The AXS Infinity LS Long Sheath should be used only by physicians trained in percutaneous procedures and/or interventional techniques.



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