AXS INFINITY LS™ PLUS
Long Sheath

Instructions for Use

℞ 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 Infinity LS Plus Long Sheath is a single lumen, flexible, variable stiffness long sheath with an 0.091 inch inner diameter. It has a radiopaque marker band on the distal end and a Luer hub at the proximal end. The AXS Infinity LS Plus Long Sheath shaft has a 10 cm lubricious coating at the distal end to reduce friction during use. The inner lumen of the AXS Infinity LS Plus Long Sheath is compatible with 6F or smaller catheters.

Each package includes one AXS Infinity LS Plus Long Sheath (INC-11196-70, INC-11196-80, or INC-11196-90), one Dilator, and one hemostasis valve. Dimensions of the AXS Infinity LS Plus Long Sheath are included on the individual device label.

INDICATIONS FOR USE

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

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

1. Do not re-sterilize or reuse, intended for single use only. Re-sterilization and/or reuse may result in cross contamination and/or reduced performance.
2. When the long sheath is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the long sheath if resistance is met during manipulation; determine the cause of the resistance before proceeding.

PRECAUTIONS

1. Store in a cool, dry, dark place.
2. Do not use kinked, damaged, or opened devices.

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

POTENTIAL ADVERSE EVENTS

- 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

DEVICE PREPARATION

1. Select the appropriately sized device based on procedure type and patient anatomy.
2. Grasp the hub and gently remove the AXS Infinity LS Plus Long Sheath from its protective tubing.
3. Inspect the product for kinks or other damage. If any damage is observed, replace with a new device.
4. Flush the inner lumen with saline and connect the Hemostasis valve to the hub of the Long Sheath.
   IF USING DILATOR:
   - Flush and wet the dilator with saline.
   - Insert the dilator completely into the Long Sheath.

DEVICE USAGE

5. Gain primary artery access using standard technique.
   IF NOT USING A SHORT SHEATH:
   - Advance the Long Sheath/dilator assembly over the guide wire and advance products into vasculature. Remove the dilator.

   IF USING A SHORT SHEATH:
   - Place an appropriately sized short sheath into the artery. Advance the Long Sheath over the guide wire into the short sheath and advance products into the vasculature.
6. Insert appropriately sized catheters as needed and advance products to the intended vascular site under fluoroscopic guidance.
7. When use of the AXS Infinity LS Plus Long Sheath is complete, remove the product using standard technique.
8. After use, the device may be a potential biohazard. Handle and dispose of product in accordance with facility protocol and applicable local, state, and federal laws and regulations.

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 affects 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.**

Legal Manufacturer

Manufactured for:
Stryker Neurovascular
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USA Customer Service 855-91 NEURO (916-3876)

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	Contents
	Recyclable Package