AXS Infinity LS™ Plus Long Sheath

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

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.

RX ONLY

CONTRAINDICATIONS

There are no known contraindications.

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

WARNINGS

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.

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.

AXS Vecta™ 71 Aspiration Catheter

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

INDICATIONS FOR USE

The AXS Vecta™ Aspiration System, including the AXS Vecta 71 Aspiration Catheter, Aspiration Tubing Set, and VC-701 Cliq Aspirator Pump, is indicated in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment.

RX ONLY

DEVICE DESCRIPTION

The AXS Vecta Aspiration System consists of the **AXS Vecta 71** Aspiration Catheter, the Aspiration Tubing Set, and the VC 701 Cliq Aspirator Pump.

The AXS Vecta 71 Aspiration Catheter is a single lumen, flexible, variable stiffness catheter. It has a radiopaque marker band on the distal end and a Luer hub at the proximal end. The AXS Vecta 71 Aspiration Catheter shaft has a lubricious coating at the distal end to reduce friction during use. The Scout Introducer may be used in conjunction with the AXS Vecta 71 Aspiration Catheter to facilitate in the introduction of the AXS Vecta 71 Aspiration Catheter into distal vasculature and aid in navigation to distal anatomy. The Scout Introducer has a lubricious coating at the distal end to reduce friction during use. The inner lumen of the AXS Vecta 71 Aspiration Catheters is compatible with the Scout Introducer, guide wires and micro catheters. The inner lumen of the Scout Introducer is compatible with guide wires and micro catheters of an outer diameter of less than 0.044in.

Each package includes one AXS Vecta 71 Aspiration Catheter, one Scout Introducer, one hemostasis valve, and two peel-away introducers. Dimensions of the AXS Vecta 71 Aspiration Catheter and Scout Introducer are included on the individual device label. The AXS Vecta 71 Aspiration Catheters are available in 3 different lengths, the device configurations including the length of the Scout packaged with each catheter and the recommended microcatheter length is presented in the table below.

Catheter part number	INC-11129-115	INC-11129-125	INC-11129-132
Catheter inner diameter (in)	0.071	0.071	0.071
Distal catheter outer diameter (in)	0.082	0.082	0.082
Catheter working length (cm)	115	125	132
Scout Introducer length (cm)	133	143	150
Recommended compatible microcatheter length (cm)	150	160	160
Recommended compatible microcatheter outer diameter (in)	0.044 max	0.044 max	0.044 max
Recommended compatible guidewire outer diameter (in)	0.038 max	0.038 max	0.038 max

The AXS Vecta Aspiration System is recommended for use in the following vessel size ranges based on non-clinical testing:

AXS Vecta 71 Aspiration Catheter	Vessel size (mm)
INC-11129-115	2-4
INC-11129-125	2-4
INC-11129-132	2-4

CONTRAINDICATIONS

The AXS Vecta 71 Aspiration Catheter has not been evaluated for use in the coronary vasculature. Do not use automated high-pressure contrast injection equipment with the AXS Vecta 71 Aspiration Catheter because it may damage the device.

POTENTIAL ADVERSE EVENTS

- Acute vessel occlusion
- Air embolism
- Allergic reaction and anaphylaxis from contrast media
- Arteriovenous fistula
- Death
- Device malfunction
- Distal embolization
- Emboli
- False aneurysm formation
- Hematoma or hemorrhage at the puncture site
- Inability to completely remove thrombus
- Infection
- Intracranial hemorrhage
- Ischemia
- Kidney damage from contrast media
- Neurological deficit including stroke
- Risks associated with angiographic and fluoroscopic radiation including but not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia
- Vessel spasm, thrombosis, dissection or perforation

WARNINGS

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker 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.

1. The AXS Vecta 71 Aspiration Catheter has not been evaluated for more than one (1) clot retrieval attempt.
2. The AXS Vecta 71 Aspiration Catheter was evaluated for an average duration of direct aspiration of 4 minutes.
3. This product is intended for single use only, do not re-sterilize or reuse. Re-sterilization and/or reuse may result in cross contamination and/or reduced performance.
4. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter if resistance is met during manipulation; determine the cause of the resistance before proceeding.
5. Operators should take all necessary precautions to limit x-radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying x-ray technical factors where possible.

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. Torqueing 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 Vecta Aspiration System should be used only by physicians trained in percutaneous procedures and/or interventional techniques.
10. The Scout Introducer should be used with a guidewire and microcatheter inserted when in vasculature.
11. If using the AXS Vecta Aspiration System for thrombectomy, monitor the canister fluid level and replace the canister if the fill level reaches 75% of the canister volume.
12. Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the American Stroke Association (ASA) guidelines.
13. Any neurological determination should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice.
14. As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.
15. Limit the usage of the AXS Vecta 71 Aspiration Catheter to arteries greater than the catheter's outer diameter.
16. Excessive aspiration with the distal tip of the AXS Vecta 71 Aspiration Catheter covered by the vessel wall may cause vessel injury. Carefully investigate location of the distal tip under fluoroscopy prior to aspiration.
17. There is an inherent risk with the use of angiography and fluoroscopy.
18. When transporting the VC-701 Cliq pump, utilize the pump handle.
19. Do not use if labeling is incomplete or illegible.

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

strykerneurovascular.com

Date of Release: SEP/2018

EX_EN_US