AXS Vecta™ Aspiration System

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 Vecta Aspiration System is composed of the following components:

- AXS Vecta 71 or 74 Aspiration Catheter
- Medela Dominant Flex Pump
- AXS Universal® Aspiration Tubing
- AXS Universal Liner Set

The AXS Vecta Aspiration Catheter delivers aspiration from the Medela Dominant Flex Pump (or equivalent vacuum pump) directly to the site of the occlusion to remove the clot. The AXS Vecta 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 Aspiration Catheter shaft has a lubricious hydrophilic coating at the distal end (distal 25cm) to reduce friction during use. It is packaged with one Scout Introducer, one hemostasis valve, and two peel-away introducers.

The Scout Introducer may be used in conjunction with the AXS Vecta Aspiration Catheter to facilitate in the introduction of the AXS Vecta Aspiration Catheter into distal vasculature and aid in navigation to distal anatomy. The Scout Introducer has a lubricious hydrophilic coating at the distal end to reduce friction during use. The inner lumen of the AXS Vecta Aspiration Catheter is compatible with the Scout Introducer, guide wires and microcatheters. The inner lumen of the Scout Introducer is compatible with guide wires and microcatheters of an outer diameter of less than 0.044in.

The AXS Universal Aspiration Tubing serves as a conduit to supply vacuum from the Medela Dominant Flex Pump (or equivalent vacuum pump) to the distal tip of the AXS Vecta Aspiration Catheter. The AXS Universal Aspiration Tubing provides a connection between the sterile and non-sterile environments. The proximal end of the AXS Universal Aspiration Tubing is connected to the AXS Universal Liner Set (outside of the sterile environment) while the distal end of the AXS Universal Aspiration Tubing is connected to the AXS Vecta Aspiration Catheter (inside the sterile environment). The AXS Universal Liner Set is connected to the Medela Dominant Flex Pump (also outside of the sterile environment).

The Medela Dominant Flex Pump (or equivalent vacuum pump) is designed to generate vacuum for the AXS Vecta Aspiration System. When used as part of the AXS Vecta Aspiration System, the AXS Vecta Aspiration Catheter requires a minimum vacuum pressure of -68 kPa [-20.08 in Hg] [-510 mmHg] from the Medela Dominant Flex Pump (or equivalent vacuum pump). The Medela Dominant Flex Pump is reusable, non-sterile, and intended to be utilized outside of the sterile environment.

The AXS Universal Liner Set is provided non-sterile and consists of an individually packaged canister liner and a ClotFinder specimen cup. The AXS Universal Liner Set is offered with and without a desiccant. The AXS Universal Liner Set is single-use and the repository for aspirated material.

User information

The AXS Vecta Aspiration System should only be used by physicians trained in interventional endovascular procedures.

Contents

One (1) AXS Vecta Aspiration Catheter

One (1) Scout Introducer

One (1) Hemostasis Valve

Two (2) Peel-away introducer sheaths

Dimensions of the AXS Vecta Aspiration Catheter and Scout Introducer are included on the individual device label. The AXS Vecta 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 1.0 below.

Table 1.0

Catheter Part Number	Catheter Inner Diameter mm (in)	Distal Catheter Outer Diameter mm (in)	Proximal Catheter Outer Diameter mm (in)	Catheter Working Length (cm)	Scout Introducer Inner Diameter mm (in)	Scout Introducer Outer Diameter mm (in)	Scout Introducer Length (cm)
INC-11129-115	1.80 (0.071)	2.09 (0.082)	2.16 (0.085)	115	1.12 (0.044)	1.48 (0.058)	133
INC-11129-125	1.80 (0.071)	2.09 (0.082)	2.16 (0.085)	125	1.12 (0.044)	1.48 (0.058)	143
INC-11129-132	1.80 (0.071)	2.09 (0.082)	2.16 (0.085)	132	1.12 (0.044)	1.48 (0.058)	150
INC-11597-115	1.88 (0.074)	2.11 (0.083)	2.21 (0.087)	115	1.12 (0.044)	1.48 (0.058)	133
INC-11597-125	1.88 (0.074)	2.11 (0.083)	2.21 (0.087)	125	1.12 (0.044)	1.48 (0.058)	143
INC-11597-132	1.88 (0.074)	2.11 (0.083)	2.21 (0.087)	132	1.12 (0.044)	1.48 (0.058)	150

Do not use the AXS Vecta Aspiration Catheter in vessel diameters that are less than or are the same as the distal outer diameter of the catheter to avoid vessel injury, dissection, or perforation.

INTENDED USE/INDICATIONS FOR USE

The AXS Vecta Aspiration Catheter, as part of the AXS Vecta Aspiration System, 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.

CONTRAINDICATIONS

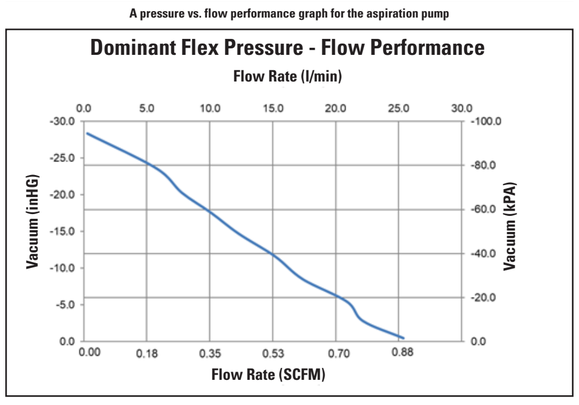
Do not use the AXS Vecta Aspiration Catheter in the coronary vasculature.

Do not use automated high-pressure contrast injection equipment with the AXS Vecta Aspiration Catheter because it may damage the device.

WARNINGS

- Do not use kinked, damaged, or opened devices.
- Exposure to temperatures above 54°C (130°F) may damage device. Do not autoclave.
- Torqueing or moving the device against resistance may result in damage to the vessel or device.
- The AXS Vecta Aspiration Catheter has not been evaluated for more than one (1) clot retrieval attempt.
- The AXS Vecta Aspiration Catheter was evaluated for an average duration of direct aspiration of 4 minutes.
- 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.
- 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.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- This device is coated with a hydrophilic coating at the distal end of the device for a length of 25 cm. Please refer to the Device Preparation 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.
- Verify aspiration pump is appropriate before use if using a vacuum pump other than the Medela Dominant Flex Pump. The AXS Vecta Aspiration Catheters have been verified for use with the Medela Dominant Flex Pump and AXS Universal Aspiration Tubing. The Medela Dominant Flex Pump is capable of delivering vacuum pressures between -20.08 inHg and -28 inHg [[-68 kPa to -95 kPa] [-510 mmHg to -713 mmHg]] during use and is characterized by the pressure-flow performance curve below. If using another vacuum pump other than the Medela Dominant Flex Pump, carefully review the vacuum pump performance parameters to ensure it is equivalent and can achieve the same operating vacuum pressures between -20.08 inHg and -28 inHg [[-68 kPa to -95 kPa] [-510 mmHg to -713 mmHg]] and corresponds to the same flow rate ranges (see pump pressure-flow performance graph). The vacuum pump should also be verified to be compatible with the AXS Universal Aspiration Tubing.
- Limit the usage of the AXS Vecta Aspiration Catheter to arteries greater than the catheter's outer diameter.

A pressure vs. flow performance graph for the aspiration pump



PRECAUTIONS

- Use the device prior to the "Use By" date specified on the package.
- Maintain a constant infusion of appropriate flush solution.
- 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.
- The AXS Vecta Aspiration System should be used only by physicians trained in percutaneous procedures and/or interventional techniques.
- The Scout Introducer should be used with a guidewire and Microcatheter inserted when in vasculature.
- 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.
- Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.
- Any neurological determination should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice.
- As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.
- Excessive aspiration with the distal tip of the AXS Vecta Aspiration Catheter covered by the vessel wall may cause vessel injury. Carefully investigate location of the distal tip under fluoroscopy prior to aspiration.
- There is an inherent risk with the use of angiography and fluoroscopy.
- 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.
- When transporting the Medela Dominant Flex Pump, utilize the pump handle.

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
- 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
- Sterile inflammation or granulomas at the access site
- Tissue necrosis
- Vessel Spasm, Thrombosis, Dissection or Perforation

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

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.

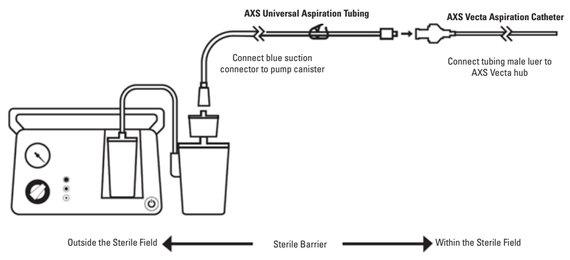
OPERATIONAL INSTRUCTIONS

Preparation for Use

1. Select the appropriately sized device based on procedure type and patient anatomy. The AXS Vecta Aspiration Catheter has been evaluated for clot removal in vessels with sizes of 2.1 – 4 mm for the AXS Vecta 71 Aspiration Catheter and 2.2 -4 mm for the AXS Vecta 74 Aspiration Catheter in non-clinical animal studies.
2. Flush both hoops with sufficient saline to fill the hoop until saline is observed exiting the opposite end of each hoop. This action ensures proper activation of the hydrophilic coating.
3. It is recommended that the devices remain in the flushed hoops until they are ready to be used and then used immediately upon removal. Removal of the units from the hoops prior to activating the coating may damage the hydrophilic coating. Not using the devices immediately after removing them from the hoops may also damage the coating.
4. Remove both the AXS Vecta Aspiration Catheter and Scout Introducer (if using) from the hoop by grasping the hub and gently removing it from the protective tubing.
5. Inspect both the AXS Vecta Aspiration Catheter and Scout Introducer (if using) for kinks or other damage. If any damage is observed, replace with new device.
6. If using, flush the inner lumen of the Scout Introducer with saline and attach continuous flush, some leaking is normal.
7. Connect a hemostasis valve to the hub of the AXS Vecta Aspiration Catheter, flush the inner lumen with saline, and attach continuous flush.
8. Attach the AXS Universal Aspiration Tubing to the Medela Dominant Flex Pump and ensure the aspiration control valve on the tubing is closed. Turn on the Medela Dominant Flex Pump (refer to the Medela Dominant Flex Pump manual). Confirm that the Medela Dominant Flex Pump reads -68 kPa to -95 kPa [-510 mmHg to -713 mmHg] [-20.08 inHg and -28 inHg] (tolerance +/- 15%). Keep the pump on and control aspiration using the aspiration tubing clamp on the AXS Universal Aspiration Tubing.

DIRECTIONS FOR USE

1. Gain primary artery access using a compatible sheath/guide catheter (0.088 inch inner diameter or larger for the AXS Vecta 71 Aspiration Catheter and 0.091 inch inner diameter for the AXS Vecta 74 Aspiration Catheter).
2. Obtain roadmap of target anatomy.
3. Gently insert a microcatheter and/or guidewire into the Scout Introducer (if using) or directly into the AXS Vecta Aspiration Catheter. If using the Scout Introducer, load the assembly into the AXS Vecta Aspiration Catheter.
4. If using, place the peel-away introducer on the distal section of the AXS Vecta Aspiration Catheter, insert the assembly into the sheath or guide catheter, and remove the peel-away introducer by pulling the two wings apart.
5. Under fluoroscopic guidance, advance the Scout Introducer (if using) and AXS Vecta Aspiration Catheter over a microcatheter and/or guide wire to the intended vascular site or just proximal to the clot.
6. If an additional manual contrast injection is necessary, such as for visualization, remove the Scout Introducer (if using).
7. Verify the position of the AXS Vecta Aspiration Catheter tip prior to starting aspiration. Once the distal end of the AXS Vecta Aspiration Catheter is in position, remove the delivery catheter and/or guidewire.
8. If aspirating through the RHV/Tuohy Borst, tighten valve to prevent backflow.
9. Ensure the AXS Universal Aspiration Tubing clamp is closed (within the sterile field).
10. Connect the AXS Universal Aspiration Tubing to the side port of the rotating hemostasis valve or directly to the catheter hub of the AXS Vecta Aspiration Catheter. To start aspiration, open the aspiration tubing clamp.



11. Advance the catheter towards the clot and continue to aspirate until the clot is withdrawn.
12. If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove catheter under aspiration and flush catheter outside of patient. If flush is unsuccessful, replace catheter.
13. When use of the device is complete, remove the device using standard technique.
14. 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 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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