Aspiration catheter

Compatibility chart

Delivery catheter compatibility with ledge effect

The ledge effect is defined as the difference between the outer diameter of the smaller catheter and the inner diameter of the larger catheter at the tip.

				Medium-bore aspiration catheters					Large-bore aspiration catheters										Extra-large-bore aspiration catheters	
				JET D	AXS Catalyst 5* Distal Access Catheter	AXS Catalyst 6* Distal Access Catheter	5Max ACE	ACE 64	AXS Catalyst 7 Distal Access Catheter		ACE 68	React 68	Sofia Flow Plus		React 71	AXS Vecta 71* Aspiration Catheter		JET 7	AXS Vecta 74* Aspiration Catheter	
		Distal ID		0.054	0.058	0.060	0.060	0.064	0.068		0.068	0.068	0.070		0.071	0.0715		0.072	0.074	
		Proximal ID		0.064	0.058	0.060	0.068	0.068	0.068		0.068	0.068	0.070		0.071	0.0715		0.072	0.074	
	Maximum OD (in)	**Length (cm)**		138	132	132	132	132	125	132	132	132	125	131	132	125	132	132	125	132
Delivery catheters	Excelsior XT-27 Microcatheter	0.038	150		11	11	7	7	14	7	7	7	14	8	7	19	12	7	19	12
	Velocity	0.040	160	11	21	21	17	17	24	17	17	17	24	18	17	29	22	17	29	22
	Phenom 27	0.040	150		11	11	7	7	14	7	7	7	14	8	7	19	12	7	19	12
	Marksman 027	0.040	160	11	21	21	17	17	24	17	17	17	24	18	17	29	22	17	29	22
	Trevo Trak 21 Microcatheter	0.040	162	13	23	23	19	19	16	19	19	19	26	20	19	31	24	19	31	24
	AXS Offset Delivery Assist Catheter	0.050	150		11	11	7	7	14	7	7	7	14	8	7	19	12	7	19	12
	3MAX	0.062	153					10	17	10	10	10	17	11	10	22	15	10	22	15

Small ledge effect

ID/OD difference <0.020in

Smaller gap helps navigate past branching arteries

Large ledge effect

ID/OD difference ≥0.020in

Gap may cause catching on branching arteries

Not compatible
Does not fit and/or working length <5cm

- Colors illustrate compatibility
- Numbers illustrate delivery catheter working length (cm)

Length measurement assumes 4cm hub + strain relief and 7cm RHV.
*Instead of 7cm RHV, 2cm Tuohy-Borst used in the length calculation.
AXS Catalyst 5 and 6 Distal Access Catheters have a 5cm hub + strain relief.

Long sheath and balloon guide catheter compatibility

				Medium-bore aspiration catheters					Large-bore aspiration catheters							Extra-large-bore aspiration catheters
				JET D	AXS Catalyst 5 Distal Access Catheter	AXS Catalyst 6 Distal Access Catheter	5Max ACE	ACE 64	Sofia Flow Plus	AXS Catalyst 7 Distal Access Catheter	AXS Vecta 71 Aspiration Catheter	React 68	ACE 68	JET 7	React 71	AXS Vecta 74 Aspiration Catheter
		Distal OD (in)		0.065	0.069	0.071	0.074	0.080	0.082	0.082	0.082	0.083	0.084	0.085	0.0855	0.083
		Proximal OD (in)		0.080	0.073	0.079	0.083	0.084	0.083	0.0825	0.085	0.083	0.084	0.085	0.0855	0.087
	Distal ID (in)	**Length (cm)**		138	132	132	132	132	125, 131	125, 132	125, 132	132	132	132	132	125, 132
Sheaths and balloon guide catheters	8F Cello Balloon Guide Catheter	0.075	95		0.002											
	8F Merci Balloon Guide Catheter	0.078	80, 95		0.005											
	8F FlowGate[2] Balloon Guide Catheter	0.084	85, 95	0.004	0.011	0.005	0.001			0.0015		0.001				
	9F Merci Balloon Guide Catheter	0.085	80, 95	0.005	0.012	0.006	0.002	0.001	0.002	0.0025		0.002	0.001			
	9F Cello Balloon Guide Catheter	0.085	90	0.005	0.012	0.006	0.002	0.001	0.002	0.0025		0.002	0.001			
	6F Shuttle Sheath	0.087	80, 90	0.007	0.014	0.008	0.004	0.003	0.004	0.0045		0.004	0.003	0.002	0.0015	
	Neuron Max 088	0.088	80, 90	0.008	0.015	0.009	0.005	0.004	0.005	0.0055	0.003	0.005	0.004	0.003	0.0025	
	AXS Infinity LS Long Sheath	0.088	70, 80, 90	0.008	0.015	0.009	0.005	0.004	0.005	0.055	0.003	0.005	0.004	0.003	0.0025	
	AXS Infinity LS Plus Long Sheath	0.091	70, 80, 90	0.011	0.018	0.012	0.008	0.007	0.008	0.0085	0.006	0.008	0.007	0.006	0.0055	0.004
	7F Shuttle Sheath	0.100	80,90	0.020	0.027	0.021	0.017	0.016	0.017	0.0175	0.015	0.017	0.016	0.015	0.0145	0.013

Fully compatible
Easy delivery with room for contrast/drip (≥0.006in ID/OD gap)

Limited compatibility
Tight fit and/or limited room for contrast/drip (<0.006in ID/OD gap)

Not compatible

- Colors illustrate compatibility
- Numbers illustrate remaining lumen space (in)

AXS Vecta Aspiration System

RX ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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

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.

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 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 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 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] from the Medela Dominant Flex 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.

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.

Catheter part number	INC-11129-115	INC-11129-125	INC-11129-132	INC-11597-115	INC-11597-125	INC-11597-132
Catheter inner diameter (in)	0.071	0.071	0.071	0.074	0.074	0.074
Distal catheter outer diameter (in)	0.082	0.082	0.082	0.083	0.083	0.083
Catheter working length (cm)	115	125	132	115	125	132
Scout Introducer length (cm)	133	143	150	133	143	150
Recommended compatible microcatheter length (cm)	150	160	160	150	160	160
Recommended compatible microcatheter outer diameter (in)	0.044 max	0.044 max	0.044 max	0.044 max	0.044 max	0.044 max
Recommended compatible guidewire outer diameter (in)	0.038 max	0.038 max	0.038 max	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. Refer to Table 2.0 below.

AXS Vecta Aspiration Catheter	Catheter part number	Vessel size in mm (Vessel size in inches)
AXS Vecta 71	INC-11129-115	2.1-4mm (0.083in – 0.157in)
	INC-11129-125	2.1-4 mm (0.083in – 0.157in)
	INC-11129-132	2.1-4 mm (0.083in – 0.157in)
AXS Vecta 74	INC-11597-115	2.2-4 mm (0.087in – 0.157in)
	INC-11597-125	2.2-4 mm (0.087in – 0.157in)
	INC-11597-132	2.2-4 mm (0.087in – 0.157in)

Contraindications

The AXS Vecta 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 Aspiration Catheter because it may damage the device.

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

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

- 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.
- 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.
- 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.

Precautions

- Do not use kinked, damaged, or opened devices.
- Use the device prior to the "Use By" date specified on the package.
- 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.
- Maintain a constant infusion of appropriate flush solution.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- 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.
- Limit the usage of the AXS Vecta Aspiration Catheter to arteries greater than the catheter's outer diameter.
- 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.
- When transporting the Medela Dominant Flex Pump, utilize the pump handle.

AXS Offset Delivery Assist Catheter

RX ONLY

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

Intended use/indications for use

The AXS Offset Delivery Assist Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature.

Contraindications

None known.

Adverse event information

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

Access site complications, Allergic reaction, Aneurysm perforation, Aneurysm rupture, CNS Tissue Inflammation, Death, Embolism (air, foreign body, plaque, thrombus), Hematoma, Hemorrhage, Infection, Ischemia, Neurological deficits, Pseudoaneurysm, Stroke, Transient Ischemic Attack, Vasospasm, Vessel dissection, Vessel occlusion, Vessel perforation, Vessel rupture, Vessel thrombosis

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.

This device should only be used by physicians who have received appropriate training in interventional neuroradiology or interventional radiology and preclinical training on the use of this device as established by Stryker Neurovascular.

This device is intended for use only by physicians trained in performing endovascular procedures.

Limited testing has been performed with saline. The use of this catheter for delivery of solutions (such as contrast media) is not recommended.

Not intended for use with power injectors.

Do not exceed pressures greater than 43.5 psi (300kPa) during clinical use of the device. Excessive pressures could result in a ruptured catheter or severed tip, causing vessel injury.

Do not use catheter with stents, retrievers, occlusion coils, glue, glue mixture or non-adhesive liquid embolic agent.

Carefully inspect all devices prior to use. Verify shape, size and condition are suitable for the specific procedure.

Exchange catheters frequently during lengthy procedures that require extensive guidewire manipulation or multiple guidewire exchanges.

Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance could dislodge a clot, perforate a vessel wall, or damage catheter and guidewire. In severe cases, tip separation of the catheter or guidewire may occur.

Inspect product before use for any bends, kinks or damage. Do not use a Delivery Assist Catheter that has been damaged. Damaged catheters may rupture causing vessel trauma or tip detachment during steering maneuvers.

Cautions/precautions

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

To reduce the probability of coating damage in tortuous vasculature, use a Distal Access Catheter with a minimum internal diameter as specified in Table 1 above.

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.

To facilitate catheter handling, the proximal portion of the catheter does not have the hydrophilic surface. Greater resistance may be encountered when this section of the catheter is advanced into the RHV.

Exercise care in handling of the catheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.

Use the product prior to the "Use By" date printed on the label.

Flush dispenser coil and hydrophilically coated outer shaft of the Delivery Assist Catheter with saline prior to removal from packaging tray. Once the Delivery Assist Catheter has been wetted, do not allow to dry.

Check that all fittings are secure so that air is not introduced into the Distal Access Catheter and Delivery Assist Catheter during continuous flush.

In order to achieve optimal performance of Stryker Neurovascular's delivery assist catheter and to maintain the lubricity of the Hydrolene Coating surface, it is critical that a continuous flow of appropriate flush solution be maintained between the Stryker Neurovascular delivery assist catheter and distal access catheter, and the delivery assist catheter and any steerable guidewire. In addition, flushing aids in preventing contrast crystal formation and/or clotting on both the steerable guidewire and inside the distal access catheter and/or the delivery assist catheter lumen.

Do not extend the Delivery Assist Catheter tip more than 30cm from the Distal Access Catheter tip.

Excelsior XT-27 Microcatheter

RX ONLY

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

Intended use / indications for use

Stryker Neurovascular Excelsior XT-27 Microcatheter is intended to assist in the delivery of diagnostic agents (such as contrast media), therapeutic agents, and non-liquid interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.

Contraindications

None known.

Potential adverse events

Potential adverse events associated with the use of microcatheters or with the endovascular procedures include, but are not limited to: access site complications, allergic reaction, aneurysm perforation, aneurysm rupture, death, embolism (air, foreign body, plaque, thrombus), hematoma, hemorrhage, infection, ischemia, neurological deficits, pseudoaneurysm, stroke, transient ischemic attack, vasospasm, vessel dissection, vessel occlusion, vessel perforation, vessel rupture, vessel thrombosis.

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.
- These devices should only be used by physicians who have received appropriate training in interventional neuroradiology.
- Limited testing has been performed with solutions such as contrast media, interventional devices such as stents, and therapeutic agents such as PVA particles. The use of these catheters for delivery of products other than the types that have been tested for compatibility is not recommended.
- Do not use catheter with glue, glue mixture or non-adhesive liquid embolic agent.
- The accessories are not intended for use inside the human body.
- Carefully inspect all devices prior to use. Verify shape, size and condition are suitable for the specific procedure.
- Exchange microcatheters frequently during lengthy procedures that require extensive guidewire manipulation or multiple guidewire exchanges.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance could dislodge a clot, perforate a vessel wall, or damage microcatheter and guidewire. In severe cases, tip separation of the microcatheter or guidewire may occur.
- Inspect product before use for any bends, kinks or damage. Do not use a microcatheter that has been damaged. Damaged microcatheters may rupture causing vessel trauma or tip detachment during steering maneuvers.
- Shaping mandrel is not intended for use inside the human body.
- Discontinue use of microcatheter for infusion if increased resistance is noted. Resistance indicates possible blockage. Remove and replace blocked microcatheter immediately. DO NOT attempt to clear blockage by over-pressurization. Doing so may cause the microcatheter to rupture, resulting in vascular damage or patient injury.
- Do not exceed 2,070 kPa (300 psi) infusion pressure. Excessive pressure could dislodge a clot, causing thromboemboli, or could result in a ruptured microcatheter or severed tip, causing vessel injury.

Cautions / precautions

- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- To facilitate microcatheter handling, the proximal portion of the microcatheter does not have the hydrophilic surface. Greater resistance may be encountered when this section of the microcatheter is advanced into the RHV.
- Exercise care in handling of the microcatheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.
- To control the proper introduction, movement, positioning and removal of the microcatheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- Use the product prior to the "Use By" date printed on the label.
- Flush dispenser coil of hydrophilically coated microcatheters prior to removal from dispenser coil. Once the microcatheter has been wetted, do not allow to dry. Do not reinsert the microcatheter into dispenser coil.
- Check that all fittings are secure so that air is not introduced into guide catheter or microcatheter during continuous flush.
- In order to achieve optimal performance of Stryker Neurovascular Microcatheters and to maintain the lubricity of the Hydrolene Coating surface, it is critical that a continuous flow of appropriate flush solution be maintained between the Stryker Neurovascular Microcatheter and guide catheter, and the microcatheter and any intraluminal device. In addition, flushing aids in preventing contrast crystal formation and/or clotting on both the intraluminal device and inside the guide catheter and/or the microcatheter lumen.
- Do not position microcatheter tip closer than 2.54 cm (1 in) from the steam source. Damage to the microcatheter tip may result.
- Excessive tightening of a hemostatic valve onto the microcatheter shaft may result in damage to the microcatheter. Removing the peel-away introducer sheath without a guidewire inserted in the microcatheter lumen might result in damage to the microcatheter shaft.

AXS Catalyst Distal Access Catheter

RX ONLY

See Directions For Use for complete indications, contraindications, warnings and directions for use.

NOTE: This Catheter has two separate indications for use. Read the Directions For Use carefully.

Indication for use as a conduit

The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.

Indication for use as a revascularization device

The AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in 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 are candidates for treatment.

Device description

The AXS Catalyst Distal Access Catheter is a single lumen, variable stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into the peripheral and neurovascular system. The catheter shaft has a hydrophilic coating to reduce friction during use. The catheter includes a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end allowing attachments for flushing and aspiration. It is packaged with a Rotating Hemostasis Valve (RHV) and Tuohy Borst valve with sideport for flushing, insertion of catheters and aspiration. The peel away introducer sheaths are designed to protect the distal tip of the catheter during insertion into the RHV or Tuohy Borst.

Additional device description when used as a revascularization device

The AXS Universal Aspiration System is composed of the following components:

- AXS Catalyst Distal Access Catheter
- AXS Universal Aspiration Tubing
- Medela Dominant Flex Pump
- AXS Universal Liner Set

The AXS Universal Aspiration System is designed to remove thrombus from the neurovasculature using continuous aspiration.

The AXS Catalyst Distal Access Catheter delivers aspiration from the Medela Dominant Flex Pump directly to the site of the occlusion to remove the clot. The AXS Catalyst Distal Access Catheter is the only component of the AXS Universal Aspiration System that is used intravascularly.

The AXS Universal Aspiration Tubing serves as a conduit to supply vacuum from the Medela Dominant Flex Pump to the distal tip of the AXS Catalyst Distal Access 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 Catalyst Distal Access 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 is designed to generate vacuum for the AXS Universal Aspiration System. When used as part of the AXS Universal Aspiration System, the AXS Catalyst Distal Access Catheter requires a minimum vacuum pressure of -68 kPa [-20.08 in Hg] from the Medela Dominant Flex 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.

Contraindications

None known.

Potential 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 • Allergic reaction • Aneurysm perforation • Aneurysm rupture • Death • Embolism (air, foreign body, plaque, thrombus) • Hematoma • Hemorrhage • Infection • Ischemia • Neurological deficits • Pseudoaneurysm • Stroke • Transient Ischemic Attack • Vasospasm • Vessel dissection • Vessel occlusion • Vessel perforation • Vessel rupture • Vessel thrombosis

Use of 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

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. The AXS Catalyst Distal Access Catheter is 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.
- Limited testing has been performed with solutions such as contrast media, and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.
- Not intended for use with power injectors.
- 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 and replace catheter.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could dislodge a clot, perforate a vessel wall, or damage the device.

Additional warning for revascularization indication only

- Excessive aspiration may cause patient complications.

Precautions

- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Ensure the catheter's labeled outer diameter is smaller than the treatment vessel diameter. Do not use a device that has been damaged in any way. Damaged device may cause complications.
- 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.
- 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.

Additional precaution for conduit indication only

- Limit use of the AXS Catalyst Distal Access Catheters with retrievers to three (3) retriever attempts per catheter.

FlowGate² Balloon Guide Catheter

RX ONLY

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

Indications for use

FlowGate² Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Possible complications include, but are not limited to, the following: infection, hematoma, distal embolization, vessel thrombosis, dissection, false aneurysm formation, acute occlusion, clot formation, hemorrhage at the puncture site, intracranial hemorrhage, arterial rupture, stroke and death.

Compatibility

Introducer sheath French size must be greater than or equal to balloon guide catheter French size.

Warnings

- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance or torque catheter against resistance without careful assessment of cause of resistance using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- To reduce risk of complications due to slow balloon deflation, adhere to the following recommendations:
  - Wet distal shaft with saline before passing into introducer sheath.
  - Minimize pushing forces on shaft during advancement. These forces can cause wrinkles in shaft that can slow balloon deflation.
  - Do not use device if shaft is damaged during use.
  - Prepare balloon according to Recommended Procedure.
- To reduce risk of complications due to air emboli, remove air from balloon according to Recommended Procedure.
- Withdrawing balloon through introducer sheath may damage balloon. Do not use catheter again after withdrawing balloon through introducer sheath.
- To avoid balloon leakage, do not allow balloon to contact calcified or stented arteries and do not allow balloon to move during inflation.
- Do not use a device that has been damaged. Use of damaged devices may result in complications.
- Do not exceed maximum recommended balloon inflation volume. Excess inflation volume may rupture balloon.
- For through-lumen, do not exceed 1896 kPa (275 psi) maximum recommended infusion pressure. Excess pressure may result in catheter rupture or tip detachment.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter.
- Do not steam shape guide catheter.

Precautions

- Store in a cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Upon removal from package, inspect device to ensure it is not damaged.
- Do not expose device to solvents.
- Use device in conjunction with fluoroscopic visualization and proper anti-coagulation agents.
- Torquing guide catheter while kinked may cause damage that could result in separation of catheter shaft.
- If a device becomes lodged in guide catheter, or if guide catheter becomes severely kinked, withdraw entire system (guide catheter, guidewire and catheter sheath introducer).
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through guide catheter lumen.

Merci Balloon Guide Catheter

RX ONLY

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

Indications for use

Merci Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Possible complications include, but are not limited to, the following: infection, hematoma, distal embolization, vessel thrombosis, dissection, false aneurysm formation, acute occlusion, clot formation, hemorrhage at the puncture site, intracranial hemorrhage, arterial rupture, stroke and death.

Compatibility

Introducer sheath French size must be greater than or equal to balloon guide catheter French size.

Warnings

- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance or torque catheter against resistance without careful assessment of cause of resistance using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- To reduce risk of complications due to slow balloon deflation, adhere to the following recommendations:
  - Wet distal shaft with saline before passing into introducer sheath.
  - Minimize pushing forces on shaft during advancement. These forces can cause wrinkles in shaft that can slow balloon deflation.
  - Do not use device if shaft is damaged during use.
  - Prepare balloon according to Recommended Procedure.
- To reduce risk of complications due to air emboli, remove air from balloon according to Recommended Procedure.
- Withdrawing balloon through introducer sheath may damage balloon. Do not use catheter again after withdrawing balloon through introducer sheath.
- To avoid balloon leakage, do not allow balloon to contact calcified or stented arteries and do not allow balloon to move during inflation.
- Do not use a device that has been damaged. Use of damaged devices may result in complications.
- Do not exceed maximum recommended balloon inflation volume. Excess inflation volume may rupture balloon.
- For through-lumen, do not exceed 1896 kPa (275 psi) maximum recommended infusion pressure. Excess pressure may result in catheter rupture or tip detachment.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter.
- Do not steam shape guide catheter.

Precautions

- Store in a cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Upon removal from package, inspect device to ensure it is not damaged.
- Do not expose device to solvents.
- Use device in conjunction with fluoroscopic visualization and proper anti-coagulation agents.
- Torquing guide catheter while kinked may cause damage that could result in separation of catheter shaft.
- If a device becomes lodged in guide catheter, or if guide catheter becomes severely kinked, withdraw entire system (guide catheter, guidewire and catheter sheath introducer).
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through guide catheter lumen.

AXS Infinity LS Long Sheath and AXS Infinity LS Plus Long Sheath

RX ONLY

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.

Trevo Trak 21 Microcatheter

RX ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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

Intended use/indications for use

The Microcatheter is indicated for use in the selective placement of devices and/or fluids, such as contrast media, into the peripheral, coronary, and neuro vasculature during diagnostic and/or therapeutic procedures.

Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Possible complications include, but are not limited to the following: death, emboli, hematoma at the puncture site, hemorrhage, ischemia, neurological deficits including stroke, vasospasm, vessel perforation.

Use of 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.

Compatibility

Refer to product label for device dimensions. Refer to labeling provided with other medical technologies to determine compatibility.

- Minimum recommended guide catheter inner diameter: 0.058in (1.47mm)
- Maximum recommended guide wire outer diameter: 0.018in (0.46mm)

Warnings

- Contents supplied STERILE using an ethylene oxide (EO) process. Nonpyrogenic.
- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance catheter against resistance without careful assessment of cause using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- Do not use device that has been damaged in any way. Damaged device may cause complications.
- Do not exceed maximum recommended infusion pressure. Excess pressure may result in catheter rupture or tip severance.

Catheter	Maximum Infusion Pressure
Trevo Trak 21 MC	1034 kPa (150 psi)

Precautions

- Prescription only – device restricted to use by or on order of a physician.
- Store in cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Upon removal from package, inspect device to ensure it is not damaged.
- Do not expose device to organic solvents.
- Use device with fluoroscopic visualization and proper anti-coagulation agents.
- Hydrate microcatheter with saline for 2 minutes minimum before use. Once hydrated, do not allow it to dry.
- To maintain hydrophilic coating lubricity, provide continuous flow of appropriate solution between microcatheter and guide catheter.
- Hemostatic side-arm adapters may be used to provide seal around guidewire and microcatheter.
- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.
- 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.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter.

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