Surpass Streamline™ Flow Diverter

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

INTENDED USE / INDICATIONS FOR USE

The Surpass Streamline Flow Diverter is indicated for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥ 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 5.3 mm.

CONTRAINDICATIONS

The Surpass Streamline Flow Diverter is contraindicated in the following patient types:

- Patients in whom the parent vessel size does not fall within the indicated range.
- Patients in whom antiplatelet and / or anticoagulation therapy (e.g., aspirin and clopidogrel) is contraindicated.
- Patients who have not received dual anti-platelet agents prior to the procedure.
- Patients with an active bacterial infection.
- Patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment due to conditions such as:
  - Severe intracranial vessel tortuosity or stenosis; and/or
  - Intracranial vasospasm not responsive to medical therapy.

POTENTIAL ADVERSE EVENTS

Risks that may be associated with the use of the Surpass Flow Diverter in the intracranial arteries include:

- Allergic reaction
- Adverse reaction to anesthesia, contrast or antiplatelet/ anticoagulation agents
- Aphasia
- Cardiac arrhythmia
- Cranial neuropathy
- Confusion, coma, change in mental status
- Death
- Device migration, fracture, misplacement
- Dissection or perforation of the parent artery
- Embolism (air, clots, device fragments)
- Groin injury (bleeding, pain, vessel/nerve damage)
- Headache
- Hemiplegia
- Hydrocephalus
- Implant or parent vessel stenosis
- Implant thrombosis/occlusion
- Infection
- Intracerebral bleeding
- Mass effect
- Myocardial infarction
- Neurological deficits
- Perforation or rupture of aneurysm
- Progressive neurologic symptoms related to intracranial aneurysm (IA)
- Pseudoaneurysm formation
- Reaction to radiation exposure (i.e., alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, delayed neoplasia)
- Renal failure
- Retroperitoneal hematoma
- Seizure
- Stroke
- Subarachnoid hemorrhage
- Thromboembolism from device
- Thrombosis of parent artery or branch vessel
- Transient ischemic attack (TIA)
- Vasospasm

Risks that are eye related with the use of the Surpass Flow Diverter may include:

- Amaurosis fugax/transient blindness
- Blindness
- Diplopia
- Reduced visual acuity/field
- Retinal artery occlusion
- Retinal ischemia
- Retinal infarction
- Vision impairment

WARNINGS

- 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.
- Do not use if the package is opened or damaged.
- Persons allergic to nickel, cobalt chromium or platinum tungsten metal may suffer an allergic response to this Flow Diverter implant.
- The system is designed to be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of resistance before proceeding.
- Do not torque or rotate the system.
- Purge the entire Delivery System carefully to avoid the accidental introduction of air into the system.
- If any defects are observed with the Surpass Streamline Flow Diverter system, replace the device.
- If excessive resistance is encountered during the use of the Surpass Flow Diverter at any time during the procedure, discontinue use of the system. Movement of the system against resistance may result in damage to the vessel, a system component, or the patient.
- Repositioning of the Surpass Flow Diverter device in the parent vessel without fully retrieving the device is not advised since it could cause vessel damage and/or perforation. After full deployment, do not re-position.
- It is important for the Surpass Streamline Flow Diverter device to be used with the Stryker Neurovascular AXS Catalyst® 5 Distal Access Catheter (Model UPN M003IC0581150) and one of the following compatible guidewires:
  - Stryker Neurovascular Synchro2® (e.g., Model UPN M00326410) or
  - Stryker Neurovascular Synchro®-14 (e.g., Model UPN M00313010) or
  - Boston Scientific Transend® EX (e.g., Model UPN M001468050)
- [**Clinical Warning**] Do not use device for ruptured intracranial aneurysms.
- [**Clinical Warning**] A decrease in effectiveness has been observed in subjects aged > 65 years old, subjects with history of smoking and history of prior non-target intracranial aneurysm treated.
- [**Clinical Warning**] Judicious patient selection is important. Patients who fall outside the therapeutic range for antiplatelet testing or at the lower limits have an increased risk of developing stent thrombosis, even with additional doses of antiplatelet medication. Another effective anti-platelet agent should be considered.
- [**Clinical Warning**] Placement of multiple Surpass Flow Diverter devices may increase the risk of ischemic complications.
- [**Clinical Warning**] Delayed aneurysm rupture may occur with large and giant intracranial aneurysms.

CAUTIONS / PRECAUTIONS

- Experience with device implants indicates that there is a risk of stenosis. Subsequent stenosis may require dilatation of the vessel segment containing the device. The risks and long-term outcome following dilatation of endothelialized devices is unknown at present.
- Confirm the device labeling reflects the desired size of the target vessel where the device is to be used.
- Do not expose the system to organic solvents (e.g., alcohol).
- Appropriate anti-platelet and anti-coagulation therapy should be employed in accordance with standard medical practice.
- A thrombosing aneurysm may aggravate pre-existing or cause new symptoms of mass effect and may require medical therapy.
- Use product prior to the "Use By" date.
- Do not remove the Surpass Flow Diverter from its Delivery System. The device and Delivery System are intended to perform as a single system and must not be altered.
- Carefully inspect the device packaging and system prior to use. Do not use the Surpass Flow Diverter if any component appears damaged or missing.
- Carefully remove the tray lid and grasp the Delivery System by its RHV and hoop to facilitate removal from the tray.
- Select a device length that is at least 10 mm longer than the intracranial aneurysm neck to maintain a minimum of 5 mm on either side of intracranial aneurysm neck.
- Do not attempt to partially deploy and recapture the Surpass Flow Diverter more than three times.
- Use caution when crossing the deployed device with guidewires or other accessory devices.
- Dispose of all used devices in accordance with hospital policy for biohazardous materials.
- Do not attempt to move the Surpass Flow Diverter more distally once it has begun apposing to the vessel walls.
- Do not apply additional force if significant resistance is experienced while attempting to recapture the flow diverter.
- This device has not been evaluated for pediatric use.
- The safety and effectiveness of the device has not been established in the treatment of small and medium wide-neck intracranial aneurysms.
- 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.
- Lower intracranial aneurysm occlusion rates may be associated with giant intracranial aneurysms (> 25 mm).
- Do not deploy Surpass Flow Diverter devices in parallel (side by side).
- The Surpass Flow Diverter may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective intracranial aneurysm treatment.

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 patient 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.

Legal Manufacturer

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Electronic instructions for use are available at www.strykerneurovascular.com/DFU.

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Understanding aneurysms and flow diversion treatment

Surpass Streamline™ FLOW DIVERTER

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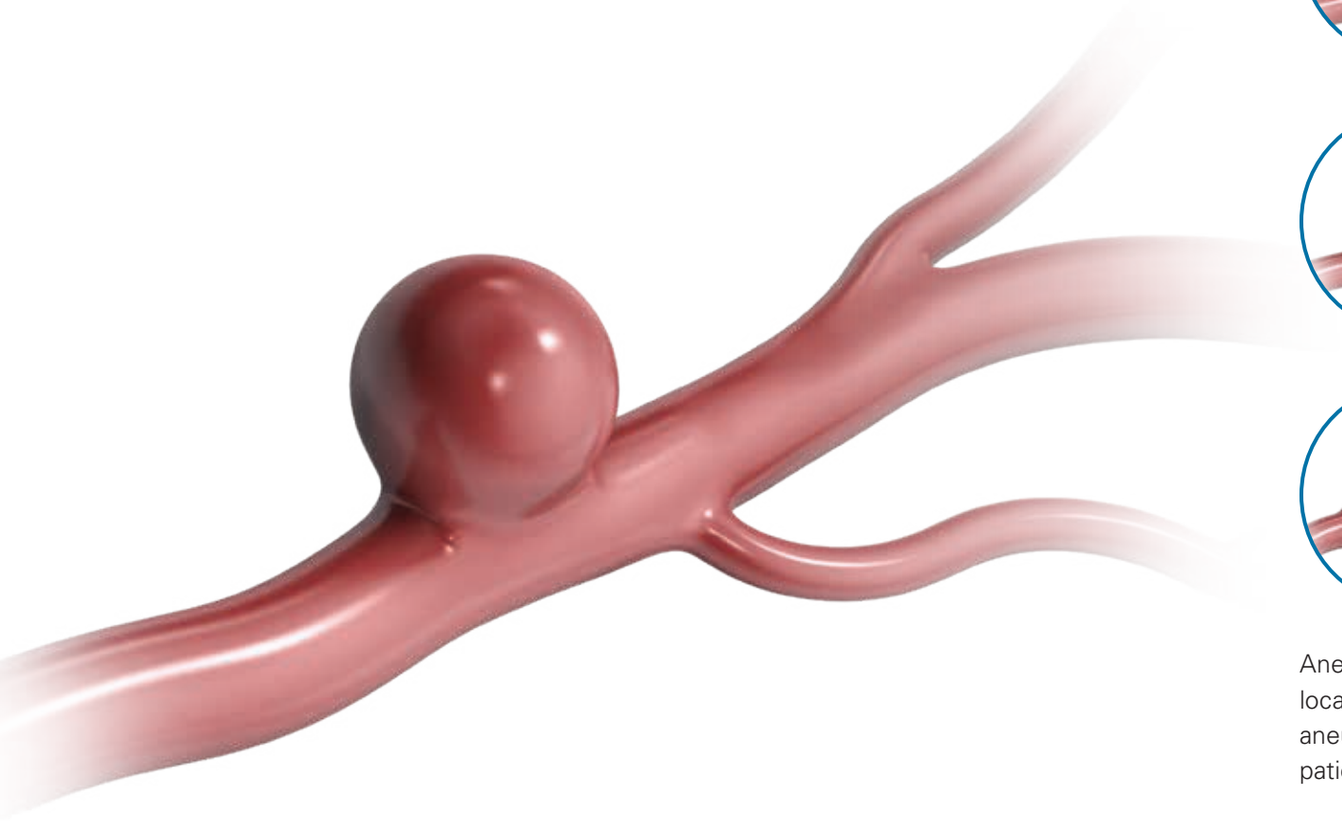
What is a brain aneurysm?

A brain aneurysm is the bulging of a weakened spot on a brain artery. As blood flows within an artery over time, a weakened portion of the vessel wall may balloon or swell outward, resulting in an aneurysm. If left untreated, a blood-filled aneurysm can leak or rupture into the space around the brain, causing serious symptoms such as severe headache, nausea, vomiting, blurred or double vision, stroke and even death.



Are all aneurysms the same?

There are three types of aneurysms that can form.

A **saccular aneurysm**, sometimes known as a "berry" aneurysm, is the most commonly seen among aneurysm patients, accounting for up to 90% of all cases. This type of aneurysm has a narrow neck, or opening from the artery.

A **wide-neck aneurysm** is a type of saccular aneurysm with a neck that is 4mm or wider, or is at least half as wide as it is high.

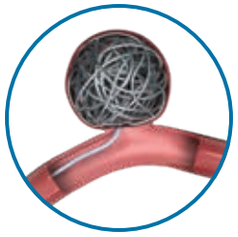
A **fusiform aneurysm** forms when swelling of both sides of an artery takes place. This type of aneurysm is less common and rarely ruptures.

Aneurysms may not only differ in appearance, but they can also differ in size and location. Through imaging screening, a doctor can identify the exact nature of an aneurysm and establish the most appropriate and effective treatment plan for the patient accordingly.

How is an aneurysm treated?

Several medical procedures are available to treat aneurysms, and the appropriate treatment depends on the shape, size and location of the aneurysm. Two procedures commonly used include **surgical clipping** and **coiling**.

Surgical clipping closes off the aneurysm by inserting a small metal clip across its opening, stopping the blood from flowing into it.

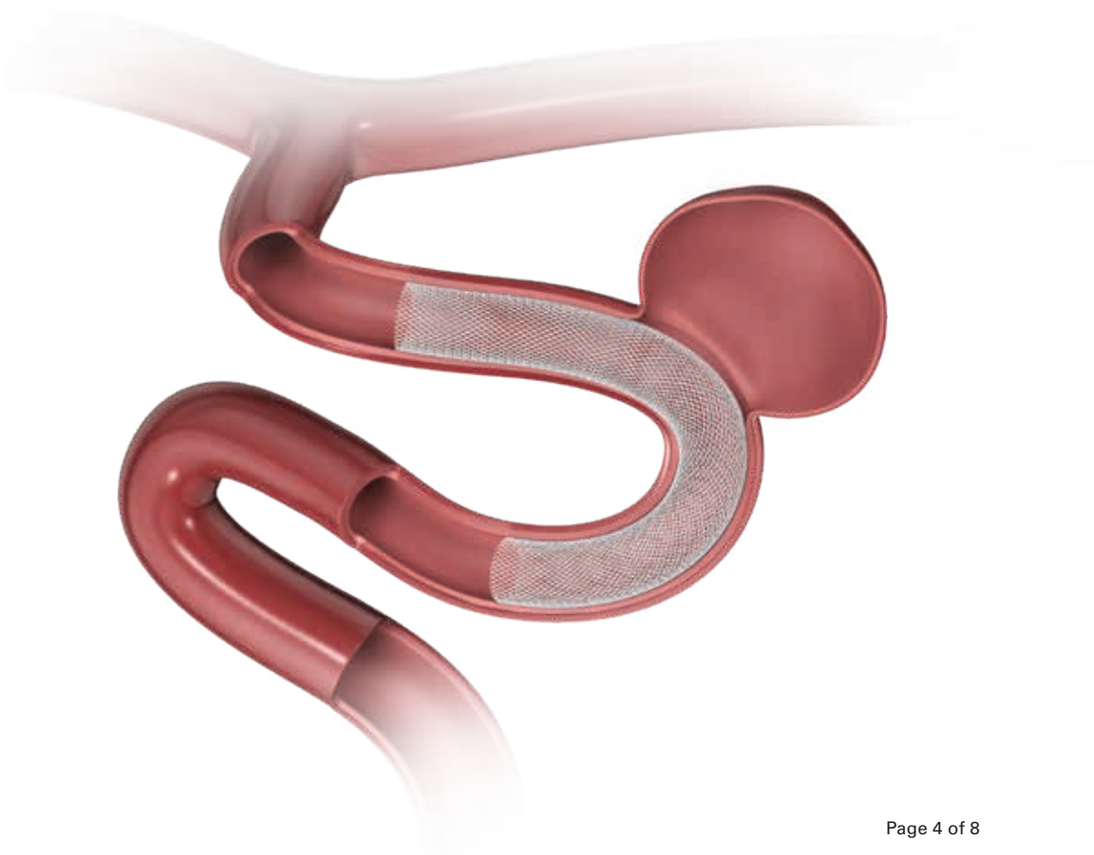


Coiling involves the insertion of a coil of soft platinum wire into the aneurysm, causing the blood to clot and create a seal between the artery and the aneurysm. Coiling procedures can be supported by additional devices, such as stents or balloons, to treat wide-neck aneurysms.

An alternative treatment option called **flow diversion** is now available for certain patients as well.

What is flow diversion and how is it different?

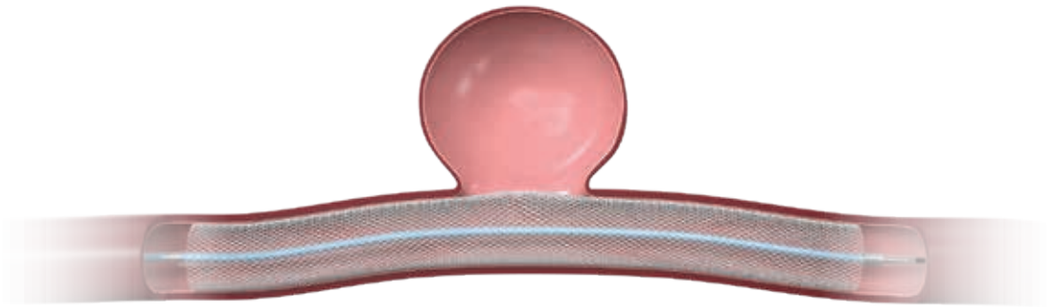
Flow diversion is different from **clipping** and **coiling** because it focuses treatment on the diseased part of the vessel that sustains the aneurysm, rather than on the aneurysm itself. A Flow Diverter is designed to restore the vessel wall in order to facilitate natural blood flow through the vessel and away from the aneurysm. When blood flow to an aneurysm is slowed and eventually eliminated, the aneurysm begins to shrink. Flow diversion is an especially effective treatment for aneurysms that have wide necks, are larger in size or are fusiform in shape.



Flow diversion (continued)

The Surpass Streamline™ Flow Diverter is a safe and effective, minimally invasive device, designed to occlude large or giant wide-neck intracranial aneurysms to prevent rupture and related neurological disability and death. Available in Europe since 2014, the Surpass Streamline Flow Diverter was approved by the FDA in 2018 after completion of the SCENT (The Surpass IntraCranial Aneurysm EmbolizatioN System Pivotal Trial to treat large or giant wide-neck aneurysms) clinical trial.

The Surpass Streamline Flow Diverter is a small braided tube made from a material called cobalt chromium and is implanted adjacent to the neck of the aneurysm, allowing for restoration of the vessel wall. It can be used independently of other technologies to treat aneurysms.



Warnings and precautions

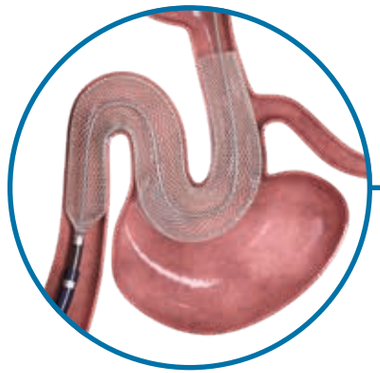
The Surpass Streamline Flow Diverter has been shown to be Magnetic Resonance Imaging (MRI) conditional. This is important to know if you should need any future MRI for any part of your body. Your doctor will also need to know if you have any allergies to drugs, contrast media (X-ray dye) or certain metals like nickel. Persons allergic to contrast media (X-ray dye), nickel, cobalt chromium or platinum tungsten metal may suffer an allergic response to this Flow Diverter implant. Refer to your physician for more information.

Medications such as aspirin and Plavix™ are required before and after treatment as instructed by your doctor.

The procedure

What happens before the procedure?

Your doctor will tell you what you need to do before you are admitted to the hospital. You may be asked to take aspirin and other prescription medications before the procedure. It is important to tell your doctor if you cannot take aspirin or if you have a history of bleeding problems.



A Flow Diverter being placed across the aneurysm neck. Immediately following placement of the Flow Diverter, blood flow into the aneurysm will slow and over time blood no longer enters the aneurysm as the aneurysm shrinks.

What happens during the procedure?

Your catheter-based aneurysm treatment will take place in a special area in radiology or the operating room of your hospital. The treatment uses X-ray and an X-ray dye called **contrast media** to allow an X-ray picture of your arteries to be taken. Your doctor will put a **sheath** (short plastic tube) in the artery in your groin. A catheter is inserted through the sheath and threaded through the artery to the aneurysm. The delivery catheter of the Surpass Streamline™ Flow Diverter will be used to deliver it to the aneurysm neck.

Then the Flow Diverter is released from the delivery catheter and deployed across the aneurysm sac. As the Flow Diverter is being released, it expands to lie against the inside of the artery wall.

The procedure (continued)

What happens after the procedure?

After the procedure, the medical staff will monitor your heart rate and blood pressure. Your doctor will limit your activities for a few weeks and will tell you when you can return to normal activities.

Your doctor may also prescribe medications to prevent blood clots from forming on the Flow Diverter or in your arteries.

Your doctor will let you know how long you need to take these medications.

Your doctor will schedule follow-up visits, specific for your medical condition. This may include a physical examination and imaging studies to look at the aneurysm area. Sometimes aneurysms may need to be treated again.

What are the potential complications?

As with any surgical procedure, there are some risks associated with the implantation of the Surpass Streamline™ Flow Diverter. Refer to the directions for use and consult with your physician.

Patient information card

Your doctor will fill out a patient information card for you after the treatment. Make sure your doctor gives this to you before you leave the hospital. You should carry this card with you. It is very important to show this card to other doctors that you go to in the future. The card will explain that you have a stent in your brain. It also lets a doctor know that the stent is MRI conditional. Refer to your physician for more information.

Notes