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 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 device to be used with the Stryker Neurovascular AXS Catalyst® 5 (Model UPN M003IC0581150) and one of the following compatible guidewires:
  - Stryker Neurovascular Synchro$^{2®}$ (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 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 aneurysm neck to maintain a minimum of 5 mm on either side of 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. The probability of risk (e.g., alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and/or delayed neoplasia) occurrence increases as procedure time and number of procedures increase.
- Lower aneurysm occlusion rates may be associated with giant aneurysms (>25mm).
- Do not deploy Surpass devices in parallel (side by side).

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.

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

strykerneurovascular.com

Date of Release: JUL/2018

EX_EN_US