Vasospasm
• Transient ischemic attack (TIA)
• Thromboembolism from device
• Subarachnoid hemorrhage
• Seizure
• Retroperitoneal hematoma
• Renal failure
• Reaction to radiation exposure (i.e., alopecia, burns ranging
• Pseudoaneurysm formation
• Neurological deficits
• Mass effect
• Infection
• Implant thrombosis/occlusion
• Hemiplegia
• Headache
• Embolism (air, clots, device fragments)
• Dissection or perforation of the parent artery
• Device migration, fracture, misplacement
• Confusion, coma, change in mental status
• Cranial neuropathy
• Cardiac arrhythmia
• Aphasia
• Allergic reaction

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

• Patients in whom the angiography demonstrates the stent is not appropriate for the parent vessel due to:
  – Severe distal vessel tortuosity or irregularity and/or
  – Intracranial aneurysm not amenable to medical therapy

POTENTIAL ADVERSE EVENTS

Adverse events may be associated with the use of the Surpass Flow Diverter in the intended treatment include:

• Allergic reaction
• Anesthesia-related events, contrast or anticoagulant-related
• Aneurysm
• Cerebral artery occlusion
• Clinical infection
• Embolization of clot or thrombus
• Headache
• Hypersensitivity
• Impairment of vision
• Inadvertent or delayed delivery system deployment
• Intracranial bleeding
• Intracranial infection
• Intracranial or subdural hematoma
• Myocardial infarction
• Neurological deficit
• Progression or rupture of aneurysm

Understanding aneurysms

Understanding aneurysms and flow diversion treatment

Flow diversion devices may increase the risk of ischemic complications.

Clinical Warning

Placement of multiple Surpass Flow Diverter devices may include:

• A decrease in effectiveness has been established in the treatment of small and medium wide-neck intracranial aneurysms.
• Judicious patient selection is important.
• A decrease in effectiveness has been established in the treatment of small and medium wide-neck intracranial aneurysms.
• Judicious patient selection is important.

After use, dispose of product and packaging in accordance with hospital administrative and/or local government policy.
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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.

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.