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Understanding aneurysms and flow diversion treatment

Surpass Evolve™

FLOW DIVERTER

Glossary

The following definitions are included to assist you in understanding the medical terms used in this booklet. If you do not know what any of the words mean, please ask your doctor.

Aneurysm – A bulging of a weakened spot on a brain artery.

Artery – A blood vessel that carries blood away from the heart to the brain.

Catheter – A long, thin, flexible tube, placed in your artery to reach the disease area in your brain.

Contrast media (dye) – A liquid dye injected into your blood vessel to see the blood flow through vessels.

Introducer sheath – A short, flexible plastic tube that is inserted into the artery to provide an access point (groin). It allows insertion of other instruments into the artery.

Intracranial – Inside the skull.

Magnetic Resonance Imaging (MRI) – A special technique similar to an X-ray used to see internal structures, such as arteries, the brain or the heart.

Stent – A small, metal mesh tube used to hold open the artery or provide a scaffolding across the neck of an aneurysm.

Stroke – When blood flow is stopped within an artery in your brain, you can have a stroke. A stroke can cause parts of the body to be paralyzed, loss of vision, loss of movement in your arms or legs, severe headaches and even cause death.

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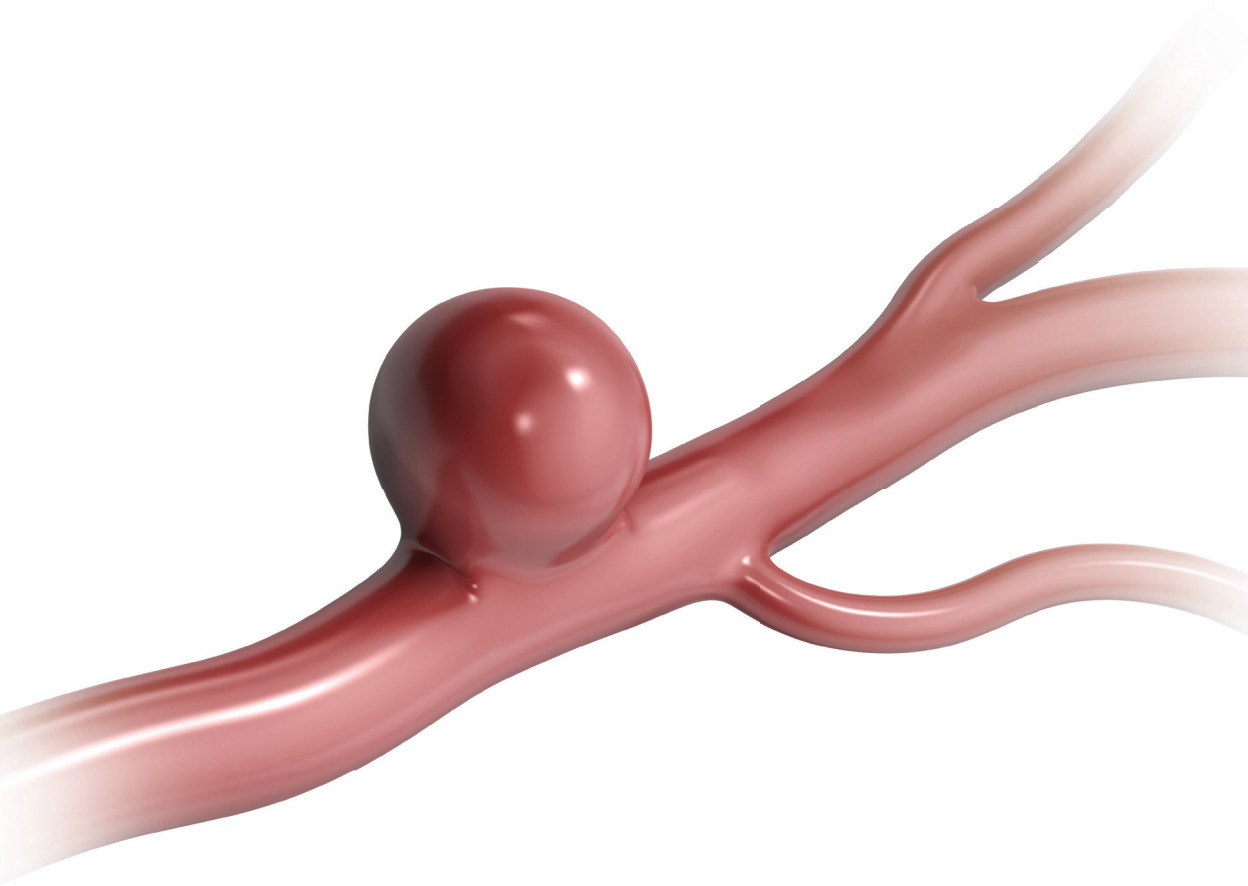
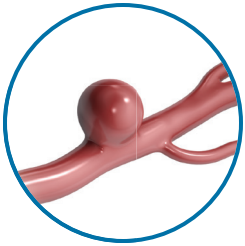
What is a brain aneurysm?

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.



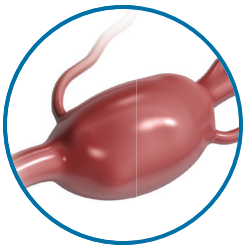
Are all aneurysms the same?

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.



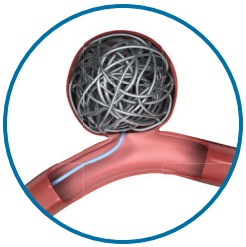
A **fusiform aneurysm** forms when swelling of both sides of an artery takes place. This type of aneurysm is less common and rarely ruptures.

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.

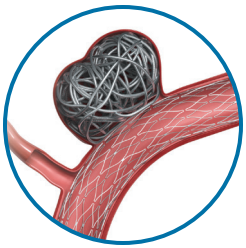
How is an aneurysm treated?

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.



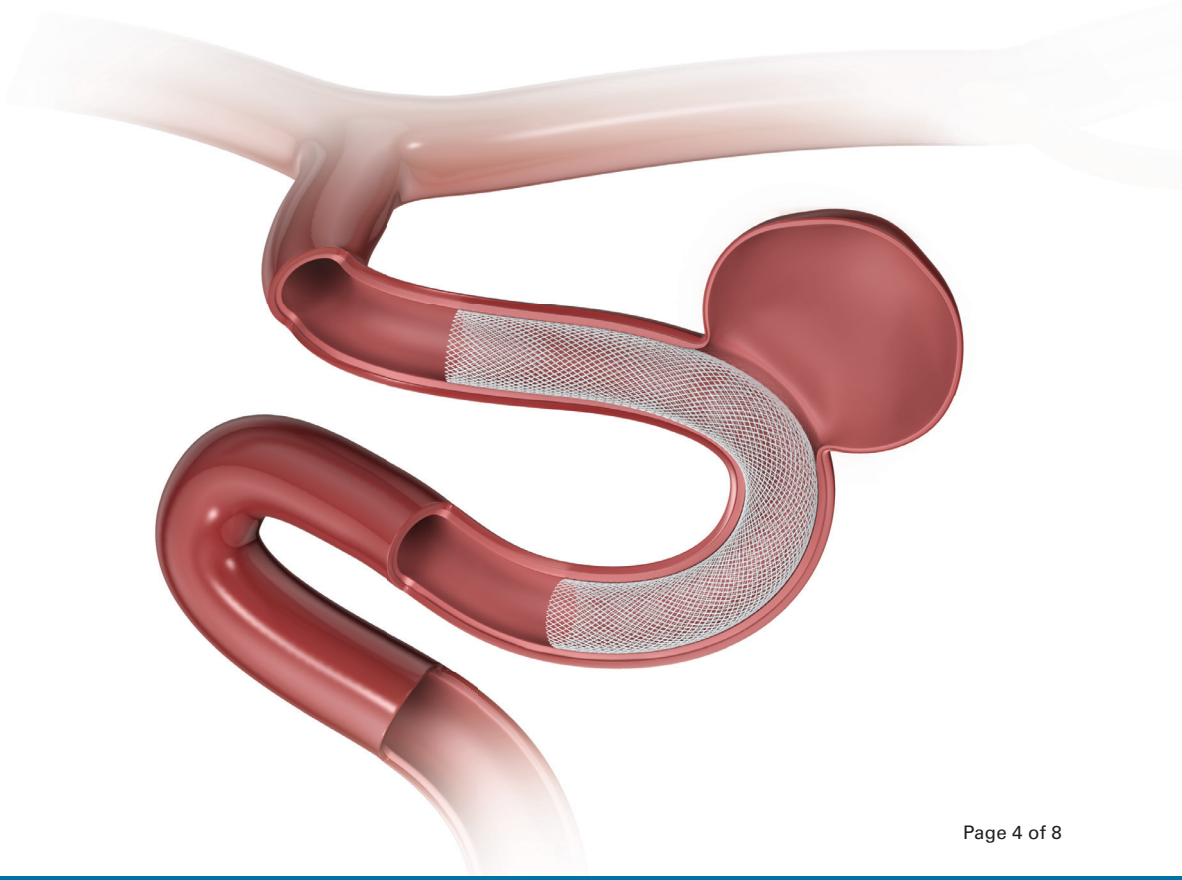
An alternative treatment option called **flow diversion** is now available for certain patients as well.

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.

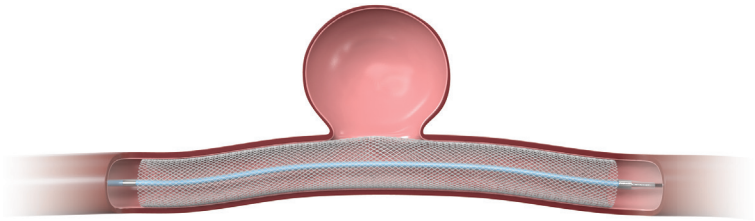


Flow diversion *(continued)*

The Surpass Evolve™ Flow Diverter is a safe and effective, minimally invasive device for patients (18 years of age and older) designed to occlude large or giant wide-neck intracranial aneurysms to prevent rupture and related neurological disability and death.

This second-generation device follows the Surpass Streamline™ Flow Diverter, which has been available in Europe since 2014 and was approved by the FDA in 2018 upon completion of the SCENT (The Surpass IntraCranial Aneurysm EmbolizatioN System Pivotal Trial to treat large or giant wide-neck aneurysms) clinical trial.

The Surpass Evolve Flow Diverter is a small braided tube made from cobalt chromium and platinum materials and is implanted adjacent to the neck of the aneurysm, allowing for restoration of the vessel wall. It can be used independent of other technologies to treat aneurysms. The Surpass Evolve Flow Diverter is permanent for the life of the patient.



Warnings and precautions

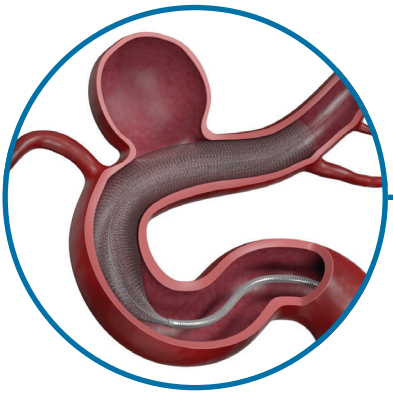
The Surpass Evolve Flow Diverter System has been shown to be Magnetic Resonance Imaging (MRI) conditional. This is important to know if you should need any future MRI for any part of your body. The device, including how it was made, has been tested and is found to be safe when in contact with body tissue and blood. However, your doctor will also need to know if you have any allergies to drugs, contrast media (X-ray dye) or certain metals. 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 an introducer sheath (short plastic tube) in the femoral artery of your thigh. A catheter is inserted through the sheath and threaded through the artery to the aneurysm. The Surpass Evolve Flow Diverter will be delivered through a microcatheter inserted through this system.

The Flow Diverter is released from the microcatheter 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.
- Tell your doctor right away if you start having any of the following symptoms:
    - Sudden numbness or weakness of the face, arm or leg, especially on one side of the body
    - Sudden confusion, trouble speaking or understanding
    - Sudden trouble seeing in one or both eyes
    - Sudden trouble walking, dizziness, loss of balance or coordination
    - Sudden, severe headache with no known cause

What are the potential complications?

As with any implant procedure, there is a chance that complications may occur, including but not limited to those listed below. Ask your doctor to discuss the risks of these complications as some are extremely rare.

Adverse events

- Allergic reaction to drugs, X-ray dyes, medications or implant material
- Aneurysm burst
- Abdominal bleeding
- Blockage of vessel such as air bubbles, tissue or clots
- Bleeding, compression or fluid buildup in the brain
- Bruising, bleeding or pain at groin area
- Death

- Device migration, fracture, misplacement
- Difficulty understanding and expressing speech
- Headache
- Heart problems such as irregular heartbeat or heart attack
- Injury or damage to the artery or wall of the artery
- Infection
- Kidney damage or failure
- Narrowing of the artery or implant
- Nerve or spinal cord problems affecting brain function
- Confusion, coma, change in mental status
- Paralysis on one side of the body
- Reaction to X-ray exposure
- Seizure
- Stroke or mini strokes
- Sudden constriction of a blood vessel
- Vision problems such as temporary or permanent blindness in one or both eyes, double vision or reduced vision

Your doctor and the medical staff will monitor you during and after the procedure for complications. If a complication does occur, your doctor will decide if you require treatment. In the event of complications, retreatment of the aneurysm may be required.

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 an implant in your brain. It also lets a doctor know that the implant is MRI conditional. Refer to your physician for more information.

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