

**stryker**



# An option for treatment of wide neck brain aneurysms

**Neuroform Atlas<sup>®</sup>**

Stent System

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# What is a brain aneurysm?

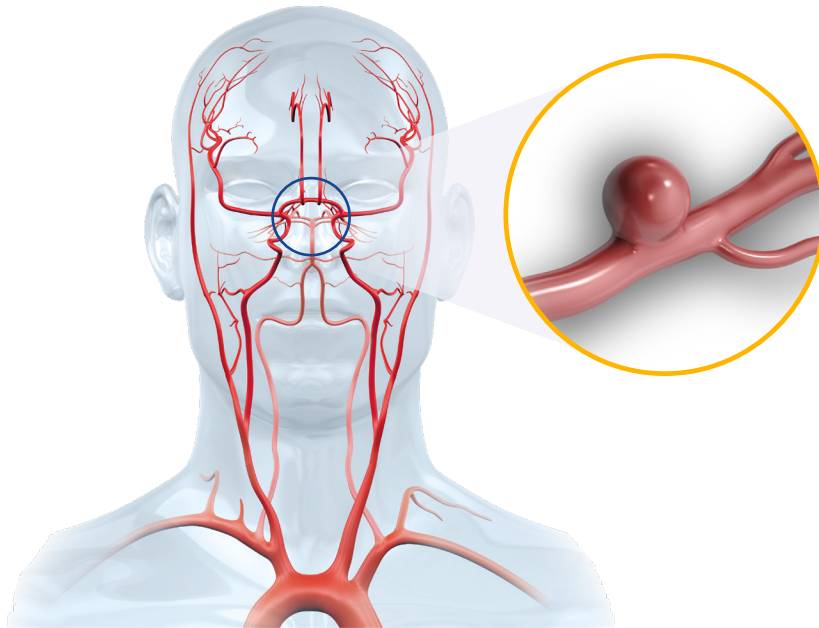
A brain aneurysm is a balloon-like sac that develops in a blood vessel of the brain called an artery.

Aneurysms have thin walls that can continue to thin and weaken as the aneurysm grows. This may cause symptoms such as headache, nausea, vomiting and vision problems.

The artery wall can become so thin that it leaks or ruptures. When an aneurysm ruptures, it releases blood into the space around your brain, which can cause a stroke. Aneurysm ruptures are a life threatening problem.

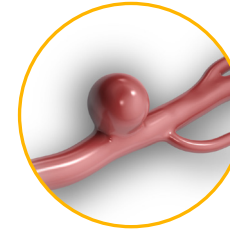
Depending on how serious the bleeding is, potential effects include:

- Functional disability
- Cognitive impairment
- Death

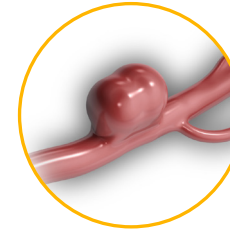


# What are the different types of aneurysms?

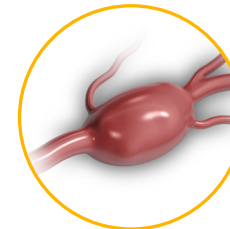
Aneurysms can be classified by shape:



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 having a neck  $\geq 4\text{mm}$  or a dome-to-neck ratio of  $< 2$ .



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.



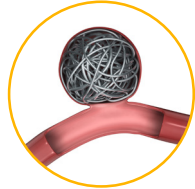
# What are the treatment options for wide necked aneurysms?



The purpose of treatment is to close off the aneurysm neck and lower the chance of aneurysm rupture.

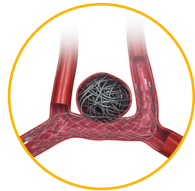
## **Surgical clipping**

Surgery involves removing a section of the skull and placing one or more clothespin-like metal clips across the aneurysm neck to prevent blood flow into the aneurysm. Wide neck, intracranial aneurysms cannot always be clipped because of their size or location.



## **Parent artery occlusion**

Blood flow to the artery feeding the aneurysm is blocked using one of multiple different methods. This prevents blood flow into the aneurysm.



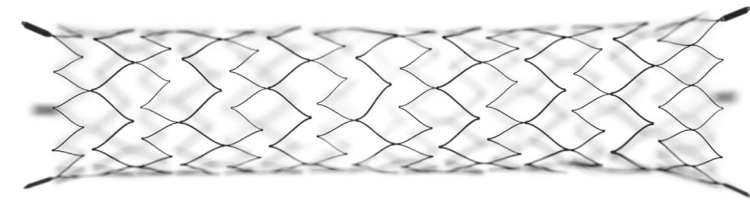
## **Endovascular embolization** (Catheter based methods)

Microcatheters are small, thin tubes that are placed in the arteries of the groin or arm through a small incision. They are guided into the arteries of your brain using an x-ray machine. Small metal coils, stents, flow diverters and liquid embolics can be placed inside these catheters and guided to your aneurysm. One method, stent assisted coiling, combines the use of a stent and coils. Each method has advantages and disadvantages. These devices help prevent blood from flowing into the aneurysm which may allow the aneurysm to occlude over time.



# What is the Neuroform Atlas Stent System?

The Neuroform Atlas Stent System is a stent designed to assist with embolic coiling of wide-necked brain aneurysms. The Neuroform Atlas Stent System consists of a stent and a delivery wire, and is used with a microcatheter. The stent is a permanent implant that is placed in the artery across the aneurysm neck to help keep coils in the aneurysm. It is a tiny mesh tube that is made from a material called Nitinol. The delivery wire is used to guide the stent through the artery across the aneurysm neck.



Neuroform Atlas Stent System

Refer to the product Directions for Use at [www.strykerneurovascular.com/DFU](http://www.strykerneurovascular.com/DFU) for a detailed description of the results of the clinical study.

# What can I expect before, during and after my procedure?



## Pre-procedure

Your doctor will perform a series of exams and diagnostic procedures to determine the size, type and location to your aneurysm. Some of the exams may include:

- Lifestyle and medical history review
- Physical examination
- Neurological examination
- Blood tests
- Diagnostic image (CT-scan, MRI)
- Cerebral Angiogram

Your doctor may require you to prepare for the procedure by taking certain medications:

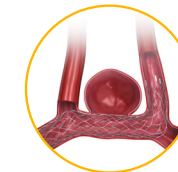
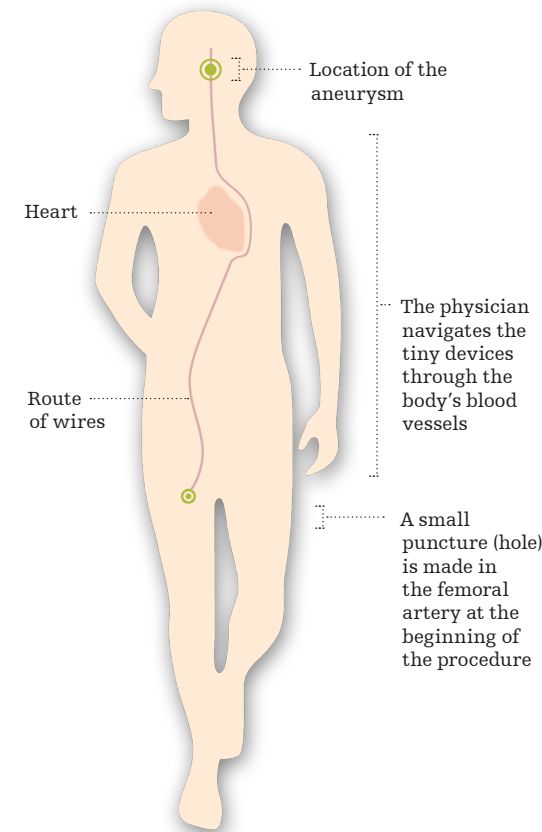
- A few days before the procedure you may be asked to take antiplatelet medications such as aspirin.
- Additional medications may be prescribed by your doctor

## During the procedure

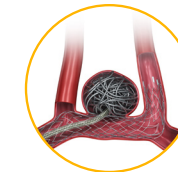
Your procedure may be performed under either local anesthesia, sedation, or general anesthesia, though general anesthesia is typically preferred since you must remain still for a long periods of time.

A microcatheter will be inserted into your artery. Stent assisted coiling using the Neuroform Atlas Stent System involves accessing the aneurysm using the delivery wire (inserted into the catheter), placing the stent across the neck of the aneurysm and coiling the aneurysm.

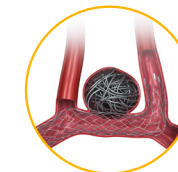
The length of the entire procedure varies, but typically takes from 1-3 hours.



Stent is placed across the aneurysm neck



A microcatheter tip is navigated through the stent and coils are deployed within the aneurysm



The microcatheter is removed. The coils, together with the Neuroform Atlas stent, help prevent blood from flowing into the aneurysm and assist in its occlusion.

# What can I expect before, during and after my procedure? (continued)

## After the procedure

You will be moved to a recovery room after the procedure is completed.

You will likely experience some pain and discomfort in your thigh/groin where the catheters were inserted into your artery.

You will be required to continue taking antiplatelet medications such as aspirin following the procedure. Your doctor will explain your medications to you.

## What are the potential risks?\*

There are potential risks that may happen with catheter-based treatments or with use of the Neuroform Atlas Stent System. Potential risks include, but are not limited to:

- Allergic reaction to Nitinol metal and medications
- Aneurysm perforation/rupture
- Coil herniation through stent into parent vessel
- Death
- Embolus
- Headache
- Hemorrhage
- In-stent stenosis
- Infection
- Ischemia
- Neurological/intracranial sequelae
- Pseudoaneurysm
- Stent fracture
- Stent migration/embolization
- Stent misplacement
- Stent thrombosis
- Stroke
- Transient ischemic attack
- Vasospasm
- Vessel occlusion or closure
- Vessel thrombosis
- Vessel perforation/rupture, dissection, trauma or damage
- Visual impairment
- Other procedural complications including but not limited to anesthetic and contrast media risks, hypotension, hypertension, and access site complications.

\*Discuss all risks with your doctor

# Patient information card

Your doctor will provide you with an MRI card (example illustration shown right) that explains how the Neuroform Atlas device will behave under various medical scans. Please keep this card with you at all times. Please contact your doctor for more information.

**Neuroform Atlas™ Stent System**  
Magnetic Resonance  
MRI Conditional

Non-clinical testing and analysis have demonstrated that the Neuroform Atlas Stent is MRI Conditional alone, or when overlapped with a second stent, and adjacent to a Stryker Neurovascular coil mass. A patient with the Neuroform Atlas Stent can be safely scanned immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla
- Maximum spatial gradient field up to 200 Gauss/cm (25 Tesla/m)
- Maximum MRI system reported whole body averaged specific absorption rate of 2.0 W/kg (Normal Operating Mode) and heat averaged specific absorption rate of 3.2 W/kg

Under the scan conditions defined above, the Neuroform Atlas Stent is expected to produce a maximum temperature rise of 4°C after 15 minutes of continuous scanning. The Neuroform Atlas Stent should not migrate in this MRI environment.

In non-clinical testing, the image artifact caused by the device extends approximately 2 mm from the Neuroform Atlas Stent when imaged with spin echo pulse sequence and 3 Tesla MRI System. This artifact may obscure the device lumen. It may be necessary to optimize MRI imaging parameters for the presence of this implant.

Persons allergic to nickel/titanium (NiTi) may suffer an allergic response to this stent implant.

Patient Name \_\_\_\_\_  
Date of Implant \_\_\_\_\_  
Location \_\_\_\_\_  
Stent Size \_\_\_\_\_  
Stent Lot \_\_\_\_\_  
Number of Coils \_\_\_\_\_

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Implanting Physician Name \_\_\_\_\_  
Physician Telephone Number \_\_\_\_\_

## Definitions

**Microcatheter** – A small diameter thin tube that travels through the blood vessels to the desired area. Once reaching the desired location, the microcatheter can be used to deliver therapeutic agents.

**Embolic Coil** – An implantable medical device that looks like a slinky which helps facilitate clot formation within an aneurysm and helps prevent blood from entering the aneurysm.

**Occlude** – To block the neck of an aneurysm to prevent blood from flowing into the aneurysm

**Stent** – A mesh tube placed into a blood vessel to help keep coils in the aneurysm and aid in healing.

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