Humanitarian Device. The Neuroform Microdelivery Stent System is authorized by Federal law for use with embolic coils for the treatment of wide neck, intracranial, saccular aneurysms arising from a parent vessel with a diameter of ≥2mm and ≤4.5mm that are not amenable to treatment with surgical clipping. Wide neck aneurysms are defined as having a neck >4mm or a dome-to-neck ratio of <2. The effectiveness of this device for this use has not been demonstrated.

Indications, contraindications, warnings, and instructions for use can be found in the product labeling (Product Information Summary) supplied with each Neuroform Microdelivery Stent System.
What is the Purpose of This Booklet?
Your doctor believes that the best treatment for the aneurysm in your brain includes the use of a device called the Neuroform™ Microdelivery Stent System. This Patient Information Booklet was developed to help you make an informed decision about this treatment. Please read it carefully. Make a list of questions and concerns and discuss them with your doctor before undergoing the treatment. We have included a Definitions section at the end of the booklet that provides definitions for the words in bold print.

What is a Wide Neck, Intracranial Aneurysm?
An intracranial aneurysm is a sac on an artery in the brain that may stretch over time. A wide neck, intracranial aneurysm is an aneurysm that has a wide opening where it attaches to the artery. This opening is called the aneurysm neck.

Aneurysms have thin, weak walls and can burst or rupture. When an aneurysm ruptures, it bleeds into and around your brain. Aneurysm ruptures can cause brain injury and/or death.

Figure 1 shows a wide neck aneurysm attached to an artery.

What is the Treatment for Wide Neck, Intracranial Aneurysms?
In general terms, intracranial aneurysms can be treated by performing surgery or using catheter-based methods. The purpose of the treatment is to close off the aneurysm neck and lower the chance of aneurysm rupture.

Surgery
Two types of surgery can be performed. The first type involves removing a section of the skull and placing one or more clips across the aneurysm neck. Wide neck, intracranial aneurysms can not always be clipped because of their size or location. The second type of surgery involves tying off the blood vessel in the neck that supplies blood to artery with the aneurysm. Tying off the blood vessel in the neck does not always lower the chance of aneurysm rupture or cannot be performed because of the location of the aneurysm.

Catheter-Based Methods
Catheters are thin plastic tubes that are commonly placed in arteries in the groin or arm and moved using an X-ray machine to arteries in other areas in the body. These catheters can be used to place small, metal coils inside intracranial aneurysms. Coils close off the neck of the aneurysm by causing blood to clot in the aneurysm. Coils do not always stay in wide neck,
intracranial aneurysms. Stents can be placed across the aneurysm neck to keep coils inside a wide neck, intracranial aneurysm.

**What is the Neuroform™ Microdelivery Stent System?**

The Neuroform Microdelivery Stent System consists of a Stent and a delivery system. The Stent is a permanent implant that is placed across the aneurysm neck. It is a tiny mesh tube that is made from a material called nitinol (Figure 2). The delivery system consists of catheters that are used to thread the Stent through your artery to the aneurysm neck. After the Stent is in place, your doctor fills the aneurysm sac with coils. The purpose of the coils is to fill the aneurysm and lower the chance of the aneurysm rupturing. The Stent keeps the coils from falling out of the aneurysm sac.

*Figure 2 is a Stent.*

**Who is Eligible for the Neuroform Microdelivery Stent System?**

The Neuroform Microdelivery Stent System can be used with small metal coils for treating wide neck aneurysms in the brain that cannot be treated with open brain surgery.

**Who is Not Eligible for the Neuroform Microdelivery Stent System?**

The Neuroform Microdelivery Stent System cannot be used if you cannot take blood-thinning drugs that make your blood less likely to clot.

**What are Warnings and Precautions to Consider?**

The Stent of the Neuroform Microdelivery Stent System has been shown to be magnetic resonance imaging (MRI) compatible, which means that it can be used in certain MRI machines without causing harm to you. However, the MRI compatibility of the coils used with the Stent has not been tested by Boston Scientific. This is very important to know if you should need any future MRI for any part of your body. You or your physician would need to review the specific labeling for the coil for MRI compatibility information of that coil.

The safety of the Neuroform Microdelivery Stent System in patients below the age of 18 has not been shown.

Testing on the 30mm length Stents was performed in the lab but not in animals or humans. However, probable benefit is still expected.
What are the Potential Complications?

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

- Allergic reaction (for example, to the contrast media or stent material)
- Anesthesia reactions
- Aneurysm tear or rupture
- Artery tear, bleeding, or blockage
- Bleeding in the brain
- Blood clot in the brain
- Coil placement in artery
- Confusion
- Death
- Groin bleeding, bruising, or infection where the catheters were entered into the body
- Headache
- Infection
- Placement of Stent in wrong place
- Stroke
- Stent movement, breakage, or blockage
- Weakness on one side of the body

What were the Clinical Study Results?

There were 31 patients entered into the study. Two of the 31 patients did not receive the Stent because of their vessel anatomy. The remaining 29 patients enrolled in the study had 30 aneurysms. There were 29 patients evaluated at the time of hospital discharge and 26 patients evaluated at 6 months.

Seventeen (17) of 29 patients had 1 or more complications. There were 12 serious complications and 21 non-serious complications, all of which happened before the time of hospital discharge. No complications happened between the time of discharge and the 6-month patient visit.

Nine (9) patients had 1 complication, 4 patients had 2 complications each, 1 patient had 3 complications each, 2 patients had 4 complications each, and 1 patient had 5 complications.

There were 12 serious complications that happened in 5 patients.

- One patient had 3 serious complications. There was a tear in the aneurysm from a guidewire that led to bleeding in the brain and death. Death of this patient was due to complications from the aneurysm tear and bleeding, pre-existing hepatitis, and problems with the blood-thinning drugs.
- One patient had 3 serious complications. There was a tear in the aneurysm from a catheter used in the coiling procedure that led to bleeding in the brain.
- One patient had 4 serious complications. There was a tear in the artery from a guidewire that led to bleeding in the brain. This patient also had a stroke that caused weakness on the left side of the body.
- One patient had bleeding at the place where the sheath and catheters were inserted in the groin.
- One patient had confusion after the procedure and needed a longer hospital stay.

There were 21 non-serious complications that happened in 15 patients. These included temporary weakness on the right side of the body (1 case), a small blood clot in the brain (4 cases), temporary artery narrowing in the brain (5 cases), bleeding at the place where the sheath and catheters were put into the groin (2 cases), a partial tear in the artery (1 case), epileptic seizure (1 case), liver failure (1 case), vomiting (1 case), headache (3 cases), fever (1 case), and urinary tract infection (1 case).

At 6 months, all 26 patients who were evaluated had at least 95% blockage of their aneurysm.

Refer to the product labeling (Product Information Summary) supplied with each Neuroform™ Microdelivery Stent System for a more detailed description of the results of the clinical study.

**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. Your doctor will also need to know if you have any allergies to drugs, contrast media (x-ray dye), or certain metals like nickel.

**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. The catheters of the Neuroform Microdelivery Stent System will be used to delivery or thread the Stent through your artery to the aneurysm neck. Then the Stent is released from the catheters and across the aneurysm sac (Figure 3). As the Stent is being released, it expands to lay against the inside of the artery wall. The catheters of the Neuroform Microdelivery Stent System are removed from your body and the Stent is left in place (Figure 4). Next, your doctor will pass a different catheter through one of the small openings of the Stent (Figure 5). Your doctor will slide coils through this catheter into the aneurysm sac (Figure 6).
Figure 3 shows a Stent being placed across the aneurysm neck.

![Figure 3](image3.png)

2F Stabilizer Catheter (green tube) inside 3F Microdelivery Catheter

Figure 4 shows a Stent after placement across the aneurysm neck.

![Figure 4](image4.png)

Figure 5 shows a catheter passing through one of the small openings of the Stent.

![Figure 5](image5.png)

Catheter tip passed through the Stent

Figure 6 shows coils being slid through the catheter into the aneurysm sac.

![Figure 6](image6.png)

Coils within the aneurysm sac
**What Happens After the Procedure?**

After the procedure, the medical staff will closely watch your heart rate and blood pressure. You will need to stay flat in bed for several hours. Your doctor will tell you when you can get up and walk around. 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 that patients often take after catheter-based aneurysm treatment. These medications may include blood-thinning medications to prevent blood clots from forming on the Stent 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.

**Patient Information Card**

Below is a sample of a Patient Information Card. Your doctor will fill out a card like this 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 while the Stent is MRI compatible, the MRI compatibility of the coils used with the Stent has not been tested by Boston Scientific.

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**MRI Compatibility**

The Neuroform™ Microdelivery Stent has been shown to be MRI compatible in MRI systems operating at a field strength of 1.5 Tesla or less. However, the MRI compatibility of the embolic coils used in conjunction with the Stent has not been tested by Boston Scientific. Refer to embolic coil labeling for MRI compatibility information.

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**Patient Information Card**

Patient Name

Date of Implant

Location of Implanted Artery(ies)

Stent Size(s) Implanted

Stent Lot Number(s)

Number of Stent(s) Implanted

Implanting Physician Name

Physician Telephone Number

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**The Neuroform™ Microdelivery Stent System**

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Natick, MA 01760-1537

Definitions

Here are definitions for some of the medical words used in this Patient Information Booklet. If there are other words used in the Booklet that are not defined and you do not know what they mean, then ask your doctor.

Aneurysm – A balloon-like swelling in the wall of an artery.
Artery – A blood vessel that carries blood away from the heart and to important organs, like the brain.
Bleeding in the Brain – A ruptured blood vessel or artery can cause blood to leak into the brain. Bleeding can be in the space around the brain or inside the brain tissue.
Blood Clot in the Brain – Blood that is no longer liquid and has turned into a solid mass in a brain blood vessel.
Catheter – A long, small, flexible plastic tube.
Catheter-Based – Inside the blood vessels. A catheter-based procedure is also called an endovascular procedure.
Contrast Media – A liquid injected into blood vessels during some X-ray procedures to help see the blood vessels.
Hematoma – Blood that has leaked out of the blood vessels.
Hemiparesis – Weakness in half of the body. May be temporary or permanent.
Hepatitis – A liver disease that can cause death.
Intracranial – Inside the skull.
Intracerebral Hematoma – Blood that has leaked out of the blood vessels and inside the skull.
Magnetic Resonance Imaging (MRI) – A special technique used to see pictures of internal structures, such as arteries, the brain, or the heart.
Rupture – Tearing of an artery or aneurysm.
Sheath – A short plastic tube used to help insert catheters to an artery.
Stent – A small, metal mesh tube used to support the walls of an artery.
Stroke – A blockage in an artery of the brain that can stop the supply of blood. A stroke can cause parts of the body to be paralyzed and can even cause death.
Thromboembolic Stroke – A blockage in an artery caused by a blood clot.
Wide neck, intracranial aneurysm – An aneurysm in the brain that has a wide opening where it attaches to the artery. This opening is called the aneurysm neck.