



Affix Patient Label

Name _____ Date of Birth _____

This information is given to you so that you can make an informed decision about having this procedure.

Reason and Purpose of the Procedure

This device is used to treat the narrowing of blood vessels in the brain. Narrowing happens when the inside wall of the blood vessels thicken from buildup of cholesterol or other substances in the blood. The buildup is called plaque. The plaque narrows the blood vessel and makes it hard for the blood to flow through the area. It is harder for oxygen and nutrients to flow to your brain. This may cause headaches or other symptoms. A complete blockage of the blood flow can result in a stroke.

Opening the blockages using a specially made balloon is called angioplasty. A very thin tube, called a catheter, is passed through the large blood vessel in your groin to the blockage in your brain. Once the tube is placed at the blockage the balloon is filled. The balloon smoothes out the narrowed areas of the blood vessel. Then the balloon is emptied and removed.

Sometimes a stent is used along with the balloon catheter. A stent is a small wire mesh tube that can be placed in the blood vessel to help prop the walls of the blood vessel open. Stents may help keep the vessels from collapsing. The stent will be left in your blood vessel. Over time, the blood vessel wall will heal around the stent.

Your doctor is recommending the use of the Wingspan Stent system with the Gateway PTA Balloon Catheter.

The Food and Drug Administration (FDA) approved the use of this stent as a Humanitarian Use Device (HUD). A HUD is used where there is no other device available for treatment.

The Wingspan Stent System with the Gateway PTA Balloon Catheter is designed to help treat the narrowing of blood vessels in the brain. The stent will be placed under general anesthesia.

Benefits of this surgery:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Placing a stent in the narrow portion of the blood vessel may help open the blocked portion of the blood vessel. The stent may lower the chances of future blockages in that area.

**Risk of Surgery:**

Affix Patient Label

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor can't expect.

General Risks of Surgery:

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- A strain on the heart or a stroke.
- Reaction to the anesthetic. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.
- Bleeding may occur. If bleeding is excessive you may need a transfusion.

Risks of this Surgery:

- Bacteria may grow at the insertion site or the stent site. This could cause an infection. We would use antibiotics to treat the infection.
- The stent may move or the blood vessel may collapse or fail to stay open. This would block the blood flow to the brain and cause a stroke. The effects of the stroke may be permanent. In some cases we may be able to reinsert the catheter and use the balloon to reopen the blood vessel.
- The catheter may irritate the blood vessel. The vessel may tighten up and get smaller. This is called vasospasm. This can cause stroke like problems that may be temporary or cause permanent damage to the brain.
- The catheter may damage the narrowed blood vessel. This can create a small hole in the blood vessel and allow blood to leak into the brain, or cause an aneurysm. An aneurysm is a bulge in the blood vessel. These injuries to the blood vessel could cause a stroke and may require emergency surgery. You may need a blood transfusion.
- The catheter may injure the large blood vessel in your groin. You may need surgery to repair this. Rarely the injury may cause problems with the ability to move the leg or cause problems with the blood flow in the leg.
- Air, tissue or blood clots may block the blood vessel. This would result in a stroke.
- You may have an allergic reaction to the stent or the materials used to place the stent. Rarely, these reactions can cause kidney failure or death.
- You may have high or low blood pressure, or irregular heart beats during the procedure. This is very rare, but may require medications be used to help control your blood pressure and heartbeat. If the treatment for these problems doesn't work, you could die.

Risks associated with smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks associated with obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.



Affix Patient Label

Risks specific to you:

Alternative Treatments:

Other choices:

- Pain medication
- Do nothing. You can decide not to have the procedure.

If you chose not to have this treatment:

- The plaque deposits in your blood vessel may continue to build up. This will add to the narrowing of the blood vessel. This would cause your symptoms to get worse or may lead to a stroke.

General Information

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure the doctor may need to do more testing or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

Medical Implants/Explants

I agree to the release of my social security number, my name and address, and my date of birth to the company that makes the medical device that is put in or removed during this procedure. Federal laws and rules require this. The company will use this information to locate me, if needed.

My insurance company may not pay for this device or procedure. I know I am responsible for charges not covered by my insurance.

I have been given the Wingspan Stent for Neuroform Information booklet and have had time to read it. My questions about the booklet have been answered. Patient Initials: _____ Time: _____



Affix Patient Label

By signing this form I agree:

- I have read this form or had it explained to me in words I can understand
- I understand its contents
- I have had time to speak with the doctor. I have had my questions answered.
- I received a copy of the patient booklet on this stent. I have reviewed the information. My questions have been answered.
- I want to have this procedure: Placement of the Wingspan Stent using Gateway PTA Balloon Catheter.
- I understand that other doctors, including medical residents, will help with surgery. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross before surgery. If so, obtain consent for blood or blood products.

Patient Signature _____

Relationship Patient Closest relative (relationship) Guardian

Provider's Signature _____ Date: _____
 Time _____

Interpreter's Statement: I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

Interpreter (if applicable) _____

Teach Back

Patient shows understanding by stating in his or her own words:

- Reason(s) for the treatment/procedure: _____
- Area(s) of the body that will be affected: _____
- Benefit(s) of the procedure: _____
- Risk(s) of the procedure: _____
- Alternative(s) to the procedure: _____

or

_____ Patient elects not to proceed _____ (patient signature)

Validated/Witness: _____ Date: _____
 Time: _____