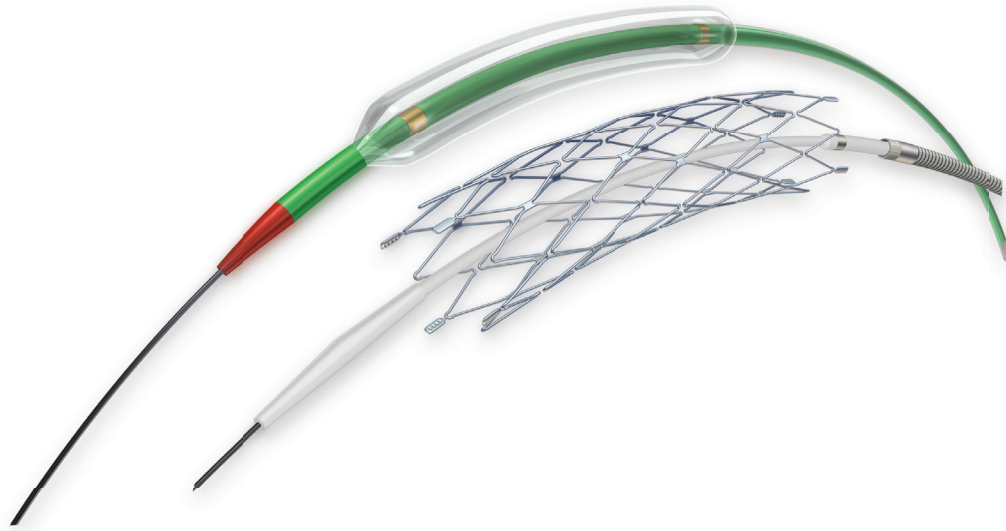


stryker



Wingspan[®] Stent System with Gateway[®] PTA Balloon Catheter

Patient Guide

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Humanitarian Device: The Wingspan Stent System with Gateway PTA Balloon Catheter is Authorized by Federal law for use in improving cerebral artery lumen diameter in patients 22 to 80 years old with recurrent (2 or more) strokes refractory to a comprehensive regimen of medical therapy and due to atherosclerotic disease of intracranial vessels with 70-99% stenosis that are accessible to the system. The most recent stroke must have occurred more than 7 days prior to treatment with the Wingspan Stent System. Patients are eligible for treatment with the Wingspan Stent System if their Modified Rankin Score (mRS) is 3 or less at the time of treatment.

The effectiveness of this device for this use has not been demonstrated.

What is the Purpose of This Guide?

Your doctor believes that the best treatment for the disease in your brain includes the use of a device called the Wingspan® Stent. This Patient Guide was created to help you make an informed decision about this treatment. Please read it carefully. Make a list of your questions and concerns and discuss them with your doctor before agreeing to the treatment.

Note to Physician: Indications, contraindications, warnings, and instructions for use can be found in the product labeling (Directions for Use) supplied with each Wingspan Stent System. A subset of information from the physician labeling has been provided in the Patient Guide.

Definitions

The following definitions are included to assist you understand the medical terms used in this Guide. If you do not know what any of the words mean, please ask your doctor. Words included in this definitions section are bolded each time they appear in the text.

Aneurysm – A bubble-like swelling in the wall of an **artery**.

Angioplasty – A procedure in which a balloon is used to open blocked vessels. Also known as percutaneous transluminal angioplasty (PTA).

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

Atherosclerosis – A disease that causes the inside walls of your **artery** to thicken or harden by the accumulation of **plaque**. When this disease prevents blood from flowing through the arteries in your brain, it can cause a **stroke**.

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.

Ischemic – Caused by a lack of blood due to a blockage in a blood vessel.

Lesion – A general term for an area in the body that is not normal such as a narrow section in an **artery** caused by **atherosclerosis**.

Lumen – The inner channel of a vessel.

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.

Modified Rankin Score (mRS) – A scoring system used to describe the level of disability of a person who has had a stroke when trying to perform daily activities. The scoring scale ranges from 0 to 6. A 0 score means a person with no stroke symptoms, and a 6 score means a person with severe disability.

Neurovascular Artery or Arteries – Arteries in the brain that supply blood containing oxygen and nutrients to the brain.

Plaque – A buildup of cholesterol, fatty deposits, or calcium, collagen in an artery that can block the flow of blood through the artery.

Stenosis – A narrowing of or blockage in an artery caused by atherosclerosis or closure of the vessel due to growth of tissue within the vessel.

Stent – A small, metal mesh tube used to hold open the artery after the blockage has been removed or reduced.

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.

Transient Ischemic Attack (TIA) – ATIA is when blood flow to a part of your brain stops for a brief period of time. ATIA is felt to be a warning sign that a true stroke may happen in the future if something is not done to prevent it.

Vessel Recoil – Arteries that are stretched during an **angioplasty** procedure may “shrink back” after they are stretched.

Indication for Use

The Wingspan® Stent System with Gateway® PTA Balloon Catheter is Authorized by Federal Law for use in improving cerebral artery lumen diameter in patients:

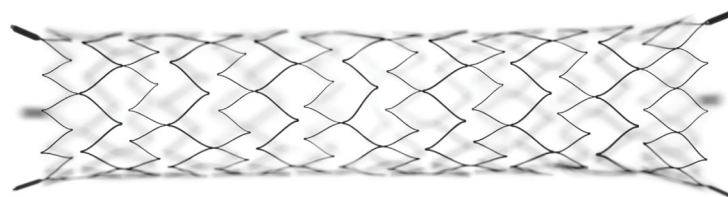
- 22 to 80 years old,
- with repeat (2 or more) strokes,
- which have not responded to a comprehensive program of medical therapy,
- with atherosclerotic disease of intracranial artery with 70-99% blockage,
- that can be treated with the stent

The most recent stroke must have occurred more than 7 days prior to treatment with the Wingspan Stent System. Patients are eligible for treatment with the Wingspan Stent System if their Modified Rankin Score (mRS) is 3 or less at the time of treatment.

What is the Wingspan® Stent System with Gateway® PTA Balloon Catheter?

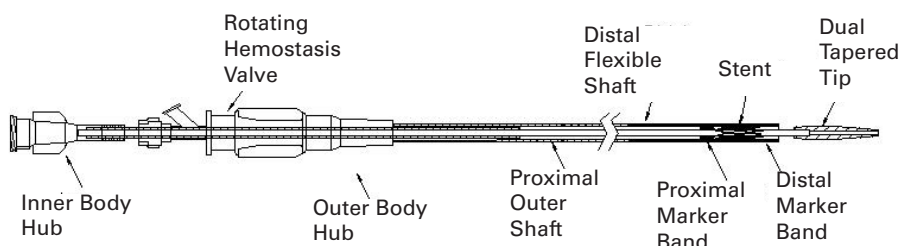
The Wingspan Stent System with Gateway PTA Balloon Catheter consists of a Wingspan Stent, a Wingspan Delivery System, and a Gateway PTA Balloon Catheter. The Balloon Catheter is temporarily placed in an **artery** in the brain to open the blockage before the **Stent** is inserted. The Gateway Catheter is removed and the Wingspan Delivery System, which holds the **Stent**, is moved to the area of blockage. The **Stent** is a permanent implant that is placed across the blockage. The **Stent** is a tiny mesh tube that is made from a metal alloy.

Wingspan Stent



*Actual Stent size is 4.0mm x 20mm

The Wingspan Stent System consists of a **catheter** that is used to thread the Stent through your **artery** to the blockage. The **Stent** helps to keep the **artery** open.



What is an Intracranial Lesion?

An **intracranial lesion** is a section of one or more arteries within your brain that have become partially or fully blocked caused by **atherosclerosis**. These arteries supply blood with oxygen and other nutrients to the brain to make it function properly. An **intracranial lesion** occurs when the inner walls of the arteries thicken due to a buildup of cholesterol, fatty deposits, calcium, and other elements. This material is known as **plaque**. As **plaque** forms, the vessel narrows. When the vessel narrows, blood flow through the vessel is reduced so there is less oxygen and other nutrients reaching the brain, especially during physical effort or mental activity. The reduced blood flow may cause mild to severe headaches or other symptoms. Complete blockage (no blood flow) of a neurovascular artery can result in a stroke. Anyone who has symptoms of severe headaches should see a doctor promptly.

Nearly 800,000 Americans suffer from **stroke** each year with the majority caused by blockage of the blood vessel (**ischemic** disease).

Who is at Risk?

Several factors increase the risk of getting **atherosclerosis** in the **neurovascular arteries**. These factors include a history of smoking, high cholesterol, diabetes, high blood pressure, being overweight, and a family history of **stroke** or heart disease.

What are your Treatment Options for Intracranial Lesions?

Intracranial lesions may be treated in several ways. The treatment that your doctor recommends will depend on the severity of your condition. Treatments may include medical management with medication, **angioplasty**, and/or **stent** placement.

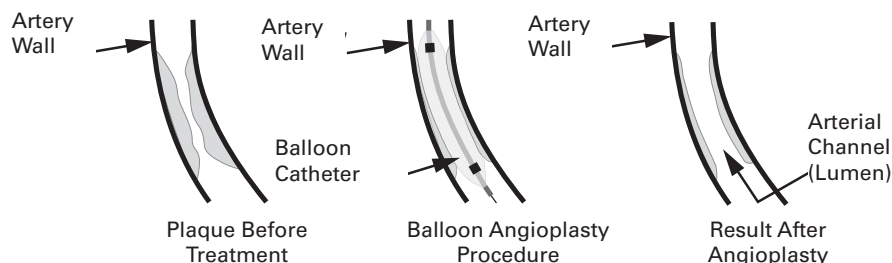
• Medical Management with Medication

A comprehensive program to manage your blood pressure, cholesterol levels and blood sugar, along with the use of blood thinning drugs such as aspirin are important medical treatments for intracranial disease. When these measures have not been effective or cannot be used, angioplasty with or without stenting or bypass surgery may be considered.

• Angioplasty

Percutaneous Transluminal Angioplasty (PTA) is a non-surgical treatment of a **neurovascular artery**. It is performed in the hospital to open a blocked artery. A thin tube known as a **catheter** is inserted through the artery in the groin area and is passed through a major blood vessel to the site of the blockage. PTA can be performed with a balloon alone, or can include inserting a **stent**.

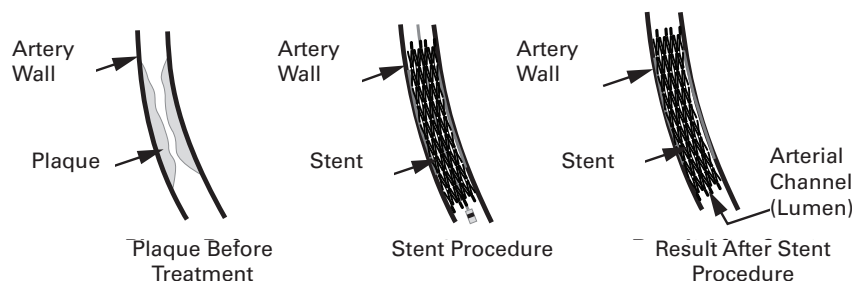
Sequence of Angioplasty Procedure



• Neurovascular Stents

Neurovascular stents are devices that can help reduce the risk of recurrent blockage or of narrowing after an **angioplasty** procedure. A **stent** is a tiny expandable metal tube that is implanted in a vessel. It expands to fit the size, shape, and bend of the vessel wall and props it open to help prevent future blockages. Once it is in place, the **stent** will remain in your **artery**. Over time, the **artery** wall should heal around the **stent** as it continues to support the vessel.

Sequence of Stenting Procedure



Who is not eligible to receive the Wingspan® Stent System?

The Wingspan Stent System cannot be used:

- If you are younger than 22 or older than 80 years of age.
- if you cannot take blood thinning drugs that make your blood less likely to clot.
- if the plaque build-up has calcified (hardened) to an extent that could prevent access or appropriate expansion of the Stent.
- if your most recent stroke occurred less than 7 days prior to scheduled treatment with the Wingspan System.
- to only treat transient ischemic attacks (TIAs).

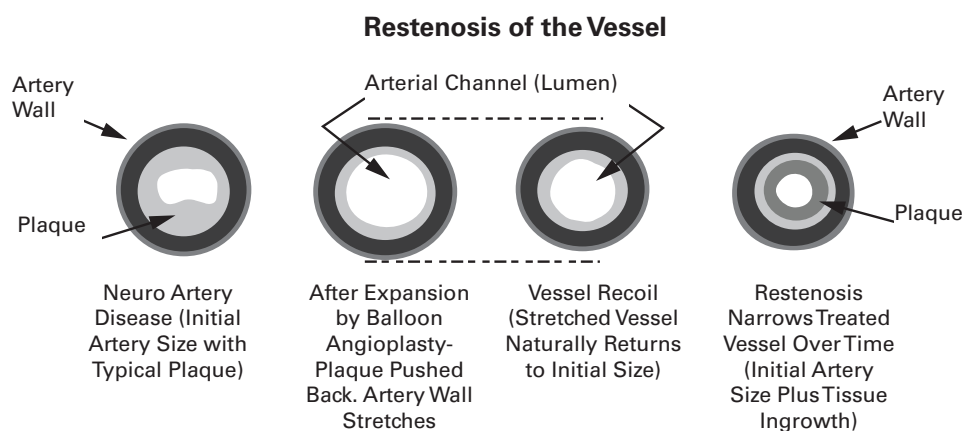
What are the Potential Complications?

Potential complications, which may be linked to angioplasty and neurovascular stent insertion include:

- air, tissue, or clots which can block the vessel (emboli)
- allergic reaction to the **contrast media** (could include kidney failure)
- allergic reaction to the metal used to make the stent (nickel, titanium, or platinum)
- **aneurysm**
- bleeding that would require a blood transfusion
- bruising of the blood vessel (pseudo-aneurysm)
- headache or discomfort
- bleeding inside the skull (intracranial hemorrhage)
- vasospasm (vessel closure)
- death
- high or low blood pressure
- poor supply of blood to the brain (ischemia)
- infection or pain at the access site
- injury or tearing of blood vessel (dissection)
- irregular heart beat (arrhythmia)
- movement of the **Stent** after insertion
- blockage of the **Stent or vessel** with blood clots
- **restenosis** in the treated vessel
- side effects due to **contrast media** or heparin
- **stroke** or other neurological events
- abnormal connection between vein and **artery** (arterio-venous fistula)
- vessel trauma requiring medical treatment
- worsening of neurological symptoms
- Transient Ischemic Attack (TIA)

What is Restenosis?

Some patients who undergo **balloon angioplasty** treatment will have a re-narrowing of the **artery**, or **restenosis**, in the area that was treated. Many patients who do not receive a **stent** after their balloon angioplasty procedure may have **restenosis** within the first six months. The re-narrowing can be caused by a combination of things including **vessel recoil** and tissue growth in the treated area.



Although stents may reduce **restenosis** compared to **balloon angioplasty** alone, **restenosis** may still occur in patients who receive a **stent**. Unlike **restenosis** after **balloon angioplasty**, **restenosis** in a **stent** (in-stent **restenosis**) is not normally caused by **vessel recoil**. Instead, in-stent **restenosis** is mainly caused by tissue growth around or through the **stent**.

What were the Clinical Study Results?

The initial study of safety and probable benefit of the Wingspan® Stent System was evaluated in a trial that included 45 patients. All patients were followed for 6 months. The study results showed that patients who received a Wingspan Stent had a significant reduction in the narrowing of the neurovascular **artery** treated. One out of 45 patients in this trial needed retreatment with a **stent**, 2 out of the 45 had a stroke within 30 days and 4 out of 45 patients had a **stroke** within 6 months. One patient died of a stroke within 6 months of having the procedure. Additional studies of the Wingspan Stent System have been conducted since approval. The largest study to date enrolled 451 patients with TIA or stroke attributable to $\geq 70\%$ stenosis of an intracranial artery compared aggressive medical management to aggressive medical management with drugs plus transluminal angioplasty and stenting with the Wingspan System with Gateway® PTA Balloon Catheter. The early analysis of the 30-day study data indicated that patients in the stenting arm had a significantly higher rate of stroke or death within the first 30 days (14.7%) compared to the arm randomized to aggressive drug therapy alone (5.8%). Based on the 30-day results, the study has demonstrated that aggressive medical management (drug therapy) should be the first line of treatment in the patient population studied.

A group of 33 patients in this study had been taking at least one anti-platelet or antithrombotic drug at the time of a recurrent stroke that had occurred more than 7 days prior to enrollment in the study. This group is similar to the group in the first study of the Wingspan® System. In this group of patients, the rate of stroke or death at 30 days was 12.2% in the medical management arm compared to 12.5% in the medical management plus stenting arm. Please ask your doctor about this study to gain a full understanding.

How Do You Prepare for the Angioplasty and Stent Placement Procedure?

Your doctor will instruct you on how to prepare for the **angioplasty** and **stent** insertion procedure. Your doctor may ask you to take aspirin and other prescribed medications for several days before the procedure. This is done to “thin” the blood to prevent blood clots from forming during the procedure. It is important to tell your doctor if you can not take aspirin or if you have a history of bleeding problems. Your doctor also needs to know if you are taking any other medications, have drug allergies, or are allergic to any metals or plastics.

What Happens During the Angioplasty and Stent Placement Procedure?

Your **angioplasty** and **stent** implant procedure will be performed in a specially equipped area of the hospital. You will have to lie flat on your back during the procedure. You may either be awake or asleep. If you stay awake, this will allow you to follow your doctor's instructions or answer questions if asked. Your groin will be shaved and cleaned with antiseptic, and you will be given a local anesthetic to numb the area.

Your doctor will place an **introducer sheath** in your groin area to gain access to the **artery**. The sheath allows the doctor to slide a small guide catheter up to the entrance of the blocked **artery**. Through the guide **catheter**, **contrast media** will be injected to help the doctor see the blocked arteries on the X-ray machine. A guidewire is then advanced through the guide **catheter** to the blockage, in the diseased **artery**. The guide catheter provides the "railway track" that carries all the tools necessary for the procedure.

Using the guide **catheter**, a balloon **catheter** is placed in the blocked area of the **artery**. Once in place, the balloon is inflated, which compresses the **plaque** and widens the **artery**. At this time you may have some discomfort. Although this is normal, let your doctor know if you are having any pain.

After the **artery** has been widened, your doctor will insert the Wingspan Stent, mounted inside a delivery catheter, into the **artery** where the balloon was inflated. Your doctor will insert the **Stent**. The **Stent** will expand by itself to the size and contours of the inner wall of your **artery**. Once in place, the Wingspan Stent will stay as a permanent implant in your **artery**.

What Happens After the Procedure?

After the procedure

After the **Stent** is implanted, you will be moved to a neurology ward for a short time where you can be observed closely as you begin to recover. On average, your hospital stay may last one to three days before you are discharged.

Activity

- Follow your doctor's guidelines.
- It is important to keep taking your medications unless you are asked to stop by your doctor.
- Return to normal activities slowly, pacing your return to your activities as you feel better. Check with your doctor about strenuous activities.
- Let your doctor know about any changes in lifestyle you make during your recovery time.
- Report side effects from medications to your doctor.
- Keep all follow-up appointments, including laboratory blood testing.
- Carry your Wingspan® Patient Information Card (shown in the back of this Guide) at all times. If you receive dental or medical care or report to an emergency room/center, show your Wingspan Patient Information Card.

Medications

Your doctor may prescribe a number of medications to thin the blood and prevent blood clots from forming and sticking to the surface of the **Stent**. You will be asked to take a daily dose of aspirin indefinitely. In addition to aspirin, you will also need to take drug prescriptions for a period of several months. It is extremely important to take your drug prescriptions as ordered by your doctor. Check with your doctor prior to stopping the use of these medications, even if only temporarily.

Follow-Up Examinations

You will need to see the doctor who implanted your **Stent** for routine follow-up examinations. During these visits, your doctor will check your progress and assess your drug prescriptions. Your doctor will also check to see how the **Stent** is working for you. 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

Frequently Asked Questions

Can the Stent move or rust?

Once your doctor inserts the **Stent**, it does not move on its own. It is manufactured so that it will not rust.

Can I walk through metal detectors with a Stent?

Yes, without any fear of setting them off.

How soon can I go back to work?

The majority of people return to work within a few days after the procedure.

What if I still get symptoms?

If you start having symptoms, immediately tell either your doctor or the center where the procedure was performed.

Can I have Magnetic Resonance Imaging (MRI) or scanner testing with a Stent?

The Wingspan® Stent has been shown to be magnetic resonance conditional, which means that it can be scanned in certain MRI conditions without causing harm to you. This is very important to know if in the future you need an MRI scan for any part of your body. Before you have an MRI scan, or for questions regarding your Wingspan Stent System or procedure, please contact the implanting doctor. Your Stent should not move during an MRI scan. Prior to undergoing these examinations, inform your doctor that you have a **Stent**.

What should I change in my diet?

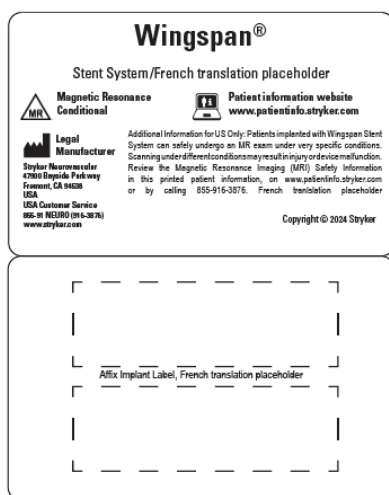
Your doctor may prescribe a low-fat, low-cholesterol diet to help lower the levels of fat in your blood. This may also lower your risk of future **stroke**.

Patient Information Card

Below is a sample of a Wingspan® Stent System Patient Information Card. Your doctor will fill out a card like this for you after the treatment. Make sure your doctor gives this card to you before you leave the hospital. You should keep this card with you at all times. 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 MR Conditional.

Card Outside



Wingspan®
Stent System/French translation placeholder

Magnetic Resonance Conditional
Additional Information for US Only: Patients implanted with Wingspan Stent System can safely undergo an MRI exam under very specific conditions. Scanning under different conditions may result in injury or device malfunction. Review the Magnetic Resonance Imaging (MRI) Safety Information in this printed patient information, on www.patientinfo.stryker.com or by calling 855-916-3876. French translation placeholder

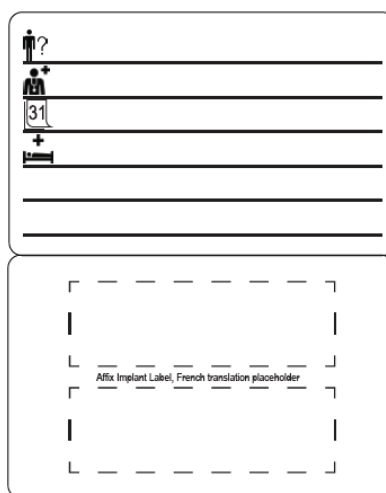
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Patient information website
www.patientinfo.stryker.com

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Affix Implant Label, French translation placeholder

Card Inside



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Affix Implant Label, French translation placeholder



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