

A patient's **guide** to **STENT IMPLANTATION**

GUIDANT CORPORATION

"It's a great time to be aliveSM"

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Humanitarian Device. Authorized by Federal (U.S.) law for use in the treatment of recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 mm to 4.5 mm in diameter with $\geq 50\%$ stenosis and that is accessible with the stent System. The effectiveness of this device for this use has not been demonstrated.

This booklet is provided as a service by Guidant Corporation. Guidant is one of the world's largest medical device companies and a leader in cardiovascular and vascular therapeutic device solutions. We are committed to providing high quality medical devices for doctors and patients around the world.

This brochure has been given to you because you have been told by your doctor that further treatment may be necessary for the symptoms you are experiencing. One treatment option may be the NEUROLINK Stent. This brochure provides information about the NEUROLINK Stent and the procedure that may be done to put this stent in the blood vessels in your brain. As you read, you might think of some questions that you would like to discuss in more detail with your doctor or nurse -- you'll find a place in back for your notes.

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INTRODUCTION

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Definitions of Medical Terms

We have underlined these words when they appear in the brochure, so that you can refer back to these definitions.

angiogram - x-ray pictures of your blood vessels taken with contrast dye

angiographic suite - a combined x-ray room and operating room

angioplasty - a procedure in which a balloon is used to open the blood vessels

anti-coagulant or antiplatelet – drugs given to slow down the clotting of blood

artery – a kind of blood vessel

atherosclerosis - a collection of fatty deposits on the inside the blood vessel walls.

This causes the path for the blood flow to become narrow and hardens the vessel walls

balloon catheter – a thin tube with a balloon on the tip that can be inflated to expand vessel blockages

catheter - a thin tube through which fluids or objects can be put into or removed from the body

cath lab/catheterization lab- another name for angiographic suite

diagnosis - the disease or condition that is causing symptoms

embolus (plural is emboli) - when something like a blood clot, air bubble or fatty deposit is released into the vessel and moves downstream with your blood flow. This may cause narrowing or blockage of the blood vessel

endovascular – through or inside blood vessels

fluoroscope – a kind of x-ray machine that is used to show the arteries to be treated

general anesthesia - medication given to make you sleep during the stenting procedure

intracranial - inside the head

intracranial arteries - the arteries inside the head that supply blood to the brain

ischemic stroke – a kind of stroke resulting from lack of blood flow to an area of the brain

local anesthesia - medication that numbs the body part being treated, so that you don't feel the discomfort of the stenting procedure.

neurovascular - blood vessels in, or leading to, the brain

sedation - medication given to make you very relaxed and sleepy

stenosis - a narrowing in your blood vessel

stent - a tiny wire mesh tube that is placed inside a blood vessel to keep it open

Transient Ischemic Attack (TIA) - temporary symptoms of stroke, such as problems seeing, speaking, or walking, that go away within 48 hours (see your doctor if you experience these symptoms)

vessel – the same as an artery

POTENTIAL COMPLICATIONS

Potential Complications

Although stents (tiny wire mesh tubes that help to keep open clogged arteries) have been widely used in other vessels in the body, it is relatively new to put them in the arteries in the head. The possible benefit to you of choosing this treatment has not yet been proved to the FDA (Food and Drug Administration) by the manufacturer, Guidant Corporation.

There is always a chance of complications from endovascular procedures (procedures that are done through the blood vessels) including –

Allergic reactions, bleeding, heart attack, stroke or TIA (temporary symptoms of a stroke), or even death

Damage to your blood vessels

Emboli (air, blood clots, or even the stent breaking off moving downstream from where your doctor is working)

Restenosis (blocked blood flow in the stent)

Infection or bruising of your groin area (at the top of your leg) where the catheter (narrow tube) was inserted for the stent procedure.

If any of this happens to you, your doctor will treat you as needed.

Risks - Benefits

THIS STENT SHOULD NOT BE USED IF -

The narrowed area in the artery in your head is too small to allow the balloon catheter (tubing with a balloon at the end) and/or stent (tiny wire mesh tube) to fit into place.

You can't take blood thinners (anti-coagulants or anti-platelets), which are drugs that make your blood take longer to form a clot.

Note: Some doctors give combinations of anti-platelet and anti-coagulant drugs to decrease the risk that you will form a blood clot in your artery.

ATHEROSCLEROTIC DISEASE (ATHEROSCLEROSIS)

Atherosclerotic Disease

Its Causes

Atherosclerotic disease is caused by a build up of fatty substances like cholesterol. Where they collect in the blood vessel, the lining of the vessels thickens, the blood vessel narrows, and blood flow slows down. Atherosclerosis (the build up of fatty substances) can happen in any blood vessel in the body. Your symptoms have occurred because of atherosclerosis in the arteries in your brain.

Its Effects

Your brain is a very active organ. To work well, it needs a constant supply of oxygen and nutrient-rich blood. Four main arteries (two internal carotid arteries and two vertebral arteries) and a network of vessels supply the blood to your brain. If these arteries become partially blocked by fatty deposits, the brain may not receive enough oxygen and blood. In addition, blood clots can form at the narrowed part of the blood vessel or pieces of fatty build-up can be embolized (break off and release into the blood stream). At this point you may experience a stroke or TIA (transient ischemic attack, or temporary symptoms that seem like a stroke).

ISCHEMIC STROKE – TIAs

Reaching a Diagnosis

The Angiogram: This test is the main method used to diagnose (when your doctor decides the disease or condition that is causing your symptoms) the location and severity of atherosclerotic disease (a disease caused by a build up of fatty substances) in your blood vessels. A special dye is injected into the arteries in your head, and an x-ray is taken using a fluoroscope (a type of x-ray machine). The dye shows the arteries on a monitor (special television screen) so that your doctor can see the narrowed parts.

Remember - the sooner the diagnosis is made, the sooner treatment can begin.

Risk Factors for Atherosclerosis, Stroke, and TIA

Any of the following risk factors may increase your chances of developing atherosclerosis (a build up fatty substances inside the blood vessel)

Smoking	Being overweight
Diabetes	Lack of exercise
High blood pressure	High cholesterol diet
Family history of <u>atherosclerosis</u>	

YOUR TREATMENT OPTIONS

Treatment Options

Once your doctor has made a diagnosis (the disease or condition that is causing your symptoms) he or she will recommend the most appropriate form of treatment. The most common treatment is medications. Other alternatives might include bypass surgery, angioplasty, or treatment with a stent (tiny wire mesh tube). There may be other options, and you should ask your doctor.

Medications

Your doctor may prescribe blood thinners known as anti-platelets or anti-coagulants. Common drugs used include aspirin, Plavix, Coumadin (also known as warfarin), or Aggrenox. These drugs lower the risk of blood clots forming at the narrowed part of the blood vessel, and can help relieve your symptoms.

Angioplasty

The purpose of angioplasty is to open blocked arteries to increase blood flow. The procedure will be done in an angiographic suite (a combined x-ray and operating room) after giving you local anesthesia (medication given to numb the body part being treated) or general anesthesia (medication to make you sleep). A needle is put into a blood vessel in the groin (top of your leg) or arm. A catheter (small tube) is fed into your blood vessel. Contrast dye is injected through the catheter and your doctor uses a fluoroscope (a special x-ray machine) to see the arteries in your brain.

YOUR TREATMENT OPTIONS

While your doctor watches the picture of your arteries on the monitor (a special television screen), a wire and a balloon catheter (a tube with a small balloon on the end) are fed into the vessel. Your doctor will move the balloon into the narrowed part of the artery, and then inflate it to press the fatty deposits against the wall and stretch the artery. This increases the size of the artery and improves blood flow. The balloon is then deflated and removed. Over time the blockage may happen again. This is called "restenosis". If this happens, your symptoms might return and your doctor may recommend another treatment.

Bypass Surgery

With bypass, the surgeon bypasses or "goes around" the blocked artery to restore normal flow. A piece of blood vessel is taken from another part of the body and is sewn onto the blood vessel beyond the narrowed area. This makes a new path for the blood to flow past the narrowed area.

[Insert illustration of a bypassed vessel]

THE STENT PROCEDURE

Stenting

This treatment is similar to angioplasty (opening the blood vessel with a balloon; see page 9 for a description of angioplasty) except that a stent (tiny mesh wire tube) is used to help keep the artery open. Your doctor may recommend a stent in combination with asking you to take medications. A description of the NEUROLINK® Stent procedure follows below:

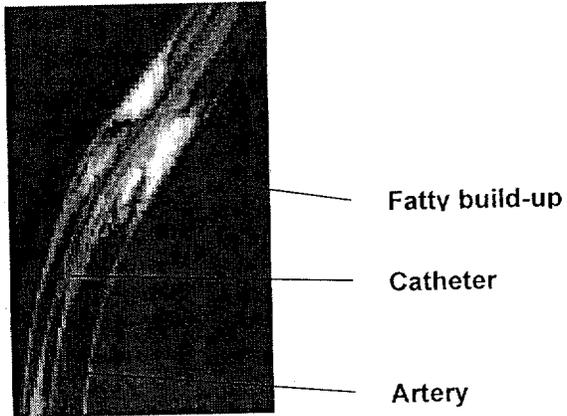
The NEUROLINK® Stent is a tiny wire mesh tube that is placed on a balloon catheter (a tube with a balloon at the end). The catheter is fed into the narrowed blood vessel.

The doctor moves the NEUROLINK® Stent on the balloon catheter into the blocked artery and inflates the balloon. This causes the stent to open up, pressing it against the vessel wall.

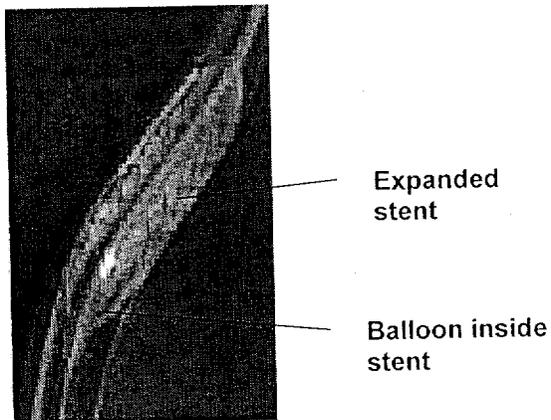
Then the balloon is deflated and removed from the vessel. The stent stays in place permanently.

THE STENT

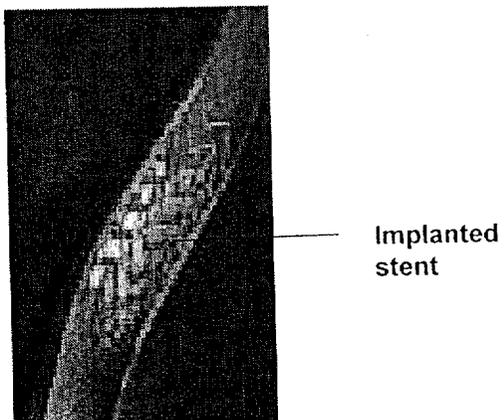
The catheter is fed into the narrowed area of the artery caused by fatty build-up.



The balloon is inflated. This opens up the narrowed artery and expands the Stent.



The balloon and catheter are removed from inside the vessel. The Stent is left in place in the artery.



PREPARING FOR TREATMENT

In the days before your treatment, make sure you take all of the following PRECAUTIONS:

- Take all of your prescription medications
- Tell your doctor if you are taking any other medication
- Tell your doctor if, for any reason, you cannot take aspirin
- Make sure your doctor knows about any allergies you have
- Do not eat or drink after midnight on the night before your treatment
- Follow all instructions given to you by your doctor or your nurse

The procedure may be done under local or general anesthesia (medication that causes numbness or makes you fall asleep, so that you do not feel discomfort). If the doctor needs you to be perfectly still so that the x-ray picture is very clear, general anesthesia (medication that makes you fall asleep) might be used. If the doctor needs you to be awake so that you can take deep breaths and respond to instructions, local anesthesia (medication that will numb the body part being treated) may be used.

Once you are in the angiographic suite (the combined x-ray and operating room where the procedure is performed) you will be moved onto an x-ray table and covered with a sterile sheet. Your groin (the area at the top of your leg) will be washed with an antibiotic solution, and a local anesthetic will be administered.

DURING THE PROCEDURE

Next, your doctor will put a needle into the artery (puncture site) in your groin (at the top of your leg) or arm to feed the stent (tiny wire mesh tube) on its balloon catheter (a tube with a balloon at the end) into the vessel. The procedure usually takes about 90 minutes. For the most part you will be comfortable -- but you may feel some pressure at the puncture site or headache or dizziness when the balloon is inflated. After a stent is put in an artery in the brain, some patients experience a headache that may take hours to go away.

Immediately after the procedure, you will be sleepy and may be confused from the sedation (the medication given to make you relaxed and sleepy) or general anesthesia (medication that makes you fall asleep), but this will clear as the medications wear off. You will be taken to a special room where you will be watched closely by the nurses and doctors: they will ask you questions, ask you to move your fingers and toes, and check your eyes with a flashlight. Your blood pressure and puncture site will also be closely watched.

[Insert an illustration showing vascular access of balloon catheter and stent]

MAKING A GOOD RECOVERY

During your stenting procedure (the procedure to place the stent, or tiny mesh tube, in your blood vessel), you will have been given a blood thinner (anti-coagulant). You may still have a sheath (thin tube placed inside the blood vessel) in your groin (top of your leg), which will be removed when the effects of the blood thinner wear off and your doctor decides that you are recovering from the stenting procedure. Pressure will be applied to puncture site (where the needle was placed in the vessel) until bleeding stops. Once you are awake, you should drink fluids to flush the dye out of your system. You will have to stay in bed for several hours, keeping your leg straight to allow your puncture site to start healing. Your doctor will allow you to gradually become more active. You will need to avoid lifting and straining for a couple of days. You may need to stay in the hospital for several days. After you are discharged, be sure to call your doctor or the hospital immediately if the symptoms you had before the procedure get worse, or if you have any new symptoms, such as -

- severe headache,
- dizziness
- slurred speech
- weakness on one side of your body (for example, your right arm, leg, or face becomes weaker than your left)
- fever
- problems at your puncture site such as swelling, pain, or bleeding.

GETTING ON WITH LIFE

To begin with, you will have to return for regular check-ups. After 6 months, you may be asked to have another angiogram (x-ray of your blood vessels using a contrast dye). Regular check-ups are the only way to check your progress, so please be sure to keep your appointments. Your doctor will also prescribe medication, and it is important to take your medication exactly as your doctor tells you. Be sure to take all of your medication until your doctor tells you to stop.

It may take weeks to months before you feel back to normal, and some effects from the stroke may be permanent. If you have had a stent (tiny wire mesh tube) placed in your brain, it will not limit your activities in any way. **It is very important to tell any doctor or dentist who treats you for any reason that you have a Stent implant in your brain, and keep your stent implant card with you at all times.** As the manufacturer of your stent, Guidant is required by the federal government to have your current address and telephone number on file. If your address or telephone number changes, please notify Guidant at 1 (800) 227-9902.

If anything you have read in this booklet has made you think of other questions regarding the procedure, now is the time to discuss them with your doctor.

YOUR NOTES

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