



A Guide for Patients and Their Families

**GUIDANT**

**CAROTID ARTERY STENTING**

This brochure, provided by Guidant Corporation, has been given to you because your doctor has told you that treatment of your carotid artery disease may be necessary. Endovascular treatment (procedures that are done through the blood vessels) using the ACCULINK™ Carotid Stent System and the ACCUNET™ Embolic Protection System may be one treatment option.

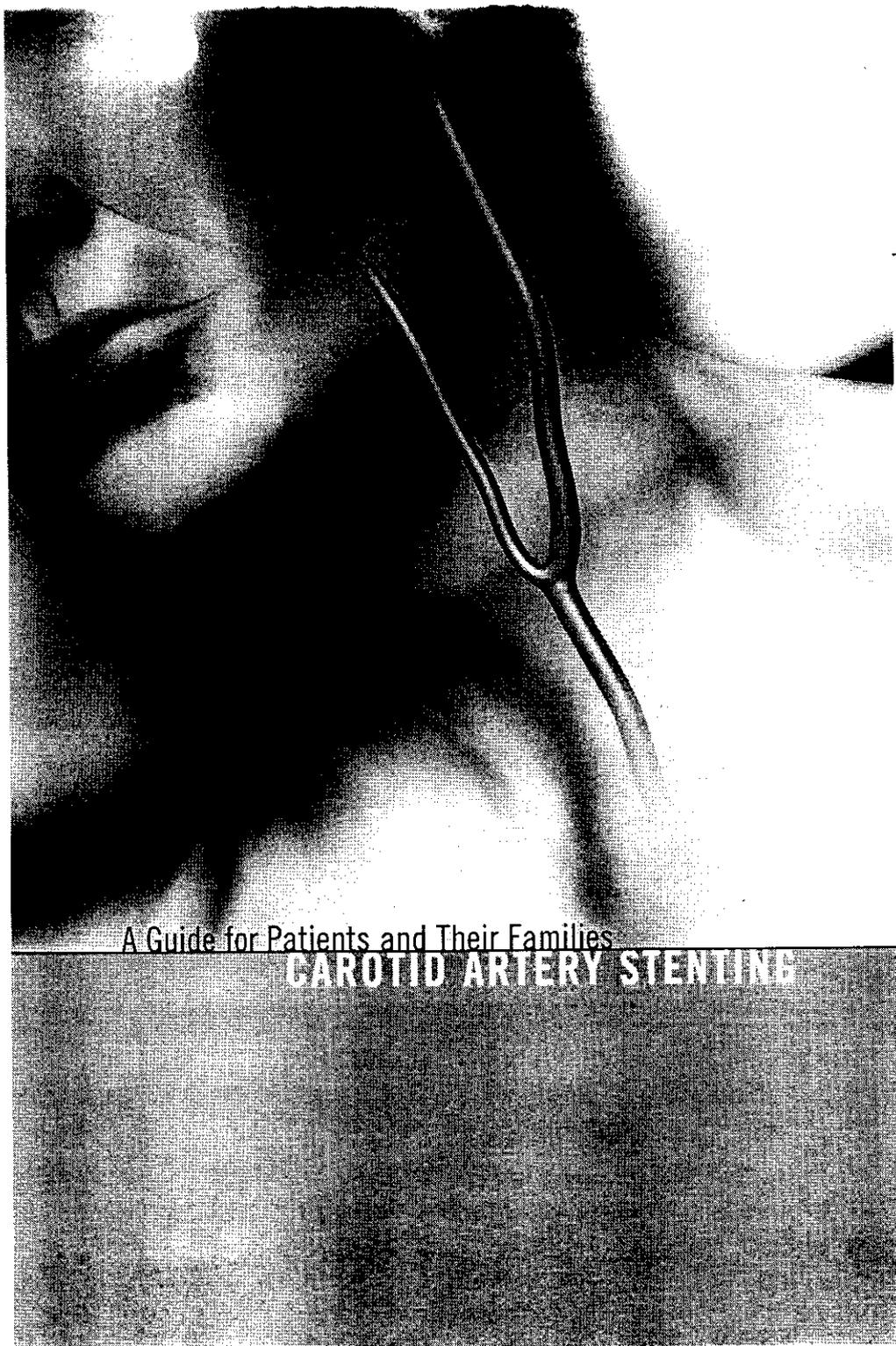
The ACCULINK™ and RX ACCULINK™ Carotid Stent Systems and the ACCUNET™ and RX ACCUNET™ Embolic Protection Systems are intended for use in the treatment of carotid artery disease for patients who are ineligible for current surgical options or are at high risk for surgical or anesthesia-related complications.

This brochure provides you with information about the ACCULINK™ Carotid Stent and the procedure used to insert this stent into your carotid arteries. The brochure contains technical terms that may be unfamiliar to you. Underlined words are defined in the glossary at the end of the brochure.

As you read, you might think of questions you would like to discuss with your doctor or nurse. You will find a place in the back of this brochure for your questions and notes.

Guidant Corporation





A Guide for Patients and Their Families

## CAROTID ARTERY STENTING

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Note: This brochure contains technical terms that may be unfamiliar to you. Underlined words are defined in the glossary at the end of the brochure.

## CAROTID ARTERY DISEASE

Your brain is a very active organ. It is the control center of your body. To work efficiently, your brain needs a constant supply of oxygen and nutrient-rich blood. A significant portion of the blood flow to your brain comes from the carotid arteries. The common carotid arteries (CCA), located on both sides of your neck, divide into two vessels. These vessels are called the external carotid arteries (ECA) and the internal carotid arteries (ICA) (Figure 1). The external carotid arteries bring blood to your face. The internal carotid arteries bring blood to the front part of your brain.

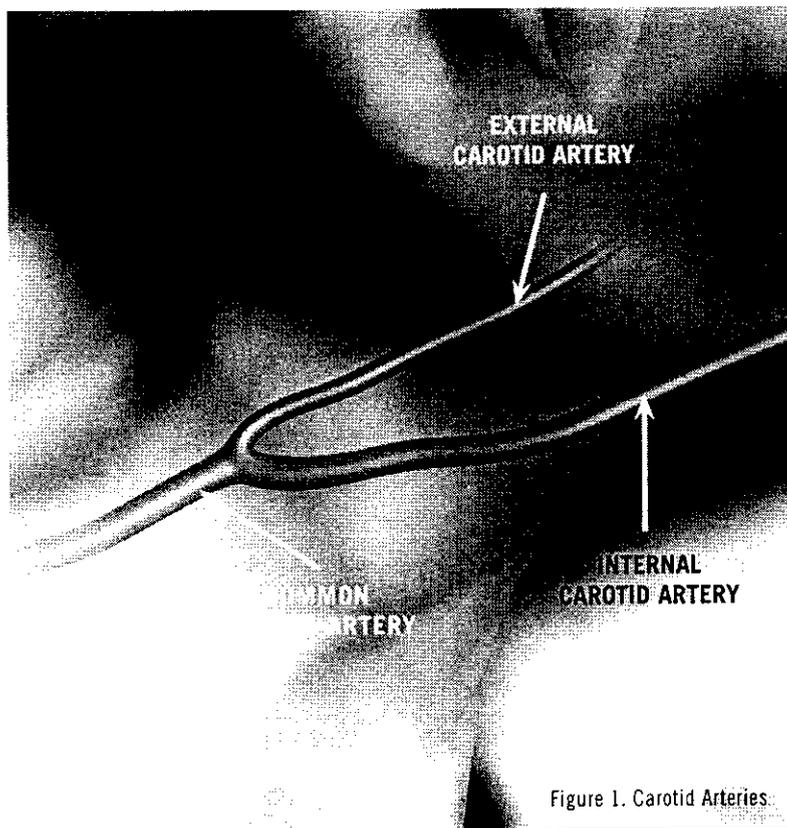


Figure 1. Carotid Arteries.

One type of carotid artery disease is atherosclerosis, which is caused by a buildup of fatty substances like cholesterol. These fatty buildups are sometimes called "plaque". This results in a thickening and hardening of the vessel, so that the flow of blood is slow down. Atherosclerosis can develop in one or both carotid arteries.

Atherosclerosis in the carotid artery may lead to stroke in one of two ways:

1. Plaque buildup narrows the blood vessel so that the flow of blood to the brain is blocked.
2. The plaque or blood clots formed on the plaque embolize (break off) and travel to a smaller artery in the brain, resulting in a blockage of that artery.

In either case, an artery becomes blocked and the brain doesn't receive enough blood. This can cause a stroke called an ischemic ("lack of blood") stroke. This can also create temporary symptoms that seem like a stroke, known as a transient ischemic attack or TIA. (For more information on stroke, please go to page 6). This is why it is important for you and your doctor to know about any risk factors you might have.

### Risk Factors for Carotid Artery Disease

Certain factors, such as your lifestyle or family history, can increase your risk of carotid artery disease. While some of these risk factors cannot be modified or changed, others can be reduced, treated, or controlled.

#### Risk factors that cannot be changed:

- Increasing age
- Gender
- Family history of stroke
- A relative with atherosclerosis
- Prior history of stroke and/or heart attack
- Race

#### Risk Factors that can be reduced, treated or controlled:

- High blood pressure
- Smoking
- Diabetes
- Heart disease (e.g., heart attack, heart failure)
- Artery disease outside the heart and the major vessels
- Obesity
- High blood cholesterol level
- Lack of exercise

## DIAGNOSIS OF CAROTID ARTERY DISEASE

### Symptoms of Carotid Artery Disease

Many people do not have any symptoms from carotid artery disease. Some people may experience TIA or stroke. A stroke or "brain attack" is an injury to the brain caused by lack of oxygen. Stroke occurs in about 700,000 people a year in the United States. About 280,000 patients die each year from stroke-related causes.

Transient ischemic attacks (TIAs), also called "temporary strokes" or "mini strokes", are warning signs that you are at high risk for experiencing a stroke. Because there are no specific symptoms of carotid artery disease, it is important to know these warning signs. If you have any of the warning signs of a stroke or TIA, it may be a sign of blockage in the carotid arteries.

### Symptoms of Stroke or TIA

During a stroke or TIA the blood flow to the brain is interrupted. Symptoms of stroke and TIA are very similar and depend on the area of the brain affected, how long your symptoms last, and the amount of the injury.

#### Common signs and symptoms of a stroke or TIA may include:

- Sudden numbness or weakness of the face, arm or leg, especially on one side
- Sudden confusion or dizziness
- Sudden trouble speaking or understanding
- Sudden trouble seeing in one or both eyes
- Sudden trouble walking, loss of balance or coordination
- Sudden, severe headache with no known cause
- Sudden trouble swallowing

#### Call your doctor immediately if you have any of these symptoms.

If the symptoms go away within 24 hours or so, this may be due to a TIA. But be aware that TIAs are extremely important stroke warning signs so it is important to let your doctor know that you've had these symptoms.

If your doctor suspects that you have carotid artery disease because you have atherosclerosis in other blood vessels in your body or if you have symptoms of the disease, your doctor may use one or more of the following tests to help diagnose your condition.

- **History and Physical Exam:** The doctor will examine you and ask you about symptoms that you may have. It is important to tell the doctor all of your symptoms, even if some were only temporary.
- **Doppler Ultrasound:** Ultrasound, which uses sound waves to create an image, allows the doctor to see if you have blockages in your carotid arteries. This test is painless and non-invasive (the testing is done from outside the body).
- **Angiogram:** A catheter (small hollow tube) is used to inject contrast (dye) into the carotid arteries. Then x-rays are taken to allow the doctor to see any narrowing in your carotid arteries.
- **Computerized Axial Tomography Scan** (CT or CAT Scan): A CT scan, also called a CAT scan, uses x-rays to create three-dimensional images of a part of the body. It can be done with contrast (x-ray dye) if the doctor wants to see the vessels.
- **Magnetic Resonance Imaging** (MRI): An MRI uses a very strong magnet to make three-dimensional images of a part of the body. An MRI can show atherosclerosis of the carotid arteries, or areas of the brain damaged by a previous stroke, in addition to other abnormalities. It can be done with contrast (dye) if the doctor wants to see the vessels (magnetic resonance angiogram, also called an MRA).

Using the information gathered from one or more of these tests, your doctor will be better able to recommend the most appropriate treatment. The doctor will explain the risks and benefits of your treatment options and answer any questions you or your family may have.

## TREATMENT OPTIONS FOR CAROTID ARTERY DISEASE

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Treatment options for atherosclerotic carotid artery disease include: medication, surgery and less invasive procedures such as placing a stent in the narrowed artery. Using stents in the treatment of carotid artery disease is a relatively new option for some patients.

### Medications and Risk Factor Changes

Your doctor may prescribe blood thinners known as anticoagulant or antiplatelet medications. Common drugs used include aspirin, Plavix®, Coumadin® (also known as warfarin), or Ticlid®. These drugs lower the risk of blood clots. In addition, your doctor may prescribe medications to lower your blood pressure or cholesterol. Your doctor may recommend ways to control your risk factors, such as quitting smoking, exercising and losing weight.

### Carotid Endarterectomy

Carotid Endarterectomy (CEA) is a surgical procedure that removes the blockage in the carotid artery. An incision is made in your neck and into the carotid artery, the plaque is removed from the artery, and then the artery is closed with stitches. The procedure is usually done under general anesthesia, although some doctors use local anesthesia. CEA is one of the most common surgical procedures in the United States and has been performed for over 50 years.

### Carotid Stenting

Carotid stenting is a relatively new endovascular treatment (done through or inside the blood vessels) for carotid artery disease. You might decide that carotid stenting is a better option for you because you would not need to have the incision in your neck or general anesthesia necessary for CEA. However, carotid stenting does not have the long history that CEA does, although clinical studies have shown that carotid stenting is as safe and effective as CEA.



ACCULINK™ Carotid Stent

The procedure uses a stent (small latticed metal tube) to open partially blocked arteries and to hold the plaque against the artery wall. The picture above shows an ACCULINK™ Carotid Stent. The stent is made from nickel-titanium, a metal that is bendable but springs back into its original shape after being bent. An embolic protection device is also used to help catch any pieces of plaque or other particles that may be released during the procedure.

The stent is introduced into the narrowed blood vessel on a catheter, after an embolic protection device has been placed beyond the narrowed area of the artery. The doctor maneuvers the stent on a catheter into the vessel, and positions the stent across the narrowed area in your carotid artery. The stent is released and stays in place permanently, holding the artery open and improving blood flow. The stent also holds the plaque against the artery wall. This reduces the risk of plaque breaking off, traveling into your brain, and causing a stroke. All of the devices, except the stent, are taken out your body at the end of the procedure.

The following pages review the stenting procedure in more detail.

## CAROTID STENT PROCEDURE

### Preparing For Your Procedure

In the days prior to your treatment, make sure you:

- Take all of your prescription medications. Tell your doctor if you are taking any other medication.
- Tell your doctor about any allergies you have, especially to contrast dye or iodine, or to materials such as metals (nickel-titanium or stainless steel) or plastics (polyurethane).
- Tell your doctor if you cannot take aspirin, since aspirin and other medications are usually begun prior to a procedure and continued for several months thereafter.
- Do not eat or drink anything after midnight on the night before your procedure.
- Follow all instructions given to you by your doctor or your nurse.

### Before Your Procedure

- Your doctor will explain the possible risks and benefits of the stenting procedure and answer any questions you or your family may have.
- You may be given a sedative before the procedure to relax you. The sedative may also make you sleepy.

### During Your Procedure

- Once you are in the angiographic suite or catheterization lab, you will be moved onto an x-ray table. The procedure will be done through an artery in your leg, so your groin area (at the top of the leg) will be washed with an antibiotic solution and then covered with a sterile sheet.
- Your doctor will inject a local anesthetic (numbing medicine) into the area where the catheters will be inserted. You may feel a sting when the needle is put into your groin and a brief warm sensation when the medicine is injected.
- Next, your doctor will put a needle into the artery in your groin to feed the guiding catheter into your artery (Figure 2). When the needle is first placed in the artery in your groin, you may feel some pressure.
- Your doctor will inject contrast (x-ray dye) into the guiding catheter to allow him to see the arteries in your neck and brain. Your face and neck may feel warm or flushed when this happens, but this usually goes away after a short time.

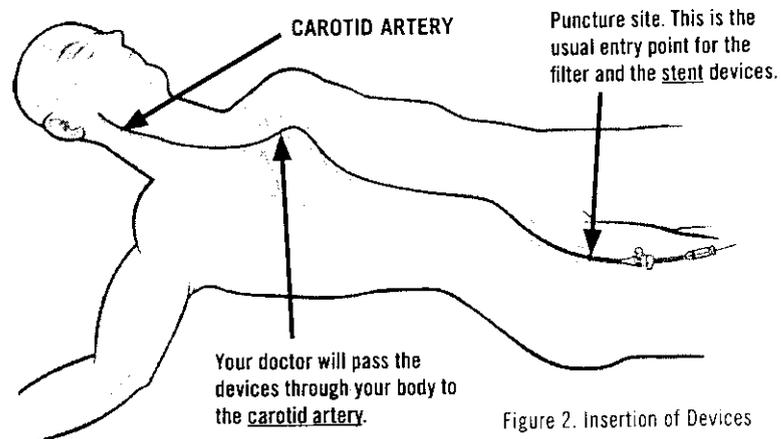


Figure 2. Insertion of Devices

- Your doctor will pass the ACCUNET™ Embolic Protection System into the carotid artery. The ACCUNET™ Embolic Protection System is a wire with a small filter on the end that looks like a basket. You should not feel any discomfort during this part of the procedure.
- Once your doctor crosses the diseased area of the artery with the ACCUNET™ Embolic Protection System, he will open up the small filter. The ACCUNET™ Embolic Protection System will stay in place during the procedure to help capture any plaque or particles that could travel into the smaller vessels in the brain (Figure 3).

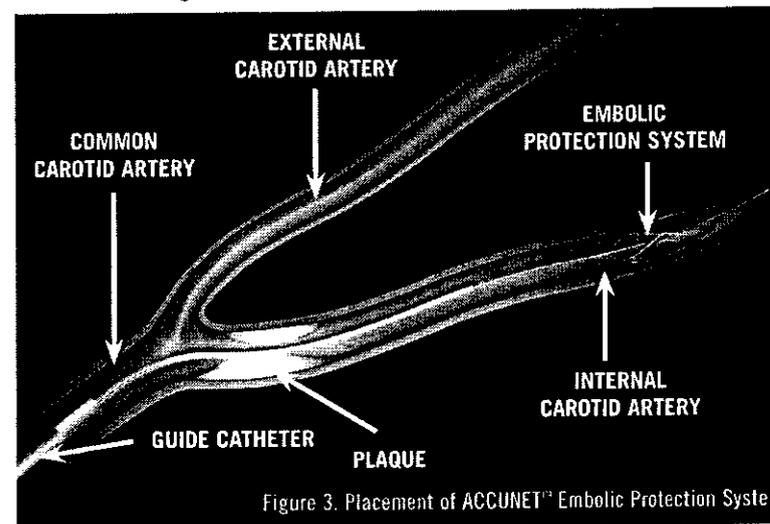
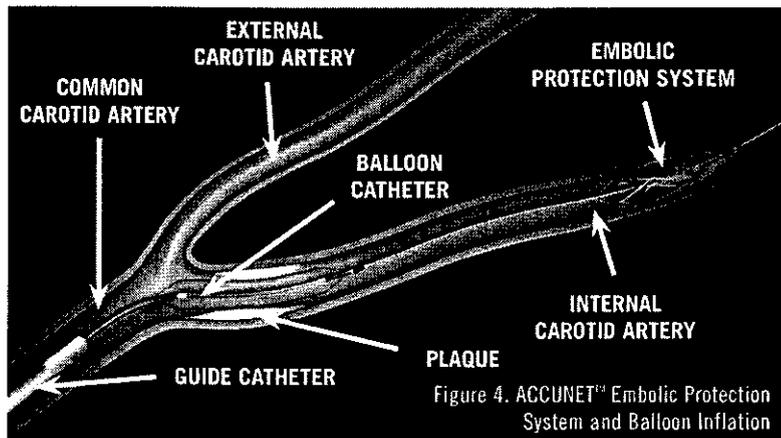
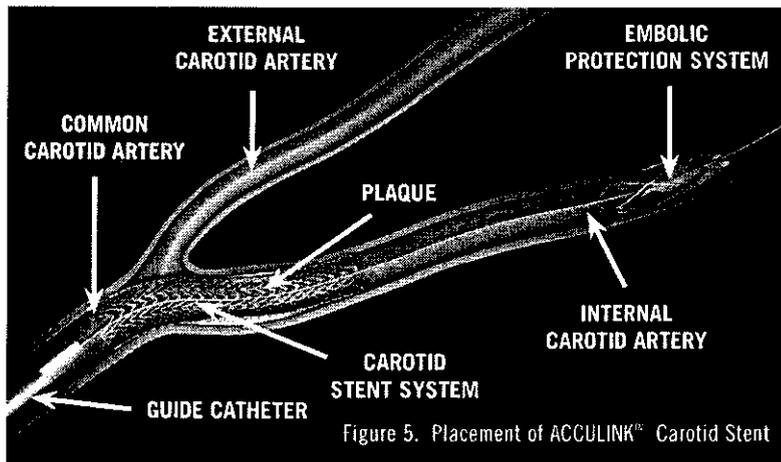


Figure 3. Placement of ACCUNET™ Embolic Protection System

- The doctor may insert a balloon catheter into the narrowed area and then temporarily inflate the balloon in order to open up the artery. Your doctor will then remove the balloon catheter from your body (Figure 4).

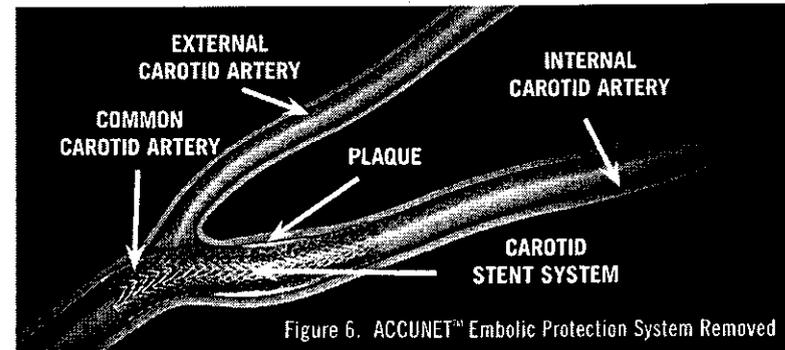


- Your doctor will feed the ACCULINK™ Carotid Stent System through the vessels to the area of the plaque. After careful positioning, he will open the ACCULINK™ Carotid Stent to cover the plaque (Figure 5).



- The doctor may, if necessary, insert a balloon catheter into the ACCULINK™ Carotid Stent to open it wider. The stent will remain in place permanently, but the balloon will be removed.

- The doctor will then remove the ACCUNET™ Embolic Protection System and all other devices from your body (Figure 6).



#### Following Your Procedure

- Immediately after your procedure you may feel sleepy from the sedation. This will clear as the medication wears off.
- You will be taken to a special observation unit where nurses and doctors will monitor your condition closely.
- Your vital signs (heart rate and blood pressure) and the area in which the catheter was inserted will be checked frequently.
- In addition, your neurological status will be checked by your nurse who will ask you questions, instruct you to move your fingers and toes, and check your pupils with a flashlight.
- Your blood pressure and puncture site will also be closely watched.
- During the ACCULINK™ stenting procedure, an access line called a “sheath” was inserted into your groin. The sheath will remain in place until the effects of the anticoagulant medication wear off.
- Your doctor may use a special vascular closure device to close the small incision in your groin. Pressure will be applied to your puncture site until bleeding stops.
- You should drink plenty of 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. If your doctor uses a vascular closure device, you may be able to get up sooner.
- While you are in the hospital, you should let your doctor know if you have any dizziness, severe headache, sudden numbness in your legs, arms, or just on one side of your body, sudden weakness, blurred vision, blindness in one or both eyes, difficult swallowing or speaking, or pain at the puncture site in your groin.
- Your doctor will allow you to gradually become more active. You should avoid lifting and straining for as long as your doctor tells you.

## YOUR RECOVERY

You may need to stay in the hospital for one or two days. Before you leave the hospital, your doctor will give you guidelines for activities, diet, and medications. Your doctor will also give you your Stent Implant Card (a sample is shown on page 16), which has important information regarding your ACCULINK™ Carotid Stent.

After you are discharged, be sure to call your doctor or hospital immediately if you have any new symptoms or worsening of the symptoms you had before the stent placement, such as:

- severe headache
- dizziness
- slurred speech
- problems at your puncture site such as increasing swelling, pain or bleeding
- fever
- weakness or numbness affecting one side of your body (for instance, your right arm, leg, or face becomes weaker than your left)
- blurry vision or sudden lost of vision one or both eyes

Because medications will be an important part of your treatment, your doctor will prescribe drugs to take at home. It is important to follow your medication regimen exactly. These medications will help prevent blood clots from forming in the newly opened carotid artery. These medications can also slow or prevent clotting if you have bleeding resulting from your stenting procedure, from an injury, or from any other medical treatment. Notify your doctor if your medications cause unpleasant reactions, but do not stop taking them unless instructed to do so. Your doctor may be able to prescribe new medications that better suit you.

It is important to keep all scheduled follow-up appointments. Your doctor will want to follow your progress closely and may require you to have tests to make sure that your carotid arteries are open and that blood flow through the treated area is sufficient. Most of the patients who go home after a successful procedure have no further problems. In some patients (less than 5% in clinical studies of the ACCULINK™ Carotid Stent), the narrowing in the artery may return. Such recurrences, called restenosis, usually occur within the first six to twelve months after a procedure. If you have any questions, ask your doctor.

You may need to have an MRI or MRA to look at your arteries some time after your stent implant. You can have an MRI or MRA at any time after your stent is implanted; the ACCULINK™ Carotid Stent is “MRI compatible”. However, make sure you let the people running the MRI test know you have a stent. Give them your Stent Implant Card so they use the right kind of MRI machine. Make sure to notify your doctor if your address or telephone number changes so that he can contact you if any information about your stent becomes available in the future.

Follow your doctor's advice about life style changes. You should stop smoking if you currently smoke, eat a healthy diet, get enough exercise, and make sure to take all of the medicines regularly that your doctor has prescribed for you.

## RISKS-BENEFITS AND CONTRAINDICATIONS

Although stents have been widely used in other vessels in the body, it is relatively new to put them into the carotid arteries. The possible benefit of choosing this treatment has been demonstrated to the FDA (Food and Drug Administration) by Guidant Corporation, the manufacturer of the ACCULINK™ Carotid Stent System and ACCUNET™ Embolic Protection System, through rigorous clinical trials involving patients having carotid artery disease similar to yours.

**There is always a chance of complications from endovascular procedures. These include:**

- Complications that can occur during any endovascular procedure such as allergic reactions, bleeding, heart attack, stroke, or TIAs, even death
- Damage to your blood vessels
- Emboli (air, blood clots, or even the stent) moving downstream from where the doctor is working
- Blood clots or restenosis blocking blood flow through the stent
- Infection or bruising of your groin area at the catheter insertion site

If any of these complications happen to you, your doctor will treat you as needed. Treatments will vary widely depending upon the type of complication and your medical history. Examples include:

- Use of icepacks or pressure bandages to treat bruising or bleeding at the catheter insertion site
- Use of antibiotics or other medications to treat an infection or allergic reaction
- Use of a second stent or surgery to treat a damaged or blocked artery

Your doctor can help explain the possible complications and treatments related to endovascular procedures.

**YOUR DOCTOR SHOULD NOT USE THIS STENT IF:**

- The narrowed area in your carotid artery is located beyond sharply curved vessels, making it difficult to place the stent and embolic protection device
- You can't take anticoagulants (medicines that make your blood take longer to form a clot)
- You can't take antiplatelets (medicines that make it harder for cells in your blood to form a blood clot)
- You are allergic to nickel-titanium, the metal used to make the ACCULINK™ Carotid Stent

Note: Some doctors prescribe combinations of antiplatelets and anticoagulants to decrease the risk of forming a blood clot in your artery.

## YOUR STENT IMPLANT CARD

Tell any dentist or doctor who treats you for any reason that you have a stent implant in your neck, and keep your Stent Implant Card with you at all times. Your Stent Implant Card identifies the doctor who implanted your stent and how to reach him/her, the hospital where you received your ACCULINK™ Carotid Stent, the date it was implanted, and where it was placed in your carotid artery. It also identifies important information about your stent, such as the size of the stent and the date the stent was manufactured. The card gives your doctor valuable information that is necessary if you need an MRI or MRA. There are also phone numbers on the card that your doctor can call if he/she has any questions. Figure 7 below shows a Stent Implant Card.

If anything you have read in this booklet that raises further questions about the stenting procedure, now is the time to discuss them with your doctor.

Your ACCULINK™ Carotid Stent is designed to keep your carotid artery open. However, to stay healthy, you need to keep all appointments with your doctor, take all of the medications regularly that have been prescribed for you, call your doctor if you are not feeling well, stop smoking if you currently smoke, get enough exercise, and maintain a healthy diet.

Figure 7. ACCULINK™ Carotid Stent Implant Card

<p>Please carry this card at all times. Show it to any medical personnel who may be treating you.</p> <hr/> <p><b>ACCULINK™</b> CAROTID STENT</p> <p><b>COVANT</b> Covant Corporation Santo Domingo, CA 95054-2867 USA</p> <p>TEL: (800) 227-0602 FAX: (800) 401-8874 Outside USA TEL: (951) 914-4669 Outside USA FAX: (951) 914-2531</p>	<p><b>Stent Patient Implant Card</b></p> <p>Physician Name: _____ Physician: _____          Hospital/Physician Office: _____ Phone Number: _____          Hospital Address: _____          City/State: _____ Zip/Zip+4: _____</p> <p>The ACCULINK™ Carotid Stent is made of the following materials:          Titanium and Polyethylene Glycol (PEGL) in the form of  <a href="http://www.covant.com">www.covant.com</a> or call (800) 227-0602 for further information.</p> <p><b>Stent Identification Information</b></p> <table border="1"> <thead> <tr> <th>Left Portals Left Side of Artery</th> <th>Left Portals Right Side of Artery</th> <th>Right Portals Left Side of Artery</th> <th>Right Portals Right Side of Artery</th> </tr> </thead> <tbody> <tr> <td>Manufacturer Part: _____</td> <td>Manufacturer Part: _____</td> <td>Manufacturer Part: _____</td> <td>Manufacturer Part: _____</td> </tr> <tr> <td>Location of First Stent</td> <td>Location of Second Stent</td> <td>Location of Third Stent</td> <td>Location of Fourth Stent</td> </tr> </tbody> </table>	Left Portals Left Side of Artery	Left Portals Right Side of Artery	Right Portals Left Side of Artery	Right Portals Right Side of Artery	Manufacturer Part: _____	Manufacturer Part: _____	Manufacturer Part: _____	Manufacturer Part: _____	Location of First Stent	Location of Second Stent	Location of Third Stent	Location of Fourth Stent
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OUTSIDE CARD

INSIDE CARD

## DEFINITIONS OF MEDICAL TERMS

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

**Angiogram:** X-ray pictures of your blood vessels taken with a special liquid called contrast dye. Angiograms are used to see narrowing or blockage in arteries.

**Angiographic suite:** A combination x-ray room and operating room where endovascular procedures are performed.

**Angioplasty:** A procedure in which a balloon is passed through to the blocked area of an artery and inflated to push the plaque against the vessel wall. Also called PTA (Percutaneous Transluminal Angioplasty).

**Anticoagulant and antiplatelet:** Medicines that slow down the clotting of blood.

**Artery (Plural is arteries):** A blood vessel that carries oxygen-rich blood away from the heart to the rest of the body.

**Atherosclerosis:** Build-up of fatty substances (for example, cholesterol) that causes narrowing and hardening of the blood vessels.

**Balloon catheter:** A thin tube with a balloon attached to the tip that can be inflated to open blocked arteries.

**Blood vessel:** Any of the veins and arteries that carry blood to and from the heart.

**Catheterization lab (Cath lab):** An x-ray room in which endovascular procedures are performed.

**Carotid arteries:** Arteries in your neck that supply blood to the brain.

**Carotid artery disease:** A condition that reduces the blood flow through the carotid arteries to the brain.

**Carotid Endarterectomy (CEA):** A surgical procedure in which the fatty plaque causing the blockage of the carotid artery is removed.

**Catheter:** A tube through which fluids or devices can be introduced or removed from the body.

**Cerebrovascular:** Relating to blood vessels in the brain.

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**Computerized Axial Tomography Scan (CT or CAT Scan):** A diagnostic test that uses x-rays to make three-dimensional images.

**Contrast:** X-ray dye used in diagnostic tests.

**Doppler ultrasound:** A non-invasive test that uses sound waves to produce images, such as images of a narrowed blood vessel.

**Embolic protection device:** A device used during the carotid artery stent procedure to capture and remove plaque and other particles that may be released during the procedure.

**Embolus (plural is emboli):** A piece of blood clot, air bubble or fatty plaque that breaks away within the vessel and travels to another part of the body. The embolus may be trapped in a blood vessel and cause blockage of the vessel.

**Endovascular treatment (procedure):** A procedure that is done through the blood vessels.

**General Anesthesia:** Medication given to put you into a deep sleep during a carotid endarterectomy (CEA) procedure.

**Guiding Catheter:** A special kind of catheter (tube) through which fluids or other devices can be introduced or removed from the body. A guiding catheter provides support for other devices your doctor will use during your stenting procedure, and helps them stay in the right place.

**Hemorrhage:** Bleeding.

**Hypertension:** High blood pressure.

**Ischemic:** Due to lack of blood flow.

**Local anesthesia:** A substance used to numb the area to which it is applied.

**Magnetic Resonance Angiogram (MRA):** an MRI that is done with contrast dye to see blood vessels more clearly.

**Magnetic Resonance Imaging (MRI):** A non-invasive test that uses a very strong magnet to make three-dimensional images.

**Non-invasive procedure:** A procedure that is done without putting anything inside the body.

**Percutaneous Transluminal Angioplasty (PTA):** A procedure in which an inflatable balloon catheter is passed through to the blocked area of an artery. Once inflated, the balloon pushes the plaque against the vessel wall.

**Peripheral vascular disease:** A condition that affects the blood vessels outside of the heart.

**Plaque:** An accumulation or build-up of fatty deposits, calcium and/or cell debris in an artery that leads to narrowing of the artery.

**Restenosis:** Re-narrowing of the artery after treatment.

**Sedative:** Type of medication that makes you relaxed and sleepy. Also called sedation.

**Stenosis:** Narrowing in your artery.

**Stent (stenting):** A small latticed metal tube that is permanently placed inside a blood vessel to give it structural support and keep it open. The metal used in the ACCULINK™ Carotid Stent is nickel-titanium, a metal commonly used in medical products that are permanently placed in the body. Stenting means placement of a stent.

**Stroke:** Tissue damage in the brain caused by lack of oxygen. Damage depends on the location and extent of brain tissue affected.

**Transient Ischemic Attack (TIA):** Temporary symptoms of stroke. A patient who has a TIA may be at a higher risk for stroke.

**Vascular Closure device:** A small device that is used to close a small hole in a blood vessel, using either stitches or a small, soft plug.

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**Notes:**

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**Questions:**

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**Medications:**

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**Guidelines For Activities:**

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**Scheduled Appointments:**

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For more information about indications for use, contraindications, warnings and precautions for the ACCUJUNK<sup>®</sup> Carotid Stent System and the ACCUNET<sup>™</sup> Embolic Protection System, see the instructions for use for both products that can be found on the Guidant website at [www.guidant.com](http://www.guidant.com). You can also call Customer Service at 800-227-9902 to request copies of the instructions for use.

**CAUTION:** Federal (USA) law restricts these products to sale by or on the order of a physician.

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