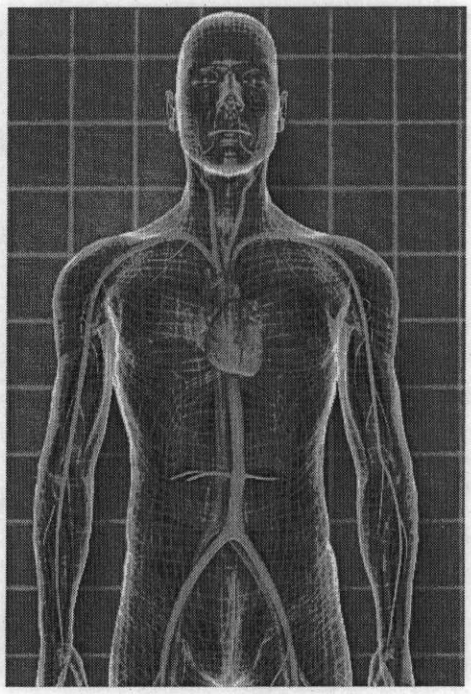
Understanding Carotid Artery Disease



Information Guide for Patients and Their Families

TABLE OF CONTENTS

Glossary of Terms

Angiogram: X-ray pictures of arteries taken with a special liquid called contrast dye that is delivered into arteries in the body through a straw like tube called a catheter. Angiograms are used to see if there is narrowing or blockage of the arteries.

Angiographic suite: A combination x-ray room and operating room where minimally invasive vascular procedures are performed.

Angioplasty: A minimally invasive treatment of the arteries, to open blocked arterial vessels.

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

Artery: A blood vessel that carries oxygen-rich blood away from the heart to the rest of the body.

Atherosclerosis: Build-up of fatty substances (i.e., cholesterol, plaque) that causes narrowing and hardening of the blood vessels.

Balloon Angioplasty: A procedure in which a tube equipped with a tiny inflatable section at the tip is inserted into an artery that has been narrowed by the accumulation of fatty deposits. The inflatable section is then expanded outwards to clear the blockage and widen the artery.

Balloon catheter: A thin tube with a tiny inflatable section attached to the tip that can be expanded to open blocked arteries.

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

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.

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

Contrast: a special liquid or dye used in diagnostic tests that provide X-ray images or pictures.

Duplex 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. This type of medication is usually given to you via a straw like tube or catheter that is inserted into one of your veins.

Guiding Catheter: A special kind of 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: Lack of blood flow.

Local anesthesia: A medication used to numb the area to which it is applied. Local anesthetics are often injected just below the skin surface or topically applied.

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

Magnetic Resonance Angiogram (MRA): A non-invasive test that uses a very strong magnet to make three-dimensional images (MRI) that is done with contrast dye to see blood vessels more clearly.

Minimally Invasive Procedure: A medical procedure that does not require significant surgery or extensive surgical incision. Such procedures usually take less time and are associated with less pain or discomfort for the patient, decreased hospital stays and faster healing time or recovery.

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

Percutaneous: pertains to any medical procedure where access to inner organs or other tissue is done via needle-puncture of the skin, rather than by using an "open" approach where inner organs or tissue are exposed. In vascular procedures this involves a needle catheter getting access to a blood vessel, followed by the introduction of a wire through the lumen of the needle. It is over this wire that other catheters can be placed into the blood vessel.

Percutaneous Delivery System: A means, technology, or device (i.e. a Catheter) used to transfer a medical treatment (i.e. a carotid stent) to a target region within 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 can lead to narrowing of the artery.

Restenosis: The artery narrowing reoccurs after treatment to open the artery has been completed.

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

Stenosis: Narrowing within the 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. **Stenting** means placement of a stent.

Stroke: Damage or injury to the brain tissue caused by lack of oxygen or bleeding. The extent of the damage or injury depends on the location and size of the brain tissue area that is affected.

Transient Ischemic Attack (TIA): Temporary symptoms of stroke, such as blurred vision, dizziness, slurred speech, muscle weakness or numbness. A patient who has a TIA may be at a higher risk for stroke.

Vascular: Relating to vessels that carry or circulate fluids, such as blood through the body.

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

Understanding Carotid Artery Disease

What is carotid artery disease?

The carotid arteries are the two large blood vessels on either side of the neck (See Figure 1 – Carotid Arteries). They are the main source of blood to the brain. Carotid artery disease occurs when one or both arteries become narrowed or blocked by a buildup of plaque. Plaque is made up of scar tissue, blood cells in the artery wall, cholesterol and other fatty substances. This buildup is caused by atherosclerosis, or the hardening of the arteries, and can slow or stop blood flow to the brain.

Interrupted blood flow to the brain caused by carotid artery disease can cause symptoms (see below for list of symptoms) that may be associated with a stroke or transient ischemic attack (TIA).

How is carotid artery disease related to stroke?

Carotid artery disease is the leading cause of stroke. This disease should be detected and treated as soon as possible to reduce serious risks to your health.

Prevention of stroke is twofold. First, the buildup of plaque in the carotid arteries must be prevented from restricting blood flow to the brain. Second, clots must be prevented from traveling into the brain, blocking its smaller vessels and causing a stroke.

What is stroke or TIA?

Stroke causes one out of every 10 deaths worldwide,[1] making it one of the top three killers on the planet.[2] And with over 20 million strokes globally every year, stroke is also a leading cause of disability. Carotid artery disease is the cause of more than half of all these strokes.

A stroke occurs when a part of the brain is damaged by vascular complications. The vast majority of strokes occur when a blood clot blocks an artery and circulation to the brain is cut off. Carotid artery disease is the source of most of these blockages.

The loss of circulation kills brain cells and affects the physical abilities once controlled by those areas of the brain. The resulting damage depends on the severity of the stroke and length of time circulation is lost. However, a stroke can impair functions such as speech, movement and memory. Effects can range from mild weakness in an arm or leg to paralysis and even fatality.

Sometimes, instead of a stroke, some people may experience a temporary ischemic attack (TIA), sometimes called "mini-strokes". The difference between a stroke and a TIA is that, in a TIA, the symptoms go away within 24 hours. But a TIA should be taken as seriously as a stroke because if any of the above conditions occurs, even if they resolve within 24 hours (TIA), they serve as warning signs that, if left untreated, may lead you to experience a stroke (a permanent injury to the brain). Therefore, it is important to identify these warning signs because they may be a sign of blockage in the carotid arteries. **It is important that you immediately contact your doctor and let him or her know of your symptoms.** Below you will find a list of risk factors and symptoms associated with a TIA or a stroke.

[1] "National Stroke Association Joins the World Stroke Congress," National Stroke Association. Available at: http://www.stroke.org

[2] "About Stroke," American Stroke Association. Available at: http://www.strokeassociation.org

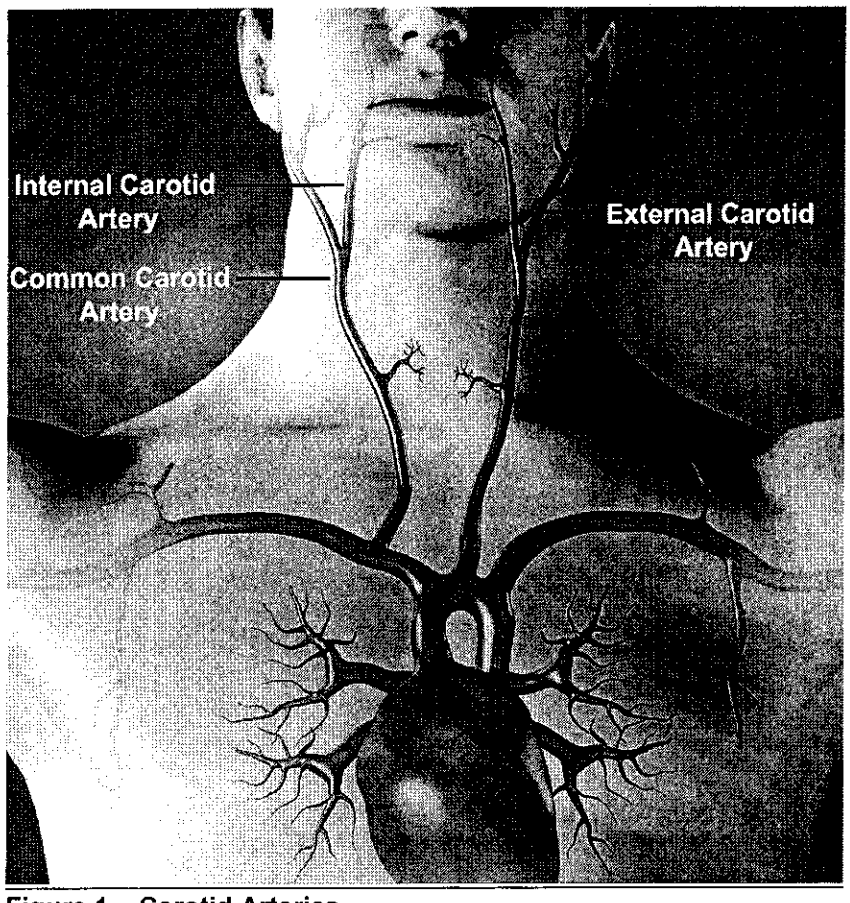


Figure 1 – Carotid Arteries

Carotid Artery Disease, Stroke or TIA risk factors:

- Age
- Diabetes
- High cholesterol
- Hypertension (high blood pressure)
- Irregular heartbeat
- Lack of exercise
- Family history of stroke or heart disease
- Obesity
- Prior stroke and/or heart attack
- Prior treatment for severe circulatory problems
- Stress
- Smoking

Carotid Artery Disease, Stroke or TIA symptoms:

- Severe dizziness, near blackout or fainting
- Severe, unrelieved headache
- Sudden blurriness or blindness in one eye or both eyes
- Sudden weakness or clumsiness of a hand
- Sudden weakness or paralysis of an arm or leg or face
- Unexplained difficulty or slurring of speech or comprehension

Detecting Carotid Artery Disease and Treatment Options

Detecting Carotid Artery Disease

Detecting carotid artery disease is not difficult, but monitoring the condition is extremely important.

WARNING: Tell your doctor if you have had temporary vision problems, minor paralysis or any other stroke warning signs.

Sometimes carotid artery disease can be detected in a doctor's office by listening to blood flow in the neck with a stethoscope. However, there are several more advanced tests a doctor may use. Often, the most reliable means of diagnosis is a duplex ultrasound scan. This simple, painless test takes only a few minutes and provides an immediate, accurate diagnosis.

Tests for diagnosing carotid artery disease:

Duplex Ultrasound

This imaging technique uses sound waves to show vessels, the size of the blockage and the amount of blood flowing through the artery.

MRA (Magnetic Resonance Angiography)/**MRI** (Magnetic Resonance Imaging)

These procedures use magnetic fields and pulses of radio energy to reveal blood vessels and blood flow without the need of contrast dye.

CT (Computed Tomography) **Scan**

This computerized x-ray assembles two-dimensional images of the head to outline brain structures and rule out a recent stroke.

Angiography

This procedure uses a special contrast dye that is injected into the vessels to make them visible on screen and in x-rays to identify the size and location of the blockage.

Treatment for carotid artery disease:

Carotid artery disease should be monitored regularly, and if a significant blockage occurs or a patient suffers a transient ischemic attack, or mini-stroke, treatment may be necessary. Today there are several treatment options available, ranging from medication to surgery to endovascular (less-invasive) treatment.

Medication treatment

Many cases of carotid artery disease do not require interventional treatment (surgery or endovascular). Some buildup of plaque in the carotid arteries is a normal part of aging. Often doctors will recommend simple changes or prescribe medicine that thins the blood or prevents blood clots (aspirin, Plavix®, Coumadin®, or Ticlid®). These treatments could be as simple as living a healthier lifestyle and taking an aspirin a day.

Surgical treatment

There are a number of procedures that require incisions to reach and treat the carotid arteries. The most common are explained below.

Carotid endarterectomy

Carotid endarterectomy (en-dar-ter-EK-toe-me) or CEA is a surgical procedure to remove the buildup of plaque within the artery. During this procedure, an incision is made in the neck. The surgeon opens the carotid artery and is able to manually remove the plaque. This procedure requires anesthesia, and patients must stay in the hospital but are often able to return home the following morning.

Carotid grafting

Sometimes, although rarely, an entire section of the carotid artery is removed around a severe blockage. A vein graft is then used to reconnect the carotid artery. A graft is usually a vein taken from another part of the body that replaces the missing section of the carotid artery.

Endovascular treatment

During these minimally invasive procedures, physicians place a stent in the narrowed carotid artery. The stent is delivered through a catheter that has been introduced into your body through a small incision located in the groin, arm or wrist. Patients remain awake while the physician performs the intervention and monitors the function of the brain. This treatment encompasses the following devices.

Distal protection

Distal protection devices are special filters or balloons that are placed beyond the narrowed section of the artery during the procedure to catch any debris that could be dislodged preventing the debris from traveling to the brain and causing further damage.

Angioplasty

After placing the distal protection device, the physician may perform angioplasty to enlarge the artery and make room for the stent. During this procedure, a small, deflated balloon is delivered through the guide catheter to the blocked area of the carotid artery.

Once the balloon is positioned precisely, it is inflated, pushing the plaque buildup aside and reopening the artery to restore blood flow.

Stent

A stent is a small mesh, metal tube that is delivered to the carotid artery on a catheter, the stent is expanded within the artery and acts like scaffolding to prop the artery open allowing blood flow to the brain. The NexStent Carotid Stent - from EndoTex Interventional Systems - is a closed cell stent designed for better scaffolding of the artery and to prevent plaque from protruding into the artery. After the stent is implanted, the catheter is removed and the incision in the groin, arm or wrist is closed. The stent remains in place to help prevent future narrowing of the carotid artery.

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 any medication, 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.

What should I expect before the procedure?

The carotid artery stent implantation is done as an in-patient procedure and will require admission to the hospital. In preparation for your admission to the hospital you will be asked to undergo some testing which includes: an electrocardiogram or ECG, a chest x-ray and routine blood testing. Your physician will meet with you to discuss the details of the procedure and will explain the risks, as well as the benefits, and will answer any questions you or your family may have.

Your physician and/or his or her staff will most likely instruct you not to eat or drink anything after midnight the night before your procedure.

PRECAUTION: If you have diabetes and are currently receiving medication therapy, please speak with your physician about any special instructions concerning your diabetes medications.

An intravenous (IV) needle and tube may be placed in one of the veins in your arm or hand. The IV will allow your physician to administer fluids and/or medications if they are needed.

The medical staff will create small marks on your feet (or hands if applicable) prior to the procedure. These marks indicate where your pulses can be felt and they are used to monitor your circulation during or after the procedure.

The area where the catheters are to be inserted is usually cleaned and prepared by the medical staff prior to beginning the procedure. Typically the groin areas may be used for catheter

insertion, however it is possible that the arm or wrist may be used if appropriate for the patient. The area where the catheters are to be inserted is scrubbed with an antiseptic solution to prevent infection and the area will be shaved if needed. Sterile sheets will then be placed over the area.

This procedure is performed under a local anesthetic (numbing medicine), so you will be completely awake during the procedure. It is important that you remain awake as the physician and/or the medical staff may periodically give you instructions during the procedure, which you will have to follow.

Your physician will inject the local anesthetic or numbing medicine where the catheters are to be inserted and it is possible that you will feel a stinging or burning sensation at the site. This usually passes quickly and over the next few minutes as the medication takes effect, the area will become numb and you will only feel dull pressure.

PRECAUTION: If you do feel pain at any time during the catheter insertion or the procedure, be sure to tell your physician.

What should I expect during the procedure?

The procedure is routinely performed in a catheterization laboratory (angiographic suite) or in some cases a special radiology procedure room. Such a room typically includes an x-ray table, special x-ray camera(s), x-ray monitor, heart monitor(s), and a sterile table to hold the catheters and instruments the physician requires for the procedure. When you enter the procedure room you will be transferred to the special x-ray table. Small sticky pads or tags will be placed on your chest, body and sometimes your arms and legs and you will be connected to a special monitor so that the medical staff can monitor your heart rate and rhythm during the procedure. Your blood pressure will also be monitored during the procedure.

The catheters will then be inserted into the groin area where a small incision is also made by your physician to allow an introducer sheath (straw-like short tube) to be inserted into your femoral artery. Next a guide catheter (a long flexible tube) will be inserted into the introducer sheath and advanced into your artery, through your aorta up to the arch in your aorta where your arteries branch off and go to the heart, the brain and other areas of the body. Your physician may choose to insert the catheters in another area (arm or wrist). The incision is made in the appropriate area and catheters inserted using different arteries located in the arm or wrist.

Once the catheters have been inserted into the arterial system X-ray dye is injected by the physician to view the narrowing of the carotid artery. Your physician will watch the monitor to view the x-ray pictures. While the x-ray pictures are being taken, the physician may ask you to take a deep breath and hold it for a few seconds. You may also be asked to cough after the x-ray pictures are completed. This maneuver helps speed up the process of clearing the dye from your arteries.

Your physician and the medical staff will be monitoring your clinical and neurological status throughout the procedure. The physician and his or her staff may be asking you questions regarding your orientation to the date, time and place as well checking your ability to follow instructions.

If your physician feels it is appropriate he or she will perform Angioplasty to the target area of the carotid artery that will receive the stent. Once the angioplasty is completed a filter catheter is introduced and placed just beyond the narrowed artery segment.

The filter catheter or FilterWire is used to catch any piece(s) of plaque that may break off during the procedure. Once the FilterWire is in place, the stent delivery system will be introduced and the stent will be released and placed at the narrowed area of the carotid artery being treated.

Angioplasty:

1. The guide catheter is passed through the guiding sheath to the area near the narrowing. A guidewire inside the guide catheter is then advanced through the artery until the tip is beyond the arterial narrowing.
2. The angioplasty catheter is moved over the guidewire until the balloon is within the narrowed segment of the artery.
3. The balloon is then inflated and compresses the plaque against the artery wall (See Figure 2 – Balloon inflation)

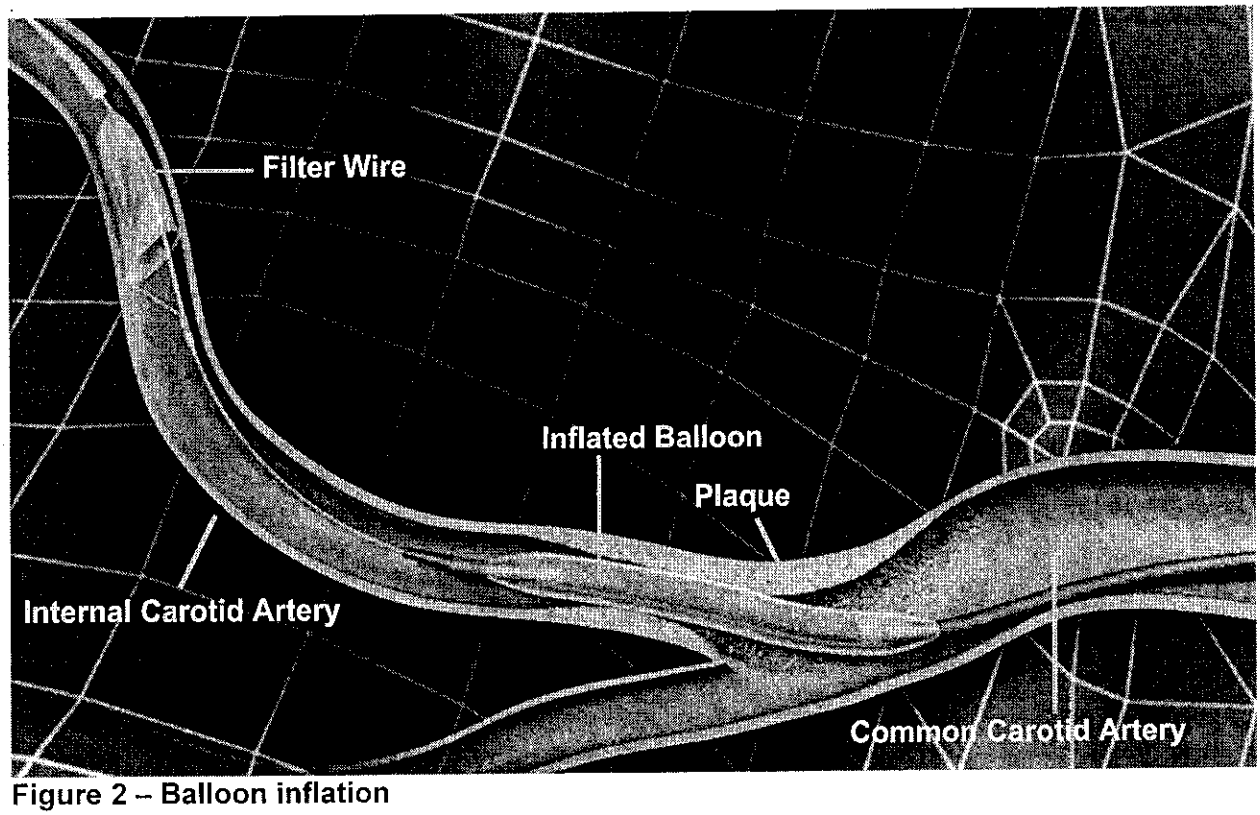


Figure 2 – Balloon inflation

4. Once the narrowed artery has been opened sufficiently (your physician will make this decision), the balloon catheter is deflated and then removed.

FilterWire and Stent Placement:

1. A FilterWire is introduced into the artery through the guide catheter and advanced to just past the narrowed segment of the artery to be treated (See Figure 3 – Filter catheter placement).

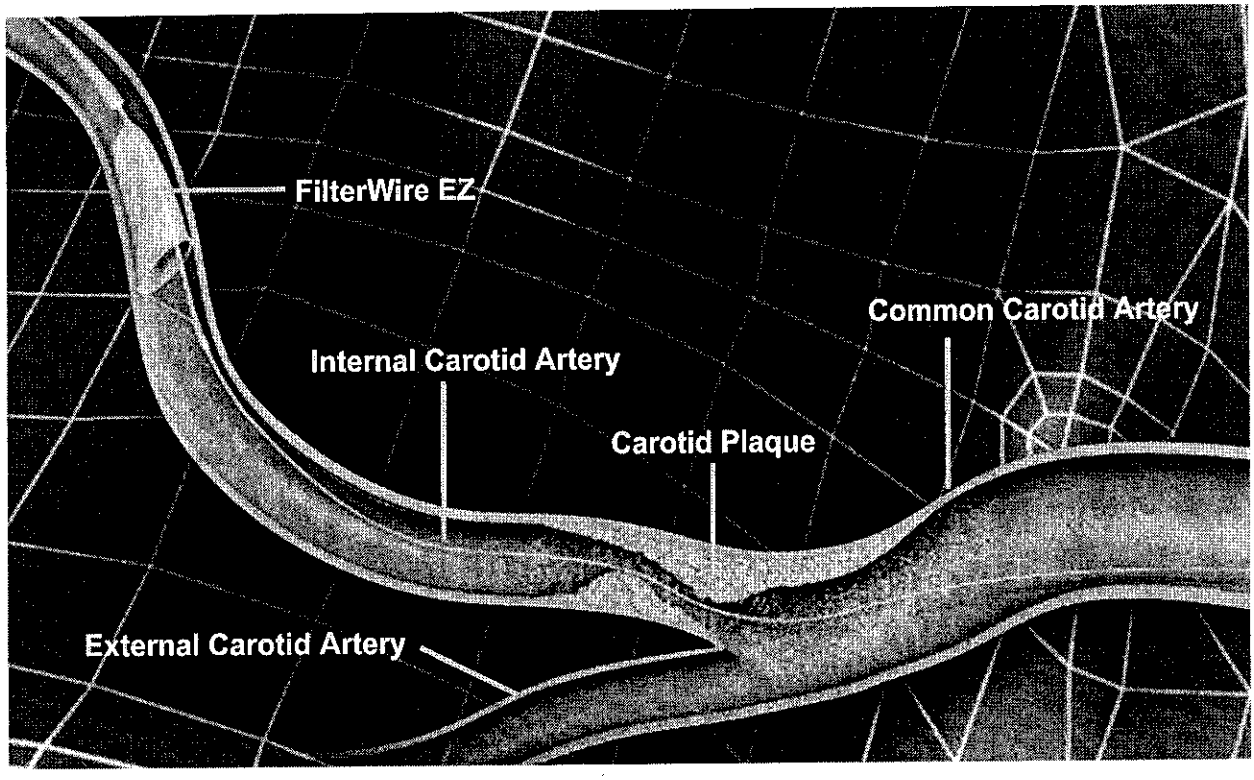


Figure 3 – Filter catheter placement

2. Once the FilterWire is in place, the stent delivery system (which contains the stent) is introduced into the artery through the guide catheter and advanced to the area or segment of the artery that is narrowed.

3. The stent is released or deployed and will begin to self expand against the walls of the artery, holding the vessel open and improving the flow of blood (See Figures 4 – Deployed Stent and Figure 5 – Deployed Stent Inner Vessel View).

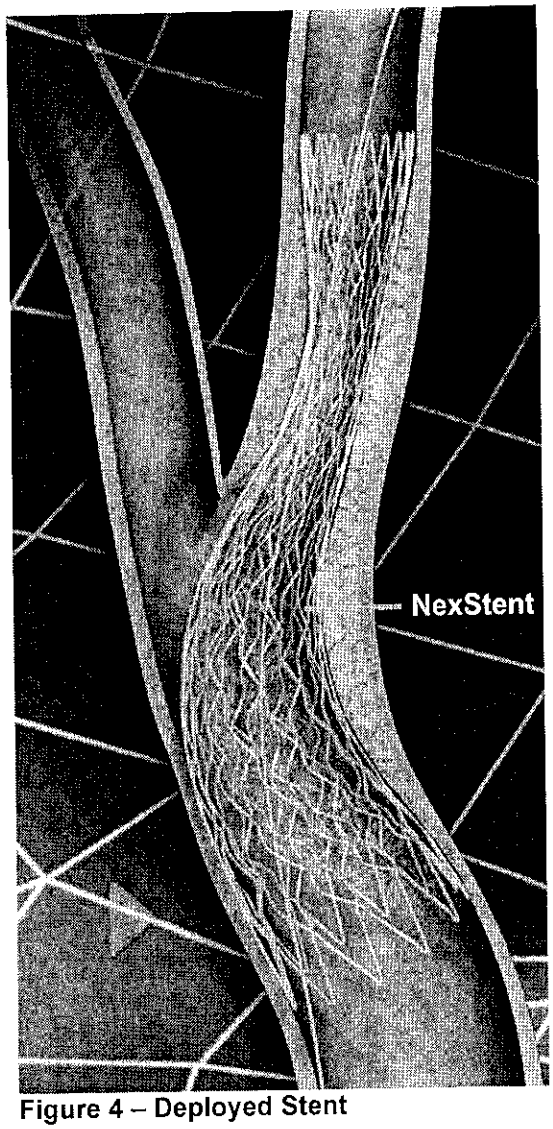


Figure 4 – Deployed Stent view)

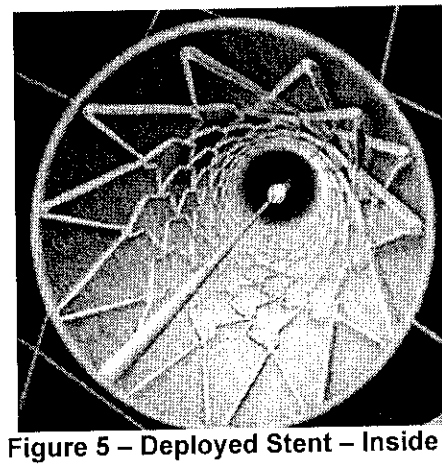


Figure 5 – Deployed Stent – Inside Vessel

Once the stent is in place the delivery system and the FilterWire are removed

Note: *In some cases the physician is not able to successfully implant the stent in the artery being treated. If this should occur your physician will discuss other treatment options with you and your family. If the implant is not successful the recovery is similar in that you will still need to follow the same instructions as patients who actually receive a stent (see section, "What should I expect after the procedure?").*

What should I expect after the procedure?

You will be returned to your hospital room or recovery area following the procedure. Your vital signs (temperature, heart rate, blood pressure and respirations) will be monitored closely and you will be examined as to your clinical and neurological status following the procedure. The introducer sheath remains in the artery up to 6 hours after the procedure and is typically stitched in place so as to prevent movement of the catheter during the initial hours following the procedure. You can expect a large dressing to be placed over the insertion site and around the introducer sheath. If heparin, a medication given during the procedure is continued the catheters may remain in longer than 6 hours. While the introducer sheath remains in and up to 6 hours after its removal you will be asked to lie flat on your back in bed and keep your leg (where the catheter was inserted) straight and still.

When the introducer sheath is removed a physician or nurse will apply pressure to the groin area for 20-30 minutes or until there is no further bleeding. In some cases a sandbag or pressure control device will be placed over the puncture site if necessary.

PRECAUTION: It is important for you to lay flat and keep your leg straight as instructed. If you should need to cough or sneeze the nurse will instruct you how to hold pressure over the puncture site using your fingers.

WARNING: While bleeding is generally controlled by the procedures just described, if you should feel a warm, wet sensation or sharp pain in the area of the puncture, call the nurse or physician at once.

Do not attempt to sit up or get out of bed. You should continue to lie flat until you receive instructions from your physician or nurse as to when you may sit up and/or get out of bed. If you become uncomfortable, call the nurse for help so that they may assist in making you more comfortable with either a slight position change or if necessary, pain medication can be administered.

You will be asked to drink extra fluids following the procedure to assist your kidneys with clearing the x-ray dye from your body.

PRECAUTION: Because of the additional fluids you most likely will have to urinate more frequently. Please ask your nurse for assistance in using the bedpan, urinal or bathroom.

Your physician or nurse will instruct you to walk or ambulate usually within 12-24 hours following the procedure. You will be assisted by your nurse the first time you get out of bed.

Patients are usually discharged 1-3 days after the procedure depending on your clinical status. Your physician will monitor your progress and inform you as to when you can be discharged from the hospital. You should arrange for someone to pick you up at the hospital and transport you home.

Your Recovery

Your physician will give you guidelines and instructions regarding activities, medications and diet. You may be asked to avoid strenuous activities such as heavy lifting and bending for at least a week. Your physician will let you know when it is appropriate for you to begin resuming your normal daily activities.

PRECAUTION: Although you may feel better after the procedure it is important not to over exert yourself.

You will be placed on specific medications that will help prevent blood clots from forming in the newly dilated artery and help prevent spasms of the artery as well.

PRECAUTION: If you have any unpleasant reactions to any of the medications you are taking, please contact your physician for instructions. Do not stop taking the medications without guidance from your physician.

While most patients go home after their successful procedure with no further problems, it is possible that the narrowing of the artery can occur again. Such occurrences are called "restenosis". Restenosis most often occurs within the first 3-6 months after the procedure.

PRECAUTION: If you are not feeling well or have any symptoms such as severe pain, severe headache, dizziness, visual disturbances (blindness or blurred vision), slurred speech, difficulty swallowing, loss of consciousness, blackout or near blackout, generalized weakness or numbness and/or tingling of the extremities immediately contact your physician.

Whether you and your physician decide on treatment or decide to monitor your condition over time, carotid artery disease cannot be completely eliminated. However, you can control it to help prevent blockage and stroke. Both aspirin and surgery reduce the risk of carotid artery disease without eliminating it entirely. In addition, making the following positive lifestyle changes can significantly improve how well these preventative measures work for you:

- **Don't smoke.**
- **Work with your physician to lower your high blood pressure.**
- **Eat foods low in saturated fat and cholesterol.**
- **Lose excess pounds if you are overweight.**
- **Exercise regularly.**
- **Lower your blood sugar if it is high.**
- **If you have diabetes, see your physician regularly and follow all instructions.**
- **Take medications, such as aspirin, recommended or prescribed by your**
- **physician.**
- **Try to reduce stress in your life.**

Talk to your physician today about how you can live a healthier, more rewarding life with carotid artery disease.

Risks, Benefits and Contraindications

Stents have been widely used in blood vessels throughout the body; however placement in the carotid arteries is relatively new and has been made available in the past 5 years.

PRECAUTION: While stent placement is done in a minimally invasive manner and does not require general anesthesia, it is still possible that complications may occur.

WARNING: Complications that may occur as a result of receiving a carotid artery stent or undergoing the procedure may include but are not limited to:

- **air bubble(s) in your artery**
- **allergic reactions**
- **bleeding**
- **blood clot(s)**
- **bruising of your groin area or catheter insertion site**
- **death**
- **heart attack**
- **infection**
- **injury or damage to your artery or wall of the artery**
- **minor movement of the stent from its original placement**
- **restenosis or reoccurrence of the artery narrowing around or within the stent**
- **stroke or TIA (transient ischemic attack)**

Your doctor and the medical staff will review possible complications before the procedure and will monitor you during and after the procedure for such complications. If a complication does occur, your doctor will decide if you require treatment and determine what type of treatment you may need.

The benefits of undergoing carotid stent placement include improved blood flow through the artery being treated; this improves circulation to your brain. If you had symptoms prior to your procedure, it is possible that they may resolve or improve, but there is no guarantee that this will happen.

PRECAUTION: You should not undergo carotid artery stent placement if any of the following conditions are present:

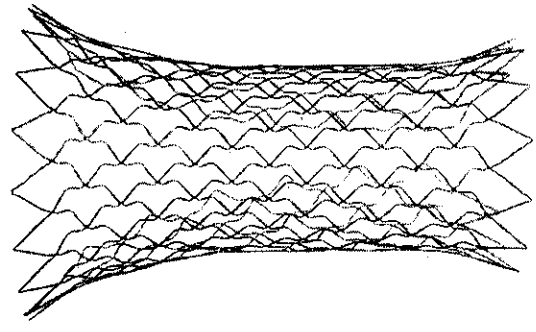
- **You cannot take anticoagulants (medicines that make your blood take longer to clot)**
- **You cannot take antiplatelets (medicines that make your blood cells slippery and make it more difficult for your blood to clot)**
- **You are allergic to nickel or titanium; components of the metal used to make the NexStent® Carotid Stent**
- **If your doctor tells you that the arteries connected to your carotid artery are sharply curved blood vessels, which could make it difficult for the doctor to place the embolic protection device (a filter placed in the artery, before implanting the stent that protects you from piece(s) of plaque that may break off during the stent implant procedure) and implant the stent.**

PRECAUTION: It is very common for your doctor to prescribe specific medications before, during and after your stent placement. Common drugs that may be prescribed by your physician include antiplatelets and anticoagulants. These medications are used to help decrease the risk of forming a blood clot in your artery. Please check with your doctor as to the appropriate medication that is right for you.

Device Description

The NexStent Carotid Stent System is intended to deliver a self-expanding stent to the extra-cranial carotid arteries via a percutaneous Delivery System. The NexStent Carotid Stent is a closed cell, flexible, self-expanding Nitinol (nickel-titanium alloy) stent. One stent size is used for treating vessel diameters ranging from 4mm to 9mm. The stent is a thin, flexible mesh that expands to appose the vessel wall thereby providing support to hold the vessel open and improving blood flow to the brain. The length of the stent is approximately 30mm at a fully deployed diameter of 9mm. An enlarged image of the NexStent Carotid Stent is shown in Figure 6.

Figure 6. The NexStent Carotid Stent



Your Stent Implant Card

Your Stent Implant Card (see Figure 7) identifies that you have received a NexStent Carotid Stent. This card also identifies the physician who implanted your stent, the doctor's contact information, the hospital where the procedure was performed, the date the stent was implanted, and the location where the stent was placed in your carotid artery. Other important information such as the model and lot number of the stent is also included. The card gives your physician valuable information that is necessary if you should need to undergo any special diagnostic testing such as 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.

Your NexStent 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 Stent Implant Card

INSTRUCTIONS Please carry this card at all times and show it to any medical professional who may be treating you.	Patient Name _____ Implanted Device _____ Implant Date _____ Implanted Vessel _____ Model No. _____ Lot No. _____
EndoTex Interventional Systems **Implanted Device** **PATIENT INFORMATION CARD**	Implanting Physician _____ Phone Number _____ Hospital Name _____ Hospital Address _____ _____ Primary Physician _____ Phone Number _____

Notes:

Questions:

Medications:

Guidelines For Activities:

Scheduled Appointments:

For more information about indications for use, contraindications, warnings and precautions for the NexStent® Carotid Stent System and the Boston Scientific FilterWire™ Embolic Protection System, see the Instructions for Use for both products that can be found by calling EndoTex Interventional Systems Customer Service at (888) 336-3683 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.