

X.ACT™

Carotid Stent System

Patient Information Guide



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Your Contact and Device Information

Have your doctor or nurse help you complete the information below:

Doctor name: _____

Phone number: _____

Address: _____

Hospital name: _____

Phone number: _____

Address: _____

Catalogue number: _____

Lot number: _____

Unique device identifier (UDI) number: _____

Device description: _____

Your doctor can explain the risks and benefits of your treatment and answer any questions you or your family may have. You are encouraged to discuss your treatment with your doctor.

Carotid Artery Disease

Carotid artery disease is a condition that occurs when the arteries that supply oxygen-rich blood to the brain become narrowed or blocked. Usually, this narrowing is caused by a build-up of “plaque.” Plaque is made up of fatty deposits (cholesterol), white blood cells, calcium, and other substances that collect over time in the wall of a carotid artery. This process is called “atherosclerosis.”

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

1. Plaque build-up 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 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 lack of blood can cause a medical condition called a stroke also known as an ischemic (lack of blood) stroke. Lack of blood to your brain can also create temporary symptoms that seem like a stroke, known as a transient ischemic attack or TIA. This is why it is important for you and your doctor to know about any risk factors you might have for stroke.

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. 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.

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

Treatment Options

This patient guide is not intended to explain everything you need to know about the treatment options for carotid artery disease. Please discuss any questions you have with the doctor to determine which treatment option is right for you.

Once you have been diagnosed with carotid artery disease, your doctor will recommend the most appropriate form of treatment depending on the condition and severity of your carotid artery disease. Carotid artery disease can be managed by a combination of changes in lifestyle (eating a healthy low-saturated fat diet, regular exercise, quitting smoking, and properly controlling other physical ailments). Your treatment may include medications to lower the risk of blood clots or lower your blood pressure or cholesterol.

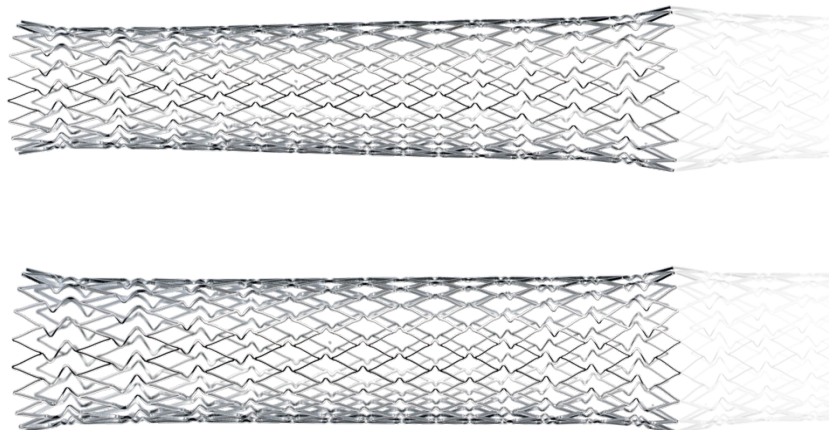
Surgery

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.

Carotid Stenting

Carotid stenting is an endovascular treatment (done through or inside the blood vessels) for carotid artery disease. You and your doctor might decide that carotid stenting is a better option for you.

Figure 1: Tapered and Straight X.ACT Carotid Stents



A stent is a metal mesh tube that is designed to open the narrowed carotid artery and help maintain the opening. **Figure 1** shows a carotid stent. This stent will be permanently implanted. An embolic protection device is a wire with a small filter on the end that looks like a basket. It was developed to capture material that could break off from the narrowed area of the artery while the stent is being implanted. This material could block blood flow to the arteries beyond the narrowing and be harmful to the brain. During the stenting procedure, the filter system is first positioned beyond the narrowed part of the artery and is opened like an umbrella to capture any material that breaks off. Next, the stent will be placed in the required area of the artery. Once the stent is implanted, the filter system will be completely removed.

How Do I Know Which Treatment Option Is Right?

The treating doctor will determine the best treatment option based on an assessment of your condition.

X.ACT™ Carotid Stent System

Device Description

The X.ACT Carotid Stent System is made up of a delivery system and a self-expanding stent. The X.ACT Carotid Stent System may be used with an embolic protection device, which is a small diameter wire that has a filter, that looks like a windsock or basket, at the tip of it to catch any cholesterol plaque material and prevent that material from traveling to the arteries in the brain. The stent is made from nitinol into a flexible tube. Once it is deployed in the vessel, it expands and keeps the vessel open.

The information contained in this guide covers X.ACT Carotid Stent System catalogue numbers. The exact stent, catalogue number(s), and size(s) that you received can be located on the Patient Implant Card that was provided to you upon your discharge.

Table 1: X.ACT Carotid Stent System

Part #	Stent Configuration	Unconstrained Stent Diameter	Proximal Outside Diameter	Distal Outside Diameter	Stent Length
XRX 020 07S	Straight	7 mm	7 mm	7 mm	20 mm
XRX 020 08S	Straight	8 mm	8 mm	8 mm	20 mm
XRX 020 09S	Straight	9 mm	9 mm	9 mm	20 mm
XRX 020 10S	Straight	10 mm	10 mm	10 mm	20 mm
XRX 030 07S	Straight	7 mm	7 mm	7 mm	30 mm
XRX 030 08S	Straight	8 mm	8 mm	8 mm	30 mm
XRX 030 09S	Straight	9 mm	9 mm	9 mm	30 mm
XRX 030 10S	Straight	10 mm	10 mm	10 mm	30 mm
XRX 030 08T	Tapered	8 mm – 6 mm	8 mm	6 mm	30 mm
XRX 030 09T	Tapered	9 mm – 7 mm	9 mm	7 mm	30 mm
XRX 030 10T	Tapered	10 mm – 8 mm	10 mm	8 mm	30 mm
XRX 040 08T	Tapered	8 mm – 6 mm	8 mm	6 mm	40 mm
XRX 040 09T	Tapered	9 mm – 7 mm	9 mm	7 mm	40 mm
XRX 040 10T	Tapered	10 mm – 8 mm	10 mm	8 mm	40 mm

What Are the Conditions That Serve As a Reason to Withhold Treatment (Contraindications)?

- Patients in whom anticoagulant and / or antiplatelet therapy is contraindicated (Patients who can't take medicines that help minimize blood clot formation)
- Patients who are allergic to nickel-titanium or contrast dye
- Patients with untreated bleeding disorders

What Are the Warnings About Use of the X.ACT™ Carotid Stent in You?

- After the stent is placed inside you, if instructed by your doctor, you will take medicine that prevents your blood from clotting and / or thins your blood. An example of medicine that prevents blood clotting is aspirin. Take medicine as instructed by your doctor.
- The safety and effectiveness of the X.ACT Carotid Stent System has not been established in pregnant patients and patients under the age of 18. Check with your doctor if the X.ACT Carotid Stent System is the right device for you.

Potential Adverse Events (Side Effects) Associated With the X.ACT™ Carotid Stent

- Allergic reactions or hypersensitivity to rubber, contrast agent, anesthesia, device material, drugs used to minimize blood clot formation
- Vascular complications in arteries used to access the carotid artery which may require blood transfusion or surgical artery repair, including:
 - Pain, infection, or discomfort at the access site
 - Bleeding
 - Formation of an abnormal connection between an artery and a vein next to it
 - Creation of a false pouch within a vessel wall where blood or fluid can accumulate
 - Weakness in wall of vessel due to vessel puncture
 - Partial or complete tear or separation of the inner wall of a blood vessel
 - Hole or tear in a blood vessel
 - Unintended movement of air, tissue, plaque, blood clot or device material downstream in a vessel resulting in blockage in blood flow
 - Blood clots in a vein, with possible pain, swelling, and / or redness
- Complications at the target arteries which may require additional treatment or surgery, including:
 - Total occlusion or sudden blockage of diseased artery
 - Formation of an abnormal connection between an artery and a vein next to it
 - Creation of a false pouch within a vessel wall where blood or fluid can accumulate
 - Weakness in wall of vessel due to vessel puncture
 - Partial or complete tear or separation of the inner wall of a blood vessel
 - Hole or tear in a blood vessel
 - Unintended movement of air, tissue, plaque, blood clot or device material downstream in a vessel resulting in blockage in blood flow
 - Development of blood clots partially or completely blocking blood flow within the artery, implanted stent, and / or filter
 - Narrowing or re-narrowing of the treated artery
 - Narrowing of blood vessels due to blood vessel spasm which may cause blockage of blood flow
- Irregular heartbeats (originating from abnormal electrical activity in the heart, or from the upper or lower chambers of the heart)
 - Rapid, irregular beating of the heart's upper chambers. Blood may pool and clot inside the heart, increasing the risk for heart attack and stroke.
 - Irregular heartbeat in the lower chamber of the heart

- Decreased blood and / or oxygen supply to part of the heart muscle which may cause:
 - Decreased oxygen supply to blood vessels of the heart
 - Heart attack (permanent damage of an area of the heart tissue, due to interruption in the blood flow to the heart muscle)
 - Chest pain due to decreased blood and / or oxygen supply to part of the heart muscle
- Stroke and temporary stroke symptoms as a result of a brief episode of decreased oxygen to the brain causing blurred vision, dizziness, fainting and numbness
- Altered organ function in acutely ill patients, including:
 - Sudden stopping of the heart and lungs
 - The heart is not able to pump blood properly, which can cause weakness and tiredness, fluid retention, fluid build-up in the lungs, and shortness of breath
 - Lung function failure (potentially leading to severe breathing difficulty)
 - Kidney failure or insufficiency
 - Shock (a life-threatening condition in which blood pressure is too low to maintain adequate blood flow to your organs)
- Bleeding
- A disease or condition affecting the blood's ability to clot, decrease in blood clotting cells due to use of heparin, decrease in blood clotting cells (platelets) or blood clotting factors
- Low or high blood pressure
- Nerve damage caused by compression of the nerves, injury to the nerve or interruption of blood supply to the nerves
- Decrease or loss of blood supply to a tissue / organ
- Infection (anywhere in the body) or sepsis (a serious condition that occurs when an infection spreads to the bloodstream and causes widespread inflammation, which may result in poor blood supply to vital organs and may rapidly lead to life-threatening clinical deterioration)
- Urge to vomit and vomiting
- Chest pain
- Difficult or labored respiration / shortness of breath
- Swelling caused by excess fluid trapped in body's tissues / collection of excess fluid in brain tissue
- Fever
- Pain, including headache
- Increase in blood supply to a tissue or organ
- Other neurologic and systemic complications
 - Convulsions
- Bleeding in brain tissue
- Death

- Device-related complications which may require additional intervention, including:
 - Detachment and / or implantation of a component of the system
 - Stent or filter entanglement / damage
 - Stent malposition
 - Stent migration or embolization (stent passage or blockage of a blood vessel)
- Emergency endarterectomy surgery (CEA)

Patient Exposure to Materials and Substances

Cobalt is present as part of a cobalt alloy in the X.ACT™ Carotid Stent. Scientific information shows that medical devices made with metal alloys containing cobalt do not cause an increased risk of cancer or problems with reproduction.

A patient receiving a X.ACT Carotid Stent can be exposed to metallic stent and system components (stainless steel, polyether block amide, polytetrafluoroethylene, polyamide, silicone, polyethylene, polyetheretherketone, polyimide, tungsten, barium sulphate, and platinum-iridium alloy). Exposure to the stent materials on the X.ACT Carotid Stents is related to the number and lengths of the stents placed in you. Use of two or more stents will expose you to larger amounts of the stent materials.

Table 2 : Qualitative and Quantitative Information for X.ACT Carotid Stent System

Design	Stent Length (mm)	Nitinol (Ni-Ti) Stent Mass (mg)
Straight	20	76
	30	100
Tapered	30	101
	40	139

If You Experience Adverse Events or Unwanted Effects From Your X.ACT™ Carotid Stent System

If you experience any of these adverse events (side effects) or any other unexpected effects because of the X.ACT Carotid Stent System, please report this to your doctor as soon as possible.

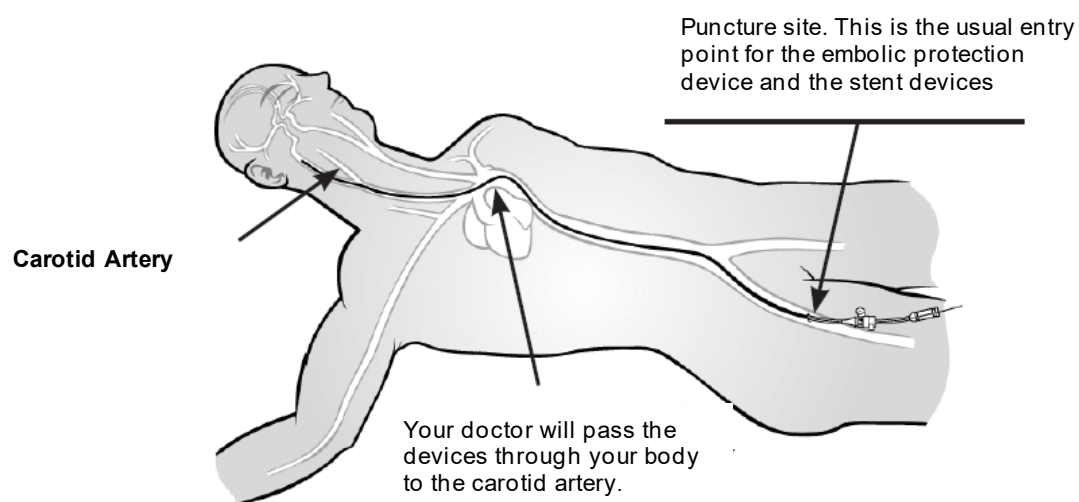
What Happens During the Procedure?

Once you are in the cardiac catheterization lab (Cath 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 dye into the guiding catheter to allow him or her 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.

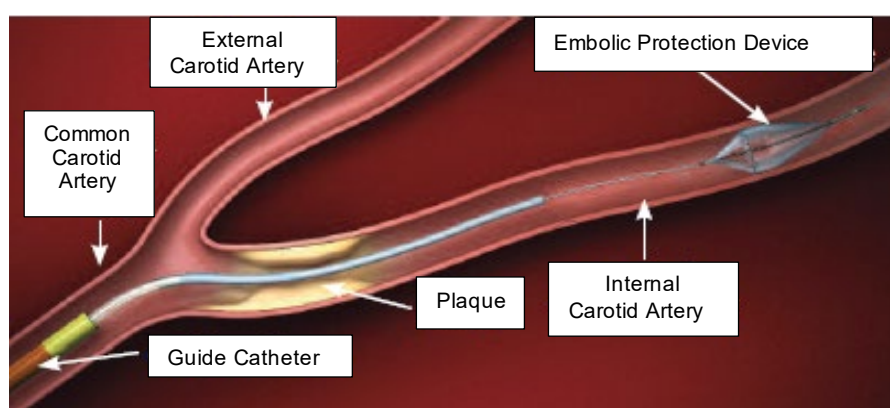
Figure 2: Insertion of Devices



Your doctor will pass the embolic protection device into the carotid artery. The embolic protection device 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.

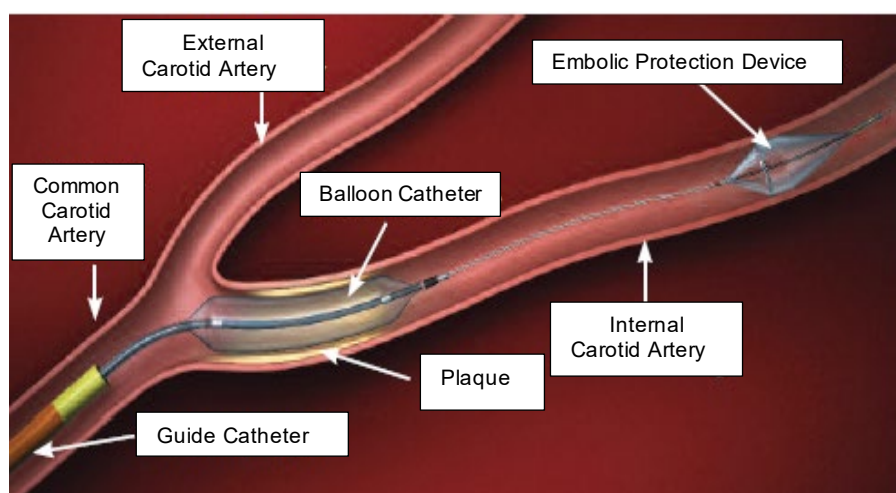
Once your doctor crosses the diseased area of the artery with the embolic protection device, the doctor will open the small filter. The embolic protection device will stay in place during the procedure to help capture any plaque or particles that could travel into the smaller vessels in the brain (**Figure 3**).

Figure 3: Placement of Embolic Protection Device



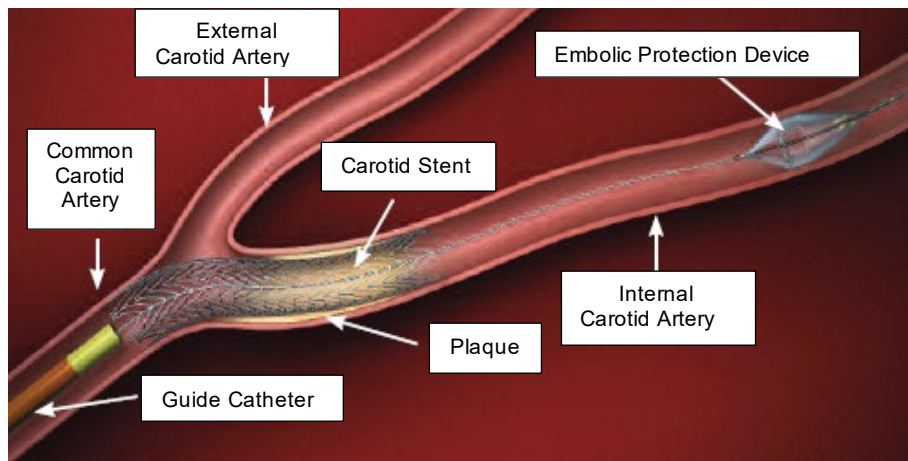
The doctor may insert a balloon catheter into the narrowed area and then temporarily inflate the balloon in order to open up the artery. Your doctor will then remove the balloon catheter from your body (**Figure 4**).

Figure 4: Embolic Protection Device and Balloon Inflation



Your doctor will feed the carotid stent system through the vessels to the area of the plaque. After careful positioning, the doctor will open the carotid stent to cover the plaque (**Figure 5**).

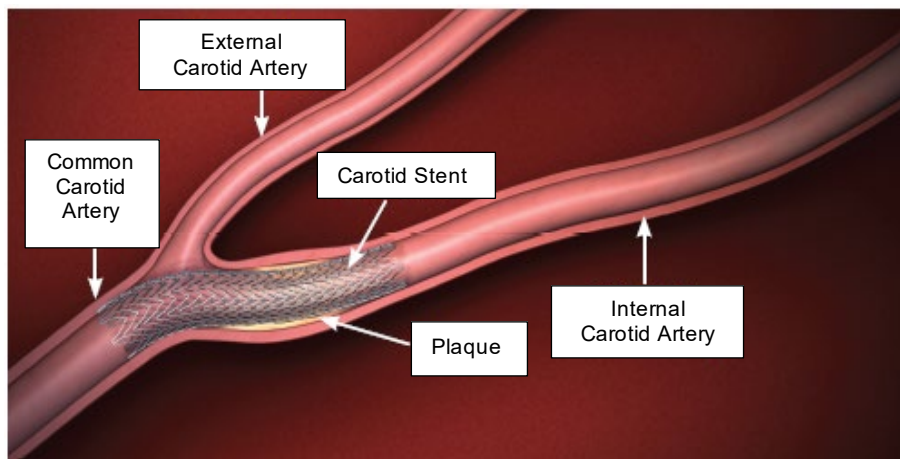
Figure 5: Placement of Carotid Stent



Your doctor may, if necessary, insert a balloon catheter into the 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 embolic protection device and all other devices from your body (**Figure 6**).

Figure 6: Embolic Protection Device Removed



Pressure will be applied to your puncture site until bleeding stops. Your doctor may use a special vascular closure device to close the small incision in your groin.

What Happens After the 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 area where nurses and doctors will monitor you closely.
- Your vital signs (heart rate and blood pressure) and the area in which the catheter was inserted will be checked frequently.
- A nurse 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.
- You should drink plenty of fluids to flush the dye out of your system.
- 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.
- You will have to stay in bed for several hours, keeping your leg straight to allow your puncture site to heal.
- Your doctor will allow you to gradually become more active. You should avoid lifting and straining for as long as your doctor tells you.

Follow-up Care

You were discharged to the care of your doctor. You should be able to return to your normal activities soon.

CAUTION: Notify your doctor immediately if you experience or notice a severe headache, dizziness, slurred speech, weakness or numbness affecting one side of your body (for example, your right arm, leg, or face becomes weaker than your left), facial drooping, blurry vision or a sudden loss of vision in one or both eyes. These symptoms may indicate a re-narrowing in your stented artery.

Your doctor will ask you to return for follow-up visits. The first visit is usually two to four weeks after your stent is implanted, with follow-up visits every six months for the first year. Be sure to keep all appointments for follow-up care, including blood tests.

Expected Lifetime of the Device

The X.ACT™ Carotid Stent is a medical device implanted into totally or partially blocked vessels. The X.ACT Carotid Stent has been shown to be safe in a human carotid artery for a minimum of 10 years. The X.ACT Carotid Stent is a permanent implant designed to remain safely in your body for the rest of your life.

Your Stent Implant Card

Before you left the hospital or surgery center, you were given a card that includes important information about the procedure that was done, and the stent that was implanted.

Tell any medical person who treats you that you have a stent in your artery. **Keep your Stent Implant Card with you at all times.** It has the name of the doctor who implanted your stent and how to reach him / her, the hospital where you received your stent, the date it was implanted, and where it was placed in your artery. It also identifies the size of your stent and the date the stent was made. The card has valuable information that is necessary if you need a magnetic resonance imaging (MRI). There are also phone numbers on the card that your doctor can call if he / she has any questions.

Magnetic Resonance Imaging (MRI)



IMPORTANT: You must tell the people conducting the MRI test that you have a **stent**. Show them your Stent Implant Card so that they will have the information needed about your stent to perform the testing correctly.

If you require an MRI scan, tell your doctor or MRI technician that you have a stent implant. Test results indicate that X.ACT™ Carotid Stents are MR conditional. Patients with single or overlapped X.ACT Carotid Stents can undergo MRI scans safely under the following conditions:

MRI Safety Information	
Non-clinical testing has demonstrated that the X.ACT Carotid Stent is MR Conditional for single and overlapping lengths up to 75 mm in length. A person with the X.ACT Carotid Stent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	X.ACT Carotid Stent
Static Magnetic Field Strength (B_0)	1.5 or 3 Tesla
Maximum Spatial Field Gradient	3000 Gauss/cm (30 T/m)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum MR System reported whole-body-averaged specific absorption rate (SAR)	2.0 W/kg (normal operating mode)
Scan Duration	60 minutes of continuous RF scanning with 2 W/kg whole-body average SAR (Under the scan conditions defined above, the X.ACT Carotid Stent is expected to produce a maximum temperature rise of less than 5°C* after 15 minutes of continuous scanning.)
MR Image Artifact	In non-clinical testing, the image artifact caused by the device extends approximately 4 mm from the X.ACT Carotid Stent when imaged with a gradient echo or spin echo pulse sequence and a 3 Tesla MRI system.

*Note: temperature rise considers physiologic cooling due to blood flow inside the vessel and perfusion in the capillary bed outside the stent

The stent(s) should not migrate in this MRI environment, and MRI may be performed immediately following the implantation of the X.ACT Carotid Stent(s). Prior to undergoing an MRI scan, inform your doctor that you have an X.ACT Carotid Stent.

Frequently Asked Questions

How long will the stent stay in my body?

Stents are designed to stay in your body permanently.

What are the restrictions or cautions after I've received a stent?

If you require MRI, tell your doctor or MRI technologist that you have an implanted stent.

When can I resume my regular activities?

Your doctor will advise you. Many patients can return to work and follow their normal routine about a week after their stent procedure. Please confirm with your doctor.

Will my stent set off the metal detector at airport security checkpoints?

No, your stent implant will not trigger alarms at security checkpoints.

Will I be able to feel the stent inside me?

No, you will not be able to feel the stent once it has been implanted in your artery.

Could I have recurring symptoms?

Yes, it is possible that you will experience symptoms again, either due to a new blockage in the region treated with the stent or due to a blockage at another place in your arteries. Your doctor will monitor your progress. If you experience pain in and / or beyond the area of your body where the stent was inserted, please notify your doctor.

How can I help prevent a recurrence of symptoms?

While there is no sure way to prevent a recurrence of symptoms, you can reduce your risk through exercise, not smoking, controlling your blood pressure and cholesterol, taking prescribed medications, and eating a healthy diet. Your doctor can advise you about lifestyle changes.

Definition of Medical Terms

Angioplasty: A minimally invasive procedure in which a balloon dilatation catheter is passed through to the blocked area of an artery. Once inflated, the catheter compresses the plaque against the blood vessel wall and enlarges the vessel opening. An angioplasty can also be performed with placement of a stent.

Anticoagulant: A medication to prevent or slow the clotting of blood by thinning the blood.

Antiplatelet: A substance to reduce clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

Atherosclerosis: A disease that causes narrowing or blockage of arteries caused by a build-up of fat (cholesterol) and scar tissue within the artery wall. The build-up is sometimes referred to as "plaque."

Cardiac Catheterization Laboratory (Cath Lab): A sterile X-ray theater or procedure room in which catheterization is performed.

Catheter: A thin, hollow, flexible tube used to access the arteries during an angiogram or during an angioplasty procedure. A catheter can be used to inject medication, fluids, or contrast dye during your procedure. A catheter is also used to deliver the balloon or stent during an angioplasty procedure.

Electrocardiogram (ECG / EKG): A test that records changes in the electrical activity of the heart. An ECG / EKG will be used to monitor your vital signs during and after the procedure.

Femoral Artery: The main artery of the thigh, supplying blood to the leg. Often used as an access site to perform angiography and angioplasty.

In-Stent Restenosis: Recurrent blockage or narrowing of a previously stented vessel.

Interventional Radiology Suite (IR): A sterile X-ray theater or procedure room in which catheterization is performed.

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

Lumen: The inner channel or cavity of a vessel or tube. In a blood vessel, it is the opening through which blood flows.

Magnetic Resonance Imaging (MRI): A non-invasive diagnostic procedure used to obtain images of internal body structures through the use of magnets and radio waves.

Percutaneous: Performed through the skin without requiring a deep incision.

Plaque: An accumulation or build-up of fatty deposits, calcium, inflammatory cells, and scar tissue in the artery wall that results in narrowing of the vessel lumen.

Restenosis: A recurring blockage caused by the excessive growth of scar tissue inside the artery or stent, following an interventional procedure such as angioplasty.

Stent: A metallic mesh tube that is implanted into an artery during an angioplasty, providing a scaffold to help hold the artery open, ensuring blood flow to the heart muscle.

Transluminal: Through the inside opening of a vessel or artery.

Definition of Symbols Used in Patient Labeling

Symbol	Definition
	Patient identification
	Manufacturer
	Authorized representative in the European Community/European Union
	Patient information website
	MR Conditional
	Medical device
	Catalogue number
	Batch code
	Unique device identifier
	Health care centre or doctor
	Date
	UK Responsible Person
	Rapid exchange

Notes

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This product is intended for use by or under the direction of a doctor. It is important to read thoroughly the instructions for use, warnings, and potential complications associated with the use of this device.

Reference Abbott website for patent markings: www.abbott.com/patents

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