

Coronary Artery Disease

UNDERSTANDING YOUR DRUG-ELUTING STENT PROCEDURE

Resolute Onyx™
Zotarolimus-Eluting Coronary Stent System

Patient Guide



Medtronic
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This booklet is provided to doctors for use in educating their patients about the options available for treating coronary artery disease. This information does not replace medical advice. Only a doctor can diagnose your health problem and determine which treatment is best for you.

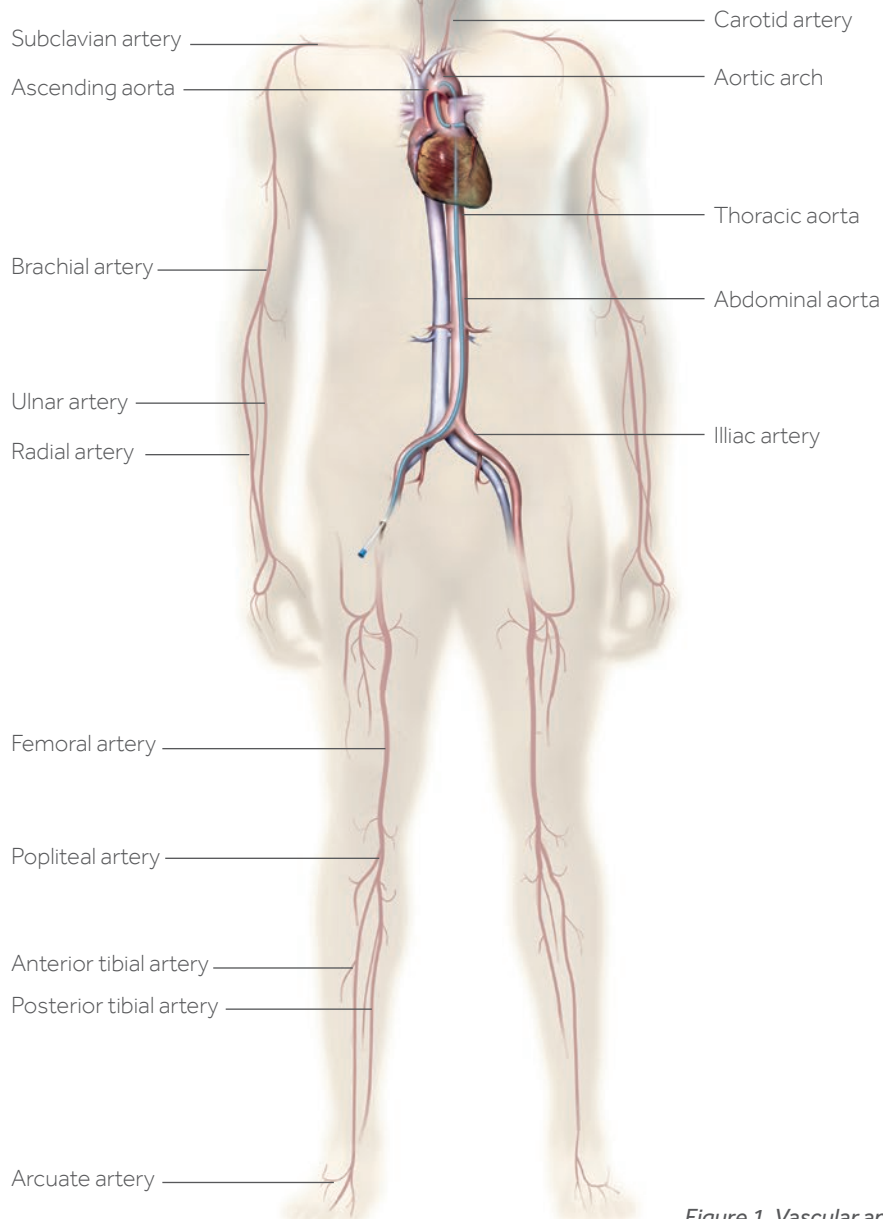


Figure 1. Vascular anatomy

Your Heart

Your heart is a muscle that pumps blood throughout your body (see **Figure 1**). The blood carries oxygen and nutrients that your body needs to work correctly. For the heart to be able to function properly, it also needs a constant supply of oxygen-filled blood. The vessels that supply this blood to the heart are called coronary arteries (see **Figure 2**).

If these arteries become narrowed or blocked resulting in reduced blood flow to the heart muscle, treatment is usually required.

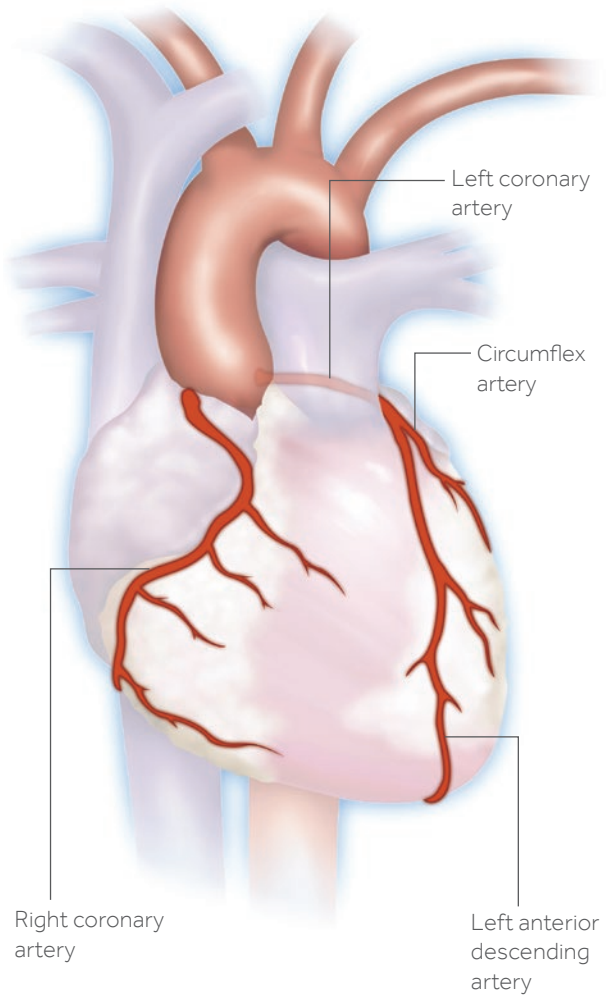


Figure 2. Coronary arteries

Understanding Coronary Artery Disease

What Causes It?

Fatty, waxy deposits called plaque (fat, cholesterol, calcium and other substances in your blood) can build up on the inside of your coronary arteries in a process known as atherosclerosis. These plaque deposits can narrow or clog the inside of your arteries, decreasing the supply of blood and oxygen to your heart (see **Figure 3**). This process is known as coronary artery disease (CAD). CAD is the leading cause of death for both men and women in the United States.¹

What Are the Signs and Symptoms?

Some of the most common signs of reduced blood flow and oxygen to the heart include:

- Angina (chest pain)

Sometimes mistaken for heartburn or indigestion, angina can spread to the arms, shoulders, back and jaw. In some cases, if a coronary artery becomes completely blocked, you could have a heart attack, also known as a myocardial infarction.

- Shortness of breath

- Nausea

- Sweating

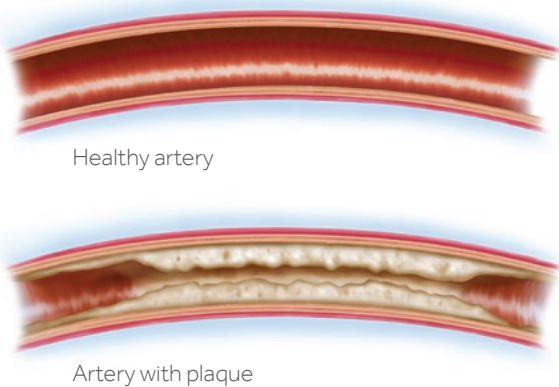


Figure 3. Comparison of coronary arteries

Did you know?

Although the most common symptom of a heart attack is chest pain or pressure, women are more likely to also have symptoms unrelated to chest pain such as:

- Neck, jaw, shoulder and upper back pain
- Burning sensation in the chest or upper abdomen
- Shortness of breath or irregular heartbeat
- Lightheadedness or dizziness
- Unusual or unexplained fatigue
- Nausea or vomiting
- Sweating or "cold sweat"

Source: www.mayoclinic.com

¹National Heart, Lung and Blood Institute

Who Is at Risk?

Some hardening and plaque accumulation within the arteries is expected as you grow older. However, certain risk factors, which include behaviors, conditions or habits, can speed up the process of your developing CAD. Also, the more risk factors you have, the higher your chances of developing CAD. For more information about risk factors, see Page 12.

Although some risk factors are beyond your control, such as your age and family history, others can be managed or eliminated to lower your risk. These include smoking, diabetes, high blood pressure, high cholesterol, obesity, and lack of exercise (leading a sedentary lifestyle). Your doctor can support your efforts to make healthier choices regarding your diet, tobacco use, activity level and stress management. For more steps you can take to prevent or slow CAD, see Page 19.

How Is It Diagnosed?

When making a diagnosis, your doctor will review your medical and family history, your risk factors and symptoms. If your doctor suspects you have CAD, you may be referred to a cardiologist — a doctor who specializes in problems of the heart, arteries and veins.

Before deciding on a treatment plan, your doctor or cardiologist may order some blood tests, a chest X-ray and other tests to measure how well your heart is working. A baseline electrocardiogram (ECG or EKG) is a simple test that records your heart's activity while you sit quietly. An exercise EKG, or stress test, shows how your heart responds

to physical activity. Both tests can determine whether or not your heart is working properly due to a lack of oxygen.

Risk factors for CAD:

- High blood pressure
- High "bad" cholesterol; low "good" cholesterol
- Certain diseases, such as diabetes
- Obesity and being overweight
- Smoking
- Lack of exercise
- Stress
- Age (over 45 for men, over 55 for women)
- Family history of CAD
- Ethnicity (Hispanics and African Americans are at higher risk)

Source: American Heart Association



A coronary angiogram can identify the exact location of a narrowed or blocked artery.

Figure 4. Typical cardiac catheterization laboratory

Angiogram and heart catheterization

If one or more tests suggest that you may have CAD, your doctor may perform a coronary angiogram. The results of this test can help your doctor decide which treatment option is best for you.

The procedure consists of an imaging technique called fluoroscopy, which uses X-ray technology and a special fluid called contrast dye to obtain real-time moving pictures of the blood flow in your arteries. The fluoroscopic images can identify the exact location of your narrowed or blocked arteries and show the degree of your plaque buildup. This test, which usually takes 20 to 40 minutes, is performed in a cardiac catheterization laboratory, or cath lab, which is a room designed especially for the procedure (see **Figure 4**).

Procedure

For the heart catheterization, you may be given a mild sedative to help you relax. Small sticky pads, called electrodes, will be placed on your chest to monitor your heart rate and rhythm. Other devices will monitor your oxygen level and blood pressure. Your doctor will determine the best entry point for evaluating your heart arteries — leg, wrist, or arm. That area will be cleaned, shaved and numbed before a tiny puncture is made. After the artery puncture is made, a short tube known as a sheath will be placed in the artery to provide a temporary passageway for the necessary medical devices to reach your heart. Your doctor will next insert a long, thin, flexible hollow tube, or catheter, to access your coronary artery (see **Figure 5**). The contrast dye will be injected through the catheter and into your bloodstream to allow

your doctor to view your arteries on the X-ray monitor, much like a television screen, and measure the extent of your CAD. It is normal to feel a warm but temporary sensation when the contrast dye is injected. Tell your doctor or nurse if you feel any pain or discomfort during the procedure.

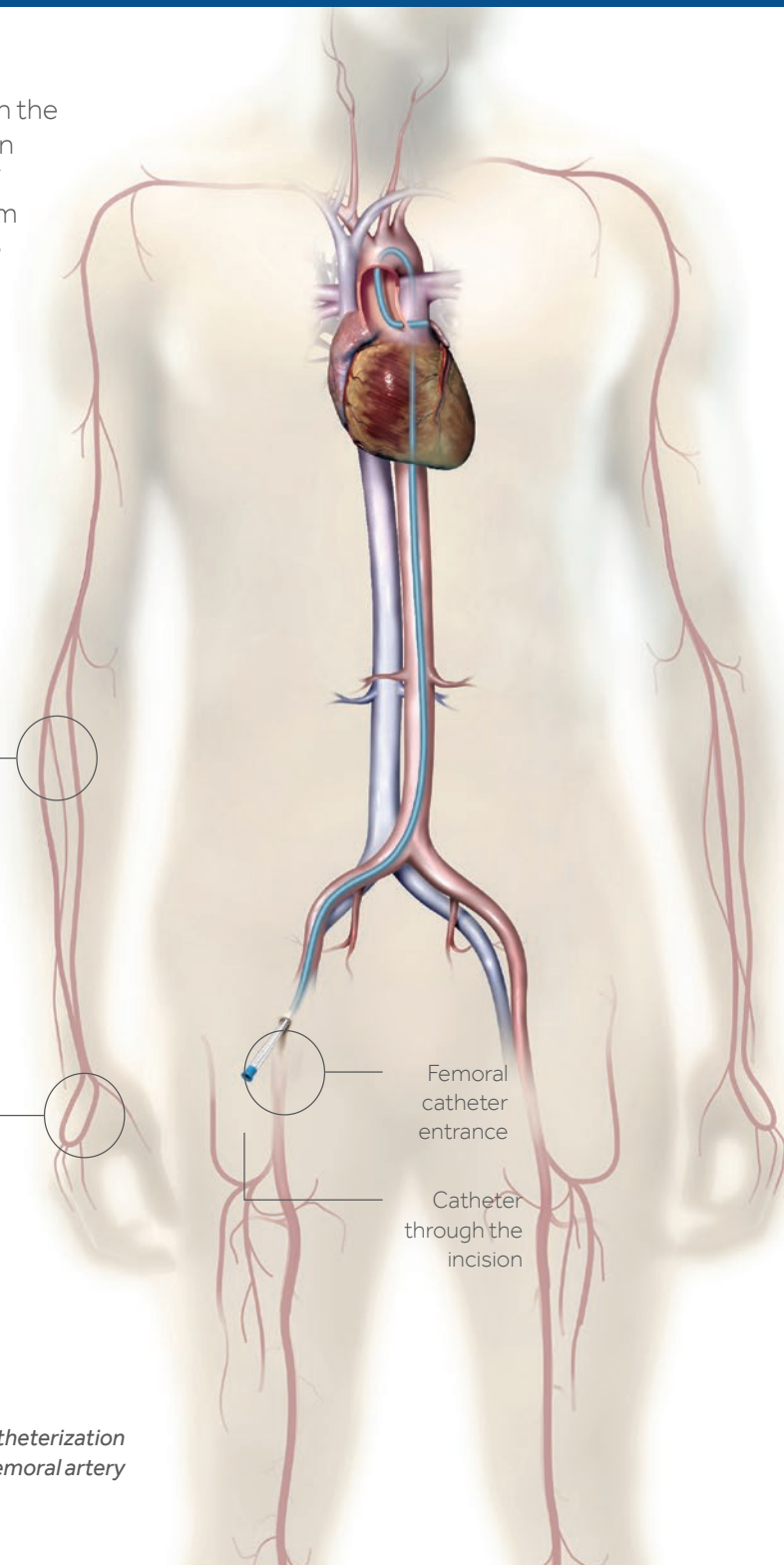
Brachial catheter entrance

Radial catheter entrance

Femoral catheter entrance

Catheter through the incision

Figure 5. Heart catheterization through the femoral artery



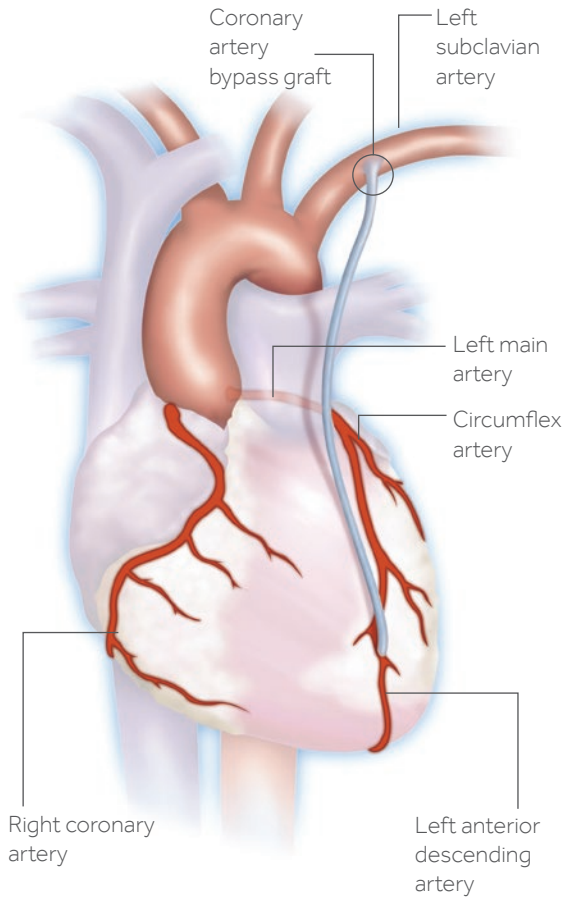


Figure 6. Coronary artery bypass grafting

Treatment Options for Coronary Artery Disease

CAD can be managed in several ways. Your doctor will recommend a treatment plan based on your symptoms, test results, medical history and future potential risks. This plan may include medications to relieve your chest pain, heart bypass surgery, and/or stenting to expand your coronary arteries and increase blood flow to your heart. Each of the treatment options discussed below has potential benefits and risks. Your doctor will discuss which of the choices is likely to be best for you.

Medical Therapy

Nitroglycerin may be given to relieve chest discomfort due to coronary blockages. Drugs such as beta blockers and cholesterol-lowering medications may be given to slow the disease's progress or to ease certain symptoms.

Surgery

Heart bypass surgery, also known as coronary artery bypass graft (CABG) surgery, is an open heart procedure. Typically, a section of vein from your leg (and sometimes an artery from your wrist) is removed. Then an artery from your chest and the section of the vein from your leg are attached (grafted) onto your coronary artery just past the blockage site (see **Figure 6**), creating a new path for blood to flow (bypass) around the blocked artery.

Today, there are options regarding the surgical approaches for CABG surgery with respect to the type and location of chest incisions. The heart surgeon may discuss these options with you. Following successful CABG surgery, patients typically stay in the hospital for less than one week and continue their recovery at home.

Balloon Angioplasty

Balloon angioplasty is one type of a group of heart procedures known as percutaneous coronary intervention (PCI) and is performed in the catheterization laboratory — the same room where you may have had a coronary angiogram. Balloon angioplasty does not require open surgery. A local anesthetic will be used to numb the puncture site, and you may be given a sedative to help you relax. Your doctor will determine the best entry point for evaluating your heart arteries — leg, wrist, or arm. That area will be cleaned, shaved, and numbed before the artery puncture is made. After the artery puncture is made, a short tube known as a sheath will be placed in the artery to provide a temporary passageway for the necessary medical devices to reach your heart. During the coronary angiogram, your doctor will inject a contrast dye through a catheter into your bloodstream, which allows your doctor to view your arteries on the X-ray monitor. A catheter with a small balloon on its tip is inserted through the sheath and threaded through your arteries until it reaches your blocked coronary artery. Then the balloon

is inflated to flatten the plaque against the wall of the artery. It is normal to have some chest pain when the balloon is inflated. Tell your doctor or nurse if you feel any pain or discomfort during the procedure. The balloon is then deflated and the catheter is removed from your artery. This procedure opens the narrowing in your coronary artery, and increases blood flow through the artery (see **Figure 7**).

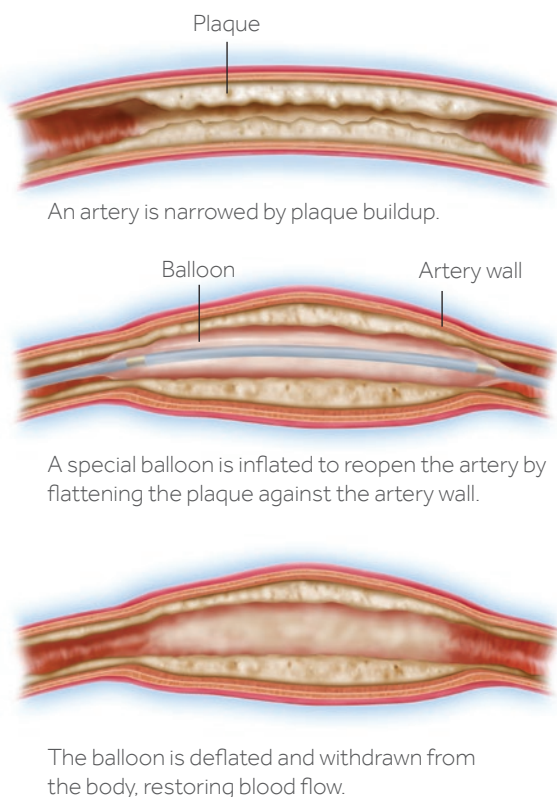


Figure 7. Balloon angioplasty inside an artery

Stent Therapy

In many cases, balloon angioplasty alone may not be successful in effectively opening your blocked artery. Therefore, your doctor may recommend placing a coronary stent at the site of the artery blockage. Stent implantation in a heart artery is another type of PCI procedure. Implanting a stent does not require open surgery.

A stent is a tiny, metallic, expandable mesh-like tube that supports the artery and helps to keep it open (see **Figure 8**). You will likely already have a short tube known as a sheath in an artery in your leg, wrist, or arm. Your doctor will insert a specially designed balloon catheter through the sheath and deliver the stent to the blocked area of the coronary artery. The balloon is inflated to expand the stent. As the stent expands, it helps flatten the plaque against the artery wall, increasing blood flow. Once the stent is properly expanded, the balloon is deflated and the catheter is removed from your body. The stent stays in your artery permanently to help keep it open to maintain blood flow.

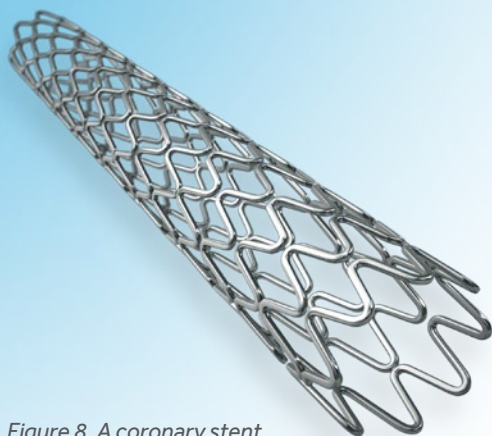


Figure 8. A coronary stent

Restenosis

Restenosis is the renarrowing of the artery due to the overgrowth of tissue within the stent during the healing process. Although stenting is a less invasive way to open clogged arteries compared with CABG surgery, restenosis may occur in some patients who receive stents.

Drug-Eluting Stents for Coronary Artery Disease

To help prevent restenosis from occurring, scientists developed drug-eluting stents. Drug-eluting stents reduce the risk of restenosis and reduce the potential need for future treatment. They provide the same support to the artery wall as uncoated stents, except they have a coating on the stent that includes a drug that is released over time. The drug helps limit the overgrowth of tissue within the stent as the artery heals, preventing renarrowing (see **Figure 9**).

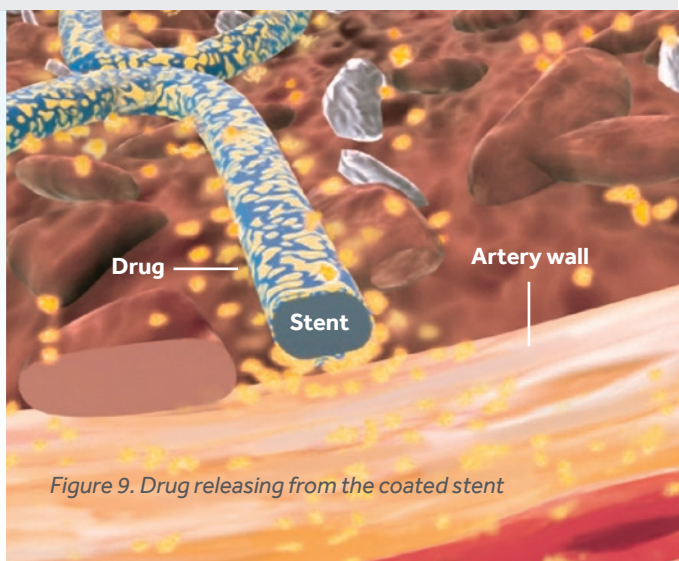


Figure 9. Drug releasing from the coated stent

Did you know?

- Since the introduction of stents, millions of people around the world have been treated with this therapy.
- Stents come in a variety of sizes so that doctors can best match the size of the diseased artery.

Source: American Heart Association

Diabetes and heart disease

If you have diabetes, you are at an increased risk for having a heart attack. Therefore, in addition to all the measures aimed at lowering the risk of CAD, diabetic individuals should pay attention to the following measures to lower the chances of CAD:

- Adopt a heart-healthy diet rich in fiber, fruits and vegetables
- Aim for at least 30 minutes of physical activity daily
- Take your medications as directed
- Keep your blood glucose under control
- Check your feet daily for cuts, blisters, sores, swelling, redness or sore toenails
- Brush and floss your teeth daily
- Manage your blood pressure and cholesterol
- Maintain a healthy weight
- Do not smoke

Source: National Diabetes Information Clearinghouse

Resolute Onyx™ Zotarolimus-Eluting Coronary Stent

Medtronic Resolute Onyx™ zotarolimus-eluting coronary stents are drug-eluting stents (see **Figure 10**). They are made of an alloy containing the following metals: cobalt, chromium, molybdenum, nickel, and platinum-iridium. They are coated with a drug called zotarolimus, which is contained within a polymer (a plastic material designed specifically to control the drug release). The drug helps limit the growth of tissue in the artery where the stent is placed. Each stent is polished for a smooth surface and shaped to allow it to pass through your arteries on a specially designed balloon catheter.

Contraindications

You should not receive the Resolute Onyx™ stent if you have a known allergy to:

- Drugs used for suppression of the immune system such as zotarolimus, tacrolimus, sirolimus or related drugs
- Cobalt, nickel, chromium, molybdenum, or platinum-iridium
- The polymer or its individual components, including: polybutyl methacrylate, polyhexyl methacrylate, polyvinyl acetate and PVP (polyvinyl pyrrolidone)

Coronary artery stenting is contraindicated for use in the following:

- If you are unable to take aspirin or other blood-thinning drugs (also called antiplatelet or anticoagulation therapy) such as heparin, bivalirudin, clopidogrel, prasugrel, ticagrelor, or ticlopidine

- If your doctor decides that your blockage will not allow complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system

A drug-eluting stent for people with diabetes:

- Diabetes affects 25.8 million people in the United States* and is on the rise. People with diabetes are more likely to have high blood pressure, heart disease or suffer a stroke. In fact, CAD is the leading cause of death in patients with diabetes.*
- Resolute™ stents, including Resolute Onyx™ DES, have been evaluated in people with diabetes and have been approved by the FDA as safe and effective treatment options for this patient population.
- If you have diabetes, it is important to adopt healthy habits (see Page 5) and talk with your doctor about ways you can further reduce your risk of CAD.

**American Diabetes Association*

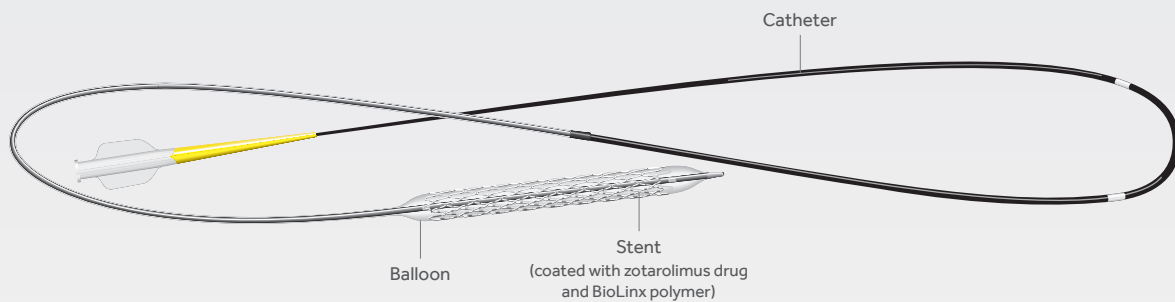


Figure 10. Resolute Onyx™ coronary stent and delivery system



Potential Adverse Events

The risks of using the Resolute Onyx™ stent are similar to those associated with any stent procedure. Discuss all of your available treatment options with your doctor, who can advise you as to whether or not a drug-eluting stent is right for you. If the stent clots, you may need another angioplasty procedure. It may also lead to a heart attack, the need for urgent bypass surgery, or death. Even with successful stent implants, there is a chance of renarrowing (restenosis). This may require additional treatment, such as repeat angioplasty and/or bypass surgery, to reopen the artery and to increase blood flow to the heart. The risks from using balloon catheters within a previously implanted stent are similar to the risks that may occur during the initial stent

implant. These may be serious enough to require additional surgery or cause death.

Some risks associated with standard balloon angioplasty and stenting include, but are not limited to:

- Bruise or bleeding at the catheter insertion site in the leg, wrist or arm
- Pain at the catheter insertion site
- Irregular heartbeats, possibly life-threatening
- Chest pains during and after the procedure
- Decreased or increased blood pressure
- Renarrowing of the coronary artery
- Tearing, puncture or rupture of the coronary artery

- Air, pieces of devices or fragments of clots blocking the coronary artery
- Complete blockage of the coronary artery, which may require a repeat procedure to reopen the coronary artery
- Bleeding around the heart
- Heart attack or death
- Stent deformation, collapse or fracture
- Damage to the stent or injury to the coronary artery requiring emergency heart surgery
- Bleeding requiring transfusion or surgery
- Allergic reaction, which may be due to contrast dye, antiplatelet therapy, stent material (cobalt, chromium, nickel, and platinum-iridium), drug or polymer coating
- Infection or fever
- Nerve injury
- Aneurysm (weakening of a portion of the wall of a blood vessel)
- Failure to release the stent from the catheter
- Stent misplacement in the artery
- Movement of the stent from where it was placed
- The balloon used to expand the stent may break
- Shock
- Stroke/transient ischemic attack
- Renal failure

The risks of the zotarolimus drug are not yet fully known. The risks that might occur include but are not limited to:

- Blood in the urine and/or diarrhea
- Diarrhea
- Dry skin
- Fatigue
- Headache
- Infection
- Pain (abdominal, joint, injection site)
- Skin reaction (at injection site)
- Tingling feeling around the mouth

Exposure to zotarolimus and the Resolute Onyx™ polymer coating is directly related to the number of implanted stents. The use of multiple Resolute Onyx™ stents will result in your receiving larger amounts of drug and polymer.

Questions to ask your doctor:

- Do I have a blocked or clogged artery?
- How severe is my CAD?
- What are my treatment options and the benefits and risks of each?
- What happens if I wait to receive treatment?
- Is stent implantation an option?
- What kind of stent is best for me?
- What will I need to do to take care of myself after the procedure?

Clinical Studies

The safety and effectiveness of the Resolute Onyx™ stent was based on data from the RESOLUTE ONYX Study and a series of clinical studies that evaluated the Resolute™ stent and Resolute Integrity™ stent. The Resolute Onyx™, Resolute Integrity™ and Resolute™ stents are similar with regard to their metal stent design and identical with respect to their drug and polymer coating. Given the similarities between the three stents, plus additional laboratory tests, the findings described below for the Resolute Onyx™, Resolute Integrity™ and Resolute™ stent clinical studies apply to the Resolute Onyx™ stent.

RESOLUTE ONYX Core Clinical Study

In the RESOLUTE ONYX Core (2.25 mm–4.0 mm) Clinical Study, 75 patients in the United States were treated with Resolute Onyx™ drug-eluting stents. After eight months, angiogram data showed that the Resolute Onyx™ stent was noninferior to another approved drug-eluting stent at reducing the renarrowing of the artery where the stent was placed.

RESOLUTE ONYX 2.0 mm Clinical Study

In the RESOLUTE ONYX 2.0 mm Clinical Study, 101 patients in the United States and Japan received at least one Resolute Onyx™ stent measuring 2.0 mm in diameter to treat a blocked artery. After one year, 5% of patients who received a Resolute Onyx™ stent had a heart-related death, heart attack, or need for a repeat procedure at the site of the originally placed stent.

The Global RESOLUTE Clinical Trial Program

There have been five clinical studies that together show the safety and effectiveness of Resolute™ coronary stents in patients with coronary artery disease. A short description of these studies is provided below:

1. RESOLUTE First-In-Man (FIM): RESOLUTE FIM was the first clinical study conducted with the Resolute™ stent. This study had 139 patients and was performed in Australia and New Zealand. After nine months, the Resolute™ stent was noninferior to another approved drug-eluting stent in reducing the renarrowing of the artery where the stent was placed. At four years after the initial procedure, 2.2% of patients who had received the Resolute™ stent needed a repeat procedure at the site of the originally placed stent.

2. RESOLUTE US: RESOLUTE US (R-US) was conducted in the United States to evaluate the safety and effectiveness of the Resolute™ stent. There were a total of 1516 patients enrolled in the RESOLUTE US study; 1242 patients in the main study (which included 100 patients towards the 150 patients in the 2.25 mm cohort*), 100 patients in the Angiographic and Intravascular Ultrasound (IVUS) Substudy, 60 patients in the 4.00 mm Substudy and 114 patients in the R-US 38 mm Substudy (the 38 mm Substudy included a total of 223 patients; 114 from the R-US study and 109 from the R-Asia study).

- **2.50 mm–3.50 mm Substudy:** A total of 1112 patients received at least one Resolute™ stent to treat blocked heart arteries measuring 2.50 mm to 3.50 mm in diameter. After one year, 3.8% of patients had a heart-related death, heart attack, or

*The 2.25 mm cohort included 130 patients who were part of the main study and 20 patients who were part of the 2.25–3.50 mm Angio/IVUS substudy.

need for a repeat procedure at the site of the originally placed stent

- **Angiographic and Intravascular Ultrasound (IVUS) Substudy:** A total of 100 patients received a Resolute™ stent. Eight months later, the patients had a repeat angiogram and an ultrasound test to look at whether renarrowing of the artery had occurred. The angiogram at eight months showed that the Resolute™ stent was noninferior to another approved drug-eluting stent at reducing the renarrowing of the artery where the stent was placed.

- **2.25 mm Cohort:** A total of 150 patients received at least one Resolute™ stent measuring 2.25 mm in diameter to treat a blocked artery. After one year, 5.5% of patients who received a Resolute™ stent had a heart-related death, heart attack, or need for a repeat procedure at the site of the originally placed stent.

- **4.00 mm Substudy:** A total of 60 patients received at least one Resolute™ stent measuring 4.00 mm in diameter to treat a blocked artery. After eight months, the Resolute™ stent was noninferior to an approved bare metal stent in reducing the renarrowing of the artery segment where the stent was placed.

- **38 mm Length Substudy:** A total of 223 patients, 114 in the USA and 109 in Asia, received at least one stent measuring 38 mm in length. After 12 months 4.5% of patients had a heart-related death, heart attack or a need for a repeat procedure at the site of the originally placed stent.

3. RESOLUTE All Comers: In RESOLUTE All Comers, 1140 patients received at least one Resolute™ stent. Many patients had coronary artery disease that was more complicated than in the RESOLUTE FIM, RESOLUTE US and RESOLUTE Japan studies.

This study was conducted in Europe. After one year, 8.1% of patients treated with Resolute™ stents had a heart-related death, heart attack, or need for a repeat procedure at the site of an originally placed stent. After two years, 11.2% of patients treated with Resolute™ stents had a heart-related death, heart attack, or need for a repeat procedure at the site of an originally placed stent.

4. RESOLUTE International: In RESOLUTE International, a total of 2349 patients received at least one Resolute™ stent. Many patients had coronary artery disease that was more complicated than in the RESOLUTE FIM, RESOLUTE US and RESOLUTE Japan studies. This study was conducted in Europe, India, South Africa and Argentina. After one year, 4.3% of patients had a heart-related death or heart attack.

5. RESOLUTE Japan: This study involved 100 Japanese patients. After eight months, the Resolute™ stent was noninferior to an approved drug-eluting stent at reducing the renarrowing of the artery where the stent was placed.

Resolute™ Stent in Patients with Diabetes:

The safety and effectiveness of the Resolute™ stent in diabetic patients was evaluated by combining the results of 878 diabetic patients from the five studies noted above. After one year, 8.1% of diabetic patients who received a Resolute™ stent had a heart-related death, heart attack, or need for a repeat procedure in the same vessel where the original stent was placed.

Resolute Integrity™ Stent in Patients with

Chronic Total Occlusions (CTO): The safety and effectiveness of the Resolute Integrity™ stent was evaluated by assessing the results of 183 patients from the PERSPECTIVE investigator-initiated study in the United States. After one year, 18.2% of CTO patients who received a Resolute Integrity stent had a heart-related death, heart attack, or need for a repeat procedure in the same vessel where the original stent was placed.

Your Stent Procedure: What to Expect

Preparing for your procedure

If you know in advance that you will be getting a coronary stent, ask your doctor any questions you may still have.

Before you receive a Resolute Onyx™ stent

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

- Take all of your prescribed medicines.
- Tell your doctor if you cannot take aspirin and/or blood-thinning medications such as Plavix®, also known as clopidogrel, or if you have a history of bleeding problems.
- Tell your doctor about any medications you are taking.
- Tell your doctor about your drug allergies, or if you are allergic to any metals or plastics. Ask your doctor which medications are safe for you to continue taking.
- Follow all instructions given to you by your doctor or nurse, including limits on what you eat and drink before your procedure, arrangements for going home after your procedure, what activities are safe to do after your procedure, and when you should see your physician after you go home.

Implanting the stent

Your stent procedure will be performed in a cath lab by an interventional cardiologist, a doctor who specializes in this procedure. You will be awake for the procedure and will receive fluids and drugs to relax you. Your

Be sure to tell your doctor if you:

- Cannot take aspirin or other blood-thinning medications
- Are allergic to drugs/metals/plastics/shellfish
- Have a history of bleeding problems
- Are or might be pregnant, or are nursing
- Are planning other surgeries or dental work soon

procedure will begin with an angiogram to determine the number and location of the blockage(s), and will usually include a balloon angioplasty prior to implanting the stent.

Using X-ray images to guide the way, your physician will insert an unexpanded stent mounted onto a deflated balloon through the sheath placed in an artery in your leg, wrist or arm. You might feel pressure at the sheath site while this is being done. You won't be able to feel the catheter as it moves through your body. The stent and balloon are carefully guided to the site of the blockage in the artery. Then the balloon is inflated, expanding the stent, flattening the plaque against the artery wall. It is common to feel some mild discomfort as the stent is expanded, but this should subside when the balloon is deflated.

Once the stent is in place, more X-ray images are taken to ensure that the stent is fully expanded and that blood flow to your heart has improved. Your doctor may inflate and deflate the balloon several times to make sure the stent is firmly pressed against the artery wall. When your doctor sees that

blood is flowing properly, the catheter will be removed from your body. The stent will remain permanently inside the artery to hold it open and maintain blood flow to your heart (**see Figure 11**). After the procedure is completed, the sheath in the artery in your leg, wrist or arm will be removed, and the puncture site will be sealed with a special closure device or by applying pressure over the artery. The stenting procedure lasts 30 minutes to two hours.

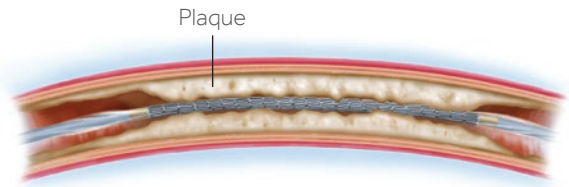
After Your Procedure

Resting in the hospital

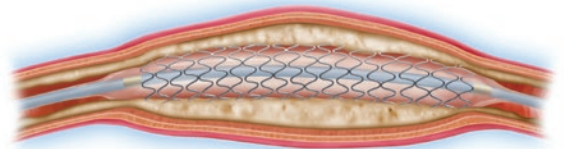
Immediately after the procedure, you will be instructed to lie still and not bend your leg, wrist or arm where the catheter was inserted. You will probably stay in a special hospital unit for several hours or up to one or two days while nurses monitor your heart, blood pressure and catheter insertion site. It is normal to feel some bruising and soreness at the insertion site in your leg, arm or wrist. You may also feel groggy or forgetful from the sedating medication. Gradually, you will be allowed to get up and walk around — most people are up within two to six hours.

Going home

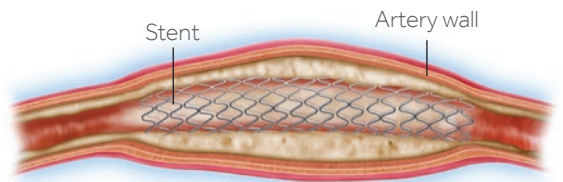
- Before leaving the hospital, your cardiologist or nurse will give you instructions about what drugs you will need to take.
- You will also receive a stent implant identification (ID) card.
- It is important to rest and drink plenty of fluids to rid your body of the contrast dye.



The unexpanded stent is delivered to the treatment area via a special catheter.



The balloon is inflated to expand the stent.



The balloon is deflated and withdrawn from the body, leaving the stent to support the artery and maintain blood flow.

Figure 11. Implanting a stent inside a narrowed artery

- Do not lift heavy objects or exercise for at least 24 hours after going home.
- If you are a smoker, talk to your doctor about quitting.
- You should be able to return to your normal activities quickly, but be sure to discuss this with your doctor.

Your stent implant identification card

Your stent implant ID card identifies you as a patient who has had a stent implanted. It contains important information including the kind of stent you have and its location inside your body, the date of your stent implant procedure, and your doctor's name and contact information.

Keep your stent implant ID card with you at all times and be prepared to show it to other doctors and dentists you may see in the future. They may need to take special precautions when treating you. If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a stent implant.

Signs to watch for:

Call your doctor or hospital staff immediately if:

- Your catheter insertion site is painful, or starts to bleed or swell
- You have signs of infection such as fever or warmth, redness, swelling, or drainage at the catheter insertion site
- You feel chest pain, discomfort or shortness of breath
- You feel faint, dizzy or weak

Caution: If you experience any of these symptoms and your doctor is unavailable, call for an ambulance to take you to the nearest hospital emergency room.

Resolute Onyx™

Zotarolimus-Eluting
Coronary Stent System

Implant Card

Important Health Information

Medtronic

Recovering from Your Stent Procedure

Before you leave the hospital, your doctor will ask you to take certain drugs. It is important to precisely follow your doctor's advice about taking these medications.

Blood-thinning drugs

Blood-thinning or antiplatelet medicine helps prevent blood clots from forming on your stent, a condition called stent thrombosis. Stent thrombosis is a dangerous condition that can cause a heart attack or sudden death. The most commonly used antiplatelet medications are Plavix, also known as clopidogrel, Ticlid®, also known as ticlopidine, Effient®, also known as prasugrel, and Brilinta®, also known as ticagrelor. You will need to take one of these blood thinners

for up to a year or more after your procedure, but be sure to let your doctor know if you have bleeding problems. Most people will also need to take aspirin for life. It is extremely important to take the full dose your doctor prescribes and to not miss any doses.

Caution: Call your doctor if you cannot continue taking your medications because of side effects such as rash, bleeding or upset stomach.

Caution: Do not stop taking your prescribed medications unless you are instructed to do so by the doctor who performed your stent procedure.

Caution: If your dentist or another doctor has told you to stop taking your medication, talk to your cardiologist before you stop taking your antiplatelet medications — even if you are asked to stop for only a short time. If surgery or dental work that would require you to stop taking antiplatelet medications is recommended after you have received the stent, you and your doctor should carefully consider the risks and benefits of this surgery or dental work vs. the possible risks from early discontinuation of these medications.

Follow-up visits

Along with taking your medications, seeing your doctor on a regular basis is very important to your recovery. Your first visit is usually within four weeks after your stent is implanted. Be sure to keep all appointments for follow-up care, including blood tests. If you receive a drug-eluting stent, your doctor will monitor you for possible side effects of this drug. It is also very important

to work with your doctor to keep coronary artery disease risk factors (high cholesterol, diabetes, obesity, high blood pressure, and smoking) under control.

Caution: Notify your doctor immediately if you experience new, severe or frequent chest pain, especially in the first month after your procedure. These symptoms may indicate a re narrowing in your coronary arteries.

Staying Healthy with a Stent Implant

Although CAD can be treated effectively, it has no cure. Along with learning everything you can about the disease, you can help slow or prevent its advancement by making some healthy lifestyle changes.

Heart-healthy choices

Smoking, leading a sedentary or stressful lifestyle, and consuming a diet high in fat and low in fruits and vegetables all increase your risk for CAD. Ask your doctor how you can learn to:

- Stop smoking — it is the single most important thing you can do for your health
- Control diabetes
- Control blood pressure
- Eat heart-healthy food
- Exercise
- Maintain a healthy weight
- Manage stress
- Learn more about living with CAD



Frequently Asked Questions

Are stents safe?

More than two million people receive stents each year, and doctors have been recommending them to their patients for more than ten years. However, a stent may not be the right treatment option for you. If you cannot take aspirin or other blood-thinning (antiplatelet) medicines, or if you are allergic to certain metals and plastics, then a stent is not right for you. Talk with your doctor about the risks of stent therapy and how it may affect you. For more information, see Page 12.

How long does the procedure take and when can I go home?

A stent procedure lasts 30 minutes to two hours depending on the extent of your CAD. Some patients are discharged the same day that the stent is implanted, but you should expect to stay overnight in the hospital and return home the next day. However, your hospital stay may be longer.

Do I need to be worried about contrast dye and its impact on my kidneys?

Like any procedure requiring use of contrast dye, there are risks that may include kidney damage. Your doctor will explain the risks involved and try to minimize the amount of contrast dye you receive during your procedure. Afterwards, be sure to drink plenty of water to help your kidneys flush away the dye.

Will drug-coated stents interfere with other over-the-counter or prescription medicines I may be taking?

Although drug interactions are uncommon, certain drugs may interact with the specific medication used on drug-coated stents. It is important to tell your doctor about any drugs you may be taking.

How long will the stent stay in my body?

Stents are designed to stay in your body permanently.

Will I be able to feel the stent inside me? Will it move?

No, you will not be able to feel the stent once it has been implanted in your artery. Once the stent is implanted and pressed against the artery wall, it will remain there permanently. Tissue will grow over the stent and hold it in place so it will not move.

Can the stent rust? What is it made of?

The Resolute Onyx™ stents are made of a non-rusting alloy containing the following metals: cobalt, chromium, molybdenum, nickel, and platinum-iridium.

When can I resume my regular activities (for example, working, exercising, sexual activity, traveling, playing sports)?

Your doctor will advise you. Most patients can return to work and follow their normal routines in about one week.

Do I need to contact my private insurance before or after the procedure?

As with any medical procedure, it is a good idea to contact your insurance company in advance to check on the specific benefits, limitations, copayments and deductibles that may apply to your treatment.

If I have a drug-coated stent, what medications do I need to take, for how long, and what do they do?

After your stent is implanted, you will need to take blood-thinning medicines for up to a year or more to prevent stent thrombosis, which is the formation of blood clots within the stent. Most people will need to take aspirin for the rest of their lives. The most important thing that you can do to minimize the risk of stent thrombosis is to take the medicines your doctor prescribes. Do not stop taking them until your doctor tells you to, even if you are feeling better. Follow your doctor's instructions exactly.

What follow-up care is required for drug-coated stents?

You will need to return to see your doctor for regular follow-up visits after undergoing stent implantation. It is very important not to miss any scheduled follow-up visits with your doctor. Along with taking your prescribed medications, your doctor will monitor you for possible side effects and help keep your risk factors under control. See Page 3 for more information.

Why should I carry a stent implant identification card?

Your stent implant ID card notifies medical personnel that you have a stent implanted in your body. It tells them the type of stent you have, its location and that you are likely to be taking antiplatelet medication. Carry your card with you at all times and present it whenever you see a new doctor, have a medical test or procedure, go to the emergency room or see your dentist.

Will my stent set off metal detectors at airports or security checkpoints in stores?

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

Is it safe to have an MRI/mammogram/CAT scan?

Mammography, CAT scans, X-rays and nuclear stress tests are safe for people with stents. However, if you need an MRI, the technician will need to operate the machine within certain limits. Be sure to tell all doctors treating you that you have a stent, and show them your stent implant ID card.

Do I need to be careful around microwaves?

You can safely use a microwave oven. A microwave oven will not harm your stent.

Could I have recurring symptoms?

Yes, it is possible that you will experience symptoms again, either due to a reblockage in the artery with the stent or a new blockage in a different heart artery. Notify your doctor if you have recurring symptoms.

How can I 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 and adopting a healthy diet. Your doctor can advise you about lifestyle changes.

What if my arteries renarrow?

If this happens, you may experience symptoms similar to those you experienced before your stent procedure. These symptoms may include chest pain or shortness of breath, especially during physical activity. Inform your doctor immediately if you experience any of these symptoms. You may need additional treatment.

Resources

These resources provide additional information about heart disease and treatment options:

- **American Heart Association**
(www.heart.org)
- **American College of Cardiology**
(www.cardiosource.org)
- **Food and Drug Administration**
(www.fda.gov/forconsumers)
- **National Heart Lung and Blood Institute**
(www.nhlbi.nih.gov)
- **Mayo Clinic**
(www.mayoclinic.com)

Glossary

Angina. Pain or discomfort in the chest because of reduced blood flow and oxygen supply to the heart muscle.

Angiogram. Special X-ray test that indicates the number, exact location and extent of narrowed or blocked coronary arteries.

Angioplasty. Procedure used to unblock an artery clogged with plaque; also known as percutaneous transluminal coronary angioplasty (PTCA), or balloon angioplasty. Often followed by the placement of a stent.

Antiplatelet medications. Drugs that inhibit the function of platelets, the blood cells that clump together to begin the process of blood clot formation. Examples include Plavix, also known as clopidogrel, Ticlid, also known as ticlopidine, Effient, also known as prasugrel, and Brilinta, also known as ticagrelor.

Arrhythmia. Irregular heart beat or abnormal heart rhythm.

Atherosclerosis. Disease process involving the buildup of a waxy substance called plaque on the inside of arteries.

Balloon angioplasty. Nonsurgical medical procedure in which a specially designed balloon catheter is used to open a narrowed or blocked artery.

Bare metal stent (BMS). Stent not coated with a drug that prevents renarrowing of a heart artery. Also known as an uncoated stent.

Cardiac catheterization. Procedure in which a thin, hollow tube (catheter) is inserted into an artery for the purposes of visualizing the heart and blood vessels, and diagnosing and treating heart disease.

Cardiac catheterization laboratory. A hospital room designed especially for the catheterization procedure.

Catheter. A thin, flexible hollow tube used to access a body cavity; in angioplasty, a catheter provides access to the artery for the delivery of a balloon or stent.

Cholesterol. Used by your body to build healthy cells and some vital hormones. High blood cholesterol can lead to the buildup of fatty deposits in your blood vessels (atherosclerosis) and may lead to restricted blood flow to your arteries.

Contrast dye. Liquid injected into your blood to improve the visibility of veins and arteries on an X-ray. It is later eliminated from your body through your kidneys and your urine.

Coronary artery disease (CAD). Atherosclerosis (blockage) in the coronary arteries. Also called coronary heart disease

Coronary arteries. Blood vessels on the outside of the heart that provide oxygen-rich blood to the heart.

Coronary artery bypass graft (CABG) surgery. Open-heart surgery that uses a vein from another part of your body to create a different route for blood to flow around a blocked coronary artery. Also called open heart or bypass surgery.

Drug-coated or drug-eluting stent (DES).

A stent coated with a drug, such as zotarolimus, that helps prevent restenosis (renarrowing of the arteries) after a stent has been implanted.

Electrocardiogram (ECG or EKG). Medical test in which several electronic sensors are placed on your body to monitor electrical activity associated with the heartbeat.

Fluoroscopy. Examination of the tissue and deep structures of the body by using X-rays.

Hematoma. An abnormal, localized collection of blood outside a blood vessel. Caused by a break in the wall of a blood vessel.

Hemorrhage. Escape of blood from an injured blood vessel.

Myocardial infarction (MI). Damage or death of an area of your heart muscle, resulting from a blocked blood supply to the area. Commonly referred to as a heart attack.

Plaque. Waxy substance consisting of fats and cholesterol that can build up on the inner lining of your arteries and restrict blood flow to the heart muscle.

Polymer. Plastic material that when combined with a drug and coated on a stent, helps control the release of the drug into the heart vessel wall to help prevent restenosis.

Restenosis. Renarrowing of an artery at the site of angioplasty and/or an implanted stent, due to the overgrowth of tissue at the treatment site.

Thrombosis. Vessel blockage caused by a blood clot. Stent thrombosis refers to the blockage of the stent by a blood clot.

This educational booklet provides valuable information about the causes and treatment options for coronary artery disease.

For more information on treatment options for coronary artery disease, visit **www.medtronic.com**.

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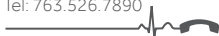
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