BIOFREEDOM™

POLYMER- & CARRIER-FREE DRUG-COATED CORONARY STENT SYSTEM

Patient Information Guide

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Coronary Artery Disease (CAD)

Your Heart

Your heart is a muscle that pumps blood throughout your body. The blood carries oxygen and nutrients that your body needs to function properly. 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. If these arteries become blocked or narrowed, treatment may be required to restore blood flow and the vital supply of oxygen to the heart.

What is CAD?

CAD is the most common form of heart disease. It is a condition that occurs when the arteries that supply oxygen-rich blood and nutrients to the heart muscle become narrowed or blocked by a gradual 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 coronary artery. As the plaque narrows the opening (lumen) of a coronary artery, it makes it difficult for adequate quantities of blood to flow to the heart muscle. This process is called “atherosclerosis”. Gradual reduction of blood flow to the heart muscle can cause chest pain (angina). A heart attack (myocardial infarction) can occur if the artery suddenly becomes completely blocked, usually by a blood clot that forms over ruptured (broken) plaque.

Heart attacks cause irreversible damage to the heart muscle, which could lead to sudden death in certain cases.

In about half of the patients who have coronary artery disease, a heart attack is the first clinical manifestation of the disease.

Improved medical treatment, combined with earlier diagnosis, and increased public awareness of the symptoms and risk factors that contribute to this disease are helping to decrease the death rate from CAD.

What are the Symptoms of CAD?
Two common symptoms of CAD are chest pain, also known as angina, and shortness of breath, which are caused by the reduction of blood flow to the heart muscle. If plaque build-up does not reduce blood flow excessively, there may be no noticeable symptoms at rest, but symptoms such as heaviness in the chest may occur with increased activity or stress.

Other symptoms that may be experienced are:

- Pain in the jaw or neck
- Pain radiating to the arms or back
- Heartburn
- Nausea
- Vomiting
- Heavy sweating

When blood flow is significantly reduced and the heart muscle does not receive enough blood to meet its needs, severe symptoms such as chest pain (angina pectoris), heart attack (myocardial infarction), or heart rhythm disturbances (arrhythmias) may occur.

There are some patients who report no symptoms of CAD. It is possible to have a heart attack without experiencing any symptoms.

Recent research has shown that some women experience different CAD symptoms from men and are less likely than men to report chest pain, heaviness in the chest, or chest discomfort during a heart attack. Women may notice other early symptoms, such as unusual tiredness or sleep disturbances up to one month prior to a heart attack. These differences in symptoms may cause some women to delay seeking help or treatment.

What are the Risk Factors of CAD?

Two main risk factors for CAD are:

- Increasing age (over age 65)
- Being male or a menopausal female[1]

Other risk factors that may increase your chances of developing CAD are:

- Family history of heart disease (close relatives with heart disease at a young age)
- Diabetes
- High blood cholesterol levels
- Smoking
- High blood pressure
- Stress
- Obesity (being overweight)
- High fat diet

[1] Menopausal women begin to develop and die of heart disease at a rate equal to men. Menopause is the transition in a woman's life when production of the hormone estrogen in the body falls permanently to very low levels, the ovaries stop producing eggs, and menstrual periods stop.

- Lack of exercise

How Can My Doctor Tell If I Have CAD?
If your doctor suspects that you have CAD or if you have symptoms of the disease, he or she will ask you about your risk factors and your symptoms. A complete physical exam and blood tests to identify injury to your heart muscle will also be completed. In addition, some of the tests used to make the diagnosis are:

Electrocardiogram (ECG/EKG) is a commonly used test that records your heart's electrical activity and can show certain problems such as abnormal heartbeats or damage to the heart muscle. An ECG can be done at rest or while you are walking or running on a treadmill or pedaling a stationary bicycle (Stress ECG).

Stress Tests are used to evaluate your heart rate, heart rhythm, and ECG while you are exercising. The results of a stress test can help your doctor determine the areas of heart muscle that are affected by lack of blood flow due to CAD.

Echocardiography is an exam of the heart using sound waves.

Coronary Angiogram or Heart Catheterization is a procedure carried out in the cardiac catheterization laboratory (cath lab) by a cardiologist. Angiography is a procedure in which coronary arteries are visualized using X-rays.

A catheter (long, thin, hollow tube) is inserted into an artery in the groin or arm. The tip of this tube is positioned at the

beginning of the arteries supplying blood to the heart. A special fluid called contrast dye is injected through the tube to visualize the blood vessels on X-rays so that pictures called angiograms can be taken. These angiograms allow the doctor to see any blockage and/or narrowing in your coronary arteries and determine their severity.

Using the information gathered from one or more of these tests, your doctor is better able to decide the best treatment plan for you.

Your Treatment Options

Once a diagnosis has been made, your doctor will recommend the most appropriate form of treatment, depending on the condition and severity of your CAD. CAD can be managed by a combination of changes in lifestyle (eating a healthy diet low in saturated fat, regular exercise, and quitting smoking) and medical treatment. Your treatment may include medications to relieve your chest pain and/or to expand the coronary arteries, increasing blood flow to your heart.
However, because medicine alone may not clear blocked arteries, you may need more treatment, including surgery, angioplasty, and/or stenting to treat your symptoms.

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

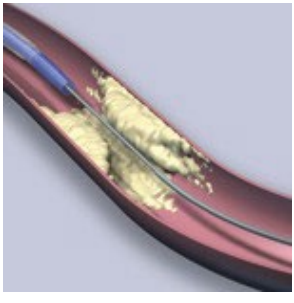
Surgery
Coronary artery bypass grafting is a common surgical procedure that removes a section of artery or vein from another part of your body. This vessel is then connected (grafted) to the coronary artery beyond the blockage site. This creates a new path for blood to flow around (bypass) the blocked artery and to your heart. Often, several blocked arteries are bypassed during the same operation. Most coronary bypass patients remain in the hospital for about a week, followed by a recovery period at home.

Angioplasty

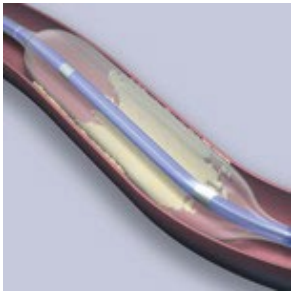
Angioplasty is a procedure used to open blocked arteries. You may also hear it referred to as percutaneous transluminal coronary angioplasty (PTCA) or balloon angioplasty. This procedure is performed under local anesthetic in a cardiac catheterization laboratory (also commonly called a cath lab). A catheter with a small balloon mounted on the end is passed into the coronary artery. The catheter is then positioned at the narrowed portion of the artery and the balloon is inflated. As the balloon inflates, it pushes out against the wall of the coronary artery and compresses the plaque. The balloon is then deflated and the catheter is removed from the artery. This opens the narrowing in the coronary artery and improves the blood flow to the heart muscle. In balloon angioplasty, no permanent device remains in the artery after the balloon catheter is removed. Balloon angioplasty can be performed with a balloon alone or can involve placement of a permanent device called a stent, within the coronary artery.

Although balloon angioplasty enlarges the lumen of coronary arteries, many patients develop re-narrowing of the vessel in the months following the procedure. This process is called restenosis, and it is caused by the growth of scar tissue within the coronary artery.

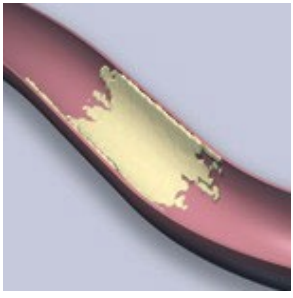
Step 1:
The doctor guides a catheter with a small balloon through the blood vessel to the narrowed section of the artery. By watching the progress of this catheter on the fluoroscope (an X-ray device that creates real-time images of the internal structures of the body that can be viewed on a TV monitor), the doctor is able to maneuver it into the blocked coronary artery.



Step 2:
The balloon is inflated, pushing out against the wall of the artery and compressing the plaque. The balloon is deflated and the catheter is removed.

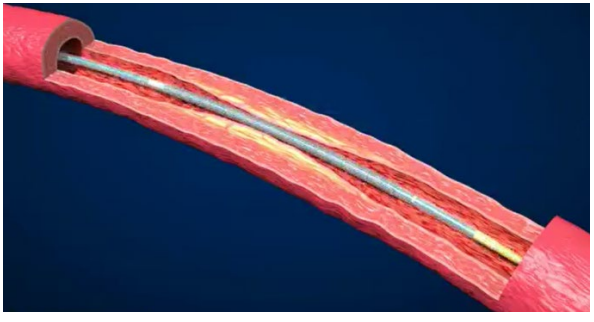


Step 3:
The inside of the blood vessel is now larger and the blood flow is improved.

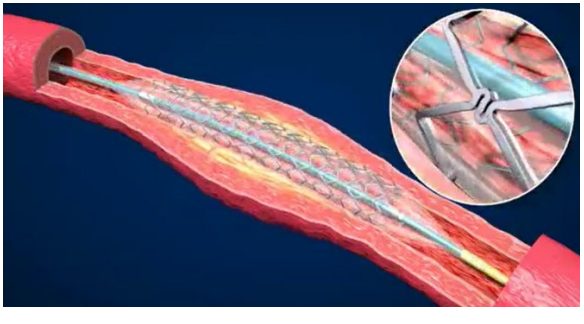


Coronary Artery Stents
Coronary artery stents are devices (small metallic mesh tubes) that are placed over a balloon catheter and delivered to the narrowed portion of the coronary artery. The balloon is used to expand the stent. The stent presses against the narrowed vessel wall, holding the vessel open. This makes a wider channel to improve blood flow to the heart muscle. This may be followed by repeat balloon inflations within the stent to achieve the result desired by your doctor. Once the balloon has been deflated and withdrawn, the stent stays in place permanently, holding the coronary artery open. The inner lining of the artery grows over the surface of the stent, making the stent a permanent part of your artery.
Coronary artery stents are less invasive than bypass surgery. Stenting involves a shorter hospital stay— usually one to three days—and faster recovery than surgery. However, restenosis can also occur in some patients who receive stents (in-stent restenosis), due to the build-up of scar tissue within the stent leading to narrowing of the stent lumen.

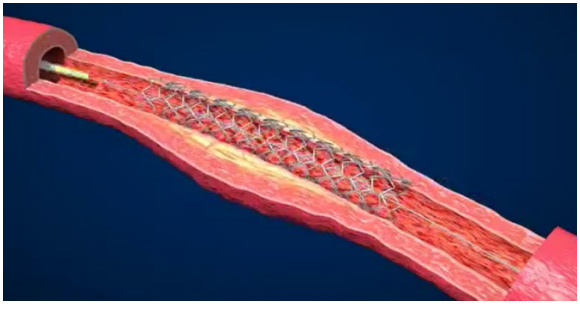
Step 1:
The doctor maneuvers the catheter into the blocked artery and inflates the balloon.



Step 2:
The stent expands against the vessel wall as the balloon is inflated.



Step 3:
Once the balloon has been deflated and the catheter is withdrawn, the stent stays in place permanently, holding the blood vessel open and improving blood flow.



Drug-Coated Stents (DCS)

To help prevent restenosis, “drug-coated” stents have been developed. These stents provide the same structural support as uncoated stents but they are coated with a drug. Drug-coated stents do not contain any additional elements called polymers or carriers to control the release of the drug since some people may be allergic to these substances. The drug is released over time, helping to prevent restenosis by limiting the overgrowth of normal tissue within the stent.

The BioFreedom™ Drug-Coated Coronary Stent System (BioFreedom™ DCS) is manufactured by Biosensors Interventional Technologies and distributed by Biosensors International USA, Inc.

The BioFreedom™ DCS is designed to treat the narrowing of your coronary arteries, especially when you have high risk for bleeding. It consists of a medical grade stainless steel stent with the coating of a drug called Biolimus A9 (BA9) on its surface. This stent provides mechanical support to the artery while Biolimus A9 is released into the artery wall around the stent. The BioFreedom™ DCS does not contain any polymer

or carrier to help control the release of Biolimus A9 into the arterial wall. Polymers are known to cause allergic reactions in some patients. The release of Biolimus A9 is intended to limit the overgrowth of tissue within the coronary stent. The BioFreedom™ DCS stent is available in various diameters (2.25, 2.5, 2.75, 3.0, 3.5 and 4.0 mm).

Contraindications

- If you cannot take blood-thinning medications (also called antiplatelet or anticoagulant therapy)
- If your physician decides that the coronary artery blockage will not allow complete inflation of the angioplasty balloon
- If you have a known hypersensitivity (allergy) or contraindication to Biolimus A9 or the structurally-related compounds such as stainless steel, nickel or other metal ions found in 316L
- If you have a known hypersensitivity (allergy) or contraindication to contrast agents that will be used for the implantation of the stent

Potential Adverse Events

The risk of using the BioFreedom™ DCS is similar to those that are associated with standard stent procedures. 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 re-narrowing of your coronary artery. This may require further treatments, 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 after

stent implants are similar to the risks that may occur during the initial stent implant. These may be serious enough to require surgery or cause death.

Other risks from these devices are the same as treatment procedures for a narrowed coronary artery. Some problems associated with standard balloon angioplasty and stenting include, but are not limited to:

Common Risks

- Bruise or bleeding at the catheter insertion site in the groin or arm

Rare Risks

- Tearing, puncture, or rupture of the coronary artery

Clinical Trials

The BioFreedom stent has been tested in several clinical trials and has been available for use in 68 countries worldwide since 2014. Approximately 200 000 patients were already treated with this stent. Biosensors safety surveillance has not detected any abnormalities in manufacturing quality, clinical safety or performance of the BioFreedom stent.

BioFreedom First-In-Man (FIM) Clinical Trial
BioFreedom First-In-Man was the first trial to evaluate the BioFreedom™ Biolimus A9 Drug-Coated stent in humans. Two different drug doses were tested on the BioFreedom stent and the Taxus® Liberté® stent served as control for the treatment of narrowed coronary arteries in patients with coronary artery disease. The trial was conducted at 5 sites in Germany.

One hundred eighty two patients participated and received either a BioFreedom™ stent, a BioFreedom™ low-dose stent, or a TAXUS® stent. Follow-up through cardiac catheterization and/or intravascular ultrasound was performed at 4 months and/or 12 months.

The main outcome measure (primary endpoint) was the loss of free inner lumen in the stent (late lumen loss) at 12 month**.** Clinical outcome measures including death, myocardial infarction, stent thrombosis and the need for repeat catheter intervention were also assessed over a period of five years. The major finding of the trial was that the BioFreedom™ stent was not inferior to the Taxus® stent for re-narrowing. Further, the BioFreedom™ stent was found to be safe as patients did

not have higher event rates than with the Taxus® stent, and the rate of stent clotting (stent thrombosis) was zero to five years of follow-up.

LEADERS FREE Trial
LEADERS FREE was a large randomized double-blind study comparing the safety and effectiveness of the BioFreedom™ stent with a bare-metal stent in 2,466 patients at high bleeding risk who can tolerate only one month of blood thinning medical therapy (dual anti-platelet therapy) to prevent stent thrombosis. The trial was conducted in 68 centers in 20 countries in Europe, Australia, Asia and Canada.

Patients with coronary artery disease requiring stent implantation were included once they fulfilled at least one of 13 criteria for a high risk of bleeding.

The primary outcome measure for safety (primary safety endpoint) was the combination of cardiac death, heart attack, and stent thrombosis at one year. The primary outcome measure for efficacy (primary efficacy endpoint) was the rate of clinically required repeat catheter intervention of the stent. Patients were clinically followed for 2 years.

Receiving a BioFreedom™ stent reduced the safety risk (safety endpoint) by 29% (relative risk reduction) and the risk of needing another intervention by 50% at 1 year. The difference between the patient groups was statistically significant for both safety and effectiveness at 1 year and at 2 years of follow-up.

In conclusion, the main finding of the trial is that treatment with a BioFreedom™ stent was safer and more effective for high bleeding risk patients than treatment with a conventional bare metal stent, once blood thinning therapy needs to be limited to one month.

LEADERS FREE II Trial

LEADERS FREE II was a single-arm trial conducted in 68 sites in the US, Canada and Europe. As the purpose of the trial was to reproduce the findings of LEADERS FREE in a North American patient population, patient selection, treatment with the BioFreedom™ stent and blood thinning medication as well as other technical trial aspects were designed as similar as possible to the LEADERS FREE trial. The trial enrolled a total of 1,203 patients which have to date all reached 1 year of follow-up, while the trial will be ongoing for up to three years. LEADERS FREE II used the bare-metal stent arm of LEADERS FREE as reference for comparison.

The trial outcome was similar to that of LEADERS FREE. It was shown with statistical significance that North American patients at high bleeding risk receiving BioFreedom™ stents have better outcomes than patients receiving bare-metal stent in terms of safety and efficacy. Receiving a BioFreedom™ stent in LEADERS FREE II reduced the risk for experiencing cardiac death or a heart attack by 28% (relative risk reduction) and the need for a repeat catheter intervention by 28% in comparison with bare-metal stent patients. Both differences were statistically significant.

Therefore, the conclusion of the trial was that the beneficial findings of LEADERS FREE are reproducible and generalizable to patients and clinical practice in the United States.

Your Drug-Coated Stent Placement Procedure

How Do I Prepare for My Procedure?

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

- Take all of your prescribed medicines
- Tell your doctor if you are taking any other medication
- Tell your doctor if, for any reason, you cannot take aspirin and/or thienopyridine medications such as Plavix®, Brilianta® (ticagrelor), or Effient®
- Make sure your doctor knows about any allergies you have
- Refrain from eating and drinking starting at midnight prior to your treatment
- Follow all instructions given to you by your doctor or nurse

You may be given a mild sedative to help you relax, but you will not be put to sleep. There are two reasons for this. First, most people experience little to no discomfort during the procedure. Secondly, your doctor may need to ask you to take a deep breath while X-rays are being taken to improve the quality of the pictures.

The procedure usually lasts about 90 minutes, during which time your doctor will ask you to remain very still. For the most part, you will be comfortable, but you may feel some pressure or chest pain when the balloon is inflated. This is normal and will quickly fade when the balloon is deflated.

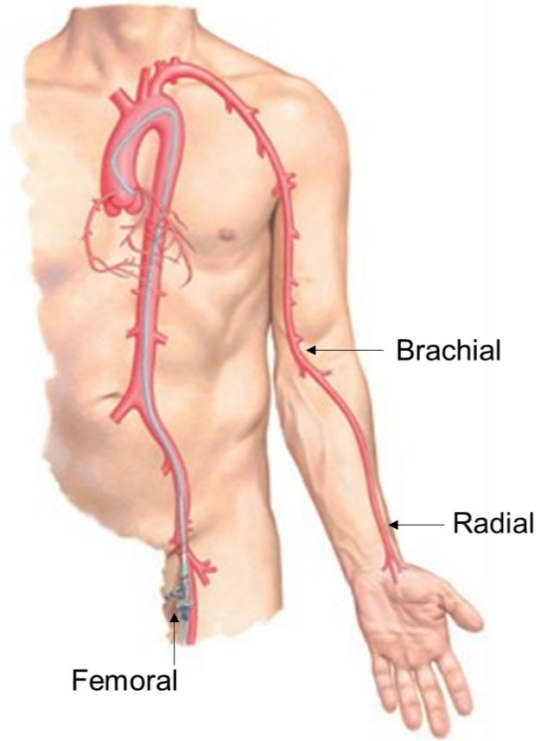
Your drug-coated stent placement procedure
Your procedure will be performed in a cardiac catheterization laboratory (cath lab). You will lie on the X-ray table, and an X-ray camera will move over your chest during the procedure. The staff will monitor your heart by attaching several small sticky patches to your chest and using a specialized ECG recorder and monitor.

The groin (femoral approach) is the most common site for catheter introduction and requires a very small needle puncture to be made on the inside of your upper thigh. The area will be shaved and cleaned with an antiseptic, and you will be given a local anesthetic to numb the area. This needle puncture will allow an introducer sheath (short tube) to be inserted into your femoral artery (the main artery of the thigh, supplying blood to the leg). Your doctor will then insert a guiding catheter (long, flexible tube) into the introducer sheath and advance it to where the coronary arteries branch off to the aorta. A guide wire is then advanced through the guiding catheter to the narrowing in the coronary artery. This helps carry all the necessary devices required during the stenting procedure.

The wrist/radial approach is also a common access site (incision is made on the inside of your wrist). Equipment and patient preparation are simple and similar to those with the femoral approach. Your hand is positioned along the body with the palm pointing upward and obliquely. After local skin anesthesia, puncture is performed with a venous cannula or a bare needle to allow an introducer sheath (short tube) to be inserted into your radial artery (one of the two main arteries of the forearm). Accordingly, your doctor will then insert a

guiding catheter (long, flexible tube) into the introducer sheath and advance it to where the coronary arteries branch off to the aorta. A guide wire is then advanced through the guiding catheter to the narrowing in the coronary artery. This helps carry all the necessary devices required during the stenting procedure.

Another option for catheter introduction is the arm/brachial approach (needle puncture is made on the inside of your elbow).



Blood vessel access for heart catheterization through the femoral, radial or brachial artery

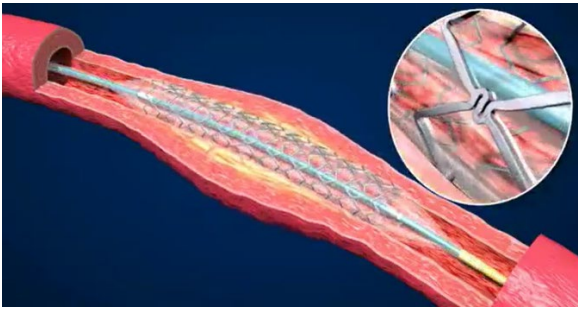
After the catheters are inserted, your doctor will inject a contrast dye through the guiding catheter into your coronary artery to view the narrowing. Your doctor will watch the injection on an X-ray monitor, much like a TV screen. While these X-rays are being taken, your doctor may ask you to take a deep breath and hold it for a few seconds.

Using the guiding catheter, a balloon catheter is positioned in the narrowing in the coronary artery and the balloon is then inflated. This compresses the plaque and widens the coronary artery. This procedure is called pre-dilatation.

Stenting procedure steps:

Step 1:
The BioFreedom™ stent mounted on a balloon catheter is delivered to the narrowing in the coronary artery by a delivery catheter.

Step 2:
The balloon is then inflated and this expands the stent, pressing it against the coronary artery wall. Your doctor may choose to expand the stent further by using another balloon so that the stent can make better contact with the artery wall. This is known as post- dilatation.



Step 3:
Once in place, the BioFreedom™ stent will remain as a permanent implant in your coronary artery.

Immediately after Procedure
You will be asked to lie flat for four to six hours following the procedure and to not bend your leg or arm, depending on which area your doctor used to insert the catheters. Pressure will also be placed on the area.

A vascular closure device may be used to seal the needle puncture site in your groin or arm. You will be allowed to get up and walk around sooner if this type of device is used. Your hospital stay may range from one to three days.

Medications will be prescribed for you after stent placement. Antiplatelet medications such as aspirin and thienopyridine medications (for example Plavix®, Brilianta® (ticagrelor), or Effient®) are the most commonly prescribed. They help prevent a blood clot (thrombus) from forming and blocking the stent lumen. Your doctor or nurse will give you instructions about your medications before you leave the hospital.

CAUTION: If you have any chest pain, or discomfort or bleeding from your incision site, call your doctor immediately. If your doctor is **unavailable, call for an ambulance to take you to the nearest hospital emergency room.**

Take All Medications as Instructed
After you leave the hospital, your cardiologist will instruct you to take a daily dose of aspirin and another antiplatelet drug such as Plavix®, Brilianta® (ticagrelor), or Effient®. Your doctor will tell you how long you should continue taking the

antiplatelet drugs. It is very important that you take these medications exactly as your doctor instructs you:

- Follow your medication schedule exactly to avoid possible complications after you receive your stent. Do not miss any doses.
- Call your doctor if you cannot keep 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: Notify your cardiologist or family doctor if you are scheduled to see the dentist while on antiplatelet medication. Your doctor may prescribe antibiotics to avoid the potential of an infection. You should review with your doctor any recommendations from your dentist to stop your prescribed medications.**
- **CAUTION: Before undergoing implantation of a drug-coated stent, if you plan to have any type of surgery that may require you to stop taking antiplatelet medications, you and your cardiologist should discuss whether or not placement of a drug-coated stent is the right treatment choice for you.**

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 doctors should carefully

consider the risks and benefits of this surgery or dental work versus the possible risks from early discontinuation of these medications.

If you do require discontinuation of antiplatelet medications because of significant bleeding, your cardiologist will carefully monitor you for possible complications. Once your condition has stabilized, your cardiologist may put you back on these medications.

Follow-up Care
You will be discharged to the care of your cardiologist or family doctor. You should be able to return to your normal activities soon.

CAUTION: Notify your doctor immediately if you experience chest pain (angina), or notice any changes such as more severe or frequent chest discomfort, especially in the first month after a procedure. These symptoms may indicate a re-narrowing in your coronary arteries.

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.

Keep Your Implant Card Handy
CAUTION: Show your identification card if you report to an emergency room. This card identifies you as a patient who has had a stent implanted.

Prior to undergoing an MRI scan, inform your doctor or MRI technician that you have BioFreedom™ Drug-Coated Coronary Stent implanted.

Preventing CAD

Coronary artery disease can be treated effectively, but this means rather "managing" than curing the disease. You can help to prevent your coronary artery disease from progressing by carefully following your doctor's advice. Your doctor may prescribe medications to help control your blood pressure, diabetes, and/or high cholesterol. Your doctor may also recommend some lifestyle changes. Among the healthy choices you can make:

Stop smoking. If you smoke, quitting is the single most important thing you can do to lower your risk of coronary artery disease. Chemicals in cigarette smoke may make it easier for plaque to build up on your artery walls. And smoking increases your heart rate and blood pressure, raising your risk of heart attack and stroke. If you are ready to quit, ask your doctor for advice—he or she can recommend smoking cessation aids to help you quit.

Increase your activity and eat a healthy diet. A sedentary

lifestyle increases your risk. Your doctor can recommend an activity program tailored for your situation. Regular exercise can help you lower your blood pressure and blood cholesterol and reach a healthy weight. It can also help you manage the daily stresses of modern life more easily. Choose a healthy diet. A diet low in saturated fats and cholesterol and rich in lean protein, fresh fruits, vegetables and whole grains, can help you achieve a healthy weight, as well as help you control your blood pressure and cholesterol levels.

Manage your stress. Stress is an inescapable aspect of modern day living, but you can help lessen its negative health effects by practicing the “relaxation response”. Research has shown that relaxation techniques can improve your ability to cope with stressful events while decreasing your heart rate, blood pressure, and stress hormone levels.

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?
Most importantly, there is an anti-clot drug regimen mandatory for a certain amount of time as prescribed by your doctor. This regimen protects you from stent thrombosis and must be followed.

Should you require magnetic resonance imaging (MRI), tell your doctor or MRI technician that you have a metallic stent implanted in your heart.

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.

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 coronary arteries. Your doctor will monitor your progress.

How can I help prevent a recurrence of symptoms?
While there is no sure way to prevent a recurrence of symptoms, you can reduce the risk through not smoking, eating a healthy diet, and controlling your blood cholesterol levels. Your doctor can advise you about lifestyle changes.

Definition of Medical Terms

Angina: Chest pain caused by inadequate supply of arterial blood to the heart muscle.

Angioplasty (also referred to as Percutaneous Transluminal Coronary Angioplasty – PTCA, or balloon angioplasty): A minimally invasive procedure in which a balloon dilatation catheter is passed through 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 followed by placement of a stent.

Anticoagulant: A medication to prevent or slow the clotting of 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) within the artery wall. The build-up is sometimes referred to as “plaque”.

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

Catheter: A thin, hollow, flexible tube used to access the

coronary arteries during an angiogram or during an angioplasty procedure. This catheter can be used to inject medication, fluids, or contrast dye during your procedure. Catheter is also used to describe the device used to deliver the balloon or stent during an angioplasty procedure.

Coronary Angiography (or Heart Catheterization or Cardiac Cath): A test in which contrast dye is injected to create images of the coronary arteries and the chamber of the heart. This allows the doctor to see the extent of the disease in the coronary arteries and make a decision on how to best treat the blockages.

Coronary Arteries: The blood vessels that carry oxygenated blood from the aorta to the heart muscle. There are three major coronary arteries: the right coronary artery (RCA), the left anterior descending (LAD), and the circumflex (Cx). The two latter arteries originate from the left main (LM) coronary artery.

Coronary Artery Bypass Graft Surgery (CABG): Open-heart surgery to treat CAD. Veins or arteries from your body are used to bridge narrowed coronary arteries.

Coronary Artery Disease (CAD): Also called Ischemic Heart Disease. The formation of blockages or atherosclerotic plaques within coronary arteries that result in restricted blood flow to the heart muscle.

Electrocardiogram (ECG/EKG): A test that records changes in the electrical activity of the heart. An ECG/EKG may show whether parts of the heart muscle are damaged due to decreased blood flow to the heart muscle.

Femoral Artery: The main artery of the thigh, supplying blood to the leg.

Fluoroscope: An X-ray device that creates an image of the body that can be viewed on a TV-like monitor. This permits the doctor to obtain real-time images of the internal structures of a patient.

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

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.

Myocardial Infarction (MI): Also called a heart attack. Permanent damage of an area of the heart muscle, caused by a transitional of permanent interruption in the blood flow to the heart muscle (myocardium).

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.

Plaque: An accumulation or build-up of fatty deposits, calcium, white blood cells, and other substances in the wall of an artery that results in narrowing of the vessel lumen.

Radial Artery: One of the two main arteries of the forearm.

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.

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