

NIRxcell™

CoCr Coronary Stent on RX System

A PATIENT'S GUIDE TO CORONARY ARTERY DISEASE AND YOUR NIRxcell™ CoCr CORONARY Stent on RX System

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ABOUT THIS BOOKLET

Your doctor has prescribed a NIRxcell™ stent to help manage your coronary artery disease (CAD). The NIRxcell™ CoCr Coronary Stent on RX System will be implanted into your coronary vessel following the angioplasty procedure. This stent will act as miniature scaffolding to help your vessel maintain its shape, strength and integrity.

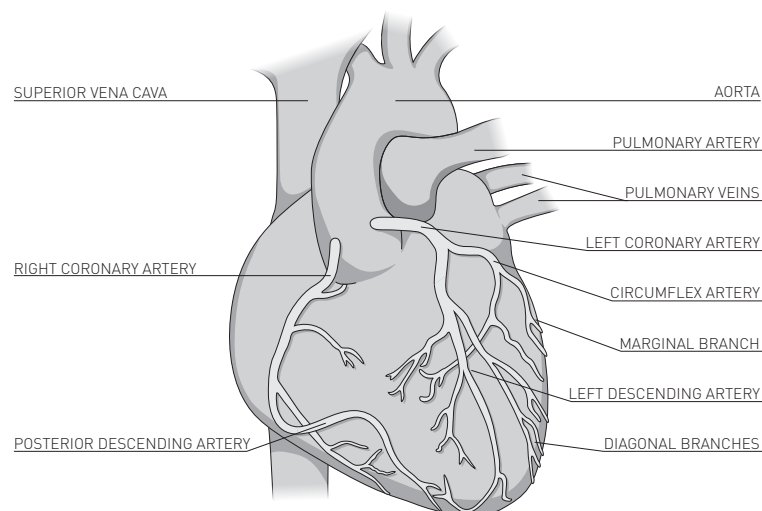
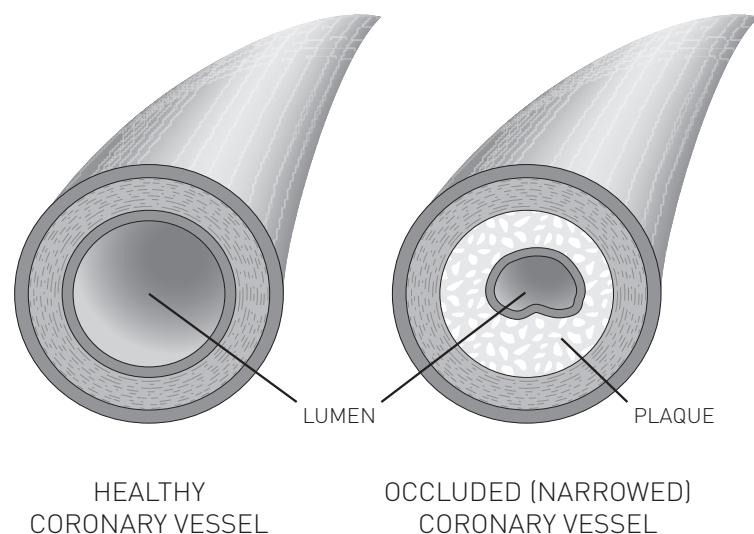
The information in this booklet will help to prepare you for your hospital stay, the stenting procedure and your recovery. It describes the NIRxcell™ stent, how the NIRxcell™ stent is implanted and what you can do to facilitate your recovery.

If you have any questions about the NIRxcell™ stent or the stenting procedure after you read this booklet, be sure to ask your doctor.

If you need additional information about the NIRxcell™ stent, please call Medinol's Customer Service at +1-800-477-5801.

WHAT IS CORONARY ARTERY DISEASE (CAD)

Coronary Artery Disease (CAD) affects the coronary arteries that surround the heart. These coronary arteries supply blood with oxygen to the heart muscle to allow it to function properly. CAD occurs when the inner walls of the coronary arteries thicken due to plaque, a buildup of cholesterol, fatty deposits, calcium, and other elements carried in the blood. As the plaque develops, the vessel narrows. When the vessel narrows, blood flow through the lumen, the center of the vessel, is restricted, so less oxygen and other nutrients reach the heart muscle. This condition, known as atherosclerosis, may lead to chest pain (angina pectoris) or a heart attack (myocardial infarction).



CORONARY ARTERIES CARRY BLOOD THAT SUPPLY NUTRIENTS AND OXYGEN TO THE HEART

CORONARY ARTERY DISEASE RISK FACTORS

The likelihood of having CAD is greater if you:

- Are male
- Have high blood pressure
- Have diabetes
- Have a high level of blood cholesterol
- Smoke cigarettes
- Are overweight
- Have a close relative with CAD

SYMPTOMS OF CORONARY ARTERY DISEASE

Symptoms of CAD differ from person to person; however, typical symptoms include: pressure, tightness or pain in the chest, arm, back, shoulder, neck or jaws. Heartburn, nausea, vomiting, shortness of breath and heavy sweating may also occur.

Women are more likely than men to have atypical chest pain which may be fleeting or sharp and noticed in the abdomen, back, or arm and are somewhat more likely than men to experience other warning signs of a heart attack, including nausea and back or jaw pain.

Sometimes a heart attack occurs without any apparent signs or symptoms.

DIAGNOSIS OF CORONARY ARTERY DISEASE

When making a diagnosis, your doctor will ask about your symptoms, medical history, and risk factors. Based on this information, your doctor may ask you to undergo a series of tests to see how healthy your arteries are.

Doctors may use various tests to diagnose CAD. An ECG (or EKG), or electrocardiogram, measures your heart's electrical activity and may show whether parts of your heart muscle have been damaged by heart attack caused by CAD. A stress test records your heart's electrical activity while you are exercising and may tell your doctor whether part of your heart muscle is damaged. The most accurate way to diagnose CAD is to perform a coronary angiogram. This is done by injecting a contrast dye into the coronary arteries so they can be seen on an x-ray screen. The x-ray will show if artery narrowing has occurred.

TREATMENT OF CORONARY ARTERY DISEASE

To determine what treatment is right for you, your cardiologist will take a number of factors into consideration, including your overall medical condition, your cardiovascular condition, the condition of your coronary arteries, your age, your health history, and the results of the previously mentioned series of tests.

Coronary artery disease may be managed through a combination of changes in lifestyle and physical activity, diet, and medical treatment. The therapy your doctor recommends will depend on the condition and severity of the disease. Medical treatments of the blockage may include medications, angioplasty (widening the opening with a balloon), stent implantation or coronary artery bypass surgery.

ANGIOPLASTY

Angioplasty, also known as Percutaneous Transluminal Coronary Angioplasty (PTCA), is a minimally invasive treatment performed in the hospital to open the blocked coronary arteries. A thin tube known as a catheter is inserted through the groin or wrist and is then threaded through a major blood vessel to the site of the blockage. A small balloon, located on the tip of the catheter, is then expanded to reduce the blockage. PTCA can be performed with a balloon alone, or can involve the placement of a coronary stent (see Coronary Artery Stents, below).

CORONARY ARTERY STENTS

Stenting is a common procedure in which a stent is implanted in a blocked vessel.

Coronary artery stents are devices that can help to reduce the risk of re-narrowing of the treated artery following an angioplasty procedure. Stents are small steel tubes that are implanted into a

vessel and expanded to fit the size, shape and bend of the vessel wall, propping it open to help prevent further blockages.

During the stenting procedure, the stent is mounted onto a tiny balloon that is opened inside of a coronary artery to push back plaque and to restore blood flow. After the plaque is compressed against the arterial wall, the stent is fully expanded into position, acting as miniature "scaffolding" for the artery. The balloon is then deflated and removed, and the stent is left behind in the patient's coronary artery to help keep the blood vessel open. For some patients it may be necessary to place more than one stent in the coronary artery.

Some of the factors that could help determine whether you are a good candidate for stenting are:

- Your overall health
- The size of the vessel and number of coronary arteries involved
- The location of the blocked coronary artery
- How easily the blockage can be reached by angioplasty
- Your recent coronary health history – including heart attacks

THE NIRxcell™ STENT

The NIRxcell™ stent is a small, mesh, metal tube. The stent is secured to a balloon at the end of a delivery catheter that delivers it to the location where it will be implanted. When the balloon is inflated, the stent expands until it has made full contact with the vessel wall, adapting to fit the shape, size, and bends of the vessel. Once in place, the stent will remain in your artery. Over time, the lining of the artery wall will grow around the stent as the stent continues to support the vessel.



NIRxcell™ STENT

CLINICAL DATA

The NIRxcell employs the identical stent as the Presillion™ and the Presillion™ plus Stent Systems.

The NIRxcell, Presillion and Presillion plus Stent Systems have different delivery catheters.

The PIONIR Study was the main clinical study to investigate the NIRxcell Stent. In this study, 278 patients received the NIRxcell Stent. After 9 months, the NIRxcell Stent was as effective as other bare metal stents at preventing major adverse cardiac events (need for a repeat procedure, heart attack and death; 12.7% for the NIRxcell vs. 16.46% in a combined analysis of other approved coronary bare metal stents).

WHO SHOULD NOT RECEIVE THE NIRxcell™ CoCr CORONARY STENT ON RX SYSTEM

Coronary artery stenting is generally contraindicated for:

- Patients for whom blood thinning medications (anticoagulants) and/or antiplatelet is contraindicated
- Patients judged to have a lesion which prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery system.

POTENTIAL RISKS OF TREATMENT WITH THE NIRxcell™ CoCr CORONARY STENT ON RX SYSTEM

Use of the NIRxcell™ CoCr Coronary Stent on RX System carries the risks associated with all coronary stent placements in native coronary arteries. The following complications may occur during or after placement of a coronary stent in your body:

- Abrupt vessel closure – sudden blockage or closure of the vessel caused by stent
- Allergic / drug reaction - to contrast dye, stent material (Cobalt Chromium) or medication
- Aneurysm / Pseudoaneurysm – weakening of a portion of the wall of the blood vessel
- Arrhythmias, ventricular fibrillation – irregular heart beat
- Cardiac tamponade – bleeding around the heart
- Coronary artery spasm

- Death
- Dissection – ruptured or torn artery
- Emboli – air, pieces of devices or fragments of clots blocking the blood vessel
- Emergency CABG – emergency bypass surgery
- Failure to deliver the stent to the intended site
- Fever
- Fistulization - an abnormal connection between two vessels that normally do not connect
- Hemorrhage (bleeding), or hematoma
- Hypotension / Hypertension – decreased or increased blood pressure
- Infection and pain at the insertion site groin or arm
- Myocardial infarction – heart attack
- Myocardial ischemia, Angina – chest pain due to reduced oxygen to the heart
- Occlusion / restenosis of the stented artery section– re-narrowing of the treated artery
- Perforation – tearing, puncture or rupture of the heart artery
- Renal failure
- Repeat percutaneous intervention – repeat procedure to reopen the heart artery
- Stent compression – damage to the stent
- Stent misplacement / migration / embolization – movement of the stent from where it was placed
- Stroke
- Thrombosis (acute, subacute or late) – blood clot in the heart artery, in different times from stent implantation

BEFORE THE PROCEDURE

INSTRUCTIONS

Your doctor will instruct you on how to prepare for the angioplasty and stent implantation procedures prior to being admitted to the hospital. Your doctor may ask you to take aspirin and other prescribed medications for several days before the procedure. This is done to “thin” the blood to prevent blood clots (thrombus) from forming during the stenting procedure. It is important to tell your doctor if you cannot take aspirin or have a history of bleeding problems. Your doctor also needs to know if you are taking any other medications or if you have any drug allergies.

DURING THE PROCEDURE

Your angioplasty procedure and the stent implantation will be performed in a specially equipped area of the hospital called the cardiac catheterization laboratory. The PTCA and stent implantation will be performed by an interventional cardiologist, a doctor who specializes in angioplasty and stenting. After the stent is implanted, you will be moved to a cardiology ward for a short period where you can be monitored closely as you begin to recover.

ANGIOPLASTY – OPENING A BLOCKED CORONARY VESSEL

Your doctor will decide which site on your body would be the best place to access one of your arteries – your groin area, wrist, or arm. The selected area will be shaved and cleaned with antiseptic and you will be given a local anesthetic to numb the area.

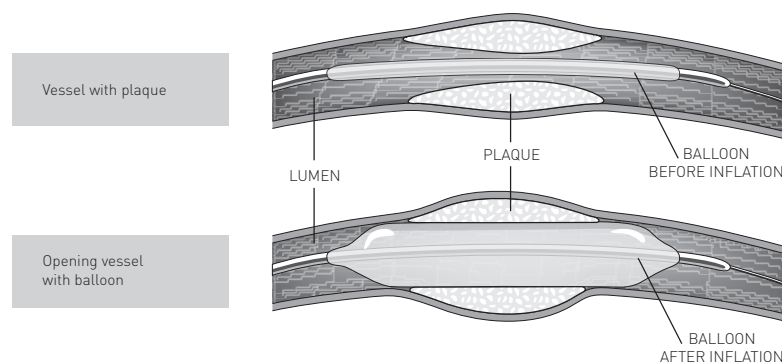
During the procedure, you will have to lie flat on your back and you will remain awake, allowing you to follow your cardiologist’s instructions (e.g., “breathe deeply”). Devices will monitor your heart rate and blood pressure.

The procedure will begin with an angiography test to determine the number and exact location of blockages.

To obtain access to the artery, a short smooth catheter, called a sheath, is inserted via the groin or arm.

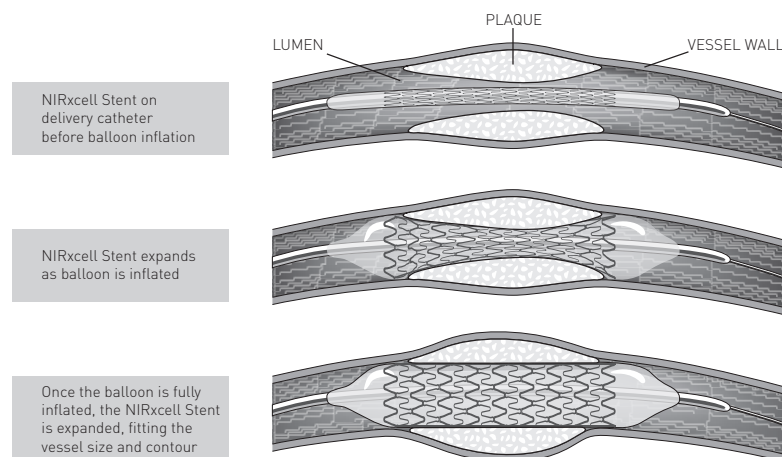
A thin tube called a guiding catheter is inserted into the sheath and maneuvered up to the heart. The guiding catheter acts as a conduit or pathway to the coronary arteries for subsequent devices (including the stent) and contrast fluid. With the area being observed on an x-ray screen, contrast dye is injected through the guiding catheter and the coronary arteries become visible on the screen. After the exact position of the narrowing has been determined, a small wire is advanced through the artery and past the narrowing.

Then, over this wire, a balloon catheter is advanced and when positioned within the narrowing, the balloon is inflated. By inflating the balloon, the stenosis (blockage) is dilated (opened), and the vessel is widened. Let your doctor know if you are experiencing any pain.



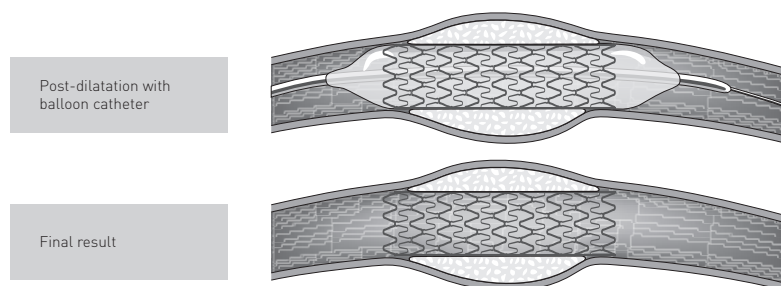
HOW IS THE STENT IMPLANTED

- After the artery is widened, your doctor will pass the stent, mounted on a balloon catheter used as the delivery catheter, into the coronary artery through the same guiding catheter.
- Then, your doctor will carefully position the stent at the place where the blockage was before angioplasty, known as the target site. By using a type of x-ray machine called a fluoroscope, your doctor will be able to see the NIRxcell™ stent inside the vessel. This helps to position the stent at exactly the right location.
- Once the stent is in place, your doctor will inflate the balloon and expand the stent, using an inflation device, and position it to the inner wall of the artery. The stent will shape itself to the size and contours of your vessel and keep the artery open. It is common for patients to feel some mild discomfort when the balloon is inflated because the artery is being stretched.
- When the stent is in place, the balloon is deflated and the delivery catheter is removed. The stent will remain in place and continue to keep the artery open.



IMPLANTING STENT

- Your doctor may choose to expand the stent further by using another balloon. If required, the balloon catheter is inserted inside the stent and then inflated to allow the stent to make better contact with the vessel wall. This part of the procedure is called post-dilatation.
- The stent achieves full contact with the vessel wall and provides unobstructed blood flow, just like a healthy vessel does. When the stent is flush with the vessel wall physicians call this proper stent apposition. Once in place, the NIRxcell stent will remain in your artery permanently.



FURTHER EXPANSION OF STENT

AFTER THE PROCEDURE

After the procedure, you may be instructed to lie flat for several hours. You will go to a special care unit where medical staff will monitor your heart rate and blood pressure closely. Before returning to your room, the sheath that was used to enter the vessel may be removed and pressure applied to the puncture site until the bleeding has stopped.

The catheter insertion site may be bruised and sore. If the sheath was inserted into your arm or wrist, it will be removed and the site will be bandaged. If the catheter was inserted into your groin, you may need to lie in bed with your leg straight for several hours. In some cases, your doctor may use a device that seals the small hole in the artery; this may allow you to move around more quickly. The place on your body where the catheter was inserted will be monitored for any changes in color, temperature, or sensation.

Your blood will be frequently tested to monitor and regulate medication levels that control the clotting of your blood.

TAKING CARE OF YOURSELF AT HOME

- Contact your doctor or the hospital immediately if you experience pain, bleeding, discomfort, or changes such as severity or frequency in angina symptoms (chest pain).
- Follow your doctor's instructions exactly regarding the use and dosage of medications prescribed.
- Tell your dentist or other medical personnel you are on blood thinners prior to any treatment. Postpone dental work until after your recovery.
- Avoid strenuous exercise unless approved by your doctor.
- Return to normal activities gradually, pacing your return to activity as you feel better. Check with your doctor about strenuous activities.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Report side effects from medications immediately. These may include headaches, nausea, vomiting or rash.
- Do not stop taking your medications unless you are asked to stop by the doctor who implanted your stent.
- Keep all follow-up appointments, including laboratory blood testing.

MEDICATIONS

Your doctor may prescribe a number of medications which thin the blood to prevent blood clots from forming and adhering to the surface of the stent. Patients who take these medications are also required to take blood tests frequently so their blood clotting time can be monitored. Your doctor will let you know when you can stop taking this medication. Until then, it is extremely important to follow your medication regimen. Check with your doctor before taking antacids as they may decrease absorption of aspirin and other medications.

FOLLOW-UP EXAMINATIONS

You will need to see the doctor who implanted your stent for routine follow-up examinations. During these visits, your doctor will monitor your progress and evaluate your medications, the clinical status of your CAD, and how the stent is working for you.

MAGNETIC RESONANCE IMAGING (MRI)

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a NIRxcell™ stent. The technician will need to operate the machine within certain limits.

FREQUENTLY ASKED QUESTIONS

If you are a candidate for stenting to treat coronary artery disease (CAD), you will most likely have a lot of questions to discuss with your doctor. Here are some questions and answers to get you started. Keep in mind that your doctor is your best source of information and advice about CAD and treatment for CAD. Be sure to bring up any additional questions and concerns you may have about CAD with your doctor.

WILL I FEEL THE STENT?

No. You will not feel the stent inside of you.

CAN THE STENT MOVE OR RUST?

Once the stent is opened and presses into the inside wall of your coronary artery, it will remain in place permanently; the stent does not move on its own. Vessel tissue will grow around the stent and hold it in place. It will not rust because it is made of non-corroding metal.

CAN I WALK THROUGH METAL DETECTORS WITH A STENT?

Yes, without any fear of setting them off. The stent is made of non-magnetic metals.

WHY HAS MY DOCTOR RECOMMENDED STENTING?

You have heart disease. Most likely your doctor has recommended medication and lifestyle changes that have not been enough to reduce the effects of your clogged arteries. For most patients, the doctor decides that a balloon alone is not enough to keep the coronary artery from narrowing and stent implantation is recommended.

HOW LONG SHOULD I TAKE MY MEDICATIONS?

The most important thing that you can do to minimize the risk of stent thrombosis is to take the medications your doctor prescribes. Do not stop taking these medicines until your cardiologist tells you to, even if you are feeling better.

WHAT IF I STILL GET PAINS?

If you experience pain, inform your cardiologist or the center where the procedure was performed immediately.

CAN I PLAY SPORTS?

Yes, but be cautious! Your doctor will tell you what sports you can play and when you can start.

WHAT SHOULD I CHANGE IN MY DIET?

Your doctor may prescribe a low-fat, low-cholesterol diet to help reduce the levels of fat in your blood and reduce your risk.

WILL I EXPERIENCE THE SYMPTOMS OF CORONARY ARTERY DISEASE AGAIN, SUCH AS CHEST PAIN?

It is possible that you will experience symptoms again, either because of a new blockage in the treated coronary artery or a new blockage in a different place. If you experience these symptoms, notify your doctor immediately.

HOW WILL I KNOW IF MY ARTERY RE-NARROWS?

Although the stents are intended to reduce restenosis, it is still possible for your artery to re-narrow. If this happens, you may experience symptoms similar to those experienced when you first noticed you had coronary artery disease or before your stent procedure. These symptoms may include chest pain or shortness of breath, especially during physical activity. If you experience pain, inform your doctor immediately.

GLOSSARY

ANGINA PECTORIS

Discomfort, pain, tightness or pressure in the chest, usually due to interference with blood flow to the heart muscle and precipitated by excitement or effort. May also cause profuse sweating, nausea, shortness of breath and associated pain in the neck, jaw, back, or arm.

ANGIOGRAPHY

An imaging test performed by injecting contrast dye into the coronary arteries so that the vessels can be seen on an x-ray screen. The x-ray will show if any blockages and/or artery narrowing has occurred and if the blocked coronary arteries can be treated with angioplasty or stenting.

ANGIOPLASTY

A minimally invasive treatment that uses a balloon to open blocked arterial vessels, also known as percutaneous transluminal coronary angioplasty (PTCA).

ANTICOAGULANT

Medicine such as heparin, which slows or prevents blood from clotting by interfering with blood clotting agents.

ANTIPLATELET

Medicine such as aspirin, which acts against blood platelets in order to prevent the release of blood clotting agents.

APPOSITION

Refers to the position of the stent against the vessel wall.

ATHEROSCLEROSIS

A disease in which the flow of blood to the heart is restricted with plaque deposits (a build-up of cholesterol and other fats, calcium and certain other elements carried in the blood) causing less oxygen and other nutrients to reach the heart muscle. This may lead to chest pain (angina pectoris) or to a heart attack (myocardial infarction).

CATHETER

A small thin plastic tube used to provide access to parts of the body, such as into the coronary arteries of the heart or into the bladder.

CLOPIDOGREL

A medicine that thins the blood and helps prevent clot formation.

CORONARY

Related to arteries that supply blood to the heart.

CORONARY ANGIOGRAM

A test that can determine if CAD is present. Contrast dye is injected into the coronary arteries and a fluoroscope allows the doctor to see the narrowed or blocked vessels, a stent, or catheter on an x-ray screen.

CORONARY ARTERY DISEASE (CAD)

Disease affecting the coronary arteries that surround the heart and supply blood to the heart muscle. CAD occurs when the lumen of the coronary arteries becomes narrowed with plaque deposits (a build-up of cholesterol and other fats, calcium, and other elements carried in the blood).

CORONARY ARTERIES

The arteries that surround the heart and supply blood containing oxygen and nutrients to the heart muscle. Oxygen deprivation to the heart restricts heart function and may lead to chest pain (angina pectoris) or to a heart attack (myocardial infarction).

CORONARY ARTERY BYPASS GRAFT SURGERY (CABG)

Open heart or bypass surgery.

ECG

Electrocardiogram. See STRESS TEST.

EXERCISE ELECTROCARDIOGRAM

See STRESS TEST.

ISCHEMIA

A condition that results from reduced oxygen supply to cells, usually due to an obstruction that reduces blood flow.

LUMEN

The inner channel of a vessel or tube.

MINIMALLY INVASIVE

A minimally invasive procedure is any procedure (surgical or otherwise) that is less invasive than an open surgery used for the same purpose.

MYOCARDIAL INFARCTION

Permanent damage to the heart muscle due to the interruption of blood supply to the area, commonly referred to as a heart attack; can occur when blood clots form within the blood vessels.

MAGNETIC RESONANCE IMAGING (MRI)

A non-invasive way to take pictures of the body. MRI uses powerful magnets and radio waves, unlike x-rays and computed tomography (CT) scans, which use radiation.

NATIVE LESION

is a coronary artery lesion not previously treated

PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

See ANGIOPLASTY

PLAQUE

An accumulation or build-up of cells, cellular debris, cholesterol, calcium, fatty deposits, and collagen in a blood vessel that leads to narrowing of the lumen.

POST-DILATATION

After the stent has been expanded, another balloon catheter may be inserted inside the stent and inflated to size the stent more precisely to the normal diameter of the blood vessel.

PTCA

Percutaneous Transluminal Coronary Angioplasty.

RESTENOSIS

Recurrent blockage or narrowing of a previously treated vessel.

STENT

A small, expandable, metal tube that is inserted into a coronary artery to support the blood vessel wall and maintain healthy blood flow through the opened vessel.

STENT THROMBOSIS

Stent thrombosis is a rare condition that occurs when a blood clot forms on the surface of a stent, raising the risk of blood flow in an artery being reduced or cut off

STRESS TEST

A test to measure electrical activity in the patient's heart (ECG) while the patient is performing controlled exercise. The results help determine if there is damage to the heart muscle or if blood flow has been restricted to areas of the heart.

TRANSLUMINAL

Through the lumen which is the inner channel of a vessel.

VESSEL

A vein or artery.

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ISRAEL



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