



**EluNIR™**

**Ridaforolimus Eluting Coronary Stent System**  
**Patient Information Guide**

**Caution:** Federal law restricts this device to sale by or on the order of a physician

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## ABOUT THIS BOOKLET

Your doctor has recommended an EluNIR™ stent to help manage your coronary artery disease (CAD). The EluNIR™ Ridaforolimus Eluting Coronary Stent System (EluNIR™) is a drug-eluting stent (metal stent coated with a drug). It will be implanted into your coronary vessel following the angioplasty procedure. This stent will function 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 EluNIR™ stent, how the stent is implanted and what you can do to facilitate your recovery.

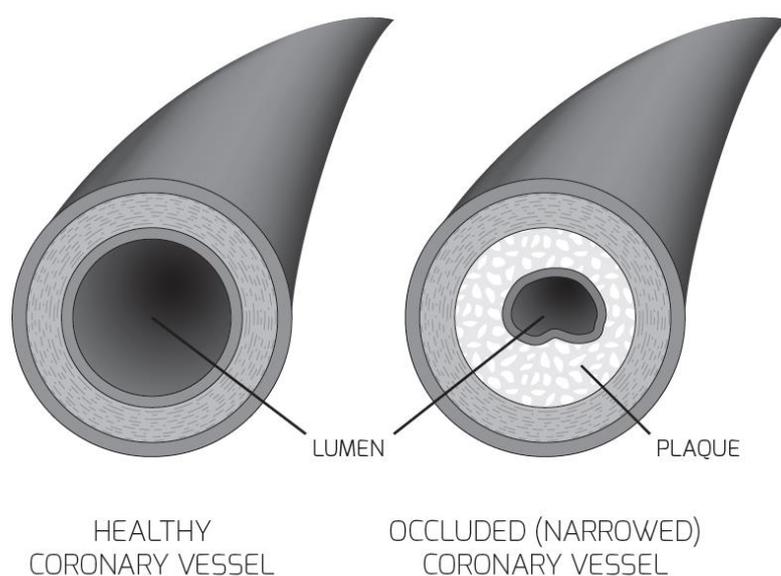
If you have any questions about the EluNIR™ stent or the stenting procedure after you read this booklet, be sure to ask your doctor.

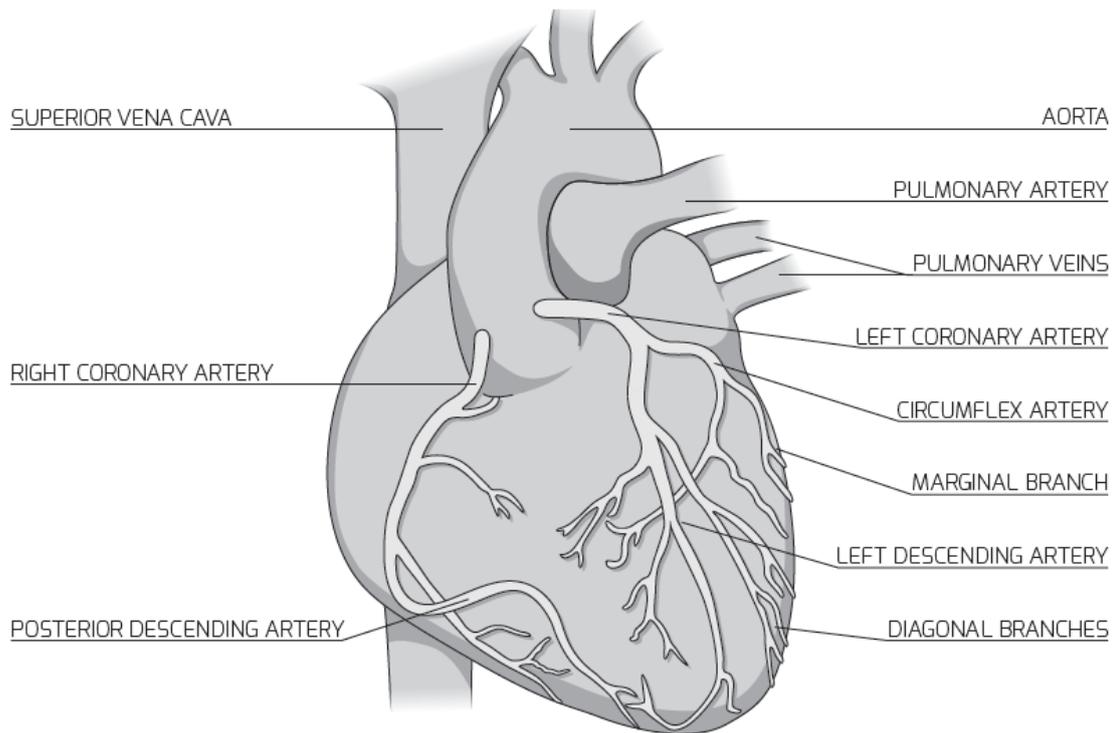
If you need additional information about the EluNIR™ stent, please call Medinol's Customer Service at **(800)-477-5801**.

## 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, which is 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 SUPPLIES NUTRIENTS AND OXYGEN TO THE HEART**

## **Coronary Artery Disease Risk Factors**

Common risk factors for CAD include:

- Being male or a postmenopausal female
- Increasing age
- High blood pressure
- Diabetes
- High blood cholesterol
- Smoking
- Obesity
- Family history of heart disease
- Lack of physical activity

## **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. Women also are somewhat more likely than men to experience other warning signs of a heart attack, including nausea and back or jaw pain.

In some cases 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. These will include some or all of the following:

- **Electrocardiogram (ECG/EKG)** – This test measures your heart’s electrical activity and may show whether parts of your heart muscle have been damaged by a heart attack caused by CAD.
- **Stress test** – This test records your heart’s electrical activity while you are exercising and may tell your doctor whether part of your heart muscle is damaged.
- **Angiogram** - This test 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.
- **Echocardiography** – Ultrasound evaluation of the heart muscle movements can identify areas of reduced or absent movements indicative of CAD.
- **Nuclear Imaging / Scan** – The use of isotopes can identify areas of reduced blood flow. These areas may be caused by CAD.
- **Troponin, CK-MB, CK** – Measurements of blood levels of various proteins originating from diseased heart muscle enable identification of patients with CAD.

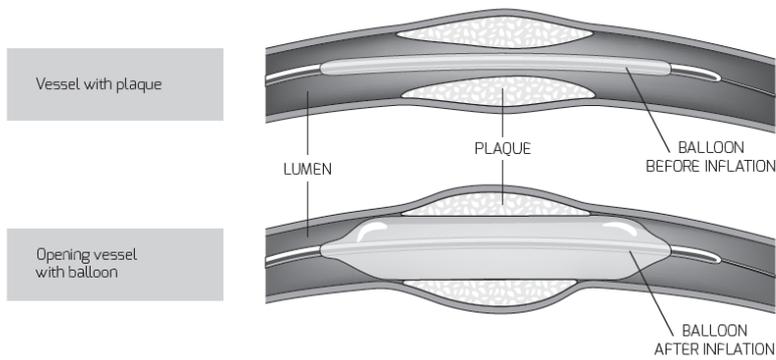
## Treatment of Coronary Artery Disease

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, stent implantation or coronary artery bypass surgery.

### Angioplasty

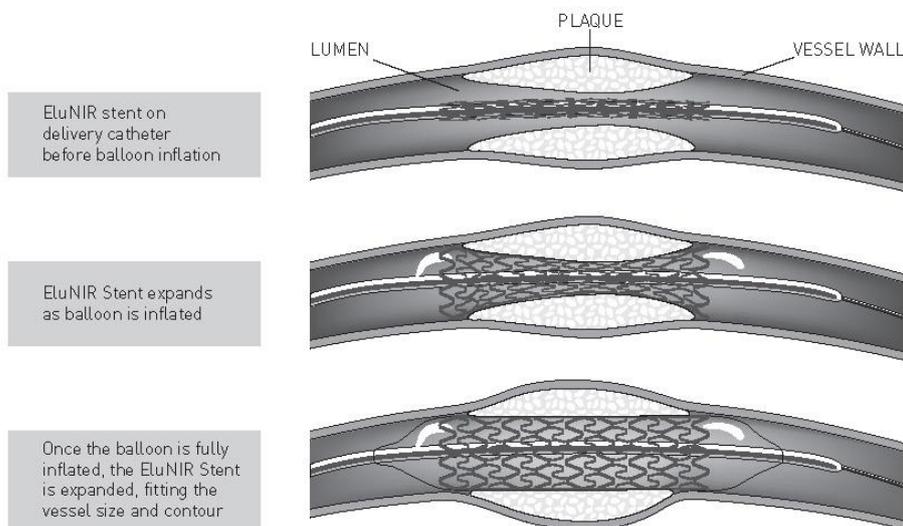
Angioplasty, also known as Percutaneous Transluminal Coronary Angioplasty (PTCA), is a minimally invasive treatment performed in the hospital to open the blocked coronary arteries. This procedure is performed under local anesthesia, and at times under monitored sedation, in a cardiac catheterization laboratory. A thin tube known as a catheter is inserted, under X-ray guidance, through the radial artery (wrist) or femoral artery (groin) and is then guided to the site of the blockage. A small balloon, located on the tip of the catheter, is expanded to reduce the blockage by compressing the plaque. The balloon is then deflated and the catheter is removed from the artery. PTCA can be performed with a balloon alone, or can involve the placement of a coronary stent (see *Coronary Artery Stents*, below). Some patients may develop re-narrowing of the vessel in the following months, a process which is termed restenosis.



## Coronary Artery Stents

A **stent** is a small metallic mesh tube used to treat narrow or weak arteries. Stenting is a common procedure that helps maintain the patency of coronary arteries undergoing catheter based intervention.

The stent is mounted onto a balloon, which is inflated 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 a miniature "scaffold" for the artery. The balloon is then deflated and removed, and the stent is left behind in the artery to help keep the blood vessel open. For some patients it may be necessary to place more than one stent in one or more of their coronary arteries.

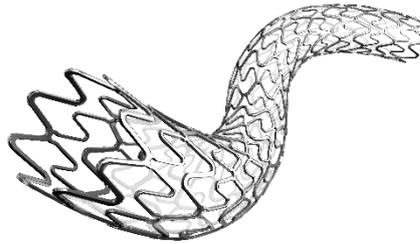


### IMPLANTING STENT

## THE ELuNIR™ STENT

The decision as to which type of stent suits your needs best depends on various medical parameters that your doctor has considered. Your doctor has determined that the EluNIR™ drug eluting stent is suitable for you.

The EluNIR™ is a Drug Eluting Stent, coated with an elastic polymer (elastomer). A drug called ridaforolimus is incorporated in the elastomer coating, which helps control the release of the drug into the arterial wall. The drug is released over time and helps block cell proliferation and prevent restenosis. 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.



**EluNIR™ Stent**

## **Clinical Data**

The safety and effectiveness of the EluNIR™ stent was substantiated by data collected from two global clinical studies, and a supplemental clinical study.

The clinical studies include the BIONICS study and the NIREUS study, in which the EluNIR™ Stent was compared to another approved drug eluting stent, Medtronic's Resolute drug eluting stent. Approximately 2,300 patients participated in these studies, over half of which received the EluNIR™ Stent.

The BIONICS study was conducted at 76 medical centers in the US, Canada, Europe, and Israel. A total of 1,919 patients with coronary artery disease (CAD) participated in the study, 958 patients received the EluNIR™ stent and 961 patients received the Resolute stent. The study results after 1 year showed that the EluNIR™ stent was similar to the Resolute stent in clinical outcomes. The observed rate of cardiac death, heart attack associated with the blood vessel treated by the stent, or treatment of the lesion due to vessel re-narrowing was 5.4% for both EluNIR™ and Resolute. Additionally, the EluNIR™ stent had a low rate of stent thrombosis/occlusion, with no events beyond 30 days. All patients are undergoing follow up for a period of five (5) years.

The NIREUS study was conducted at 28 medical centers in Europe and Israel. A total of 302 patients participated in the study. This study also compared the EluNIR™ stent to the Resolute stent; however, the main purpose of this study was to observe the occurrence of re-narrowing of the artery after six (6) months. This was done using a repeat angiogram test. The study results showed that the EluNIR™ is similar to the Resolute stent in reducing the re-narrowing of the artery where the stent was placed. All patients are undergoing follow up for a period of five (5) years.

The BIONICS-Israel clinical study was conducted to assess the EluNIR™ stent with a modified delivery system (the catheter leading the stent to its location within the artery). In this study, a total of 58 patients participated at three (3) medical centers in Israel.

The EluNIR™ with the modified delivery system was successfully implanted in all patients. All patients are undergoing follow up for a period of 1 year.

No safety signals of concern were identified in all EluNIR™ clinical studies.

## **Who Should Not Receive the EluNIR™ Stent**

Coronary artery stenting is generally contraindicated for:

- Patients who cannot take blood thinning medications (anticoagulants/antiplatelets), such as heparin or bivalirudin, clopidogrel (also called Plavix), prasugrel, ticagrelor or aspirin.
- Patients judged to have a lesion which prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery system.
- Patients with hypersensitivity (allergy) to ridaforolimus, the polymer or its individual components CarboSil® 20 55D (Thermoplastic Silicone-Polycarbonate-Urethane) and Poly n-Butyl Methacrylate (PBMA), compounds in a metallic stent such as nickel, cobalt, chromium and molybdenum or hypersensitivity (allergy) to contrast media.

## **Potential Risks and Complications of Treatment with EluNIR™ Ridaforolimus Eluting Coronary Stent System**

Angioplasty and stent placement for CAD have become increasingly common but, as with any invasive procedure, there are potential risks and complications.

Use of the EluNIR™ stent carries the same risks as those associated with standard stent placements. The following complications may occur during or after placement of a coronary stent in the patient's body (in alphabetical order):

- Air, tissue or clots which can block the vessel
- Allergic reaction, which may be due to contrast dye, antiplatelet therapy, stent material (nickel, cobalt, chromium, molybdenum), drug or the polymer or its individual components CarboSil® 20 55D (Thermoplastic Silicone-Polycarbonate-urethane) and Poly n-Butyl Methacrylate (PBMA) coating the stent
- Anxiety
- Blood Vessel spasm
- Bleeding around the heart
- Bleeding complications which may require transfusions or surgery
- Bruising, bleeding, or pain at the catheter insertion site in the leg, wrist or arm
- Cardiac arrest due to electrical imbalance of the heart
- Chest pain or discomfort during or after the stenting procedure
- Coronary artery complications: Including re-narrowing of the artery, artery blockage / injury / puncture / tearing, that may require a repeat procedure to re-open the artery
- Death
- Delay in growth of artery wall cells after stent implantation
- Discomfort or fainting mediated by the vagus nerve
- Excess body fluids

- Failure of the heart with/without low blood pressure
- Failure of the lungs to adequately supply oxygen to the body
- Failure to deliver the stent to the correct place in the artery
- Fever
- Fluid accumulation around the heart
- Formation of blood clots inside the stent
- Heart attack
- High/low blood pressure
- Inadequate supply of blood to the heart
- Infections: Infection of the inner layer of the heart; Infection of the lungs and upper airways Irregular heartbeat
- Kidney failure
- Need for heart surgery; emergent or non-emergent
- Puncturing of the heart or great vessels
- Stent compression
- Stent misplacement in the artery / movement of the stent from where it was placed or from the balloon into the artery
- Stroke or other neurological events
- Weakening and enlargement of a portion of the wall of a blood vessel

Ridaforolimus is a drug originally developed for patients with cancer. Patient exposure to ridaforolimus is directly related to the number of implanted stents (total stent surface area).

The risks of the Ridaforolimus drug are not yet fully known. The risks that might occur include, but are not limited to (in alphabetical order):

- Anemia
- Anorexia
- Constipation
- Dehydration
- Diarrhea
- Distortion of the sense of taste
- Fatigue
- Fever
- Hair loss
- High levels of Glucose/Fat/Potassium/Phosphate in the blood
- High levels of liver enzymes in the blood
- High levels of muscle enzymes due to damage to muscle cells
- Inflammation of mucous membranes
- Irritation of the stomach
- Itching
- Low levels of white/ platelet blood cells
- Low levels of Potassium/Phosphate in the blood
- Lung infection/ inflammation
- Nausea and Vomiting
- Nail disorder
- Rash
- Renal injury
- Skin inflammation
- Severe loss of white blood cells
- Tingling sensation
- Weight decrease

## **BEFORE THE PROCEDURE**

### **Instructions**

Your doctor will instruct you on how to prepare for the angioplasty and stent implantation procedures prior to your admission 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 procedure will be performed by an Interventional Cardiologist, a doctor who specializes in angioplasty and stenting. The procedure usually lasts about 60 minutes. 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. 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 from which to access one of your arteries – your wrist or groin area. 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”). You may be given a mild sedative to help you relax. 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 wrist.

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 (this part of the procedure is called predilatation). Let your doctor know if you are experiencing any pain.

## Implanting the Stent

1. 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.
2. Your doctor will then carefully position the stent at the place where the blockage was detected, known as the target site. By using a type of X-ray machine called a fluoroscope your doctor will be able to see the EluNIR™ inside the vessel. This helps to position the stent at exactly the right location.
3. Once the stent is in place, your doctor will inflate the balloon and expand the stent using an inflation device, and then 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.
4. 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.
5. 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.
6. 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 EluNIR™ will remain in your artery permanently.

## 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 you return 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 wrist, it will be removed and the site will be bandaged. If the catheter was inserted into your groin, you will be asked 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 sooner. The place on your body where the catheter was inserted will be monitored for any changes in color, temperature, or sensation.

Antiplatelet medication such as Aspirin, or any other blood thinning medications, will be prescribed for you before and after stent placement. 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.

Your blood will be frequently tested to monitor and regulate medication levels that control the clotting of your blood. Your hospital stay may be less than one day or up to three days.

## 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.

**CAUTION: Do not stop taking your medications unless you are asked to stop by your cardiologist.**

- Tell your dentist or other medical personnel that 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 to your doctor immediately. These may include headaches, nausea, vomiting or rash.
- Keep all follow-up appointments, including laboratory blood testing.
- Keep your Implant Card handy. Show it if you report to an emergency room. This card identifies you as a patient who has had a scaffold implanted (see MRI section below).

## 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. These medications may include: Aspirin and other antiplatelet medications (e.g. clopidogrel, ticagrelor, prasugrel).

**CAUTION:** Early cessation of your blood thinners may cause abrupt blockage of your stent and result in heart attack or even death. Do not stop these medications without consulting your doctor.

Your doctor may prescribe other medications to treat your heart and risk factors, which may include drugs to lower your heart rate, to lower your blood pressure and to optimize your blood cholesterol levels. 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 an EluNIR™ and present your patient implant card. 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 you.

**How long will the stent stay in my body?** Stents are designed to stay permanently.

**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?** Based on your individual CAD progression and symptoms, your doctor feels that placing one or more stents is the best treatment option for you.

**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 recommend specific dietetic changes to help to reduce your risk for future events.

**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 positioning 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.

**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 coronary arteries.

**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.

**Percutaneous Coronary Intervention (PCI)** – A non-surgical procedure used to treat narrowing of the coronary arteries of the heart found in coronary artery disease.

**Percutaneous Transluminal Coronary Angioplasty (PTCA)** – 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.

**Pre-Dilatation** – Before the stent is placed, a balloon catheter may be inserted inside the lesion and inflated to exert pressure against the arterial wall.

**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.

**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.