

**A PATIENT'S GUIDE TO CORONARY ARTERY DISEASE
AND your NIRflex™ STENT**

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ABOUT THIS BOOLET

Your doctor has prescribed a NIRflex™ Stent to help manage your coronary artery disease (CAD). The NIRflex™ Stent 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 implant procedure and your recovery. It describes the NIRflex™ stent, how the NIRflex™ stent is implanted and what you can do to speed your recovery.

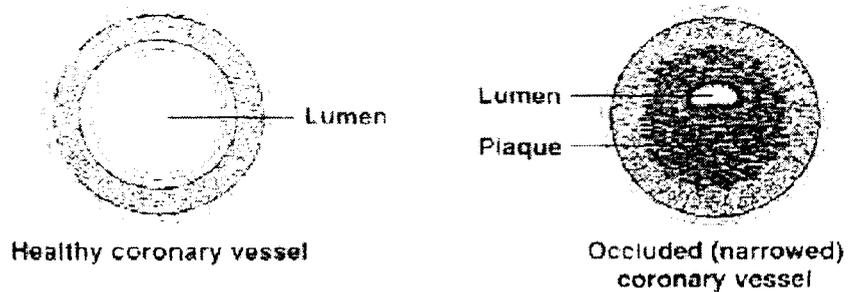
If you have questions about your stent or the procedure after you read this booklet, be sure to ask your doctor.

If you need additional information about the NIRflex™ Stent, Please call Medinol's Customer Service at +972-3-767-9000.

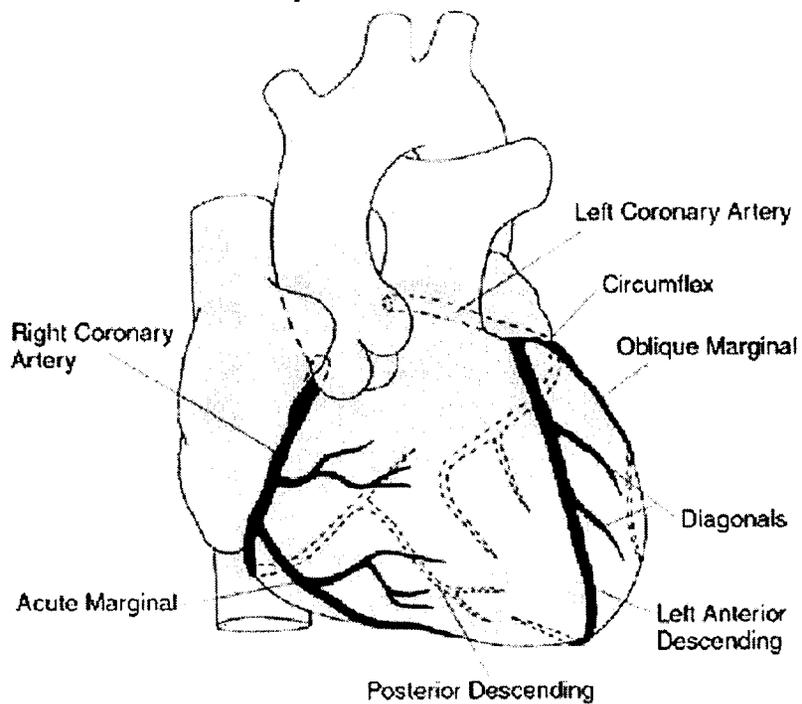
WHAT IS CORONARY ARTERY DISEASE (CAD)

Coronary Artery Disease (CAD) affects the coronary arteries that surround the heart. These coronary arteries supply blood with oxygen to the heart muscle to make it function properly.

CAD occurs when the inner walls of the coronary arteries thicken due to a build up of cholesterol and other fats, calcium and other elements carried in the blood. This build-up is called *plaque*. As the plaque develops, 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 of the Heart



CAD 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 CAD

Symptoms of CAD include pressure, tightness or pain in the chest, arm, back, neck or jaws. Heartburn, nausea, vomiting, shortness of breath and heavy sweating may also occur.

Diagnosis of CAD

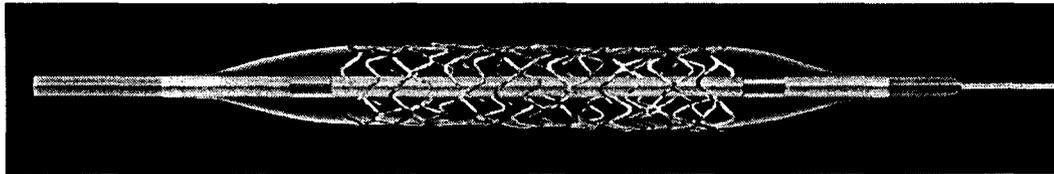
Doctors may use various tests to diagnose CAD. An ECG (or EKG), or electrocardiogram, measures your heart's electrical activity and may show whether parts of your heart muscle have been damaged by heart attack caused by CAD. A stress test records your heart's electrical activity while you are exercising and may tell your doctor whether part of your heart muscle is damaged. The most accurate way is 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 CAD

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

YOUR NIRflex™ STENT

The NIRflex™ stent is small, mesh, metal tube. The NIRflex™ stent is secured to a balloon at the end of a delivery catheter. The catheter delivers the stent 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.



NIRflex™ Stent

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 procedure. It is important to tell your doctor if you cannot take aspirin or have a history of bleeding problems. Your doctor also need to know if you are taking any other medications or have drug allergies.

On the day of the procedure, you may be given a urinary catheter prior to the angioplasty and stent procedure. This is done to minimize movement to and from a bedpan immediately after the procedure. Excess movement shortly after the procedure can increase the chance of bleeding at the puncture site.

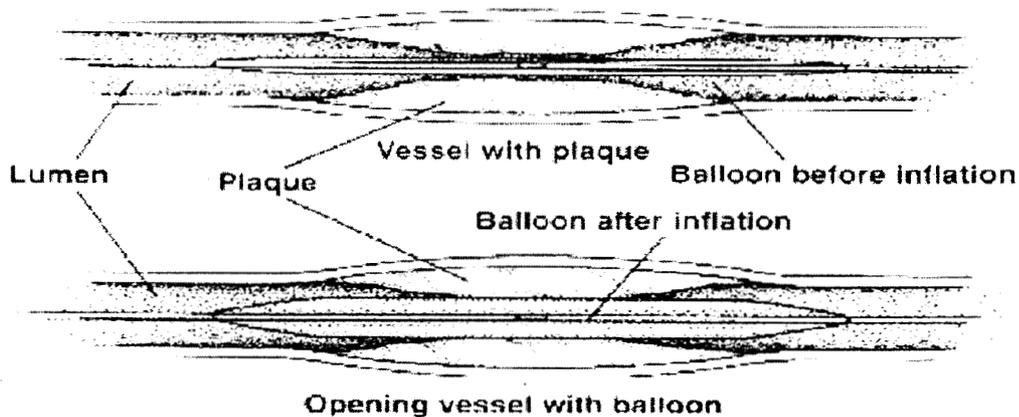
DURING THE PROCEDURE

Your angioplasty procedure and the stent implantation will be performed in a specially equipped area of the hospital called the catheterization laboratory. 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. Altogether, your hospital stay could last one to three days before you are discharged to the care of your family.

Angioplasty – Opening a Blocked Coronary Vessel

To obtain access to your ^{femoral} artery, a short smooth catheter, called a sheath, is inserted via the groin. Into the sheath, a thin tube called a guiding catheter, is inserted 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. While viewing the area on an x-ray screen, contrast fluid 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.

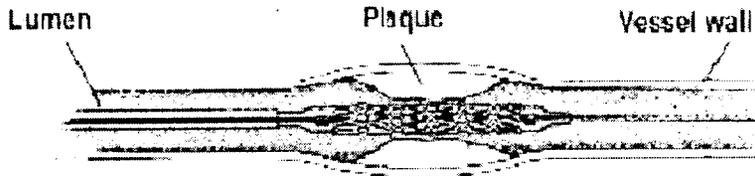
After this initial balloon inflation, your doctor will implant the NIRflex™ stent to fully open the previously obstructed vessel.



HOW THE STENT IS IMPLANTED

- First, 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 NIRflex™ stent inside the vessel. This helps to position the stent at exactly the right location.
- Once the stent is in place, your doctor will expand the balloon and stent on the end of the delivery catheter, using an inflation device (a type of threaded syringe) connected to the delivery catheter.
- As the balloon expands, the NIRflex™ stent expands until it fits to the inner wall of the vessel, shaping itself to the size and contours of your vessel. With the stent in place the balloon is deflated and the delivery catheter is removed. The stent will remain permanently in place.

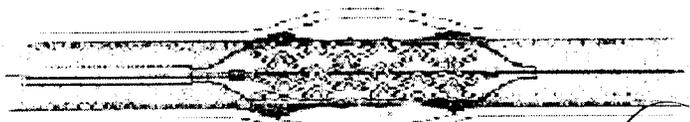
Implanting Stent



NIRflex Stent on delivery catheter before balloon inflation



NIRflex Stent expands as balloon is inflated



Once the balloon is fully inflated the NIRflex stent is expanded, fitting the vessel size and contour

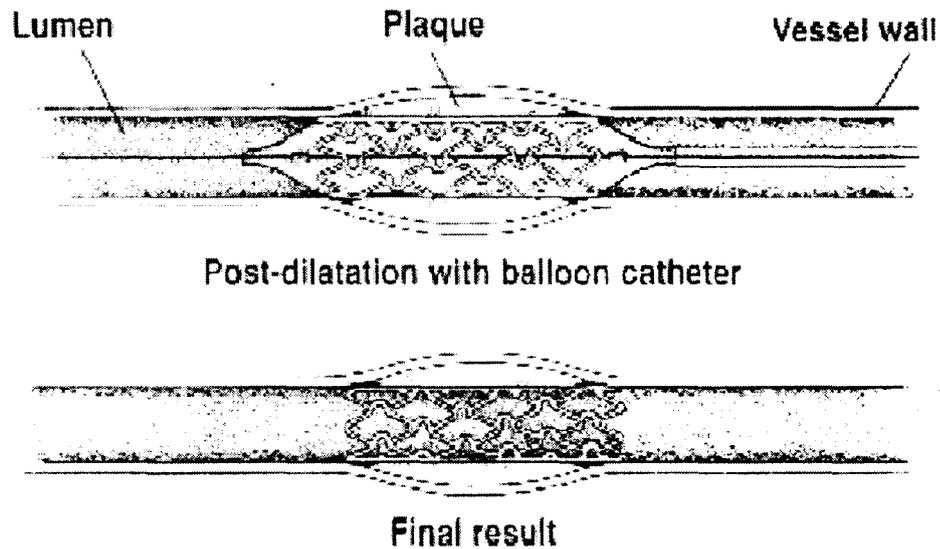
*increase
final size*



How the Stent is Implanted (*continued*)

- Your doctor may choose to expand the stent further using other inflatable balloons similar to the one used to perform angioplasty. The balloon catheter is inserted inside the stent and is 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*.

Further Expansion of Stent



AFTER THE PROCEDURE

Recovery

After the procedure, 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 from your leg and pressure applied to the puncture site until the bleeding has stopped. Your blood will be frequently tested to monitor and regulate medication levels that control the clotting of your blood.

Once you return to your room from the recovery unit, family and friends may visit. You may drink and eat, if permitted by your doctor. Drinking plenty of fluids helps flush contrast dye used during the procedure out of your system. For the first few days, your doctor will restrict your activities. Your doctor will advise you when to increase activities.

Patient Information Card

Attached to the back cover of this patient guide is a patient Information Card. You should carry this card with you at all times. In case of an emergency, the card tells medical personnel that you have a NIRflex™ coronary stent and provides limited information about your stent.

Taking Care of Yourself at Home

When you return home, you have an important role to play in your recovery. In a small fraction of patients, chest pain may return due to build up of scar tissue at the treated site. If this occurs, talk to your doctor to determine the cause of your pain and possible treatment recommendations. Carefully following your doctor's instructions regarding medications, exercise, diet and activities will speed your recovery and help prevent future recurrence of chest pain due to coronary artery narrowing. The medication chart at the end of this booklet lets you keep track of your treatment program, including medications, along with any questions you may have for your doctor at follow-up visits.

WARNING :

- Contact your doctor or the hospital immediately if you experience pain, bleeding, discomfort or changes in angina symptoms (chest-pain) such as severity or frequency.
- 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.
- Avoid MRI scans (Magnetic Resonance Imaging) within eight weeks of stent implant.

Here are some guidelines to follow:

- 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.
- You may wish to carry your Patient Information Card with you and show it when you receive dental or medical care or report to an emergency room /center.

Medications

Your doctor may prescribe a number of medications. Two commonly prescribed medications are aspirin and *Clopidogrel*. They thin the blood to prevent blood clots from forming and adhering to the surface of the stent. Patients who take these medications also are 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. Follow-up visits should be scheduled at two weeks, four weeks, and nine months after the procedure. 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.

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.

Angioplasty - A procedure which proceeds and/or follows stent placement. A balloon catheter compresses the plaque against the vessel wall, leaving a larger opening for the blood to pass through. Also known as percutaneous transluminal coronary angioplasty (PTCA).

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

Antiplatelet- Medicine such as aspirin, that 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 of cholesterol and other fats, calcium and certain other elements carried in the blood) and therefore, less oxygen and other nutrients reach the heart muscle. This may lead to chest pain (angina pectoris) or to a heart attack (myocardial infarction)

GLOSSARY (*continued*)

CAD- See **Coronary Artery Disease**.

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 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 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).

ECG – Electrocardiogram. See **stress test**.

Exercise Electrocardiogram – See **Stress test**.

GLOSSARY (*continued*)

Ischemia – A condition that results from reduced blood flow to cells due to an obstruction. Ischemia is reversible if normal blood flow is restored.

Lumen- The inner channel of a vessel or tube.

Myocardial Infarction – Permanent damage to the heart tissue and muscle due to the interruption of the blood supply to the area. Commonly referred to as a heart attack, which can occur when blood clots form on top of the atherosclerosis.

Percutaneous – Performed through the skin.

Percutaneous Transluminal Coronary Angioplasty- See **Angioplasty**

Plaque – An accumulation or build-up of calcium, cell debris, fatty deposits and collagen in a coronary 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 vessel.

PTCA – Percutaneous Transluminal Coronary Angioplasty.

Restenosis – Recurrent blockage or narrowing of a vessel due to scar tissue after correction of the primary blockage with angioplasty or stent implantation.

GLOSSARY (*continued*)

Stent - An expandable metal tube that supports the vessel wall and maintains healthy blood flow through the opened vessel.

Stress Test – A test to measure electrical activity in the patient’s heart (ECG) while the patient is doing a controlled exercise. The results determine if there is damage to the heart 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.

MEDICATION CHART

This chart will be filled in by your nurse or physician to detail your medication schedule following implantation of a coronary stent.

Date	Drug	Dosage	Time

Questions/ Notes: _____

PATIENT IMPLANT INFORMATION

Patient's Name: _____
 Date of Stent Implantation _____

Date	Stent Diameter	Stent Length	Catalog Number	Lot Number	Stent Location

Physician's name: _____
 Phone number: _____

Suggested goals: check to see what goals your physician has recommended for you.

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Patient Card
Side A

Patient Name

Implanting Physician Name

Physician Telephone Number

NIRflex™
Coronary Stent
Designed for Performance

Medinol
Techniques that last

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Side B

Please keep this card in a safe place!!!

- Implantation Date _____
- Stent Size and Lot #: Diameter _____ (mm)
Length _____ (mm)
Lot # _____
- Stent Placement: _____
(Please indicate the exact segment location)

WARNING!

- A magnetic resonance imaging (MRI) scan should not be performed until approximately eight weeks after implantation.
- This patient may be receiving anti-platelet therapy.

The stent utilized in connection with your procedure was produced by Medinol Ltd. Jerusalem, ISRAEL