

TAXUS[®] Express^{2™}

Paclitaxel-Eluting Coronary Stent System

**Boston
Scientific**

Patient
Information
Guide

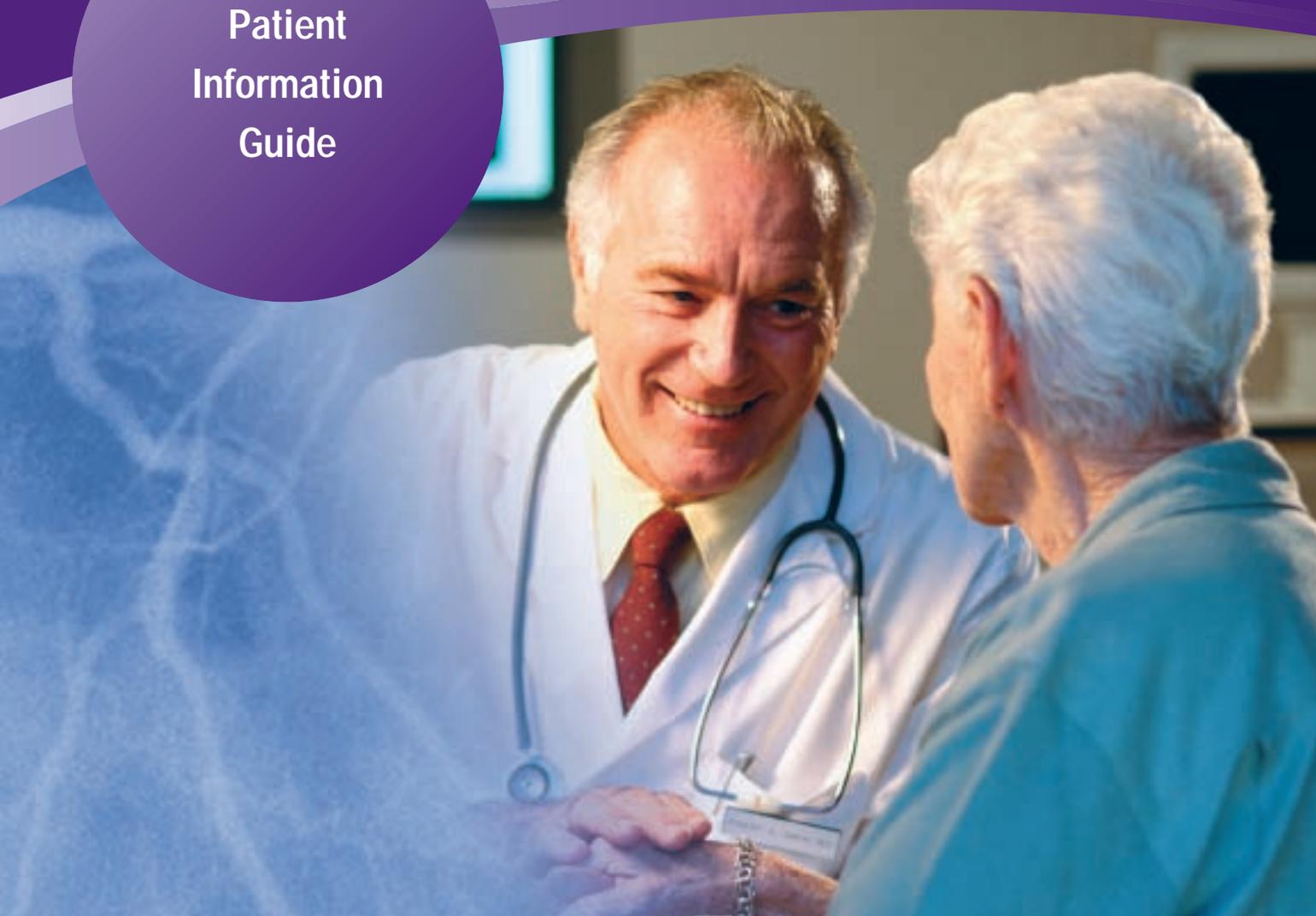


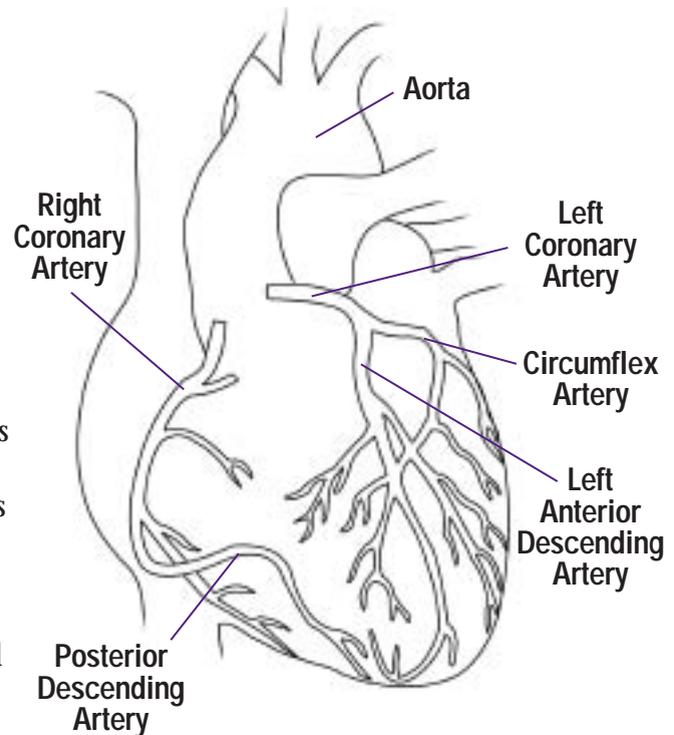
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Coronary Artery Disease

Coronary Artery Disease (CAD) is usually caused by *atherosclerosis*, and affects the *coronary arteries* that surround the heart. These coronary arteries supply blood with oxygen and other nutrients to the heart muscle to make it function properly. CAD occurs when the inner walls of the coronary arteries thicken due to a buildup of cholesterol, fatty deposits, calcium, and other elements. This material is known as *plaque*. As plaque develops, the vessel narrows. When the vessel narrows (for example

with physical exertion or mental stress), blood flow through the vessel is reduced so less oxygen and other nutrients reach the heart muscle. This reduced blood flow may cause mild to severe chest pains or chest pressure. This pain or pressure can also spread to the arms or jaw, a condition known as *angina pectoris*. Complete obstruction (no blood flow) of a coronary artery can result in a heart attack (*myocardial infarction*).



Anyone who experiences symptoms of angina pectoris or myocardial infarction should promptly seek medical care.

Over 13 million Americans suffer from CAD each year. However, treatment options for CAD have substantially improved in recent years, and many CAD patients are now able to return to a normal lifestyle shortly after treatment.

Who Is at Risk?

People with a history of high cholesterol, diabetes, smoking, high blood pressure, being overweight and a family history of CAD have an increased risk of developing atherosclerosis in the coronary arteries. Increasing age adds to the risk of CAD. In addition, menopausal status may play a role in women.

Diagnosis of Coronary Artery Disease

Doctors may use various tests to diagnose CAD. An *electrocardiogram (ECG or EKG)* measures your heart's electrical activity and may show whether parts of your heart muscle have been damaged by a heart attack due to 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. A *coronary angiogram* is a procedure performed by a cardiologist in a Cardiac Catheterization Lab. This procedure is done by injecting a contrast dye into the coronary arteries so that the vessels can be seen on an x-ray screen. The angiogram will show if any blockages and/or artery narrowing has occurred. This will help your doctor decide how to treat you.

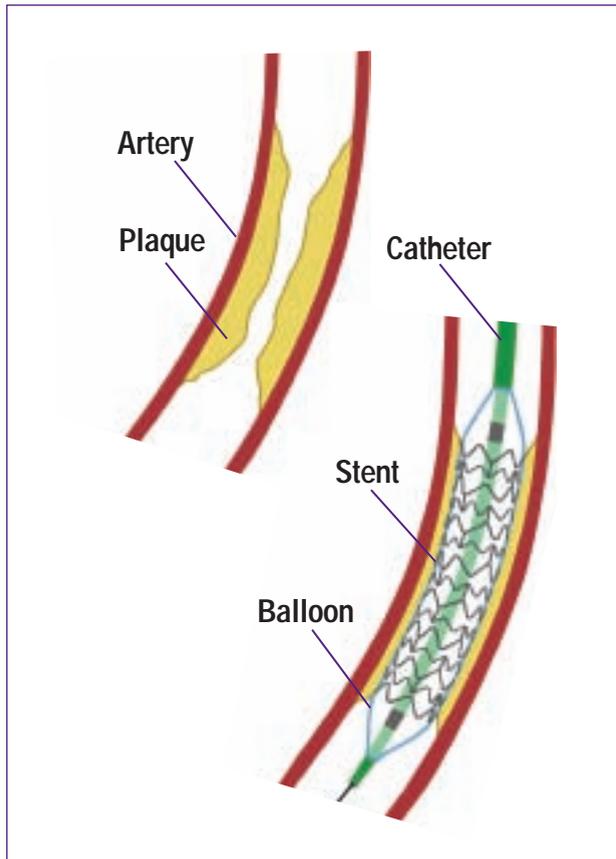
Treatment of Coronary Artery Disease

CAD 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. Nitroglycerin is often given to relieve chest discomfort due to blockages, but does not treat the blockage itself. Medical treatments of the blockage may include medications, *angioplasty*, with or without *stent* placement, or *coronary artery bypass graft surgery (CABG)*.

Notes

Angioplasty

Angioplasty is a minimally invasive treatment of the coronary arteries performed in the hospital to open blocked arteries, also known as percutaneous transluminal coronary angioplasty (PTCA). 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.

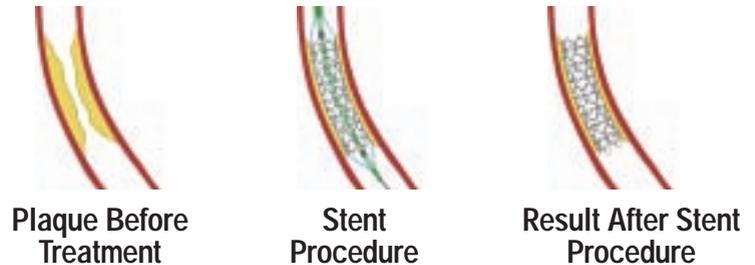


Side View of Coronary Artery



Coronary Artery Stents

Coronary artery stents are devices that can help to reduce the risk of recurrent blockage or narrowing following an angioplasty procedure. Stents are small expandable metal tubular structures (lattice) 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. Once in place, the stent will remain in your artery. Over time, the artery wall will heal around the stent as it continues to support the vessel.



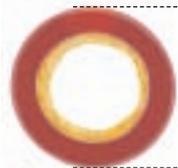
Restenosis

Many patients who undergo *balloon angioplasty* treatment will experience a renarrowing of the artery, or *restenosis*, in the area that was being treated. The rate of restenosis is between 30 and 50 percent for angioplasty patients who do not receive a stent within the first six months after their initial procedure. The renarrowing can be caused by a combination of factors including vessel recoil and formation of tissue ingrowth in the treated area.

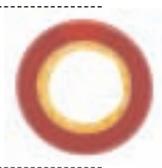
Cross-Section of Coronary Artery



Coronary Artery Disease (Initial Artery Size with Typical Plaque)



After Expansion by Balloon Angioplasty—Plaque Pushed Back. Artery Wall Stretches



Vessel Recoil (Stretched Vessel Naturally Returns to Initial Size)



Restenosis Narrows Treated Vessel Over Time (Initial Artery Size Plus Tissue Ingrowth)

Notes

Notes

Although coronary artery stents have proven to reduce the occurrence of restenosis compared to balloon angioplasty, restenosis still occurs in approximately 10 to 30 percent of patients who receive bare metal stents. Unlike restenosis after balloon angioplasty, restenosis in a stent (*in-stent restenosis*) is not typically associated with *vessel recoil*. Instead, in-stent restenosis primarily results from increased tissue ingrowth.

Stent Strut



Coronary Artery Disease
(Initial Artery Size with Typical Plaque)



After Expansion by Balloon Angioplasty with Stent Plaque Pushed Back. Artery Wall Stretches



Stent Prevents Stretched Vessel from Recoiling to Initial Size

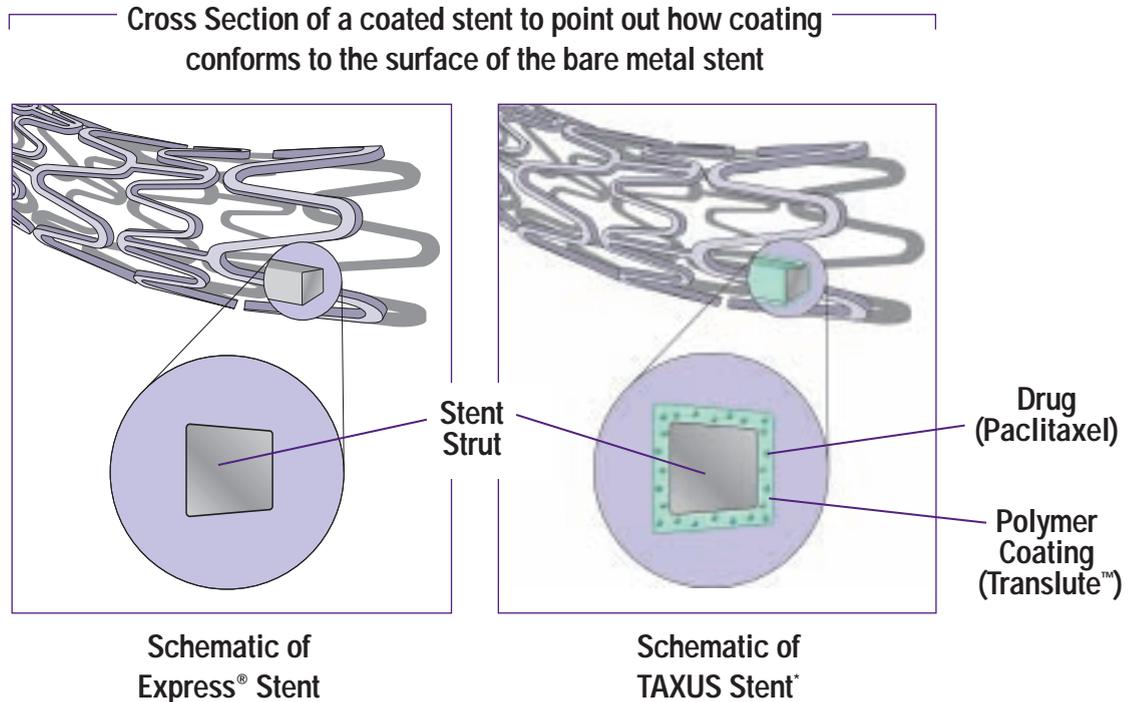


Restenosis Narrows Treated Vessel Over Time (Initial Artery Size Plus Tissue Ingrowth)

Your Drug-Eluting Stent, the TAXUS® Express^{2™} Paclitaxel-Eluting Coronary Stent System

Drug-Eluting Stents

A drug-eluting stent is a bare metal stent that has been coated with a drug and a polymer. Drug-eluting stents are designed to deliver a drug locally to reduce tissue ingrowth.



**Note: A green color is used to show coating but actual coating is clear*

The Express Stent Platform for the TAXUS Express Stent (i.e. TAXUS Stent)

The Express Stent, the small steel tube upon which the drug/polymer coating is applied, has been used extensively as a bare metal stent and is very flexible, allowing it to conform to the natural curves of your artery.

The Polymer Coating on the TAXUS Stent

The stent is coated with a proprietary polymer (a chemical compound) called Translute™, which was developed specifically for the TAXUS Stent. The Translute Polymer is also known as SIBS [poly(styrene-b-isobutylene-b-styrene)]. The polymer carries and protects the drug before and during the procedure. Then, once the stent is implanted in the coronary artery, it helps control drug release into the arterial wall. This contributes to even and consistent distribution of the drug from the stent.

The Drug that is Released from the TAXUS® Stent

The TAXUS stent was designed by coating the Express® Stent with the drug paclitaxel, and the polymer. The paclitaxel/polymer coating has been designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls, to minimize release into the blood stream. Both the amount of drug and release rate have been determined so that healing can occur while allowing the processes leading to restenosis to be minimized, thus reducing the need for additional treatment in the stented area.

The TAXUS Stent uses a very small but effective dose of paclitaxel, which is released slowly over the time period when restenosis is most likely to occur. Some paclitaxel will remain on the stent, with no additional measurable amount being released into the body.

NOTE: Paclitaxel is also available in injection form, known by the trade name Taxol®, and is also available in generic formulations. Let your doctor know if you are currently using this drug.

When should the TAXUS Stent NOT be Used? (Contraindicated)

- If you have an allergy to the drug paclitaxel or structurally related drugs, or to the SIBS polymer.
- If you cannot take aspirin or blood-thinning medications (also called antiplatelets or anticoagulants).
- If the physician decides that the blockage will not allow complete inflation of the angioplasty balloon or proper placement of the stent.

What are the Risks & Potential Benefits of Treatment with the TAXUS® Stent?

Potential adverse events, which may be associated with the implantation of a coronary stent, include:

- air, tissue, or clots which can block the vessel (emboli)
- allergic reaction to the contrast dye (which could include kidney failure)
- allergic reaction to the metal used to make the stent (stainless steel)
- aneurysm
- bleeding that would require a blood transfusion
- bruising which resides on a blood vessel (pseudo-aneurysm)
- chest pain or discomfort
- collection of blood in the lining of the heart
- coronary spasms
- death
- emergency bypass surgery
- heart attack
- high or low blood pressure
- inadequate supply of blood to the heart
- infection and/or pain at the access site
- injury or tearing of blood vessel
- irregular heart beat (arrhythmia)
- movement of the stent as it is sliding from the balloon into the blood vessel (embolization)
- plugging of the stent with blood clots
- renewed formation of a narrowing in the treated vessel (restenosis)
- side effects due to contrast dye or heparin
- shock/pulmonary edema
- stroke or other neurological events
- total occlusion of the vessel
- unnatural connection between vein and artery (arterio-venous fistula)
- vessel trauma requiring surgical repair or reintervention
- worsening of heart and lung function

Potential adverse events related to the drug paclitaxel (based on studies of patients who used the drug for a prolonged period of time) or the polymer include:

- abnormal liver values
- allergic or immunologic reaction to the drug (paclitaxel)
- allergic reaction to the polymer [Translute™: poly(styrene-b-isobutylene-b-styrene)] or polymers with similar chemical structures
- anemia
- blood transfusion
- changes in blood profile (decrease of white and red blood cells and platelets)
- changes of the tissue in the vessel wall including inflammation, cell injury, and cell death
- disturbances of the gastrointestinal (GI) tract and stomach
- loss of hair
- muscle pain/joint pain
- nerve disease in arms and legs

There may be other potential adverse events that are unforeseen at this time.

Exposure to paclitaxel and the polymer coating is directly related to the number of implanted stents. Use of more than one TAXUS® Stent has not been adequately evaluated. Use of multiple stents will result in your exposure to a larger amount of paclitaxel and polymer coating than experienced in the clinical studies.

There is no clinical experience on the performance of the TAXUS Stent before or after use of *brachytherapy*, or when used with other types of coated or drug-eluting stents.

The safety and effectiveness of the TAXUS® Stent was compared to the Express® Stent (an uncoated stent) in the TAXUS IV trial that included 1,314 patients. All patients were followed for 1 year. The study results showed that patients who received a TAXUS Stent had a significantly lower incidence of repeat procedures in the vessel where the stent was placed, when compared to the uncoated Express Stent, (6.9% for TAXUS Stent, 16.9% for Express Stent). The combined occurrence of Major Adverse Cardiac Events which is comprised of death, heart attacks, bypass surgery, and repeat angioplasty was 10.7% for TAXUS Stent patients and 20% for Express Stent patients.

The study showed the risks associated with the TAXUS Stent are equivalent to the risks associated with the uncoated Express Stent.

Long term risks and benefits (i.e., greater than one year) associated with the TAXUS Stent are currently unknown.

Alternative Practices and Procedures

Treatment of patients with coronary artery disease including in-stent restenosis may include exercise, diet, drug therapy, percutaneous coronary interventions (such as angioplasty, bare metal stents, coated stents, and other drug eluting stents), and coronary artery bypass surgery.

The Angioplasty Procedure

Preparation for the Procedure

Your doctor will instruct you on how to prepare for the angioplasty procedure and stent implantation procedure 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 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 needs to know if you are taking any other medications, have drug allergies, or are allergic to any metals or plastics.

Angioplasty and Stent Placement Procedure

Your angioplasty procedure will be performed in a specially equipped area of the hospital called the Cardiac Catheterization Laboratory. You will have to lay flat on your back during the procedure and you will remain awake, allowing you to follow your cardiologist’s instructions (e.g., “breathe deeply”). Your groin or arm will be shaved and cleaned with antiseptic and you will be given a local anesthetic to numb the area.

Your cardiologist will place an *introducer sheath* either in your groin or in your arm to gain access to the artery. The sheath enables the cardiologist to slide a small guiding catheter up to the entrance of the coronary artery. Through the guiding catheter, a contrast dye will be injected that helps the doctor see the coronary arteries on the x-ray machine. A finer guide wire is then advanced through the guiding catheter to the stenosis, or blockage, in the diseased artery. This provides the “railway track” which carries all the equipment necessary for the procedure.

Using the guiding catheter, a balloon catheter is then positioned precisely in the clogged area of the coronary artery. Once in place, the balloon is inflated, compressing the plaque buildup and widening the artery. At this time you may experience some chest pain. Although this is normal, let your doctor know if you are experiencing any pain.

After the artery has been widened, your doctor will then pass the stent, mounted on a delivery catheter, into the coronary artery where

the balloon was inflated. Your doctor will again inflate the balloon to expand the stent and deliver it to the inner wall of the artery. The stent will expand to shape itself to the size and contours of your vessel.

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 help the stent make better contact with the artery wall. This part of the procedure is called *post-dilatation*. Post-dilatation is done to enable full contact of the stent to the artery wall. Once in place, the TAXUS® Stent will remain as a permanent implant in your artery. The TAXUS Stent uses a very small but effective dose of paclitaxel, which is released slowly over the time period when restenosis is most likely to occur. Some paclitaxel will remain in the stent, with no additional measurable amount being released into the body.

POST-TREATMENT

After the Procedure

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. On average, your hospital stay may last one to three days before you are discharged.

Activity

- Follow your doctor's guidelines.
- 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.
- Carry your Patient Information Card (provided in the back of this booklet) at all times. If you receive dental or medical care or report to an emergency room/center, show your Patient Identification Card.

Medications

Your cardiologist may prescribe a number of medications to thin the blood and prevent blood clots from forming and adhering to the surface of the stent. You will be asked to take a small daily dose of aspirin indefinitely. In addition, your treatment regimen will include either clopidogrel (Plavix®) or ticlopidine (Ticlid®) for a period of 6 months in combination with aspirin. It is extremely important to follow your medication regimen. **If you stop taking these medications before being instructed to do so by your cardiologist, the chances of blood clot formation on the stent, subsequent heart attack or even death, are increased.**

If you plan to have any type of surgery or dental work which may require you to stop taking these medications prematurely, you and your cardiologist should discuss whether or not placement of a drug-eluting stent is the right treatment choice for you.

If surgery or dental work which would require you to stop taking these medications prematurely is recommended after you've received the stent, you and your doctors should carefully consider the risks and benefits of this additional surgery versus the possible risks from early discontinuation of these medications.

If you do require premature discontinuation of these medications because of significant bleeding, then your cardiologist will be carefully monitoring you for possible complications. Once your condition has stabilized, your cardiologist will possibly put you back on these 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.

FREQUENTLY ASKED QUESTIONS

Can the stent move or rust?

Once positioned by your physician, the stent does not move on its own. It is manufactured so it will not rust.

Can I walk through metal detectors with a stent?

Yes, without any fear of setting them off.

How soon can I go back to work?

The majority of people return to work within a few days following the procedure.

What if I still get pains?

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

Can I undergo MRI or scanner testing with a stent?

MRI safety testing has shown that the stent should not migrate in the MRI environment typically used in a clinical setting, and that MRI may be performed immediately following stent implantation. Testing also demonstrated stent heating due to the MRI is less than 1 degree Celsius and should not affect performance of the implanted

stent or the drug coating. Please refer to the TAXUS® Express^{2™} Directions for Use for additional information.

Can I play sports?

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

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.

Does paclitaxel have any drug interactions that I should be concerned about?

Formal drug interaction studies with paclitaxel after use of a TAXUS Express® Stent have not been conducted. Since some paclitaxel will remain on the stent, interactions at the location of the stent itself affecting the performance of the drug cannot be ruled out. Be sure to discuss with your doctor any drugs you are taking or planning to take.

What if I have taken paclitaxel before for cancer treatment and had a reaction to it?

Be sure to let your doctor know if you have had a previous allergic reaction to paclitaxel.

GLOSSARY

Angina Pectoris Symptoms experienced when the heart muscle is not receiving adequate oxygen (may include chest, arm or back pain, shortness of breath, nausea, vomiting).

Angiogram X-ray of the heart using contrast dye injection.

Angioplasty A minimally invasive treatment of the coronary arteries, to open blocked arterial vessels. Also known as percutaneous transluminal coronary angioplasty (PTCA).

Atherosclerosis A disease in which the flow of blood to the heart is restricted with plaque deposits 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).

Balloon Angioplasty Opening the blocked artery by using a balloon catheter that is inflated inside the vessel.

Brachytherapy The use of a locally delivered dose of radiation to control the process of restenosis.

Catheter A small, thin plastic tube used to provide access to parts of the body, such as the coronary arteries.

Coronary Angiogram A test in which contrast dye is injected into the coronary arteries and allows the doctor to see the vessels on an x-ray machine.

Coronary Arteries The arteries that surround the heart and supply blood containing oxygen and nutrients to the heart muscle.

Coronary Artery Bypass Graft Surgery (CABG) Open heart or bypass surgery.

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 buildup of cholesterol and other fats, calcium and elements carried in the blood).

Electrocardiogram (ECG/EKG) A test that records changes in the electrical activity of the heart.

May show whether parts of the heart muscle have been damaged due to insufficient oxygen flow to the heart.

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

Introducer Sheath A tube that is inserted into the body to provide an access point and allow the insertion of other instruments into the artery.

Lumen The inner channel of a vessel.

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.

Percutaneous Transluminal Coronary Angioplasty (PTCA) See Angioplasty.

Plaque Accumulation or buildup of cholesterol, fatty deposits, calcium and collagen in a coronary vessel that leads to blockages in the blood vessel.

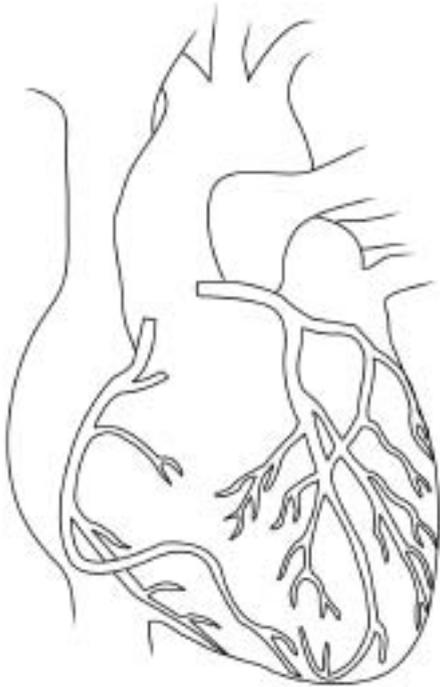
Post-Dilatation After the stent has been expanded, another balloon catheter may be inserted inside the stent and inflated to size the stent more precisely to the wall.

Restenosis Recurrent blockage or narrowing of a previously treated vessel.

Stent An expandable metal tubular structure (lattice) that supports the vessel wall and maintains blood flow through the opened vessel.

Stress Test A test that records the heart's electrical activity while the patient exercises. May show whether parts of the heart muscle have been damaged due to insufficient oxygen flow to the heart.

Vessel Recoil When an artery is stretched during an angioplasty procedure, the elastic properties of the coronary vessel wall may cause the vessel to "shrink back" after the procedure.



Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each product. CAUTION: Federal (USA) law and governing law outside the U.S.A. restricts these products to sale by or on the order of a physician. TAXUS® Express^{2™} Stent is a product of Boston Scientific Corporation.

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**TAXUS® Express²™ Paclitaxel-Eluting
Coronary Stent System**

Patient Name

Patient Phone Number

Implanting Physician's Name

Stent Material

Physician's Phone Number

Date of Implant

PLEASE CARRY YOUR CARD AT ALL TIMES.

Your cardiologist has prescribed a number of medications to thin the blood and prevent blood clots after your implant. It is extremely important to follow the medication regimen as prescribed by your cardiologist. Before considering any surgery or dental work which would require you to stop taking these medicines early, you and your doctors should consider the risks from premature discontinuation of these medications. **For questions regarding your Coronary Stent System or other procedures (e.g., MRI), please contact your implanting cardiologist.**

Stent Identification Information

Product Code

Product Code

Product Lot Number

Product Lot Number

Stent Location

Stent Location

Product Code

Product Code

Product Lot Number

Product Lot Number

Stent Location

Stent Location

TAXUS[®] Express^{2™}

Paclitaxel-Eluting Coronary Stent System

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Stent Implant Location