

Angioplasty and Stent Education Guide

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Treating coronary artery disease

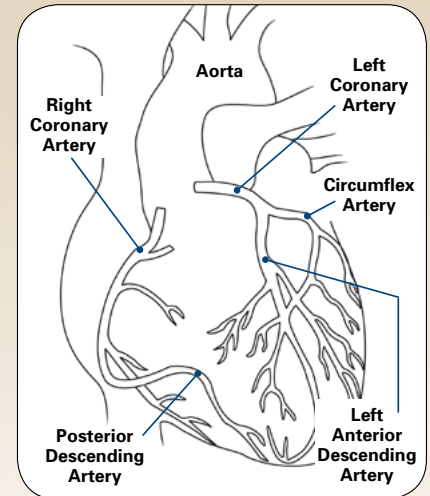
Your doctor may want you to have a stent placed in your coronary artery. This is to help treat your coronary artery disease. This guide explains the procedure and what you can expect from start to finish. A glossary at the end of this guide defines common medical terms related to this procedure.

You will also learn steps you can take to live a healthier life with coronary artery disease.

What is coronary artery disease?

Coronary Artery Disease (CAD) is the narrowing of the arteries in the heart. This narrowing can also be called stenosis. It is usually caused by a build up of fat or calcium deposits called plaque. Over time, this plaque can build to a total blockage of the artery. This process is called atherosclerosis.

When the heart doesn't receive enough blood flow due to blockage in the artery, it may cause mild to severe chest pain or pressure. This pain or pressure can also spread to the arms or jaw. If the artery is completely blocked, it can result in a heart attack. Anyone who experiences symptoms like those described above should promptly call 911. More than 13 million Americans suffer from CAD each year. However, the treatment of CAD has changed in recent years, and many CAD patients are able to return to a normal lifestyle shortly after treatment.



Who is at risk?

If you have a history of high cholesterol, diabetes, smoking, high blood pressure, being overweight or a family history of CAD, you have an increased chance of developing blockage in your coronary arteries. As you get older, you have a greater chance of developing CAD. In addition, women who have reached menopause have a greater chance of having CAD.

How do I know if I have coronary artery disease?

There are a number of tests that your doctor can perform to help determine if you have CAD. A test that measures the electrical activity in your heart is called an electrocardiogram (ECG or EKG). A stress test can be done to measure the electrical activity in your heart while you are exercising. These tests may show your doctor if part of your heart has been damaged or is not receiving enough blood. To directly determine if your arteries may be blocked or narrowed, your doctor may schedule a procedure with a cardiologist. This procedure is called a coronary angiogram and is performed in a Cardiac Catheterization Lab. During the coronary angiogram, dye is injected into your coronary arteries. By doing this procedure, the cardiologist can see your coronary arteries on an X-ray screen and can make a decision of how best to treat you.

Coronary artery disease treatment options

There are many different treatment options for treating coronary artery disease. The options focus on increasing blood flow to the heart, along with changes to your every day lifestyle, including diet, physical activity and medications. The type of treatment your doctor recommends for you depends on your symptoms and how much damage has been done to your heart.

Treatment options for coronary artery disease may include:

1. Medications
2. Balloon angioplasty
3. Coronary artery stenting
4. Coronary artery bypass graft surgery (CABG)

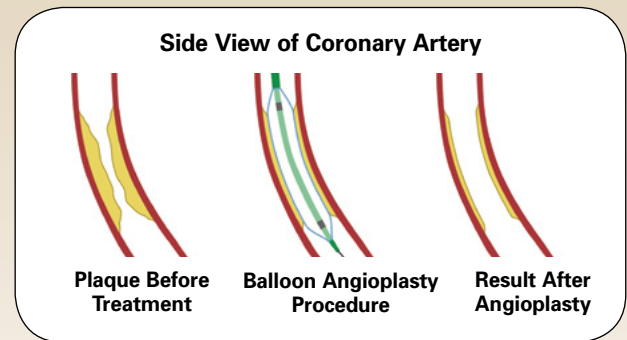
1. Medications

Nitroglycerin may be given to relieve chest discomfort due to coronary blockages. It does not treat the blockage itself. Your cardiologist may prescribe a number of medications (aspirin, beta-blockers, cholesterol medications, etc.) to thin your blood and to help prevent blockage of the arteries.

Coronary artery disease treatment options *continued*

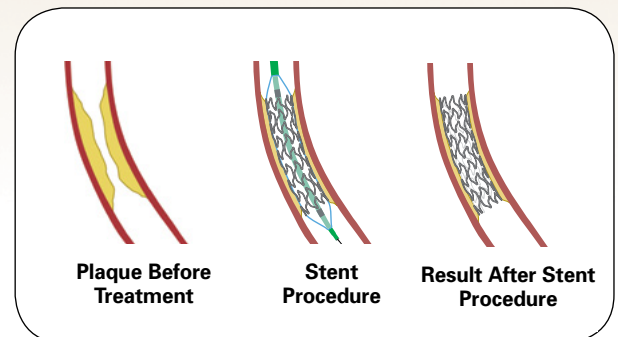
2. Angioplasty

A procedure known as angioplasty can also treat artery narrowing. A thin tube known as a guide catheter is inserted into the artery at the groin or wrist. A small balloon located on the top of a second catheter is moved through the guide catheter to the site of the narrowing. The balloon is then inflated to reduce the blockage. The balloon is deflated and removed after the angioplasty is done. The patient remains awake while the cardiologist performs the procedure. The procedure may end here or you could have a bare-metal or drug-eluting stent implanted to help keep the artery open.



3. Coronary artery stenting

During this procedure a small mesh tube is implanted into the artery to widen the artery and restore adequate blood flow to the heart. This mesh tube is called a stent. Once the stent is placed into the coronary artery, it is expanded with the inflation of a balloon catheter. The stent is left in the artery to keep it open and help prevent further narrowing of the coronary artery.



4. Coronary artery bypass graft surgery (CABG)

This surgery is also called a heart bypass or open heart surgery. Your surgeon will need to take a short length of artery from your inner chest wall and/or a vein from your leg and surgically attach it above and below the blocked area of the heart artery.

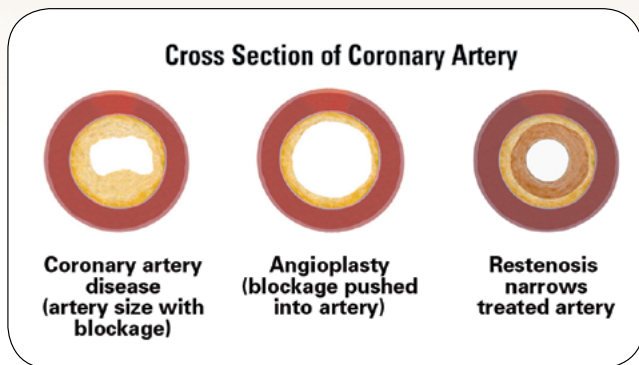
What are coronary artery stents?

Coronary artery stents are small mesh tubes that can help to reduce blockage of a coronary artery. The stent is implanted into an artery and expanded to fit the size, shape and bend of the coronary artery. The stent props the artery open and helps to prevent the blockage from returning. Once the stent is 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 artery.

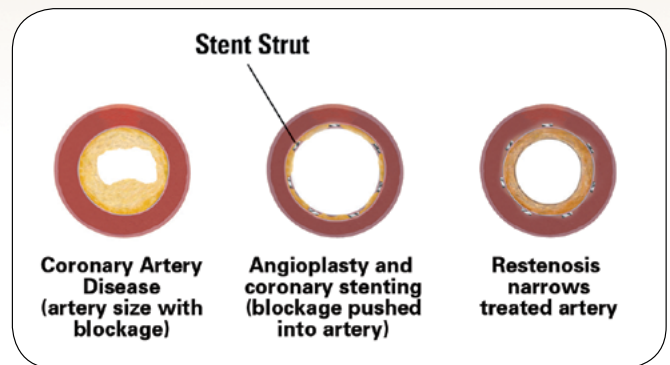
Why are stents used?

Many patients who undergo balloon angioplasty treatment will experience a re-narrowing of the artery. This re-narrowing is called restenosis. This re-narrowing of the coronary artery can happen more often following a balloon angioplasty procedure than for patients who receive a stent. The re-narrowing can be caused by a combination of factors including the blockage reforming or new tissue growth within the treated area.

Coronary artery with angioplasty



Coronary artery with stenting



What are the different types of coronary stents?

There are several kinds of stents, including bare-metal stents and different types of drug-eluting stents.

Bare-metal stents provide support to help keep the artery open after angioplasty. A permanent polymer drug-eluting stent is a bare-metal stent with a special drug and polymer coating added to help reduce the chance of the artery becoming blocked again. The drug is released from the stent over the period of time during which re-blockage is most likely to occur. A bioabsorbable polymer drug-eluting stent offers the additional benefit of having the polymer go away once the drug has been released eliminating long-term polymer exposure. The stents were designed to be very flexible, allowing them to fit the shape of your artery.

Boston Scientific offers bare-metal, permanent polymer drug-eluting and bioabsorbable polymer drug-eluting stents. The SYNERGY™ Stent is a bioabsorbable polymer drug-eluting stent. Depending upon your specific needs, your doctor may choose to place a bare-metal, permanent polymer drug-eluting, bioabsorbable polymer drug-eluting or some combination of these stents. There are differences between the stent types such as the need for longer-term dual antiplatelet therapy that you should discuss with your doctor. Please refer to the Patient Information Guide for more details about the stent.

How does the drug coating and polymer work on the SYNERGY bioabsorbable polymer drug-eluting stent?

Polymer Coating

The SYNERGY™ Stent is coated with a bioabsorbable polymer that is positioned on the outside of the stent (side in contact with the coronary artery wall). The polymer carries and protects the drug before and during the procedure. Once the stent is implanted, it helps control drug release into the coronary arterial wall. The polymer on the SYNERGY Stent is bioabsorbable and preclinical data have shown that the polymer on the SYNERGY Stent should be absorbed by your body in approximately four months.

Drug Release

The SYNERGY drug-eluting stent is coated with a drug (Everolimus) and polymer and has been designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls. Both the amount of drug and release rate have been selected so that healing can occur while minimizing the processes leading to restenosis (recurrent blockage of the artery), thus reducing the need for additional treatment in the stented area.

Risks of treatment option

You should not have a drug-eluting stent placed in your coronary artery if you have any of the following conditions:

- You are allergic to the drug or related drugs
- You are allergic to the polymer
- You are allergic to stainless steel or platinum chromium
- You are unable to take medications that make your blood thinner and more difficult to clot (also called antiplatelets and anticoagulants)
- You have a blockage that will not allow proper placement of the stent
- You are allergic to the dye used during the procedure (also called contrast agent)
- Your doctor decides that you are not able to have the required medication prior to stent placement

Your doctor and the medical staff will monitor you during and after the procedure for complications. If a complication does occur, your doctor will decide what type of treatment you may need.

Risks of treatment options *continued*

The placement of stents in arteries is done to treat blockages and to try to prevent re-narrowing.

As with any stent procedure, there is a chance that complications may occur, including, but not limited to, the following:

- Air bubbles, tissue or clots which can block the artery (emboli)
- Allergic reaction to the contrast dye (which could cause kidney failure)
- Allergic reaction to the drug
- Allergic reaction to the polymer
- Allergic reaction to the metal used to make the stent (stainless steel or platinum chromium)
- Aneurysm
- Arterial trauma which could require surgical repair or intervention
- Bleeding (which may require a blood transfusion)
- Bruising at the access site
- Bruising which occurs on a blood vessel (pseudo-aneurysm)
- Chest pain or discomfort
- Collection of blood in the lining of the heart
- Coronary spasm
- 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 artery
- Irregular heartbeat (arrhythmia)
- Movement of the stent to an unintended location
- Plugging of the stent with blood clots

- Re-narrowing of the treated artery (restenosis)
- Shock/pulmonary edema
- Side effects due to contrast dye, heparin or other medications
- Stroke or other neurological problems
- Total blockage (occlusion) of the artery
- Unnatural connection between vein and artery (arterio-venous fistula)
- Arterial trauma requiring surgical repair or reintervention
- Worsening of heart and lung function

Adverse events associated with daily oral administration of everolimus to organ transplant patients include but are not limited to:

- Abdominal pain
- Abnormal laboratory tests which may include:
 - Increased levels of creatinine in the blood (which reflect reduced kidney function)
 - Increased or decreased levels of potassium in the blood
 - Decreased levels of magnesium or phosphorous in the blood
 - Increased sugar (glucose) levels in the blood (possible new-onset diabetes)
 - Increased cholesterol levels in the blood
 - Increased levels of fats and triglycerides in the blood
- Back pain
- Blood in the urine
- Constipation
- Cough
- Decrease or changes in sense of taste
- Decreased red blood cell, white blood cell, or platelet cell counts (platelet cells help the blood clot)

Risks of treatment options *continued*

- Decrease or loss of sperm count in men
- Delayed wound healing/fluid accumulation (may include surgical wounds)
- Diarrhea
- Dry or itchy skin
- Fatigue
- Fever
- Headache
- Increased blood pressure
- Indigestion
- Infections: increased risks of bacterial, viral, fungal, or protozoal infections (may include herpes virus infections, BK virus infection, polyoma virus infection, opportunistic infections, or a combination of the above)
- Inflammation of the lining of the digestive system and mucous membranes
- Inflammation of the lung (not due to infections)
- Infection of the lungs and upper airways
- Insomnia
- Interactions with medications that are influenced by the CYP3A4 metabolic pathway (consult your doctor for more information)
- Loss of appetite
- Lymphoma and other malignancies (may include skin cancers)
- Mouth ulcers or sores
- Nosebleeds
- Nausea
- Pain in the arms, chest, legs, incision site or related to the procedure
- Pain or difficulty with urination
- Presence of protein in the urine
- Rash
- Reactive swelling, usually in the face

- Shortness of breath, and lung or breathing problems
- Swelling in the body (usually in the legs) caused by water retention
- Tremor
- Urinary tract infection
- Vomiting
- Weakness

Live vaccines and close contact with people that have received them should also be avoided. There is also potential harm to a fetus for pregnant women.

When used with cyclosporine medication, there may be an increased risk of the following:

- Blood clots in the small blood vessels
- Bleeding that appears as purple patches or spots on the skin
- Blood clotting in the smallest blood vessels of the body that may affect the kidneys

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

Before your coronary artery stenting procedure

Before your coronary artery stenting procedure:

- Tell your doctor about any medications you are taking.
- Let your doctor know about any allergies you have. It is important he or she knows about allergies to contrast dye, iodine, cobalt, chromium, nickel, titanium, stainless steel, platinum or plastics.
- Tell your doctor if you cannot take aspirin or blood thinning medicines. These medications are usually prescribed before and after your procedure.
- Make sure you understand the possible risks and benefits of your coronary stent procedure.

Below is a typical checklist. Your doctor may ask you to go through this before your procedure:

- Do not eat or drink anything after midnight on the night before your procedure.
- Follow the instructions you receive from your doctor and nurses.
- Take all your medications with you.
- You may be given a sedative to relax you before starting your stent procedure. The sedative can make you sleepy.

During a typical coronary artery stenting procedure

1. You will be taken to an area of the hospital called the Cardiac Catheterization Laboratory. While in the cath lab, you may be given a sedative that will make you feel sleepy during the procedure.
2. A small puncture is made in your arm or groin. A needle is used to gain access to your artery and a guide catheter and guide wire are fed through the artery and moved up into the coronary artery. All of this is done using X-rays for a guide.
3. The diseased artery first needs to be enlarged to make room for the stent. To do this, the doctor places a small, deflated balloon over the guide wire and through the catheter to the blocked area of the coronary artery. When the balloon is in the correct position, it is inflated. This pushes the plaque buildup aside and reopens the artery to restore blood flow.
4. The balloon is deflated and removed, and a small metal mesh tube called a stent is advanced into the same blocked area of the artery and expanded against the artery wall to fit the shape of your artery. Your doctor may choose to expand the stent by using another balloon. This is to make sure the stent is in better contact with the artery.
5. If your doctor places a drug-eluting stent into your artery, a drug will be released from the stent over a period of approximately 3 months.
6. After the stent is implanted, the catheter and wire are removed and the puncture site is closed. The stent remains in place permanently and is designed to help keep the artery open and prevent future narrowing of the coronary artery. The SYNERGY™ Stent is designed so the bioabsorbable polymer is absorbed once the drug has been released. The bioabsorbable polymer is eliminated from the body as carbon dioxide and water through natural metabolic mechanisms.

After a typical coronary artery stenting procedure

- You may feel sleepy from the sedative given to you. This will wear off over the next few hours.
- You will be taken to a unit where nurses and doctors can monitor you.
- You will be asked to stay in bed for several hours. You will be asked to keep your arm or leg straight so the entry site can heal.
- You may need to stay in the hospital before you can go home.
- You should follow your doctor's recommendations and let them know if you are experiencing any of the following:
 - Chest pain
 - Shortness of breath
 - Sudden weakness or paralysis of the face, arm or leg
 - Pain, bleeding or infection at the entry site in your arm or leg
 - Any other unexplained symptoms
- You can return to normal activities gradually. Check with your doctor about physical activities.
- You should not stop taking your medications unless you are asked to stop by the doctor who implanted your stent.
- You should keep all of your follow-up appointments, including blood testing.
- You should carry your Stent Implant Card at all times.
- You should always show your dentist or medical doctor your Stent Implant 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. These medications will include aspirin and blood thinning drugs such as clopidogrel (Plavix®), ticlopidine (Ticlid®), prasugrel (Effient®), or ticagrelor (Brilinta®). It is extremely important that you follow your doctor's instructions on 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 stent is the right treatment for you.

If surgery or dental work is recommended which would require you to stop taking these medications prematurely after you've received the stent, you and your doctor should carefully consider the risks and benefits of this additional surgery or dental work 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 probably put you back on these medications.

Follow-Up Examinations

You will need to see the cardiologist 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 coronary artery disease, and how the stent is working for you.

Frequently Asked Questions

Can the stent move or rust?

Once positioned by your doctor, the stent does not move on its own. It is manufactured so that 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 have pain?

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

Can I undergo MRI or scanner testing with a stent?

MRI safety testing has shown that the SYNERGY™ Stent is MR Conditional and that a patient with a coronary stent may safely undergo an MRI scan under certain conditions listed on the SYNERGY Stent Implant Card. Prior to undergoing an MRI scan, inform your doctor or MR technologist that you have a coronary stent and show them your the SYNERGY Stent Implant Card.

Can I play sports?

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 recommend changes to your diet in order to reduce your risk of future cardiac events.

Does everolimus (the drug eluted from the SYNERGY Stent) have any drug interactions that I should be concerned about?

Everolimus is delivered to the wall of your coronary artery from the stent placed in your coronary artery. It is estimated that the everolimus drug will be released into the surrounding arterial tissue for approximately 3 months following stent implantation. However, it is highly unlikely that the levels of everolimus in your blood will be measurable after one week or will have effects anywhere other than in your heart. The dose of everolimus that you would receive from the SYNERGY Stent is less than the recommended daily dose of everolimus that an organ transplant patient would be prescribed. Formal drug interaction studies with everolimus-based stents have not been conducted. Since some everolimus could remain on the stent, drug 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 everolimus (the drug eluted from the SYNERGY Stent) 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 everolimus.

Where does the bioabsorbable polymer go once it's absorbed?

The bioabsorbable polymer is eliminated from the body as carbon dioxide and water through natural metabolic mechanisms.

Glossary

Angina Pectoris

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

Angioplasty

A minimally invasive treatment to open blocked *coronary arteries*. Also known as *percutaneous transluminal coronary angioplasty (PTCA)*.

Atherosclerosis

A disease in which the flow of blood to the heart can be 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 artery.

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* allowing the doctor to see the arteries 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. A section of an artery or vein from your chest or leg is harvested and surgically attached to a coronary artery above and below the blocked area of the heart.

Coronary Artery Disease (CAD)

Disease affecting the *coronary arteries* that surround the heart and supply blood to the heart muscle.

Electrocardiogram (ECG/EKG)

A test that records changes in the electrical activity of the heart. May show whether sections of the heart muscle have been damaged due to insufficient blood or oxygen flow to the heart.

Glossary continued

In-Stent Restenosis

Recurrent blockage or narrowing of a previously stented area in an artery.

Lumen

The inner channel of an artery.

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 tomographic (CT) scans which use radiation.

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 *coronary arteries*.

Restenosis

Recurrent blockage or re-narrowing of a previously treated artery.

Stent

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

Stress Test

A test that records the patient's symptoms and the heart's electrical activity while the patient exercises. May show whether parts of the heart muscle have been damaged and if there is insufficient blood or oxygen flow to the heart.



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