


Cordis[®]
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Ground breaking, Life changing™

Endovascular

**Cordis
S.M.A.R.T.[®] and
S.M.A.R.T.[®] CONTROL™
Nitinol System
For the Iliac Arteries**

**A Patient's Guide to
Peripheral Vascular
Disease in the
Iliac Arteries**



this guidebook...

This guidebook is proudly brought to you and your family by Cordis Corporation.

If you or a member of your family has been diagnosed with *peripheral vascular disease (PVD)*, you may have



questions about the disease and its treatment, especially if your doctor has recommended angioplasty and possible stent implantation.

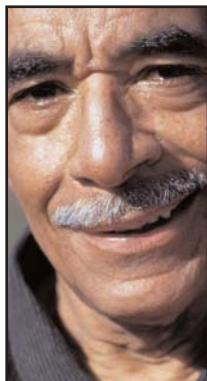
This guidebook answers some of the questions patients with peripheral vascular disease often ask.

NOTE. The contents of this patient brochure are applicable to both the Cordis S.M.A.R.T.[®] CONTROL™ Nitinol Stent System and the Cordis S.M.A.R.T.[®] Nitinol Stent System. Both will be referred to as the Cordis S.M.A.R.T.[®] Stent System in this brochure.

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this guidebook
answers
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introduction

This guidebook is designed to help you and your family understand peripheral vascular disease (PVD) and treatment with a vascular stent. If you have any questions as you read,



please write them down and discuss them with your doctor or nurse.

peripheral vascular disease

Peripheral vascular disease is caused by the build-up of fatty substances that collect and adhere to the linings of the arteries, in a process known as *atherosclerosis*. You may also hear the terms "*plaque*", "*blockage*", "*lesion*", or "*stenosis*". As the build-up continues, the internal lining of the artery thickens which causes the artery to narrow and limit blood flow to vital tissues and organs.

peripheral vascular disease (continued)

Some of the more commonly affected arteries are those which are located in the legs, arms, neck and kidneys. The symptoms from these blockages depend on what artery is affected and the severity of the blockage causing limited blood flow.

Some of the symptoms you may experience in the affected areas are:

- A dull, cramping pain in the hips, thighs, buttock or calf muscles (*claudication*).
- Numbness/tingling in the leg, foot or toes
- Changes in skin color such as paleness or bluish color in leg, foot, or toes
- Changes in skin temperature of leg, foot or toes
- *Ulceration* or *gangrene* due to sores that have not healed
- Uncontrolled high blood pressure (*hypertension*)
- Kidney damage (renal failure)

peripheral vascular disease - risk factors

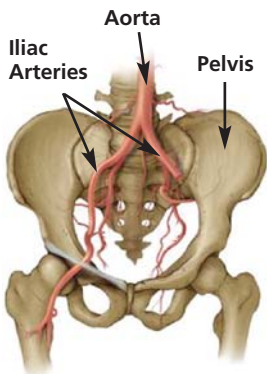
You are at the greatest risk for peripheral vascular disease if you:

- Are diabetic
- Are obese
- Smoke
- Have high blood pressure
- Have a family history of the disease
- Are inactive
- Have coronary artery disease
- Have high cholesterol

the iliac arteries

Arteries are vessels that carry blood away from the heart.

The iliac arteries extend from the bottom of the aorta and then branch into smaller arteries carrying oxygen-rich blood to the pelvis and legs.



The iliac arteries extend from the bottom of the aorta and branch into smaller vessels

iliac artery narrowing (stenosis)



When atherosclerotic plaque builds up in the iliac arteries, they begin to narrow and restrict blood flow to the pelvis and legs. This is called iliac artery stenosis. Severe iliac artery stenosis can

lead to complete blockage and loss of function.

diagnosis

Patients should be screened for iliac artery stenosis if they have:

- Pain in legs with exertion or walking which is relieved with rest.
- Diminished leg pulses or other abnormal sounds of blood flow heard through a stethoscope placed over the iliac arteries.
- Slow wound healing on legs.

The following diagnostic tests may be performed if iliac artery disease is suspected.

Iliac artery ultrasound: A sound-wave test that produces an image of iliac arteries onto a screen. This test allows the size of the vessel to be measured and the flow of blood to the pelvis and legs to be tracked. This can be helpful in identifying narrowing in the iliac arteries. This test is painless and does not require the use of needles, dye or x-rays.

diagnosis (continued)

Angiography: An *angiogram* is an x-ray test obtained by injecting dye through a small tube (*catheter*) inserted into an artery in the groin or arm. This procedure will determine exactly where the narrowing is located and will help to guide further treatments. You will be awake for the test, although you may be given a light sedative. The injection of dye is expected to cause a warm sensation and you may get a metallic taste in your mouth. After the test is complete you will need to lie flat for 5 – 6 hours to allow the puncture site in the arm or groin to heal.

treatment options

There are four basic treatment options for patients with iliac artery *stenosis*.

- 1. Diet Modification and Exercise:** Decreasing the amount of fat and cholesterol in your diet in combination with walking exercises are the cornerstones of treating iliac artery stenosis. Your doctor will make specific dietary and exercise recommendations for you. Other life style changes may also need to be made, especially the discontinuation of smoking.

treatment options (continued)

2. Medical Management:

Medicine can be prescribed to help dilate the blood vessel in your legs in order to improve blood flow. Additionally, medications that help to lower your cholesterol and fats may be prescribed. If you have *diabetes*, your physician may recommend modifications to medications to help reduce your blood sugar levels.

3. Iliac Artery Bypass Surgery:

A man-made graft, one of your own veins, or a synthetic material will be used to act as a detour to create new channels to carry blood to the pelvis and legs.

4. Iliac Artery Balloon

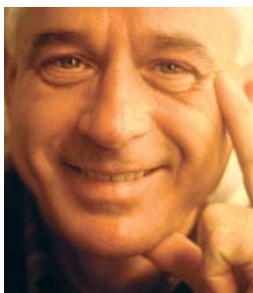
Angioplasty and Stenting:

This procedure uses a small tube (catheter) with a small balloon on the end to open the narrowed iliac artery by compressing the plaque against the vessel wall. This process reduces the narrowing until it no longer interferes with blood flow. The balloon is deflated and removed from the artery.

treatment options (continued)

Iliac Artery Balloon Angioplasty and Stenting: (continued)

In most cases, a stent, which is a metallic wire-mesh tube, is then placed into the opened artery. The size of a stent used is about 1½ inch in length and 1/2 inch in diameter when fully expanded in the artery. When expanded, the stent acts as a brace to keep the artery open, restoring normal blood flow.



Over several weeks, the healthy inner lining of the artery will grow over the stent, permanently incorporating it into the vessel.

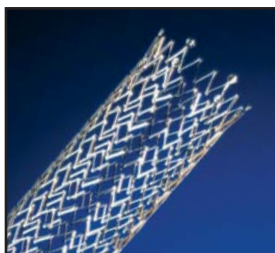
In a clinical investigation, patients with iliac artery stenosis received the Cordis S.M.A.R.T.® CONTROL™ Nitinol Stent System. After nine months, 3.5 percent of the cases evaluated had a 50 percent or more re-narrowing or blockage of their iliac artery.

Be sure to ask your doctor to explain the risks and benefits of your treatment options and answer any questions you or your family may have.

Cordis S.M.A.R.T.® Stent System for Iliac Arteries

The Cordis S.M.A.R.T.® Stent System for iliac arteries is made of a metal alloy called nitinol (nickel titanium). The stent is contained in a delivery system for passage into the body to the iliac arteries.

The Cordis S.M.A.R.T.® Stent System should only be used by physicians who are trained in



Cordis S.M.A.R.T.® Stent System

angioplasty and stent placement. You may wish to ask your doctor about his or her experience with this stent and the procedure used for its placement.

If you are pregnant, speak to your doctor about this before undergoing the angioplasty or stent placement procedure.

Cordis S.M.A.R.T.® Stent System for Iliac Arteries (continued)

Patients with one or more of the following characteristics might not be suitable candidates for stent placement:

- Poor kidney function or severe high blood pressure
- History of low number of white blood cells, low number of platelets, or significant low number of red blood cells
- Allergy or sensitivity to nitinol (nickel titanium alloy)



It is important to inform your doctor about your entire medical history, which includes all medications you are presently taking.

before your procedure

Upon admission to the hospital, you usually will have undergone tests such as iliac artery ultrasound, angiography and routine blood tests. Be sure to tell your doctor what medications you are currently taking and any allergies you might have. You will probably be asked not to eat or drink anything after midnight on the night before your procedure. You may be asked to take aspirin for one to two days prior to the procedure. If you are a patient who requires the use of medications called antacids or H-2 antagonists, please ensure that your doctor is aware of this. Your doctor will be able to advise you whether or not to stop this medication.

The procedure will be performed in a *catheterization* laboratory or a radiology suite. You will lie on an x-ray table, and a x-ray camera (*fluoroscope*) will move over your body during the procedure. Your heart and blood pressure will be monitored during the procedure.

risks of the procedure

B Be sure that your doctor has discussed the procedure in detail with you in addition to the approximate time the procedure takes. The possible risks and benefits will be explained to you and any questions you have should be answered.

The procedure itself usually involves little to moderate pain in addition to the discomfort usually experienced during the first few hours following angioplasty. During the procedure, you may be injected with the same dye you were given during the previous angiogram you might have received. Although rare, dye injection may produce an allergic type reaction causing low blood pressure and breathing difficulties.

risks and benefits
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answered

risks of the procedure (continued)

The angioplasty procedure you will undergo may involve possible risks. These risks include, but are not limited to:

- Bleeding at the access (puncture) site in your groin or arm
- Bruising, swelling at the puncture site
- Rupture of the iliac artery (dissection)
- Excessive bleeding (hemorrhage)
- Infection/fever
- Abnormal blood-filled dilation of an artery (aneurysm)
- Recurrence of the blockage (restenosis)
- Reaction to dye (*contrast media*)
- Plaque dislodgment
- Clot formation
- Stroke
- Unexpected limb loss
- Nerve damage (peripheral neuropathy)
- Heart attack (myocardial ischemia/infarction)
- Death

risks of the procedure (continued)

The risks associated with stent implantation include all risks listed on the previous page with the addition of the following:

- Increased risk of clot formation
- Movement of the stent
- Allergic reaction to the metal of the stent
- Damage to the iliac artery
- Failure to deliver the stent to the site of the blockage
- Persistent vessel spasm
- Expansion of one or more layers of the vessel wall (pseudoaneurysm)
- Dislodgment of the stent into your arterial *circulation* and it becoming permanently wedged itself into a small branch vessel in your body



the angioplasty procedure

Your procedure will be performed in a room equipped with special instruments and x-ray equipment. Once you enter this room, you will be moved onto an x-ray table. You will be covered with sterile sheets and the area where the catheter will be inserted (groin, arm, or wrist) will be shaved and washed with an antiseptic solution to prevent infection.

A numbing medication (*local anesthetic*) will be used at the site where the catheter is inserted. You may feel a stinging sensation during the administration of the medication. After the medication takes effect, you should only feel dull pressure where the doctor is working with the catheters. If the insertion is made in your inner thigh, a small tube called a sheath will be inserted into the vessel. The balloon catheter will then be placed through the sheath. If your incision is made in your arm or wrist, a guiding catheter will be inserted into the artery and advanced to the iliac arteries. Dye injected through the catheter will allow the doctor to see the area of blockage in your vessels.

the angioplasty procedure (continued)

An x-ray machine called a fluoroscope with a TV screen allows the doctor to see your vessels and the catheter as it is moved forward in your vessel. Your doctor may ask you to take a deep breath and hold it for a few seconds. When the catheter reaches the diseased area to be treated, a tiny balloon on the tip of the catheter will be inflated. The balloon applies pressure to the plaque in the vessel, causing the vessel to open and increase blood flow. It is normal to experience some pain during the balloon inflation. Please tell your doctor if you feel any pain during the procedure.



Inflated balloon catheter applying pressure to the vessel with plaque

You will be awake during your procedure. Your doctor or a hospital member may give you instructions. It is important to listen for these instructions and do what is asked.

stent implantation procedure

The procedure for stent implantation is similar to a standard angiogram procedure.

The Cordis S.M.A.R.T.[®] Stent System is introduced into the iliac artery on a catheter-based delivery system and advanced to the blocked area of the artery. The stent is self-expanding and will open to fit the artery. One or more stents may be implanted in the iliac artery depending on the extent of the disease. The delivery system is withdrawn from the body, while the expanded stent(s) remain(s) in the iliac artery.



Stented vessel

Your doctor may choose to further expand the stent with a balloon catheter similar to the one used in the angioplasty procedure. This procedure is called post-dilatation and ensures that the stent is in full contact with the vessel wall. The Cordis S.M.A.R.T.[®] Stent System stays in place permanently, holding the vessel open and improving the flow of blood.

The angioplasty and stent procedure will usually take approximately 60 to 90 minutes.

after your procedure

After the procedure, you will be moved to a special care unit where you will be closely monitored by the hospital staff. Your blood pressure and heart rhythm will be monitored continuously.

If your groin was used as an access site for the procedure, you can expect to stay in bed for several hours. The sheath will be removed within six hours of the procedure, but may be left in longer if heparin, a medication given during the procedure, is continued. While the sheath is in place, and for about six hours after its removal, you will have to lie flat on your back, keeping the sheath straight and still. You will not be allowed to bend your leg. As the sheath is removed, the doctor or nurse will apply pressure to the puncture site for 20 – 30 minutes, until the bleeding has stopped. A sandbag may be placed over the puncture site to keep pressure on it.

you will be
closely monitored
by the
hospital staff

precautions

- Should you see or feel any blood at the puncture site, notify the hospital staff immediately
- Do not try to sit up until your nurse or doctor asks you to do so
- It is important to lie flat and keep still preventing bleeding from your vessel
- If your arm was used for the procedure, you may be allowed to sit up afterwards, but you may be asked to stay in bed for several hours
- You may drink and eat foods that are light until you are fully able to sit upright. Drink all of the fluids that are offered to you. The fluids will help flush out the x-ray dye that was used during your procedure
- Your doctor may allow you to walk within 12-24 hours after your procedure, providing your puncture site is healing. A member of the hospital staff will be there to assist you



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your recovery

Before you leave the hospital, your doctor will give you guidelines for activity, diet and medications. You will be asked to avoid demanding activities like heavy lifting for at least a week. You will be advised when you can resume normal activity and return to work. Your doctor will prescribe medications for you to take to prevent blood clots from forming in your newly opened vessel. Please notify your doctor if these medications cause unpleasant reactions. **Do not stop taking them unless your doctor advises you to do so.** Different medications may be prescribed that suit you better.

Patients who undergo angioplasty and stent implantation are usually discharged from the hospital the next day. You should arrange to have someone take you home rather than driving yourself. After you leave the hospital your progress will continue to be monitored by medical personnel. **It is important to keep all of your scheduled follow-up appointments.**

usually
discharged
from the hospital
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your recovery (continued)

If you have any pain, discomfort or bleeding from your puncture site, call your doctor immediately. If your doctor cannot be reached, call 911 to be taken to the nearest hospital emergency room. You will also be asked to take aspirin. The amount of the dose will vary from 81 to 325 mg/day and will need to be taken for at least three months after your procedure. Your doctor will advise you about the exact amount of aspirin you should be taking.

The healthy lining of the vessel will slowly grow over the stent, permanently incorporating it into the vessel wall. You will not feel the stent and your daily activities will not be affected. Patients who have had a vascular stent implant should tell this to any doctor who treats them in the future.

If you require magnetic resonance imaging (MRI), the stent does not interfere with, nor is it affected by, the operation of an MRI device.

After stent placement, you will be followed closely to monitor your recovery. An ultrasound, identical to the one performed prior to the procedure may be performed to determine if any narrowing has occurred.

lifestyle changes

You and your doctor have formed a team in an effort to reduce the risk of restenosis (re-occurring blockage) in the area of your stent.

To help yourself stay healthy in the future, you are encouraged to make important diet, exercise and lifestyle changes. Some patients may need few modifications while others may need to make many changes. Those patients who are able to reduce the fats and cholesterol in their diets are less likely to redevelop blockages in the stent. A low-fat, low-cholesterol diet can lower the levels of fat in your blood and reduce your risk. Choosing to eat healthy foods in the right proportions will also help you to achieve and maintain a healthy weight.

In addition to a healthy diet, it is extremely important to avoid smoking. If you need help quitting, please notify your healthcare provider.

conclusion

You have a very important role to play in order to ensure that your angioplasty and stent implantation will be successful. It is essential that you cooperate with your doctor and follow through with your responsibilities as part of the patient/medical team. Keep your appointments and adopt a healthy lifestyle. If you have any questions or concerns, please contact your doctor to discuss them. It is important that you get the most benefit from your treatment and join the thousands of people with peripheral vascular disease who are leading healthy, productive lives.



adopt a
healthy
lifestyle

glossary

Angiogram: A procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of the artery.

Angioplasty: A procedure whereby a dilation catheter is passed through to the blocked area of an artery. Once the balloon is inflated, the catheter opens the blocked area in the artery. Also called Percutaneous Transluminal Angioplasty (PTA).

Anticoagulant: A substance that slows or prevents the clotting of blood.

Antiplatelet: A medicine that reduces the clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

Atherosclerosis: The process of fatty deposits and/or calcium build-up (plaque) on the inside of the arteries.

Balloon Catheter: A tube used for gaining access to the arteries with a tiny balloon on its tip. The balloon is gently inflated after the catheter is in position.

Blood Vessel: An artery or vein.

glossary

Catheter: A hollow tube used for gaining access to a blood vessel.

Catheterization: A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.

Cholesterol: A substance that circulates in the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fat.

Circulation: The movement of blood through the vessels of the body, which is produced by the pumping action of the heart, enabling the flow of nutrients and oxygen through the body.

Claudication: Pain in the leg that occurs with work or exercise, but may also occur when resting.

Contrast: X-ray dye used to view the arteries during an angiogram.

Diabetes: A disease affecting one's metabolism of glucose (sugar) which causes changes in the blood vessels. These changes may aid in the development of peripheral vascular disease.

glossary

Dilation Catheter: A catheter with a balloon on the end that can be inflated.

Doppler Ultrasound: A non-invasive test using sound waves to determine the presence of arterial narrowing.

Fluoroscope: Equipment used in a catheterization procedure that captures a “motion picture” x-ray image of the arteries.

Gangrene: Tissue death (necrosis), usually due to inadequate or lack of blood supply.

Guiding Catheter: A hollow tube through which fluids or objects can be introduced or removed from the body.

Hypertension: High blood pressure.

Lesion: A blockage in a blood vessel. Also known as a plaque or stenosis.

Local Anesthetic: A substance used to numb the area to which it is applied.

Lumen: The inner channel or cavity of a vessel or tube.

glossary

MRI (Magnetic Resonance Imaging): A diagnostic test that uses magnetic fields to obtain images of the inside of your body.

Percutaneous: Performed through a small opening in the skin.

Peripheral Vascular Disease: Vascular disease which affects the blood vessels, especially those of the extremities.

Plaque: An accumulation or build-up of fatty deposits, calcium and/or cell debris in an artery that leads to narrowing of the lumen.

Platelet Inhibitors: Medications to prevent blood cells called platelets from sticking together and blocking the artery.

Restenosis: The recurrence of a narrowing or blockage in an artery after treatment.

Stenosis: A narrowing of any canal, especially one of the iliac vessels.

Stent: An expandable, metallic, tubular shaped device that provides structural support for a vessel.

Thrombus: A blood clot.

glossary

Transluminal: Through the inside opening of an artery.

Triglycerides: Substances in the blood that are a component of the “bad” type of cholesterol.

Ulceration: The formation or development of an ulcer.

Vascular Closure Device: A device used to seal or close the artery puncture after an angiogram or angioplasty. Made from either collagen plugs (special fiber that seals the puncture site) or internal sutures (stitches).

Vascular System: The heart, blood, and network of blood vessels that lead to and from the heart.

contact information

Your doctor or nurse will review this material with you. We encourage you to ask them any questions regarding your treatment and recovery.

Additionally, your doctor may recommend that you join a support group to speak with others who have undergone similar procedures. Ask your doctor for contact information about these groups and possible web site addresses.

Cordis S.M.A.R.T.® CONTROL™ Iliac Stent

Indications for Use: • The improvement of luminal diameter in patients with symptomatic atherosclerotic disease of the common and/or external iliac arteries. **Contraindications:** • There are no contraindications known at this time based on the clinical data. **Warnings/Precautions:** Not recommended for patients with a history of contrast not amenable to pretreatment with steroids and/or antihistamines, or a hypersensitivity to Nitinol (nickel titanium). • Safety and effectiveness has not been demonstrated in patients with totally calcified or densely calcified lesions, uncontrollable hypercoaguability and/or other coagulopathy, pregnant women, or pediatric patients. • Use caution in patients with poor renal function who may be at risk for contrast medium reaction. • Thrombus, distal embolization, or migration may occur if correct size stent is not used. • The device should only be used by physicians trained in interventional techniques. • The long-term outcome following repeat dilatation of endothelialized stents is unknown at present. • With the exception of stainless steel stents, do not implant different metal stents where overlap or contact with the S.M.A.R.T. stent is possible. • Patients should receive appropriate antiplatelet and anticoagulant therapy prior to the procedure. • Use only in conjunction with fluoroscopy. • Do not use with power injection system. • Do not use with Ethiodol or Lipiodol contrast media. • Do not expose the delivery system to organic solvents (e.g. alcohol) • Do not re-sterilize and/or reuse the device. • The stent cannot be dragged or repositioned. • Do not attempt to recapture the stent once it is partially deployed. • Avoid stent placement that may obstruct access to a vital side branch. • Do not overstretch the stent. • When treating multiple lesions, the most distal lesion should be stented first followed by the stenting of proximal lesions. Overlap of sequential stents is necessary but the amount of overlap should be kept to a minimum. • In the event of complications such as infections, pseudoaneurysm or fistulization, surgical removal of the stent may be required. • Use caution when re-crossing a stent with adjunct devices. • In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents may be adversely affected. • Antiplatelet therapy should be maintained for at least three months post-procedure.

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