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Express™ LD

Iliac Premounted Stent System

Understanding Iliac Artery Disease
Patient Information Guide

Express™ LD

Iliac Premounted Stent System

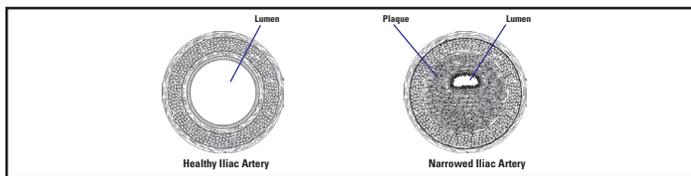
Treating iliac artery disease

Your doctor wants you to have a stent placed in your iliac artery. This is to help treat your iliac 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 about this procedure.

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

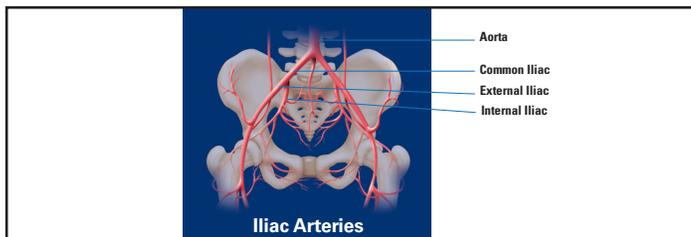
What is iliac artery disease?

Iliac artery disease is caused by the narrowing of the arteries leading to the legs. This narrowing can also be called stenosis. It is usually caused by a buildup of fat or calcium deposits called plaque. Over time, this plaque can build to a total blockage of the artery. This is also called atherosclerosis.



When a leg doesn't receive enough blood flow because of a blockage in an artery, it can cause pain in the lower leg when walking. In severe cases, low blood flow can cause tissue loss.

You have two iliac arteries, one located at the top of each leg. The iliac arteries start at the base of the aorta, just behind the navel (belly button). The iliac arteries branch into smaller arteries that supply blood to the legs and feet.



Iliac artery disease treatment options

There are four different treatment options for iliac artery disease. All four treatment options focus on increasing blood flow to the legs. The type of treatment your doctor recommends depends on your symptoms.

1. Medical therapy

For patients with mild to medium symptoms, doctors often choose medical therapy. This can include drugs, exercise, and regular checkups. Doctors also say to stop smoking. The doctor may prescribe drugs to decrease clotting, expand the arteries, lower blood pressure, and reduce cholesterol. Regular checkups can help determine if more treatment is needed.

2. Angioplasty

A procedure, angioplasty, can also treat vessel narrowing. A thin tube known as a guide catheter is inserted into the artery. A small balloon located on the tip of a catheter is moved to the site of the narrowing and inflated to reduce the blockage. The balloon is deflated and removed after the angioplasty is done. Angioplasty is less invasive than surgery, and the patient remains awake while the doctor performs the procedure.

3. Iliac artery stenting

During this procedure, a small balloon is inflated in the artery. The balloon has a small mesh tube called a stent wrapped around it. It expands the stent in the artery which keeps the artery open and helps prevent further narrowing.

4. Surgery

For patients with severe narrowing with blocked blood flow to the legs, surgery may be needed. There are two types of surgery to treat iliac artery disease. During an iliac artery endarterectomy, the doctor makes an incision in the pelvis. This exposes the iliac artery and the plaque inside the artery is removed. Patients who have this type of surgery are usually in the hospital for about a week. In an iliac artery bypass, a healthy vein is removed from another part of your body. This vein is used to make a new path around the narrowed or blocked iliac artery. Patients are also in the hospital for about a week after this surgery.

Risks

You should not have a stent placed in your iliac artery if you have any of the following conditions:

- You are unable to take medicines that make your blood take longer to clot (anticoagulants).
- You are unable to take medicines that make your blood cells slippery and make it more difficult for your blood to clot (antiplatelets).
- You are allergic to stainless steel, chromium or nickel. These are the metals used to make the Express LD Iliac Premounted Stent System.
- You have poor kidney function.

Note: It is very common for your doctor to prescribe specific medications before, during and after your stent placement. Common drugs that may be prescribed by your doctor include anticoagulants and antiplatelets. These medications are intended to help decrease the risk of forming a blood clot in your artery. Please check with your doctor to find the right medication for you.

The placement of stents in blood vessels 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 bubble(s) in your artery
- Allergic reactions
- Bleeding
- Blood clot(s)
- Bruising at your groin area
- Death
- Heart attack
- Infection

- Injury or damage to your artery or wall of the artery. This could require emergency surgery
- Leakage of blood where the catheter was inserted
- Movement of the stent from where it was originally placed
- Restenosis or re-narrowing of the artery around or within the stent
- In the event of complications, surgical removal of the stent may be required

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 if you require treatment. He or she will determine what type of treatment you need.

Benefits

The benefits of undergoing iliac stent placement can be improved blood flow to the legs through the artery being treated. If you had symptoms before surgery, they might improve or go away.

Summary of clinical data

The safety and effectiveness of the Express LD Premounted Stent System was compared to the Palmaz™ Stent in the International MELODIE study. It included 151 patients. The study results showed that patients who received an Express LD Stent had similar blood vessel narrowing at six months compared to patients who received a Palmaz Stent. The occurrence of major adverse events was 6.3% at 6 months and 10.2% at 2 years for the Express LD Premounted Stent System. Major adverse events include death, repeat angioplasty and distal embolization. The long term outcome (beyond 24 months) for this permanent implant is unknown.

Before your procedure

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

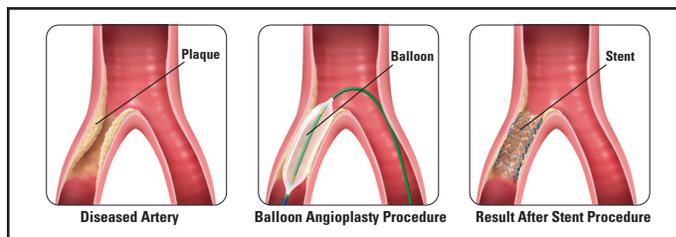
- Tell your doctor about any medications you are taking, and bring the medications to your appointments.
- Let your doctor know about any allergies you have. It is important he or she knows about allergies to contrast dye, iodine, cobalt, chromium, nickel, titanium, stainless steel or plastics.
- Tell your doctor if you cannot take aspirin or blood thinning medicines. These medications are usually prescribed before and after 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.
- Make sure you understand the possible risks and benefits of your iliac stent procedure.
- You could be given a sedative to relax you before starting your stent procedure. The sedative can make you sleepy.

During a typical iliac stenting procedure

1. A small puncture is made in your groin. A needle is used to gain access to the femoral artery. This wire is then fed through the femoral artery and moved up into the iliac artery. A catheter is then put in your body. The doctor moves it to the narrowed section of your iliac artery. All wire and catheter movement is done using x-rays for a guide.
2. 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 wire and through

the catheter to the blocked area of the iliac 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.

3. 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.
4. After the stent is implanted, the catheter and wire are removed and the puncture site in your groin is closed. The stent remains in place and is designed to help keep the artery open and prevent future narrowing of the iliac artery.



Images courtesy of Boston Scientific. Images are for illustration purposes only, and are not necessarily to scale.

After a typical iliac 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.
- Your heart rate, blood pressure, brain function and the entry site in your groin will be checked frequently.
- You will be asked to drink a lot of liquids to flush the contrast dye out of your system.
- You will have to stay in bed for several hours. You will be asked to keep your leg straight so the entry site in your groin can heal well.
- You may need a short hospital stay.
- You should alert your doctor or nurse if you experience any of these symptoms
 - Leg or foot pain
 - Unusual coldness and/or pallor in the leg or foot
 - Numbness in the leg or foot
 - Reappearance of the symptoms you had before treatment
 - Pain, bleeding or infection at the entry site in your groin
- You should avoid straining yourself or lifting items heavier than 5 pounds until your doctor lets you know that it is okay to do so.

Your stent implant card

Your stent implant card tells doctors, dentists and nurses that you have a stent implanted in your iliac artery. This card also has:

- The doctor who put in your stent
- The doctor's phone number
- The date the stent was put in
- Where the stent was placed in your Iliac artery
- The size of the stent
- The manufacturer's lot number for the stent

The card gives your doctors, dentists and nurses information that is needed if you have any special diagnostic tests such as:

- MRI

There are also phone numbers on the card that your doctors can call if they have any questions. Your discharge nurse will fill in the card. If he or she does not, please call the doctor who placed the stent for this information.

Living with Iliac artery disease

Treatment for iliac artery disease includes controlling things that cause the disease. You cannot control some risk factors. You cannot change your age, gender, ethnic background or family history. However, you can change many of the risk factors for this disease.

Your doctor may suggest the following healthy lifestyle changes:

- Lose excess weight
- Quit smoking
- Exercise regularly
- Control stress and anger
- Decrease fat in your diet
- Limit alcohol consumption

Reducing your risk factors can also have a positive impact on the long-term success of iliac artery disease treatment. Talk to your doctor today about how to increase your chances for a healthier outcome and a more rewarding life with iliac artery disease.

Glossary

Angioplasty

A minimally invasive treatment of the arteries that opens blocked arteries.

Anticoagulant and Antiplatelet

Medicines that slow down the clotting of blood.

Artery

A blood vessel that carries oxygen-rich blood away from the heart to the rest of the body.

Atherosclerosis

A disease in which the flow of blood is slowed down by plaque in the arteries.

Balloon Angioplasty

Inflating a balloon catheter in the blood vessel to open a blocked artery.

Balloon Catheter

A thin tube with a balloon attached to the tip that can be inflated to open blocked arteries.

Blood Vessel

Any of the veins and arteries that carry blood to and from the heart.

Catheter

A long, flexible tube that can be passed through the blood vessels.

Contrast

X-ray dye used in diagnostic tests.

Claudication

Pain that develops in the calf muscles of the legs. It can cause limping and an inability to walk long distances.

Femoral Artery

The blood vessels that supply blood to the legs.

Iliac Arteries

The blood vessels that supply blood to the legs.

Iliac Artery Bypass

A surgical procedure used to create an alternate route for blood to flow to the legs around narrowed or blocked iliac arteries.

Iliac Artery Endarterectomy

A surgical procedure that removes plaque from the walls of the Iliac arteries.

Minimally Invasive Procedure

A procedure that uses small instruments or devices to reduce the size of the insertion site and cause a smaller amount of trauma

MRI (Magnetic Resonance Imaging)

A method of using a magnetic field and radio waves to produce detailed images of the inside of the human body.

Occlusion

Blockage of blood flow in the artery.

Peripheral

Related to areas of the body outside the heart and brain.

Plaque

A buildup of cholesterol, fat calcium and collagen in a vessel.

Restenosis

Re-narrowing of the artery after treatment.

Sedative

A type of medication that makes you relaxed and sleepy. Also called sedation.

Stenosis

A narrowing of the artery.

Stent

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

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To order product or for more information contact customer service at 1.888.272.1001.

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Magnetic Resonance Image (MRI) Safety Information



Non-clinical testing has demonstrated that the Express™ LD Stent is MR Conditional for single and overlapped conditions up to 101 mm. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla only
- Maximum spatial gradient magnetic field of 1900 gauss/cm or less)
- Maximum system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) for landmarks above the umbilicus and 1 W/kg for landmarks below the umbilicus

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the Express LD Stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact obscures the device lumen.

RECOMMENDATIONS

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

PLEASE CARRY YOUR CARD AT ALL TIMES.

Please ask your physician for a copy of the Patient Information Guide. Additionally, the Patient Information Guide for this product is available from the Express™ LD Iliac website. To view, download or print the Patient Information Guide, go to www.bostonscientific.com/expressld. You may also request a hard copy of the Patient Information Guide by calling **1.888.272.1001**.

_____	_____
Patient Name	Implanting Physician's Name
_____	_____
Date of Birth	Hospital
_____	_____
Date of Implant	City/State

	Phone Number

Stent Identification Information

Product Name: _____	Product Name: _____
Product Lot Number: _____	Product Lot Number: _____
Stent Location: _____	Stent Location: _____

Product Name: _____	Product Name: _____
Product Lot Number: _____	Product Lot Number: _____
Stent Location: _____	Stent Location: _____

For more information about indications, contraindications, warnings and instructions for the Express™ LD Iliac Premounted Stent System, visit www.bostonscientific.com.

You can also call Boston Scientific customer service at 1.888.272.1001 to request copies of the Directions for Use (DFU).

CAUTION: Federal (USA) law restricts these products to sale by or on the order of a doctor.

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