

Patient Guide to the PALMAZ MULLINS XD™ Pulmonary Stent

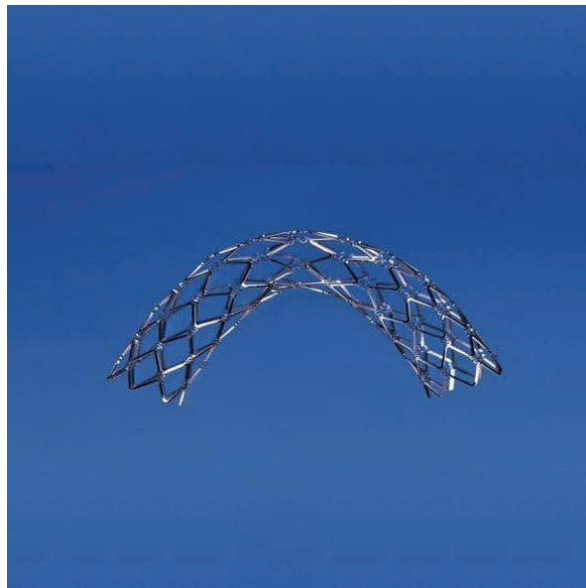
This brochure is intended to provide you with general information about the PALMAZ MULLINS XD™ Pulmonary Stent. The information in this guide is not an alternative to medical advice from your physician. If you have any specific questions about any medical matter, you should consult your physician.

What is Pulmonary Artery Stenosis?

Pulmonary artery stenosis is a narrowing in one or more of the branches of the pulmonary arteries. These are the blood vessels that carry blood from the heart to the lungs. Pulmonary artery stenosis can cause a lack of oxygen in the blood. It may also put increased pressure on the heart, making the heart work harder. Over time, this can cause damage to the heart muscle. In some cases, pulmonary artery stenosis may get worse over time.

The PALMAZ MULLINS XD™ Pulmonary Stent

The PALMAZ MULLINS XD™ Pulmonary Stent may be used to treat a narrowed pulmonary artery. PALMAZ MULLINS XD™ Pulmonary Stent is a stainless-steel metal mesh tube that is placed inside a narrowed artery and expanded to widen it. This device contains stainless steel, which contains nickel. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. You should let your doctor know if you have a nickel allergy.



What are My Treatment Options?

You should discuss with your doctor to learn about the best treatment option for you; however, there are a few standard approaches of which you should be aware.

One option is to take medication.

Another option is opening the narrowed artery. The narrowed artery may be opened using one of the following approaches:

- **Balloon dilation (angioplasty):** A small, thin tube (catheter) is inserted into a blood vessel in the groin and guided to the inside of the narrowed artery. The tube has a deflated balloon at the tip. When the catheter is placed in the narrowed artery, the balloon is inflated to widen the narrowed artery. The balloon is then deflated and the catheter with the balloon is removed from the body.
- **Balloon dilation and stent placement:** A stent (metal mesh tube) placed on a small, thin tube (catheter) with a deflated balloon at the tip is inserted into a blood vessel in the groin. Together, the catheter and stent are guided to the inside of the narrowed artery, where the balloon is inflated to expand the stent against the pulmonary artery wall, which widens the narrowed part of the artery. The balloon is then deflated and the catheter is removed from the body. The stent permanently stays in the body to hold the vessel open.
- **Surgery:** Pulmonary artery stenosis can also be repaired by surgery. The surgeon may use different methods depending on what the narrowed artery and other blood vessels look like.

Is the PALMAZ MULLINS XD™ Pulmonary Stent Right for You?

Your doctor can help you decide if the PALMAZ MULLINS XD™ Pulmonary Stent is the right treatment for you.

The stent should not be used in patients:

- who have an active infection
- who have an aneurysm, dissection, or in-situ thrombus (blood clot) formation at the treatment site
- in whom there is an inability to cross the narrowed vessel segment safely
- who have a vessel too small for the delivery system

About The Procedure

The procedure is usually performed in a special radiology room, called the catheterization laboratory (cath lab, for short). Your physician will place the PALMAZ MULLINS XD™ Pulmonary Stent on a catheter that has a deflated balloon at the tip (balloon catheter). The balloon catheter with the stent is placed through the skin, typically into a blood vessel in the groin. The catheter is threaded through the blood vessels toward the heart until it reaches the narrowed artery. The PALMAZ MULLINS XD™ Pulmonary Stent is then placed across the narrowed part of the artery. Once in position, the balloon is inflated to expand the stent against the pulmonary artery, which widens the narrowed part of the artery. The balloon is then deflated and the catheter is removed from the body. The PALMAZ MULLINS XD™ Pulmonary Stent stays in the body and is a permanent implant.

Once the procedure is finished, the patient will return to a recovery room to be closely monitored. Please consult with the patient's physician and/or care staff with any questions about care or discharge.

The following is general information regarding the PALMAZ MULLINS XD™ Pulmonary Stent placement procedure and some general post-procedure guidelines. Please consult your physician regarding any questions about the implant or recovery instructions.

What Happens After the Procedure?

The patient's physician will determine the need for post-implant medications and activity limitations. The following transient conditions may occur.

- Mild tenderness at the catheter insertion site
- Some bruising or discomfort at the catheter insertion site

The pressure dressing over the catheter insertion site will be removed by your care team.

Discharge

The patient's physician will determine whether the patient is discharged the same day or if an overnight stay is required. Some factors that may affect how long before a patient is discharged include, but are not limited to:

- The type and severity of your disease
- Size/age of patient
- Hospital protocol
- Medications given during the procedure
- Time of day procedure occurs
- Need for further tests
- Access to care facilities/social situation

Please consult with the patient's physician with any questions on plans for post-op and follow-up care.

Please immediately contact the patient's physician if the patient experiences any of the following signs and/or symptoms.

- Persistent tenderness or pain, swelling, bruising, bleeding or oozing at the catheter insertion site
- Increasing redness or warmth at the catheter insertion site
- Numbness or tingling at the catheter insertion site
- Drainage from the catheter insertion site
- Non-healing wound
- Fever or chills

- Any other unusual symptoms or concerns

Taking Care of the Catheter Insertion Site

- Instructions will be given to you by your physician. Follow the physician's care instructions for the catheter insertion site.
- It is important to keep the site clean and dry until healing has completed.
- It is important to follow these instructions to produce the best possible results from your procedure. Follow-up visits are often recommended.

Modify Activity as Directed

- Your doctor can provide guidelines for activities and medications. Follow your physician's instructions before resuming or modifying activity. Your doctor may prescribe drugs that you should take at home to continue your treatment and recovery. The decision to prescribe drugs is at the discretion of your doctor. Many doctors require multiple follow up appointments to ensure your recovery is going well.

Growing Patients

As a patient continues growing, they may need to have another procedure performed using a balloon catheter to attempt to widen (dilate) the implanted PALMAZ MULLINS XD™ Pulmonary Stent. This may or may not be successful. The patient's physician will determine the timing for any future widening of the stent (dilations), if necessary.

Will I be able to feel the device?

No, you will not be able to feel the device once it is implanted.

What are the Possible Benefits of the PALMAZ MULLINS XD™ Pulmonary Stent Placement?

The possible benefit of treatment with the PALMAZ MULLINS XD™ Pulmonary Stent is the widening of a narrowed artery to allow for better blood flow.

What are the Possible Side Effects or Complications of the PALMAZ MULLINS XD™ Pulmonary Stent Placement?

As with any medical procedure, there is a chance of side effects or complications during or after the PALMAZ MULLINS XD™ procedure, which may be serious, including death. Complications that may occur during or after this procedure include:

- Irregular heartbeat (arrhythmia)
- Bleeding at the site of where the device is introduced into the body
- Creation of an abnormal passageway between an artery and vein (fistula formation)
- Coughing up blood or blood-stained mucus (hemoptysis)
- Low blood pressure (hypotension)
- Infection
- Clot formation in the stent (in-stent thrombosis)

- Decreased oxygen to tissue due to decreased blood flow (ischemia/reperfusion injury)
- Blockage of vessels that come out of the main pulmonary arteries (Jailed side branches of the pulmonary arteries)
- Heart attack (myocardial infarction)
- Obstruction
- Bulge or tear in the pulmonary artery (pulmonary artery aneurysm, dissection or rupture)
- Blockage in the pulmonary artery because of a blood clot (pulmonary artery thrombosis/thromboembolism)
- Fluid in the lungs (pulmonary edema)
- Recurrence of the blockage in the artery (restenosis)
- Partial or complete break in the stent (stent fracture)
- Failure to deliver the stent to the site of the blockage, movement of the stent or clot formation requiring additional treatment including surgical removal (Stent malposition, dislodgement/migration or embolization requiring transcatheter or surgical adjustment or retrieval)
- Reduction or complete blockage of blood supply to the brain (stroke or transient ischemic attack)
- Tear, injury, or rupture of vessels

Additional Information

If a PALMAZ MULLINS XD™ Pulmonary Stent is used during the procedure, a separate Stent Implant Card will be given prior to leaving the facility. This card contains information about the physician, facility, and the specific device that was implanted. The purpose of this card is to provide important information to healthcare providers who may be unfamiliar with this type of stent, including information on the MRI safety and compatibility of the stent. Keep this card in a safe place and accessible when needed. We recommend keeping a digital copy for easy reference.

MRI Compatibility

Please refer to the Stent Implant Card for Magnetic Resonance Imaging (MRI) Safety Information. Please consult the patient's physician regarding your stent and MRI considerations. If you need an MRI scan, tell your doctor or MRI technician that you have a PALMAZ MULLINS XD™ Pulmonary Stent.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions.

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