

Edwards Transcatheter Mitral Valve Repair

*A guide for patients
with mitral regurgitation*



The Edwards PASCAL Precision Transcatheter Valve Repair System



This patient guide is for those who have significant mitral regurgitation (MR) and are considered at prohibitive risk for mitral valve surgery by your Heart Team.

The information in this booklet will help you understand more about a less invasive procedure called transcatheter mitral valve repair.

Be sure to ask your Heart Team to explain all of your treatment options and the possible risks and benefits of each.



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Edwards Lifesciences is the global leader in patient focused medical innovations for structural heart disease and has been helping critically ill patients for over 60 years. Driven by a passion to help patients, Edwards works to improve outcomes and enhance the lives of patients.

The Edwards PASCAL Precision system is designed to repair the mitral valve and help reduce mitral regurgitation.



What is mitral regurgitation (MR)?

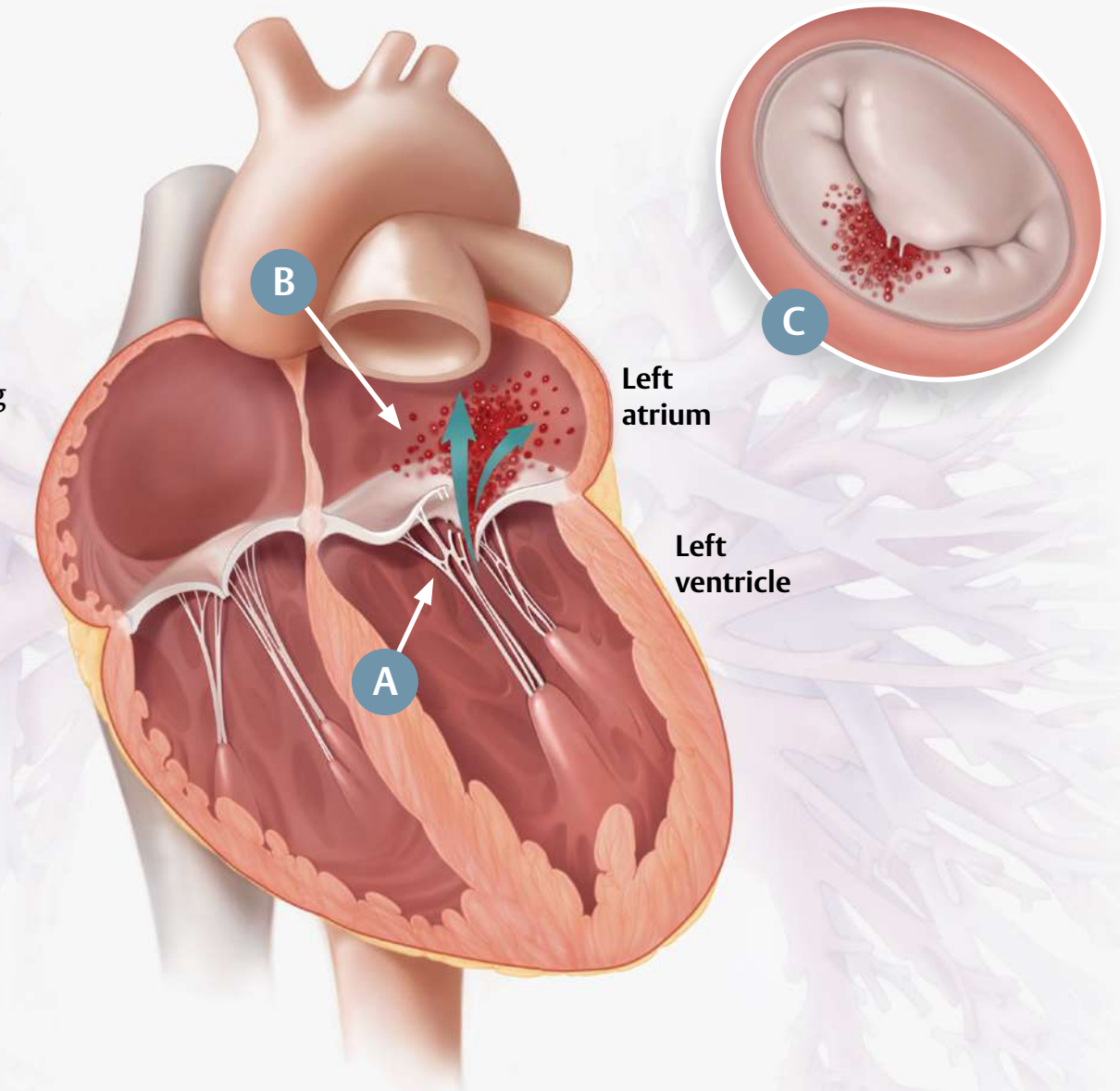
Mitral regurgitation is a condition in which the leaflets of the heart's mitral valve do not close properly, and blood flows backward from the left ventricle into the left atrium during contraction of the heart muscle.

One of the causes of mitral regurgitation is abnormality of the mitral valve leaflets and/or its structure, and it may be referred to as Degenerative MR or Primary MR by your doctor.

Because of this condition, it is difficult for your heart to move blood through to the rest of your body efficiently. It may make you feel tired or out of breath, and it may cause an overall decrease in your quality of life.

Heart with Degenerative Mitral Regurgitation

- A** A structural problem with the valve's leaflets prevents them from closing properly
- B** Blood flows backward through the valve
- C** Top view of leaflets showing blood escaping through valve during closure



Understanding Your Treatment Options

If you have mitral regurgitation and your doctor has evaluated you as prohibitive risk for open heart surgery, transcatheter valve repair may be an option for you. Only a specialized Heart Team can determine which treatment option is appropriate for you.

There are a few different ways to treat degenerative mitral regurgitation. Two common methods include treating with medical therapy, or repairing the mitral valve in order to prevent backward leakage and help blood flow properly.

Transcatheter Mitral Valve Repair

This treatment is a less invasive method performed through a small incision in the leg. Your doctor places a thin tube called a catheter through a delivery system into a large vein in your leg to reach your heart, and then implants a small device to repair the mitral valve.

What Are the Benefits of Treating Mitral Regurgitation?

Treating mitral regurgitation is key to maintaining your heart health, and could make a difference for your quality of life.

What Is the Best Treatment Option for You?

A specialized doctor on a Heart Team will evaluate you for treatment options. They will consider factors about your health to decide the most appropriate treatment option for you.

Your doctor will consider these factors:

- Your medical history
- Your age
- Your current health status
- Your ability to undergo the procedure and recover from it
- The overall condition of your heart



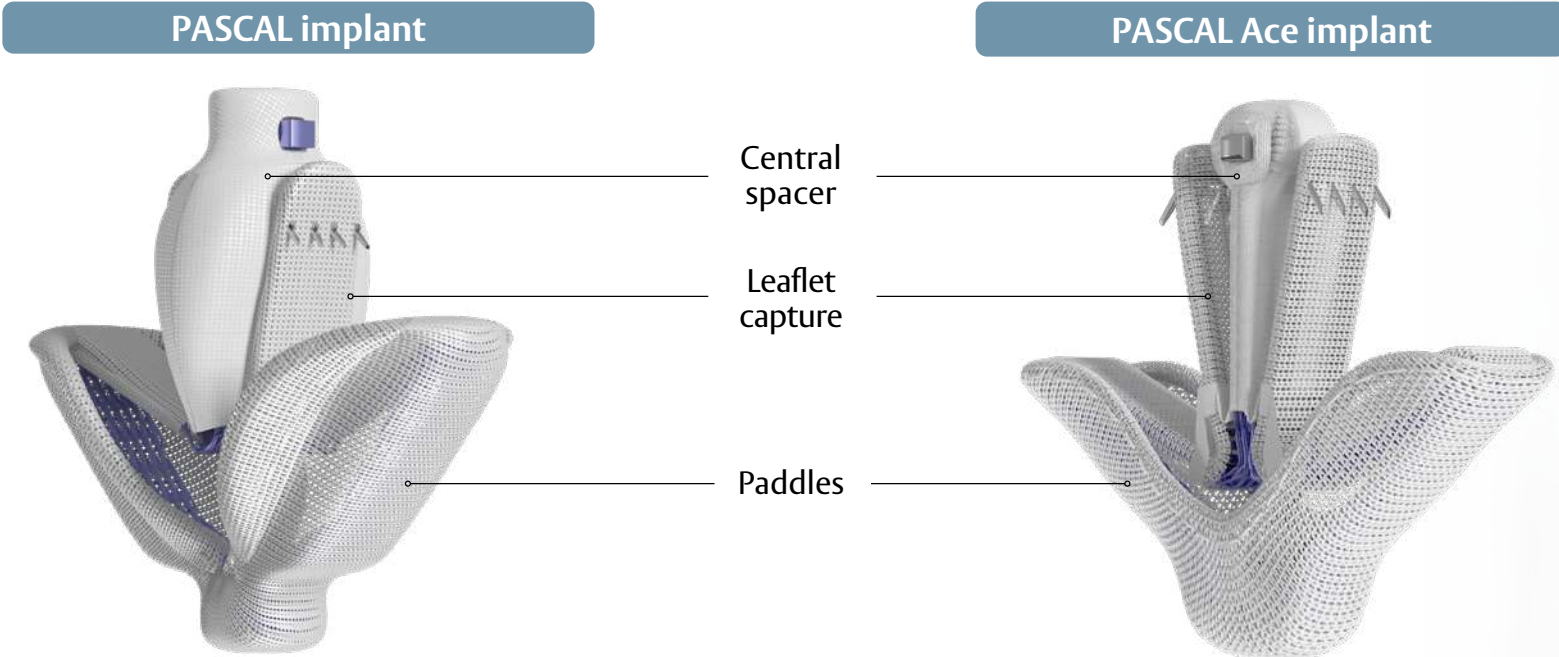
The Edwards PASCAL Precision System – Implant

Designed to repair the mitral valve and help reduce mitral regurgitation

The PASCAL Precision implant system delivers the PASCAL implant to your mitral valve via a catheter-based delivery system through your femoral vein.

The implant is secured to the leaflets of your mitral valve and the central spacer acts as a filler in the regurgitant opening.

The PASCAL Precision system has two implant sizes (below) and your physician will select the best implant option for your anatomy.



Images are larger than actual implant size.



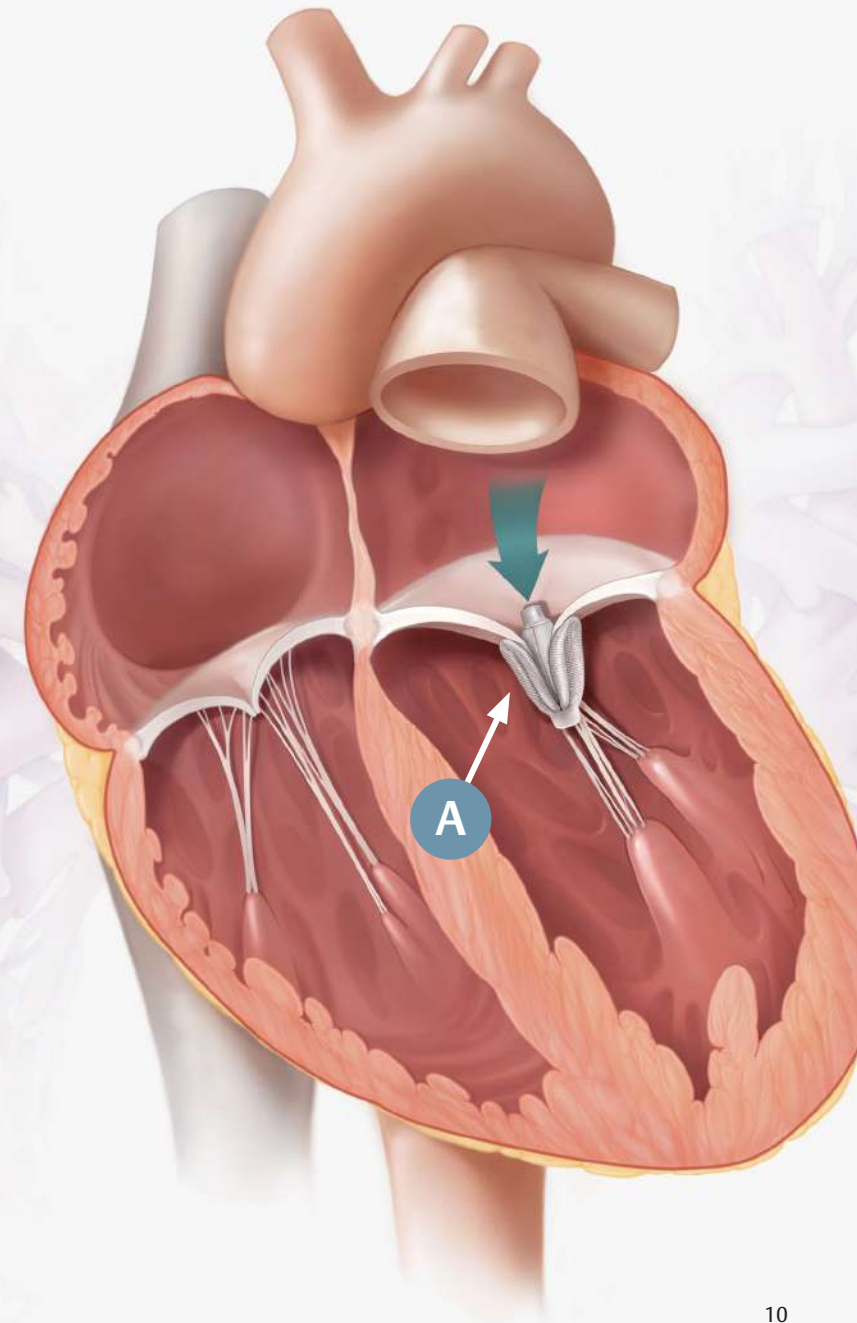
The Transcatheter Valve Repair Procedure

This section describes what happens during transcatheter mitral valve repair. It is intended as a general overview, and your experience may be different. Please talk to your doctor for more information about what you should expect.

- A**
1. Your doctor will make a small cut in your groin area to access the largest vein there.
 2. Your doctor will then insert a tube-like device (delivery catheter) through the small cut and direct it to your mitral valve under imaging guidance. The PASCAL implant is attached to the tip of the delivery catheter.
 3. Once the implant is properly positioned in your mitral valve, your doctor will grasp the two leaflets of your mitral valve and secure them together.
 4. Lastly, your doctor will release the implant from the delivery catheter and remove the delivery catheter from your body.

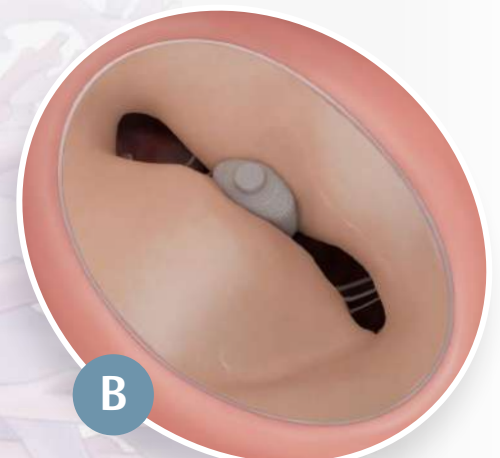


On average, the transcatheter valve repair procedure lasts 1.5–2 hours.



A

B Top view of leaflets with PASCAL implant in place



B

What Happens After the Transcatheter Mitral Valve Repair Procedure?

After your procedure, you may spend a number of days in the hospital. Every patient is different in how they recover.

Before you leave the hospital, your doctor will discuss your aftercare plan with you. They will give you specific instructions to help you with your recovery.

It is important to carefully follow your doctor's directions, especially if you need to take any blood thinning medication.

Transcatheter Mitral Valve Repair Follow-Up Visits

Regular check-ups with your doctor are very important. You may be asked to return to your doctor to have your heart valve checked at 30 days and up to 5 years after your procedure.

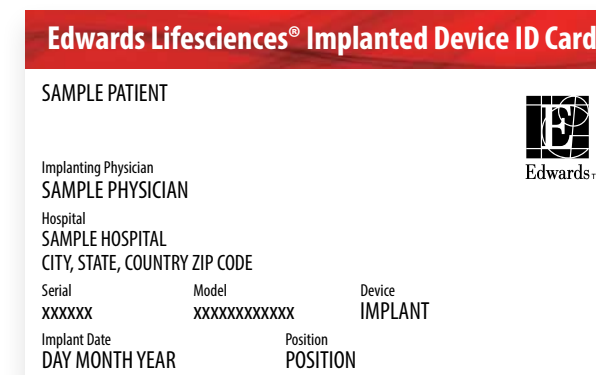
However, call or see your doctor whenever you have questions or concerns about your health.

Your Edwards Implant Card

As you leave the hospital, your valve clinic coordinator or nurse should give you an implant card.

This card has information about your Edwards PASCAL Precision heart valve repair implant.

It is important to inform all members of your healthcare team about your heart valve repair. Show this card before any future medical or dental procedures. If you need an MRI (magnetic resonance imaging), tell your doctor you have a PASCAL implant.



For more information on your implant card, please go to [Edwards.com](https://www.edwards.com)



Edwards Transcatheter Valve Repair Clinical Data

If you were to undergo mitral valve repair with the PASCAL Precision system, the risks you could expect are shown in the following table. These risks were based on a clinical study of the PASCAL Precision system.

Transcatheter Mitral Repair with the PASCAL Precision System		
Major Complications	Risk within 30 days	Risk within 6 months
Death from any cause	2 out of 100	5 out of 100
Death from a heart related cause	1 out of 100	1 out of 100
Stroke	1 out of 100	1 out of 100
Heart attack	1 out of 100	1 out of 100
Kidney failure requiring dialysis	1 out of 100	1 out of 100
Severe bleeding	3 out of 100	4 out of 100
Unplanned repeat procedure or surgery	1 out of 100	2 out of 100



What Are the Risks?

As with any medical procedure, there is a possibility of risks.

The most serious risks are:

- Death
- Stroke
- Serious bleeding
- Unplanned repeat procedure or surgery

The PASCAL Precision system cannot be used in people who:

- Cannot tolerate certain blood thinners during or after the procedure
- Have an untreatable allergy to nickel, titanium or X-ray contrast media
- Have an active infection of the mitral valve (endocarditis)
- Have mitral regurgitation caused by rheumatic disease
- Have evidence of blood clots in the heart or veins leading to the heart

Additional potential risks associated with the procedure include:

- Abnormal heart rhythms or cardiac arrest, which may require a pacemaker
- Abnormal low or high blood pressure
- Allergic reaction to anesthetic, contrast, heparin, Nitinol (Nickel and Titanium) and/or other medications
- Aneurysm or pseudoaneurysm
- Bleeding, stomach bleeding, hemolysis, or decreased blood count, which may require transfusion
- Blood clots in the legs (Deep Vein Thrombosis)
- Blood clots, particles, catheter fragments or air in the blood vessels, lungs, body or brain
- Cardiogenic shock
- Chest pain
- Damage or puncture of the heart or blood vessels that may require surgery
- Damage, injury to, narrowing, or tearing of the mitral valve or other valve structures
- Damage to the swallowing passage (esophagus), with possible puncture or narrowing
- Dislodgement of a previous implant
- Failure to retrieve any PASCAL Precision system components
- Fever or infection, including of the heart valve
- Fluid or blood around the heart or lungs
- Heart attack
- Implant deterioration (wear, tear, fracture or other), malposition, clotting, movement or embolization
- Kidney failure
- Lab values that are not normal
- Nerve injury, paralysis or neurological symptoms, including problems with movement or walking
- Organ failure, including heart failure
- Pain
- Respiratory compromise that may require prolonged need for a respirator
- Shortness of breath, fainting or dizziness, nausea, swelling, weakness, diminished exercise ability
- Skin burn, injury or tissue changes due to exposure to X-rays
- Single leaflet device attachment (SLDA)
- Vascular injury or trauma, including decreased blood flow, dissection or occlusion
- Worsening of valvular insufficiency
- Wound healing infection or slow healing



Warnings

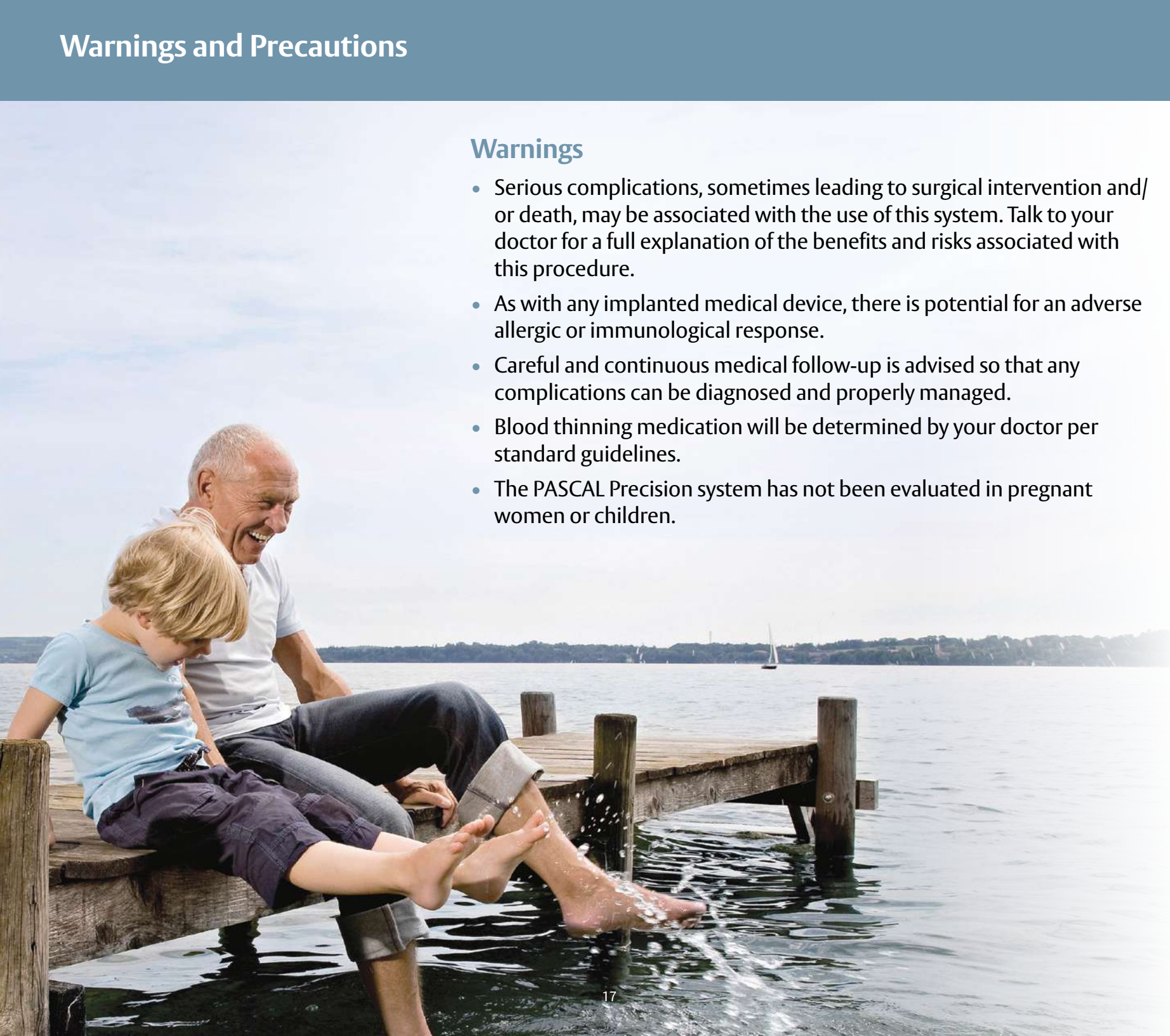
- Serious complications, sometimes leading to surgical intervention and/or death, may be associated with the use of this system. Talk to your doctor for a full explanation of the benefits and risks associated with this procedure.
- As with any implanted medical device, there is potential for an adverse allergic or immunological response.
- Careful and continuous medical follow-up is advised so that any complications can be diagnosed and properly managed.
- Blood thinning medication will be determined by your doctor per standard guidelines.
- The PASCAL Precision system has not been evaluated in pregnant women or children.

Precautions Prior to Use

Your heart team will do an assessment to decide if you are a suitable candidate for this procedure.

Precautions After Use

- Follow all care instructions to ensure the best possible results. Regular follow-up is advised to evaluate the performance of your device.
- Short-term blood thinning medication may be necessary after valve repair with the PASCAL Precision system. Your doctor should prescribe this and other medical therapy per standard guidelines.



For More Information about the Edwards Transcatheter Valve Repair Procedure:

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CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

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