

What to ask before your transcatheter mitral valve repair

How to talk to your doctor
about the PASCAL Precision
system procedure



If you are reading this guide, you may be considering transcatheter edge-to-edge repair (TEER) as a treatment option for your degenerative mitral regurgitation.

As with any procedure, you may have questions and concerns. Your Heart Team is there to answer your questions and help you feel more prepared for your procedure.



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As you plan for your procedure, you will likely have a lot of questions for your Heart Team. You can refer to this guide when you talk with them. Here are some things to ask your cardiologist in the weeks and days leading up to your procedure:

Before your procedure

- Are there any risks I should consider?
- Do I need to modify my physical activity leading up to my procedure?
- Do I need to change what I eat leading up to my procedure?
- Should I continue taking my medications as normal up to the day of my procedure?
- What allergies should I tell my cardiologist about?
- Do I need to set up any other specialist or doctor's appointments before my procedure?
- How do I make sure my insurance covers my procedure?
- What do I need to do for pre-admission testing?

The day of your procedure

- How late can I eat the night before?
- What can I eat and drink on the day of my procedure?
- What should I pack for the day of my procedure?
- Do I need to bring any documents?
- Are there any special bathing instructions I should follow?
- Can I take my medications as usual?
- Do I need to bring my medications with me?
- How long will my procedure last?
- How much pain should I expect? How long does the pain usually last?
- How soon after the procedure is it okay to get out of bed and start walking?
- Who will care for me during my hospital stay?
- How will my doctor know the procedure was successful?
- How long will I be in the hospital?
- Do I need someone to drive me home?
- When I go home, will I need help?

After your procedure

- How soon will I feel better?
- When can I go back to my usual daily activities?
- How much and what type of exercise is safe for me?
- Will I be able to feel the device in my heart?
- What will my follow-up appointment schedule look like?
- Will I have stitches? If so, how long will they stay in?
- How do I take care of my incision site? Will I have a scar?
- Will I be in pain?
- How will I manage any pain?
- When can I resume taking the medications I was taking before my procedure?
- Will I be on blood-thinning (anticoagulation) medication? If so, for how long?
- What symptoms should I watch out for and call the doctor about?
- Can I have an MRI, X-ray or CT scan?
- Is it safe to have radiation/chemotherapy treatment with my device?
- What do I need to do before any upcoming dental procedures?
- Can I go through airport security or metal detectors with my device?
- Will I get an implant card?
- How can I keep my heart healthy?

Is there anything else I should know about my procedure?

Talk with your doctor if you notice any change in the way you feel, especially if something does not feel right.

My doctor's contact info:

My procedure plan:

Important Risk Information

Edwards PASCAL Precision Transcatheter Valve Repair System

Who can be treated:

The PASCAL Precision transcatheter valve repair system (the PASCAL Precision system) is approved for treating patients with abnormality of the mitral valve leaflets and/or its structure, which may be referred to as Degenerative Mitral Regurgitation or Primary Mitral Regurgitation. Patients should work with their doctor and a specialized Heart Team, which should include a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, to confirm their surgical risk. The specialized Heart Team will determine if the patient is a suitable candidate for the PASCAL procedure.

Who should not use:

The PASCAL Precision system should not be used in patients 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

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:

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.

Potential Risks

The most serious risks associated with the procedure are:

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

Additional potential risks 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 and/or vomiting, 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

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indication, contraindications, warnings, precautions and adverse events.

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