Edwards Lifesciences

Transcatheter Mitral Valve Repair

A guide for patients with mitral regurgitation

This patient brochure is for those who have severe mitral regurgitation (MR) and are considered at prohibitive risk for mitral valve surgery by their specialized care team. The information in this brochure will help you understand more about mitral regurgitation and a minimally invasive procedure called transcatheter mitral valve repair.

The Edwards PASCAL transcatheter valve repair system is designed to repair the mitral valve and reduce mitral regurgitation.[1,2]

Ask your specialized care team to explain this treatment option and the possible risks and benefits.

Learn more at www.TreatMyValve.com/gb

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What is Mitral Regurgitation (MR)?

As your heart pumps blood throughout your body, four valves open and close to help blood flow at the right time and in the right direction. The heart's four valves are called aortic, mitral, pulmonary, and tricuspid.

Mitral regurgitation is a condition in which the mitral valve doesn't close properly, causing blood to leak back through the valve. MR is the most common type of heart valve disease.[3,4]

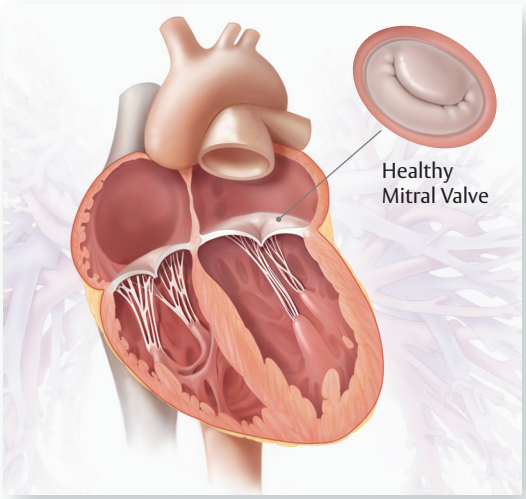
Because this leakage can reduce overall blood flow, the heart must work harder to get enough blood to the rest of the body. MR can worsen over time and you may not develop symptoms until the condition is severe.[5]

With MR, you may experience symptoms that cause an overall decrease in your quality of life:

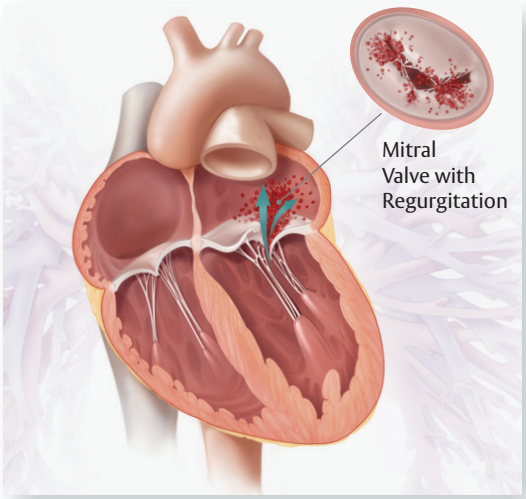
- Shortness of breath
- Fatigue
- Heart palpitations
- Swelling in your feet, ankles, or abdomen[5]

There are two types of mitral regurgitation: primary (also called degenerative) and secondary (functional). Primary MR is a disease that is commonly caused by an abnormality of the valve structure. Secondary MR is the result of left ventricle or left atrium abnormalities/disease.[6]

Healthy Heart



Heart with Mitral Regurgitation



What is Transcatheter Mitral Valve Repair?

Transcatheter mitral valve repair (TMVr) is a catheter-based procedure to repair your mitral valve. Unlike traditional heart surgery, in which the surgeon cuts through the chest wall and then the heart to access the valve, TMVr involves implanting a device through a small incision in your groin.

The Procedure

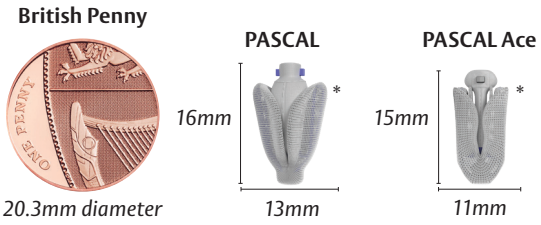
The following is a general overview of the procedure:

1. While you are under general anesthesia, your doctor will make a small incision in your groin to access your femoral vein. They will then insert a tube-like device called a delivery catheter. The implant is attached to the tip of the delivery catheter
2. The implant will be guided to your mitral valve using imaging equipment
3. The implant will be positioned to clasp together your mitral leaflets to reduce the blood leak
4. After verifying the final position of the implant, your doctor will release it from the delivery system. The implant will stay in your heart[2]

The Edwards PASCAL Transcatheter Valve Repair System for MR

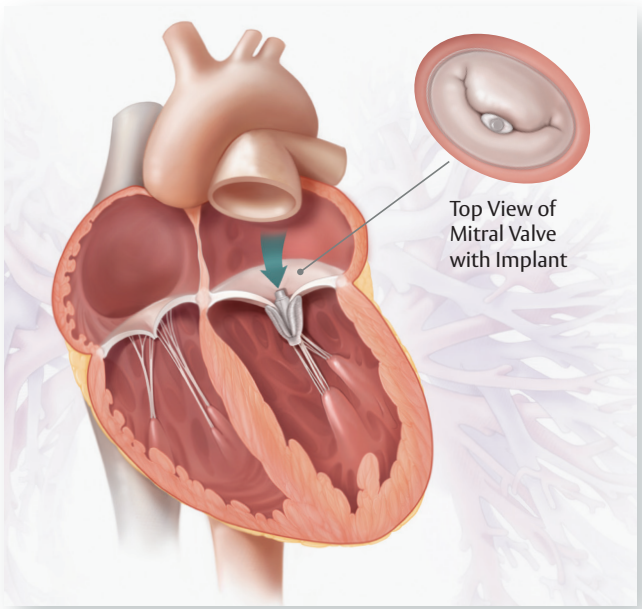
The Implants

The PASCAL and PASCAL Ace implants are made of nitinol (nickel and titanium) and have paddles that clasp the leaflets of the mitral valve together. Your physician will determine the best implant option for your valve.



*Actual implant size comparison shown

The implant will be placed in between your mitral valve leaflets. It is designed to prevent blood from leaking back through the valve.[2]



Safety & Efficacy

85%
reduction in annual heart failure hospitalization rate[1]*

93%
of patients achieved moderate to no MR[1]*

*Results at three-year post-procedure follow-up

Patients experienced improved quality of life[1]* and exercise capacity[1]

As with any implanted medical device, there are risks associated with this procedure. Talk to your doctor for a full explanation of the benefits and risks.[2]

Frequently Asked Questions

- **How long will the procedure take?** Although procedure times may vary due to your anatomy and the severity of your condition, on average the procedure takes 90 minutes.[7]
- **How long will I stay in the hospital after the procedure?** After your procedure, you may spend a few days in the hospital.[7] Before you leave the hospital, your doctor will discuss your aftercare plan to help with your recovery.
- **What can I expect after the procedure?** Regular check-ups with your doctor are very important. You may be asked to return to your doctor for a follow-up appointment and to have your heart valve checked after your procedure.
- **When can I resume my regular activities?** It is important to carefully follow your doctor's directions, especially if you need to take any medications. Ask your doctor if and when you can resume other medications, travel, exercise, and other medical procedures like dental work.
- **Is it safe for me to have an MRI scan?** Mitral implants are MRI-conditional, which means they can be safely scanned under certain conditions.[2] Please tell your physician that you have a mitral implant if you are considering an MRI.
- **How long will my implant last?** The implant should not need to be replaced. Your cardiologist will regularly check the status of your implant.

Learn more at www.TreatMyValve.com/gb

References

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