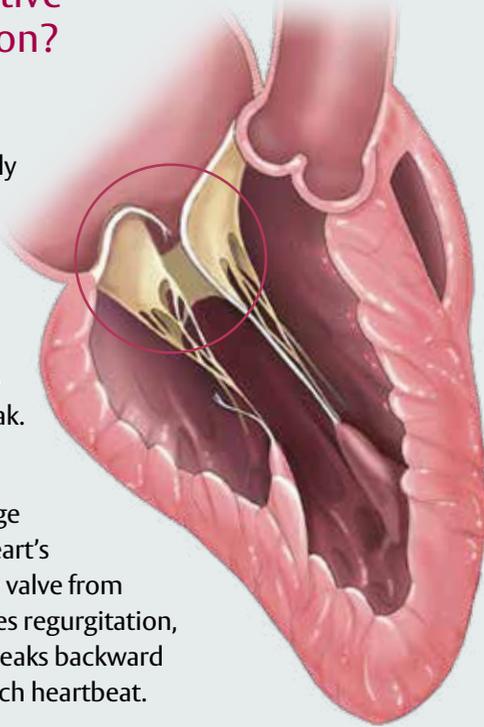


## What is degenerative mitral regurgitation?

Degenerative mitral valve regurgitation is a type of heart disease. It's commonly caused by mitral valve prolapse, a condition in which the valve's two flap-like leaflets and supporting string-like structures (chords) are too stretchy and may even break.



When the heart contracts, one of the leaflets may bulge (prolapse) back into the heart's left atrium and prevent the valve from closing correctly. This causes regurgitation, which occurs when blood leaks backward into the left atrium with each heartbeat.

Symptoms may include:

- Chest pain
- Shortness of breath
- Fainting
- Fatigue
- Lightheadedness
- Difficulty when exercising

However, some patients may not experience any symptoms at all.

## Who's at risk for mitral valve prolapse?

Mitral valve prolapse can occur at any age and affects about 2% of the population.

Most people with mitral valve prolapse have no leak or a mild leak, which is not a cause for concern.

Less than 1% of people have a severe leak and need further treatment or surgery.

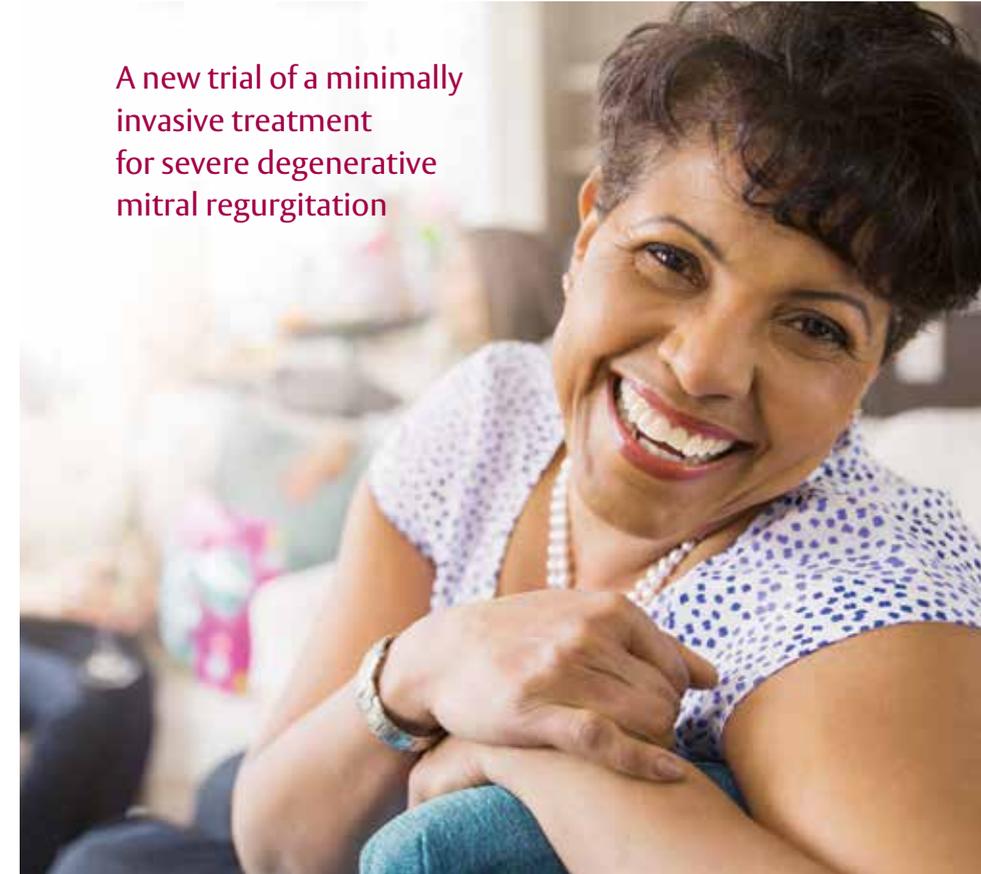


Talk to your doctor  
to learn more or visit  
[www.theRESTOREtrial.com](http://www.theRESTOREtrial.com)



## HARPOON Beating Heart Mitral Valve Repair System

A new trial of a minimally  
invasive treatment  
for severe degenerative  
mitral regurgitation



**Caution: Investigational device. Limited by Federal (United States) law to investigational use.**  
The device is not available for marketing or commercial sale in the United States.  
Edwards Lifesciences is the sponsor of the RESTORE trial.

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## What are my current treatment options?

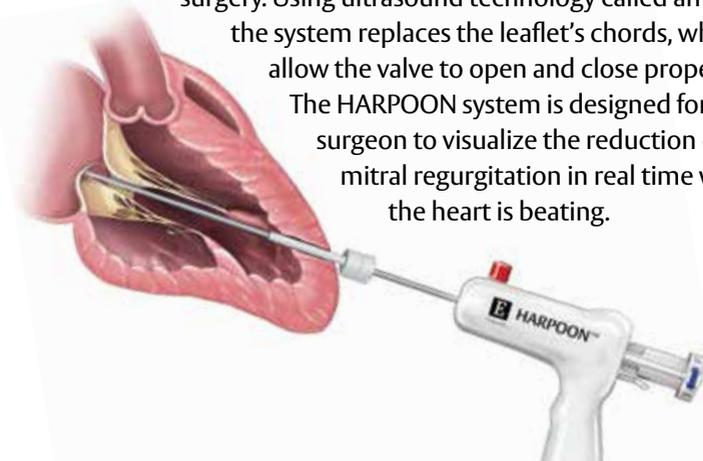
It depends on how far the disease has progressed. Open-heart surgery to repair or replace the valve is the most common though there are also less invasive options. Depending on the severity of your condition, your doctor will work with you to determine the best treatment for you.

## What is the RESTORE trial?

RESTORE is a clinical trial that will study up to 360 patients who need mitral valve repair surgery due to severe degenerative mitral regurgitation. Using a less invasive treatment than open-heart surgery, the trial will evaluate the safety and effectiveness of a device called the HARPOON Beating Heart Mitral Valve Repair System to repair the mitral valve.

## What is the HARPOON system?

The HARPOON system is an investigational device designed to repair the damaged mitral valve. Unlike open-heart surgery, this minimally invasive procedure occurs through a small incision on the left side of the chest. This approach eliminates the need for a bypass machine to do the work of the heart and lungs while the heart is stopped for surgery. Using ultrasound technology called an echo, the system replaces the leaflet's chords, which allow the valve to open and close properly. The HARPOON system is designed for the surgeon to visualize the reduction of mitral regurgitation in real time while the heart is beating.



## Am I good candidate for this trial?

You may qualify if you:

- Are 21 years of age or older.
- Have severe degenerative mitral regurgitation.
- Have mitral valve prolapse in the mid-segment posterior leaflet.

You may not qualify if you:

- Have secondary or functional mitral regurgitation caused by other forms of heart disease.
- Have mitral valve prolapse in the anterior leaflet or both leaflets.
- Had any prior heart valve repair or replacement surgery.
- Are scheduled to have other cardiac procedures at the same time.
- Are scheduled to have other cardiac or peripheral vascular procedures 30 days before or after the trial procedure.

Talk to your doctor or the clinical trial coordinator about the full list of eligibility criteria.



## Why should I consider participating?

If eligible, you'll get early access to a new, investigational treatment option for mitral valve disease while a medical team carefully monitors your health and progress. Your participation will also help advance medical research. However, there are potential risks, so ask your doctor if the RESTORE trial is right for you.

## What should I expect if I participate?

If you participate, you'll undergo two echo screenings, including:

- Transesophageal echocardiography (TEE): An ultrasound of the heart taken with a probe in the esophagus
- Transthoracic echocardiography (TTE): An ultrasound of the heart scanned over the chest

Once your eligibility is confirmed, there will be additional doctor's visits and testing, including:

- A baseline evaluation before surgery, consisting of lab tests, a physical exam and an electrocardiogram (ECG) to check your heart rhythm
- Post-surgery evaluation at seven days, 30 days, six months and 12 months
- Annual doctor's visits for the next five years

**RESTORE**  
TRIAL

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