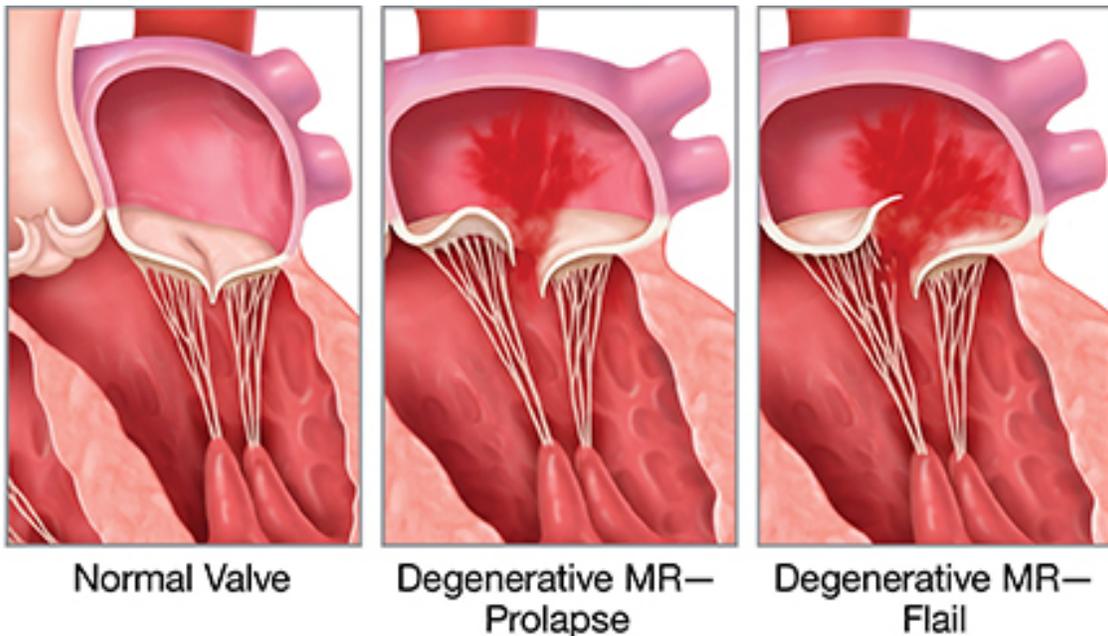


MitraClip for Mitral Regurgitation

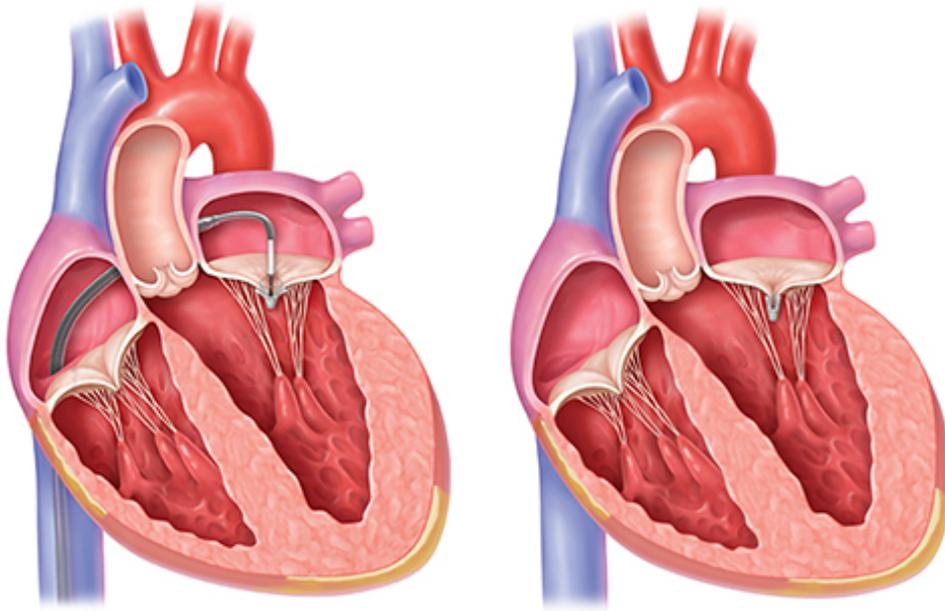
Mitral regurgitation impacts millions of adults in the United States and if left untreated, can be life-threatening.

The mitral valve, located between the left atrium and the left ventricle of the heart, is responsible for regulating the flow of oxygen-rich blood received from the lungs. Proper one-way flow of blood through the mitral valve is made possible by the two leaflets (flap-like structures) of the mitral valve.

Mitral regurgitation occurs when the mitral valve leaflets do not close completely and blood flows backward or “leaks,” creating symptoms that may include shortness of breath, fatigue and chest pain.



Severe, mitral regurgitation is often treated with open-heart valve surgery. However for high-risk patients, open-heart surgery may not be the best treatment option. For these patients, MitraClip is the only approved minimally invasive, non-surgical treatment option.



During a MitraClip procedure, the MitraClip device is inserted into the body through a catheter placed in the patient's femoral (leg) vein. The catheter is then threaded up the vein to the heart.

Once in the heart, a small hole is made in an internal wall of the heart (the atrial septum) and the MitraClip device is advanced across the mitral valve. The device is positioned and placed to join or "clip" together a portion of the mitral valve leaflets, reducing or eliminating the backward flow of blood.

FDA approves new indication for valve repair device to treat certain heart failure patients with functional mitral regurgitation

The U.S. Food and Drug Administration today approved a new indication for a heart valve repair device that is intended to reduce moderate-to-severe or severe mitral regurgitation, a leakage of blood backward through the mitral valve into the heart's left atrium that can cause heart failure symptoms such as shortness of breath, fatigue and swelling in the legs.

When first approved in 2013, the MitraClip Clip Delivery System (MitraClip) was indicated to reduce mitral regurgitation in certain patients whose significant mitral regurgitation and heart failure symptoms result from abnormalities of the mitral valve (commonly known as primary or degenerative mitral regurgitation) and whose risks for mitral valve surgery are prohibitive.

The new indication, approved today, is for treatment of patients with normal mitral valves who develop heart failure symptoms and moderate-to-severe or severe mitral regurgitation because of diminished left heart function (commonly known as secondary or functional mitral regurgitation) despite being treated with optimal medical therapy.

Optimal medical therapy includes combinations of different heart failure medications along with, in certain patients, cardiac resynchronization therapy and implantation of cardioverter defibrillators.

Treating Mitral Regurgitation Without Opening the Chest

While open-heart surgery is still the preferred treatment method for low-risk patients with mitral regurgitation, also known as a “leaky valve,” it requires opening the chest via a large incision, the use of a heart-lung machine and a longer recovery time.

Due to the intensity of this treatment route, some patients are deemed ineligible due to their age or health history. These patients may benefit from having a MitraClip inserted instead.

MitraClip is a new device by Abbott Vascular that is used to clip together the leaflets of the mitral valve and stop the valve from leaking. Instead of opening the chest, cardiologists enter the heart through arteries in the groin to put the clip in place.

Before the invention of the MitraClip, medically managing the symptoms associated with mitral regurgitation was the only option available if surgical repair could not be performed.

How is MitraClip performed?

MitraClip is performed through a vessel in the groin using a catheter.

Who is a candidate for MitraClip?

The best candidates for the FDA-approved usage of the MitraClip are patients who:

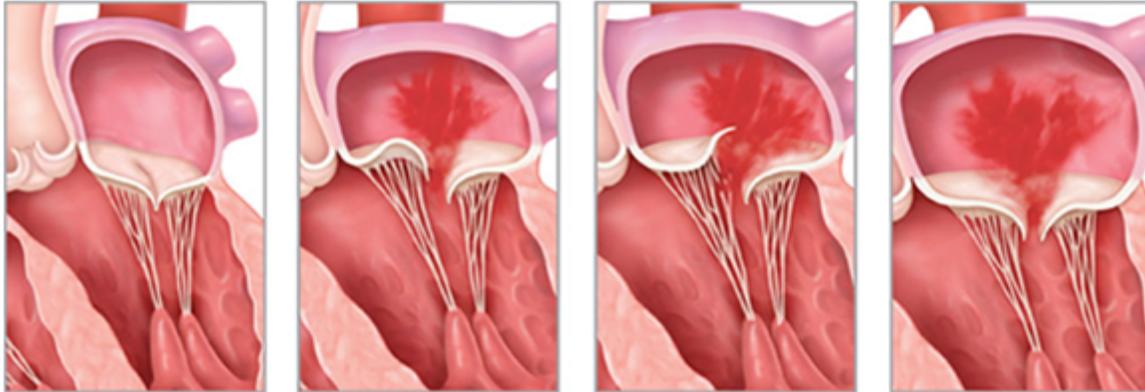
- Have a structural problem with their mitral valve that causes it to leak (degenerative mitral regurgitation)
- Are experiencing symptoms
- Have been deemed too high risk for surgery

What is Mitral Regurgitation?

Mitral regurgitation is a condition where the mitral valve leaflets do not close tightly. When this happens, blood flows backward from the heart's left ventricle into the left atrium, making the heart work harder to push blood through the body.

There are two types of mitral regurgitation: degenerative and functional. Degenerative mitral regurgitation, also called primary mitral regurgitation, is caused by damage to the mitral valve leaflets. Functional mitral regurgitation, also called secondary mitral regurgitation, is caused by enlargement of the heart due to heart attack or heart failure. The ventricle becomes enlarged and doesn't contract like normal, which causes the leaflets of the valve not to meet in the center.

If left untreated, mitral regurgitation can cause lots of stress on the heart, recurrent episodes of heart failure, severe shortness of breath, swelling of the legs, frequent hospital stays, and ultimately leads to death. Repairing the leak may change the course of the disease and increase a patient's overall quality of life.



Normal mitral valve

Degenerative MR
caused by mitral
valve prolapse

Degenerative MR
caused by flail leaflet

Functional MR

Photo source: Abbott Vascular

Mitral Regurgitation Signs & Symptoms

Many people do not realize that they have mitral regurgitation until they start experiencing symptoms. This can occur gradually over time and may include:

- Fatigue, exhaustion and light-headedness due to the stress placed on the heart
- Shortness of breath that increases with activity and eventually when lying down
- A feeling of heaviness on the chest when laying down
- Excessive urination at night
- Swelling in the legs

If you feel something may be wrong, discuss your symptoms with your doctor and ask to be referred to one of our Tallahassee Memorial Physician Partners cardiologists to have your heart checked.