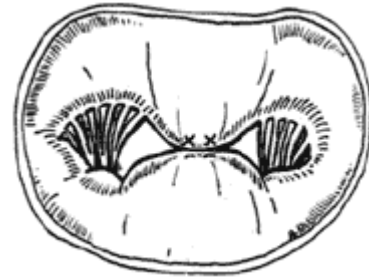


## PERCUTANEOUS MITRAL VALVE REPAIR

The mitral valve is a one-way valve that connects the left atrium to the left ventricle of the heart. With mitral valve regurgitation, the valve does not seal completely and blood leaks back into the left atrium. This reverse flow can cause the heart and lungs to swell. Symptoms may include an audible heart murmur, shortness of breath, and heart palpitations. Four million Americans are estimated to suffer from mitral valve regurgitation, with nearly 250,000 Americans diagnosed each year. In turn, approximately 40,000 Americans undergo surgery for mitral valve regurgitation annually, according to the Society of Thoracic Surgeons.



For most patients, traditional mitral valve repair requires an invasive procedure called a sternotomy (which involves making an incision in the center of the chest to access the heart), undergo cardiopulmonary bypass, and have their valve repaired or replaced with a tissue or mechanical substitute. They typically remain three to five days in the hospital and experience a lengthy recovery period at home. Nationally, patients undergoing mitral valve surgery face a 2.3 percent mortality rate for repair and 5.6 percent for replacement.

### The Evalve Percutaneous Mitral Repair System with the MitraClip® Device

The system consists of three major subsystems:

- A Guide Catheter,
- A Clip Delivery System, and
- The MitraClip Device (implant).

With the Evalve system, a cardiologist guides a catheter, or thin tube, through the vascular system to the heart's mitral valve, using fluoroscopic and echocardiographic imaging to show the way. The Evalve MitraClip™, located on the tip of the catheter, is then placed on the center of the valve leaflets, holding them together. The heart beats normally throughout the procedure. (This approach is based upon an open surgical method known as either an edge-to-edge repair or the Alfieri technique, in which a surgeon sutures the valve leaflets together to reduce leaking). During the procedure, the cardiologist can test the clip's effectiveness in reducing regurgitation and can reposition as needed.

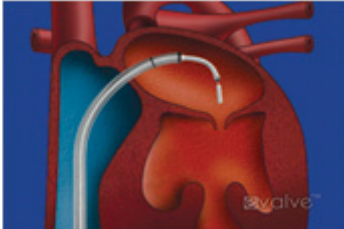
Once a satisfactory placement is achieved, the clip is detached from the catheter and the catheter is removed. The patient remains under general anesthesia throughout the procedure and can return home within 48 hours. There is no surgical wound—just a Band-Aid where the catheter was placed. Patients take clopidogrel for a month and aspirin for six months; there is no need for a blood thinner, such as warfarin.

In March 2005, initial results with six months follow-up were released from the Phase I trial, known as **EVEREST I (Endovascular Valve Edge-to-Edge Repair Study)**. The findings demonstrated that over 90 percent of patients whose MR was significantly reduced one month after receiving the clip, maintained that reduction at six months. In addition, 75 percent of the patients who received the clip through the trial remained surgery-free at the six-month mark. **EVEREST II**, is the Phase II follow-up trial, and is presently in progress.

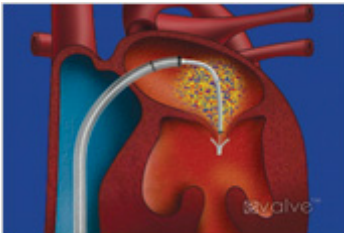
"Evalve is part of the natural evolution of mitral valve repair for regurgitation—from open heart surgery to minimally invasive approaches to robotic repairs and now a non-surgical solution,"

says Allan Schwartz, MD, Harold Ames Hatch Professor of Medicine and Chief, Division of Cardiology, Department of Medicine, Columbia University College of Physicians & Surgeons.

Currently, Evalve is the only device for valve repair in clinical trials in the United States. The EVEREST II trial builds upon the findings from Phase I. Eligible patients will be randomized—some receiving traditional open-heart mitral valve surgery; others undergoing an Evalve procedure



Accurate device positioning over valve before grasping valve leaflets.



Leaking of the heart valve before placing clip.



Procedure completed, clip in place, and leaking resolved

For viewing a video clip of the procedure, visit Evalve website or click on the link <http://www.evalveinc.com/pages/Lg.html>