

***Heart Surgery without the Surgeon:
Evalve for Non-Invasive Mitral Valve Repair***

The **Evalve Cardiovascular Repair System** seeks to take repair for mitral valve regurgitation out of the operating room and into the cardiac catheterization lab.

Evalve adopts for valve repair the catheterization techniques commonly used in cardiac catheterization. A phase one clinical trial of **Evalve**, known as **EVEREST I (Endovascular Valve Edge-to-Edge Repair Study)**, is currently underway at Columbia University College of Physicians & Surgeons. Initial results with the system have demonstrated that successful repair of the mitral valve is feasible using this approach.

"**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 at Columbia University College of Physicians & Surgeons. "No one should undergo mitral valve surgery without first being evaluated for **Evalve**."

Using fluoroscopic and echocardiographic imaging to show the way, an interventional cardiologist guides a catheter, or thin tube, through the vascular system to the heart's mitral valve. The **Evalve** clip, located on the tip of the catheter, is then placed on the center of the valve leaflets, binding them together. The heart beats normally throughout the procedure. This approach is based upon an open surgical technique known as either

an edge-to-edge repair or the Alfieri technique, wherein 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 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 Plavix for a month and aspirin indefinitely; there is no need for a blood thinner, such as Coumadin.

"From the patient's point of view, **Evalue** offers a less invasive procedure with a virtually nonexistent recovery. It's a major paradigm shift from surgery to a nonsurgical approach," reports Hal Wasserman, MD, Associate Clinical Professor of Medicine and Associate Director of the Interventional Cardiology Center, Columbia University College of Physicians & Surgeons.

Columbia is proud to be one of only seven premier centers in the world participating in **EVEREST I**, and the only center in the tri-state area. Currently, **Evalue** is the only device for valve repair in clinical trials in the United States. To qualify for the trial, individuals must:

- Have moderately severe to severe mitral regurgitation with symptoms or with evidence of left ventricular dysfunction

- Experience regurgitation originating from the middle section of the valve
- Qualify as a candidate for mitral valve surgery including cardiopulmonary bypass

Key exclusion criteria include an ejection fraction <30%, endocarditis, rheumatic heart disease, and renal insufficiency. There is no upper age limit. Eligibility can be determined through a brief medical history in conjunction with an echocardiogram conducted by a physician who is not a study participant.

According to the *Society of Thoracic Surgeons National Adult Cardiac Surgery Database*, each year approximately 40,000 Americans undergo surgery for mitral valve regurgitation. For most patients, this means enduring a full sternotomy, going on cardiopulmonary bypass, having their valve repaired or replaced with a tissue or mechanical valve, staying three to five days in the hospital, and experiencing a lengthy recovery at home. Nationally, patients undergoing mitral valve surgery face a 2.3% mortality rate for repair and 5.6% for replacement.

"The goal of any minimally invasive surgical procedure has always been to achieve the technical success of surgery while minimizing trauma and recovery time," says Michael Argenziano, MD, Assistant Professor of Surgery, Columbia University College of Physicians & Surgeon and Director, Minimally Invasive and Robotic Cardiac Surgery, NewYork-Presbyterian Hospital/Columbia University Medical Center. "With the **Evalue** approach, we hope to fully achieve just that goal."

Four million Americans are estimated to suffer from mitral valve regurgitation and nearly 250,000 Americans are diagnosed with significant regurgitation each year. The mitral valve is a one-way valve that connects the left atrium to the left ventricle. 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 and can eventually lead to congestive heart failure. Symptoms may include an audible heart murmur, shortness of breath, and heart palpitations.

Columbia University has a proud heritage of advancing medicine through less invasive techniques. In 1956, Columbia professors André Frédéric Cournand and Dickinson W. Richards, together with Werner Forssmann of Mainz University in Germany, won the Nobel Prize in Medicine "for their discoveries concerning heart catheterization and pathological changes in the circulatory system."

"Today, we are known as pioneers in minimal access surgery and robotic surgery at Columbia," says Mehmet C. Oz, MD, Professor of Surgery, Columbia University College of Physicians & Surgeons and Director, Cardiovascular Institute, NewYork-Presbyterian Hospital/Columbia University Medical Center. "Now we are once again pushing the boundaries of non-invasive care."

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