



Prairie

EDUCATION & RESEARCH COOPERATIVE

326 North 7th Street, Suite 101, Springfield, IL 62701 • (217) 544-6464 X 66044 • Fax: (217) 522-1206

RESTOR-MV

- Trial Sponsor:** Myocor
- Principal Investigator:** Carl Arentzen, MD
- Trial Name:** Randomized Evaluation of a Surgical Treatment for Off-Pump Repair of the Mitral Valve (RESTOR-MV)
- Purpose:** The purpose of this prospective, randomized, multi-center, pivotal trial is to compare the safety and effectiveness of the off-pump, closed heart Coapsys Annuloplasty System (Myocor, Inc.) to open surgical repair of the mitral valve using an annuloplasty ring or band in patients with moderate to severe functional mitral regurgitation.
- Details:** Patient clinical evaluations will consist of 3-month, 6-month, and 12-month follow up of the primary endpoints. Additional follow up of 18-month, 24-month, and annually thereafter will also be included.

Eligibility

Ages Eligible for Study: 18 – 80 years

Genders Eligible for Study: Both

Inclusion Criteria:

- Grade 2, 3, or 4 functional mitral valve regurgitation per 2D echocardiography
- Patient undergoing concomitant coronary artery bypass graft surgery, either on-pump or off-pump
- Left ventricular ejection fraction greater than or equal to 25%
- Age between 18 and 80 years, inclusive
- Patient is willing and available to return for study follow up
- Ability of the patient or legal representative to understand and provide signed consent for participating in the study.

Exclusion Criteria:

- Structural abnormality of the mitral valve (e.g. calcification or thickening of the valve leaflets, ruptured papillary muscle, ruptured chordae tendinae, mitral valve prolapse, mitral stenosis, etc.)
- Asymptomatic Grade 2 MR (those with NYHA Class < II AND LVEF > 40%)



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- Organic valve disease resulting in insufficiency or stenosis of the aortic, pulmonary or tricuspid valve requiring surgical intervention
- Transmural myocardial infarction within 30 day period prior to surgical placement of Coapsys
- NYHA class IV
- Left ventricular end diastolic diameter > 7.0 cm
- Cardiac surgery on an emergency or salvage basis
- Left atrial or left ventricular thrombus
- Left ventricular aneurysm
- Previous mitral valve surgery or other previous cardiac surgery that would preclude proper placement of the Coapsys
- Chronic renal failure requiring dialysis
- Open chest surgery contraindication (e.g., acute respiratory distress, endocarditis, myocarditis, pericarditis)
- Active infection
- Life expectancy of less than 24 months due to conditions other than their cardiac status
- Participation in another investigational drug or device protocol
- Abnormal coronary or cardiac anatomy such that the device could not be placed without interfering with those anatomical structures.