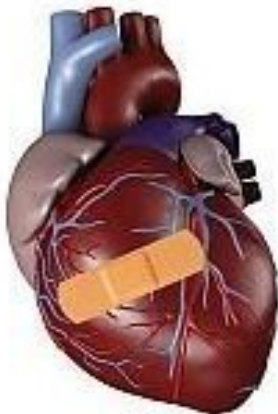


## Phoenix's heart repair device trial is underway

15 January 2013 | News | By BioSpectrum Bureau



**Singapore:** Phoenix Cardiac Devices, a medical device company with a novel method of repairing leaky heart valves without open-heart surgery, has enrolled its first patient in a clinical trial in India and Europe, aimed at achieving CE Mark approval in Europe.

The trial will assess the safety and efficacy of the firm's BACE device, an adjustable tension band that encircles the heart and supports the mitral valve leaflets so they close properly to prevent the back flow of blood into the heart. Known as mitral regurgitation, the leakage of blood backward into the left atrium contributes to the development of congestive heart failure.

Previous studies of BACE, including a proof-of-concept study in 12 patients and a feasibility study in 14 patients, demonstrated a significant reduction in mitral regurgitation and no device-related serious adverse events following implantation.

The current study will enroll 60 patients in India and Europe, who have moderate-to-severe functional mitral regurgitation. Patients will undergo implantation of BACE, a device designed by a cardiothoracic surgeon to prevent many of the complications that occur with traditional surgical repair of mitral valves. Such complications are also caused due to open-heart surgery, which requires temporarily stopping the heart and pumping blood through a heart lung by-pass machine during the procedure.

"Our device sits outside the heart, so there is no need to open the heart and no contact with blood flow, both of which are associated with an increased risk of thrombosis, stroke and infections," said Dr Jai Raman, inventor of BACE.