Saint Luke's Mid America Heart Institute Clinical Trial To Investigate Effectiveness Of Cardiac Surgery Device

PR Newswire

Clinical trial to determine if chest closure device leads to better bone healing following cardiac surgery

KANSAS CITY, Mo., Feb. 25, 2013 /PRNewswire-USNewswire/ -- Patients undergoing open heart procedures such as coronary artery bypass or valve surgery may be eligible to enroll in a clinical trial available in the Kansas City area only at Saint Luke's Mid America Heart Institute [1].

The SternaLock® Blu clinical trial will compare patients whose sternum (breastbone) is closed with conventional stainless steel wire to patients whose sternum is closed with Biomet's SternaLock® Blu Primary Closure System to evaluate sternal bone healing following a full median sternotomy.

A median sternotomy is the incision typically used when performing an open heart procedure. Following the procedure the breast plate is typically put back together with wires. The SternaLock closure uses plates and screws commonly used during orthopedic cases. This study is designed to determine if one method of sternal closure results in better healing of the breastbone compared to the other and if there are differences in the amount of pain, the use of pain medication, and functional recovery following heart surgery between the two closure methods. More than 700,000 sternotomies are performed in the U.S. annually.

Outcomes in this trial will include bone healing, post-operative pain, analgesic usage, patient function, and quality of life, in addition to economic costs between wires and the SternaLock system.

Keith Allen , M.D., director of surgical research and a cardiothoracic surgeon at Saint Luke's Mid America Heart Institute, is the trial's national principal investigator. The trial plans to enroll 236 patients from up to 12 leading cardiac centers in the U.S.

"The standard of care to date has been use of wires to close and stabilize the breastbone following cardiac surgery," said Dr. Allen. "Previous research has shown improved bone healing and reduced post-operative pain in patients receiving a rigid fixation device following sternotomy. Saint Luke's looks forward to contributing to the pioneering research into this new surgical option."

Saint Luke's enrolled its first patient on Feb. 8 with a patient who received an aortic

valve replacement performed by J. Russell Davis , M.D. The 56-year-old man is healing well after surgery to correct a defective heart valve.

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