First Artificial Disc FDA Approved

St. Joseph Medical Center only study site in Maryland

WHAT: The CHARITE™ Artificial Disc was approved by the U.S. Food and Drug Administration on Tuesday, October 26, 2004 making it the first motion-preserving device approved for use for chronic, lower back pain and degenerative disc disease. Until now, lumbar spinal fusion surgery, which produces limited motion, has been the common surgical treatment for degenerative disc disease, with 200,000 procedures performed annually in the U.S.

At St. Joseph Medical Center, one of 15 spine centers that took part in the two-year randomized study, 60 patients were enrolled in the double blind study, and another 50 patients were enrolled as continued access patients to be followed for up to five years.

The study demonstrated that patients implanted with the CHARITE Artificial Disc improved more quickly, were discharged from the hospital a half-day earlier, and had pain and function scores that were statistically superior than the fusion patients.

WHO: Dr. Paul McAfee, chief of Spinal Surgery, St. Joseph Medical Center and main investigator of the CHARITE study at St. Joseph Medical Center
Dr. Ira Fedder and Dr. Justin Tortolani, orthopaedists and co-investigators

The CHARITE Artificial Disc is made of two metallic endplates and a polyethylene core that allows for motion and function very much like a normal disc. Two-thirds of the 304 patients enrolled in the U.S. study received the new disc, while one-third had traditional spinal fusion surgery. More than 7,000 patients throughout the world have received the new disc, which has been available in more than 30 countries prior to the U.S. study. St. Joseph Medical Center was the only center in Maryland to participate in the CHARITE study.