

NEWS RELEASE
For Immediate Release

**FDA APPROVES THE FIRST ARTIFICIAL DISC FOR LOW BACK SURGERY
IN U.S.**

**TRAINING AWARDED TO
SOUTHERN NY NEUROSURGICAL GROUP, P.C. &
UNITED HEALTH SERVICES**

On Tuesday, October 26th the U.S. Food and Drug Administration (FDA) approved the first artificial disc for lumbar (low back) spine surgery. This comes as welcomed news and one of the most important advances in spine surgery for people who suffer with severe low back pain. The Charite™ Artificial Disc available through DePuy, Inc., a Johnson & Johnson company is a revolutionary device that treats severe low back pain by replacing the degenerative or damaged spinal disc with the artificial one. Unlike spinal fusion surgery, the artificial disc will not only relieve pain but will also preserve range of motion.

"Artificial discs are designed to replicate the movement of the patient's own disc. Following surgery, patients will have less pain, greater mobility and a much better quality of life," says Saeed A. Bajwa, neurosurgeon at southern NY Neurosurgical Group, P. C.

The CHARITE Artificial Disc is a high-tech device made of two metallic endplates and a moveable high-density plastic center that once implanted, is designed to help align the spine and preserve its ability to move.

in clinical trials comparing artificial disc replacement to spinal fusion surgery, CHARITE artificial disc patients maintained flexibility, experienced improvements in pain and function, left the hospital sooner and were more satisfied with the procedure.

The artificial disc is one of the most important advances in the history of back surgery. In June, 2004, the FDA Advisory Panel unanimously recommended the approval of the first Artificial Disc for degenerative disc disease. The FDA is expected to approve the Charite™ Artificial Disc available through DePuy, Inc., a Johnson & Johnson company, as early as Fall, 2004.

DePuy Spine, Inc. presented results from a two-year, 15 center randomized U.S. clinical study to the advisory panel. The study states that "patients reported that they maintained or improved their range of motion, experienced pain relief sooner, and had a higher degree of satisfaction with the procedure than patients who received lumbar spinal fusion surgery. Their level of pain and functional test scores were statistically superior at many points through 12 and at 24 months of follow-up care".

Previously, a degenerative or herniated disc had to be removed, and the vertebrae had to be fused together with bone or with surgical hardware. Now, surgeons will remove the disc and replace it with the new Charite™ Artificial Disc. This disc is intended to provide an alternative to lumbar spinal fusion surgery that is performed on more than 200,000 people each year in the U.S.

Locally, the surgeons at Southern NY Neurosurgical Group, P.C. have been chosen as one of the top training teams in the entire eastern region of the U.S., including, Maine, Washington, D.C. and Ohio to teach other neurosurgeons and orthopedic surgeons how to perform the artificial disc surgery.

“This is the biggest step forward in spine surgery in decades, exclaimed Dr. Saeed A. Bajwa, neurosurgeon at Southern NY Neurosurgical Group, P.C. “It will change the way people with disc problems live. With this replacement disc, we can rebuild the spine to function normally.”

The surgical training will take place at Wilson Memorial Regional Medical Center in Johnson City, said Matthew J. Salanger, President and Chief Executive Officer of United Health Services Hospitals.

“We are very pleased that Wilson has been selected for this advanced type of surgical training,” Mr. Salanger said. “This is the kind of medical advance that can vastly improve the lives of people in our community and around the world.”

Nationwide, hundreds of surgeons will be trained on how to perform artificial disc surgery, a critical advancement in lumbar spine surgery.

Earl Fender, Worldwide President, DePuy Spine said, “We are pleased with the recommendation for approval and we will work closely with the FDA to bring this important new option to those patients who can benefit from artificial disc technology as soon as possible. DePuy Spine is prepared to make a major commitment to world class training and education on artificial disc technology and techniques to foster its optimal and appropriate use.”