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FDA

FDA Approves Artificial Disc; Another Alternative to Treat Low Back Pain

The Food and Drug Administration (FDA) has approved an artificial spinal disc for use in treating pain associated with degenerative disc disease (DDD). The device is intended to replace a diseased or damaged intervertebral disc.

The device--the first of its kind--is the Charité artificial disc manufactured by DePuy Spine, Inc., of Raynham, Mass. It was approved for use in patients who have DDD at one level in the lumbar spine (from L4-S1) and who have had no relief from low back pain after at least six months of non-surgical treatment.

Currently, patients with DDD who get no relief from pain after several weeks of non-invasive therapy may have surgery to implant a variety of devices intended to stabilize the spine while bone grafts fuse together the two vertebrae surrounding the diseased or damaged disc. The artificial disc provides another alternative for these patients.

The Charité artificial disc is made up of a plastic core sandwiched between two metal endplates. The device helps restore the natural distance between the two vertebrae, which can allow movement at the level where it is implanted. However, it may not necessarily allow movement, or may allow too much movement, which can over-stress the device.

The new system is placed in the spine through a small incision just below the belly button. The diseased or damaged disc is removed and the artificial disc is placed in the space. Patients require general anesthesia.

FDA approved the device based on a review of a clinical study of safety and effectiveness conducted by DePuy at 16 medical centers. The objective of the study was to determine whether the Charité artificial disc was any less safe and effective than a commercially available spinal fusion cage using bone graft.

The firm studied the use of the artificial disc in 205 patients who had been diagnosed with DDD and had failed to have their pain relieved after six months of non-surgical therapy and compared them to 99 patients who received the control device. Additional safety information was obtained from another 71 patients when doctors in the study were being trained to use the Charité artificial disc.

The study showed that two years after surgery, patients treated with the artificial disc did no worse than patients treated with intervertebral body fusion. The rates of adverse events from use

of the artificial disc were similar to those from treatment with fusion. In addition, the study showed that there was no statistically significant relationship between motion at the level where the disc was implanted and the patient's relief from pain.

FDA is requiring DePuy Spine to conduct a post-approval study to assess the product's long-term safety and effectiveness, including its impact on other discs and on the bony structures on the back of the spine.