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Medtronic INFUSE® Bone Graft + LT-CAGE® Lumbar Tapered Fusion Device Fact Sheet

Fact Sheet

INFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device

Overview

INFUSE® Bone Graft and the LT-CAGE® Lumbar Tapered Fusion Device, used in combination to treat degenerative disc disease, represent a revolutionary new approach to spinal fusion surgery. INFUSE® Bone Graft contains a genetically engineered version of a protein that occurs naturally. This protein has been isolated in the laboratory and then purified and reproduced using recombinant DNA technology. The resulting recombinant human protein is known as rhBMP-2, and when combined with an absorbable collagen sponge, is marketed by Medtronic Sofamor Danek under the trade name INFUSE® Bone Graft.

Spinal Fusion for Degenerative Disc Disease

Spinal fusion surgery is often the only effective method to treat degenerative disc disease, one of the most common causes of low back pain. However, until now, spinal fusion procedures actually required two surgeries -- one to harvest pieces of bone from the patient's hip (autograft) and a second to implant them into the spine. Surgeons implant INFUSE® Bone Graft instead of pieces of bone, which are chipped off the patient's hip in a painful surgical procedure. According to numerous studies, the harvesting procedure is actually more painful than the fusion itself, and nearly a third of patients experience hip pain two years following surgery. When compared to traditional spinal fusion procedures, INFUSE® Bone Graft, when used with the LT-CAGE® Device, eliminates the pain and blood loss, and reduces the amount of time spent in the hospital to treat complications resulting from the second site of surgery.

The LT-CAGE® Lumbar Tapered Fusion Device

INFUSE® Bone Graft is labeled for use with the LT-CAGE® Lumbar Tapered Fusion Device. The LT-CAGE® is a thimble-like device made of titanium that keeps the INFUSE® Bone Graft at the fusion site, maintains the proper height between the vertebrae and stabilizes the spine while it is fusing. The tapered design of the cage fits more naturally between vertebrae in the spine, as compared to traditional cylindrical cages.

Spinal Fusion Procedures with INFUSE® Bone Graft and the LT-CAGE® Device

- INFUSE® Bone Graft is packaged with a collagen sponge and sterile water for

reconstitution.

- Prior to surgery, the powdered rhBMP-2 is mixed with the sterile water to create a liquid solution.
- The collagen sponge, which is used to carry the rhBMP-2 solution, is cut and/or sized to fit inside two LT-CAGE® Devices.
- The sponges are soaked with the rhBMP-2 protein for at least 15 minutes, rolled up and placed inside the cages.
- Surgeons remove the damaged disc from the patient's spine and prepare the adjacent vertebrae for the insertion of the cages.
- Surgeons implant the cages with the sponge soaked in INFUSE® Bone Graft, in the space between the vertebrae, and the rhBMP-2 promotes the growth of bone to fuse the spine at that location.

Surgical Experience with INFUSE® Bone Graft and Follow up for Patients

- Spinal fusion surgery with INFUSE® Bone Graft and the LT-CAGE® Device is essentially the same as traditional autograft procedures, without the need for the additional surgery to harvest bone from the patient's hip.
- Orthopedic surgeons are already very familiar with the role of BMP in stimulating bone growth as a result of their medical school studies and medical residencies, and through numerous scientific publications over many years.
- After spinal fusion procedures, patients return to their surgeons for follow-up visits, which may include radiographic evaluations.

History

More than 40 years ago, orthopedic surgeons determined that the protein extracts required for bone to heal, or regenerate, in the body were contained within the bone itself. In 1979, Dr. Marshall Urist, a professor in the Department of Orthopaedic Surgery at the University of California at Los Angeles School of Medicine, coined the term "bone morphogenetic protein" (BMP) to describe these proteins.

Dr. Urist determined that bone contains only trace amounts of naturally occurring BMP, and that isolating enough BMP to be clinically useful would require hundreds of kilograms of donor (cadaveric) bone. Therefore, scientists concluded that producing a recombinant version of BMP was the only practical option for using BMP in routine medical procedures for endochondral bone formation.

To produce a practical version of BMP, scientists isolated one protein (BMP-2) from the bone tissue and used recombinant DNA technology to create genetically engineered cells, which they called recombinant human BMP-2 (rhBMP-2). Through this process, they determined that the cells they created could produce pure, natural human BMP-2 protein, a substance capable of initiating bone growth.

Approximately 20 BMPs with different amino acid structures have been isolated to date, but only six appear capable of initiating bone growth. Of these, BMP-2 has demonstrated the greatest potential to form bone.

Scientists determined that rhBMP-2, with an absorbable collagen sponge as the carrier, (INFUSE® Bone Graft) is an effective replacement for autograft bone in spinal fusion surgery. This conclusion is based on data resulting from a large-scale, multi-center, prospective, randomized, two-year study involving 279 degenerative disc disease patients implanted with INFUSE® Bone Graft and the LT-CAGE® Lumbar Tapered Fusion Device. The study assessed the safety, efficacy and therapeutic benefits of the new procedure as compared to traditional autograft procedures. Approximately half of the patients in the study received autograft bone and the other half received INFUSE® Bone Graft. The data showed that the study met all of its primary endpoints, and that:

- After surgery, 100 percent of the autograft bone patients experienced hip donor site pain. Patients implanted with INFUSE® Bone Graft did not experience hip pain, because they did not require the second procedure to harvest the bone graft from the hip.
- Fusion rates for both treatment groups were high and, although the results were not statistically different at any time point, the fusion rates of the INFUSE® Bone Graft patients were nearly six percentage points higher on average (94.5 percent fused versus 88.7 percent) at 24 months.
- The average operative time for INFUSE® Bone Graft patients was statistically shorter than for those in the control group (1.6 hours as compared to 2.0 hours).
- Blood loss for the INFUSE® Bone Graft patients was significantly less than the control group patients (109.8 versus 153.1 milliliters).
- Based on results from a standardized low back pain questionnaire, the control group and the INFUSE® Bone Graft patients both received similar levels of low back pain relief (greater than 50 percent improvement in mean pain scores at two years).

Cost and Coverage

- For most patients, lumbar spinal fusion procedures are covered by their private medical insurance and/or Medicare.
- Spinal fusion surgery using INFUSE® Bone Graft with the LT-CAGE® Lumbar Tapered Fusion Device is more cost-effective -- immediately following surgery and over time -- than procedures using bone harvested from the patient's hip, due to the following:

Immediate cost offsets:

- o Decreased time spent in the operating room, and reduction of blood lost during surgery
- o Reduction or elimination of medical/surgical supplies used to harvest bone from a patient's hip, including autograft extenders and harvesters

Long-term cost offsets (within two years of surgery):

- o Significantly fewer complications that would require follow-up visits
- o Elimination of pain at harvest site (in autograft procedures)



Medtronic, Inc. 2013