InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device - P000058

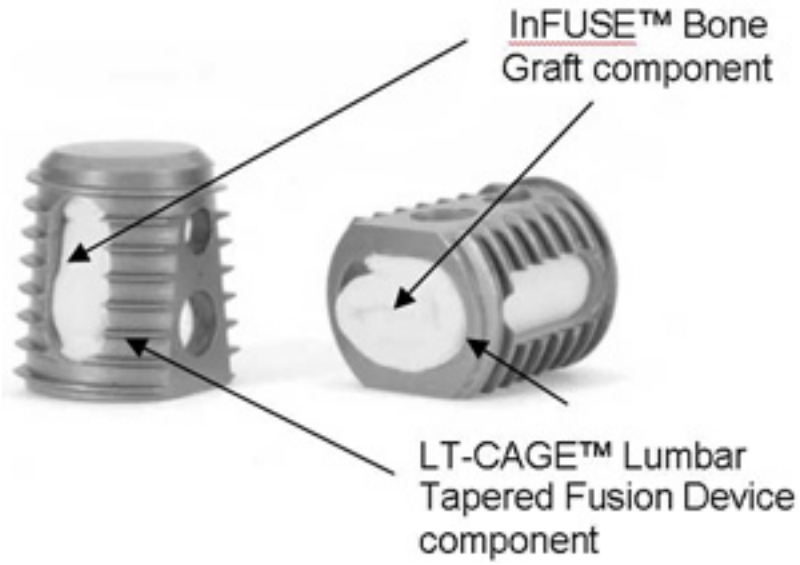
This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device
Manufacturer:	Medtronic Sofamor Danek
Address:	1800 Pyramid Place Memphis, Tennessee 38132
Approval Date:	July 2, 2002
Approval Letter:	http://www.fda.gov/cdrh/pdf/P000058a.pdf

What is it? A device to help fuse vertebrae in the lower spine in order to treat degenerative disc disease. It differs from other, similar devices in that it uses genetically engineered protein to help build bone tissue in the fusion process, instead of using a graft of the patient's own bone (an autograft).

The device consists of three components spilt among two parts -

1. a metallic tapered spinal fusion cage (known as the LT-CAGE™ Lumbar Tapered Fusion Device); and
2. a bone graft substitute (InFUSE™ Bone Graft) which consists of a genetically-engineered human protein (rhBMP-2) along with a carrier/scaffold for the protein (manufactured from bovine [cow] Type I collagen) that is placed inside the fusion cage.



How does it work? The fusion cage component maintains the spacing and temporarily stabilizes the diseased region of the spine, while the InFUSE™ Bone Graft component is used to form bone which would permanently stabilize (fuse) this portion of the spine.

When is it used?The device is used in the lower region of the spine (L4-S1) to treat degenerative disc disease.

What will it accomplish? A clinical study showed that the use of this device was as safe and effective in promoting spinal fusion as the same fusion cage component filled with autograft bone.

When should it not be used? This device should not be used for patients:

- who are pregnant or might be pregnant,
- who may be allergic to any of the materials contained in the device,
- who have an infection near the area of the surgical incision,
- who have had a tumor removed from the area of the implantation site or currently have a tumor in that area, or
- whose bones have not stopped growing.

In addition, it is not known if a woman who becomes pregnant after receiving the device could have a second immune reaction to the BMP-2 normally found in a developing fetus, which might harm either mother or fetus.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/P000058.html

Other:

- Comprehensive information on spine and spinal disorders: http://www.mayoclinic.com/invoke.cfm?objectid=D5ABE130-D4B7-4257-A1FA934408C8B6CD
- Descriptions of most used diagnostic tests for spinal disorders: http://www.neurosurgery.org/health/patient/answers.asp?disorderID=77
- General description of the spine: http://www.neurosurgery.org/health/patient/answers.asp?DisorderID=44

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