New Device Approvals

AFFINITY™ Cage System -

P000028

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:	AFFINITY™ Cage System
Manufacturer:	Medtronic Sofamor Danek
Address:	1800 Pyramid Place, Memphis, Tennessee 38132
Approval Date:	June 13, 2002
Approval Letter:	http://www.fda.gov/cdrh/pdf/P000028a.pdf

What is it? This device is a system of special screws and surgical tools used to help make the neck (cervical spine) more stable and relieve pressure on spinal nerves. The screws, which are hollow and have holes in their sides, are implanted into the neck bones (vertebrae), causing them to grow together (spinal fusion). This surgical procedure is often used when there is damage to the spinal discs (the "cushions" between the bones of the spine). For pictures of the spine, information on discs, go to: http://www.neurosurgery.org/health/images/spinbodybig.gif or http://www.yoursurgery.com/ProcedureDetails.cfm?BR=6&Proc=14

How does it work? In the surgical procedure that uses this device, the surgeon goes into the neck from the front. A hole is made between the vertebrae to receive the screw. In a grafting procedure, bits of the patient's hip bone are put into the hollow screw, which is then screwed into the hole. The screw separates the vertebrae to relieve pressure on the spinal nerves, and, in time, the bits of bone from inside the screw grow into the spine and help hold it together in this new position.

When is it used? This device is for individuals who have reached full growth, have a damaged disc between the second and eighth vertebrae (C-2 to T-1), and have symptoms, such as pain or numbness, that show there is pressure on a nerve (a radicular symptom).

What will it accomplish? This device may help stabilize the affected part of the neck. This can lessen pain and disability in the neck, and reduce muscle weakness and numbness. In a study by the implant manufacturer, 68 out of 100 patients who were treated with this device had a good result. After their vertebrae were fused, they had less neck pain and disability, and they had stronger muscles and less numbness.

When should it not be used? This device should be used only by surgeons who have received special training in its use. It should not be used on patients who have an active infection, or who are allergic to the titanium alloy used to make the screws.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/P000028.html

Other:

- Comprehensive information on spine and spinal disorders: http://www.mayoclinic.com/invoke.cfm?objectid=D5ABE130-D4B7-4257-A1FA934408C8B6CD
- Information on cervical spine disorder and treatments: http://www.neurosurgery.org/health/patient/detail.asp?DisorderID=76
- Descriptions of most used diagnostic tests for spinal disorders: http://www.neurosurgery.org/health/patient/answers.asp?disorderID=77

(Updated 8/20/2002)