



CEDARS-SINAI MEDICAL CENTER.

NEWS

8700 Beverly Blvd., Room 2429A ■ Los Angeles, CA 90048-1865

Office (310) 423-4767 ■ Fax (310) 423-0435

Media Contact: Sandra Van

Telephone: 1-800-880-2397

E-mail: sandy@vancommunications.com

FOR IMMEDIATE RELEASE – Jan. 14, 2003

IRB# 3938-01: SB Charite III Intervertebral Disc Spacer

HIGHLIGHTS:

Although spinal fusion offers relief from pain caused by damaged discs, it reduces movement and may lead to long-term problems in adjacent discs. An artificial disc that may be a viable alternative – especially for younger, active patients – is entering Phase II trials in the United States. It is available at Cedars-Sinai Medical Center’s Institute for Spinal Disorders, the largest multidisciplinary spine center in the western United States.

ARTIFICIAL DISC AVAILABLE TO MORE PATIENTS AS SPINE INSTITUTE TAKES STUDY TO NEXT PHASE

LOS ANGELES (Jan. 14, 2003) – An artificial disc being studied as a replacement for damaged discs of the spine has been approved to move into Phase II trials, making it available to more patients, according to John J. Regan, M.D., director of Cedars-Sinai Medical Center’s Institute for Spinal Disorders.

A recently completed Phase I study compared the prosthesis to traditional fusion. In that phase, patients were randomized, with one having a fusion operation for every two that received the artificial disc. Now all patients who qualify to participate in the study will receive the artificial disc.

A healthy disc is a complex structure between the bones of the spine. The nucleus, sandwiched in the center of the disc, contains fluid that serves as a cushion. Layered collagen fibers of the adjacent annulus provide strength. When the components work together, they give the back both stability and flexibility. But when a disc is damaged, the cushion can deflate, bulge or leak, and the collagen loses its elasticity.

Pain is often intense, especially when nerves get caught between degenerating components. To relieve the pain and strengthen the spine, surgeons sometimes remove a disc or place a bone graft in the spine to fuse two bones together and stop the grinding, crunching action in between. While fusion may relieve the pain, it prevents natural, independent motion.

“If something is going to move and one disc is not moving, motion at the discs next to it will increase,” said Dr. Regan. “The major benefit that the artificial disc appears to offer is that motion remains at the disc, which does not put additional stress on adjacent discs.”

(more)

Dr. Regan, who at Cedars-Sinai directs the largest multidisciplinary spine center in the western United States, said surgeons inserting the artificial disc enter through the abdomen, just below the navel, sparing the large muscles of the back. The operation usually takes about an hour and a half, which is less than fusion surgery because it does not require bone grafting. Also, while patients who undergo fusion surgery need to restrict their motion for up to a year, those who receive artificial discs are usually able to be mobile right away.

“Fusion is a very good operation for many people, helping them quite a bit in terms of relieving pain,” said Dr. Regan. “But one of the concerns we have with fusion is that long-term, people often come back with problems at the next disc, and they may need another operation. The artificial disc may prove to be a viable alternative, especially for younger, active patients.”

The Food and Drug Administration will use the results of the current studies to decide whether to approve the device for general use throughout the United States. It was previously approved in Europe.

Cedars-Sinai Medical Center is one of the largest nonprofit academic medical centers in the Western United States. For the fifth straight two-year period, it has been named Southern California's gold standard in health care in an independent survey. Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as breakthrough in biomedical research and superlative medical education. Named one of the 100 "Most Wired" hospitals in health care in 2001, the Medical Center ranks among the top 10 non-university hospitals in the nation for its research activities.

###

If you have received this news release in error and do not wish to receive future advisories, or if they should be directed to someone else in your organization, please call 1-800-396-1002, so we can update our records. Alternatively, you may fax your updated information or your request for removal from our list to 808-263-3364 or e-mail it to sandy@vancommunications.com.