

**FOR IMMEDIATE RELEASE**

**FIRST EVER MULTI-LEVEL ARTIFICIAL DISC CLINICAL TRIAL STARTS FOR  
THE TREATMENT OF CERVICAL (NECK) CONDITIONS**

*Local Beverly Hills surgeon is now enrolling patients in PRESTIGE® LP Cervical Artificial Disc  
Clinical Trial*

**BEVERLY HILLS, Calif.** – John J. Regan, M.D., orthopedic surgeon and medical director of Spine Source in Beverly Hills, is currently enrolling patients in a clinical trial designed to evaluate the safety and effectiveness of the PRESTIGE® LP Cervical Disc. Studied in early 2005 for use in one level of the cervical spine (neck), this clinical trial will examine the use of the PRESTIGE® LP Cervical Disc at two vertebral levels. It is the first multi-level artificial disc study in the United States.

The clinical trial will be used to help support an application to the U.S. Food and Drug Administration (FDA) that could allow the approved future use of the device. The purpose of the clinical trial is to assess the outcomes of patients who receive the PRESTIGE® LP Cervical Disc.

If you are interested in being considered a candidate for the PRESTIGE® LP Cervical Disc clinical trial, please visit [www.neckreference.com/clinicaltrial](http://www.neckreference.com/clinicaltrial).

“I am excited to be one of the surgeons implementing this new technology in a way never done before in the United States,” said Dr. Regan. “The PRESTIGE® LP Cervical Disc will allow surgeons to tailor treatments to the patients needs, offering patients alternatives in spinal surgery.”

About 200,000 cervical fusion procedures are performed each year, often to treat painful degenerative disc disease. During a fusion procedure, the degenerated disc is removed and a bone graft, sometimes taken from the patient’s iliac crest (hip area), or from a donor (cadaver) bone, is inserted in-between the two vertebrae located above and below the removed disc. Often, metal implants are then attached to the two vertebrae to stabilize the area until the bone graft can fuse to the vertebrae creating one solid piece of bone.

A fusion with an anterior cervical plate is currently a very good option for many patients, leaving most symptom-free and back to normal activities within a very short period of time. The artificial disc clinical trial will study another potential treatment option for those patients suffering from degenerative disc disease – an artificial disc to replace the removed disc. Half of the patients who enroll in the clinical study will receive the PRESTIGE® LP Device.

Degenerative disc disease (DDD) is part of the natural process of growing older. As people age, their intervertebral discs lose their flexibility, elasticity, and shock absorbing characteristics. Discs are gel-like cushions that act as shock absorbers between each of the bones of the spine. For approximately half of the population over 40, this process can cause several different symptoms, including chronic pain, nerve root pathology, and spinal cord compression.

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Patients who meet specific inclusion and exclusion criteria will be considered for this study. A few of those criteria are that patients must:

- Be at least 18 years of age with skeletal maturity
- Not be pregnant or nursing at the time of surgery
- Have been diagnosed with cervical degenerative disc disease
- Have not responded to non-operative treatment for a period of 6 weeks
- Meet the following conditions as documented by CT, MRI, or plain x-rays:  
Radiculopathy, myelopathy or both with the presence of disc herniation and/or osteophytes
- Require treatment at only two adjacent cervical levels
- Are willing to comply with the study plan

Both the commonly used fusion method and the new investigational procedure have risks that will be explained to you by the surgeon. All potential candidates are subject to the above and additional non-listed clinical trial criteria. Patients enrolled in the study must be evaluated by their surgeon at regular intervals for a minimum of two years following the surgery.

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

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