



*News Release*  
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## Applied Spine Technologies receives permission from FDA to commence pivotal clinical trial of its flagship product, Stabilimax *NZ*<sup>TM</sup> Dynamic Spine Stabilization System

### Randomized, controlled clinical study will compare Stabilimax *NZ* Dynamic Spine Stabilization System to traditional posterolateral fusion

NEW HAVEN, Conn., Jan. 16, 2007—Applied Spine Technologies (AST) Inc. ([www.appliedspine.com](http://www.appliedspine.com)) announced today that it has received permission under an Investigational Device Exemption (IDE) from the FDA to commence a multi-center, randomized, controlled clinical trial comparing posterior dynamic stabilization using the **Stabilimax *NZ* Dynamic Spine Stabilization System** to patients receiving traditional fusion stabilization to treat degenerative lumbar spinal stenosis. A total of 266 *Stabilimax NZ* patients and 133 control patients will be enrolled in the trial, which is expected to start next month at 20 sites across the U.S.

Stabilimax *NZ* is a posterior dynamic-stabilization system designed to support an injured or degenerated spine. Requiring no tissue removal or replacement, Stabilimax *NZ* is intended to be a substantially less-invasive option for many patients who are currently limited to fusion or artificial disc implants. In Europe, a multi-center, prospective, controlled clinical trial of Stabilimax *NZ* is already underway, and patients have thus far been implanted successfully by Rudolf Bertagnoli, M.D., one of the most experienced *motion-preservation* spine surgeons in the world.

“Spine *fusion* used to be the only option for patients suffering from chronic back pain,” said Thomas E. Wood, President and Chief Executive Officer. “Now, the market is moving rapidly to adopt new *motion-preserving* implants, including artificial discs and dynamic stabilization implants. Our initial product, Stabilimax *BAR*, which was granted a 510(k) last July, is offered as a semi-rigid fusion system that incorporates a unique ball-and-socket pedicle screw feature. However, Stabilimax *NZ*, our flagship product, is designed to be a dramatic advance in back pain treatment by stabilizing the spine without eliminating motion with a therapy that (a) is far less invasive than fusion or disc replacement, (b) uses traditional surgical techniques, and (c) is easily adopted by most spine surgeons. Patients can garner the benefits of Stabilimax *NZ*, which may delay or prevent progression of degenerative spine disease, while leaving the door open to future treatments, such as fusion, should they become necessary.”

Stabilimax *NZ* is the culmination of more than 30 years of focused research by Manohar Panjabi, Ph.D. The underlying premise of Stabilimax *NZ* is that painful spine motion increases in an injured spine and that this abnormal motion is most pronounced in the ‘Neutral Zone’—the area of laxity in the center portion of the spine’s range of motion (ROM). Stabilimax *NZ* utilizes a novel dual-spring mechanism with a uniquely variable dynamic feature that maximizes stiffness and support in the Neutral Zone, where the spine needs it most, thus returning the Neutral Zone to its normal, limited range. By eliminating abnormal motion, the design of Stabilimax *NZ* is intended to alleviate abnormal loading on surrounding muscles and tissues.

AST’S scientific founder, Dr. Manohar Panjabi, is one of the world’s foremost spine authorities. Until his recent retirement, Dr. Panjabi was a professor of Orthopedics & Rehabilitation, as well as Mechanical Engineering, at Yale University School of Medicine. As Director of Yale’s Biomechanics Research Laboratory, Dr. Panjabi established himself as a world-renowned spine authority for his work on spinal joint function and its implications for *motion-preserving* implants. Dr. Panjabi has published 267 research papers and written two text books.

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Applied Spine Technologies Inc. is developing Stabilimax *NZ*<sup>TM</sup>, a posterior dynamic stabilization device designed to support an injured or degenerated spine *without eliminating motion*. Stabilimax *NZ* is expected to offer numerous advantages over current spinal fixation products and even new artificial disc products—including a much less invasive and less traumatic implant procedure, maintenance of spine motion and disc function, and the potential to prevent or slow adjacent-segment disc disease. In addition, it is expected that patients treated with Stabilimax *NZ* can go on to receive fusion surgery or artificial disc replacement, if necessary. Investors in AST include: Oxford Bioscience Partners, Bioventure Investors, InterWest Partners, and De Novo Ventures.

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