Applied Spine
WHERE SCIENCE LEADS

The *Spine Implant* segment has emerged as a favorite among investors in the medical device market. U.S. sales are projected to increase to over $10 billion by 2010. This growth is being fueled by the emergence of alternatives for back-pain patients who have historically been offered only one surgical option: *fusion*. 'Motion-preserving' alternatives, such as *Stabilimax NZ™*, will encourage many patients who have previously lived with their pain to opt for a conservative surgical solution.

Candidates for Stabilimax NZ exist across the entire range of back pain and therapy...

Current fusion patients. Currently, approximately 200,000 lumbar fusions are performed in the U.S. annually. While patients with the worst DDD (Degenerative Disc Disease) and posterior spine compromise will continue to be candidates for fusion, most can be treated with *Stabilimax NZ*: a device that maintains the spine's skeletal and soft tissues while preserving motion. These patients are the primary patient population that will benefit from Stabilimax NZ's *preservation* benefit. In contrast, the artificial disc replacement is contraindicated in patients where there is posterior spine compromise.

Discectomy patients. Over 350,000 U.S. patients receive lumbar discectomies to remove portions of disc that bulge and compress the spinal cord or nerve roots. Oftentimes the discectomy is followed by a fusion procedure to protect the newly created instability. About 40 percent of discectomy patients report with a single, sudden leg pain problem without previous DDD-associated back pain and are best treated with simple discectomy. Some 60 percent of discectomy patients have a history of chronic back pain, and are confirmed with DDD. For many of these patients it is anticipated that *Stabilimax NZ* can provide the stabilization and support to slow or stop the progression of DDD while relieving the pain.

Laminectomy patients. Lumbar laminectomy is performed over 300,000 times annually in the U.S. and most are performed concurrently with fusion. Most of these patients present with spinal stenosis and many have instability that may or may not be characterized by spondylolisthesis). Clinical literature indicates that these patients are optimally treated with fusion to compensate for the resulting instability of the decompression. With the alternative of Dynamic Stabilization, it is anticipated that fusion is an excessive treatment and that motion-preserving stabilization will be the optimal treatment of choice for these patients.

Non-surgical patients represent a potential patient pool that is far greater than all of the segments previously defined. Because Stabilimax NZ will offer a procedure that is less invasive and costly than fusion, preserves motion, and which retains all future treatment options, the Company believes that this segment will actually contribute more to future Stabilimax NZ caseloads than the other segment. ■

What the leading experts* are saying...

Edward C. Benzel, MD
Spine Surgeon
Cleveland Clinic
Cleveland, Ohio

"An enlarged Neutral Zone may very well be associated with mechanical low back pain. Hence, reduction in size of such may be expected to provide relief of associated pain."

Rudolph Bertagnoli, MD
Chief of Spine
St. Elizabeth's Hospital
Straubing, Germany

"What's particularly exciting about Stabilimax NZ is that it uses traditional techniques that can be adopted simply, because they are currently being used by spine surgeons."

John Abbott Byrd III, MD
Spine Surgeon
Private Practice
Atlantic Orthopedic Specialists

"Stabilimax NZ is likely to minimize surgical trauma, which will reduce morbidity and speed recovery to pain-free spine function."

Larry Teik-man Khoo, MD
Assistant Professor
Neurosurgery & Orthopedics
UCLA Medical Center
Los Angeles, California

"Stabilimax NZ represents a fundamental shift in the paradigm of treating back pain, providing dynamic internal support for the diseased spine, thus preserving motion and function."

Manohar M. Panjabi, PhD
Former Professor
Orthopedics & Rehabilitation
Yale Univ. School of Medicine

"Stabilimax NZ has the potential to be a significant advance in back pain therapy, by providing motion with stability, and it is less invasive than fusion surgery or disc replacement."

Hansen A. Yuan, MD
Professor
Orthopedic/Neurological Surgery
State Univ. of New York (SUNY)

"Despite the enthusiasm for artificial discs, I believe many surgeons will never adopt this difficult technique, which is unfamiliar to at least half of the spine surgeons in the U.S."

James J. Yue, MD
Assistant Professor
Orthopedic Surgery
Yale School of Medicine

"Stabilimax NZ is anticipated to be a much less invasive alternative to fusion and to disc replacement technologies, all of which require major surgery."

Ken S. Yonemura, MD
Spine Surgeon
Univ. of Utah Hospital
Salt lake City, Utah

"It's important to note that Stabilimax NZ is designed to compensate for the deficits in a patient's spine, rather than to replace deficient components."

Jack E. Zigler, MD
Spine Surgeon, Texas Back Inst;
Clinical Asso. Prof., Ortho. Surg.,
Univ. of Texas-Southwestern
School of Medicine, Dallas, Tex.

"Less-invasive solutions like Stabilimax will encourage many patients who have preferred to live with their pain, rather than undergo fusion, to opt for this more conservative surgical solution."

* All Experts Are Members of Applied Spine Technologies' Scientific Advisory Board.