



Business Wire - Press Release

Titan Spine's ENDOSKELETON(R) TA Passes Test In Competitive Lower Back Pain Market

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Titan Spine's ENDOSKELETON(R) TA Titanium Vertebral Body Replacement (VBR) device has performed extremely well in a variety of recent mechanical tests and shown that it is here to stay. In a study released by a team of doctors from the University of Wisconsin Hospital-Madison, lead by Paul A. Anderson, MD, the ENDOSKELETON(R) TA's performance on a battery of tests was stacked up against competing spine devices of varying conventional materials including PEEK (Polyetheretherketone), allograft bone implants, and titanium threaded fusion devices. Utilizing bovine lumbar spine segments, the team aimed to put each device through tests meant to simulate the type of stresses that they would face when implanted within the human spine.

The tests revealed that the ENDOSKELETON(R) TA's unique dual acid-etched surface and wide apophyseal footprint design performed exceptionally well with respect to pull-out strength. Dr. Anderson said "The ENDOSKELETON(R) TA performed well and had mean resistances of 702N and 904N for small and large devices respectively. Only the large Ray Cage had significantly greater expulsion resistance. The ENDOSKELETON(R) TA devices had significantly better results than the PEEK and allograft devices."

In addition to superior pull-out strength, the study revealed that the ENDOSKELETON(R) TA showed the greatest resistance to subsidence of all implants included in the study. "The performance of the ENDOSKELETON(R) TA in Dr. Anderson's study further corroborates the excellent outcomes I've witnessed over the years in patients with whom I've used the device. This unique design appears to minimize the tendency for subsidence compared to the shape of the other cages, where weight bearing is more centrally located," claims Peter Ullrich JR, MD of the NeuroSpine Center of WI. David DeWitt, M.D. adds "combining the bioactive dual acid-etched surface of the ENDOSKELETON(R) TA, along with its wide titanium footprint, seems to promote a positive environment for bone in-growth and better stability. I believe that this is one of the reasons our patients have significantly faster recovery times with very few of them requiring an operative revision compared to what is reported in our industry."

Steve Cichy, Vice President of Sales & Marketing and Jason Rice, Marketing Manager for Titan Spine, are both excited with the results as well. Cichy states that "our ENDOSKELETON(R) TA continues to perform extremely well within our market niche. The results of this study have added a substantial amount of data supporting ENDOSKELETON(R) TA's benefits in discussions with new physicians." Rice also adds, "the mechanical test results may not come as a very big surprise to many of the current physicians utilizing the device now, but it will no doubt serve to better substantiate and confirm what many have already experienced clinically."

Kevin Gemas, President of Titan Spine, is confident that the mechanical study will compliment the additional studies the company plans to do this year. Gemas mentioned that the company's Senior Research & Operations Engineer, Jennifer Schneider, along with the support of Titan Spine's Scientific Advisory Board, will "coordinate and manage a multi-center cohort clinical study this spring as well as a histological animal study for late 2008 or early 2009. The clinical study is aimed to gauge the outcomes of treating lumbar degenerative disc disease utilizing the ENDOSKELETON(R) TA compared with the other conventional treatments for this pathology." Titan Spine is also planning to release three new devices for commercialization later this year, but their studies still remain the top priority. "Our goal is to become the leader in this segment of the industry. With that, there are inherited responsibilities that we must meet to research, examine, and validate the most reliable bioactive surface designs and FDA approved substrates that are available to use today."

## About the Company

Titan Spine, LLC is a privately owned company in Mequon, WI focusing on the design and manufacturing of bioactive interbody fusion devices for the lumbar and cervical spine. Founded in 2005, the company is committed to developing the best products for the treatment of various pathologies that cause lower back and neck pain.

NOTE: The ENDOSKELETON(R) TA has been cleared for use as a VBR and 510k IBD Certification is pending.