MedShape Announces Breakthrough In Joint Fusion With New Device

MedShape, Inc., the industry leader in innovative shape memory orthopedic devices, today announced the introduction and first surgical use of the DynaNail™ Ankle Arthrodesis Nail, an intramedullary (IM) nail that contains an innovative internal nickel titanium (NiTiNOL) element. The product represents a breakthrough in that it is the first IM nail to harness the shape memory properties of NiTiNOL, which up to now has been impeded from clinical use due to various technological challenges ranging from basic materials science to manufacturing and device design.

After receiving 510(k) clearance from the U.S. Food and Drug Administration, DynaNail was successfully used in an ankle arthrodesis procedure performed by Dr. Doug Pacaccio, DPM, at Valley West Community Hospital in Chicago, IL.

"I was impressed with the performance of the DynaNail device," commented Dr. Pacaccio, who is a co-founder of MedShape. "The nail sustains compression across the joint like an external fixator, but because it is inserted like traditional IM nails, it reduces operating time significantly. I believe many podiatrists and orthopedic surgeons will recognize the benefits of the DynaNail device and will incorporate it in their ankle fusion procedures."

DynaNail is expected to become an effective alternative to external fixators for treating limb salvage procedures, as the NiTiNOL compressive element gives the nail unique properties over traditional IM nails. Compression across the joint is important for not only ensuring the joint bones remain in close apposition, but also in promoting healing.

"The NiTiNOL compressive element allows DynaNail the ability to apply sustained compression across the joint on the level of an external fixator. Traditional nails lose compression upon hardware removal or require follow-up procedures to re-apply compression," said Jeremy Blair, team leader for DynaNail. "NiTiNOL gives DynaNail 'shape memory' so that it can automatically transform and adapt to bone resorption minimizing the need for follow-up procedures."

The promise of NiTiNOL for orthopedic fixation implants was first identified more than 30 years ago by American metallurgist William Buehler(1) and surgeon Dr. James Hughes of Johns Hopkins in a report to the United States Army; but up to now, researchers and companies were unable to translate the alloy into a large commercial orthopedic device due to challenges across various engineering disciplines. As a result, NiTiNOL's use in orthopedic implants has been limited to small staples and suture anchors, neither of which fully harnesses the capabilities of the alloy. In addition to patenting a new surgical method to activate NiTiNOL inside the body across fracture and fusion sites, scientists at MedShape developed and

cleared a new NiTiNOL material, one that facilitates machining into complex geometries necessary to integrate the NiTiNOL into a titanium platform. The combination of the titanium and NiTiNOL provides the rigidity of traditional IM Nails in bending and torsion with the axial compressive power of an external fixation frame.

"As a leader in shape memory devices, we are proud of the DynaNail launch and enthusiastic about its efficacy in orthopedic surgery," said Blair. "Its successful use by Dr. Pacaccio in ankle arthrodesis surgery is a clear indicator of the exciting future it holds for podiatrists and orthopedic surgeons everywhere."

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