MedShape Solutions Announces FDA 510(k) Clearance of Innovative Ankle Fusion Device

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ATLANTA, Aug. 9, 2011 /PRNewswire/ -- MedShape Solutions, Inc., the industry leader in innovative shape memory orthopedic devices, today announced its new DynaNail™ Intramedullary Ankle Fusion Nail. Ankle fusion is performed to relieve pain in patients with severely degenerative ankle joints, to correct joint deformities or to revise failed total ankle replacements. The DynaNail's unique, patented design utilizes shape memory alloy technology to actively adapt to changes, such as local bone resorption, in the arthrodesis (fusion) site. By adapting to such changes, the DynaNail may better maintain close apposition of the bones and compression across the fusion zone during the healing process. Bones in contact with each other and under compressive load heal together faster than bones held apart.

The DynaNail device, intended for tibiotalocalcaneal arthrodesis procedures, incorporates an innovative shape memory internal element that is simply stretched during the insertion procedure. Once the nail is fixed in place with screws, the shape memory alloy element maintains the target fusion bones in close apposition and under sustained compression for longer time periods than static, non-adaptive intramedullary devices. Surgeons implant the DynaNail using a surgical technique similar to that of traditional ankle fusion nails, thereby dramatically reducing the learning curve required for the new technology.

Surgeons also commonly use external fixation devices, consisting of bulky frames connecting the patient's lower leg to the foot, to achieve ankle fusion. The surgeon may adjust such external fixators during the bone-healing period to maintain bony apposition and compression, but these devices often demonstrate poor patient compliance and ongoing management issues.

The DynaNail's co-inventor, Dr. Doug Pacaccio of Advanced Foot and Ankle Surgeons in Yorkville, Ill., stated, "The DynaNail combines the patient compliance and easier post-operativ
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