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SpineAlign Medical Announces Clinical Presentation on SpineAlign System by Dr. Giovanni Carlo Anselmetti

ROME and SAN JOSE, CALIF.-- (August 18, 2009) – SpineAlign Medical, Inc. (formerly SpineWorks Medical, Inc.) announced today the presentations of Dr. Giovanni Carlo Anselmetti, MD of the Institute for Cancer Research and Treatment in Turin, Italy and his associate, Antonio Manca, MD. This clinical data, using the SpineAlign System, was presented at the recent American Society of Spine Radiology (ASSR)/European Society of Neuroradiology (ESNR) joint conference in Rome. The presentation entitled, “*Vertebral augmentation performed by means of percutaneous nitinol prosthesis placement: results and follow up in 34 patients*” was conducted under the direction of Dr. Anselmetti.

“The SpineAlign implant worked well at restoring the vertebral body, lifting the endplates and allowing height restoration to be maintained until bone cement was injected. It also allowed me to slowly inject the bone cement, significantly reducing the risk of extravasation associated with traditional vertebroplasty,” said Dr. Anselmetti. “In addition, the ability to collapse and reposition, or even retrieve the implant entirely, prior to cement delivery, gives the SpineAlign device greater utility in delivering optimal reconstruction, than some of the other devices that do not even allow for simple adjustments related to positioning.”

Summary of the Presentation Results:

- 34 patients, age range was 57-88, with an average age of 78 years.
- There were no reported complications or adverse events.
- Back pain significantly improved by an average of a 7.4 point reduction in Visual Analog Scale, (0 to 10 scoring).
- Significant vertebral height gain was achieved ($p < 0.0001$) with peak value at the midpoint in sagittal view (average of 4.5 ± 3.7 mm).
- The average Oswestry Disability Index score, an indication of quality-of-life, improved from 70.3% to 5.4% , an improvement of 64.9%.
- Two (2) vertebra plana (compression fractures $>70\%$) were treated successfully.

“These data, coming from a reputable physician such as Dr. Anselmetti, demonstrate how the anatomically contoured implants work together with the bone cement to provide outcomes for this patient population and shows the potential for the SpineAlign System,” said Paul Chirico, President and CEO of SpineAlign Medical.

Dr. Anselmetti, an expert in the field of vertebroplasty, presented the largest long-term case series of 884 patients with painful vertebral collapse due to osteoporosis, metastases, myeloma, symptomatic angioma, or trauma, at the Society of Interventional Radiology (SIR) Annual

Scientific meeting in 2007. Since that presentation, he has treated more than 1,900 additional patients.

About SpineAlign

The SpineAlign device represents the first of many new innovations in the area of minimally invasive percutaneous vertebral body reconstruction and augmentation to be developed by SpineAlign Medical. The SpineAlign device is a vertebral body implant designed to treat fractures in the thoracic or lumbar spine in patients suffering from osteoporosis. The SpineAlign Implant is an expandable metal device made from nickel-titanium (Nitinol) alloy that provides internal scaffolding to engage the vertebral body endplates, while providing and maintaining lift until bone cement is injected. SpineAlign is available in two shapes and a range of sizes to address different anatomical needs for the treatment of vertebral compression fractures. Prior to injection of bone cement, the SpineAlign Implant is fully retrievable. The SpineAlign device is not yet commercially available in the United States but is currently in clinical evaluation to support a 510(k) filing with the FDA.

SpineAlign Medical, Inc., is an early-stage medical device company dedicated to the design, development and successful commercialization of minimally-invasive products for spine procedures.