



## **Spine Wave Announces Start of NuCore® RPXL Injectable Nucleus Study in Europe**

SHELTON, CT – October 31, 2011 – Spine Wave, Inc. today announced that the Company has initiated a clinical study to gather data on a second generation design of the NuCore® Injectable Nucleus Device. The purpose of this pilot study is to determine the feasibility of implanting the NuCore® device via a proprietary percutaneous technique for the treatment of Degenerative Disc Disease (DDD). NuCore® material is comprised of a synthetic polymer that has been designed to mimic the properties of the natural nucleus. This second generation device contains a transient radiopacifier which allows the material to be visualized intra-operatively on fluoroscopy during percutaneous injection.

“Being able to provide surgeons with the ability to treat early stage DDD with a percutaneous injection remains one of the greatest unmet needs in spine. We are very excited to pursue this clinical study of the NuCore® device with Dr. Berlemann,” said Mark LoGuidice, Spine Wave Chairman and CEO. “He is a well respected investigator who published his prior results with NuCore® Injectable Nucleus in the European Spine Journal<sup>1</sup>. This study will be additive to our previous clinical work, which includes 68 patients implanted with all patients at or beyond the two-year follow up time point. The device has demonstrated both safety and the ability to maintain disc height.”

“NuCore® Injectable Nucleus represents a potentially significant enhancement in the way the medical community approaches the early stages of disc degeneration within the standard continuum of care” commented Dr. Ulrich Berlemann, The Spine Center, Thun, Switzerland. “If successful, this procedure will provide patients who have failed conservative care with a new treatment option which may allow them to avoid or delay major spine surgery. Perhaps the most exciting aspect of the procedure is that it “burns no bridges”. Although the initial results from this current study are very preliminary, patients have shown significant reductions in pain scores within the three month post operative evaluation.”

NuCore® RPXL Injectable Nucleus represents another continuing effort by Spine Wave to carry on the advancement of medical device technology to improve patient care and

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<sup>1</sup> Eur Spine J (2009) 18:1706-1712

provide minimally invasive options to the surgeon community. The NuCore® material is an rDNA-based protein polymer that has physical properties very similar to those of healthy human disc nucleus. The material is completely synthetic, having no animal or human derived components used in its manufacture. The material is injected percutaneously into the disc in liquid form, then cures in situ, providing an augmentation material for the natural nucleus. The goal of treating DDD patients by injecting NuCore® material into a patient's disc space is to relieve pain, preserve the disc height and restore biomechanical function. Patient treatment with NuCore® RPXL does not preclude future treatments of the affected level such as fusion or total disc arthroplasty.

### **About Spine Wave**

Spine Wave is committed to the development and delivery of high-quality innovative medical devices for the treatment of spinal disorders. The Company is focused on commercializing technology platforms that offer spine surgeons novel and useful solutions to common surgical problems. The Company's product portfolio includes the StaXx® XD Expandable Device, StaXx® XDL Expandable Device, CapSure® PS2 Spine System, Sniper® Spine System, NuCore® Injectable Nucleus, and several additional products in development. For further information, visit the Company's website at [www.SpineWave.com](http://www.SpineWave.com).

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