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FOR IMMEDIATE RELEASE

PARADIGM SPINE ANNOUNCES U.S. FDA PMA APPROVAL OF ITS LANDMARK COFLEX® INTERLAMINAR TECHNOLOGY: The 1st Comparative Effectiveness Study For the Treatment Of Spinal Stenosis

New York, NY, October 17, 2012 - Paradigm Spine LLC, a provider of innovative spinal implant technologies, announces the U.S. Food and Drug Administration ("FDA") has granted a Premarket Approval ("PMA") Order for coflex®, a minimally invasive, Motion Preserving Interlaminar Stabilization™ device for the treatment of Moderate To Severe Stenosis With Or Without Back Pain™.

Key Points:

- First PMA for the treatment of Moderate To Severe Stenosis With Or Without Back Pain™
- First prospectively randomized comparative effectiveness Investigational Device Exemption (IDE) study that evaluated pedicle screw fusion following surgical decompression, the current standard of care for the treatment of moderate to severe spinal stenosis, as the control. This study is unique in spine because it prospectively collected Level 1 clinical, radiographic, safety and healthcare economic data. The coflex® device demonstrated better or equivalent outcomes in all major primary and secondary endpoints.
  - The coflex® patients spent 40% less time in the hospital compared to fusion (1.90 vs. 3.19 days), and coflex® surgeries were 36% faster compared to fusion (98 vs. 153 minutes)
  - At 2 years follow-up, 85.8% of coflex® patients showed clinically significant improvement in pain and function (measured by Oswestry Disability Index), compared to 76.7% of fusion patients
  - At 2 years follow-up, coflex® patients retained their pre-operative range of motion (within 10%) and translation (within 5%) at the treated level and maintained normal adjacent level motion. In contrast, fusion patients experience 62% motion reduction at the treated level, and 52% increase in range of motion at the superior adjacent level.
- First PMA to collect healthcare economic data for spinal stenosis. The study data and resulting analyses demonstrate that coflex® saves the healthcare system an average of $5,000 to $8,700 per case when used as an alternative to pedicle screw fusion[1].
- The coflex® study included a significant Medicare-aged patient population.
- The coflex® device, now available in the United States, has more than 18 years of clinical history with regulatory approval in over 40 countries throughout 6 continents.

The coflex® clinical trial supporting the PMA represents the most comprehensive Level 1 comparative effectiveness study for the treatment of spinal stenosis. The rigorous six year clinical trial proves coflex® as the first and only motion-preserving alternative to fusion for the treatment of moderate to severe spinal stenosis, by demonstrating better or equivalent outcomes in all major primary and secondary clinical and radiologic assessments, while maintaining natural motion at both treated and adjacent spinal levels. The study results are based on data evaluated from 322 patients, at 21 sites throughout the United States, who presented with a history of spinal stenosis that failed over 6 months of conservative therapy. The patients enrolled in the study

were prospectively randomized to receive a surgical decompression and either coflex® Interlaminar Stabilization™ or pedicle screw fusion. The coflex® device outperformed fusion in nearly all clinical, radiographic, and perioperative outcomes, supplemented with healthcare economic data measured through 589 data points evaluated for each individual study subject over a 2 year follow-up period. The data compiled for this study comprised more than 55,000 patient-completed case report form pages, more than 375,000 clinical and radiographic data points, more than 12,000 patient x-rays and prospective health insurance, reimbursement payment and claims data. The rigor of the clinical trial and the robustness of its results are supported by over a 95% follow-up through two years postoperatively, among the highest follow-up rate for any PMA approved device in spine.

According to a Wall Street Journal analysis of data compiled by the Centers for Medicare & Medicaid Services, it is estimated that fusion costs the United States government Medicare system more than $2.2 billion annually[2]. The coflex® study is the first and only to quantify actual cost savings based on prospective Level 1 data, compared to the current standard of care, posterolateral fusion. On average, coflex® saved $5,000 to $8,700 per case compared to fusion[1]. These substantial cost savings were achieved through significantly shorter operating room time, faster patient recovery, less blood loss, less narcotics usage by patients, and shorter hospital stay, while producing faster and more sustained clinically successful outcomes as compared to fusion in the treatment of spinal stenosis.

The PMA process is the most stringent FDA regulatory pathway for medical devices, where approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use, and that the benefits of the procedure and device outweigh its risks. The FDA's Summary of Safety and Effectiveness Data, states "Based on the clinical study results, it is reasonable to conclude that a significant portion of the indicated patient population will achieve clinically significant results. In conclusion, the coflex® device represents a reasonable alternative to posterolateral fusion for the treatment of spinal stenosis."

Marc Viscogliosi, Chairman and CEO, stated "This study provides the evidence insurance companies, surgeons and patients have been demanding. Insurance companies, surgeons and patients finally have an alternative to fusion which, based on independent study data, has demonstrated that coflex® produces better outcomes, a faster recovery, preserves motion and may be performed on an outpatient basis. For patients, the ability to walk without back pain and the progressive symptoms of stenosis is one of the most cherished functions of the aging population."

Hal Mathews, M.D., Executive Vice President and Chief Medical Officer, stated "The coflex® study results represent a celebration of evidence for surgeons, their patients and the insurance community. We now have objective evidence of the detrimental clinical effects and relatively expensive costs of pedicle screw fusion on spinal stenosis patients. Although outcomes for pedicle screw-based fusions have been historically acceptable, it was the only option surgeons had for the last 25 years to provide stabilization when indicated, along with the decompression procedure. Importantly, coflex® was able to deliver better outcomes at a significantly lower cost to the healthcare system, which we believe is an important mandate of the current healthcare reform law."

Reginald Davis, M.D.[3], Principal Investigator for the coflex® study, stated "This is the first time a new spinal technology is proven to be better and more effective than the historical gold standard, and is still actually lower cost. I am excited to be able to provide coflex® to my patients without the need for fusion through a simple, motion preserving, and minimally invasive bone-saving surgical technique."

For additional information on Paradigm Spine LLC, the coflex® interlaminar technology and the coflex® procedure, please visit our new website at www.paradigmspine.com.

About Paradigm Spine LLC

Paradigm Spine LLC, founded by Viscogliosi Bros., LLC in 2004, is a privately held company focused on the design, development and marketing of solutions for the treatment of spinal conditions and diseases. The company's signature product is the coflex® Interlaminar Stabilization™ device, which has more than 18 years of clinical history with regulatory approval in more than 40 countries throughout 6 continents.

About Lumbar Spinal Stenosis

According to the American Association of Neurological Surgeons (AANS), lumbar spinal stenosis is defined as the narrowing of the spinal canal that compresses the nerves traveling through the lower back and into the legs. While it may affect younger patients due to developmental causes, spinal stenosis is a condition most commonly caused by degenerative changes of the spine in people age 60 and older. Its symptoms include pain, weakness, or numbness in the legs, calves or buttocks and are often associated with low back pain. More than 400,000 Americans, most over the age of 60, may be suffering from the symptoms of lumbar spinal stenosis, and as many as 1.2 million Americans have back and leg pain related to any type of spinal stenosis.

As stated by Katz et al. in the New England Journal of Medicine (February 2008), lumbar spinal stenosis is the most frequent indication for spinal surgery in patients older than 65 years of age.

Forward-Looking Statements

This news release contains forward-looking statements as defined in the U.S. Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of risks and uncertainties impacting Paradigm Spine LLC's business including increased competition; the ability of Paradigm Spine LLC to expand its operations and to attract and retain qualified professionals; technological obsolescence; general economic conditions; and other risks.

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[1] These results were obtained from analyses of intraoperative, postoperative, perioperative, narcotics and supply costs, and were derived from actual costs reported by study sites, supplemented by estimates or assumptions where actual numbers were not or could not be obtained.

[2] Carreyrou, J, & McGinty, T. Top Spine Surgeons Reap Royalties, Medicare Bounty. Wall Street Journal. Retrieved October 12, 2012 from http://online.wsj.com/article/SB10001424052748703395204576024023361023138.html.

[3] Dr. Davis provides training and education services for Paradigm Spine LLC. Dr. Davis does not receive any royalty income from, and is not an investor in, Paradigm Spine LLC.