



**Contact:** Marc R. Viscogliosi  
**Tel:** (212) 367-7274, Ext. 2103  
**Email:** [marc.viscogliosi@paradigmspine.com](mailto:marc.viscogliosi@paradigmspine.com)

**FOR IMMEDIATE RELEASE**

**PARADIGM SPINE, LLC ANNOUNCES PUBLICATION OF ISASS GUIDELINES  
RECOMMENDING COVERAGE OF INTERLAMINAR STABILIZATION®**

**New York, NY December 6, 2016** – Paradigm Spine, LLC, a leader in providing solutions for the treatment of lumbar spinal stenosis (LSS) announces publication of the International Society for the Advancement of Spine Surgery (ISASS) Policy Statement on November 10, 2016 by Richard Guyer, M.D., et al of “ISASS Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization – Coverage Indications, Limitations, and/or Medical Necessity” in the *International Journal of Spine Surgery*, a high-quality peer-reviewed journal published on behalf of ISASS. Please find a link to the article here: <http://dx.doi.org/10.14444/3041>.

Per the Policy Statement, lumbar decompression with interlaminar stabilization is recommended for coverage in carefully selected LSS patients without gross instability or in which the decompression procedure itself may create iatrogenic instability. The Policy Statement accurately notes that “there exists a population of patients who present with moderate to severe stenosis, with concomitant back pain, where decompression alone does not adequately address back pain.” Interlaminar stabilization after direct decompression is a non-fusion surgical option that can provide the additional stability over decompression alone without the rigidity of an instrumented fusion. The Policy recognizes the benefits of coflex compared to fusion and further states, “In select patients within the LSS continuum, decompression with interlaminar stabilization has proven to provide equivalent outcomes with a reduced cost compared to decompression plus fusion.”

As the only spine product that has achieved FDA Premarket Approval (PMA) for up to a Grade I spondylolisthesis with a concomitant decompression, the coflex® Interlaminar Stabilization® non-fusion device maintains motion, reduces both leg and back pain, and preserves foraminal height. Marc Viscogliosi, Chairman and CEO of Paradigm Spine, LLC comments, “We are excited to have the recognition and support of ISASS in this publication. The policy statement supports our goals of improving patient access, building awareness among physicians, payors and policy makers, making coflex a compelling covered treatment option for patients with stenosis.”

Hallett Mathews, M.D., MBA, EVP & CMO of Paradigm Spine, LLC commented “We are very happy that ISASS has issued these important guidelines and are confident that it will be immensely helpful to all physicians and patients. Surgeons, health insurers and policy makers rely on publications issued by societies for current information on leading industry developments, clinical advancements and for guidance in making choices on various treatment methods for their patients. As the publication appropriately states, with the growing population in the US, there is a rising incidence of LSS and varying options of therapeutic pathways. Therefore, it is becoming increasingly important for the new treatment alternatives available for LSS to be supported by strong clinical data from long term studies, as coflex has recently published its own five-year study results. Over the last four years, more than 1,000 physicians in the US have treated nearly 20,000 patients and now with these published guidelines by ISASS and having its own new CPT code becoming effective January 1, 2017, using coflex for interlaminar stabilization after a decompression is quickly becoming the preferred choice of treatment by many physicians in both an in-patient and out-patient setting.”

**About Paradigm Spine, LLC**

Paradigm Spine, LLC was founded in 2004 and remains focused on the design and development of solutions for the disease management of spinal stenosis. The Company's signature product is the coflex® Interlaminar Stabilization® device, which has more than 20 years of clinical history and patients treated in more than 40 countries worldwide.