

PARADIGM SPINE HIGHLIGHTS DATA PRESENTED AT ISASS 2018 FURTHER VALIDATING DECOMPRESSION WITH COFLEX

Results presented in three podium presentations during the 2018 International Society for the Advancement of Spine Surgery

NEW YORK, NY April 30, 2018

Paradigm Spine, LLC, a leader in providing motion preservation solutions for the treatment of lumbar spinal stenosis, today announced results of three subanalyses from studies of coflex[®] that further validate the efficacy and benefit to patients with lumbar spinal stenosis. The data were presented during three scientific podium presentations at the 2018 International Society for the Advancement of Spine Surgery (ISASS), held April 11-13 in Toronto, Canada.

“coflex[®] is the only posterior lumbar motion preservation solution with proven long-term outcomes for patients with moderate to severe spinal stenosis,” said Marc Viscogliosi, Chairman and CEO of Paradigm Spine. “Five years after the FDA IDE study, these analyses demonstrate that coflex leads to decreased operative time, less blood loss, shorter hospital stays and overall is significantly less invasive than fusion. As a result, coflex is more cost-effective for the healthcare system while preserving positive clinical outcomes. These findings are substantial and important because they reflect real-world considerations surgeons take into account when treating patients.”

The first podium presentation “5-year Follow-up of Interlaminar Stabilization Surgery in the ≤ 65 Year Old Patient: More Value, Less Cost,” provided a sub-analysis of a cohort from the original multi-center, prospective, randomized, controlled Investigational Device Exemption (IDE) clinical trial that showed:

- coflex was significantly less-invasive as measured by shorter operative times, decreased blood loss, and shorter length of hospital stay than fusion.

The lightning podium presentation “Medical Cost Savings for Lumbar Spinal Stenosis Treated with Decompression and Interlaminar Stabilization as an Alternative to Fusion” examined the potential economic impact of utilizing decompression with coflex versus decompression with fusion. The analysis showed:

- fusion surgery is more than \$50,000 more expensive per procedure, as compared to decompression with coflex.
- coflex as an alternative to fusion in a clinically appropriate subset of LSS patients would favorably impact the total cost of care while preserving clinical outcomes.

A second lightning podium presentation “Comparison of Decompression with Interlaminar Stabilization vs. Decompression with Fusion in Patients Requiring Surgical Treatment for Spinal Stenosis Grade I Spondylolisthesis at 5 Year Follow-Up” provided a sub-analysis of a cohort from the FDA IDE trial comparing the efficacy of decompression with coflex versus decompression with fusion and concluded:

- coflex is a significantly more cost-effective option for the healthcare system due to approximately half the operative time and a hospital stay that was almost two days shorter.

About Lumbar Spinal Stenosis (LSS)

Lumbar spinal stenosis (LSS), affecting 1.6 million patients annually in the United States, is a debilitating and degenerative disease often associated with significant leg and back pain, leg numbness and weakness, and significant reduction in an active lifestyle. Historically, the two traditional surgical treatment options for LSS included decompression alone or decompression with lumbar fusion. Decompression alone has proven effective at relieving pain symptoms caused by lumbar spinal stenosis, however, patients may not experience long term symptomatic relief, resulting in subsequent epidural injections for pain management, or additional surgeries for



conversion to a fusion. Decompression with fusion has proven to provide pain relief and stabilize the diseased segment, but may lead to adjacent level disease requiring subsequent surgeries.

About Paradigm Spine, LLC:

Paradigm Spine, LLC, founded in 2004, is a privately held company 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 is currently used in over 60 countries worldwide. *coflex* is the only lumbar spinal device that has produced Level I evidence in two separate prospective, randomized, controlled studies against two different control groups, changing the standard of care for lumbar spinal stenosis treatment. For additional information visit www.paradigmspine.com or www.coflexsolution.com.

Contact:

The Ruth Group

Kirsten Thomas

Tel: (508) 280-6592

Email: kthomas@theruthgroup.com