

UPMC PINNACLE FIRST IN THE U.S. TO ENROLL PATIENT IN SPINAL STENOSIS STUDY

National FDA Pivotal Study of TOPS™ System Examines Alternative to Fusing Vertebrae

HARRISBURG, PA. (DATE) – Steven DeLuca, DO, a spine surgeon with The Orthopedic Institute of Pennsylvania (OIP), a division of OrthoPA, performed the first TOPS™ surgery in the U.S. at UPMC Pinnacle West Shore in Mechanicsburg in July 2017. The **TOPS™ System** is part of an FDA pivotal investigational device exemption (IDE) study sponsored by Philadelphia-based Premia Spine. The study evaluates the use of the TOPS™ System for patients with degenerative Grade I spondylolisthesis and spinal stenosis as an alternative to vertebrae fusion. The goal of the TOPS trial is to demonstrate patients can achieve greater range of motion in all directions with the investigational procedure.

Spinal stenosis/degenerative spondylolisthesis are back conditions that are caused by the narrowing of the spinal canal. As people age, these conditions can develop due to the drying out and shrinking of the disc spaces between the bones. (Eighty percent of the disc is made up of water.) It is most common in women over the age of 50. The condition can cause pain or numbness in the back and legs, cramping, weakness, incontinence or difficulty walking. Surgery can be recommended when non-surgical treatments do not relieve pain.

The TOPS™ System mechanical device is designed to restore motion of the spine in all directions. Instead of permanently locking the two vertebrae with a fusion, the device allows the two vertebrae to continue moving. UPMC Pinnacle is one of 30 spine centers throughout the U.S. taking part in the study to evaluate the efficacy and safety of the TOPS™ System compared to traditional lumbar fusion.

“There are many people suffering from debilitating back pain caused by a slipped disc or narrowing of the spine who fail to recover after extended physical therapy and injections,” stated Dr. DeLuca. “We anticipate that this study will provide the medical community with the data to support the continued use of both fusion and non-fusion technologies to address debilitating spinal conditions.”

Patients are randomly selected to have surgery with the TOPS™ System or lumbar spinal fusion with a 2:1 randomization (67 percent likelihood) of undergoing surgery with the Premia device. Study participants must be experiencing: radiating leg pain, greater leg or buttock pain than back pain, severe pain after walking as little as 100 yards or two minutes, and/or pain that reduces when sitting, bending forward or leaning over a shopping cart. These symptoms could be signs of degenerative spondylolisthesis, spinal stenosis and additional spinal conditions.

“We are very excited to be selected as a study center in the TOPS™ System IDE because it offers a unique opportunity for patients who meet the study’s criteria to potentially receive a motion preserving device for the surgical treatment of degenerative spondylolisthesis and spinal stenosis,” said James A. Raczek, MD, senior vice president of medical affairs and chief medical officer for UPMC Pinnacle.

About UPMC Pinnacle UPMC Pinnacle is a nationally recognized leader in providing high-quality, patient-centered healthcare services in central Pennsylvania and surrounding rural communities. Its more than 2,900 physicians and allied health professionals and approximately

11,000 employees serve a 10-county area at outpatient facilities and eight acute care hospitals with 1,360 licensed beds: Carlisle, Community Osteopathic, Hanover, Harrisburg, Lancaster, Lititz, Memorial, and West Shore. The not-for-profit system anticipates caring for more than 1.2 million area residents in FY 2018. For more information, visit www.UPMCPinnacle.com.

About The Orthopedic Institute of Pennsylvania and Steven DeLuca, DO

The Orthopedic Institute of Pennsylvania, a division of OrthoPA, is a group practice with nine locations and 35 physicians. The Orthopedic Institute of Pennsylvania specializes in a variety of services including Orthopedic Surgery of Spine, Orthopedic Surgery, Sports Medicine, Hand Surgery, Foot and Ankle Surgery, Regenerative Medicine, Fracture Care, Osteoporosis and Bone Health, Physical Medicine and Rehabilitation and Anesthesiology as well as offering acupuncture and other alternative treatments and diagnostic services.

Steven DeLuca, DO, joined The Orthopedic Institute of Pennsylvania in 2007 and specializes in Orthopedic Spine Surgery. His other areas of special interests are sports medicine, shoulder surgeries, hip and knee arthroplasty, minimally invasive spine surgery, joint replacement, fracture care and regenerative medicine. Dr. DeLuca attributes his success to staying abreast of the new advancements in orthopaedic and spine surgery techniques. He is certified by the American Board of Orthopedic Surgery and maintains multiple professional memberships.