FDA approves IDE study for Premia Spine's TOPS™ System

Press Release Source: Premia Spine Ltd. on Monday, May 8, 2017

Philadelphia, PA, May 8, 2017 -- Premia Spine, Ltd. announced today that it has secured FDA approval for its pivotal study of the new TOPS™ System.

"We are excited about the opportunity to provide U.S. patients with access to the only posterior arthroplasty device for degenerative grade I spondylolisthesis and spinal stenosis, with thickening of the ligament or scarring of the facet capsule," said Ron Sacher, CEO of Premia Spine.

The new TOPS device, with a 30% smaller footprint and a simpler surgical technique from the original device, has been in commercial use in Europe for over 5 years.

The IDE study will take place in 30 institutions and enroll 330 subjects. Patients will be randomized to either the TOPS™ System or lumbar fusion (i.e., an interbody cage plus screws and rods), with a 67% likelihood of receiving the TOPS device.

The study's lead investigator is Dom Coric, Chief of Neurosurgery, at Carolinas Medical Center. Clinicians who have received approval or are in the process of securing IRB approval include Josh Ammerman and Josh Wind (Sibley Hospital), Neel Anand and Hyun Bae (Cedar Sinai), Steve DeLuca (Orthopedic Institute of Pennsylvania), Jason Huang (Baylor Scott & White), Armen Khachatryan (The Disc Replacement Center at Jordan Valley Medical Center), Andy Kranenburg (Providence Medford Medical Center), Scott Leary (Scripps Health), Ali Mesiwala (Southern California Center for Neuroscience and Spine), Kent New, Steve Pirris, Eric Nottmeier, and Ali Chahlavi (St. Vincent's Medical Center), Pierce Nunley (Spine Institute of Louisiana), Rick Sasso (Indiana Spine Group), Bill Smith (Western Regional Brain & Spine), Don Whiting (Allegheny Health Network), Phil Yuan (Memorial Long Beach Hospital) and Jim Zucherman, Ken Hsu, and Dimitriy Kondrashov (St. Mary's Medical Center). Other leading spine research centers are preparing their IRB submissions to join what will prove to be the one of the most watched spine studies.

Clinical sites will be measuring ODI, VAS, neurologic function, device integrity, reoperation rates and other quantitative outcomes for the study device and the fusion control. "Our goal is to establish the superiority of the TOPS™ System versus traditional lumbar spinal fusion," explains Mr. Sacher.

About Premia Spine. Premia Spine licensed the TOPS System technology in 2011 from Impliant, Ltd. Over $100 million has been invested to design, develop, and commercialize the TOPS System, with over 12 years of clinical use and 1,000 patients.

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