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Precision Spine® Announces 510(k) Clearance of the ShurFit® ACIF 2C System

January 18, 2017 – Parsippany, NJ – Precision Spine, Inc., a medical device company dedicated to Made-in-the-USA manufacturing, has announced today that it recently received 510(k) clearance of its ShurFit® ACIF 2C Anterior Cervical Interbody System, which is made from medical grade polyetheretherketone (Peek Optima, LT1) and coated with both commercially pure Titanium (Ti) and Hydroxyapatite (HA). The innovative combination of two proven biomaterials is expected to provide a superior solution to physicians working to achieve biologic fusion.

"The ShurFit ACIF 2C Anterior Cervical Interbody System's distinguishing feature is its unique coating of both Titanium and Hydroxyapatite, materials which have a long clinical history of facilitating bone on-growth, and makes enhanced fixation possible while the process of biologic fusion takes place," said John Steck, MD, Clinical Associate Professor of Neurosurgery at the Louisiana State University Health Sciences Center in New Orleans, who was instrumental in the design and development of the device with Precision Spine engineers.

The novel coating combination encourages bony growth while the implant's large graft and contact areas provide generous biological coverage and optimizes vertebral body support while also minimizing the risk of subsidence. The trapezoidal design allows for proper anterior placement and an aggressive tooth patter helps resist implant expulsion. Strategically placed tantalum markers facilitate radiographic implant positioning.

"The ShurFit ACIF 2C System is an important addition to our growing portfolio of devices," said Chris DeNicola, Chief Operating Officer of Precision Spine, "and is further evidence of Precision Spine's continuing commitment to work with surgeons in the design and commercialization of advanced products that utilize the latest technological advancements to help bring greater versatility, efficiency and cost-effectiveness to the OR."

The system is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level and consists of implants with various heights to accommodate individual patient anatomy and graft material size. It is implanted from the anterior approach at the C3 to C-7 disc levels and is designed to be packed with autogenous bone graft to help facilitate fusion while providing mechanical support to the implanted level until biologic fusion is achieved.

About Precision Spine
Precision Spine, Inc. is a privately held company headquartered in Parsippany, NJ with manufacturing facilities in Pearl, MS. Precision Spine is dedicated to providing innovative, quality spine products that are made in the USA and designed to help treat serious orthopedic medical conditions in a cost effective manner. For more information, visit www.precisionspineinc.com.