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Precision Spine[™] Announces 510(k) Clearance of the VAULT[®]-*C* Anterior Cervical Interbody Fusion Device

October 15, 2014 – Parsippany, NJ – Precision Spine, Inc. announced that it recently received 510(k) clearance and initiated the launch of its VAULT-*C* Anterior Cervical Interbody Fusion Device.

VAULT-*C* represents a significant addition to the Precision Spine cervical product portfolio, and joins an array of recently introduced advanced spinal solutions from the company.

The new VAULT-*C* offers the versatility so highly sought after by surgeons. The plate/cage integrated design allows for rigid screw fixation using a zero profile construct. The zero profile design limits the risk of damage to surrounding vessels and adjacent soft tissue, while the large, open bone graft area allows for optimal graft containment. With two options for screws, self-drilling/self-tapping and blunt-tip/self-tapping, the surgeon has greater intraoperative flexibility and available thread purchase. The implant's integrated locking mechanism is designed to prevent screw back-out while enabling visual confirmation. The VAULT-*C* is available in various heights and geometric footprints to accommodate individual patient anatomy and desired graft material sizes. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

"The new VAULT-*C* cervical interbody fusion device will offer surgeons an additional treatment option, allowing for easier access to challenging levels of the cervical spine, with a true zero profile construct," said Rich Dickerson, President of Precision Spine. "The introduction of the VAULT-*C* reinforces our continuing commitment to treat the full spectrum of spinal pathologies through ongoing product development and innovation."

The VAULT-*C* is a stand-alone cervical interbody device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The VAULT-*C* implants are used with two titanium alloy screws and filled with autogenous bone graft material to facilitate



fusion in the cervical spine. The device is placed via an anterior approach at the C-3 to T-1 disc levels. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

Dr. Fabian Bitan, Director of Spinal Surgery Services at Lenox Hill Hospital, New York, NY, commented, "I believe that the VAULT-*C* represents a significant innovation over existing stand-alone devices. First, it is a two screw system, enabling the required stability and decreased surgical time, and with several available footprints, it accommodates varying patient anatomy. Secondly, its instrumentation strikes a balance between modularity and simplicity, with options to satisfy various surgeon preferences." Dr. Bitan concluded, "I feel that the VAULT-*C* builds on the strengths of existing devices while effectively addressing their flaws and weaknesses."

About Precision Spine

Precision Spine, Inc. is a privately held company headquartered in Parsippany, New Jersey, with manufacturing facilities in Pearl, Mississippi. Precision Spine is dedicated to providing innovative, quality spine products that are designed to help treat serious medical conditions in a cost effective manner. For more information, visit <u>www.precisionspineinc.com</u>