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Benvenue Medical receives FDA clearance for Luna XD minimally invasive expandable interbody device

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New device is offered as part of a lumbar fusion solution suite that also includes Orbit Discectomy Instruments

Benvenue Medical, an innovative developer of minimally invasive surgery (MIS) expandable implant solutions for lumbar fusions has announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the company's enhanced Luna XD MIS expandable interbody device.

Luna XD combines anterior lumbar interbody fusion (ALIF) principles with a minimally invasive controlled posterior approach to provide anterior column stability, strength, and fusion in patients with symptomatic degenerative disc disease (DDD). It utilizes a small incision while providing the largest implant footprint, affording surgeons a large graft chamber to facilitate fusion success, maximum height restoration, and optimized sagittal balance, with minimal impaction, neural retraction, or subsidence. The device is part of Benvenue's suite of MIS lumbar fusion products that includes the Orbit™ Articulating Discectomy System.

Orbit is a minimally invasive discectomy system that uses a small, posterior incision to achieve efficient disruption, removal of disc tissue and endplate preparation. It utilizes a novel articulating rotary shaver that enables rapid, high-volume removal of diseased tissue.

“With the introduction of Luna XD, we believe that we have an exciting opportunity to advance better patient outcomes through MIS lumbar fusion techniques,” said Robert K. Weigle, CEO of Benvenue Medical. “We are thrilled about the clinician feedback we have received in our early launch of Luna XD, which allows physicians to provide cost-effective, minimally-invasive procedures to patients, with the goal of improving overall quality of life and reducing pain. In combination with our new Orbit discectomy platform, Luna XD demonstrates our core competency with material science and commitment to developing new products that will change the future of MIS lumbar fusion in both the hospital and increasingly, in the ASC setting.”

MIS spine surgery is growing at a rate of 7.6% annually and outpatient procedures are expected to grow 35% over the next 10 years.1

“Luna XD is a significant advancement in MIS fusion surgery and offers a more robust and reproducible expandable cage that allows me to put in an ALIF footprint cage, through a TLIF approach with minimal to no nerve retraction,” said Sandeep Kunwar, M.D., F.A.C.S., Co-Medical Director, Bell Neuroscience, Professor, UCSF. “It also allows for endplate to endplate grafting post-expansion.”

“The Orbit System, combined with the Luna XD makes the procedure more efficient and truly addresses the unmet needs across all discectomy procedures,” said Richard G. Fessler, M.D., Ph.D., Rush University. “In 25 years of performing MIS surgery, the Orbit System is the best set of discectomy tools I’ve ever used.”

Luna XD will be available initially as part of a controlled launch at select centers.

[1] Sg2: Sg2 2017 Impact of Change Forecast: Finding Growth. Posted May 5, 2017; Accessed April 2, 2018.