Clinical Evidence Shows that the FlareHawk® Multiplanar Expandable Cage Delivers Favorable Fusion and Patient Outcomes Demonstrating Conformity to Endplate Anatomy with No Observed Device Subsidence

*IJSS-published peer-reviewed studies demonstrate the device’s respect for neural anatomy and conformability to bony endplates through Adaptive Geometry™*

PALM BEACH GARDENS, Fla., November 12, 2020 (GLOBE NEWSWIRE) – Integrity Implants Inc., a privately held medical device company dedicated to delivering innovative solutions for spine surgery, today announced the publication of a series of articles in the International Journal of Spine Surgery (www.ijssurgery.com) that demonstrate fusion efficacy of the FlareHawk® expandable interbody device without the use of costly processed biologics. Additionally, there were no observed reports of device subsidence. Moreover, the study set provides confirmation of the cage’s ability to conform to patients’ endplate geometry.

The October Special Issue features several studies on FlareHawk expandable cage technology, including:

The articles present favorable clinical outcomes, as well as a discussion of some of the unique design features of the multidirectional expandable FlareHawk device that may contribute to its clinical efficacy.

I. The lumbar Interbody fusion study substantiating the safety and efficacy of the FlareHawk biplanar expandable cage is presented by principal investigator Dom Coric, M.D., of Carolina Neurosurgery & Spine Associates, Chief of Neurosurgery at Carolinas Medical Center and Spine Division Chief at Atrium Musculoskeletal Institute in Charlotte, North Carolina. The study followed strict inclusion criteria including the allowance of only allograft and/or autograft to facilitate fusion and its participants represented patients with noteworthy comorbidities, including high BMI, diabetes, and current/former smokers. Among subjects with radiographs at 12 ± 3 months, nearly all (56 of 58 patients, or 96.6%, and 75 of 77 levels, or 97.4%) achieved fusion based on Bridwell-Lenke grading. Among 45 evaluable subjects, 71% (32 patients) achieved clinically significant improvements in VAS leg pain, and 76% (34 patients) achieved clinically significant improvements in VAS back pain. Additionally, there were no (0%) reported device-related adverse events (AEs). Common device-related AEs associated with interbody fusion devices include, but are not limited to, subsidence, displacement, and nerve injury. The incidence rate for non-device-related AEs was consistent with other PLIF/TLIF studies. There were no (0%) observations of cage subsidence (defined as an overlap between the vertebral endplates and the device exceeding 25% of the...
device height) and only one case (1.7%) of observed device migration (defined as displacement of the device relative to the position within intra-operative or immediate post-operative images). Analysis of that case reveals that the cage moved only slightly within the disc space and the patient went on to fuse.

Dr. Coric notes, “This study adds to the evidence base supporting the safe and effective use of expandable interbody spacers in the treatment of lumbar spine diseases. The FlareHawk implant’s ability to expand in both cephalad-caudal and lateral-medial planes is especially advantageous for decreasing neural retraction while maximizing vertebral body endplate coverage and fusion area.”

Raphael Roybal, M.D., M.B.A, co-author of the paper and Director of The Spine Institute at Chatham Orthopaedics in Savannah, Georgia, notes, “Popular minimally invasive TLIF techniques, typically involving a unilateral approach to the disc space, may limit the amount of disc space preparation and/or bone graft delivery, thereby impeding fusion rates. Biplanar expandable spacers that support minimally invasive surgery, safer implantation, and optimal patient outcomes will be relevant in delivering value-based spine care. The FlareHawk device has transformed my practice by allowing me to transition cases to an outpatient setting that is better for my patients and staff.”

Mark Grubb, M.D., co-author and minimally invasive spine surgeon at Northeast Ohio Spine Center in Akron, Ohio, adds, “Most expandable spacers use complex articulation mechanisms to expand the implant profile in either in height or width, but typically do not achieve multidirectional expansion. Furthermore, these complex mechanisms can limit the space available for bone grafting. I appreciate that the FlareHawk cage features a small insertion profile and expands in footprint, height, and lordosis via an unobtrusive mechanism that allows me to deliver bone graft through the expanded cage and into the intervertebral body space. Additionally, the ability to treat my patients via a single-
position, posterior surgery allows me to improve both the quality and efficiency of my practice.”

II.

Similarly, the work from Boyle Cheng, Ph.D., Professor at Drexel University College of Medicine in Pennsylvania and Director of Research at the Allegheny Health Network (AHN) Neuroscience Institute, assesses the feasibility of a bidirectional expandable interbody cage to achieve interbody fusion and discusses two novel aspects of the FlareHawk device: (1) its multimaterial, open-architecture design that provides a combined spring effect for a modulus of elasticity similar to that of bone while maintaining sufficient support and stiffness from the titanium shim, and (2) implant geometry that allows for the naturally occurring deformation of the PEEK shell to conform to each patient’s endplate configuration.

Dr. Cheng's study hypothesizes that utilizing two components, each with the appropriate intrinsic material stiffness, provides both flexibility and stability resulting in a device with a composite construct stiffness more favorable to load transfer over a large contact area with the endplates. Reducing the construct stiffness is essential, not only to reduce the risk of subsidence but also to increase the load sharing and improve bone formation as a function of Wolff’s Law. As such, the multimaterial construct, open architecture, and bi-directionally expanding design of the FlareHawk cage may contribute to the positive clinical outcomes observed.

Additionally, the shim-in-a-shell design conforms to patient-specific endplate anatomy. Measurement of the relative position of the tantalum markers revealed that 16 of the 18 devices showed coronal plane deformation of 1.82mm (18.55%) anteriorly and 1.41mm (15.49%) posteriorly. This measured deformation correlates well with values of endplate concavity reported in the literature (1.37 - 1.90mm), suggesting that the PEEK shell is conforming to the natural endplate anatomy. This material behavior, along with
bidirectional expansion, serves to increase the surface area of the bone-implant interface and may better distribute the loads across the endplate.

Dr. Cheng notes, “This represents yet another design aspect potentially contributing to the favorable fusion rates seen with the FlareHawk device. In the study, all 18 devices (100%) were determined to have fused based on demonstrated bone growth evidence (average volume of 586.42 mm$^3$) and Bridwell-Lenke classification. An interbody device with this unique combination of compliant and rigid components has the potential to conform to the interbody space while maintaining sufficient stability to achieve fusion. This represents a significant advancement not just in expandable cage technology, but in the larger context of achieving successful lumbar interbody fusion. The cage appears to conform in shape obliquely, sagittally, and coronally, resulting in adaptive implant geometry that surgeons may desire. Additionally, the lack of endplate violation suggests that the FlareHawk cage is an atraumatic implant.”

The FlareHawk spinal implant is the flagship product for Integrity Implants and represents the first of its kind in the expandable cage market. Much like coronary stents that offer patients a less-invasive alternative to open-heart procedures, the FlareHawk expandable cage features a PEEK shell that is inserted in a compressed form that can be effectively passed through small neural pathways and, once within the intervertebral disc space, expanded to a larger footprint and height. A titanium shim inserted within the PEEK shell produces the expansion and creates a solid-state construct that is resistant to collapse yet has shown the potential to conform to endplate anatomy to increase surface contact area and lower stresses. The Adaptive Geometry™ and advanced multimaterial composition embodied in the FlareHawk device respect patient anatomy both during insertion and for long-term stability. To date, approximately 8,500 FlareHawk cages have been implanted in more than 6,000 patients.
Chris Walsh, Integrity Implants CEO, shares, “The data suggests that the FlareHawk cage changes the PLIF/TLIF algorithm, enabling a single-position, reproducible, facility-friendly interbody solution that can provide surgeons significant efficiencies and latitude for their practices. There may be profound medical and economic ramifications to study in the future. Before founding Integrity Implants, Wyatt Geist and I observed, as distributors, the power of the lateral approach to transform the modern spine practice through a less-invasive technique. What we are observing with the FlareHawk device, we believe, is even greater in scale. The simple design works in inpatient and outpatient facilities, as well as international markets. This supports our thesis that Adaptive Geometry™ – the ability of an implant to change shape intraoperatively to respect the patient’s anatomy – reconciles the desire for a minimally invasive approach that yields a maximum clinical result through a variety of surgical approaches to the spine, and in a variety of clinical settings. In addition to these papers, IJSS has published Dr. Lee Tan’s Clinical and Radiographic Outcomes After Minimally Invasive Transforaminal Lumbar Interbody Fusion – Early Experience Using a Biplanar Expandable Cage for Lumbar Spondylolisthesis. We are excited about the promise of the FlareHawk expandable cage for MIS TLIF and will discuss those findings in a future release.”

About FlareHawk Expandable Lumbar Interbody Fusion System

The FlareHawk Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment. Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). FlareHawk system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.
About Integrity Implants Inc.

Integrity Implants, founded in 2016 by seasoned business partners and spine leaders Chris Walsh and Wyatt Geist, is a privately held medical device company headquartered in Palm Beach Gardens, Florida. The Company is dedicated to delivering innovative spine products and solutions to surgeons and their patients around the globe. Its proprietary Adaptive Geometry™ technology fundamentally respects a patient’s neural, vascular, bony, and soft tissue anatomy, both during and after implantation.

For more information, please visit the Company’s website at www.integrityimplants.com.

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