Zimmer Biomet Announces U.S. Launch of Vitality®+ and Vital™ Spinal Fixation Systems

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WARSAW, Ind., Oct. 25, 2017 /PRNewswire/ -- Zimmer Biomet Holdings, Inc. (NYSE and SIX: ZBH), a global leader in musculoskeletal healthcare, today announced the official launch of its Vitality®+ and Vital™ Spinal Fixation Systems in the United States at the 2017 North American Spine Society (NASS) Annual Meeting.

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The comprehensive Vitality+ Spinal Fixation System consists of Vitality+ POWER for simple, controlled pedicle preparation and pedicle screw insertion, Vitality+ PSO for optimal pedicle subtraction osteotomy and vertebral column resection procedures, and Vitality+ HOOKS with an extensive array of additional fixation options. In addition, the Vital Spinal Fixation System offers a compact solution for degenerative thoracolumbar procedures with its convenient, intuitive and optimized two-kit pedicle screw instrument configuration.

The launch of Vitality+ POWER follows Zimmer Biomet's recent 510(k) clearance for pedicle preparation and screw insertion under power. The addition of power offers a significant benefit to surgeons, as compared to traditional hand-driven pedicle preparation and insertion. Vitality+ POWER features the market's first flexible drill and a blunted reamer, both of which are designed to flex off cortical bone to ensure precision during procedures. The addition of the Vitality+ PSO system provides an extensive array of intuitive instruments for complex osteotomy procedures, including specially designed curettes, osteotomes, soft tissue manipulators and nerve root retractors. Finally, Vitality+ HOOKS offers an assortment of hooks with various throat depths, designed for sublaminar, pedicle and transverse process fixation.

Dr. David Skaggs, a board-certified orthopaedic spine surgeon in Los Angeles, Calif., commented, "The enhancements to the Vitality System are prime examples of Zimmer Biomet's commitment to the advancement of deformity correction. The ergonomic benefit, OR efficiencies and comprehensiveness provided by POWER, PSO and HOOKS truly support spine surgeons during procedures, and especially in complex cases, all while maintaining high quality patient care."

The Vital Spinal Fixation System is an innovative evolution to the Vitality System. The minimized two-kit configuration includes all pertinent instruments required for degenerative spine surgeries with an easy-to-follow color-coded tray layout, which is particularly beneficial to surgeons and technicians with a small OR footprint. The upgraded Vital screws incorporate one of the largest drive standards in the industry, a T27 hexalobe drive feature designed to provide 30 percent more strength than the T25 hexalobe.* The Vital System's dual lead screws require fewer revolutions for insertion, which improves surgical efficiency by allowing them to be inserted twice as fast as comparable single lead screws, without sacrificing pull-out strength.*

Dr. Justin Smith, a board-certified neurosurgeon in Charlottesville, Va., commented, "The Vital System's upgraded screw and consolidated kit design offer noticeable operational efficiencies for common one- and two-level degenerative posterior thoracolumbar spine procedures. The streamlined System allows me to complete cases faster, while still providing quality patient care."

Indications:

The Vital Spinal Fixation System is a subsystem of the Vitality Spinal Fixation System. The Vitality Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition, the Vitality Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Vitality System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vitality System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The use of the Vitality Spinal Fixation System in skeletally mature patients may include the fixation of the Instinct® Java™ Spinal Fixation System hooks, APEX Spinal System™ hooks, or fixation of the Universal Clamp® Spinal Fixation System to the rods of the Vitality Spinal Fixation System. The Vitality Spinal Fixation System may also be used in skeletally immature patients when connected with the Universal Clamp Spinal Fixation System.

In order to achieve additional levels of fixation in skeletally mature patients, the Vitality Spinal Fixation System may be connected to the Virage® OCT Spinal Fixation System and the Instinct Java Spinal Fixation System offered by Zimmer Biomet Spine, using rod connectors.

Vitality+ Power instruments and adapters are intended for use with the Zimmer Biomet Universal Power System to facilitate the preparation of the pedicle and ilium and insertion of Vitality Spinal Fixation System screws using a power surgical technique. Pedicle and iliac screws from the Vitality Spinal Fixation System may be implanted in the non-cervical spine using powered instrumentation during spinal surgery, including open and minimally invasive procedures.

*Data on file at Zimmer Biomet (TPR#00184).

About Zimmer Biomet

Founded in 1927 and headquartered in Warsaw, Indiana, Zimmer Biomet is a global leader in musculoskeletal healthcare. We design, manufacture and market orthopaedic reconstructive products; sports medicine, biologics, extremities and trauma products; office based technologies; spine, craniomaxillofacial and thoracic products; dental implants; and related surgical products.

We collaborate with healthcare professionals around the globe to advance the pace of innovation. Our products and solutions help treat patients suffering from disorders of, or injuries to, bones, joints or supporting soft tissues. Together with healthcare professionals, we help millions of people live better lives.

We have operations in more than 25 countries around the world and sell products in more than 100 countries. For more information, visit www.zimmerbiomet.com or follow Zimmer Biomet on Twitter at www.twitter.com/zimmerbiomet.

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This release contains forward-looking statements within the meaning of the safe harbor provisions of

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