# Biomet Receives FDA Clearance for Two New Products: E1 Humeral Bearing for the Comprehensive Reverse Shoulder System and the Comprehensive Segmental Revision System

WARSAW, Ind.--(BUSINESS WIRE [1])--Biomet, Inc., a global leader in the manufacture of orthopaedic and biotechnology products, today announced clearance of two new products by the United States Food and Drug Administration (FDA): the E1® humeral bearing for use with the Comprehensive® Reverse Shoulder System, and the Comprehensive® Segmental Revision System.
The E1® humeral bearing with exclusive Antioxidant-Infused Technology is the first Vitamin E advanced bearing option for reverse shoulder applications. Biomet first applied the clinically successful1 E1® technology to its hip and knee products. The integration of E1® technology into the Comprehensive® Reverse Shoulder portfolio will provide surgeons and patients with an advanced bearing surface with oxidative stability, high strength and low wear.2,3

"Biomet is the first company to bring advanced bearing surfaces to the shoulder," said John Sperling, MD, orthopaedic surgeon, Rochester, Minnesota. "The outstanding wear characteristics and proven track record of E1® bearings will provide a tremendous benefit to patients undergoing reverse shoulder arthroplasty."

The FDA also cleared Biomets Comprehensive® Segmental Revision System (SRS), a humeral replacement system designed to address significant bone loss, both proximally and distally. The Comprehensive® SRS offers oncologic options, soft tissue attachments, and multiple sizing options, and is compatible with the Comprehensive® Shoulder system and the Discovery® Elbow system.

"The Comprehensive® SRS is a breakthrough in shoulder and elbow arthroplasty design," said Dr. Sperling. "This system is specifically designed to address humeral bone deficiency in revision and oncologic settings."

"This system is particularly helpful for surgeons specializing in revision shoulder or elbow surgery where modularity and intra-operative flexibility is critical," said Quin Throckmorton, MD, orthopaedic surgeon, Memphis, Tennessee.

1 Greene M., et al. Two Year RSA Evaluation of the Wear of Vitamin E Stabilized Highly Cross-linked Polyethylene, the Stability of the Regenerex Acetabular Shells, and Femoral Components with 32mm Heads. ORS 2011 Annual Meeting; Poster No. 1176.

2 Kurtz, S., et al. The UHMWPE Handbook: Ultra High Molecular Weight Polyethylene in Total Joint Replacement (2nd ed.), Elsevier Academic Press, San Diego, CA 2009.

3 Data on file at Biomet. Bench test results not necessarily indicative of clinical performance.

About Biomet
Biomet, Inc. and its subsidiaries design, manufacture and market products used primarily by musculoskeletal medical specialists in both surgical and non-surgical therapy. Biomets product portfolio encompasses large joint reconstructive products, including orthopaedic joint replacement devices, and bone cements and accessories; sports medicine, extremities and trauma products, including internal and external orthopaedic fixation devices; spine and bone healing products, including spine hardware, spinal stimulation devices, and orthobiologics, as well as electrical bone growth stimulators and softgoods and bracing; dental reconstructive products; and other products, including microfixation products and autologous therapies. Headquartered in Warsaw, Indiana, Biomet and its subsidiaries currently distribute products in approximately 90 countries.

Posted by Sean Fenske, Editor-in-Chief, MDT



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