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CATALYST ORTHOSCIENCE ANNOUNCES 510(K) CLEARANCE FOR UNCEMENTED PRESS FIT HUMERAL COMPONENT DURING THE 2019 AAOS ANNUAL MEETING

Press Fit Humeral Implant Features Non-Spherical Anatomic Head

NAPLES, Fla., March 13, 2019 – Catalyst OrthoScience Inc. (Catalyst), a medical device company focused on the upper extremity orthopedics market, today announced 510(k) clearance for its uncemented Press Fit humeral implant. The new humeral component represents the continued evolution of the Catalyst CSR™ Total Shoulder System, a disruptive technology introduced in 2016. The company will initiate a limited market release with several of its key opinion leaders over the coming months. Samples of the new Press Fit humeral implant can be seen by visiting Catalyst at booth 621 during the American Academy of Orthopedic Surgeons (AAOS) 2019 Annual Meeting in Las Vegas.

The Press Fit humeral implant features a non-spherical head, specifically designed to restore the native anatomy of the humeral head and joint kinematics of the shoulder. The new implant has a titanium plasma spray coating on its patented, bone-facing geometry and uses press-fit fixation for initial stability without the need for bone cement. Catalyst will continue to offer its original cemented humeral component, which also features the same ellipsoid head design to replicate the native anatomy.

"Though extensive research studies have demonstrated that the natural shape of the humeral head is non-spherical, most humeral head implants used in total shoulder arthroplasty today remain as spherical surfaces," said Brian Hutchison, executive chairman and CEO of Catalyst. "The Catalyst CSR system's ellipsoid humeral components were specifically designed to mimic the shape of a normal human shoulder. We have seen excellent early clinical results, with the first patients more than two years post-surgery. We are excited to now introduce an uncemented version to the original breakthrough Catalyst CSR non-spherical humeral component."

Research to date has suggested that the use of a non-spherical humeral head in total shoulder arthroplasty will have benefits to the patient in both the short and long term. In the short term, the patient may potentially experience improved range of motion and regain the functionality of a healthy shoulder. In the long term, the glenoid implant may be exposed to lower stresses and less eccentric loading, potentially reducing wear and the risk of loosening that could ultimately increase the life of the shoulder replacement system.

Designed by surgeons for surgeons, the Catalyst CSR system represents the next evolution in shoulder surgery. The simple surgical technique creates a unique, multi-planer chamfer cut geometry on the humeral head that minimizes bone removal and preserves the strongest, densest bone for the humeral implant fixation. Patented, angled glenoid instruments aid in the glenoid exposure and lessen retraction on the soft tissue. The precision of the system's implants and instrumentation yields highly accurate and repeatable restoration of the native non-spherical anatomy. These benefits position the Catalyst CSR system as an attractive solution for anatomic total shoulder replacement surgery.

To learn more about the Catalyst CSR system, visit Catalyst at booth 621 at the AAOS meeting, March 13-15, 2019 in Las Vegas.

About Catalyst OrthoScience Inc.
Catalyst OrthoScience develops and markets surgical implants that make orthopedic surgery less invasive and more efficient for both surgeons and patients. Catalyst was founded in 2014 by orthopedic surgeon Steven Goldberg, M.D., who saw the need to make shoulder replacement surgery less invasive and give patients a more natural-feeling shoulder after surgery.

The company's first offering, the Catalyst CSR Total Shoulder System, represents the next evolution in total shoulder arthroplasty. The Catalyst CSR is a single-tray, bone-preserving total shoulder arthroplasty system containing a precision elliptical humeral head and less invasive glenoid component, using specialized ergonomic instrumentation designed for consistent anatomic joint line restoration and glenoid insertion. The Catalyst CSR system can be used in both inpatient and outpatient settings and was cleared for use by the FDA in 2016.

Catalyst OrthoScience has a growing portfolio of 10 granted U.S. patents with several more pending nationally and internationally. The company is headquartered in Naples, Fla., and its products are available across the U.S. For additional information on the company, please visit www.CatalystOrtho.com.

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