Zimmer Biomet Receives FDA Clearance for ROSA® Hip System for Robotically-Assisted Direct Anterior Total Hip Arthroplasty

Aug 18, 2021

ROSA® Hip and ONE Planner™ Hip Further Strengthens Zimmer Biomet's Comprehensive ROSA® Robotics Portfolio; Enhances ZBEdge and Complements Already Available Robotic Solutions for Total and Partial Knee Replacement

WARSAW, Ind., Aug. 18, 2021 /PRNewswire/ -- Zimmer Biomet Holdings, Inc. (NYSE and SIX: ZBH), a global medical technology leader, today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of the ROSA® Hip System for robotically-assisted direct anterior total hip replacement. ROSA Hip is the fourth robotic system introduced by Zimmer Biomet and adds to the Company's comprehensive ROSA Robotics portfolio, which includes the ROSA Knee System for total knee arthroplasty, ROSA Partial Knee System for partial knee arthroplasty and ROSA ONE® for neurosurgical and spine procedures. ROSA Hip is the newest addition to ZBEdge, Zimmer Biomet's suite of integrated digital and robotic technologies purposefully engineered to deliver transformative data-powered clinical insights, shared seamlessly across the patient journey, and with the goal of improving patient outcomes.

"We're excited to announce the FDA clearance of ROSA Hip, and to now offer one of the most comprehensive orthopedic robotic solutions through a single, multiple application platform," said Ivan Tornos, Chief Operating Officer at Zimmer Biomet. "As an integrated component of our ZBEdge Connected Intelligence Suite, ROSA Hip advances our vision to translate pre-, intra-and post-operative data into actionable clinical insights to inform personalized care decisions."

Designed to seamlessly adapt to a surgeon's existing workflow, ROSA Hip aims to assist direct anterior surgeons with preparation, positioning and component impaction, while intra-operatively quantifying cup orientation, leg length and offset. Intra-operative data collected by ROSA Hip is combined with pre- and post-operative data collected by mymobility® with Apple Watch®, a proprietary remote care management platform, and it is seamlessly consolidated and analyzed by OrthoIntel Orthopedic Intelligence Platform, which is designed to uncover new clinical insights throughout the episode of care and help surgeons and care teams make informed decisions and optimize patient care.

ROSA Hip is designed for compatibility with multiple implant systems, including the Avenir Complete® Hip System, an evolution of the Avenir® Hip Implant that has a clinically-proven heritage of over 10 years.[1,2,3,4] The Avenir Complete Hip System together with the G7® Acetabular System, a comprehensive offering of stems, shells and liners, aims to deliver greater operative flexibility and surgical excellence to help surgeons address the distinct needs of each patient.

"ROSA Hip will allow surgeons to retain complete control over case planning and execution, while providing real-time data and visualization tools," said Atul Kamath, M.D., Director, Center for Hip Preservation at the Cleveland Clinic and a ROSA Hip developer surgeon. "Even surgeons who are new to robotic-assisted surgery can easily tailor ROSA Hip to adapt to their own workflow. The robotic platform provides support during component positioning, cup impaction and other critical steps of an anterior approach total hip replacement. By reducing the intra-operative variability and inconsistency, this new technology has the potential to give surgeons and their patients greater confidence in seeking value in contemporary total hip replacement."

ROSA Hip is a fluoroscopy-based tool designed for surgeons who use the direct anterior approach, a minimally invasive approach to performing total hip replacement surgery. In addition to providing robotic assistance to guide accurate acetabular component orientation[5], as well as intra-operative assessment of leg length and offset, the application allows surgeons to create a personalized surgical plan through the use of ONE Planner™ Hip. This pre-operative planner features a spinopelvic mobility assessment tool if both a sitting and standing lateral X-ray are provided with the anteroposterior (AP) X-ray, together with an auto-plan function that allows surgeons to potentially create a pre-operative plan within five minutes. ROSA Hip may also help improve procedural efficiency with a simplified set-up that doesn't require pins or reference arrays and the convenient option to use X-ray imaging instead of CT scans.

To learn more about ROSA Hip, please visit zimmerbiomet.com/ROSAHip.

About the Company

Zimmer Biomet is a global medical technology leader with a comprehensive portfolio designed to maximize mobility and improve health. We seamlessly transform the patient experience through our

innovative products and suite of integrated digital and robotic technologies that leverage data, data analytics and artificial intelligence.

With 90+ years of trusted leadership and proven expertise, Zimmer Biomet is positioned to deliver the highest quality solutions to patients and providers. Our legacy continues to come to life today through our progressive culture of evolution and innovation.

For more information about our product portfolio, our operations in 25+ countries and sales in 100+ countries or about joining our team, visit www.zimmerbiomet.com or follow Zimmer Biomet on Twitter at www.twitter.com/zimmerbiomet.

Cautionary Statement Regarding Forward-Looking Statements

This news release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements concerning Zimmer Biomet's expectations, plans, prospects, and product and service offerings, including new product launches and potential clinical successes. Such statements are based upon the current beliefs and expectations of management and are subject to significant risks, uncertainties and changes in circumstances that could cause actual outcomes and results to differ materially. For a list and description of some of such risks and uncertainties, see Zimmer Biomet's periodic reports filed with the U.S. Securities and Exchange Commission (SEC). These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in Zimmer Biomet's filings with the SEC. Forward-looking statements speak only as of the date they are made, and Zimmer Biomet disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Readers of this news release are cautioned not to rely on these forward-looking statements, since there can be no assurance that these forward-looking statements will prove to be accurate. This cautionary statement is applicable to all forward-looking statements contained in this news release.

References

1. Boisgard S, Brientini J, et al. 7-year Results of Primary Total Hip Arthroplasty with the Uncemented Avenir Stem. Hip International 2018: 1-6. https://doi.org/10.1177/1120700018810211
2. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). 2018 Annual Report. https://aoanjrr.sahmri. com/ (accessed 21 March 2019).
3. Endoprothesen Register Deutschland (EPRD). Annual Report, 2017. https://www.eprd.de/de/ (accessed 21 March 2019).

4. NZ Joint Registry, New Zealand Orthopaedic Association. NZJR 19 Year Report Jan 1999 to Dec 2017. https://nzoa.org.nz/nzoa-jointregistry (accessed 21 March 2019).
5. Data on File. FER-SM210407-01

ZBH-Corp

Contacts:

Media

Meredith Weissman
(703) 346-3127
meredith.weissman@zimmerbiomet.com

Investors

Ezgi Yagci
(617) 549-2443
ezgi.yagci@zimmerbiomet.com

Keri Mattox
(203) 399-0856
keri.mattox@zimmerbiomet.com

C

View original content to download multimedia:https://www.prnewswire.com/news-releases/zimmer-biomet-receives-fda-clearance-for-rosa-hip-system-for-robotically-assisted-direct-anterior-total-hip-arthroplasty-301357495.html

SOURCE Zimmer Biomet Holdings, Inc.