ZIMMER BIOMET

Zimmer Biomet Announces FDA Breakthrough Designation for World's First Iodine-Treated Total Hip Replacement System

Oct 28, 2025

Prioritized Regulatory Review Process in the U.S. Follows Japan PMDA Approval in September

WARSAW, Ind., Oct. 28, 2025 /PRNewswire/ -- Zimmer Biomet Holdings, Inc. (NYSE and SIX: ZBH), a global medical technology leader, today announced the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for the company's first-to-world iodine-treated total hip replacement system. This is the first product in Zimmer Biomet history to receive this designation.

Iodine technology integrates a controlled-release iodine surface treatment into the iTaperloc® Complete and iG7™ Hip System to help address challenges associated with joint replacement procedures for patients at higher risk of infection. This system recently received approval from the Japan Pharmaceutical and Medical Devices Agency (PMDA) in September, becoming the world's first approved orthopedic implant with Iodine Technology. Indications in Japan include inhibiting bacterial adhesion on the implant surface, which is designed to address the challenging complication of Periprosthetic Joint Infections (PJI) associated with total joint arthroplasties (TJA). PJIs are estimated to occur in 1% to 2% of primary TJA procedures[1] and can have serious consequences, with mortality rates approaching the five-year mortality observed in breast cancer (11%) and far exceeding that of prostate cancer (1%).[2]

"The Breakthrough Device Designation from the FDA underscores the need for innovations to reduce complications that can happen with joint replacement procedures and highlights Zimmer Biomet's commitment to advancing technologies that improve patient outcomes and enhance the overall

success of musculoskeletal health interventions," said Ivan Tornos, Chairman, President and CEO. "We look forward to working closely with the agency to bring this first-to-world innovation to patients in the United States."

The iTaperloc® Complete and iG7™ Hip System combines the long-standing clinical heritage[3,4,5] of the Taperloc Complete Hip System and the simplicity, efficiency and performance of the G7 Acetabular System[6,7] with Iodine Technology. Iodine is a biocompatible, essential nutrient that does not cause antibiotic resistance and is commonly used in medicine as an antiseptic.

The FDA Breakthrough Devices Program offers manufacturers an opportunity to interact with experts from the agency to efficiently address topics as they arise during the regulatory review process. According to the FDA, the program provides a prioritized review of submissions and is designed to help device manufacturers receive more timely feedback from the FDA.

About Zimmer Biomet

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 on LinkedIn at www.linkedin.com/company/zimmerbiomet or X at www.x.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.

Contacts:

Media	**Investors**
Troy Kirkpatrick	David DeMartino
614-284-1926	646-531-6115
troy.kirkpatrick@zimmerbiomet.com	david.demartino@zimmerbiomet.com
Kirsten Fallon	Zach Weiner
781-779-5561	908-591-6955
kirsten.fallon@zimmerbiomet.com	zach.weiner@zimmerbiomet.com

[1] Izakovicova, P., Borens, O., & Trampuz, A. (2019). Periprosthetic joint infection: current concepts and outlook. EFORT open reviews, 4(7), 482–494. https://doi.org/10.1302/2058-5241.4.180092.
[2] Ramos MS, Benyamini B, Kompala V, et al. Periprosthetic joint infection mortality after total hip arthroplasty is comparable to 5-year rates of common cancers: a meta-analysis. J Arthroplasty. 2025;1-7. https://doi.org/10.1016/j.arth.2025.04.036.
[3] McLaughlin JR, Lee KR. Total hip arthroplasty with an uncemented tapered femoral component. J Bone Joint Surg Am. 2008 Jun;90(6):1290-6. https://doi.org/10.2106/JBJS.G.00771.
[4] Teloken MA, Bissett G, Hozack WJ, Sharkey PF, Rothman RH. Ten to fifteen-year follow-up after total hip arthroplasty with a tapered cobalt-chromium femoral component (tri-lock) inserted without cement. J Bone Joint Surg Am. 2002 Dec;84(12):2140-4. https://doi.org/10.2106/00004623-200212000-00003.
[5] Parvizi J, Keisu KS, Hozack WJ, Sharkey PF, Rothman RH. Primary total hip arthroplasty with an uncemented femoral component: a long-term study of the Taperloc stem. J Arthroplasty. 2004 Feb;19(2):151-6. https://doi.org/10.1016/j.arth.2003.10.003.
[6] Latest ODEP ratings can be found at http://www.odep.org.uk; G7 OsseoTi™ Acetabular Shell (5A), G7 OsseoTi® Dual Mobility Construct (7A), G7 Cementless Acetabular Component (10A), G7 PPS® BoneMaster™ Dual Mobility Construct (5A*), G7 PPS®Dual Mobility Construct (7A), G7 PPS Bonemaster (10A). ODEP rating received in 2024/2025.
[7] Berend KR, Adams JB, Morris MJ, Lombardi A V. Three-Year Results with a Ringless Third- Generation Porous Plasma Sprayed Acetabular Component in Primary Total Hip Arthroplasty. Surg Technol Int [Internet]. 2017 Jan; 30:295—299. Available from: http://europepmc.org/abstract/MED/28072898.

C

View original content to download multimedia:https://www.prnewswire.com/news-releases/zimmer-biomet-announces-fda-breakthrough-designation-for-worlds-first-iodine-treated-total-hip-replacement-system-302595931.html

SOURCE Zimmer Biomet Holdings, Inc.