Zimmer Biomet Receives FDA Clearance for Persona® Revision SoluTion™ Femur

Mar 07, 2025

A Revision Knee Implant Alternative for Patients with Metal Sensitivities

WARSAW, Ind., March 7, 2025 /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 Persona® Revision SoluTion™ Femur, a revision knee implant component offering an alternative for patients with sensitivities to certain metals. The Persona Revision SoluTion Femur, part of the comprehensive Persona Revision Knee System, leverages a proprietary surface-hardening treatment designed to enhance wear performance,[1,2] which offers surgeons an array of anatomic components, including tibial and femoral cones with various stem choices to address zonal fixation.

"We are pleased to expand our proprietary surface-hardening technology into the revision knee space with FDA clearance of the Persona Revision SoluTion Femur, the first metal alternative option for those with certain metal sensitivities," said Joe Urban, President, Knees at Zimmer Biomet. "We are proud to offer a total revision knee construct with no deliberate addition of the most common metal allergens (Nickel, Cobalt, & Chromium). Metal sensitivity is one of the potential causes of revision procedures, and the Persona Revision SoluTion Femur is yet another innovation that delivers on our commitment to solve the most meaningful challenges in musculoskeletal health."

Cutaneous metal hypersensitivity affects 10-15 percent of the general population, while prevalence in patients with metallic implants may be as high as 25 percent.[3] Patients may experience an immunological reaction against metallic particles (ions) that are released as a result of implant wear or corrosion.[4] When exposed to certain metals commonly used in metal knee implants such as nickel, cobalt and chromium, people with these hypersensitivities can experience an inflammatory response, pain and implant loosening that can require a total knee replacement revision procedure.[5]

The Persona Revision SoluTion Femur is made solely of a proprietary Tivanium® (Ti-6Al-4V) alloy with more than 17 years of clinical use.[6] The alloy is treated with the Ti-Nidium Surface Hardening Process, which results in a strengthened material that demonstrates hardness, comparable to that of metal implants, with enhanced wear performance that provides resistance to particle release.[2,7] The new revision femur is offered in standard and plus sizes to address flexion instability and soft tissue balancing while minimizing implant overhang.[8,9]

Persona Revision SoluTion Femur will be commercially available in the U.S. in Q3 2025.

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 / Twitter 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.

References:

1. Improved Abrasion Resistance of Nitrogen-Hardened Titanium Alloy Surfaces. Current Topics in Orthopaedic Technology. Zimmer. Vol. 3, No. 6 (1991).
2. Zimmer ZRR_WA_2537_12
3. Akila S.,et al. Metal hypersensitivity in total hip and knee arthroplasty: Current concepts. Journal of Clinical Orthopaedics and Trauma. 2018 Jan-Mar;9(1):3-6, 2018.
4. Podzimek S. Metal hypersensitivity and pro-inflammatory cytokine production in patients with failed orthopedic implants: A case-control study, Clinical Immunology, Volume 245, 2022. https://doi.org/10.1016/j.clim.2022.109152.
5. Hozack, W. et al. Primary Cementless Hip Arthroplasty with a Titanium Plasma Sprayed Prosthesis. Clinical Orthopaedics and Related Research. 333: 217-25, 1996.
6. Rossi SMP, et al. Ten-year outcomes of a nitrided Ti-6Al-4V titanium alloy fixed-bearing total knee replacement with a highly crosslinked polyethylene-bearing in patients with metal allergy. The Knee. 2020;27(5):1519-1524.
7. Improved Abrasion Resistance of Nitrogen-Hardened Titanium Alloy Surfaces. Current Topics in Orthopaedic Technology. Zimmer. Vol. 3, No. 6 (1991).
8. Royal Perth Hospital Dept. of Medical Engineering and Physics. (2005). Implant Technology and Biomaterials Bulletin: No. 4. Australia. Department of Medical Engineering and Physics.
9. Shetty, RH. Surface Hardening of Orthopedic Implants. Biomaterials Engineering and Devices. Vol. 2: 191-202 (2000).

Media

Heather Zoumas-Lubeski
445-248-0577
heather.zoumaslubeski@zimmerbiomet.com

Kirsten Fallon
781-779-5561
kirsten.fallon@zimmerbiomet.com

Investors

David DeMartino
646-531-6115
david.demartino@zimmerbiomet.com

Zach Weiner
908-591-6955
Zach.weiner@zimmerbiomet.com

C

View original content to download multimedia:https://www.prnewswire.com/news-releases/zimmer-biomet-receives-fda-clearance-for-persona-revision-solution-femur-302395239.html

SOURCE Zimmer Biomet Holdings, Inc.