Johnson&Johnson MedTech

Media contact:
Ryan Carbain
(732) 232-9062
rcarbain@its.jnj.com

Investor contact:
Tracy Menkowski
investor-relations@its.jnj.com

DePuy Synthes Receives 510(k) FDA Clearance of the VELYS™ Robotic-Assisted Solution for Use in Unicompartmental Knee Arthroplasty Procedures

System Will Utilize the SIGMA™ HP Partial Knee Implant, Which Demonstrated Improved 12-Year Survivorship Compared to Class

Palm Beach Gardens, FL – June 7, 2024 – Today, Johnson & Johnson MedTech* announced that DePuy Synthes, The Orthopaedics Company of Johnson & Johnson**, has received 510(k) FDA clearance for the clinical application of the VELYS™ Robotic-Assisted Solution in Unicompartmental Knee Arthroplasty (UKA). The expanded indication builds upon the VELYS Robotic-Assisted Solution platform used in Total Knee Arthroplasty (TKA), which has been cleared for use in 20 markets and utilized in over 55,000 procedures[1], equipping surgeons with the information needed to help preserve the soft tissue envelope, predict joint stability and work toward returning knee function[2].

The UKA application is designed for both medial and lateral procedures and will enable surgeons to guide precise implant placement without a CT scan[3-4]. It is compatible with the SIGMA™ HP Unicondylar Knee System with the new reusable INTUITION™ INSTRUMENTS. The SIGMA™ HP Implant demonstrates improved 12-year survivorship compared to class[5] as shown in a national joint registry.

“We are committed to continually improving and expanding the capabilities and user experience of our VELYS™ Enabling Technology portfolio,” said Aldo Denti, Company Group Chairman, DePuy Synthes. “We are excited to add a robotic-assisted offering with our clinically proven implant for UKA which we believe will address some of the key unmet needs in the partial knee replacement segment, including accuracy and simplicity, that other systems on the market do not fully address. Data and analytics will continue to serve as the backbone of our platform, which reveals real-time, actionable insights for surgeons to empower patient-specific operative decisions with the goal to improve outcomes and deliver personalization at scale.”

Unicompartmental knee arthroplasty, otherwise known as partial knee replacement, offers potential for bone preservation[6] and shortened recovery periods. UKA utilization offers clinical benefits and greater economic efficiency for patients, providers and payors compared to TKA[7-8]. Despite the benefits, UKA is underutilized due to complexities that include smaller incisions and lack of visibility.

Robotics has the opportunity to overcome many of the challenges surgeons face in manual partial knee replacement when they are designed to provide intra-operative insights, more accurate implant alignment and positioning, and more reproducible and consistent outcomes.

“Challenges associated with partial knee replacement include lack of access and visibility, which can lead to a longer learning curve and variability in outcomes. Achieving precise alignment and optimal implant placement is paramount for long-term success, and the ability to do so in a reproducible manner continues to be an unmet need in the UKA space[9-10],” said Dr. John Redmond, orthopedic surgeon performing both knee and hip procedures in Jacksonville, FL.† “The VELYS™ Robotic-Assisted Solution for Unicompartmental Knee Arthroplasty will enable a more personalized procedure that helps drive reproducible outcomes, while insights delivered from its planning and balancing tools will enable better precision and accuracy[11]. I am excited to see it utilized for UKA procedures and particularly in the

Johnson&Johnson MedTech

Media contact:
Ryan Carbain
(732) 232-9062
rcarbain@its.jnj.com

Investor contact:
Tracy Menkowski
investor-relations@its.jnj.com

ambulatory surgery center setting where its smaller footprint and image-free technology will enable greater operational efficiency."

Key features of the VELYS™ Robotic-Assisted Solution for UKA include:

- The single PROADJUST™ PLANNING SCREEN enables personalized planning to help ensure precise implant placement, alignment, and balance relative to soft tissue.
- An ACCUBALANCE™ GRAPH for personalized balancing throughout the full range of motion.
- Compatibility with the SIGMA™ HP Unicondylar Knee System that has been demonstrated to improve 12-year survivorship compared with its class.
- Complete UKA workflow with UKA-specific functionality.

The system will be featured at the Annual Meeting of the American Association of Hip and Knee Surgeons in November. Details on commercial availability will be forthcoming.

About Johnson & Johnson MedTech

At Johnson & Johnson MedTech, we unleash diverse healthcare expertise, purposeful technology, and a passion for people to transform the future of medical intervention and empower everyone to live their best life possible. For more than a century, we have driven breakthrough scientific innovation to address unmet needs and reimagine health. In surgery, orthopaedics, vision, and interventional solutions, we continue to help save lives and create a future where healthcare solutions are smarter, less invasive, and more personalized. For more information, visit https://thenext.jnjmedtech.com/.

About DePuy Synthes

DePuy Synthes, The Orthopaedics Company of Johnson & Johnson, provides one of the most comprehensive orthopaedics portfolios in the world that helps heal and restore movement for the millions of patients we serve. DePuy Synthes solutions, in specialties including joint reconstruction, trauma, extremities, craniomaxillofacial, spinal surgery and sports medicine, in addition to the VELYS™ Digital Surgery portfolio, are designed to advance patient care while delivering clinical and economic value to healthcare systems worldwide. Building on our proud product innovation and legacy of industry firsts, we are reimagining the orthopaedic landscape with new advancements in medical technologies and digital surgery across the entire continuum of care to Keep People Moving today and tomorrow. For more information, visit www.depuysynthes.com.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the VELYS™ Robotic-Assisted Solution. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of DePuy Synthes, Inc., Medical Device Business Services, Inc., and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care

Johnson&Johnson
MedTech

Media contact:
Ryan Carbain
(732) 232-9062
rcarbain@its.jnj.com

Investor contact:
Tracy Menkowski
investor-relations@its.jnj.com

cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of DePuy Synthes, Inc., Medical Device Business Services, Inc., nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

* Comprising the surgery, orthopaedics, vision, and interventional solutions businesses within Johnson & Johnson's MedTech segment.

** DePuy Synthes represents the products and services of DePuy Synthes, Inc. and its affiliates.

†John Redmond, MD, is a paid consultant for DePuy Synthes.

Important Information: Prior to use, refer to the instructions for use supplied with the device(s) for indications, contraindications, side effects, warnings and precautions.

---

[1] DePuy Synhtes. VELYS RAS TKA System Software Approved Country List. Downloaded 5/30/2024. Windchill 201249029

[2] Hunter M., et al., Influence of Soft Tissue Releases on 2 Year Outcomes in Total Knee Arthroplasty and Rate of Soft Tissue Releases in Robotic-Assisted Surgery. Current Concepts in Joint Replacement, Dec 2022. Poster No P-124.

[3] DePuy Synthes VELYS Robotic-Assisted Solution for Unicompartmental Knee Rev C Surgical Technique Guide.

[4] DePuy Synthes VELYS™ Robotic-Assisted Solution for Unicompartmental Knee Summative Evaluation Report. December 2023. Windchill #103414383.

[5] National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. Implant Summary Report for DePuy Sigma HP (Uni) Unicondylar. NJR Database extracted 31 Oct 2023, pages 4 - 6 Licensed for use until 6 Nov 2024.

[6] "Unicompartmental knee arthroplasty, an enigma, and the 10 enigmas of medical UKA." Journal of Orthopaedics and Traumatology. Sept. 2, 2020. https://jorthoptraumatol.springeropen.com/articles/10.1186/s10195-020-00551-x

[7] Hauer G, Sadoghi P, Bernhardt GA, et al. Greater activity, better range of motion and higher quality of life following unicompartmental knee arthroplasty: a comparative case-control study. Arch Orthop Trauma Surg. 2020;140(2):231-237. doi:10.1007/s00402-019-03296-3

[8] Jansen K, Beckert M, Deckard ER, Ziemba-Davis M, Meneghini RM. Satisfaction and Functional Outcomes in Unicompartmental Compared with Total Knee Arthroplasty: Radiographically Matched Cohort Analysis. JB JS Open Access. 2020;5(3):e20.00051. Published 2020 Sep 28. doi:10.2106/JBJS.OA.20.00051

[9] Begum FA, Kayani B, Morgan SDJ, Ahmed SS, Singh S, Haddad FS. Robotic technology: current concepts, operative techniques and emerging uses in unicompartmental knee arthroplasty. EFORT Open Rev. 2020;5(5):312-318. Published 2020 May 5. doi:10.1302/2058-5241.5.190089

[10] Mittal, A., Meshram, P., Kim, W. H., & Kim, T. K. (2020). Unicompartmental knee arthroplasty, an enigma, and the ten enigmas of medial UKA. Journal of orthopaedics and traumatology : official journal of the Italian Society of Orthopaedics and Traumatology, 21(1), 15. https://doi.org/10.1186/s10195-020-00551-x.

[11] Doan G, Courtis P, Hoeffel D. Assessment of Accuracy of a Novel Image Free Robotic-Assisted System for Unicondylar Knee Arthroplasty, Poster 282. Presented at 4H World Arthroplasty Congress. Madrid, Spain. April, 2024.