

# Press Release

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## 3D Systems Expands Orthopedic Surgical Planning Portfolio Receiving FDA Clearance for Key Ankle Indications

- New TOTAL ANKLE Patient-Matched Guides pair with Smith+Nephew's Total Ankle replacement solution, designed to help surgeons save time and ensure accuracy while performing fewer steps than standard instrumentation
- FDA clearance expands 3D Systems' leadership in supporting orthopedic surgeons, with surgical planning experience now exceeding 175,000 cases
- 3D Systems engineers and manufactures custom, patient-specific orthopedic solutions leveraging its VSP surgical planning workflows that include market-leading medical 3D printing technologies
- Furthers company strategy of accelerated expansion in orthopedics through 3D printing of patient-specific surgical solutions and customized workflows, a market anticipated to reach \$5.3 billion by 2032<sup>3</sup>

**ROCK HILL, South Carolina, September 11, 2024** – Today, [3D Systems](http://www.3dsystems.com) (NYSE:DDD) announced the Food and Drug Administration (FDA) has provided 510(k) clearance for TOTAL ANKLE Patient-Matched Guides to be used with Smith+Nephew's SALTO TALARIS<sup>◇</sup> Total Ankle Prosthesis and CADENCE<sup>◇</sup> Total Ankle System. The products feature individualized pre-surgical planning and a patient-specific 3D-printed instrument set that ensures accurate implant alignment and sizing for tailored total ankle replacement surgery. The collaboration between 3D Systems and Smith+Nephew, the global medical technology company, achieved these patient-matched solutions that enable surgeons to prepare the bony anatomy of the tibia and talus for placement of implants intended to restore proper function of the ankle joint. These patient-matched guides are engineered and manufactured using 3D Systems' [VSP<sup>®</sup> surgical planning](#)

[solutions](#) that combine best-in-class digital workflows with the industry's broadest additive manufacturing portfolio of printers and materials.

3D Systems' personalized solutions are designed to enable surgeons to capitalize on benefits such as performing the operation with less procedural steps, shorter operating room (OR) time,<sup>1-2</sup> and less intraoperative x-ray radiation<sup>2</sup> as compared to procedures using standard non-patient-specific instruments. Ben Johnson, 3D Systems' vice president, portfolio & regulatory, commented, "With over 25 years of experience, our solutions have supported more than 175,000 patient-matched cases with the goal of improving surgical outcomes and the overall patient experience. Our VSP surgical planning workflow including the expertise of our biomedical engineers, our Selective Laser Sintering technology, and our DuraForm® ProX® PA materials is a differentiator in the market and was instrumental in the success of this program within a short timeframe."

"We are excited to partner with 3D Systems and unveil our new TOTAL ANKLE Patient-Matched Guides for total ankle replacement — a breakthrough to help transform the way healthcare professionals approach surgical precision and improved patient outcomes," said Mark McMahan, vice president of marketing, global orthopaedics at Smith+Nephew. "This advanced system is designed to offer unparalleled efficiency and accuracy, ultimately enhancing the overall experience for both surgeons and patients."

3D Systems is recognized as a pioneer in the personalized medicine space. The Company has manufactured more than 2 million medical device implants and supported over 100 FDA-cleared and CE-marked devices. 3D Systems' VSP surgical planning solutions include a service-based approach to personalized surgery, combining expertise in medical image processing, surgical planning, and 3D printing. As 3D Systems' technology has evolved over the last several years, the Company is expanding its expertise beyond craniomaxillofacial applications to other parts of the human skeleton such as large joints. Additionally, the Company sees tremendous opportunity for its solutions in trauma environments where both quality and response time are extremely important to patient outcomes. 3D Systems' unique additive manufacturing solutions are helping to drive innovation in the global orthopedic devices market that is growing at a CAGR of 11.2% and is anticipated to reach \$5.3 billion by 2032<sup>3</sup>.

"3D Systems is a recognized leader in supporting the medical device industry and surgeon community with early adoption in craniomaxillofacial procedures," said Gautam Gupta, Ph.D.,

general manager and senior vice president, medical devices, 3D Systems. "Over the last several years, we have continued to leverage our VSP surgical planning workflows to expand into other personalized total joint orthopedic applications like shoulders and ankles. Through our collaboration with an industry leader such as Smith+Nephew, we leveraged our collective expertise in orthopedics to develop an end-to-end solution for total ankle replacements that is helping surgeons perform surgeries more efficiently. This is yet another great example of how our personalized orthopedics business continues to grow."

3D Systems and Smith+Nephew will showcase these guides in their respective booths — 3D Systems booth #225 and Smith+Nephew booth #115 — at the American Orthopaedic Foot & Ankle Society (AOFAS) Annual Meeting 2024 from September 11-14 in Vancouver, British Columbia, Canada. For more information, please visit [3D Systems' website](#).

1. Yau J, Emmerson B, et al. Patient-Reported Outcomes in Total Ankle Arthroplasty: Patient Specific Versus Standard Instrumentation. *Foot Ankle Spec.* 2024 Feb;17(1\_suppl):30S-37S.
2. Gauci MO. Patient-specific guides in orthopedic surgery. *Orthop Traumatol Surg Res.* 2022 Feb;108(1S):103154.
3. Allied Market Research, "Orthopedic 3D Printing Devices Market Size, Share, Competitive Landscape and Trend Analysis Report, by Type, by Application: Global Opportunity Analysis and Industry Forecast, 2023-2032," June 2023.

### **Forward-Looking Statements**

Certain statements made in this release that are not statements of historical or current facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the company to be materially different from historical results or from any future results or projections expressed or implied by such forward-looking statements. In many cases, forward-looking statements can be identified by terms such as "believes," "belief," "expects," "may," "will," "estimates," "intends," "anticipates" or "plans" or the negative of these terms or other comparable terminology.

Forward-looking statements are based upon management's beliefs, assumptions, and current expectations and may include comments as to the company's beliefs and expectations as to future events and trends affecting its business and are necessarily subject to uncertainties, many of which are outside the control of the company. The factors described under the headings "Forward-Looking Statements" and "Risk Factors" in the company's periodic filings with the Securities and Exchange Commission, as well as other factors, could cause actual results to differ materially from those reflected or predicted in forward-looking statements. Although management believes that the expectations reflected in the forward-looking statements are

reasonable, forward-looking statements are not, and should not be relied upon as a guarantee of future performance or results, nor will they necessarily prove to be accurate indications of the times at which such performance or results will be achieved. The forward-looking statements included are made only as of the date of the statement. 3D Systems undertakes no obligation to update or revise any forward-looking statements made by management or on its behalf, whether as a result of future developments, subsequent events or circumstances or otherwise, except as required by law.

### **About 3D Systems**

More than 35 years ago, 3D Systems brought the innovation of 3D printing to the manufacturing industry. Today, as the leading additive manufacturing solutions partner, we bring innovation, performance, and reliability to every interaction - empowering our customers to create products and business models never before possible. Thanks to our unique offering of hardware, software, materials, and services, each application-specific solution is powered by the expertise of our application engineers who collaborate with customers to transform how they deliver their products and services. 3D Systems' solutions address a variety of advanced applications in healthcare and industrial markets such as medical and dental, aerospace & defense, automotive, and durable goods. More information on the company is available at [www.3dsystems.com](http://www.3dsystems.com).

### **About Smith+Nephew**

Smith+Nephew is a portfolio medical technology business focused on the repair, regeneration and replacement of soft and hard tissue. We exist to restore people's bodies and their self-belief by using technology to take the limits off living. We call this purpose 'Life Unlimited'. Our 18,000 employees deliver this mission every day, making a difference to patients' lives through the excellence of our product portfolio, and the invention and application of new technologies across our three global business units of Orthopaedics, Sports Medicine & ENT and Advanced Wound Management.

Founded in Hull, UK, in 1856, we now operate in more than 100 countries, and generated annual sales of \$5.5 billion in 2023. Smith+Nephew is a constituent of the FTSE100 (LSE:SN, NYSE:SNN). The terms 'Group' and 'Smith+Nephew' are used to refer to Smith & Nephew plc and its consolidated subsidiaries, unless the context requires otherwise.

For more information about Smith+Nephew, please visit [www.smith-nephew.com](http://www.smith-nephew.com) and follow us on [X](#), [LinkedIn](#), [Instagram](#) or [Facebook](#).

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