

Press Release

3D Systems Corporation
333 Three D Systems Circle
Rock Hill, SC 29730
www.3dsystems.com
NYSE:DDD

Investor Contact: investor.relations@3dsystems.com
Media Contact: press@3dsystems.com

3D Systems Announces FDA Clearance for World's First 3D-Printed PEEK Cranial Implants

- FDA clearance enables wide-spread adoption of 3D Systems self-contained, cleanroom environment-based printing system, the EXT 220 MED, with medical-grade PEEK materials to deliver patient-specific cranial reconstruction solutions
- 3D-printed PEEK implants using the EXT 220 MED successfully demonstrated in nearly 40 cranioplasties across Europe in recent months
- Market for cranial reconstruction anticipated to exceed \$2 billion by 2030
- FDA clearance establishes strong foundation for expanded application of these unique, cost-effective technologies to additional orthopedic surgical indications

ROCK HILL, South Carolina, April 15, 2024 – Today, [3D Systems](#) (NYSE:DDD) announced the Food and Drug Administration (FDA) has provided 510(k) clearance for its 3D-printed, patient-specific cranial implant solution — VSP® PEEK Cranial Implant. VSP PEEK Cranial Implant includes a complete FDA-cleared workflow comprising segmentation and 3D modeling software, the 3D Systems EXT 220 MED 3D printer, Evonik [VESTAKEEP® i4 3DF](#) PEEK (polyetheretherketone), and a pre-defined production process. By utilizing additive manufacturing solutions, this technology can produce patient-specific cranial implants with up to 85% less material than similar implants produced by traditional machining, which can lead to significant cost savings for an expensive raw material like implantable PEEK. Furthermore, the cleanroom-based architecture of the printer combined with simplified post-processing workflows makes it an ideal technology for producing patient-specific medical devices at the hospital site with faster turnaround while keeping the overall cost under control. To date, this solution has been used to enable nearly 40 successful cranioplasties in Switzerland at University Hospital

Basel, in Austria at Salzburg University Hospital, and in Israel at Tel-Aviv Sourasky Medical Center.

“3D-printed PEEK cranial plates are an innovative solution that can improve patient care and expand the possibilities for precise, individualized neurosurgery,” said Dr. Johannes Pöppe, senior attending surgeon, department of neurosurgery, University Hospital Salzburg. “The solution is revolutionizing the field. The combination of 3D Systems’ printing technology that is uniquely engineered for sterile environments along with the mechanical properties of PEEK are helping surgeons push boundaries. Within our hospital, we have already completed several successful surgeries using these technologies. I believe the potential for customized PEEK cranial plates is significant to integrate 3D printing into routine clinical practice.”

The VSP PEEK Cranial Implant is the first FDA-cleared, additively manufactured PEEK implant intended for cranioplasty procedures to restore defects in the skull. This implant-grade, high-performance polymer has a well-known clinical history in medical device applications due to its exceptional performance with mechanical properties closely mirroring human bone. In addition, PEEK has excellent biocompatibility, resistance to bodily fluids, and stability in a wide range of temperatures, making it an ideal choice for many medical device applications. Furthermore, its inherent radiolucency ensures minimal interference in medical imaging, facilitating a clearer evaluation of the surgical site and implant integrity.

“As a leader in medical device innovation, 3D Systems prides itself on pioneering advancements that benefit both surgeons and patients,” said Dr. Gautam Gupta, SVP & general manager, medical devices, 3D Systems. “Receiving FDA clearance for our VSP PEEK Cranial Implant solution is a significant milestone in our journey. Our EXT 220 MED printing system has already enabled the production of nearly 40 cranial implants in support of successful cranioplasties throughout Europe. With this FDA clearance, we are now able to bring VSP PEEK Cranial Implant to the U.S. — setting a new standard of excellence for these procedures. We are now looking to the next applications for this technology, which includes 3D-printed spine interbody fusion implants, carbon fiber-reinforced PEEK for plating applications in trauma and fixation, and bioresorbable polymers for large bone and craniomaxillofacial applications.”

3D Systems has worked with surgeons for more than a decade to plan over 150,000 patient-specific cases and manufacture more than two million implants and instruments for 100+ CE-marked and FDA-cleared devices from its world-class, FDA-registered, ISO 13485-certified facilities in Littleton, Colorado and Leuven, Belgium.

This FDA clearance enables 3D Systems to significantly expand its PEEK product portfolio through the EXT 220 MED platform. With this milestone, the company is not just introducing a pioneering product; it is setting the stage for a comprehensive range of advanced PEEK-based solutions designed to meet the diverse needs of the medical field. 3D Systems' extensive experience in developing patient-specific, high-performance PEEK implants, combined with its robust database, places the company in an unparalleled position to accelerate the development process. This expertise is a valuable asset for all existing customers and partners, offering them an expedited pathway to bring their products to market. By leveraging 3D Systems' proven track record and the capabilities of the EXT 220 MED platform, the company is committed to supporting its partners in navigating the regulatory landscape more efficiently, ensuring faster access to innovative medical solutions that enhance patient care and outcomes.

It is anticipated that the use of 3D-printed cranial implants will accelerate based on the availability of advanced technologies. According to a report by Acumen Research and Consulting in February 2023, the cranial implants market size in 2021 was roughly \$1.2 billion and is anticipated to approach \$2.1 billion by 2030. Cranial implants can address a breadth of applications including trauma, defects, and reconstruction. The continued innovation in materials and manufacturing methodologies such as 3D printing are expected to enable new solutions to catalyze growth in this market.

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.

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