

Press Release

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3D Systems Delivers New Innovation for its VSP[®] System – Receives 510(k) Clearance for Improved Patient-Matched Surgical Guidance

- Pioneer in personalized medicine delivers additional design and material offerings for craniomaxillofacial surgical guides that improve performance
- The additions to 3D Systems' VSP products offer the maxillofacial surgeon an unmatched portfolio of options for precise patient treatments

ROCK HILL, South Carolina, October 1, 2020 – [3D Systems](http://www.3dsystems.com) (NYSE:DDD) – inventor of 3D Printing and creator of Virtual Surgical Planning for craniomaxillofacial (CMF) applications - today is announcing that the Food and Drug Administration (FDA) has provided 510(k) clearance for maxillofacial surgical guides 3D printed using its LaserForm[®] Ti and DuraForm[®] ProX PA materials. The new clearance allows for more innovative surgical guide designs that improve performance and is the latest delivery on 3D Systems' customer-centric approach to address the needs of surgeons performing maxillofacial and reconstructive surgeries. 3D Systems' surgical guides produced using these materials as part of its [VSP[®] System](#) offer unprecedented flexibility in design options, and are capable of having lower profile designs to enhance visibility and access in the surgical site, while also possessing improved strength and rigidity. Creating patient-specific surgical guides as part of the VSP System has been shown to save surgeons and patients hours in the operating room.¹

As a pioneer in the personalized medicine space, 3D Systems' VSP technology received FDA market clearance as a service-based approach to personalized surgery, combining expertise in medical imaging, surgical simulation, and 3D printing. The surgeon initiates the process,

bringing their clinical knowledge and desired surgical plan to an online web meeting with a 3D Systems biomedical engineer to simulate and plan the surgical procedure. The outcome is a digital plan that is transferred to the operating room via accurate 3D printed patient-specific models, guides, and templates. 3D Systems has provided VSP solutions or anatomical services in more than 120,000 unique patient cases.

“Through close collaboration with surgeons and Stryker’s CMF division, we’ve uncovered opportunities to refine VSP guide designs that leverage additional capabilities in our materials portfolio,” said Menno Ellis, executive vice president, healthcare solutions, 3D Systems. “Our expert biomedical engineers are now able to design surgical guides tailored to the surgeon’s needs with enhanced properties that can help improve accuracy and facilitate procedures in ways not previously possible. Our powerful VSP System continues to transform surgery – enabling better patient outcomes.”^{2,3}

Improved Surgical Guide Designs and Performance

3D System’s new material options allow for innovative surgical guide designs that improve performance in surgery. It is now possible to design surgical guides with less overall material bulk while improving strength and durability. Mechanical testing shows that Titanium cutting and marking guides produced in LaserForm Ti are 20x stronger than traditional guides.⁴ With the improvement in strength, Titanium fibula cutting guides can be 70% thinner than traditional guides – facilitating improved access to the surgical site. Similarly, Nylon marking guides produced in DuraForm ProX PA exhibit up to 88% higher toughness⁴ – rendering them better able to withstand forces applied during surgery. This enables the creation of thinner guides than previously possible and facilitates a close, snap-like, fit to patient anatomy that cannot be achieved in the traditional material.

Flexibility in Treatment Options

With the new clearance, 3D Systems is pleased to offer an unmatched portfolio of material and guide design options that provides surgeons with the flexibility to better serve the needs of their patients. The new materials allow for customizable designs, which are tailored to the cutting and drilling instrumentation to be used in surgery, to assist surgeons with accurately performing cutting and drilling operations. Additionally, the guides created using LaserForm Ti and DuraForm ProX PA have been validated with a wider range of cleaning and steam sterilization options. Users now have more flexibility in using manual or automated cleaning methods, and the devices can be steam sterilized using a wrap or pouch under a wider range of accepted sterilization

cycles. The accepted cleaning and sterilization techniques validated for the new guide materials offer unprecedented flexibility in assuring safe patient-matched instrumentation is delivered to the operating room.

Innovating with an Industry-leading Partner

In 2018, 3D Systems announced an exclusive partnership with Stryker's CMF division to deliver innovative solutions to the maxillofacial surgeon. The new clearance and enhancements to 3D Systems' VSP System are the latest delivery on the companies' shared objectives. The new guide designs and materials are compatible with Facial iD®, Stryker's market-leading portfolio of patient-matched plating solutions. The combined surgical planning, improved patient-matched guides, and patient-specific implant system offers the maxillofacial surgeon a complete end-to-end solution for patient-matched treatment. Surgeons can request more information through Stryker's CMF representatives.

¹ Sink J, Hamlar D, Kademani D, Khariwala SS: Computer-aided stereolithography for presurgical planning in fibula free tissue reconstruction of the mandible. *J Reconstr Microsurg* 28:395-404, 2012.

² Patel A, Levine J, Brecht L, Saadeh P, Hirsch DL: Digital technologies in mandibular pathology and reconstruction. *Atlas Oral Maxillofacial Surg Clin N Am* 20:95-106, 2012

³ Roser SM, Ramachandra S, Blair H, Grist W, Carlson GW, Christensen AM, Weimer KA, Steed MB: The accuracy of virtual surgical planning in free fibula mandibular reconstruction: comparison of planned and final results. *J Oral Maxillofac Surg* 68:2824-2832, 2010

⁴ Proprietary Mechanical Validation Testing Data on file at 3D Systems

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 review any forward-looking statements made by management or on its behalf, whether as a result of future developments, subsequent events or circumstances or otherwise.

About 3D Systems

More than 30 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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