



Materialise First Company to Receive FDA Clearance for Diagnostic 3D-Printed Anatomical Models

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FDA clearance supports the continued growth of point-of-care 3D printing facilities

Leuven, Belgium – March 23, 2018. Materialise NV (Nasdaq: MTLN) is the first company in the world to receive FDA clearance for software intended for 3D printing anatomical models for diagnostic use. Leading hospitals are adopting integrated 3D printing services as part of their medical practices as they recognize the added value it brings to personalized patient care. Materialise brings nearly three decades of experience in developing medical solutions that help researchers, engineers and clinicians achieve the desired patient outcomes.

In August 2017, the FDA announced that software intended to create output files used for printing 3D patient-specific anatomical models which are used for diagnostic purposes, is a class II medical device and requires regulatory clearance. Materialise is the first company to provide software which conforms to these regulations and which can be used in U.S. hospitals in combination with a compatible 3D printer. Materialise Mimics inPrint software is used for pre-operative planning and the fabrication of physical models for diagnostic purposes, including patient management, treatment and surgeon-to-surgeon communication.

Frank J. Rybicki, MD, PhD and Chief of Medical Imaging at Ottawa Hospital says: “510k clearance is an essential component to ensure quality and safety in the practice of anatomical modeling in hospitals. This milestone for Materialise serves as a benchmark for the clinical implementation of 3D printing for physicians creating 3D models at the point-of-care.”

The FDA clearance supports the creation of point-of-care 3D printing facilities in hospitals. Anatomical models help surgeons to make better-informed decisions and to accurately plan their surgeries. They are also used to enhance education and communication between multidisciplinary teams and with the patient. Hospitals recognize the added value 3D Printing brings to personalized patient care and to define treatment options. As a result, an increasing number of hospitals across the U.S. have integrated the practice of 3D Printing in their medical care and are creating point-of-care 3D printing facilities. Out of the top 20 US hospitals (as ranked by the US News and World Report), 16 have implemented a medical 3D printing strategy using Materialise Mimics technology.

“Materialise has nearly three decades of experience in developing certified medical solutions that create a better and healthier world,” says Wilfried Vancraen, Materialise CEO. “The FDA clearance for our Mimics inPrint software will support the adoption of 3D planning and printing in U.S. hospitals and the creation of point-of-care 3D printing facilities.”

About Materialise

Materialise incorporates 27 years of 3D printing experience into a range of software solutions and 3D printing services, which together form the backbone of the 3D printing industry. Materialise’s open and flexible solutions enable players in a wide variety of industries, including healthcare, automotive, aerospace, art and design, and consumer goods, to build innovative 3D printing applications that aim to make the world a better and healthier place. Headquartered in Belgium, with branches worldwide, Materialise combines the largest group of software developers in the industry with one of the largest 3D printing facilities in the world. For additional information, please visit: www.materialise.com.

About Materialise Medical

Materialise Medical, which has pioneered many of the leading medical applications of 3D Printing, enables researchers, engineers and clinicians to revolutionize innovative patient-specific care. Materialise Medical’s open and flexible platform of software and services, Materialise Mimics, forms the foundation of certified Medical 3D Printing, in clinical as well as research environments, offering virtual planning software tools, 3D-printed anatomical models, and patient-specific surgical guides and implants. For additional information, please visit: materialise.com/medical

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Cautionary Statement on Forward-Looking Statements

Some of the statements in this press release are "forward-looking" and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements relating to, among other things, our planned commercialization efforts and regulatory approvals of our technologies as well as the success thereof and our research and development projects. These forward-looking statements are based upon the expectations of management under current assumptions at the time of this press release. We caution you that forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control that may cause our actual results to differ materially from our expectations. We are providing this information as of the date of this press release and do not undertake any obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information.