



Photo Release -- Materialise's HeartPrint(R) Now Listed as a Class 1 Medical Device

October 9, 2014

LEUVEN, Belgium, Oct. 9, 2014 (GLOBE NEWSWIRE) -- **Materialise NV** (Nasdaq:MTLS), a leading provider of additive manufacturing software and of sophisticated 3D printing solutions in the medical and industrial markets, has listed its 3D-printed cardiovascular **HeartPrint®** models as a medical device in the USA and EU markets. After years of 3D printing anatomical models for educational and research purposes, the Company addressed the need for models that can assist with diagnosing, planning and practicing complex cardiovascular procedures. This move strengthens the Company's unique position in the market and is a natural extension of its Mimics® Innovation Suite of software for medical image processing which has an existing 510(k) clearance and CE mark.

A photo accompanying this release is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=28271>

By listing HeartPrint as a Class 1 medical device, the Company is able to add HeartPrint models to their offering for pre-operative planning. The 3D-printed, patient-specific cardiovascular models are created from medical image data to provide cardiologists and surgeons with supplemental information to determine the best treatment for each unique patient.

"Where I think clinically 3D printing will take us, is to the next generation of imaging. As we've seen in the history of medicine, the better and better our imaging, the more precise we are to pre-operatively be able to say what operation we're going to do," said David Morales, MD, Chief of Cardiovascular Surgery for the Heart Institute at Cincinnati Children's Hospital Medical Center.

Nearly every week, the added-value of 3D printed solutions in the medical arena makes headlines. A recent story covered a 1-week-old baby who was born with a complex form of congenital heart disease in which both the aorta and pulmonary arteries arise from the right ventricle as well as a large hole in the heart called a ventricular septal defect (VSD). Only one day after he was born, an extremely low dose chest CT scan was acquired and data was sent to Todd Pietila, Cardiovascular Business Development Manager at Materialise, who created a digital 3D model of the baby's heart using Mimics® and then 3D-printed a replica where even the smallest details were visible. With the walnut-size model in hand, the team of clinicians at the NewYork-Presbyterian/Morgan Stanley Children's Hospital were able to find a solution for repairing all of the baby's defects in one procedure rather than the typical series of palliative operations which can be life threatening.

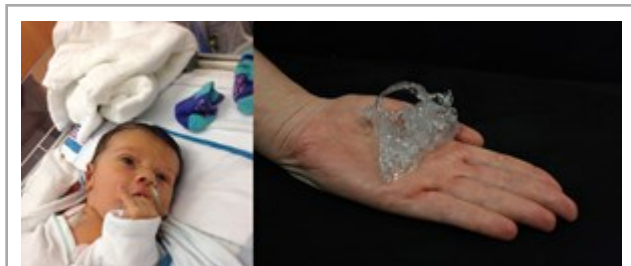
"After the success of this surgery, it's hard to imagine entering an operating room for another complex case without the aid of a 3D printed model. It's definitely going to be standard of care in the future and we're happy to be leading the way," said Dr. Emile Bacha, a congenital heart surgeon and Director of Congenital and Pediatric Cardiac Surgery at NewYork-Presbyterian/ Morgan Stanley Children's Hospital.

Regulatory entities have raised concerns about 3D printing in a clinical environment as a validated quality system is critical for ensuring accuracy and safety. Materialise is the only company who is actively addressing these issues with their Mimics Innovation Suite for segmenting the medical image data and Streamics, which is dedicated to automating, controlling and tracking the 3D printing process to ensure traceability and clinical-level quality standards.

"We're proud that the Mimics Innovation Suite is one of the few engineering packages with the appropriate validation to be considered a medical device. This makes it easier for Materialise and our customers to bring patient-specific, 3D-printed treatments to the market. It's important for us to stay ahead of the regulatory requirements," Koen Engelborghs, Director of Biomedical Engineering at Materialise, states. *"We saw the advantages for patients when HeartPrint models were used in a clinical environment and are looking forward to continuing our collaborations with hospitals to address their 3D printing needs."*

Materialise has a long track record of providing cutting-edge, 3D visualization and printing solutions to their extensive list of hospital, academic and medical device customers. With all of these great minds working together, the future of patient-specific treatments is looking bright! For more information on HeartPrint, visit heartprint.materialise.com or [watch the webinar on complex interventional planning](#).

Press Contacts



A recent example of Materialise's 3D printed HeartPrint services - Surgeons at NewYork-Presbyterian/Morgan Stanley Children's Hospital used the model to plan a surgery to repair the newborn's congenital heart disease.

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