Bioresorbable Implant 3D Printed by Materialise Enters Clinical Trial

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The clinical trial led by Materialise and University of Michigan is the next phase to facilitate regular use of *a revolutionary 3D-printed implant* to help children worldwide

Dr. Richard G. Ohye, MD, and Dr. Glenn E. Green, MD, from Michigan Medicine and University of Michigan Health, C.S. Mott Children's Hospital demonstrate a bioresorbable, 3D-printed tracheobronchial splint device educational model – original size (left) and augmented model (right). ©University of Michigan

LEUVEN, Belgium and ANN ARBOR, Mich. (March 6, 2025) – Materialise, a global leader in medical 3D printing and planning solutions, and the University of Michigan's Michigan Medicine and University of Michigan Health, a world-renowned provider of breakthrough treatments and specialized healthcare, have entered a U.S. Food and Drug Administration (FDA) pivotal clinical trial involving Materialise's innovative, bioresorbable, 3D-printed tracheobronchial splint device.

The current pivotal clinical trial opened in January 2025 and will enroll at least 35 infants and children in the eight-year study at University of Michigan Health C.S. Mott Children's Hospital and additional study sites.

Materialise Mimics software facilitates the pathway to a clinical trial

The original splint device was developed using Materialise Mimics software by Scott Hollister, Ph.D., former U-M Professor of Biomedical Engineering, and Glenn Green, MD, C.S. Mott Children's Hospital Otolaryngologist and Clinical Professor. The first child received life-saving treatment in early 2012.

Since then, Mimics software played a crucial role in case planning and providing tracheobronchial splints to more than 40 pediatric patients via FDA Expanded Access (both Compassionate Use and Emergency Use) pathways. Materialise and U-M worked together to obtain an Investigative Device Exemption (IDE), held by U-M Pediatric Cardiovascular surgeon and lead investigator Dr. Richard Ohye, MD, which opens the door to a clinical trial, and eventually regular use of the device, if the device is approved for marketing by the FDA.

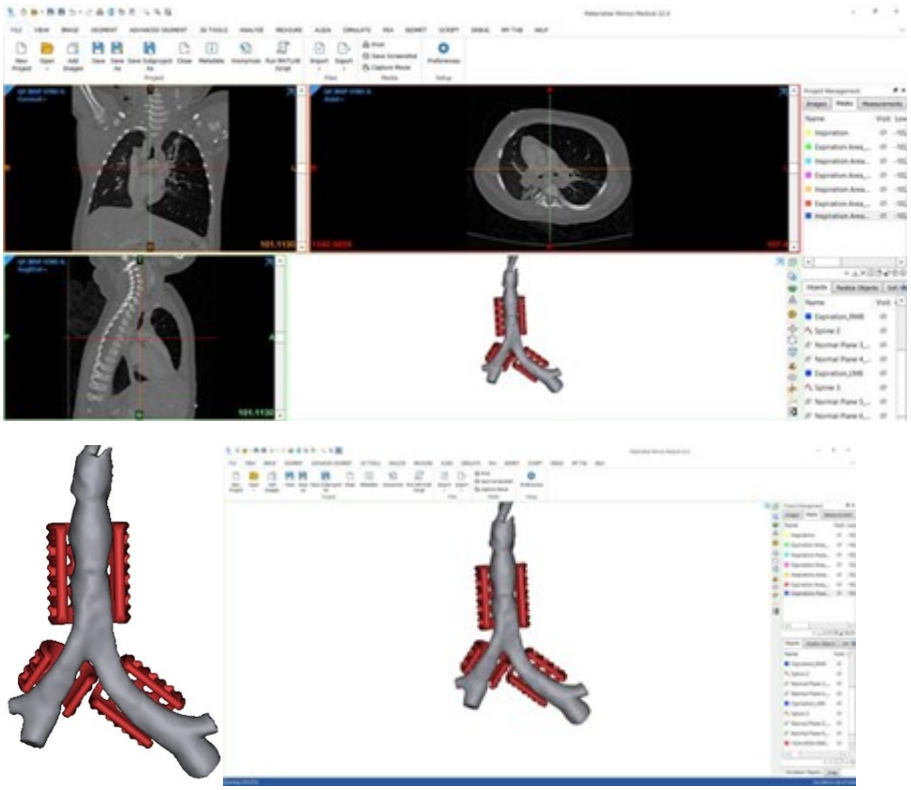
"In partnering with U-M on this life-saving clinical trial, children now have access to this ground-breaking device and procedure," said Colleen Wivell, Director of Clinical Engineering at Materialise. "We've worked tirelessly with U-M to get this project off the ground. I'm so proud to say that we are helping address an unmet need using Materialise's best-in-class innovations. It's about

saving lives, improving quality of life, and making ongoing care more reasonable and sustainable."

The project's challenges included further developing the device design, establishing the 3D printing and sterilization process, pre-clinical testing, safety and efficacy testing, obtaining appropriate regulatory approval to be able to open the trial, and establishing a clean room and good manufacturing practices. One of the team's most significant achievements, according to Ms. Wivell, was to perform the pre-clinical testing that enabled the project to obtain the IDE.

Mimics works in partnership with advanced 3D printing techniques

The clinicians and engineers use the Mimics and 3-matic modules to translate anatomical data from CT or MRI for use in pre-surgical planning and preparation for 3D printing.



Caption: *Demonstration of an educational case – pre-operative planning of a tracheobronchial splint device in Materialise Mimics.* ©Materialise

"Throughout this treatment journey with Materialise, we have remained committed to the evolution of the tracheal splint and its ability to provide critical care to those suffering from life-threatening conditions," said Richard Ohye, MD, Pediatric Cardiothoracic Surgeon, lead investigator of the clinical trial, and co-Director of the University of Michigan C.S. Mott Children's Hospital Congenital Heart Center. "We will continue to work diligently to showcase the transformative impact this 3D-printed medical device can have on patients."

3D Printing of Body-Resorbable Material—the Current Process and Future Applications

Materialise's innovative method to 3D print polycaprolactone, a biodegradable material that is gradually absorbed into the body over years. The potential future implications of such material are significant.

"Using a laser sintering process, the devices are printed right here at a dedicated Materialise facility near the U-M hospital in Ann Arbor, Michigan," explained Colleen Wivell, Director of Clinical Engineering at Materialise. "This method provides a lot of design freedom. 3D printing for hard tissue such as bone is well known, however the potential for this bioresorbable 3D printed material to open doors for significant advancements in soft tissue applications is immense. Materialise is at the forefront of such innovation, and we look forward to scaling up and making our innovations count."

Caption: Dr. Richard G. Ohye, MD, demonstrates the bioresorbable, 3D-printed tracheobronchial splint device educational model. ©University of Michigan

"This project demonstrates Materialise's commitment to transforming healthcare," said Bryan Crutchfield, Vice President and General Manager, North America at Materialise. "Our corporate responsibility to 3D printing and planning as drivers for a more personalized approach means that clinicians can tailor treatment plans to each patient's unique anatomy and thereby significantly impact patient care."

Link to the Michigan Medicine and University of Michigan Health press release: https://www.michiganmedicine.org/news-release

About Materialise

Materialise incorporates more than three decades of 3D printing experience into a range of software solutions and 3D printing services that empower sustainable 3D printing applications. Our open, secure, and flexible end-to-end solutions enable industrial manufacturing and mass personalization in various industries — including healthcare, automotive, aerospace, eyewear, art and design, wearables, and consumer goods. Headquartered in Belgium and with branches worldwide, Materialise combines the largest group of software developers in the industry with one of the world's largest and most complete 3D printing facilities. Materialise is passionate about creating innovative solutions that impact patient's lives and accelerate the mass personalization of healthcare.

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About Michigan Medicine and University of Michigan Health

At Michigan Medicine, we advance health to serve Michigan and the world. We pursue excellence every day in our 11 hospitals and hundreds of clinics statewide, as well as educate the next generation of physicians, health professionals and scientists in our U-M Medical School.

Michigan Medicine includes U-M Medical School and University of Michigan Health, which includes C.S. Mott Children's Hospital, Von Voigtlander Women's Hospital, University Hospital, the Frankel Cardiovascular Center, Kellogg Eye Center, University of Michigan Health-West, University of Michigan Health-Sparrow and the Rogel Cancer Center. The U-M Medical School is one of the nation's biomedical research powerhouses, with total research awards of more than $777 million.

More information is available at https://www.michiganmedicine.org/

L-104460-01

Materialise medical devices may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Materialise representative if you have questions about the availability of Materialise Medical devices in your area. Materialise Mimics and Materialise 3-matic are for research use only.