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TISSIUM Receives FDA De Novo Authorization for COAPTIUM® CONNECT in Atraumatic Sutureless Peripheral Nerve Repair

This regulatory milestone marks TISSIUM's entry into the U.S. market and establishes the foundation of the TISSIUM polymer platform for atraumatic tissue repair

Paris, France, Cambridge, USA, June 24, 2025 - TISSIUM, a MedTech company pioneering biomorphic programmable polymers for tissue reconstruction, today announced that the U.S. Food and Drug Administration (FDA) has granted De Novo marketing authorization for COAPTIUM® CONNECT with TISSIUM Light, a first-of-its-kind atraumatic sutureless solution for peripheral nerve repair.

This authorization represents a pivotal regulatory milestone for TISSIUM, further validating its biopolymer platform and enabling U.S. commercialization of its first product. COAPTIUM® CONNECT is now the only FDA-authorized system designed for atraumatic sutureless nerve coaptation.

Christophe Bancel, Co-Founder and CEO of TISSIUM said: "*This FDA marketing authorization validates over a decade of scientific and clinical commitment to developing next-generation solutions in tissue reconstruction. COAPTIUM® CONNECT is the first demonstration of the transformative potential of our polymer platform and an important step in making atraumatic tissue repair available to patients.*"

Peripheral nerve injuries affect hundreds of thousands of patients annually and are typically repaired using microsurgical sutures. However, this approach presents limitations—including technical complexity, risk of additional trauma, and variable outcomes. COAPTIUM® CONNECT addresses these challenges by offering a

reproducible, atraumatic sutureless alternative that preserves nerve integrity and simplifies the coaptation process[1].

In a recent clinical study on 12 patients with digital nerve injuries, COAPTIUM® CONNECT achieved 100% procedural success, defined as successful atraumatic sutureless coaptation using the polymer-assisted coaptation device, with all patients regaining full flexion and extension of the injured digit and reporting no pain 12 months after the procedure[1].

TISSIUM plans to initiate commercial rollout of COAPTIUM® CONNECT in the coming months.

The COAPTIUM® CONNECT System leverages TISSIUM's unique biopolymer platform, invented by Maria Pereira, Jeffrey Karp and Robert Langer at the MIT and Brigham & Women's Hospital, using its bioresorbable light-activated surgical polymer and its 3D-printed polymer chamber.

Maria Pereira, Co-Founder and Chief Innovation Officer, said: "*This first product illustrates the technical versatility and the potential of the TISSIUM polymer platform, not only in peripheral nerve repair where other solutions are currently under development, but also in other surgical applications, such as atraumatic hernia repair and cardiovascular sealing*."

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[1] A Sutureless Approach to Nerve Repair: Results from a Clinical Study in Digital Nerves, Randi Bindra, Journal of Hand Surgery, submitted 2025

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About TISSIUM

TISSIUM is a clinical and commercial stage MedTech company based in Paris, France, Cambridge, USA, and with a manufacturing site in Roncq, France. The company is pioneering a proprietary platform of fully biosynthetic, biomorphic, programmable, elastomeric polymers designed to address critical unmet needs in atraumatic tissue repair and tissue reconstruction.

TISSIUM's diversified pipeline includes seven products across three core verticals: sutureless nerve repair, atraumatic hernia repair, and cardiovascular sealants. Each solution is designed to optimize tissue repair through controlled and consistent procedures with specialized delivery and activation devices to maximize the performance and usability of its products.

Founded in 2013, TISSIUM is built on breakthrough research and intellectual property originating from the laboratories of Professor Robert Langer (MIT) and Professor Jeffrey M. Karp (Brigham and Women's Hospital).

For more information, please visit www.TISSIUM.com and follow us on LinkedIn: TISSIUM.

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