

NovoPedics Total Meniscus Replacement Device MeniscoFix™ Receives Breakthrough Device Designation from the U.S. Food and Drug Administration

NovoPedics, Inc. announced today that MeniscoFix™, a total meniscus replacement device currently under development, has been granted Breakthrough Device Designation from the U.S. Food and Drug Administration.

PRINCETON, N.J. ([PRWEB](#)) September 14, 2020 -- The U.S. Food and Drug Administration's (FDA) Breakthrough Device Program is intended to expedite the development and prioritize the review of medical devices that provide for more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. The Program provides patients and health care providers timely access to these medical devices by speeding up their development, assessment, and review, consistent with the FDA's mission to protect and promote public health.

“We are very pleased that the FDA recognizes the unique potential benefits of MeniscoFix™ for patients suffering from pain and loss of mobility associated with a meniscus injury and previous meniscectomy,” remarked NovoPedics Co-Founder Dr. Michael Dunn. “The Breakthrough Device Designation will enable us to interact with the FDA more rapidly and effectively to accelerate preclinical studies and subsequent clinical trials for MeniscoFix™.” NovoPedics Co-Founder Dr. Charles Gatt added, “In contrast to partial meniscus replacement devices, MeniscoFix™ is uniquely designed to be securely fixed within bone tunnels and to support mechanical loads along the entire implant periphery, making it potentially useful even in patients with a compromised meniscal rim.”

Recently, the U.S. Department of Defense (DoD), through the Joint Warfighters Medical Research Program, awarded a \$4.42 million grant to the research and development teams at Rutgers University and NovoPedics (Dr. Dunn, Principal Investigator) to support further pre-clinical development of MeniscoFix™.

Dr. Dunn added that “The FDA Breakthrough Device Designation, coupled with the new DoD funding, will synergistically accelerate our research and development efforts for MeniscoFix™, the first mechanically functional total meniscus replacement device designed to be gradually resorbed by the body and replaced by new tissue. We look forward to making this new technology available to orthopaedic surgeons to address a significant unmet need in the treatment of patients with meniscus injuries.”

About NovoPedics, Inc.

NovoPedics, Inc., a medical device company based in Princeton, New Jersey, is developing implantable medical devices designed to relieve pain and restore mobility to patients suffering from severe meniscal injuries and meniscectomies. MeniscoFix™, is a polymer fiber-reinforced scaffold for total meniscus replacement designed to be gradually resorbed by the body and be replaced by new tissue. It represents an innovative approach to replace damaged meniscal tissue with a patented fiber-reinforced design similar to the native meniscus. It is designed to be attached to both soft tissue and bone, thus potentially enabling its use in total meniscus replacement surgery. For more information visit: <http://www.novopedics.com>



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