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Medtronic earns FDA Breakthrough Device designation for IN.PACT™ BTK drug-coated balloon

Investigational device to be studied in pre-market, randomized pivotal trial

DUBLIN - September 30, 2026 - Medtronic (NYSE: MDT), the global leader in healthcare technology, today announced it has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its IN.PACT™ BTK Paclitaxel Drug-Coated Balloon Catheter, which is an investigational technology currently in development.[†]

Peripheral arterial disease (PAD) below the knee represents one of the highest-risk patient groups in the peripheral vascular space.¹ These patients are at high risk for major amputation and death,² underscoring the need for continued research and innovation to improve treatment options. The most advanced stage of PAD, chronic limb-threatening ischemia (CLTI), frequently involves below-the-knee arteries and is particularly common among patients with comorbidities such as diabetes and chronic kidney disease.²

Drug-coated balloons are widely used to treat PAD in arteries above the knee and have demonstrated improved vessel patency compared with conventional balloon angioplasty.³ However, because there is currently no commercially available drug-coated balloon indicated for PAD treatment below the knee in the U.S., uncoated percutaneous transluminal angioplasty (PTA) remains the primary endovascular treatment option for many CLTI patients despite high rates of restenosis and repeat intervention.²

"Finding effective therapies for CLTI patients with lesions below the knee is one of the most pressing unmet clinical needs in contemporary endovascular therapy," said Eric Secemsky, MD, interventional cardiologist with Beth Israel Deaconess Medical Center, who will serve as the global principal investigator for the planned IN.PACT BTK DELTA clinical trial. "The IN.PACT BTK DELTA clinical trial is an important opportunity to find a better treatment option for these at-need patients."

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide Medtronic with timely interaction and communication throughout device development and the regulatory review process.

To advance evidence-based treatment options for patients with CLTI, Medtronic is planning IN.PACT BTK DELTA, a global, randomized pivotal study of approximately 400 patients with below-the-knee lesions. The trial will evaluate the safety and effectiveness of the investigational IN.PACT BTK device. The company is working closely with regulators and investigators to finalize the study design in the coming months.

The investigational IN.PACT BTK device is built on the IN.PACT platform with the proprietary FreePac™ paclitaxel coating, which has demonstrated sustained safety and effectiveness in femoropopliteal disease through five years in randomized clinical studies.⁴ "Our planned IN.PACT BTK DELTA trial reflects our confidence in the safety and effectiveness of paclitaxel drug-coated balloons," said David Moeller, sr. vice president and president, Medtronic Peripheral Vascular Health, which is part of the company's Cardiovascular portfolio. "We look forward to generating rigorous clinical evidence to find better solutions for patients facing one of the most serious forms of PAD."

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission – to alleviate pain, restore health, and extend life – unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow Medtronic on [LinkedIn](#).

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the U.S. Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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Footnotes

† The device described is currently in development and is not yet approved or cleared for use in any region. Features and performance of future technologies may vary.

References

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3. Schneider PA, Laird JR, Tepe G, et al. Treatment Effect of Drug-Coated Balloons Is Durable to 3 Years in the Femoropopliteal Arteries: Long-Term Results of the IN.PACT SFA Randomized Trial. *Circ Cardiovasc Interv.* 2018;11(1):e005891. doi:10.1161/CIRCINTERVENTIONS.117.005891
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<https://news.medtronic.com/Medtronic-earns-FDA-Breakthrough-Device-designation-for-IN-PACT-TM-BTK-drug-coated-balloon>