Medtronic Canada Newsroom

# Medtronic TYRXTM III Absorbable Antibacterial Envelope launches in Canada

Medtronic plc, a global leader in healthcare technology, announced it has launched the TYRX™ III Absorbable Antibacterial Envelope (TYRX III envelope) in Canada with first commercial cases underway.* This third-generation envelope is based on the only absorbable antibacterial technology with robust clinical evidence demonstrating reduced infection and long-term pocket health benefits.[1-2]

The TYRX III envelope leverages data supporting the overall TYRX technology with device stabilization in the pocket[1] and proven infection reduction[2], combined with an enhanced design to enhance physician experience. This next-generation envelope includes a smoother mesh with a narrower seam and wider envelope opening compared to earlier TYRX versions; this design eases the insertion of the device into the envelope and continues to promote tissue in-growth in the pocket.[3]

An estimated two million patients worldwide receive a cardiac implantable electronic device (CIED) every year[4], with 1% to 4% of these patients developing infections[2,5] resulting in significant impacts on mortality, quality of life, healthcare utilization, and cost to global healthcare systems.[6-9]

“CIED infections can have significant consequences for both patients and the healthcare system. The TYRX technology has established an important evidence base demonstrating meaningful reductions in infection risk as well as sustained pocket health,” said Dr. François Philippon, M.D., cardiologist in the electrophysiology division at Institut universitaire de cardiologie et de pneumologie de Québec (IUCPQ), Université Laval, whose team performed the first commercial implant using the TYRX III envelope. “The TYRX III envelope retains the proven outcomes of the original envelope while incorporating design refinements intended to make implantation more intuitive. That combination of evidence and usability is meaningful in contemporary practice.”

The TYRX III envelope is an absorbable, single-use device that holds a cardiac implantable electronic device (CIED), such as implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and pacemakers, or implantable neurostimulators (INS), such as deep brain stimulators, sacral neuromodulation devices, and spinal cord stimulators. Medtronic engineers designed the TYRX III envelope to stabilize the device after implantation while releasing antibacterial agents, minocycline and rifampin, over a minimum of seven days.[10-11] The TYRX III envelope is a multifilament, knitted absorbable mesh that the body fully absorbs approximately nine weeks after implantation.[11]

"What makes the TYRX III envelope so exciting is the meaningful difference it can make for patients and clinicians,” says Rob Clifton, president, Medtronic Canada. “By combining device stabilization with localized antibacterial protection during the critical post-implant period, the TYRX III envelope reflects our commitment to advancing innovation that helps improve outcomes and enhance patient care."

The landmark WRAP-IT (Worldwide Randomized Antibiotic Envelope Infection Prevention Trial) clinical study provides foundational data for the TYRX technology. The randomized controlled trial demonstrates the TYRX envelope reduced the risk of major infection by 40% in patients with CIEDs and reduced pocket infections by 61%, compared to standard of care.[2] Patients who received the TYRX technology did not have an increase in complications out to three years.[12] Additionally, data published in *Heart Rhythm*[3] showed that the TYRX envelope contributes to accelerated healing potentially providing earlier device stability enabled by early tissue integration,[†] low inflammation, [†,‡] and simplified changeout procedures due to reduction

in adhesions with healthy tissue void of clinically significant calcification.[1,‡]

Based on the WRAP-IT results, an international consensus statement supported by seven medical societies, including Heart Rhythm Society, recommends TYRX for the WRAP-IT study population.[13, 14] The study population included patients receiving a new cardiac resynchronization therapy-defibrillator (CRT-D) and patients receiving a replacement, system revision or generator upgrade of an existing pacemaker, cardiac resynchronization therapy-pacemaker (CRT-P), ICD or CRT-D. Patients with diabetes, previous history of infection, renal failure, and/or congestive heart failure also are at higher risk for CIED infections.

Earlier this year, the Canadian Cardiovascular Society (CSS) with the Canadian Heart Rhythm Society (CHRS) published a comprehensive series of guidelines for CIED management in the Canadian Journal of Cardiology[15]. In response to increasing infection rates, they now recommend the antibacterial envelope for high-risk patients similar to those described in the WRAP-It trial.

More than two million patients worldwide have received the TYRX technology, which is backed by robust clinical data from nearly 8,000 patients across 20+ peer-reviewed publications.

[1] Philippon F, Ladich E, Virmani R, et al. An Absorbable Antibacterial Envelope Promotes Development of a Healthy Device Pocket: Results of the TYRX Pocket Health Study. J Cardiovasc Electrophysiol. 2025;36(8):1978-1986.

[2] Tarakji KG, Mittal S, Kennergren C, et al. Antibacterial envelope to prevent cardiac implantable device infection. N Engl J Med 2019;380:1895–1905.

[3] Virmani R, et al. Effects of envelopes on cardiac implantable electronic device pocket healing: A head-to-head preclinical evaluation. https://doi.org/10.1016/j.hrthm.2024.02.054

[4] Mond HG, et al. Pacing Clin Electrophysiol. 2011;34:1013-1027.

[5] Tarakji KG, et al. Arrhythm Electrophysiol Rev. 2016;5:65-71.

[6] Wilkoff BL, et al. Circ Arrhythm Electrophysiol.2020;13:e008280.

[7] Eby E, et al. EP Europace. 2018;20:i106.

[8] Sohail MR, et al. Arch Intern Med. 2011;171:1821-1828.

[9] Lopatto, et al. Antibacterial Envelope Is Associated with Medical Cost Savings in Patients at High Risk for Cardiovascular Implantable Electronic Device Infection. Poster presented at ACC 2017 Scientific Sessions. Data on file with Medtronic plc.

[10] MDT30629333_1.0 GLP Drug Release Report

[11] MDT30284405 _1.0 TYRX III Envelope Performance

[12] Mittal S, et al. The World-wide Randomized Antibiotic Envelope Infection Prevention (WRAP-IT) trial: Long-term follow-up. Heart Rhythm. DOI: https://doi.org/10.1016/j.hrthm.2020.02.011

[13] Blomström-Lundqvist C, et al. European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections - endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). EP Europace. 2020 April;22(4) https://doi.org/10.1093/europace/euz246

[14] Keene D, et al. Europace. 2025;27:euaf252.

[15] Andrade J, et al. The Canadian Cardiovascular Society/Canadian Heart Rhythm Society Comprehensive Guidelines for the Selection, Implantation, and Management of Patients With Cardiac Implantable Electronic Devices, Canadian Journal of

Cardiology 42 (2026) 1-68.

* Data on file

† Based on animal study data through 24 weeks after implant; animal data may not be indicative of human clinical performance

‡ Based on human study data through 7 years after implant

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