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Medtronic reports strong 12-month real-world outcomes for IN.PACT™ AV drug-coated balloon†

Post-approval study's primary cohort shows 70.2% target lesion primary patency consistent with pivotal randomized controlled trial results in a challenging population[1]

Medtronic, a global leader in healthcare technology, today announced new real-world data from the IN.PACT™ AV Access Post-Approval Study, demonstrating strong safety and effectiveness outcomes for the IN.PACT™ AV drug-coated balloon (DCB) in the treatment of arteriovenous fistula (AVF) stenoses in patients with end-stage kidney disease on dialysis.

The 12-month outcomes were presented in a late-breaking session at the Society of Interventional Radiology (SIR) Annual Scientific Meeting in Toronto.‡ A study intended to expand real-world experience, the prospective, multicenter study evaluated the IN.PACT AV DCB across 17 U.S. clinical sites, with independent core laboratory and clinical events committee oversight.

Building on the robust safety and effectiveness demonstrated in the pivotal randomized controlled trial,[1-3] the post-approval study was intentionally designed as a confirmatory extension – further strengthening the evidence base by evaluating performance in a real-world AV access population with high comorbidity burden.

"Real-world evidence is essential to understanding how therapies perform outside of controlled trial settings," said Sanjay Misra, MD, professor of radiology at Mayo Clinic and principal investigator of the study. "The IN.PACT AV post-approval study provides important confirmation that drug-coated balloon treatment can deliver consistent, safe outcomes for AV fistula maintenance in everyday clinical practice in this complex dialysis population."

Key 12-month primary cohort highlights:

- Most treated AV fistulas were brachiocephalic (51.6%), followed by brachiobasilic (20.8%) and radiocephalic (20.8%)
- Most common lesion locations were the cephalic arch (25.8%) and venous outflow (25.2%)
- Lesions were de novo (59.5%) or non-stented restenotic (40.5%)
- Target lesion primary patency at 12 months was 70.2% and access circuit primary patency at 12 months was 52.6%. Target lesion and access circuit patency rates were aligned with the 12-month outcomes observed for the IN.PACT AV DCB in the pivotal RCT (65.3%, 55.1%, respectively) and better than PTA rates (46.3%, 35.0%,

respectively).[1]

- Fewer than one reintervention per patient was required through 12 months, which is below the average of 1.5 reintervention procedures per year.[4]
- The serious infection rate[§] at 12 months was 13.4%, below literature reports ranging from 19-23%.[5,6]

"These strong real-world data are an important contribution to the body of clinical data supporting the role of the IN.PACT AV DCB for AV fistula maintenance," said David Moeller, SVP and president of Peripheral Vascular Health, which is part of the Cardiovascular Portfolio at Medtronic. “We are proud to lead the industry in generating long term clinical evidence in this space and grateful to improve durable AV fistula patency for patients with ESKD requiring dialysis, reducing their need for reinterventions.”

Footnotes

† The device used in this study is commercialized under the name IN.PACT AV™ drug coated balloon (DCB). The IN.PACT AV DCB is not available for sale outside the United States, Canada, or Japan. Outside of the United States, Canada and Japan, the IN.PACT™ Admiral™ DCB is CE (Conformité Européenne) marked for the treatment of failing arteriovenous fistulas in patients with end-stage kidney disease undergoing dialysis.

‡ The presentation was given by Dr. Robert Lookstein on behalf of Dr. Sanjay Misra, Principal Investigator of the Post-Approval Study.

§ The primary endpoint was chosen by the FDA and used the MedDRA system organ class coding convention that’s common for FDA-mandated post-approval studies.

References

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4. Sorber et al. Ann Vasc Surg. 2021;76:142–151
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About the IN.PACT™ AV Access Post-Approval Study

The IN.PACT™ AV Access Post-Approval Study, a prospective, multicenter study, evaluated the IN.PACT AV DCB across 17 U.S. clinical sites on the Medtronic Product Surveillance Registry (PSR) platform, with independent core laboratory and clinical events committee oversight. Outcomes from the primary cohort were presented at the Society of Interventional Radiology (SIR) Annual Scientific Meeting on April 12, 2026.

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 on LinkedIn.

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