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IN.PACT™ AV drug-coated balloon first and only to show sustained and superior performance compared to PTA through 36 months

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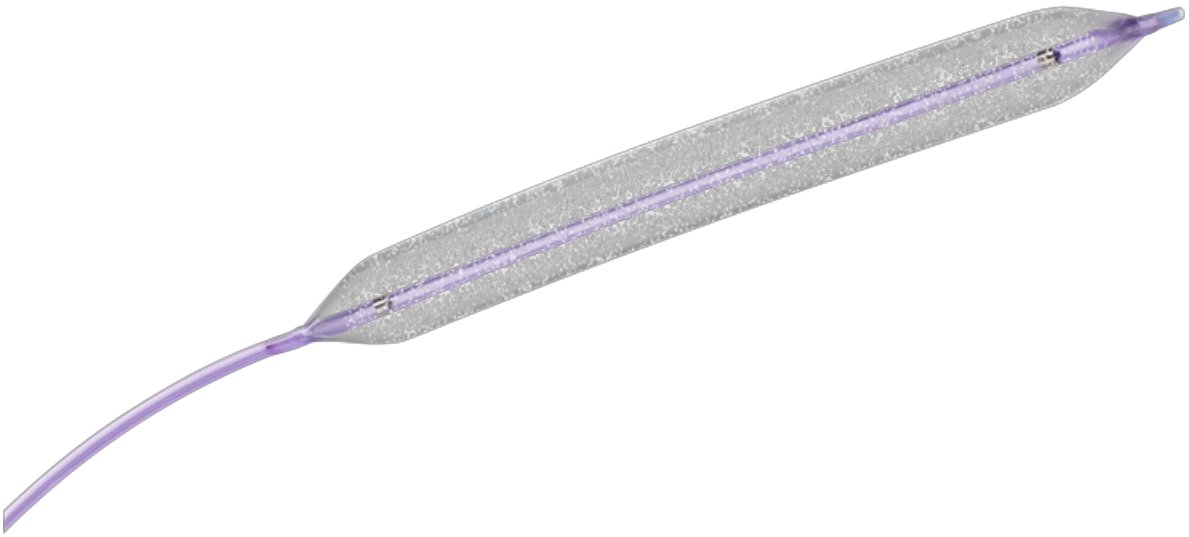
Medtronic, the global leader in medical technology, today announced new randomized controlled data demonstrating the sustained and superior performance of IN.PACT AV drug coated balloon (DCB) compared to percutaneous transluminal angioplasty (PTA) through 36 months, with no difference in mortality. The data was presented today as a podium first at the 2022 Charing Cross Symposium in London.



"The 36-month data from the IN.PACT AV Access study validates that treatment with the IN.PACT AV DCB can lead to less life disruption and fewer reinterventions for patients for an extended period of time, further reinforcing the results of earlier data milestones," said Dr. Andrew Holden, director of interventional radiology and associate

professor of radiology, Auckland University School of Medicine. “As the only pivotal DCB study in AV access to meet its primary effectiveness endpoint, the IN.PACT AV DCB has shown unrivalled long-term clinical benefits that support its use as standard of care for AV fistula maintenance in patients with end stage kidney disease.”

As vessel restenosis limits the ability to use AV fistulas effectively over time, patients often undergo up to three AV fistula maintenance procedures per year to restore function.[1] The need for frequent reinterventions can result in significant disruptions to critical hemodialysis care and increased costs to the healthcare system.

The IN.PACT AV Access study’s three-year data further demonstrates the ability for the IN.PACT AV DCB to extend time to reinterventions from the index procedure by maintaining AV access site patency, therefore maximizing a patient's uninterrupted access to lifesaving dialysis care. Over three years, the IN.PACT AV DCB group demonstrated a continued clinical benefit compared to the PTA control group. Key highlights for this data set include:

- The Kaplan-Meier estimated target lesion primary patency through 36 months was 43.1% in the IN.PACT AV DCB group compared to 28.6% in the PTA control group (log-rank p<0.001).
- The Kaplan-Meier estimated access circuit primary patency through 36 months was 26.4% in the IN.PACT AV DCB group compared to 16.6% in the PTA control group (log-rank p<0.001).
- The Kaplan-Meier estimated cumulative incidence of all-cause mortality post vital status update through 36 months was 26.6% in the IN.PACT AV DCB group and 30.8% in the PTA control group (log-rank p=0.709).

“Medtronic is committed to bring forward technologies that improve the lives of patients undergoing dialysis,” said David Moeller, president of the Peripheral Vascular Health business, which is part of the Cardiovascular Portfolio at Medtronic. “These results demonstrate IN.PACT AV DCB’s ability to significantly reduce the number of reinterventions, as well as the potential to reduce comprehensive care costs.”

About the IN.PACT AV Access Study

The IN.PACT AV Access study is a randomized controlled trial comparing the IN.PACT AV™ DCB to standard PTA in participants with de novo or non-stented restenotic AV fistula lesions. Primary endpoint results were presented at CIRSE in September 2019 and more recently published in *The New England Journal of Medicine* in August 2020.[2]

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, 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 90,000+ passionate people across 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 (NYSE:MDT), visit www.medtronic.com.

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

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[1] Lok CE, Huber TS, Lee T, et al. KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update. Am J Kidney Dis. Apr 2020;75(4 Suppl 2):S1-S164. doi:10.1053/j.ajkd.2019.12.001

[2] Lookstein et al. Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas. N Engl J Med 2020; 383:733-742.

https://news.medtronic.com/IN-PACT-TM-AV-drug-coated-balloon-first-and-only-to-show-sustained-and-superior-performance-compared-to-PTA-through-36-months