

JUL 21, 2023

Medtronic statement on the safety of paclitaxel coated devices to treat peripheral arterial disease

Newly released guidance affirms safety in use of paclitaxel-coated medical devices in treatment of PAD

On July 11, 2023, the U.S. Food and Drug Administration (FDA) [issued updated guidance to physicians](#) on the use of paclitaxel-coated devices for the treatment of peripheral arterial disease (PAD), following a 2018 meta-analysis published in the *Journal of the American Heart Association*¹ that found an increased risk of late deaths in patients treated with paclitaxel devices. The newly released guidance from the FDA stated: “Based on the FDA's review of the totality of the available data and analyses, we have determined that the data does not support an excess mortality risk for paclitaxel-coated devices.”



This updated guidance is critical to ensuring that physicians and their patients have access to these therapies, which have demonstrated safety and effectiveness across multiple studies.²⁻⁵

Medtronic plc issued the following statement related to the news:

“Medtronic would like to thank the FDA for their collaborative approach and thoughtful dedication in providing physicians, patients, and administrators with updated recommendations for the use of paclitaxel-coated medical devices,” said David Moeller, SVP and President of the Peripheral Vascular Health Operating Unit. “These updated recommendations follow the additional data from industry, independent investigators, and the clinical community over the past four years to further characterize the safety of paclitaxel-coated devices and their use in treating PAD.”

With this news, Medtronic is partnering closely with the FDA to make changes regarding the removal of additional paclitaxel-related safety warnings in the instructions for use (IFU) documents for its IN.PACT™ Admiral™, IN.PACT™ 018, and IN.PACT™ AV drug coated balloons (DCBs).

This updated guidance is critical to ensuring that physicians and their patients have access to these therapies, which have demonstrated safety and effectiveness across multiple studies.²⁻⁵

The Medtronic IN.PACT Admiral™ and IN.PACT 018 drug-coated balloons are designed to help restore and maintain blood flow in the upper leg by reopening narrowed or blocked arteries by delivering an anti-restenotic paclitaxel dose to the artery walls. The IN.PACT AV is an endovascular therapy for end-stage renal disease (ESRD) patients with a narrowed AV fistula, which delivers paclitaxel to the vessel to inhibit neointimal hyperplasia (NIH), the primary cause of AV fistula stenosis.

1. Katsanos et al. J Am Heart Assoc. 2018;7:e011245.
2. Laird JA, et al. Circ Cardiovasc Interv. 2019;12:e007702.
3. Zeller T, et al. EuroIntervention. 2022;18:e940-e948
4. Soga Y, et al. J Endovasc Ther. 2020;27:946-955.
5. Lookstein R, Haruguchi H, Ouriel K, et al. Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas. New England Journal of Medicine. 2020;383:733-742. doi:10.1056/NEJMoa1914617

Contact:

Krystin Hayward
Public Relations
+1-508-298-8246

<https://news.medtronic.com/2023-07-21-Medtronic-Statement-on-the-Safety-of-Paclitaxel-Coated-Devices-to-Treat-Peripheral-Arterial-Disease>