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Medtronic low-profile drug-coated balloon platform receives U.S. FDA approval to treat peripheral arterial disease

Built on the market-leading IN.PACT™ Admiral™ DCB technology, the IN.PACT™ 018 DCB is engineered to cross tight lesions and designed for better deliverability§

Medtronic today announced approval from the U.S. Food and Drug Administration (FDA) for the IN.PACT™ 018 Paclitaxel-Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter, a drug coated balloon (DCB), indicated for the interventional treatment of peripheral arterial disease (PAD) in the superficial femoral and popliteal arteries.

In the U.S. alone, 12 million people have PAD,[1] a buildup of plaque in the walls of arteries, which limits or stops the flow of oxygen-rich blood to the limbs – and half of these individuals remain untreated, raising the risk of amputation.[2]

“The IN.PACT 018 DCB will allow physicians to better address challenging cases, such as those with narrow lesions or complex anatomies,” said Prakash Krishnan, MD, FACC, associate professor of medicine, cardiology, and radiology at the Icahn School of Medicine at Mount Sinai, who also serves on a scientific advisory board for Medtronic. “The available long-term data* on its benefits gives physicians another effective treatment for PAD in complex anatomies."

The IN.PACT 018 DCB uses the same drug coating formulation and is built upon equivalent technology to the IN.PACT™ Admiral™ DCB, which is compatible with 0.035” guidewires. The IN.PACT 018 DCB is indicated for PTA of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm with vessel diameters of 4-7 mm. It is engineered to cross tight lesions, provide better deliverability§ and is compatible with 0.018" guidewires.

The IN.PACT 018 DCB will be the only commercially available DCB with a 200cm over-the-wire (OTW) catheter

length, providing physicians the option to treat via femoral or radial access. This is in addition to the 130 cm OTW catheter length.

"Medtronic is committed to offering physicians a suite of products to treat patients with PAD. Based on feedback from our clinical community and the need for an 018" guidewire compatible DCB, Medtronic is excited to bring this technology to market in the U.S," said David Moeller, president of the Peripheral Vascular Health Operating Unit at Medtronic. "The addition of the IN.PACT 018 DCB further reinforces Medtronic's commitment to being the market leader in drug-coated balloons."

With more than 3,500 patients enrolled in 21 clinical studies and 500,000+ patients treated worldwide†, the IN.PACT Admiral DCB has strong clinical outcomes, including: highest patency benefit through 3 years,[3‡†] having the lowest clinically driven target lesion revascularization (CD-TLR) through 5 years[3], and most publications for a DCB*. Given the design similarities, the IN.PACT Clinical Program can be considered supportive for the IN.PACT 018 DCB.

The safety and effectiveness of the IN.PACT Admiral DCB (0.035 inch guidewire compatible), as established in the clinical studies (performed primarily via femoral access) can be considered supportive for the IN.PACT 018 DCB. The IN.PACT 018 DCB has not been evaluated in a clinical study.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers a broad range of innovative medical technology for the interventional and surgical treatment of cardiovascular and peripheral vascular disease. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

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.

*References data from the IN.PACT Admiral Studies. The IN.PACT 018 has not been evaluated in a clinical study.

References

1 Goodney PP, Tarulli M, Faerber AE, Schanzer A, Zwolak RM. Fifteen-year trends in lower limb amputation, revascularization, and preventive measures among Medicare patients. JAMA Surg. January 2015;150(1):84-86.|
2 Goodney PP, Travis LL, Nallamothu BK, et al. Variation in the use of lower extremity vascular procedures for critical limb ischemia. Circ Cardiovasc Qual Outcomes. January 2012;5(1):94-102.

3 Laird JA, Schneider PA, Jaff MR, et al. Long-Term Clinical Effectiveness of a Drug-Coated Balloon for the

Treatment of Femoropopliteal Lesions. 5-year results from the IN.PACT SFA Trial. Circ Cardiovasc Interv. June 2019;12(6):e007702.

‡ Primary patency not assessed after three years.

†Based on sales units sold divided by units per procedure from approval through September 2019.

* Publications on file with Medtronic.

§ Data on file with Medtronic.

†† Compared to PTA

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https://news.medtronic.com/INPACT-018-DCB-technology