Medtronic News

Medtronic Launches Newest-Generation Drug Coated Balloon Catheter in Europe for Treatment of Coronary Artery Disease

Medtronic Prevail DCB™ Designed to Treat Complex Lesions with Superior Deliverability, Rapid Absorption of Paclitaxel

DUBLIN, July 26, 2021 /PRNewswire/ -- Medtronic plc (NYSE: MDT), the global leader in medical technology, today announced the launch of the Prevail™ drug coated balloon (DCB) Catheter in Europe following CE (*Conformité Européene*) mark. The newest coronary DCB on the market, the Prevail DCB is used during percutaneous coronary intervention (PCI) procedures to treat narrowed or blocked coronary arteries in patients with coronary artery disease (CAD).

During the catheter-based procedure, the balloon inflates within the artery, while the drug is delivered to the arterial tissue where it is absorbed. The Prevail DCB utilizes a rapid absorption drug – paclitaxel – to enable treatment of de novo lesions, small vessel disease, and in-stent restenosis (ISR). DCB angioplasty does not require a permanent implant and is often used in cases where the implantation of a drug-eluting stent (DES) is not desirable or is technically challenging.

"As physicians treat more patients with complex lesions, it is critical to have a drug coated balloon that is highly deliverable across a variety of vasculatures, and also utilizes a drug that absorbs quickly into the vessel," said Azeem Latib, M.D., lead principal investigator of the PREVAIL Study and section head of interventional cardiology and medical director of structural heart interventions at Montefiore Medical Center in New York City. "The excellent deliverability coupled with a strong safety profile that is backed by clinical evidence makes the Prevail DCB an ideal option for interventional cardiologists using DCB technology to treat their patients."

The Prevail DCB builds on the excellent safety and efficacy demonstrated in the previous generation IN.PACT™ Falcon DCB clinical program and was reaffirmed by the PREVAIL Study presented at the 2020 PCR e-Course conference. In the PREVAIL Study, the Prevail DCB showed exceptional performance in patients with complex lesions, including those with small vessels and those treated for in-stent restenosis, which occurs when a portion of a stented artery is blocked. The Prevail DCB showed favorable late loss (0.05 ± 0.44 mm) at 6 months and a strong safety profile that included no stent thrombosis, target vessel myocardial infarction (TVMI), or cardiac death and low clinically driven target lesion revascularization (6%) out to one year for all patients.[1]

"The launch of the Prevail DCB not only underscores our global leadership and commitment to interventional cardiologists around the world, but also highlights our strong focus on complex PCI," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. "We intentionally designed the Prevail DCB to address the challenges posed by smaller, more complex vessels by leveraging our coronary technologies to provide physicians the ability to navigate through tight lesions with greater confidence."

The Prevail DCB uses PowerTrac™, the same enhanced technology used in the delivery system for the Medtronic Resolute Onyx™ DES, to provide superior deliverability and two times more pushability than the previous IN.PACT Falcon technology enabling greater control for tortuous anatomies.[2] In addition, Prevail DCB has a low crossing profile for exceptional crossability.

The Prevail DCB is the latest addition to the Medtronic coronary portfolio, which also includes the market-leading Resolute Onyx DES in sizes ranging from 2.0-5.0 mm, the Euphora™ semicompliant balloon dilatation catheter, the DxTerity™ Diagnostic Angiography Catheter line, and the Telescope™ Guide Extension Catheter.

The Prevail DCB is available for use in Europe and is not approved in the U.S.

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

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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.

[1] Late Loss at 6 months was lower than the prespecified maximum acceptance rate of 0.5 mm. PREVAIL Study did not have powered endpoints.

[2] Bench testing vs. IN.PACT Falcon 3.00 mm x 20 mm balloon, 2020. Deliverability defined as pushability. Bench test data may not be indicative of clinical performance.

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