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Medtronic launches latest generation drug-eluting coronary stent system following CE Mark approval

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Medtronic announced today that it has launched its newest drug-eluting coronary stent, the Onyx Frontier™ drug-eluting stent (DES), following recent CE Mark approval. The Onyx Frontier DES offers an innovative delivery system and builds upon the acute performance and clinical data from the Resolute Onyx™ drug-eluting stent. The DES leverages the same best-in-class stent platform as Resolute Onyx™ DES, with an enhanced delivery system[1] designed to improve deliverability and increase acute performance in the most challenging cases.[2]

Onyx Frontier DES' meaningful design changes include an innovative dual-layer balloon, lower crossing profile,[3]

and increased catheter flexibility leading to a 16% improvement in deliverability vs. the previous generation Resolute Onyx DES without compromising on radial strength.[2] In addition to the delivery system enhancements, Onyx Frontier offers a broad size matrix to treat patients ranging from 2.0mm to 5.0mm diameters and its 4.50-5.00 mm sizes[1] can be expanded to 6.00 mm - specifically designed to support extra-large vessels including the left main. Onyx Frontier inherits the same clinical data and indications of Resolute Onyx, including approval for bifurcation lesions, left main PCI, and one month of dual antiplatelet therapy (DAPT) in high bleeding risk patients.[4]

"The Onyx Frontier DES launch demonstrates our commitment to interventional cardiologists by providing best-in-class products," said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business unit, which is part of the Cardiovascular Portfolio at Medtronic. "Following our launch in the US, we're thrilled to provide hospitals across western Europe and the globe with the Onyx Frontier DES, which has been thoughtfully designed with physicians' needs in mind. This launch furthers Medtronic's goal of engineering the extraordinary, and we look forward to continuing to pursue innovation each day."

The Onyx Frontier DES is used for the treatment of patients with coronary artery disease (CAD), which is caused by plaque buildup on the inside of the coronary arteries. These plaque deposits can narrow or clog the inside of the arteries, which decreases the supply of blood and oxygen to the heart. To help to restore blood flow, a physician may use a stent (a flexible metal scaffolding) that is delivered during a minimally invasive procedure to prop open the artery. A drug-eluting stent is the most common type of stent used to treat a blockage of the heart arteries.[5]

The Onyx Frontier DES received FDA approval in the United States in May and recently received CE Mark in Europe.

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[1] Stent delivery system updates were implemented on the 2.0–4.0 mm Onyx Frontier DES diameters.

[2] Based on bench test data on file at Medtronic (method D00117002). May not be indicative of clinical performance. N=7 of each DES tested (3.0mm): Onyx Frontier DES, Resolute Onyx DES, Orsiro Mission DES, Xience Sierra™ DES, Xience Skypoint DES, Synergy DES, Synergy™ XD DES, Ultimaster™ Tansei™ DES.

[3] Bench test data on file at Medtronic. May not be indicative of clinical results. N=5 of each DES tested: Onyx Frontier DES, Orsiro Mission DES, Resolute Onyx DES, Xience Skypoint DES, Synergy DES, Ultimaster™ Tansei™ DES.

[4] Onyx Frontier IFU

[5] Mayo Clinic Staff. Drug-Eluting Stents: Do they increase heart attack risk? Mayoclinic.org

approval