

Medtronic Announces FDA Clearance and U.S. Launch of the Euphora(TM) Semicompliant Coronary Balloon

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Company to Launch "Cath Lab Connect" Informational Portal and Community Website for Cath Lab Professionals

DUBLIN - May 5, 2015 - Medtronic plc (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) 510(k) clearance and U.S. launch of the Euphora(TM) Semicompliant Balloon Dilatation Catheter, a pre-dilatation therapy used during a stent implantation to reopen a narrowed coronary artery caused by plaque buildup. The first patient case with the Euphora Semicompliant Balloon Catheter was recently performed by James T. DeVries, MD, FACC, FSCAI, director of Endovascular Intervention and associate director of the Cardiac Catheterization Lab at Dartmouth-Hitchcock Medical Center in Lebanon, NH.

"We at Dartmouth-Hitchcock Medical Center are pleased to have been chosen as the U.S. launch site for the Medtronic Euphora balloon," said DeVries. "This continued access to new technology is essential to help our patients in the ongoing battle against coronary artery disease."

Pre-dilatation with a semicompliant balloon helps physicians determine lesion characteristics, stent selection and facilitates stent access to the lesions - a crucial step for patients with challenging lesions.

The Euphora Semicompliant Balloon Catheter features several new design advancements including:

- Delivery system with PowerTrac(TM) technology to provide superior deliverability (compared to major competitors)[\[i\]](#) through challenging lesions. This enhanced pushability comes from a re-designed shaft technology first introduced with the Medtronic NC Euphora(TM) Noncompliant Balloon Dilatation Catheter in September 2014.
- Ultra-slim balloon material, a tapered proprietary inner shaft design and an optimized mini-wrap to reduce the wall thickness of the balloon and contribute to the extremely low crossing profile.[i](#)
- Improved insertion and retraction force to enhance navigation to lesion sites when using the Kissing Balloon Technique.[\[ii\]](#)
- Packaging enhancements for quicker and easier identification by cath lab staff due to new product labeling and EZ Pull Corners, as well as reduced box size for optimal shelf storage.

"With the addition of the Euphora semicompliant balloon we are able to provide physicians with one of the most robust and best-in-class interventional product portfolios available on the market," said Jason Weidman, vice president and general manager of the Coronary & Renal Denervation business in Medtronic's Coronary & Structural Heart division. "This launch delivers on our strategy of introducing a breadth of premium products, and exemplifies our continued commitment to deliver innovative and differentiated technologies that address the needs of cath lab professionals around the world."

The Euphora semicompliant balloon received CE (Conformité Européene) mark in December 2014, and expands Medtronic's interventional portfolio of medical devices across Coronary, Renal Denervation and TAVR, and is one of 12 new product introductions planned over the next two years.

Medtronic to Launch "Cath Lab Connect"

In an effort to increase education and peer-to-peer engagement among cath lab professionals, Medtronic today announced it will launch "Cath Lab Connect," an informational portal and community website dedicated to cath lab nurses and technicians. The website, which will go live this month, will feature educational resources for cath lab professionals, information about upcoming events and conferences, industry news, as well as a forum for members to connect and

discuss relevant topics or share best practices. To learn more, visit: www.cathlabconnect.com.

In collaboration with leading clinicians, researchers and scientists, 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 worldwide.

ABOUT MEDTRONIC

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

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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[ii](#) Competitive Bench testing vs. Trek, Emerge(TM) and Sprinter(TM) Legend(TM) balloons. 2.50-mm x 15-mm balloons tested. Bench test data may not be indicative of clinical performance. .

[iii](#) Competitive Bench testing vs. Sprinter(TM) Legend(TM) and Emerge. Based on 6 F KBT testing. 2.50-mm x 15-mm balloons tested. Bench test data may not be indicative of clinical performance. 3.75-mm and 4.00-mm Euphora rapid exchange balloon models are not suitable for simultaneous use within a 2-mm (6 F/MGCID 1.8-mm [0.070"]) guide catheter.

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