Medtronic Launches New Angioplasty Catheter for Below-the-Knee Arteries

The Associated Press

Newly Approved Medical Device Expands Company's Growing Portfolio of Products Used to Treat Peripheral Artery Disease

MINNEAPOLIS -- October 5, 2012 -- With a focus on developing lesion specific solutions for peripheral artery disease, Medtronic, Inc. (NYSE: MDT) today announced the U.S. and international launches of the Amphirion Plus Percutaneous Transluminal Angioplasty (PTA) Catheter for the interventional treatment of atherosclerotically narrowed or occluded leg arteries below the knee.

The Amphirion Plus PTA Catheter expands Medtronic's product portfolio of medical devices used to treat peripheral artery disease. With an over-the-wire diameter of 0.014 inches, it joins the Amphirion Deep PTA Balloon Catheter, which targets lesions in arteries below the ankle. Together, the Amphirion Plus and Amphirion Deep PTA Balloon Catheters represent a comprehensive solution for below-the-knee interventions.

Physicians in Europe and the United States have started to use the new device, which recently received the CE (Conformité Européenne) mark and 510(k) clearance by the U.S. Food and Drug Administration (FDA).

"The Amphirion Plus Balloon features outstanding pushability and crossability characteristics and exceptional inflation-deflation performance," said Nezar Falluji, M.D., an interventional cardiologist at St. Joseph Cardiology Associates in Lexington, Ky., who performed the first case with the new device worldwide. "Its innovative design has made the Amphirion family of PTA balloons excellent tools in the management of critical limb ischemia and below-the-knee intervention."

Another early user of the new device, Marco G. Manzi, M.D., chief of the interventional radiology unit at Policlinico Abano Terme in Vincenza, Italy, added: "With the Amphirion Plus Balloon, even the most challenging calcified below-the-knee arteries can become more accessible."

Distinguishing features of the Amphirion Plus PTA Balloon Catheter include the device's wide inflation pressure range, which reaches 20 atmospheres (rated burst pressure) for all sizes -- from 2.0 mm to 4.0 mm in diameter and through 120 mm in length. In addition to the versatile working range and size offering, the new device's fast inflation-deflation provides an efficient angioplasty solution for "everyday" below-the-knee cases.

With risk factors including a history of smoking, poor diet and lack of exercise (similar to those for other forms cardiovascular disease), peripheral artery disease affects more than 100 million people worldwide, including an estimated 10 million people in the United States, according to the Vascular Disease Foundation. Its clinical impact on health varies by anatomical location.

Peripheral artery disease below the knee often causes critical limb ischemia, in which poor blood circulation in the calf, ankle, foot and toes can lead to ulcerated sores, amputation and premature death. Epidemiological research indicates that 50 percent of patients who undergo amputation due to peripheral artery disease die within five years.

Medtronic continues Invatec's focus on developing innovative lesion specific solutions for peripheral artery disease. For peripheral artery disease below the knee, the Amphirion Plus and Amphirion Deep PTA Balloon Catheters epitomize this focus, with the former targeting lesions between the knee and the ankle (where the blood vessels tend to be relatively straight and very often include calcifications), and the latter targeting lesions below the ankle (where the blood vessels tend to be more tortuous and smaller in diameter). The differences in design and features between the two devices reflect the distinct anatomical characteristics of the vessels that each one targets.

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, Inc. (www.medtronic.com), headquartered in Minneapolis, 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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Contacts: Joe McGrath Public Relations +1-707-591-7367 Jeff Warren Investor Relations +1-763-505-2696

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HUG#1646266

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