Medtronic Approved to Update Resolute Integrity Stent’s CE Mark Labeling on Dual Antiplatelet Therapy

Medtronic

Interruption or Discontinuation After One Month Following Implant Procedure Posed ‘Low and No Increased Risk’ of Stent Thrombosis at One Year in Clinical Studies

Of relevance to the clinical practice of interventional cardiology, Medtronic, Inc. (NYSE: MDT) announced today that it has received regulatory approval to update the CE (Conformité Européenne) mark labeling for the Resolute Integrity drug-eluting stent with new information on one month of dual antiplatelet therapy (DAPT), the shortest minimum duration referenced on the label for any device of its kind.

The updated labeling states: “One year data from the RESOLUTE Clinical Program indicates low stent thrombosis rates for those who interrupted or discontinued DAPT any time after one month. While physicians should continue to adhere to current ESC or ACC/AHA/SCAI guidelines for PCI, patients who interrupt or discontinue DAPT medication one month or more after stent implantation are considered at low risk and showed no increased risk for stent thrombosis.”

This labeling update applies to product distributed in countries that accept the CE mark. It does not apply to product distributed beyond these countries, including the United States.

Dual antiplatelet therapy –– the combination of acetylsalicylic acid (ASA) and a thienopyridine like clopidogrel –– reduces the risk of stent thrombosis, the formation of a blood clot inside the stented arterial segment; but long-term use of antiplatelet agents increases the risk of bleeding complications. Balancing these risks remains a challenge.

Dual antiplatelet therapy guidelines for patients who receive a drug-eluting stent differ by geographic region, but generally recommend daily compliance for six to 12 months.

For a variety of reasons, however, some patients interrupt or discontinue their DAPT early, which raises safety concerns.

“An independent analysis of data on nearly 5,000 patients from the global RESOLUTE Clinical Program who received a Resolute drug-eluting stent shows that the greatest risk of stent thrombosis due to DAPT interruption is within the first 30 days of the implant procedure,” explained Prof. Sigmund Silber, M.D., director of the Heart Centre at the Isar in Munich, Germany. “It also shows that DAPT interruption after 30 days is associated with a low risk of stent thrombosis and no increased risk

for cardiac death or target vessel myocardial infarction."

Prof. Silber, a member of the ESC 2010 guidelines committee for myocardial revascularization, presented this analysis at TCT 2012, which took place in Miami in October. Ajay Kirtane, M.D., an interventional cardiologist at NewYork-Presbyterian Hospital/Columbia University Medical Center, plans to present additional analysis during ACC.13, which is scheduled to take place in San Francisco from March 9–11.

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 [1]), headquartered in Minneapolis, is the global leader in medical technology –– alleviating pain, restoring health and extending life for millions of people around the world.

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