The Onyx ONE Month DAPT Program studied the most complex high bleeding risk (HBR) patients — including those at the highest thrombotic risk — to provide data reflective of real-world clinical practice and help better inform short DAPT decisions.

Unmatched patient complexity allows for high-risk subgroup subanalyses, demonstrating low event rates in complex HBR patients and further supporting the use of Resolute Onyx DES in these patients on 1-month DAPT.
The safety and effectiveness of the Resolute Onyx™ stent have not yet been established in the following patient populations: Patients with target lesions that were treated with prior brachytherapy or the use of brachytherapy to treat in-stent restenosis of a Resolute Onyx™ stent; Women who are pregnant or lactating; Men intending to father children; Pediatric patients; Patients with coronary artery reference vessel diameters of < 2.0 mm or > 5.0 mm; Patients with evidence of an acute ST-elevation MI within 72 hours of intended stent implantation; Patients with vessel thrombus at the lesion site; Patients with lesions located in a saphenous vein graft, in the left main coronary artery, ostial lesions, or bifurcation lesions; Patients with diffuse disease or poor flow distal to identified lesions; Patients with three-vessel disease.

The safety and effectiveness of the Resolute Onyx™ stent have not yet been established in the coronary, carotid, or peripheral vasculature.

Oral Antiplatelet Therapy

Dual antiplatelet therapy (DAPT) using a combination treatment of aspirin with a P2Y12 platelet inhibitor after percutaneous coronary intervention (PCI), reduces the risk of stent thrombosis and ischemic cardiac events, but increases the risk of bleeding complications. The optimal duration of DAPT (specifically a P2Y12 platelet inhibitor in addition to aspirin) following DES implantation is unknown, and DES thrombosis may still occur despite continued therapy. It is very important that the patient is compliant with the post-procedural antiplatelet recommendations.

Per 2016 ACC/AHA guidelines, a daily aspirin dose of 81 mg is recommended indefinitely after PCI. A P2Y12 platelet inhibitor should be given daily for at least 6 months in stable ischemic heart disease patients and for at least 12 months in patients with acute coronary syndrome (ACS). Consistent with the DAPT Study,1 and the 2016 ACC/AHA guidelines, longer duration of DAPT may be considered in patients at higher ischemic risk with lower bleeding risk. The Academic Research Consortium (ARC) proposed a standardized definition for identifying patients at high bleeding risk (HBB)2. Additionally, evidence from a dedicated study of Resolute Onyx in HBB patients and those who are unable to tolerate long-term DAPT after PCI has been published.3

Based on the Onyx ONE Clear Analysis, Resolute Onyx is safe and effective in patients at high risk of bleeding treated with one month of DAPT. The patients evaluated in the Onyx ONE Clear Analysis met the pre-defined criteria for high bleeding risk and were those whom in the opinion of their physician, the potential benefit of 1-Month DAPT outweighed the potential risk. In addition to at least one HBB risk factor, enrollment included 48.6% ACS patients (unstable angina 22.8%, Non-ST 21.7% and STEMI 4.2%).

Decisions about duration of DAPT are best made on an individual basis and should integrate clinical judgment, assessment of the benefit/risk ratio, and patient preferences. Premature discontinuation or interruption of prescribed antiplatelet medication could result in a higher risk of stent thrombosis, MI, or death. Before PCI, if premature discontinuation of antiplatelet therapy is anticipated, physicians should carefully evaluate with the patient whether a DES and its associated recommended DAPT regimen is the appropriate PCI choice. Following PCI, if elective noncardiac surgery requiring suspension of antiplatelet therapy is considered, the risks and benefits of the procedure should be weighed against the possible risk associated with interruption of antiplatelet therapy. Patients who require premature DAPT discontinuation should be carefully monitored for cardiac events. At the discretion of the patient’s treating physician(s), the antiplatelet therapy should be restarted as soon as possible.

Potential Adverse Events

Other risks associated with using this device are those associated with percutaneous coronary diagnostic (including angiography and IVUS) and treatment procedures. These risks (in alphabetical order) may include but are not limited to: Abrupt vessel closure; Access site; Blood clot; Cardiac tamponade; Coronary artery occlusion, perforation, rupture, or dissection; Coronary artery spasm; Death; Embolism (air, tissue, device, or thrombus); Emergency surgery; Empyema; Hemorrhage requiring transfusion; Hypertension; Hypotension; Incomplete stent apposition; Infection; MI; Pericarditis; Peripheral ischemia; Peripheral nerve injury; Renal failure; Restenosis of the stented artery; Shock; Shockwave; Thrombosis; Transient ischemic attack; Vascular occlusion or partial occlusion; Wound infection. Please refer to the following website: http://content.onlinejacc.org/article.aspx?doi=10.1016/j.jacc.2015.01.007.

Adverse Events Related to Zotarolimus

Patients’ exposure to zotarolimus is directly related to the total amount of stent length implanted. The actual adverse effects and complications that may be associated with the use of zotarolimus are not fully known. The adverse events that have been associated with this intravascular injection of zotarolimus in humans include but are not limited to: Anemia, Diarrhea, Dopamine-like effects, Electrolyte disturbances, Fever, Gastrointestinal bleeding, Gastrointestinal perforation, Hypersensitivity, Hypotension, Pulmonary edema, Rash, Respiratory failure, Septic shock, Shockwave injury, Stroke, Thrombosis, Urticaria, Vascular occlusion, Wound infection. Please refer to the following websites listed.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

For further information, please call and/or consult Medtronic at the toll-free numbers or websites listed:


