ADVANCING 1-MONTH DAPT EVIDENCE

Onyx ONE Clear Analysis

Evaluating Resolute Onyx™ DES in ~1,500 highly complex high bleeding risk (HBR) patients with 1-month DAPT, including ~600 patients in the U.S. and Japan.

RESOLUTE ONYX DES BEAT PERFORMANCE GOAL

p < 0.001
n = 1,491/1,506

Event Rates (%)

1-12 months

- Primary Endpoint Cardiac Death
- Cardiac Death
- MI
- TLR Def/Prob ST

PERFORMANCE GOAL*

9.7

REAL-WORLD PATIENT POPULATION

NO VESSEL OR LESION LIMITATIONS

- 79% B2/C LESIONS
- 37 mm AVERAGE STENTED LENGTH
- 50% MODERATE TO SEVERE CALCIFIED LESIONS

REAL-WORLD PATIENT POPULATION

- 74 AVERAGE AGE
- 39% DIABETES
- 36% PRIOR REVASC

BROADEST HBR INCLUSION CRITERIA

- 1.6 HBR CRITERIA PER PATIENT
- 44% PATIENTS HAVING TWO OR MORE HBR CRITERIA

NO VESSEL OR LESION LIMITATIONS

REAL-WORLD PATIENT POPULATION

BROADEST HBR INCLUSION CRITERIA

ONYX ONE GLOBAL STUDY

First prospective, randomized, 1-month DAPT trial comparing a DES to a DES in HBR patients.

ONYX ONE CLEAR STUDY

First study in the U.S. and Japan evaluating 1-month DAPT duration in HBR patients with a current DES.

ONYX ONE MONTH DAPT PROGRAM

The most robust clinical program studying 2,700 highly complex HBR patients with 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 restenoses 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 been established in the cerebral, 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, 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 (HBR) [4]. Additionally, evidence from a dedicated study of Resolute Onyx in HBR patients and those who are unable to tolerate long-term DAPT after PCI has been published [5]. 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 benefits of 1-Month DAPT outweighed the potential risk. In addition to at least one HBR risk factor, enrollment included 48.6% ACS patients (unstable angina 22.8%, Non-STEMI 21.7% and STEM I 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 preference. 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 pain, hematoma, or hemorrhage • Allergic reaction (to contrast, antiplatelet therapy, stent material, or drug and polymer coating) • Anemia, pseudoanemia, or anorexigenic fistula (AVF) • Arhythmias, including ventricular fibrillation • Balloon rupture • Bleeding • Cardiac tamponade • Coronary artery occlusion, perforation, rupture, or dissection • Coronary artery spasm • Death • Embolism (acutetissue, device, or thrombus) • Emergency surgery • peripheral vascular or coronary bypass • Failure to deliver the stent • Hemorrhage requiring transfusion • Hypotension/hypertension • Incomplete stent apposition • Infarction or fever • MI or Percarditis • Peripheral ischemia/peripheral nerve injury • Renal failure • Restenosis of the stented artery • Shock/pulmonary edema • Stable or unstable angina • Stent deformation, collapse, or fracture • Stent migration or embolization • Stent misplacement • Stroke/transient ischemic attack • Thrombosis (acute, subacute, or late)

Adverse Events Related to Zotarolimus Patients’ exposure to zotarolimus is directly related to the total amount of stent length implanted. The actual side effects/ complications that may be associated with use of zotarolimus are not fully known. The adverse events that have been associated with the intravenous injection of zotarolimus in humans include but are not limited to: • Anemia • Diarrhea • Dry skin • Headache • Hematoma • Infarction • Injection site reaction • Pain (abdominal, arthralgia, injection site) • Rash

Please reference appropriate product instructions for Use for more information on warnings, cautions, precautions, and potential adverse events.

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.


