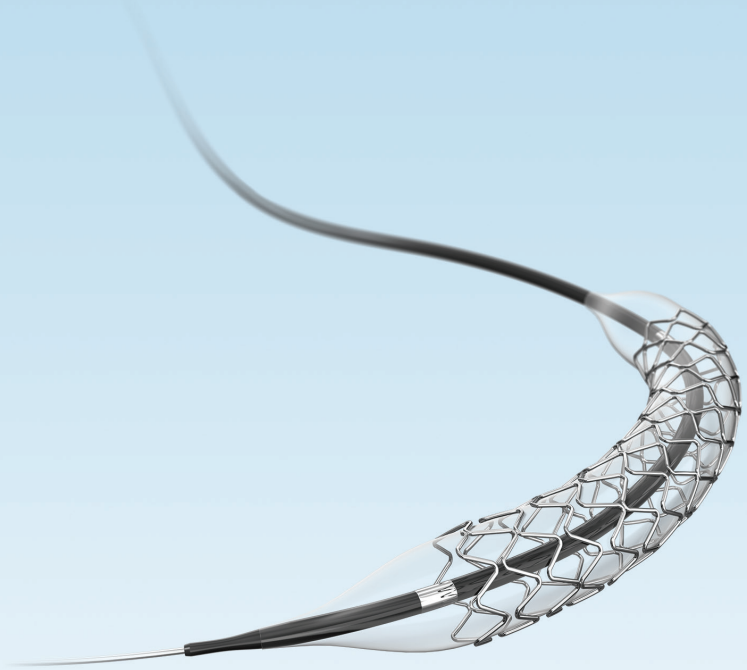
Medtronic

Onyx ONE Global Study

Evaluating Highly Complex High Bleeding Risk Patients with 1-month DAPT – DES vs. DES.[1]



Resolute Onyx™ DES

Resolute Onyx™ DES Non-inferior to BioFreedom™* DCS†

Superior Acute Performance with Resolute Onyx DES**

Highly Complex Patient Population

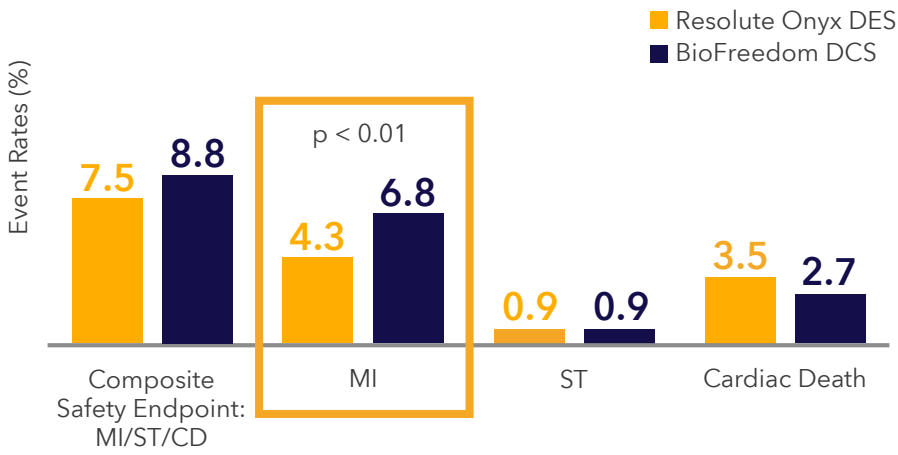
39% Diabetes

80% B2/C Lesions

46% Moderate/Severe Calcified Lesions

Low event rates for Resolute Onyx DES in a highly complex patient population, including significantly lower MI vs. BioFreedom DCS.††

Landmark Analysis after DAPT Discontinuation†††



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*Third-party brands are trademarks of their respective owners.
†At one year.
**Acute performance parameters were not powered or adjusted for multiplicity.
††Post-hoc analyses were not powered.
***From 1 month to 1 year.
[1] Windecker S, Latib A, Kedhi E, et al. Polymer-based or Polymer-free Stents in Patients at High Bleeding Risk. N Engl J Med. March 26, 2020;382(13):1208-1218.

Resolute Onyx™ Zotarolimus-eluting Coronary Stent System

Indications

The Resolute Onyx zotarolimus-eluting coronary stent system is indicated for improving coronary luminal diameter in one or two vessels and reducing restenosis in patients, including those with high bleeding risk or who are unable to tolerate long-term DAPT with symptomatic ischemic heart disease in de novo coronary artery lesions in native coronary arteries with a reference vessel diameter of 2.0 mm to 5.0 mm and a lesion length of ≤35 mm.

Contraindications

The Resolute Onyx™ Zotarolimus-eluting Coronary Stent System is contraindicated for use in: • Patients with a known hypersensitivity or allergies to aspirin, heparin, bivalirudin, clopidogrel, prasugrel, ticagrelor, ticlopidine, drugs such as zotarolimus, tacrolimus, sirolimus, everolimus, or similar drugs or any other analogue or derivative • Patients with a known hypersensitivity to the cobalt-based alloy (cobalt, nickel, chromium, and molybdenum) or platinum-iridium alloy • Patients with a known hypersensitivity to the BioLinx™ polymer or its individual components

Coronary artery stenting is contraindicated for use in: • Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated • Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system

Warnings

• Please ensure that the inner package has not been opened or damaged as this would indicate the sterile barrier has been breached. • The use of this product carries the same risks associated with coronary artery stent implantation procedures, which include subacute and late vessel thrombosis, vascular complications, and/or bleeding events. • This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

Precautions

• Only physicians who have received adequate training should perform implantation of the stent. • Subsequent stent restenosis or occlusion may require repeat catheter-based treatments (including balloon dilatation) of the arterial segment containing the stent. The long-term outcome following repeat catheter-based treatments of previously implanted stents is not well characterized. • The risks and benefits of the stent implantation should be assessed for patients with a history of severe reaction to contrast agents. • Do not expose or wipe the product with organic solvents such as alcohol. • The use of a drug-eluting stent (DES) outside of the labeled indications, including use in patients with more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death. • Care should be taken to control the position of the guide catheter tip during stent delivery, stent deployment, and balloon withdrawal. Before withdrawing the stent delivery system, confirm complete balloon deflation using fluoroscopy to avoid arterial damage caused by guiding catheter movement into the vessel. • Stent thrombosis is a low-frequency event that is frequently associated with myocardial infarction (MI) or death. Data from the RESOLUTE clinical trials have been prospectively evaluated and adjudicated using the definition developed by the Academic Research Consortium (ARC).

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 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,[1] 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,[2] 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).[3] 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.[4]

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 HBR risk factor, enrollment included 48.6% ACS patients (unstable angina 22.8%, Non-STEMI 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 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)
• Aneurysm, pseudoaneurysm, or arteriovenous fistula (AVF)
• Arrhythmias, including ventricular fibrillation • Balloon rupture • Bleeding • Cardiac tamponade • Coronary artery occlusion, perforation, rupture, or dissection • Coronary artery spasm • Death • Embolism (air, tissue, device, or thrombus) • Emergency surgery: peripheral vascular or coronary bypass • Failure to deliver the stent
• Hemorrhage requiring transfusion • Hypotension/hypertension
• Incomplete stent apposition • Infection or fever • MI • Pericarditis
• 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 the 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 • Hematuria
• Infection • Injection site reaction • Pain (abdominal, arthralgia, injection site) • Rash

Please reference appropriate product Instructions for Use for more information regarding indications, warnings, precautions, and potential adverse events.

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

[1] Levine GN, et al. 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients With Coronary Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2016; doi:10.1016/j.jacc.2016.03.513. For full text, please refer to the following website: http://content.onlinejacc.org/article.aspx?doi=10.1016/j.jacc.2016.03.513
[2] Mauri L, et al. Twelve or 30 months of dual antiplatelet therapy after drug-eluting stents. N Engl J Med. 2014; 371:2155–66.
[3] Urban P, Mehran R, Colleran R, et al. Defining High Bleeding Risk in Patients Undergoing Percutaneous Coronary Intervention. Circulation. 2019;140:240–6.
[4] Windecker S, Latib A, Kedhi E, et al. Polymer-based or Polymer-free Stents in Patients at High Bleeding Risk. N Engl J Med. 2020:10.1056/NEJMoa1910021.

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