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.

COMORBIDITIES¹
Onyx ONE Clear Study data
- Diabetes: 40%
- Acute Coronary Syndrome (ACS): 49%
- Atrial Fibrillation (AF): 36%
- Previous Myocardial Infarction: 26%
- Prior Revascularization: 36%
- Hypertension: 84%

LESION COMPLEXITIES¹
Onyx ONE Clear Study data
- B2/C lesions: 79%
- Mod/severe calcification: 50%
- Average stented length: 37 mm
- Stented length in 225 patients²: > 60 mm

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.
Resolute Onyx™ Zotarolimus-eluting Coronary Stent System

Indications

The Resolute Onyx™ Zotarolimus-eluting Coronary Stent System is indicated for improving coronary luminal diameters in patients, including those with diabetes mellitus or high bleeding risk, with symptomatic ischemic heart disease due to de novo lesions of length ≤ 35 mm in native coronary arteries with reference- vessel diameters of 2.0 mm to 5.0 mm. In addition, the Resolute Onyx™ Zotarolimus-eluting Coronary Stent System is indicated for treating de novo chronic total occlusions.

Contraindications

The Resolute Onyx™ Zotarolimus-eluting Coronary Stent System is contraindicated for use in: • Patients with a known hypersensitivity or allergies to aspirin, heparin, bisaludin, 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™. • Patients in whom antiplatelet and/or anti-coagulation therapy is contraindicated. • Patients who are judgement 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 dissection, stent 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 use in patients who are not likely to comply with the recommended antiplatelet therapy, stent material, or drug and polymer coating. • Antibiotics, 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. • Hypotension or coronary or bypass graft failure. • Failure to deliver the stent. • Hemorrhage requiring transfusion. • Hypertension. • Incomplete stent apposition. • Infection. • Mi. • Pericarditis. • Peripheral ischemia. • Peripheral nerve injury. • Renal failure. • Restenosis of the stented artery. • Shock (shock-like) syncope. • Stable or unstable angina. • Silent deformation, collapse, or fracture. • Stent migration or embolization. • Stent malposition. • Strokes/syncope. • Transient ischemic attack. • Thrombosis (acute, subacute, or late).

Potential Adverse Events


Adverse Events Related to Zotarolimus

Patients’ exposure to zotarolimus is directly related to the total amount of stent length implanted. The actual adverse effects or complications that may be associated with the use of zotarolimus are not fully known. The adverse events that have been associated with this intravenous injection of zotarolimus in humans include, but are not limited to: Anemia. Diarrhea. Dry skin. Headache. Hematoma. Infection. Injection site reaction. Pain. Abdominal. Antiplatelet, secondary. Rash. Please refer to the respective product instructions for use for more information regarding indications, warnings, precautions, and contraindications. 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.

Medtronic
Tel: 707.525.0111
LifeLine Customer Support Tel: 877.526.7890
Product Services Tel: 888.283.7868

medtronic.com

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