Medtronic is committed to developing additional evidence to help guide dual antiplatelet therapy treatment decisions, which are best made on an individual basis and should integrate current guidelines, clinical judgement, assessment of the benefit/risk ratio, and patient preference. Resolute Onyx™ DES is not currently indicated for high bleeding risk patients on 1-month DAPT.

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

**ONYX ONE GLOBAL STUDY**

Evaluating Highly Complex High Bleeding Risk Patients with 1-month DAPT† — DES vs. DES.¹

**HIGHLY COMPLEX PATIENT POPULATION**

<table>
<thead>
<tr>
<th></th>
<th>DIABETES</th>
<th>B2/C LESIONS</th>
<th>MODERATE/SEVERE CALCIFIED LESIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolute Onyx™ DES</td>
<td>39%</td>
<td>80%</td>
<td>46%</td>
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<tr>
<td>Non-inferior to</td>
<td></td>
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<tr>
<td>BioFreedom™ DCS</td>
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<tr>
<td>Superior Acute</td>
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<td>Performance with</td>
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<tr>
<td>Resolute Onyx DES</td>
<td></td>
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</tbody>
</table>

**LANDMARK ANALYSIS AFTER DAPT DISCONTINUATION””**

- **Composite Safety Endpoint: MI/ST/CD**
  - Resolute Onyx DES: 7.5%
  - BioFreedom DCS: 8.8%
  - **p < 0.01**

- **MI**
  - Resolute Onyx DES: 4.3%
  - BioFreedom DCS: 6.8%
  - **p < 0.01**

- **ST**
  - Resolute Onyx DES: 0.9%
  - BioFreedom DCS: 0.9%

- **Cardiac Death**
  - Resolute Onyx DES: 3.5%
  - BioFreedom DCS: 2.7%
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, with symptomatic ischemic heart disease due to de novo lesions of length ≤ 5.0 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 to cobalt-based alloys, nickel, iridium, or any other alloy-based or derivative; Patients with a known hypersensitivity to the 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 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 percutaneous coronary intervention 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 dilation) 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 store this 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; Non-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 acute ST-segment 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 vascular bed.

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; Acute reaction (to contrast, antiplatelet therapy, stent material, or drug and polymer coating); Anaphylaxis; pseudoaneurysm, or artifactual aneurysm (AFA); Atrial fibrillation; 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; Hypertension; Hypotension; Incomplete stent apposition; Infection or fever; MI; Percutaneous coronary intervention injury or disease; 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; Infections; 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.

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

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Medtronic

LifeLine Customer Support Tel: 888.283.7689
Fax: 800.838.3103

medtronic.com

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