1-MONTH DAPT EVIDENCE IN COMPLEX PATIENTS

Onyx ONE Month DAPT Program
Evaluating Resolute Onyx™ DES in ~1,700 patients with 1-month DAPT.†

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.
High bleeding risk (HBR) patients are a large, growing, complex population that historically had little evidence to support treatment decisions. HBR patients often have more complex disease than all-comer patients. For these reasons, Medtronic initiated the Onyx ONE Month DAPT Program.

Medtronic is committed to developing additional evidence to help guide DAPT decisions.

**Onyx ONE Month DAPT Program**
Evaluating Resolute Onyx DES in ~1,700 patients with 1-month DAPT.

**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.
ONHX ONE MONTH DAPT PROGRAM

The most robust clinical program studying 2,700 highly complex HBR patients with 1-month DAPT.

COMPLEX HBR PATIENT POPULATION

THE ONHX ONE MONTH DAPT PROGRAM ENROLLED HIGHLY COMPLEX HIGH BLEEDING RISK PATIENTS, REFLECTIVE OF A REAL-WORLD PATIENT POPULATION.¹

<table>
<thead>
<tr>
<th>NO VESSEL OR LESION LIMITATIONS</th>
<th>REAL-WORLD PATIENTS</th>
<th>BROAD HBR INCLUSION CRITERIA**¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AVERAGE AGE</td>
<td>DIABETES</td>
</tr>
<tr>
<td>Resolute Onyx DES Arm (1,003 patients)</td>
<td>74</td>
<td>39%</td>
</tr>
<tr>
<td>“Clear” patients treated with Resolute Onyx DES (1,506)</td>
<td>74</td>
<td>39%</td>
</tr>
</tbody>
</table>

HBR INCLUSION CRITERIA¹

<table>
<thead>
<tr>
<th>PATIENTS MEETING CRITERIA</th>
<th>RESOLUTE ONYX DES (N = 1,506)</th>
<th>RESOLUTE ONYX DES (N = 1,003)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elderly (age ≥ 75 yr)</td>
<td>59.0</td>
<td>61.1</td>
</tr>
<tr>
<td>OAC</td>
<td>41.0%</td>
<td>38.5%</td>
</tr>
<tr>
<td>Anemia or transfusion</td>
<td>14.4%</td>
<td>15.6%</td>
</tr>
<tr>
<td>Renal failure</td>
<td>12.5%</td>
<td>14.3%</td>
</tr>
<tr>
<td>Active or recent cancer</td>
<td>7.4%</td>
<td>8.5%</td>
</tr>
<tr>
<td>Planned surgery</td>
<td>6.6%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Expected DAPT noncompliance</td>
<td>4.2%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Stroke &lt; 1 yr</td>
<td>2.6%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Hospital for bleeding</td>
<td>2.8%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Long-term NSAID or steroids</td>
<td>3.1%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Previous intracranial bleed</td>
<td>1.7%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>1.7%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Severe liver disease</td>
<td>0.9%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>
ONXY ONE GLOBAL STUDY

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

TRIAL DESIGN

HBR patients undergoing PCI in a prospective, randomized, clinical trial, DES vs. DES

ONE-YEAR RESULTS

PRIMARY ENDPOINT MET WITH RESOLUTE ONYX DES (17.1%) NONINFERIOR TO BIOFREEDOM* DCS (16.9%)²

LANDMARK ANALYSIS AFTER DAPT DISCONTINUATION

LANDMARK ANALYSIS AFTER DAPT DISCONTINUATION² IN A HIGHLY COMPLEX PATIENT POPULATION***

RESULTS PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE
ONyx One Clear Study

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

**Trial Design**

“Clear” HBR patients undergoing PCI in a prospective, multicenter, single-arm trial

**Resolute Onyx DES with 1-mo DAPT**
- United States and Japan (n = ~600)
- Onyx ONE Global Study (n = ~900)
  (N = ~1,500)

**Performance Goal**

“Clear” patients are defined as being event-free and DAPT-adherent for the first 30 days post-procedure. Events include spontaneous MI, repeat revascularization, stroke, stent thrombosis, and death through 1 month.

**Primary Endpoint Results**

Resolute Onyx DES Beat Performance Goal for Cardiac Death and MI

\[
p < 0.001 \quad n = 1,491/1,506
\]

9.7% performance goal

\[
\begin{align*}
\text{Event Rates (\%)} & \\
1-12 \text{ months} & \\
\text{Primary Endpoint} & \\
\text{Cardiac Death/MI} & \\
\text{Cardiac Death} & 7.0 & 2.6 & 4.8 & 3.4 & 0.7
\end{align*}
\]

THE ONYX ONE CLEAR ANALYSIS showed 7.0% cardiac death or myocardial infarction at one year, beating the performance goal of 9.7%.

Performance goal derived from contemporary 1-month DAPT trials.†††
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 ≤ 3.5 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 the platinum-iridium alloy or to 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.

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.

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 • Angiographic reaction (to contrast, antiplatelet therapy, stent material, or drug and polymer coating) • Aneurysm, pseudaneurysm, 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/ hyperventilation • Incomplete stent apposition • Injury or infection • MI • Pericardiectomy • 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 • Nausea • 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.

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