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 judgment, 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.

ADVANCING DAPT EVIDENCE

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.
ONYX 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 ONYX 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 Criteria¹†</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONYX ONE GLOBAL STUDY</td>
<td>Resolute Onyx DES Arm (1,003 patients)</td>
<td>80% 38 mm 46% 74 39% 31% 1.6 46%</td>
</tr>
<tr>
<td>ONYX ONE CLEAR STUDY</td>
<td>“Clear” patients treated with Resolute Onyx DES (1,506)</td>
<td>79% 37 mm 50% 74 39% 36% 1.6 44%</td>
</tr>
</tbody>
</table>

HBR INCLUSION CRITERIA¹

<table>
<thead>
<tr>
<th>Patients Meeting Criteria</th>
<th>Resolute Onyx DES (N = 1,506) ONYX ONE CLEAR STUDY</th>
<th>Resolute Onyx DES (N = 1,003) ONYX ONE GLOBAL STUDY</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>
**ONYX 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

- **Resolute Onyx DES**
  - (N = 1,003)
- **BioFreedom DCS**
  - (N = 993)

### ONE-YEAR RESULTS

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

![Graph showing event rates (%)](image)

- **Event Rates (%)**
  - ST: 1.3 vs. 2.1 (p = 0.22)
  - MI: 13.4 vs. 14.7 (p = 0.43)
  - Cardiac Death: 4.5 vs. 3.7 (p = 0.43)
  - TLR: 2.8 vs. 4.0 (p = 0.17)

### LANDMARK ANALYSIS AFTER DAPT DISCONTINUATION

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

![Graph showing event rates (%)](image)

- **Event Rates (%)**
  - Composite Safety Endpoint: MI/ST/CD: 7.5 vs. 8.8 (p = 0.28)
  - MI: 4.3 vs. 6.8 (p < 0.01)
  - ST: 0.9 vs. 0.9 (p = 0.99)
  - Cardiac Death: 3.5 vs. 2.7 (p = 0.25)

**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.

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**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**

Event Rates (%)

<table>
<thead>
<tr>
<th>Event</th>
<th>1–12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Endpoint</td>
<td>Cardiac Death</td>
</tr>
<tr>
<td>Cardiac Death/MI</td>
<td>7.0</td>
</tr>
</tbody>
</table>

THE ONYX ONE CLEAR ANALYSIS showed 7.0% cardiac death or myocardial infarction at one year, beating the performance goal of 9.7%.²

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**PRIMARY ENDPOINT RESULTS**

Resolute Onyx DES BEAT PERFORMANCE GOAL FOR CARDIAC DEATH AND MI

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

Performance goal derived from contemporary 1-month DAPT trials.¹¹¹
The 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 ≤ 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 intended 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 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 antikleptide 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 antikleptide therapy.

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