CTO PERFORMANCE BACKED BY EVIDENCE

Reach for Resolute Onyx™ DES in your complex CTO cases — offering the exceptional deliverability and enhanced visibility\(^1\) you look for, along with the clinical performance you depend on.\(^2\)

See what makes Resolute Onyx™ DES different at medtronic.com/CTO

**NOW OFFERING SPECIALIZED CTO TRAINING**

MORE DELIVERABLE\(^1\)
MORE VISIBLE\(^1\)
MORE SIZES\(^3\)

Resolute Onyx™
Zotarolimus-Eluting
Coronary Stent System
Medtronic is committed to providing physicians with compelling and high quality evidence that supports the use of its Resolute™ DES family in patients with chronic total occlusions (CTO). The PERSPECTIVE study showed Resolute Integrity™ DES to be safe and effective in the treatment of patients with CTO and demonstrated a clear improvement in quality of life measures.

**PERSPECTIVE**

<table>
<thead>
<tr>
<th>Clinical outcomes at 1 year</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>5 (2.8)</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>4 (2.2)</td>
</tr>
<tr>
<td>MI (Protocol definition)</td>
<td>6 (3.3)</td>
</tr>
<tr>
<td>MI (ARC definition)</td>
<td>29 (16.0)</td>
</tr>
<tr>
<td>Periprocedural MI (ARC definition)</td>
<td>27 (14.9)</td>
</tr>
<tr>
<td>Spontaneous MI (ARC definition)</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Clinically-driven TLR</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Def/Prob ST (ARC definition)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>MACE (Protocol MI definition)</td>
<td>12 (6.6)</td>
</tr>
<tr>
<td>MACE (ARC MI definition)</td>
<td>33 (18.2)</td>
</tr>
<tr>
<td>TLF (Protocol MI definition)</td>
<td>12 (6.6)</td>
</tr>
<tr>
<td>TLF (ARC MI definition)</td>
<td>33 (18.2)</td>
</tr>
</tbody>
</table>

Three groups of patients were compared in Kaplan-Meier cumulative curves to 5 years:

- **CTO:** patients (n=436)
- **Non-chronic TO**: patients (n=467)
- **Patients without TO**: (n=4584)

**RESOLUTE Pooled CTO Analysis** showed no difference in outcomes between patients with CTO and patients without CTO. Combined, these studies demonstrated safe and effective clinical outcomes in the treatment of total and CTO in over 1,000 patients studied with the Resolute™ DES family.

**IMPROVEMENTS IN QUALITY OF LIFE**

- **R-ZES cohort – Seattle Angina Questionnaire**
- **R-ZES cohort – Angina Frequency**

**SAFETY AND EFFICACY TO 5 YEARS**

- **Non CTO (n=4584)**
- **Non-chronic TO (n=467)**
- **CTO (n=436)**
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System is contraindicated for use in:
- arteries with reference vessel diameters of 2.0 mm to de novo chronic total occlusions.
- patients with a history of severe reaction to contrast agents.
- patients with a known hypersensitivity to the BioLinx™ polymer or its individual components.
- 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.

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
- 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.

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