DELLIVERING WHAT MATTERS

Resolute Onyx™
Zotarolimus-Eluting Coronary Stent System
Resolute Onyx™ DES combines Continuous Sinusoid Technology and Core Wire Technology in a novel manufacturing process that offers thinner struts, exceptional deliverability, and enhanced visibility — without compromising structural strength. The result is an advanced workhorse ready for your complex cases.

Resolute Onyx™ DES further evolves the flexible stent platform achieved by Continuous Sinusoid Technology.

- Thinner struts, a low crossing profile, and an enhanced delivery system enable exceptional deliverability.
- 20% more deliverable
- 36% more pushable
- 11% thinner struts

Resolute Onyx™ 3.0 mm x 18 mm DES compared with Resolute Integrity™ 3.0 mm x 18 mm DES in benchtop testing. Data on file at Medtronic. May not be indicative of clinical performance.

Delivering what matters

1Resolute Onyx™ 3.0 mm x 18 mm DES compared with Resolute Integrity™ 3.0 mm x 18 mm DES in benchtop testing. Data on file at Medtronic. May not be indicative of clinical performance.
2Based on bench test data. May not be indicative of clinical performance.
3Based on net sales data through Q1FY2017 and data on file at Medtronic.
4Yeh et al. 5-year safety and efficacy of Resolute zotarolimus-eluting stent, JACC Cardiovascular Interventions. 2017:10:247-254.
The first DES with 4.5- and 5.0-mm sizes, featuring predictable performance with sustained structural and coating integrity, and minimal foreshortening. Even at maximum overexpansion.

A platinum iridium core within a cobalt alloy shell enhances radiopacity — for more accurate stent placement.

**Resolute Onyx™ DES**
5.0 mm x 18 mm

0.8% foreshortening

**Synergy™ DES**
4.0 mm x 20 mm

14.7% foreshortening

Both stents deployed to 5.75 mm (maximum labeled overexpansion)

**CORE WIRE TECHNOLOGY**

**Resolute Onyx™ DES**

Cobalt alloy

Platinum iridium core material

**Resolute Integrity™ DES**

**6+ MILLION**
stents implanted worldwide

**1.2% 5-YEAR ST RATE**
including real-world patients
Indications
The Resolute Integrity Zotarolimus-Eluting Coronary Stent System is contraindicated for use in: • Patients with a known hypersensitivity to everolimus or similar drugs or any other analogue or bivalirudin, 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) • Patients with a known hypersensitivity to the Biotin® polymer or its individual components

Contraindications
The Resolute Integrity Zotarolimus-Eluting Coronary Stent System is contraindicated for use in: • Patients in whom antithrombotic and/or anticoagulation therapy is contraindicated • Patients who are judged not 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 antiplatelet therapy.

Precautions
• Only physicians who have received adequate training should perform implantation of the stent. • Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery (CABG) can be readily performed. • Subsequentpci or occlusion may require repeat catheter treatments (including balloon dilation) or the use of a segment containing the stent. The long-term outcomes of subsequent follow-up catheter-based treatments of previously implanted stents are not well characterized.

The safety and effectiveness of the Resolute Integrity stent have not yet been established in the following patient populations: • Patients with target lesions which were treated with prior brachytherapy or the use of brachytherapy to treat in-stent restenosis of a Resolute Integrity stent • Women who are pregnant or lactating • Men intending to father children • Pediatric patients • Patients with coronary artery reference vessel diameters of >2.25 mm or <2.00 mm • Patients with coronary artery lesions longer than 35 mm or requiring more than one Resolute Integrity stent • Patients with evidence of an acute 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 bifurcations lesions • Patients with diffuse disease or poor flow distal to identified lesions • Patients with tortuous vessels in the region of the target vessel or proximal to the lesion • Patients with 'in-stent' restenosis • Patients with moderate or severe lesion calcification at the target lesion • Patients with occluded target lesions, including chronic total occlusions • Patients with three-vessel disease • Patients with a left ventricular ejection fraction of <30% • Patients with a serum creatinine level of ≥2.5 mg/dL or patients with longer than 24 months of follow-up.

The safety and effectiveness of the Resolute Integrity stent have not been established in the cerebral, carotid or peripheral vasculature.

Adverse Events Related to Zotarolimus
Patients' exposure to zotarolimus is directly related to the total amount of stent length implanted. The actual side effect profile of complications that may be associated with the use of zotarolimus are not fully known. The adverse events that have been associated with the intracoronary injection of zotarolimus in humans include but are not limited to: • Arthralgia • Arteritis • Drug reaction • Eosinophilia • Glomerulonephritis • Hematoma • Infection • Injection site reaction • MI (atrial or ventricular) • Myocardial infarction • Nausea • Pain • Peripheral vascular occlusion or bypass • Pulmonary edema • Renal failure • Shock/pulmonary edema • Stable or unstable angina • Stent deformation/collapse or fracture • Stent migration or embolization • Stent misplacement • Stent thrombosis (acute, subacute or late)

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: • Acute vascular occlusion • Access site pain, hematoma or hemorrhage • Allergic reaction (to contrast, antipatelet therapy, stent material, or drug and polymer coating) • Aneurysm, pseudoaneurysm or arteriovenous fistula (AVF) • Amyloidosis, including visceral fibrosis • 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 occlusion or coronary bypass • Failure to deliver the stent • Hemorrhage requiring transfusion • Hypertension • Hyperperfusion • Immune-mediated vessel obstruction • Infection or fever • MI or death • Neurologic events • Peripheral ischemia/peripheral nerve injury • Renal failure • Restenosis of the stent • Stroke/deep vein thrombosis or artery occlusion, perforation, rupture or dissection • Stent deformation/collapse or fracture • Stent migration or embolization • Stent misplacement • Stent thrombosis (acute, subacute or late)

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