EXPAND YOUR DES EXPECTATIONS

With Resolute Onyx™ DES

EXCEPTIONAL DELIVERABILITY
ENABLED BY THINNER STRUTS

EXPANDED TREATMENT OPTIONS
WITH THE BROADEST DES SIZE MATRIX:
2.0–5.0 mm

ENHANCED VISIBILITY
FOR ACCURATE STENT PLACEMENT

Ordering Information

STENT LENGTH (mm) — Added sizes — Postdilatation limit

STENT DIAMETER (mm)	8	12	15	18	22	26	30	34	38	POSTDILATATION LIMIT (mm)
2.00	RONYX20008UX/W	RONYX20012UX/W	RONYX20015UX/W	RONYX20018UX/W	RONYX20022UX/W	RONYX20026UX/W	RONYX20030UX/W	–	–	3.25
2.25	RONYX22508UX/W	RONYX22512UX/W	RONYX22515UX/W	RONYX22518UX/W	RONYX22522UX/W	RONYX22526UX/W	RONYX22530UX/W	RONYX22534UX/W	RONYX22538UX/W	3.25
2.50	RONYX25008UX/W	RONYX25012UX/W	RONYX25015UX/W	RONYX25018UX/W	RONYX25022UX/W	RONYX25026UX/W	RONYX25030UX/W	RONYX25034UX/W	RONYX25038UX/W	3.25
2.75	RONYX27508UX/W	RONYX27512UX/W	RONYX27515UX/W	RONYX27518UX/W	RONYX27522UX/W	RONYX27526UX/W	RONYX27530UX/W	RONYX27534UX/W	RONYX27538UX/W	3.75
3.00	RONYX30008UX/W	RONYX30012UX/W	RONYX30015UX/W	RONYX30018UX/W	RONYX30022UX/W	RONYX30026UX/W	RONYX30030UX/W	RONYX30034UX/W	RONYX30038UX/W	3.75
3.50	RONYX35008UX/W	RONYX35012UX/W	RONYX35015UX/W	RONYX35018UX/W	RONYX35022UX/W	RONYX35026UX/W	RONYX35030UX/W	RONYX35034UX/W	RONYX35038UX/W	4.75
4.00	RONYX40008UX/W	RONYX40012UX/W	RONYX40015UX/W	RONYX40018UX/W	RONYX40022UX/W	RONYX40026UX/W	RONYX40030UX/W	RONYX40034UX/W	RONYX40038UX/W	4.75
4.50	–	RONYX45012UX	RONYX45015UX	RONYX45018UX	RONYX45022UX	RONYX45026UX	RONYX45030UX	–	–	5.75
5.00	–	RONYX50012UX	RONYX50015UX	RONYX50018UX	RONYX50022UX	RONYX50026UX	RONYX50030UX	–	–	5.75

The Resolute Onyx™ stents should not be expanded to a diameter beyond the maximum labeled diameter listed on the label per the IFU. Do not dilate the 2.0-mm stents to greater than 3.25 mm. Postdilatation required for overexpansion.

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.

Contraindications

The Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System is contraindicated for use in: • Patients with a known hypersensitivity or allergies to aspirin, heparin, 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) 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 antiplatelet 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 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 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. • 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 wipe the 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 • Men 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 an acute ST-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 occluded target lesions including chronic total occlusions • 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 • Hypotension/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.

Medtronic

For further information, please call and/or consult Medtronic at the toll-free numbers or websites listed.

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Product Services
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Fax: 800.838.3103

medtronic.com
resoluteonyx.com

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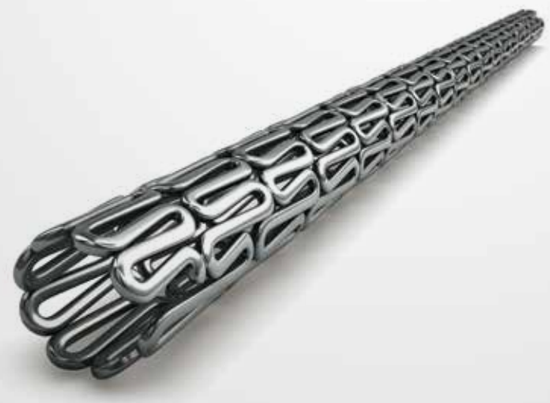
SMALLEST DES. BIG POSSIBILITIES.

Resolute Onyx™ 2.0-mm DES

Zotarolimus-Eluting Coronary Stent System



Medtronic
Further, Together

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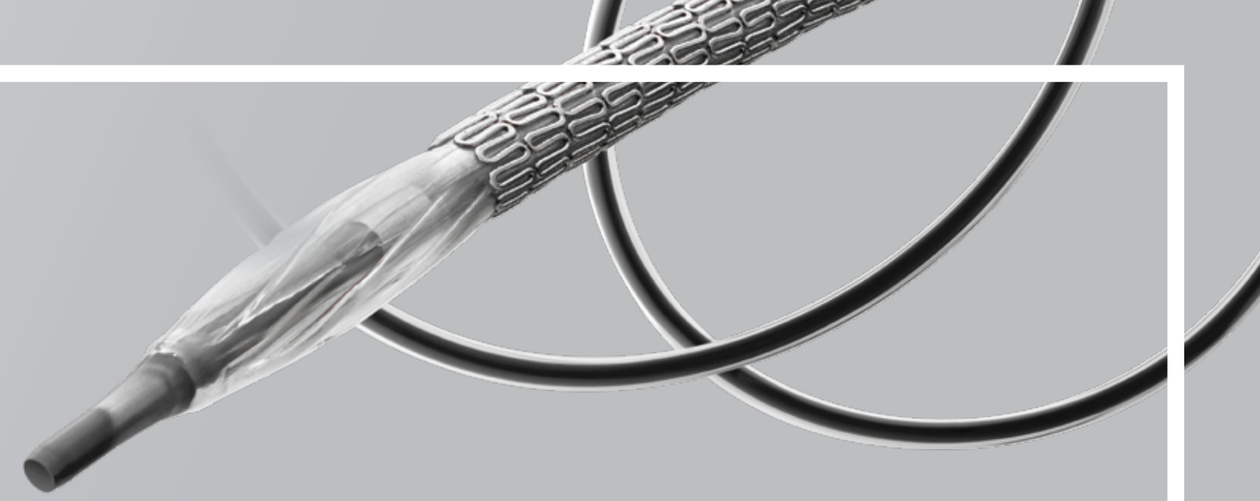
BIG POSSIBILITIES.

Resolute Onyx™ 2.0-mm DES



THE LOWEST CROSSING PROFILE FOR SUPERIOR DELIVERABILITY

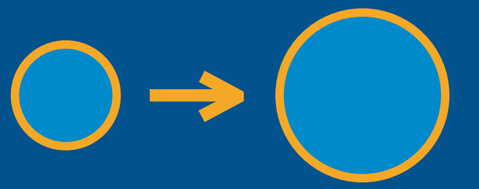
SMALLEST STENT CROSSING PROFILE

<1.0 mm

Bench test data on file at Medtronic. May not be indicative of clinical performance. Testing performed on smallest diameters available for Abbott Xience Alpine™*, Boston Scientific Promus Premier™*, Boston Scientific Synergy™*, Medtronic Resolute Integrity™, and Medtronic Resolute Onyx™ coronary stents.

ENGINEERED TO EXPAND FROM 2.0 mm TO 3.25 mm

SMALLEST DES WITH EXPANSION CAPABILITIES FROM



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PROVEN CLINICAL PERFORMANCE IN SMALL VESSELS

AT 12 MONTHS, IN THE RESOLUTE ONYX 2.0-mm CLINICAL STUDY, RESULTS SHOWED

5% TLF **2% TLR** **0% STENT THROMBOSIS**

Price et al. *JACC Cardiovasc Interv.* 2017;10(14): 1381–1388.
Study only powered for TLF clinical endpoint. Rates are taken from KM estimates.

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