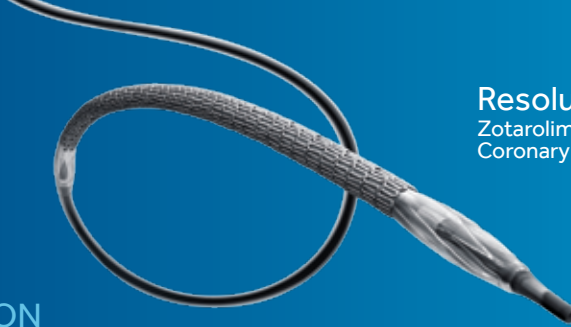


EXPAND YOUR DES EXPECTATIONS

PRODUCT ORDERING INFORMATION

Resolute Onyx™
Zotarolimus-Eluting
Coronary Stent System

OTW



(240)RONYX20008W

RONYX20008W



(240)RONYX20026W

RONYX20026W



(240)RONYX22518W

RONYX22518W



(240)RONYX22538W

RONYX22538W



(240)RONYX25022W

RONYX25022W



(240)RONYX27508W

RONYX27508W



(240)RONYX27526W

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(240)RONYX30012W

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(240)RONYX30030W

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(240)RONYX35015W

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(240)RONYX35034W

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(240)RONYX40018W

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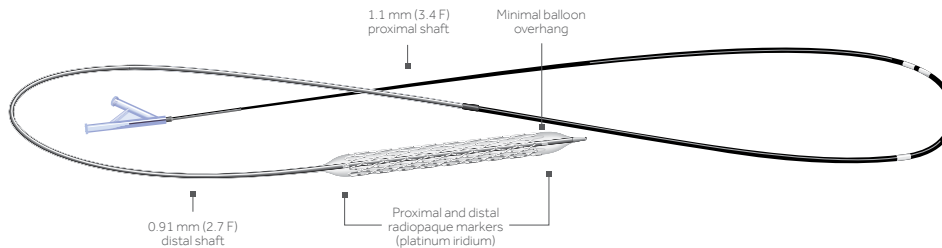
(240)RONYX40034W

RONYX40034W

RESOLUTE ONYX™ DES — OTW CORONARY STENT SYSTEM

General Characteristics:

Supplied sterile.
Items per box: 1



Resolute Onyx™ DES

Product Code
RONYX22508W

Over-the-Wire
Length
Diameter
Product

Stent Diameter (mm)	Stent Length (mm)								
	8	12	15	18	22	26	30	34	38
2.00	RONYX20008W	RONYX20012W	RONYX20015W	RONYX20018W	RONYX20022W	RONYX20026W	RONYX20030W	—	—
2.25	RONYX22508W	RONYX22512W	RONYX22515W	RONYX22518W	RONYX22522W	RONYX22526W	RONYX22530W	RONYX22534W	RONYX22538W
2.50	RONYX25008W	RONYX25012W	RONYX25015W	RONYX25018W	RONYX25022W	RONYX25026W	RONYX25030W	RONYX25034W	RONYX25038W
2.75	RONYX27508W	RONYX27512W	RONYX27515W	RONYX27518W	RONYX27522W	RONYX27526W	RONYX27530W	RONYX27534W	RONYX27538W
3.00	RONYX30008W	RONYX30012W	RONYX30015W	RONYX30018W	RONYX30022W	RONYX30026W	RONYX30030W	RONYX30034W	RONYX30038W
3.50	RONYX35008W	RONYX35012W	RONYX35015W	RONYX35018W	RONYX35022W	RONYX35026W	RONYX35030W	RONYX35034W	RONYX35038W
4.00	RONYX40008W	RONYX40012W	RONYX40015W	RONYX40018W	RONYX40022W	RONYX40026W	RONYX40030W	RONYX40034W	RONYX40038W

5 F min. guide catheter I.D.: 1.4 mm (0.056 in)

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.

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

Medtronic

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