Medtronic

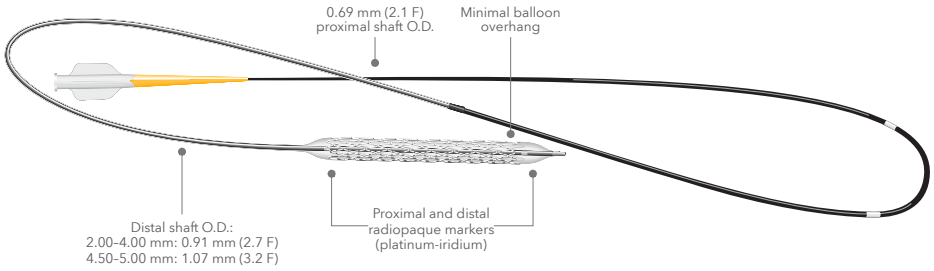
Rapid exchange (RX)

Resolute Onyx™ DES

Product ordering information

(240)RONYX20008UX RONYX20008UX	(240)RONYX20012UX RONYX20012UX	(240)RONYX20015UX RONYX20015UX	(240)RONYX20018UX RONYX20018UX	(240)RONYX20022UX RONYX20022UX
(240)RONYX20026UX RONYX20026UX	(240)RONYX20030UX RONYX20030UX	(240)RONYX22508UX RONYX22508UX	(240)RONYX22512UX RONYX22512UX	(240)RONYX22515UX RONYX22515UX
(240)RONYX22518UX RONYX22518UX	(240)RONYX22522UX RONYX22522UX	(240)RONYX22526UX RONYX22526UX	(240)RONYX22530UX RONYX22530UX	(240)RONYX22534UX RONYX22534UX
(240)RONYX22538UX RONYX22538UX	(240)RONYX25008UX RONYX25008UX	(240)RONYX25012UX RONYX25012UX	(240)RONYX25015UX RONYX25015UX	(240)RONYX25018UX RONYX25018UX
(240)RONYX25022UX RONYX25022UX	(240)RONYX25026UX RONYX25026UX	(240)RONYX25030UX RONYX25030UX	(240)RONYX25034UX RONYX25034UX	(240)RONYX25038UX RONYX25038UX
(240)RONYX27508UX RONYX27508UX	(240)RONYX27512UX RONYX27512UX	(240)RONYX27515UX RONYX27515UX	(240)RONYX27518UX RONYX27518UX	(240)RONYX27522UX RONYX27522UX
(240)RONYX27526UX RONYX27526UX	(240)RONYX27530UX RONYX27530UX	(240)RONYX27534UX RONYX27534UX	(240)RONYX27538UX RONYX27538UX	(240)RONYX30008UX RONYX30008UX
(240)RONYX30012UX RONYX30012UX	(240)RONYX30015UX RONYX30015UX	(240)RONYX30018UX RONYX30018UX	(240)RONYX30022UX RONYX30022UX	(240)RONYX30026UX RONYX30026UX
(240)RONYX30030UX RONYX30030UX	(240)RONYX30034UX RONYX30034UX	(240)RONYX30038UX RONYX30038UX	(240)RONYX35008UX RONYX35008UX	(240)RONYX35012UX RONYX35012UX
(240)RONYX35015UX RONYX35015UX	(240)RONYX35018UX RONYX35018UX	(240)RONYX35022UX RONYX35022UX	(240)RONYX35026UX RONYX35026UX	(240)RONYX35030UX RONYX35030UX
(240)RONYX35034UX RONYX35034UX	(240)RONYX35038UX RONYX35038UX	(240)RONYX40008UX RONYX40008UX	(240)RONYX40012UX RONYX40012UX	(240)RONYX40015UX RONYX40015UX
(240)RONYX40018UX RONYX40018UX	(240)RONYX40022UX RONYX40022UX	(240)RONYX40026UX RONYX40026UX	(240)RONYX40030UX RONYX40030UX	(240)RONYX40034UX RONYX40034UX
(240)RONYX40038UX RONYX40038UX	(240)RONYX45012UX RONYX45012UX	(240)RONYX45015UX RONYX45015UX	(240)RONYX45018UX RONYX45018UX	(240)RONYX45022UX RONYX45022UX
(240)RONYX45026UX RONYX45026UX	(240)RONYX45030UX RONYX45030UX	(240)RONYX50012UX RONYX50012UX	(240)RONYX50015UX RONYX50015UX	(240)RONYX50018UX RONYX50018UX
(240)RONYX50022UX RONYX50022UX	(240)RONYX50026UX RONYX50026UX	(240)RONYX50030UX RONYX50030UX		

Resolute Onyx DES – RX coronary stent system



General characteristics:

Supplied sterile.
Items per box: 1

Resolute Onyx DES product code

RONYX22508UX

- Rapid exchange
- Length
- Diameter
- Product

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

Indications
The Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System is indicated for improving coronary luminal diameters in patients, including those with diabetes mellitus or high bleeding risk, 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 indicated 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 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 below the age of 18 years • 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 three-vessel disease
The safety and effectiveness of the Resolute Onyx™ stent have not been established in the cerebral, carotid, or peripheral vasculature. Additionally, the safety and effectiveness of using atherectomy devices with Resolute Onyx™ stent have not been established. The effect of potential drug interactions on the safety or effectiveness of the Resolute Onyx™ stent has not been investigated. Potential interactions of the Resolute Onyx™ stent with other drug-eluting or coated stents have not been evaluated and should be avoided whenever possible.
Clinical studies of the Resolute™ stent did not suggest any significant differences in safety and effectiveness for male and female patients and did not include sufficient numbers of patients to assess for differences in safety and effectiveness due to ethnicity.

Oral Antiplatelet Therapy
Dual antiplatelet therapy (DAPT) using a combination treatment of aspirin with a P2Y12 platelet inhibitor after percutaneous coronary intervention (PCI), reduces the risk of stent thrombosis and ischemic cardiac events, but increases the risk of bleeding complications. The optimal duration of DAPT (specifically a P2Y12 platelet inhibitor in addition to aspirin) following DES implantation is unknown, and DES thrombosis may still occur despite continued therapy. It is very important that the patient is compliant with the post-procedural antiplatelet recommendations.
Per 2016 ACC/AHA guidelines,[1] a daily aspirin dose of 81 mg is recommended indefinitely after PCI. A P2Y12 platelet inhibitor should be given daily for at least 6 months in stable ischemic heart disease patients and for at least 12 months in patients with acute coronary syndrome (ACS). Consistent with the DAPT Study,[2] and the 2016 ACC/AHA guidelines, longer duration of DAPT may be considered in patients at higher ischemic risk with lower bleeding risk. The Academic Research Consortium (ARC) proposed a standardized definition for identifying patients at high bleeding risk (HBR)[3]. Additionally, evidence from a dedicated study of Resolute Onyx in HBR patients and those who are unable to tolerate long term DAPT after PCI has been published[4].
Based on the Onyx ONE Clear Analysis, Resolute Onyx is safe and effective in patients at high risk of bleeding treated with one month of DAPT. The patients evaluated in the Onyx ONE Clear Analysis met the pre-defined criteria for high bleeding risk and were those whom in the opinion of their physician, the potential benefit of 1-Month DAPT outweighed the potential risk. In addition to at least one HBR risk factor, enrollment included 48.6% ACS patients (unstable angina 22.8%, Non-STEMI 21.7% and STEMI 4.2%). Decisions about duration of DAPT are best made on an individual basis and should integrate clinical judgment, assessment of the benefit/risk ratio, and patient preference. Premature discontinuation or interruption of prescribed antiplatelet medication could result in a higher risk of stent thrombosis, MI, or death. Before PCI, if premature discontinuation of antiplatelet therapy is anticipated, physicians should carefully evaluate with the patient whether a DES and its associated recommended DAPT regimen is the appropriate PCI choice.
Following PCI, if elective noncardiac surgery requiring suspension of antiplatelet therapy is considered, the risks and benefits of the procedure should be weighed against the possible risk associated with interruption of antiplatelet therapy. Patients who require premature DAPT discontinuation should be carefully monitored for cardiac events. At the discretion of the patient's treating physician(s), the antiplatelet therapy should be restarted as soon as possible.

[1] Levine GN, et al. 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients With Coronary Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2016; doi:10.1016/j.jacc.2016.03.513. For full text, please refer to the following website: http://content.onlinejacc.org/article.aspx?doi=10.1016/j.jacc.2016.03.513.
[2] Mauri L, et al. Twelve or 30 Months of Dual Antiplatelet Therapy After Drug-Eluting Stents. N Engl J Med. 2014; 371:2155-66.
[3] Urban P, Mehran R, Colleran R, et al. Defining High Bleeding Risk in Patients Undergoing Percutaneous Coronary Intervention. Circulation 2019;140:240-6.
[4] Windecker S, Latib A, Kedhi E, et al. Polymer-based or Polymer-free Stents in Patients at High Bleeding Risk. The New England Journal of Medicine 2020:10.1056/NEJMoa1910021.

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
The potential adverse reactions in nursing infants from zotarolimus have not been determined. The pharmacokinetic and safety profiles of zotarolimus in infants are not known.

Adverse Events Related to BioLinx™ polymer
Although the type of risks of the BioLinx™ polymer coating are expected to be no different than those of other stent coatings, the potential for these risks are currently unknown as the coating has limited previous use in humans. These risks may include but are not limited to the following: • Allergic reaction • Focal inflammation at the site of stent implantation • Restenosis of the stented artery
Please reference appropriate product Instructions for Use for more information regarding indications, contraindications, 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.com

Medtronic
Tel: 707.525.0111

LifeLine Customer Support
Tel: 877.526.7890

Product Services
Tel: 888.283.7868

Medtronic