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. • Patients with three-vessel disease. • Patients who are pregnant or lactating. • Patients with a history of severe reaction to contrast agents. • Patients with a known hypersensitivity to the BioLinx® polymer or its individual components. The safety and effectiveness of the Resolute Onyx™ DES 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. • Patients with three-vessel disease. • Patients who are pregnant or lactating.

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 or hematoma • Allergic reaction to contrast, antiplatelet therapy, stent material, or drug and polymer coating • Angina • Arteriosclerosis • Arterial thrombosis • Arterial spasm • Arteriovenous fistula • Autonomic dysfunction • Balloon rupture • Bleeding • Cardiac tamponade • Coronary artery occlusion • 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 • Incomplete stent apposition • Infection or fever • MI • Peripheral ischemia • Peripheral ischemia due to peripheral nerve injury • Renal failure • Restenosis of the stented artery • Shock or hypersensitivity or allergy to aspirin, heparin, bivalirudin, ciloprodil, prazosin, ticagrelor, ticlopidine, drugs such as zotarolimus, ticagrelor, ticlopidine, drugs such as zotarolimus, zotarolimus, 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-radium alloy. • Patients with a known hypersensitivity to the BioLinx® polymer or its individual components. • Subsequent stent restenosis or occlusion may require repeat catheter-based treatments (including balloon dilation) 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 glabeling catheter movement into the vessel. • Stent thrombosis is a low-frequency event that is sequently 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).

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

### 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 ≤ 35 mm in native coronary arteries with reference vessel diameters of 2.0 mm to 5.0 mm. The use of these devices is contraindicated for use in: • Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated • Patients with a known hypersensitivity to the BioLinx® polymer or its individual components. • Subsequent stent restenosis or occlusion may require repeat catheter-based treatments (including balloon dilation) 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 glabeling catheter movement into the vessel. • Stent thrombosis is a low-frequency event that is sequently 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).