Resolute Onyx™ DES is different by design, including:

- A single-wire design with thin, rounded struts for greater deliverability and conformability.
- A broad size matrix for optimal deployment and expansion, including sizes 2.0 mm to 5.0 mm.
- A platinum iridium core for enhanced visibility.

**Technical Feature** | **Resolute Onyx DES**
--- | ---
Stent design | Continuous Sinusoid Technology with Core Wire Technology
Polymer and drug | BioLinx™ polymer and zotarolimus
Delivery system | Resolute Onyx™ delivery system
Catheter distal O.D. (Fr) | 2.00–4.00 mm: 2.7
 | 4.50–5.00 mm: 3.2
Catheter distal O.D. (in) | 2.00–4.00 mm: 0.036
 | 4.50–5.00 mm: 0.042
Crowns | Small vessel (2.00–2.50 mm): 6.5
 | Medium vessel (2.75–3.00 mm): 8.5
 | Large vessel (3.50–4.00 mm): 9.5
 | Extra-large vessel (4.50–5.00 mm): 10.5
Stent material | Shell: Cobalt alloy, Core: Pt–Ir
Strut thickness | 2.00–4.00 mm: 81 μm (0.0032 in)
 | 4.50–5.00 mm: 91 μm (0.0036 in)
Base coating | Parylene C
Polymer coating | BioLinx™ polymer (C10:C19:PVP = 27:63:10)
Drug density | Zotarolimus (~1.6 μg/mm²)
Balloon material | Enhanced Fulcrum™ material
Platform | RX (2.00–5.00 mm) and OTW (2.00–4.00 mm)
Catheter length (cm) | 140
Nominal pressure (atm) | 12
Rated burst pressure (atm) | 2.00–4.00 mm: 18
 | 4.50–5.00 mm: 16
Marker band material | Platinum iridium

**Diameter (mm)** | **Stent Length (mm)** | **MSID (mm)**
--- | --- | ---
2.00 | 8 | 3.50
2.25 | 8 | 3.50
2.50 | 8 | 3.50
2.75 | 8 | 4.00
3.00 | 8 | 4.00
3.50 | 8 | 5.00
4.00 | 8 | 5.00
4.50 | — | 6.00
5.00 | — | 6.00

Maximum stent inner diameter (MSID)

4.50- and 5.00-mm sizes are not available in OTW. Resolute Onyx stents should not be expanded to a diameter beyond the listed MSID.
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 > 3.0 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 yet been established in the cerebral, carotid, or peripheral vasculature.

Oral Antiplatelet Therapy

Dual antiplatelet therapy (DAPT) using a combination treatment of aspirin with a P2Y12 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 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, a daily aspirin dose of 81 mg is recommended indefinitely after PCI. A P2Y12 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,1 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). In their video from a dedicated study of Resolute Onyx in HBR patients and those who are unable to tolerate long term DAPT after PCI.2

Based on the Onyx 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 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 48.8% 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 antplatelet medication could result in a higher risk of stent thrombosis.3 MI, or death. Before PCI, a 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.

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; Heimorrhage; or hematoma; Allergic reaction (to contrast, antiplatelet therapy, stent material, or drug and polymer coating) Anaphylaxis; pseudoadamantiasis, or arteriosclerosis fibuluv (AFF) Atherosclerosis; angina; myocardial infarction; or death. Data from the RESOLUTE clinical trials have

References


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