Resolute Onyx™ DES

NOW CE MARKED FOR 1-MONTH DAPT IN HIGH BLEEDING RISK PATIENTS

Addressing the unmet high bleeding risk (HBR) patient need

Up to
40%
of PCI patients are at high bleeding risk[1]

LIMITED EVIDENCE
HBR patients have historically been excluded from stent and drug trials[2]

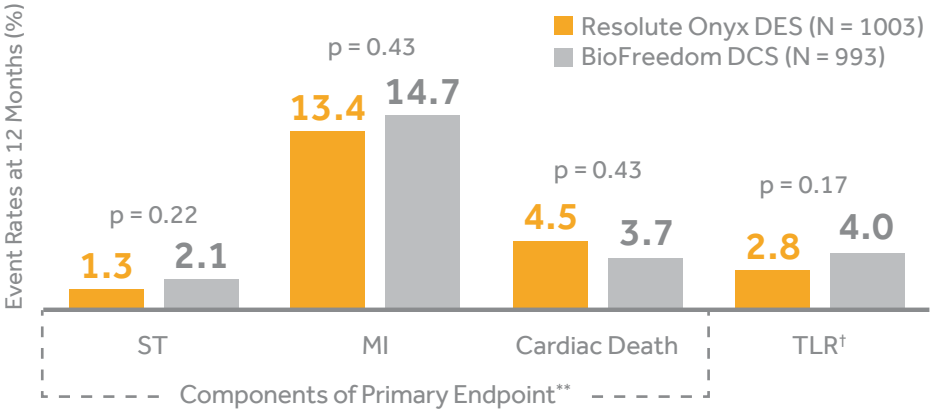
COMPLEX
HBR patients appear to have complex disease more often than all-comer patients[3]

~3X
Greater risk of bleeding events for HBR patients on extended DAPT regimen[4]

Resolute Onyx DES was safe and effective in highly complex HBR patients on 1-month DAPT[5,6]

Onyx ONE Global Study

PRIMARY ENDPOINT MET WITH RESOLUTE ONYX DES (17.1%) NONINFERIOR TO BIOFREEDOM™* DCS (16.9%)[5]



Highly complex HBR patient population

Resolute Onyx DES arm (N = 1003)

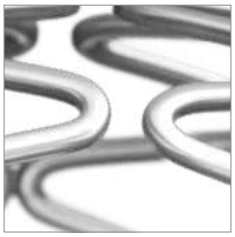
NO VESSEL OR LESION LIMITATIONS			REAL-WORLD PATIENTS			BROADEST HBR INCLUSION CRITERIA††7	
B2/C LESIONS	AVERAGE STENTED LENGTH	MOD/SEV CALCIFIED LESIONS	ACS	AF	DIABETES	HBR CRITERIA PER PATIENT	PATIENTS HAVING TWO OR MORE HBR CRITERIA
80%	38 mm	46%	53%	33%	39%	1.6	46%

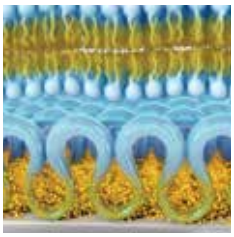
CE MARK based on results from the study, the first prospective, randomised, 1-month DAPT trial comparing a DES to a DES in HBR patients.

PART OF THE ONYX ONE MONTH DAPT PROGRAM
The most robust clinical program studying **2700**** highly complex HBR patients with 1-month DAPT.

Medtronic

Thin struts and biocompatible polymer promote fast healing and enable short DAPT duration[8]





BioLinx™ polymer is specifically designed for DES.

Single wire design for best-in-class deliverability, conformability, and apposition

Resolute Onyx DES is optimised for your complex clinical practice

1-month DAPT in HBR patients
Diabetes mellitus
In-stent restenosis (ISR)
Multivessel disease
Chronic total occlusions (CTO)
Acute coronary syndrome (ACS)
Total occlusions (TO)
Acute myocardial infarction (AMI)
Left main (LM)
Unstable angina (UA)
Small vessel (SV)
Bifurcation lesions

CE
2797

*Third party brands are trademarks of their respective owners.
†Primary endpoint does not include TLR.
**ST, MI, and CD were not separately powered endpoints.
††Matching LEADERS FREE inclusion criteria.
***Combines Onyx ONE Global Study patients (N = 1996) and Onyx ONE Clear Study patients (N = 752).

[1] Windecker S. Stent Selection for 1-3 Month DAPT: Current Evidence Ongoing Studies. Presented at TCT 2018; San Diego, CA.
[2] Urban P, Meredith IT, Abizaid A, et al. Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk. *N Engl J Med.* November 19, 2015;373:2038-2047.
[3] Lipiecki J, Brunel P, Morice MC, et al. Biolimus A9 polymer-free coated stents in high bleeding risk patients undergoing complex PCI: evidence from the LEADERS FREE randomised clinical trial. *EuroIntervention.* July 20, 2018;14(4):e418-e425.
[4] Costa F, van Klaveren D, James S, et al. Derivation and validation of the predicting bleeding complications in patients undergoing stent implantation and subsequent dual antiplatelet therapy (PRECISE-DAPT) score: a pooled analysis of individual-patient datasets from clinical trials. *Lancet.* March 11, 2017;389(10073):1025-1034.
[5] Windecker S, Latib A, Kedhi E, et al. Polymer-based or Polymer-free Stents in Patients at High Bleeding Risk. *N Engl J Med.* March 26, 2020;382(13):1208-1218.
[6] Kirtane A, et al. One Month Dual Antiplatelet Therapy in High Bleeding Risk Patients: Primary Results of Onyx ONE Clear. Presented online at ACC 2020.
[7] Kedhi E, Latib A, Abizaid A, et al. Rationale and design of the Onyx ONE global randomized trial: A randomized controlled trial of high bleeding risk patients after stent placement with 1 month of dual antiplatelet therapy. *Am Heart J.* August 2019;214:134-141.
[8] Roleder T, Kedhi E, Berta B, et al. Short-term stent coverage of second-generation zotarolimus-eluting durable polymer stents: Onyx one-month optical coherence tomography study. *Adv Interv Cardiol.* 2019;15(2):143-150.

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