

ONYX ONE IS MORE RIGOROUSLY DESIGNED THAN XIENCE 281 AND POEM2

Trial	Size	Comparator	Randomised Control Trial	Included ACS Patients	Angiographic Exclusions	HBR Exclusions	Primary Endpoint Follow-up
Onyx ONE Global Trial	1,996	BioFreedom™* DCS	✓	✓	None	None	12 months
Onyx ONE Clear Analysis	1,506	Performance Goal	X	✓	None	None	12 months
XIENCE 28	1,392	Single-arm Historical Control (XIENCE V USA Study) 2008–2011	×	No STEMI	Excluded: Left main CTO ISR Overlapping stents SVG	Planned surgery	6 months
POEM (Synergy [™] Stent)	443	Objective Performance Criteria	×	✓	None	None	12 months

ONYX ONE STUDIED A MORE COMPLEX HIGH BLEEDING RISK (HBR) POPULATION THAN XIENCE 28¹ AND POEM²

		Lesion Characteristics	Patient Characteristics		
Trial	B2/C	Average Stented Length	Moderate/Severe Calcified Lesions	ACS	Prior MI
Onyx ONE Global Trial†	80%	38 mm	46%	53%	26%
Onyx ONE Clear Analysis	79%	37 mm	50%	49%	26%
XIENCE 28	36%	27 mm	Not Reported	34%	16%
POEM (Synergy [™] Stent)	49%	24 mm	Not Reported	41%	Not Reported

[†]Results include the Resolute Onyx DES treated arm.

Resolute Onyx[™] DES

DIFFERENT BY DESIGN TO PROMOTE **FAST HEALING**

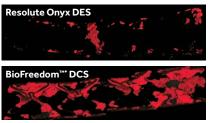
Single-wire design

provides a fluid range of motion and the conformability needed for superior strut apposition3

BioLinx[™] biocompatible polymer provides superior thromboresistance4

Fast healing as evidenced by nearly 90% strut coverage at 30 days,5 providing the option to shorten DAPT









Resolute Onyx is the first DES CE indicated for 1-month DAPT in HBR patients based on results from the Onyx ONE Global Study which proved safety and efficacy⁶



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Mehran R, et al. The Xience Short DAPT Program: Xience 90/28. Evaluating the Safety of 3-month and 1-month DAPT in HBR Patients. Presented at TCT Congress 2020.

 2 Stefanini G, et al. The POEM Study: One-Month DAPT in HBR Patients. Presented at PCR 2021

Data on file at Medtronic

⁴ Jinnouchi H, Sato Y, Cheng Q, et al. Thromboresistance and endothelial healing in polymer-coated versus polymer-free drug-eluting stents: Implications for short-term dual anti-platelet therapy. Int J Cardiol. March 15, 2021;327:52-57.

⁵ 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. Postepy Kardiol Interwencyjnej. 2019;15(2):143-150.

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.

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