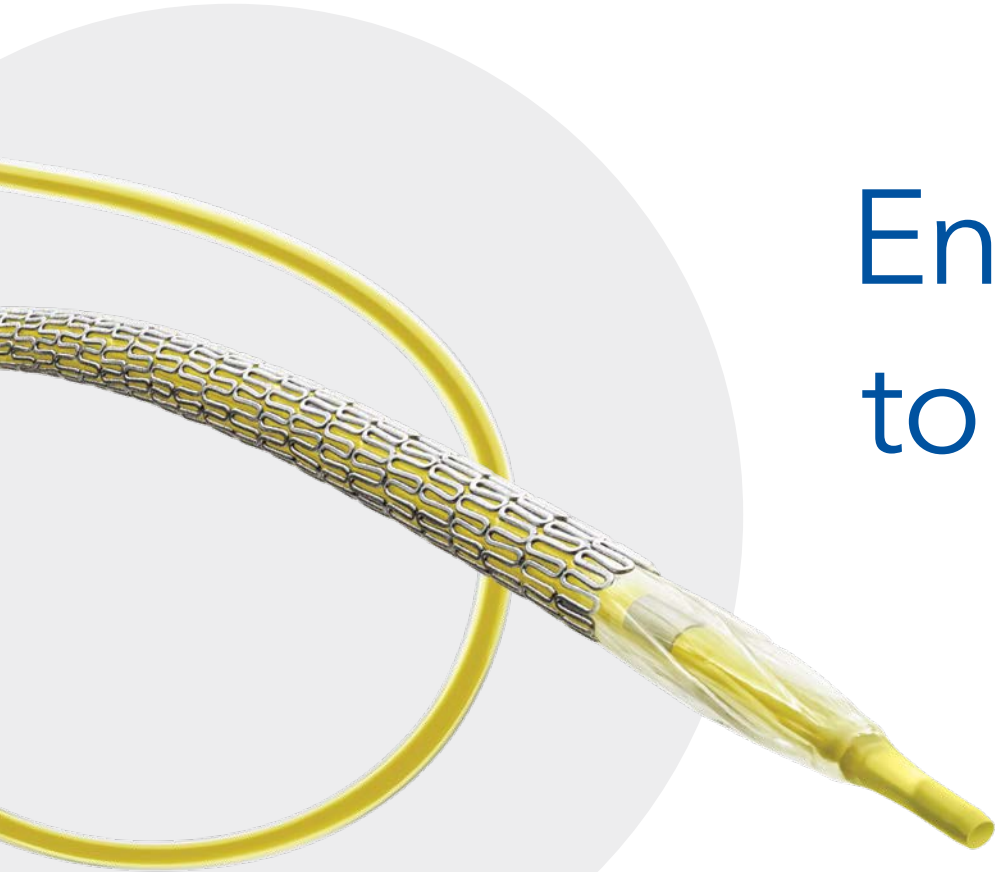
Medtronic

Onyx Frontier™ DES



Engineered to deliver

Engineered to deliver

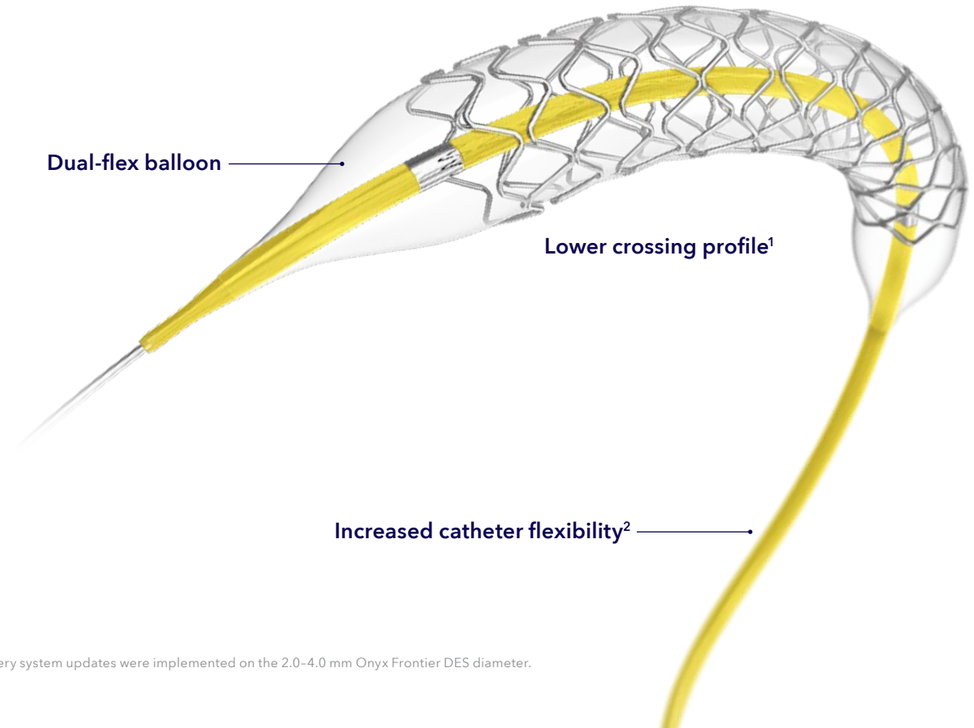
Different by design

Optimised for complex PCI

Engineered to deliver

Onyx Frontier DES introduces an enhanced delivery system† designed to take the acute performance of Resolute Onyx™ DES even further.

Enhanced delivery system† features:

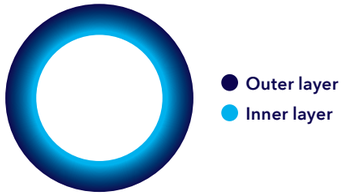


†Stent delivery system updates were implemented on the 2.0–4.0 mm Onyx Frontier DES diameter.

Dual-flex balloon provides increased flexibility and is comprised of a unique blend of two layers[2]:

- Inner layer enhances flexibility[2]
- Outer layer maintains strength[2]

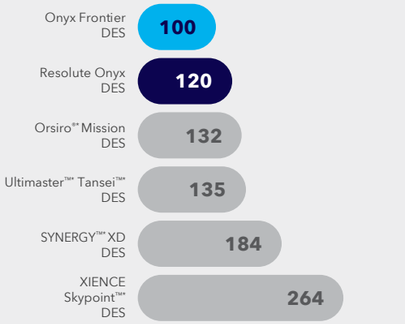
This results in a **thinner balloon** with the same rated burst pressure (RBP) as Resolute Onyx DES.[2]



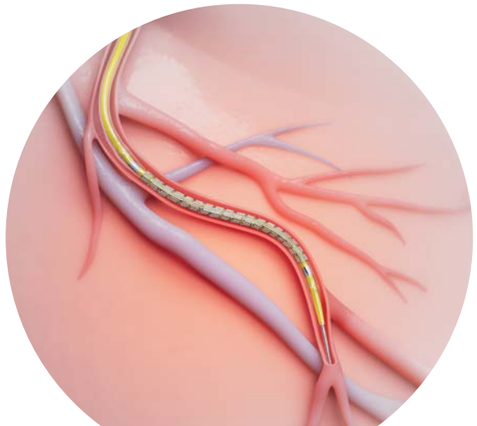
The dual-flex balloon enables a **7.5% lower crossing profile** than Resolute Onyx DES.[2]

At least **24%** more deliverable than competitive DES†[3]

Deliverability comparison
3.0 mm DES



2-D track maximum force (gf scaled)
Lower is better

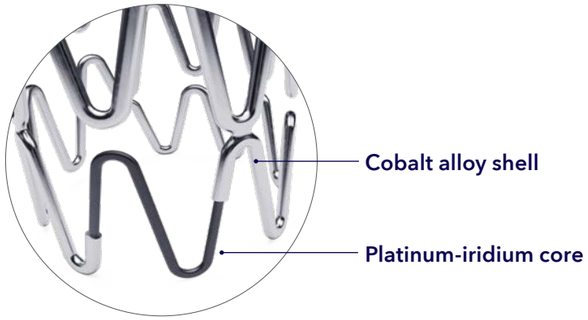


An updated manufacturing process applied to the outer shaft results in a **29% more flexible catheter** (compared to Resolute Onyx DES) for improved deliverability.[2]

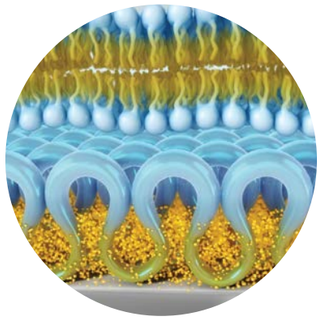
Different by design

Onyx Frontier DES builds off the legacy of Resolute Onyx DES, featuring the same stent design differentiators that provide the conformability,[4] visibility,[5] fast healing,[6] and size matrix you've come to rely on.

In comparison to laser-cut drug-eluting stents, only Medtronic DES are made from a single wire to enable a fluid range of motion and the conformability needed for **superior strut apposition.**[4]



The platinum-iridium core within Onyx Frontier DES is **more visible** than competitive DES, while enabling greater radial strength with thin struts.‡[7]



The zotarolimus drug inhibits neointimal growth,[8] while the BioLinx™ biocompatible polymer – the only polymer specifically designed for a DES – **promotes faster healing.**[6]

Only Medtronic offers DES in **2.0 mm to 5.0 mm** sizes to treat the broadest range of coronary vessel diameters.

Platform	Diameter (mm)	Stent length (mm)									MSID[5] (mm)
Small vessels	2.00	8	12	15	18	22	26	30	—	—	3.50
	2.25	8	12	15	18	22	26	30	34	38	3.50
	2.50	8	12	15	18	22	26	30	34	38	3.50
Medium vessels	2.75	8	12	15	18	22	26	30	34	38	4.00
	3.00	8	12	15	18	22	26	30	34	38	4.00
Large vessels	3.50	8	12	15	18	22	26	30	34	38	5.00
	4.00	8	12	15	18	22	26	30	34	38	5.00
Extra-large vessels	4.50	—	12	15	18	22	26	30	—	—	6.00
	5.00	—	12	15	18	22	26	30	—	—	6.00

Four platforms specifically designed to meet the unique needs of each vessel size.

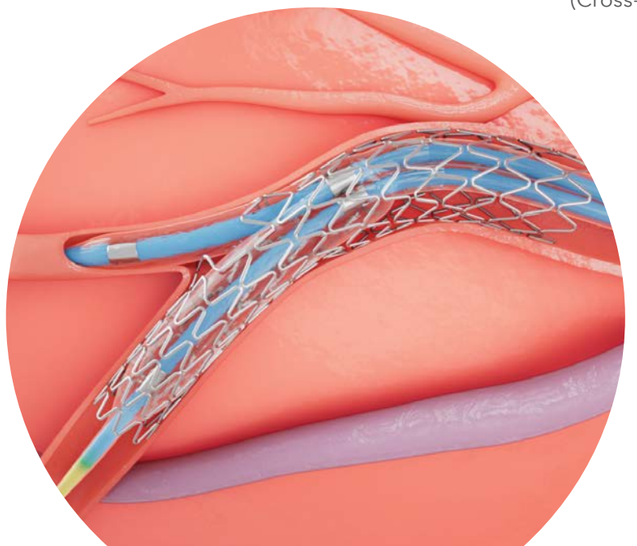
Optimised for complex PCI

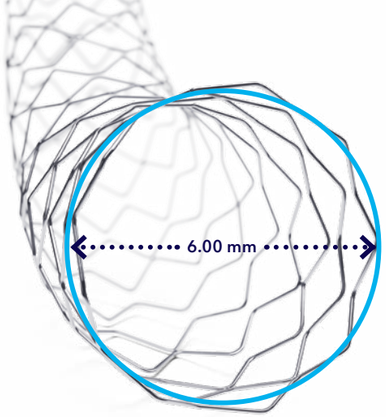
An exclusive set of design features and meaningful clinical data inherited from Resolute Onyx DES provide support for your most challenging cases.

Bifurcation PCI

- Other DES feature irregular cell shapes, which may obstruct wire or catheter advancement through the cell's opening
- Round struts create a smooth passage when accessing the side branch, while lowering the propensity to catch[5]

(Cross-section of actual stents)





4.50–5.00 mm expand up to 6.00 mm[§] while maintaining structural integrity

Left main and other extra-large vessel PCI
(4.50–5.00 mm)

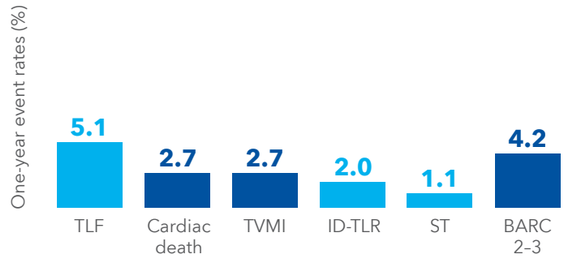
- Specifically designed with additional crowns and thicker struts to provide the radial strength needed for extra-large vessels[5]
- Maintains a low profile,[5] allowing for 5 F compatibility
- ROLEX Registry showed Resolute Onyx DES was safe and effective in left main PCI in a complex patient population[9]

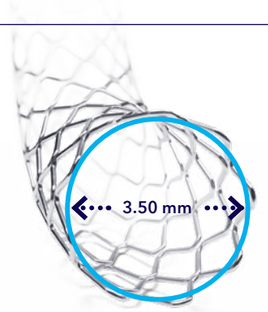
59% multivessel disease

53% acute coronary syndrome

30% diabetic

Low 5.1% TLF, 2.0% TLR, and 1.1% ST at one year





2.00–2.50 mm expand up to 3.50 mm[§] with minimal foreshortening for tapered and extra-small vessels[5]

Extra-small vessels
(2.00–2.50 mm)

- 2.0 mm offers the lowest crossing profile of any DES[5]
- Demonstrated 2% target lesion revascularisation and 0% stent thrombosis at one year in a complex, small-vessel population[10]

1-mo DAPT

Onyx Frontier DES is indicated for 1-month DAPT in high bleeding risk (HBR) patients, including those unable to tolerate long-term DAPT

Onyx ONE Global Trial[11]

1,003 Resolute Onyx DES patients studied

COMPLEX PATIENTS

33% AF patients

53% ACS patients

39% diabetic patients

COMPLEX LESIONS

46% moderate to severe calcified lesions

80% B2/C lesions

38 mm average stented length

- Indication is based on the results from the Onyx ONE Global Trial, which evaluated real-world, complex, HBR patients on 1-month DAPT treated with a Resolute Onyx DES or a BioFreedom™* DCS
- The data is intended to better inform short-DAPT decisions in these patients, including those at high risk of thrombotic events[11]
- Results showed that Resolute Onyx DES was safe and effective[11]

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†Stent delivery system updates were implemented on the 2.0–4.0 mm Onyx Frontier DES diameter.

‡Onyx Frontier DES has the same platinum-iridium core as Resolute Onyx DES.

§Stents should not be expanded to a diameter beyond the maximum labeled diameter listed per the IFU. Post-dilation required for overexpansion.

1 Based on bench test data on file at Medtronic. [D00339634 - Test Report for DES Competitive Comparison with Frontier test methods, Rev C, 05-May-2022] May not be indicative of clinical performance. N = 5 DES of each tested: Onyx Frontier DES, Orsiro Mission DES, Resolute Onyx DES, XIENCE Skypoint DES, SYNERGY DES, Ultimaster Tansei DES.

2 Based on bench test data on file at Medtronic. [44RD21031-040047 Onyx Frontier Vs Resolute Onyx Balloon Extrusion, Version 1.0, 17-Feb-2022] May not be indicative of clinical performance.

3 Based on bench test data on file at Medtronic. [D00339634 - Test Report for DES Competitive Comparison with Frontier test methods, Rev C, 05-May-2022] May not be indicative of clinical performance. N = 7 of each DES tested.

4 Third-party modeling and analysis. [Mortier MDT-ON14-report-curved-v10-20150220_Onyx_Synergy] Data may not be indicative of clinical performance. Evaluated the following stent platforms: Resolute Onyx DES, Multi-Link 8™* BMS, SYNERGY™* DES, XIENCE Alpine™* DES, and Multi-Link 8 platform.

5 Based on bench test data on file at Medtronic. [University of Budapest Visibility Testing, V0.1, 28-Sep-2021] May not be indicative of clinical performance.

6 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.

7 Based on bench test data on file at Medtronic. [University of Budapest Visibility Testing, V0.1, 28-Sep-2021; 10166182DOC Competitive Analysis Test Report, Rev AC, 08-Jun-2021] May not be indicative of clinical performance. Stents tested include Resolute Onyx DES, SYNERGY DES, XIENCE Sierra™* DES, and Orsiro DES.

8 Yeh RW, Silber S, Chen L, et al. 5-Year Safety and Efficacy of Resolute Zotarolimus-Eluting Stent: The RESOLUTE Global Clinical Trial Program. *JACC Cardiovasc Interv.* February 2017;10(3):247-254.

9 Tarantini G, et al. The ROLEX Registry (Revascularization Of LEft Main With Resolute onyX). Presented at PCR 2022. Investigator-initiated study funded by Medtronic.

10 Cuellas C, et al. Use of a Zotarolimus-eluting stent for small vessel disease (DISCO 9 Study). Presented at PCR 2021.

11 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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See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.