Medtronic

Onyx TruStar™ DES

Technical specifications

Vaistais padengti vainikinių arterijų stentai

Technical feature	Onyx TruStar DES†
Stent design	Single-wire design with platinum-iridium core
Polymer and drug	BioLinx™ polymer and zotarolimus (density ~1.6 µg/mm²)
Catheter distal shaft color	2.00–4.00 mm: yellow 4.50–5.00 mm: black
Catheter distal O.D. (Fr)	2.00–4.00 mm: 2.8 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: platinum-iridium
Strut thickness	2.00–4.00 mm: 81 µm (0.0032 in) 4.50–5.00 mm: 91 µm (0.0036 in)
Stent crossing profile (in)[1]	0.038 (3.0 mm x 18 mm)
Tip O.D. (in)[1]	0.023 (3.0 mm x 18 mm)
Balloon material	2.00-4.00 mm: dual-flex balloon comprised of Pebax®* blend 4.50-5.00 mm: single-layer balloon comprised of Pebax blend
Platform	Rapid exchange
Catheter length (cm)	140
Nominal pressure (atm)	12
Rated burst pressure (atm)	2.00–4.00 mm: 18 4.50–5.00 mm: 16
Stent marker bands	Average 0.5 mm between stent edges and two platinum-iridium marker bands (3.0 mm x 18 mm). Tolerances of up to 1.0 mm for 8-12 mm lengths and 1.5 mm for 15-38 mm lengths.
Latex-free	Onyx TruStar DES does not contain natural rubber latex as either a component or packaging of the device
MRI compatibility	MR-conditional for single and overlapping stent lengths up to 120 mm. Please refer to IFU for additional conditions.

Padengti -limus klasės vaistu.

Tinka ir stambioms ir smulkioms koronarinėms arterijoms

kobalto-chromo lydinys su platinos-iridžio šerdimi

Stento sienelės storis:
0,0032” (81 µm) 2-4 mm diametro stentams
0,0036” (91 µm) 4-5 mm diametro stentams

Nominalus slėgis 12 atm, išbandytasis plyšimo slėgis (RBP)18 atm (16 atm stentams, kurių diametrai 4.5-5.00 mm)

Du rentgeno kontrastiniai markeriai ant baliono visiems ilgiams, geras rentgeno kontrastavimas.

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

Galimybė išplėsti stentą papildomai 1.5 mm nuo nominalaus diametro, nepažeidžiant stento integralumo

Maksimalus stento išsiplėtimo diametras (MSID)

Size matrix

Diameter (mm)	Stent length (mm)									MSID‡ (mm)
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
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
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
4.50	––	12	15	18	22	26	30	––	––	6.00
5.00	––	12	15	18	22	26	30	––	––	6.00

Stentų dydžiai:
2.00 mm diametro stentų ilgiai - 8, 12, 15, 18, 22, 26, 30 mm,
nuo 2,25 mm iki 4,00 mm diametrų stentų ilgiai - 8, 12, 15, 18, 22, 26, 30, 34, 38 mm,
4,50 mm ir 5,00 mm diametro stentų ilgiai - 12, 15, 18, 22, 26, 30 mm

‡Maximum stent inner diameter. Onyx TruStar DES should not be expanded to a diameter beyond the listed MSID. Onyx TruStar DES is not available in OTW.
†Based on bench test data on file at Medtronic. May not be indicative of clinical performance. N = 5 of each DES tested.

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Onyx TruStar™ DES

Designed to lead the way

Designed to deliver

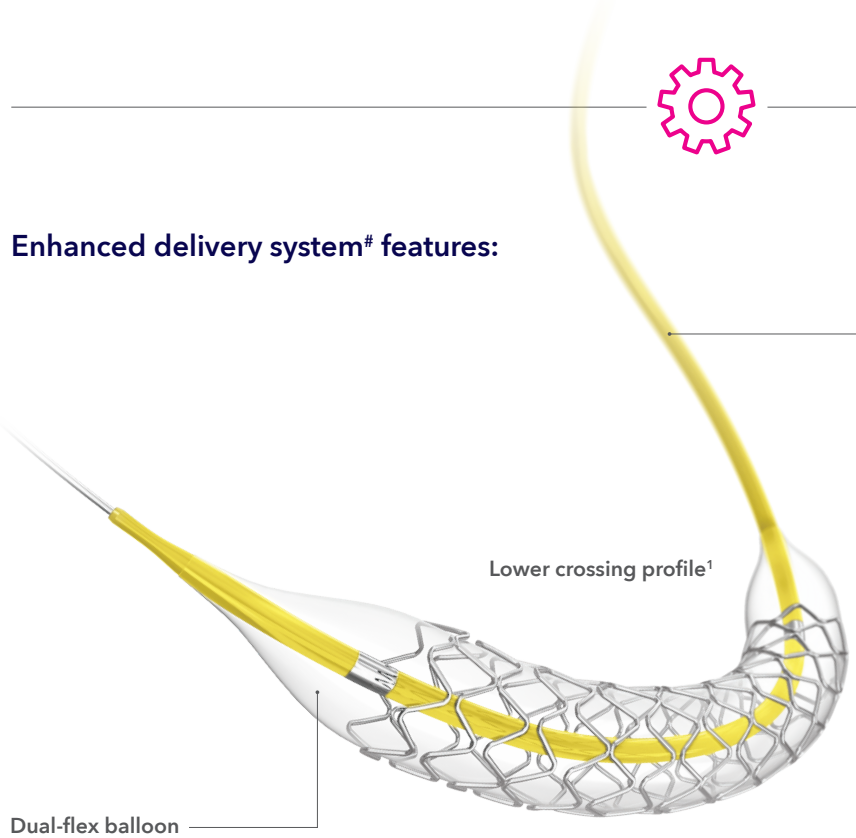
Designed differently

Designed for complex PCI

Designed to deliver

Onyx TruStar DES introduces an enhanced delivery system[#] designed to take the acute performance of Resolute Onyx™ DES even further.

Enhanced delivery system[#] features:

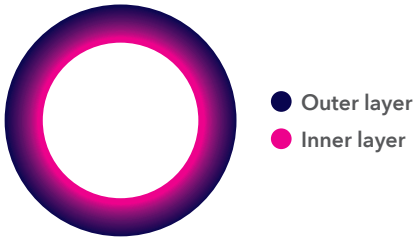


An updated manufacturing process applied to the outer shaft results in a 29% more flexible catheter[1] (compared to Resolute Onyx DES) for improved deliverability.[2]

Provides increased flexibility and is comprised of a unique blend of two layers:

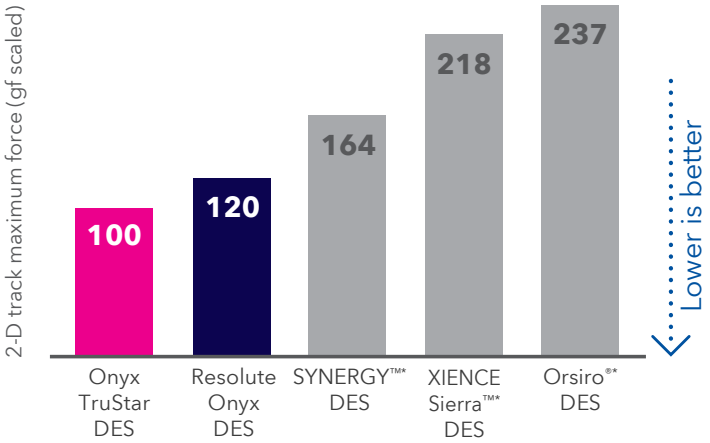
- Inner layer enhances flexibility[3]
- Outer layer maintains strength[4]

This results in a thinner balloon[##] with the same rated burst pressure (RBP)[4] and a 7.5% lower crossing profile compared to Resolute Onyx DES.[1]



Deliverability comparison

3.0 mm DES



At least

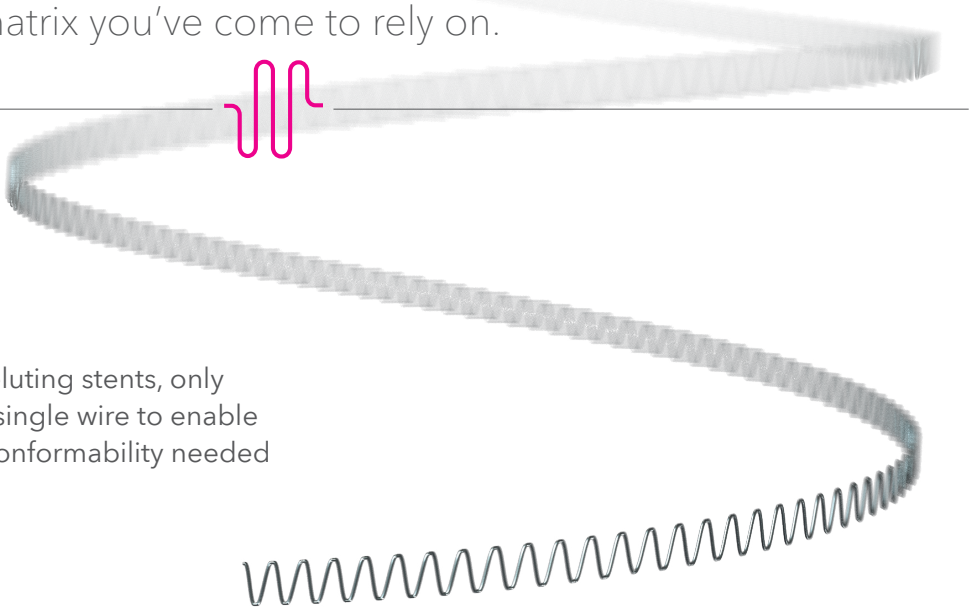
39%

more deliverable than competitive DES[#2]

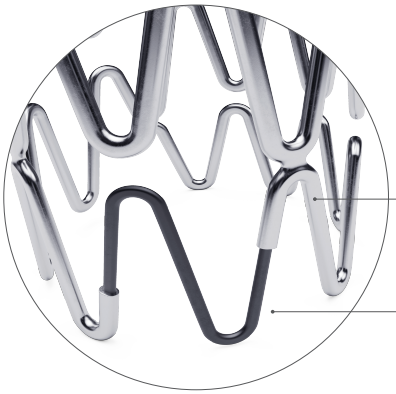
[#]Stent delivery system updates were implemented on the 2.0–4.0 mm Onyx TruStar DES diameters.

Designed differently

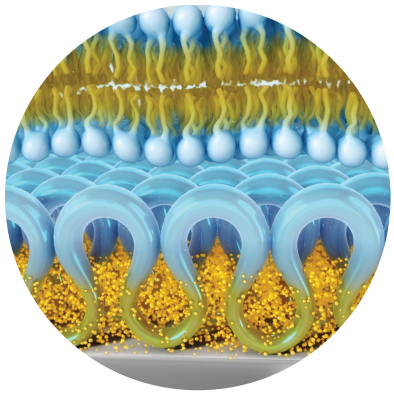
Onyx TruStar DES builds off the legacy of Resolute Onyx DES, featuring the same stent design differentiators that provide the conformability,[5] visibility,[6] fast healing,[7] and size matrix you've come to rely on.



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.[5]



The platinum-iridium core within Onyx TruStar DES is more visible[6] than competitive DES, while enabling greater radial strength[6] with thin struts.



The zotarolimus drug inhibits neointimal growth,[8] while the BioLinx™ biocompatible polymer – the only polymer specifically designed for a DES – promotes faster healing.[7]

Only Medtronic offers DES in 2.0 mm to 5.0 mm sizes, with overexpansion capabilities up to 6.0 mm,[§] to treat the broadest range of coronary vessel diameters.

Platform	Diameter (mm)	Stent length (mm)									MSID[§] (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.

Designed 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.

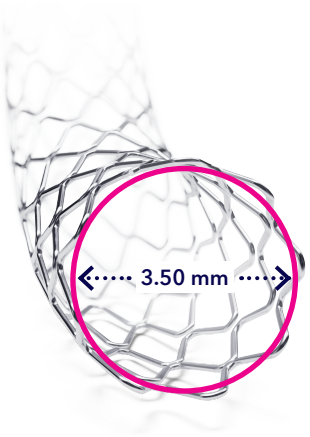
(Cross-section of actual stents)

Bifurcation PCI

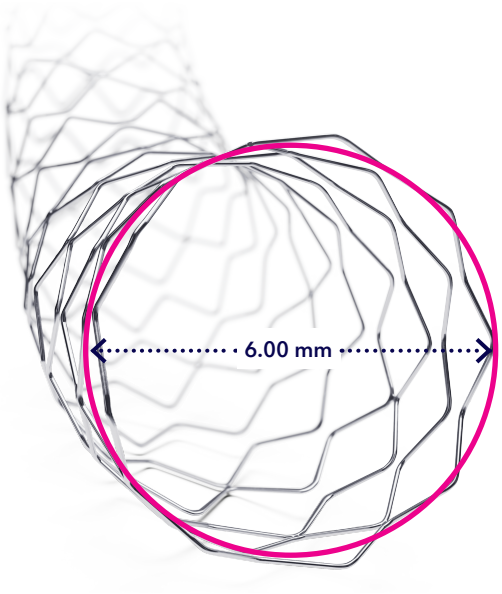
- Other DES feature irregular cell shapes, which may obstruct wire or catheter advancement through the cell's opening
- Round struts create a smooth passage when accessing the side branch, while lowering the propensity to catch[9]

Extra-small vessels (2.00–2.50 mm)

- 2.0 mm offers the lowest crossing profile of any DES[10]
- Demonstrated 2% target lesion revascularisation and 0% stent thrombosis at one year in a complex, small-vessel population[11]

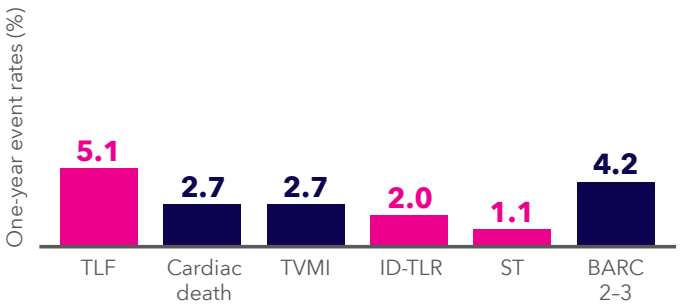


2.00–2.50 mm expand up to 3.50 mm[§] with minimal foreshortening for tapered and extra-small vessels[12]



4.50–5.00 mm expand up to 6.00 mm[§] while maintaining structural integrity[12]

ROLEX Registry
Low 5.1% TLF, 2.0% TLR, and 1.1% ST at one year[13]



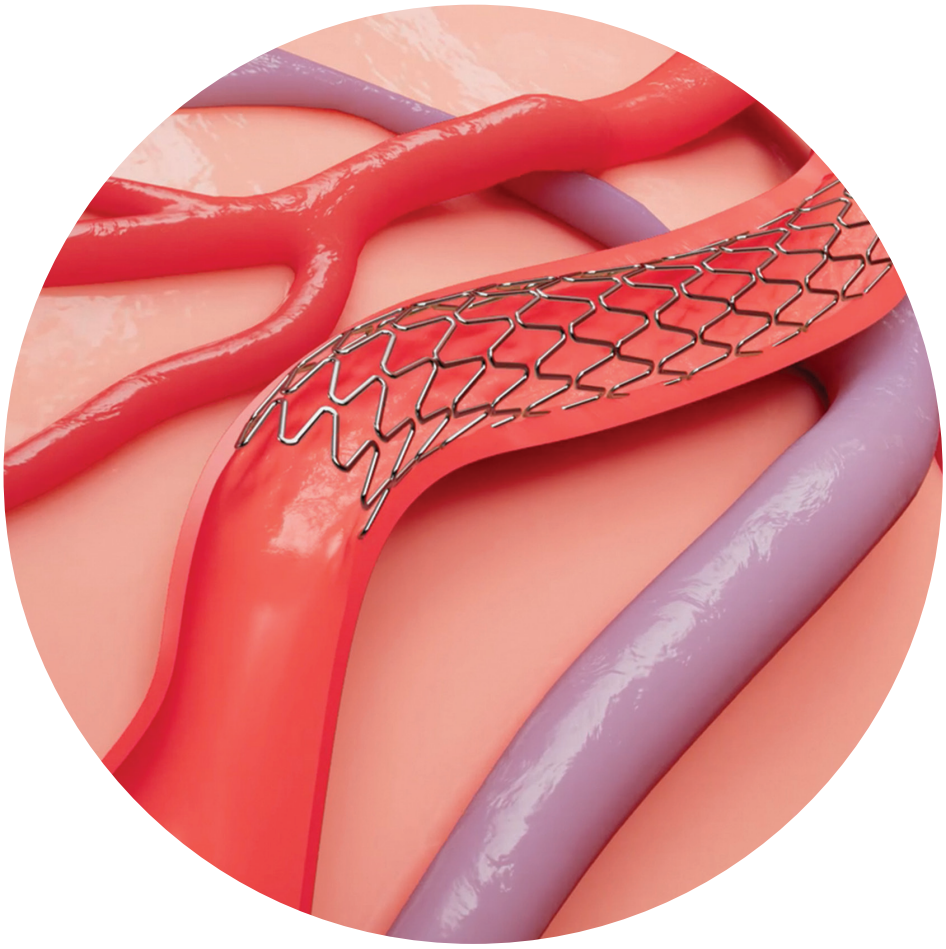
Left main and other extra-large vessel PCI (4.50–5.00 mm)

- Specifically designed with additional crowns and thicker struts[¤] to provide the radial strength needed for the left main and extra-large vessels[12]
- ROLEX Registry showed Resolute Onyx DES was safe and effective in left main PCI in a complex patient population[13]

59% multivessel disease

53% acute coronary syndrome

30% diabetic



1-mo DAPT

Onyx TruStar 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[14]

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[14]
- Results showed that Resolute Onyx DES was safe and effective[14]

Ordering information

TSTAR225**08**X

- Rapid exchange
- Length
- Diameter
- Product

Stent diameter (mm)	Stent length (mm)								
	8	12	15	18	22	26	30	34	38
2.00	TSTAR20008X	TSTAR20012X	TSTAR20015X	TSTAR20018X	TSTAR20022X	TSTAR20026X	TSTAR20030X	––	––
2.25	TSTAR22508X	TSTAR22512X	TSTAR22515X	TSTAR22518X	TSTAR22522X	TSTAR22526X	TSTAR22530X	TSTAR22534X	TSTAR22538X
2.50	TSTAR25008X	TSTAR25012X	TSTAR25015X	TSTAR25018X	TSTAR25022X	TSTAR25026X	TSTAR25030X	TSTAR25034X	TSTAR25038X
2.75	TSTAR27508X	TSTAR27512X	TSTAR27515X	TSTAR27518X	TSTAR27522X	TSTAR27526X	TSTAR27530X	TSTAR27534X	TSTAR27538X
3.00	TSTAR30008X	TSTAR30012X	TSTAR30015X	TSTAR30018X	TSTAR30022X	TSTAR30026X	TSTAR30030X	TSTAR30034X	TSTAR30038X
3.50	TSTAR35008X	TSTAR35012X	TSTAR35015X	TSTAR35018X	TSTAR35022X	TSTAR35026X	TSTAR35030X	TSTAR35034X	TSTAR35038X
4.00	TSTAR40008X	TSTAR40012X	TSTAR40015X	TSTAR40018X	TSTAR40022X	TSTAR40026X	TSTAR40030X	TSTAR40034X	TSTAR40038X
4.50	–	TSTAR45012X	TSTAR45015X	TSTAR45018X	TSTAR45022X	TSTAR45026X	TSTAR45030X	––	––
5.00	–	TSTAR50012X	TSTAR50015X	TSTAR50018X	TSTAR50022X	TSTAR50026X	TSTAR50030X	––	––

5 F min. guide catheter I.D.: 1.4 mm (0.056 in)

™*Third-party brands are trademarks of their respective owners.
#Stent delivery system updates were implemented on the 2.0–4.0 mm Onyx TruStar DES diameter.
##Compared to Resolute Onyx 3.0 mm balloon design.
§Stents should not be expanded to a diameter beyond the maximum labeled diameter listed per the IFU. Post-dilation required for overexpansion.
ΩCompared to 2.0–4.0 mm sizes.

1 Based on bench test data on file at Medtronic, D00624519, Rev A. Compared to Resolute Onyx DES. May not be indicative of clinical performance.
2 Based on bench test data on file at Medtronic, D00339634, Rev C. May not be indicative of clinical performance. N = 7 DES of each tested: Onyx TruStar DES, Resolute Onyx DES, Orsiro®* DES, XIENCE Sierra™* DES, SYNERGY™* DES.
3 Based on bench test data on file at Medtronic, 44RD21031-040047, Version 1.0. Compared to Resolute Onyx DES. May not be indicative of clinical performance.
4 Resolute Onyx DES IFU M989444A002 C 2021-12-03 and Onyx TruStar DES IFUs M031943C002 A 2022-04-28.
5 Third-party modeling and analysis, Mortier MDT-ON14-report-curved-v10-20150220_Onyx_Synergy.pdf. May not be indicative of clinical performance. Evaluated the following stent platforms: Resolute Onyx DES, SYNERGY™* DES, and XIENCE Alpine™* DES (Multi-Link 8 platform).
6 Based on bench test data on file at Medtronic, CO10276086 University of Budapest Visibility Testing, v1. May not be indicative of clinical performance.
7 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.
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 13, 2017;10(3):247-254.
9 Based on bench test data on file at Medtronic, Concept Select Tip Catch Frequency for S10 MV_Jason_.xls, V1.0. May not be indicative of clinical performance.
10 Based on bench test data on file at Medtronic, D00339634 , Rev C. May not be indicative of clinical performance. N=5 of each DES tested.
11 Cuellas C, et al. Use of a Zotarolimus-eluting stent for small vessel disease (DISCO 9 Study). Presented at PCR 2021.
12 Bench test data on file at Medtronic, D00333762, Rev A. May not be indicative of clinical performance.
13 Tarantini G, Fovino LN, Varbella F, et al. A large, prospective, multicentre study of left main PCI using a latest-generation zotarolimus-eluting stent: the ROLEX study. *EuroIntervention.* Published online August 31, 2022.
14 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.

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.

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DEVICE SPECIFICATIONS

	Resolute Onyx™ DES	Synergy™* DES
Stent Material	Cobalt alloy with PtIr core	Platinum Chromium alloy
Stent Design	Single Wire CST Core Wire Technology	Laser cut slotted tube
Drug Elution	180 days	90 days
Polymer	Durable BioLinx™	Bioabsorbable PLGA
Polymer Resorption Time	N/A	120 days
Strut thickness dimensions	81 µm (2.0 – 4.0 mm) 91 µm (4.5 –5.0 mm)	74 µm (2.25 – 2.75 mm) 79 µm (3.0 – 3.5 mm) 81 µm (4.0 – 5.0 mm)
Nominal Pressure	12 atm	11 atm
Rated Burst Pressure	18 atm (2.0 - 4.0 mm) 16 atm (4.5 –5.0 mm)	18 atm (2.25 – 2.75 mm) 16 atm (3.0 –5.0 mm)
Total sizes approved (OUS)	73	65

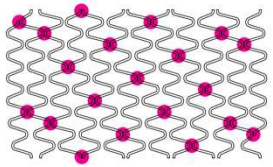
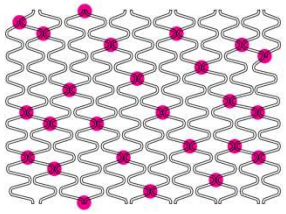
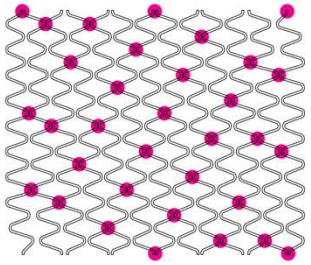
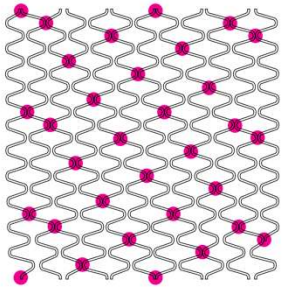
kobalto-chromo lydinys su platinos-iridžio šerdimi

Padengti biosuderinamu polimeru, galinčiu užtikrinti vaisto išskyrimą iki 180 dienų.

Per Resolute Onyx™ IFU & Synergy™* IFU

Medtronic

Onyx TruStar™ DES technical specifications

Characteristic per stent diameter (mm)	2.00, 2.25, 2.50	2.75, 3.00	3.50, 4.00	4.50, 5.00
Strut thickness dimensions (in/µm)	0.0032/81	0.0032/81	0.0032/81	0.0036/91
Stent design	Single-wire design with platinum-iridium core			
Crowns	6.5	8.5	9.5	10.5
Maximum expansion/MSID† (mm)	3.50	4.00	5.00	6.00
Cell diameter (mm)[1]	3.8	4.6	4.4	5.0
Stent core/outer material	Platinum-iridium/cobalt alloy			
Fusion pattern	Every 4th crown fused	Every 5th crown fused	Every 4th crown fused	Every 4th crown fused
				

†Stents should not be expanded to a diameter beyond the maximum labeled diameter listed per the IFU. Post-dilatation required for overexpansion.
[1] Based on bench test data. May not be indicative of clinical performance. n=5 of each DES.
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