1.1 Device Component Description

The Medtronic Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System (Resolute Onyx™ system) consists of a balloon-expandable, intracoronary, drug-eluting stent (DES) premounted on a Rapid Exchange (RX) or an Over-the-Wire (OTW) stent delivery system. The Resolute Onyx™ stent is manufactured from a composite material of cobalt alloy and platinum-iridium alloy and is formed from a single wire bent into a continuous sinusoid pattern and then laser fused back onto itself. The stents are available in multiple lengths and diameters. The delivery system has two radiopaque markers to aid in the placement of the stent during fluoroscopy and is compatible with 0.014-inch (0.36-mm) guidewires and 1.42-mm (5-Fr/0.056-in) minimum inner diameter guide catheters. The Resolute Onyx™ RX delivery system (Figure 1-1) and the Resolute Onyx™ OTW delivery system (Figure 1-2) have an effective length of 140 cm.

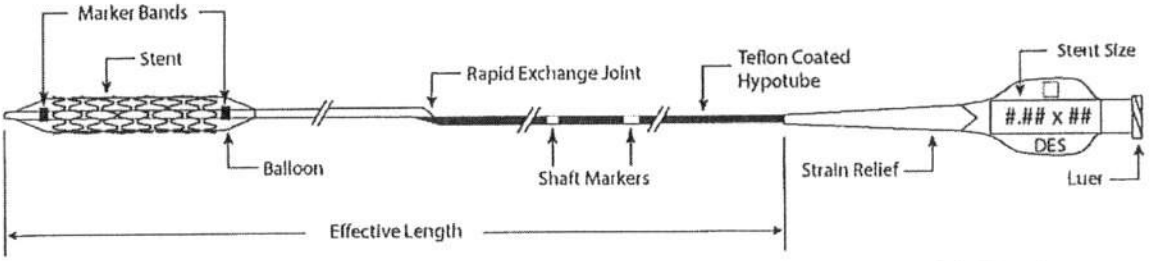


Figure 1-1: Resolute Onyx™ Rapid Exchange (RX) Delivery System (with Stent)
Illustration is not to scale

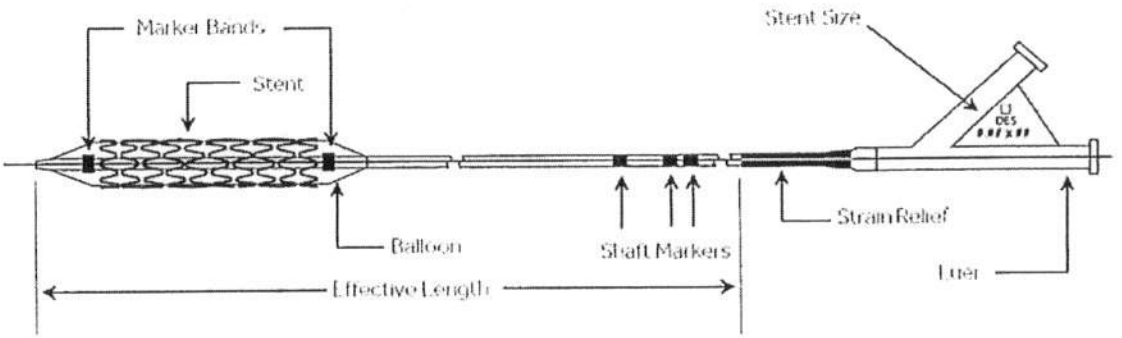
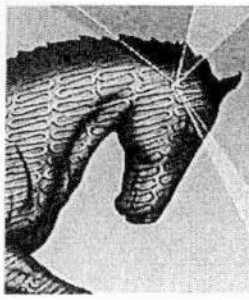


Figure 1-2: Resolute Onyx™ Over-the-Wire (OTW) Delivery System (with Stent)
Illustration is not to scale

The stent is crimped on various sizes of delivery catheter balloons, which range from 2.25 mm to 5.0 mm. The Resolute Onyx™ available stent sizes are listed in Table 1-2.



Medtronic

Resolute Onyx™

ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

THE ADVANCED WORKHORSE | POWERED BY CORE WIRE TECHNOLOGY

TECHNICAL SPECIFICATIONS

Overview

The Resolute Onyx™ coronary stent system (CE Mark approval: 2.00–4.00-mm diameters, September 2014; 4.50–5.00-mm diameters, April 2015) is being introduced to enhance the already high-performing Resolute™ portfolio.

Design and Clinical Rationale

The Resolute Onyx coronary stent system further enhances stent deliverability and radiopacity without compromising key mechanical attributes and elution characteristics of the Resolute™ and Resolute Integrity™ stents.

- **Resolute Onyx™ stent:** Stent performance is improved by combining Core Wire Technology (CWT) and Continuous Sinusoid Technology (CST). In combination, these two innovations in stent manufacturing allow for reduced strut thickness and improved radiopacity without compromising radial strength, recoil or scaffolding. By utilising a composite wire material, stent visualisation is enhanced with a more radiopaque core while maintaining all of the proven performance of the cobalt alloy shell.
- **Resolute Onyx™ delivery system:** The delivery system improves upon the proven MicroTrac™ delivery system, enhancing deliverability, nominal deployment (12 atm) and rated burst pressure (18 atm*). Optimising the design provides a well-balanced delivery system with greater flexibility, a lower crossing profile and utilisation of PowerTrac™ technology, resulting in a more deliverable device.
- **Zotarolimus drug:** The Resolute Onyx stent system delivers the same concentration of noncytotoxic zotarolimus drug to the vessel lesion.
- **BioLinx™ polymer:** The BioLinx polymer continues to be used to ensure biocompatible and extended drug delivery.

Features and Benefits

- **Most deliverable DES,† featuring Core Wire Technology**
  - Resolute Onyx DES builds on the Integrity™ platform's acute procedural success‡ for even greater flexibility and conformability
  - Core Wire Technology enables thinner struts with increased radiopacity and no compromise to radial or longitudinal strength
- **Broadest size matrix to optimise treatment of complex clinical scenarios**
  - A new 2.00-mm diameter with longer stent lengths expands treatment options for patients with diabetes and diffuse disease
- **Proven long-term safety and efficacy shown in the Global RESOLUTE Program**
  - No increased risk for stent thrombosis with interruption or discontinuation of DAPT after one month§
  - Sustained safety of 1.2% ST through five years in more than 7500 patients from the RESOLUTE Pooled analysis

2.6

*RBP for 4.50–5.00-mm sizes is 16 atm.
†Based on bench test data vs. Promus Premier™ DES, Synergy™ II DES, Xience Xpedition™ DES and Resolute Integrity DES
‡DELIVER study
§Silbers et al. *Eur Heart J.* 2014;35(29):1949–1956.

Resolute **Onyx**™

ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

Resolute Onyx DES is designed to build on the market-leading clinical performance that Resolute DES demonstrated in the RESOLUTE All Comers clinical trial. Resolute Onyx DES offers the superior deliverability of the Integrity platform without compromising the drug elution characteristics of Resolute Integrity DES.

Expanded Size Matrix

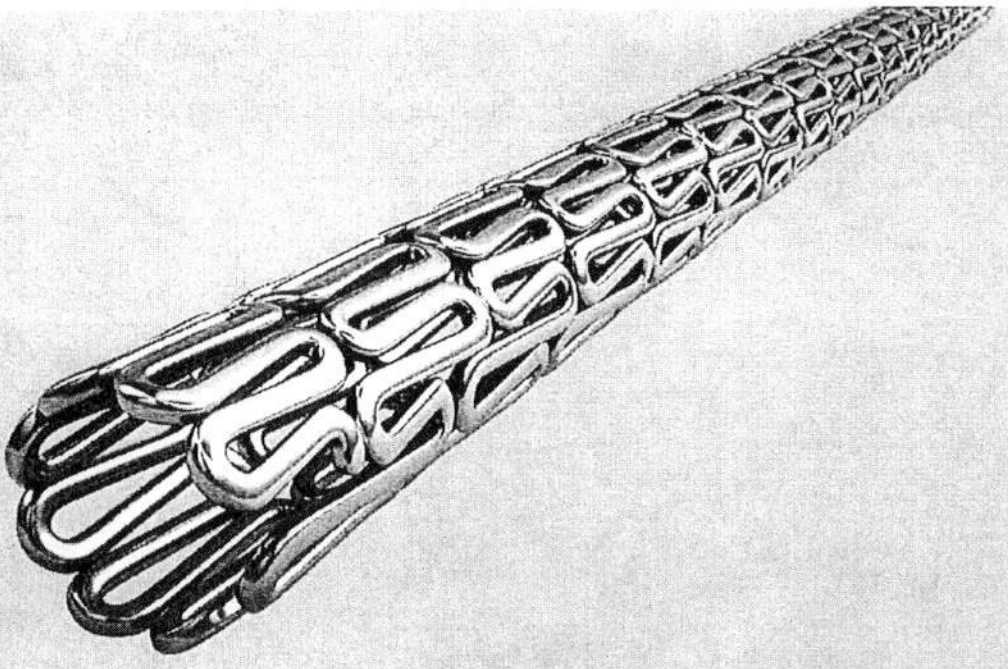
Diameter (mm)	Stent Length (mm)								
2.00 ✓	8	12	15	18	22	26	30		
2.25	8	12	15	18	22	26	30	34	38
2.50	8	12	15	18	22	26	30	34	38
2.75	8	12	15	18	22	26	30	34	38
3.00	8	12	15	18	22	26	30	34	38
3.50	8	12	15	18	22	26	30	34	38
4.00	8	12	15	18	22	26	30	34	38 ✓
4.50		12	15	18	22	26	30		
5.00		12	15	18	22	26	30		

Shaded cells highlight modifications to the size matrix: 2.00-mm stents and 34- and 38-mm lengths expand the size matrix; an 8-mm length replaces the 9-mm Resolute Integrity length; and a 15-mm length replaces the 14-mm Resolute Integrity length.
2.00–2.50-mm stents can be expanded to 3.25 mm; 2.75–3.00-mm stents can be expanded to 3.75 mm; 3.50–4.00-mm stents can be expanded to 4.75 mm; 4.50–5.00-mm stents can be expanded to 5.75 mm.

Technical Improvements

Technical Feature	Resolute Integrity DES	Resolute Onyx DES
Stent design 2.4 ✓	Integrity™ BMS Continuous Sinusoid Technology	Continuous Sinusoid Technology with Core Wire Technology
Drug and polymer	BioLinx and zotarolimus	No change
Delivery system	MicroTrac	Resolute Onyx
Catheter distal shaft O.D. (F)	2.7	2.7 (2.00–4.00 mm) 3.2 (4.50–5.00 mm)
Catheter distal shaft O.D. (in.)	0.036	0.036 (2.00–4.00 mm) 0.042 (4.50–5.00 mm)

Visit



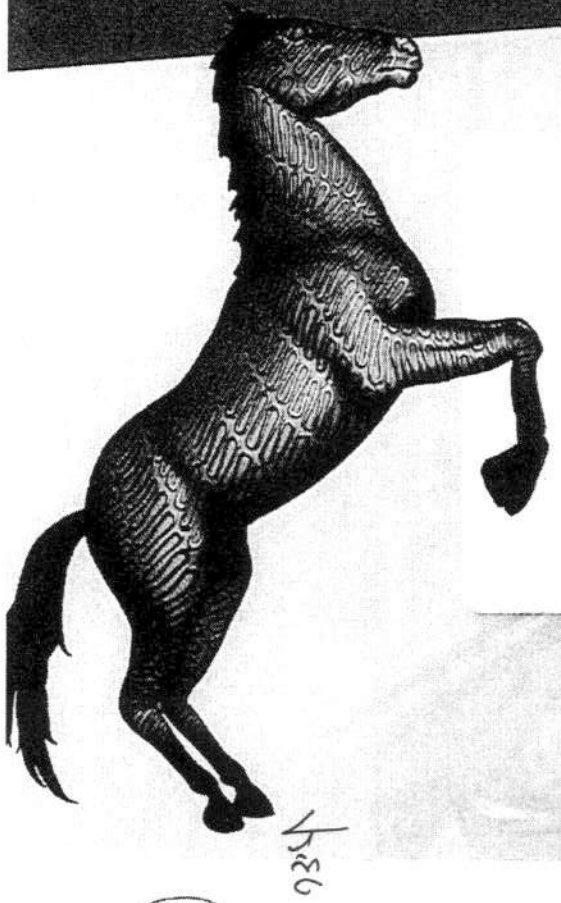
Changes in Selected Technical Specifications

Technical Feature	Resolute Integrity DES	Resolute Onyx DES
Crowns	Small vessel (2.25–2.75 mm): 7.5 Medium vessel (3.00–4.00 mm): 9.5	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	Cobalt alloy conforming to ASTM F562-02	Shell: No change Core: Pt–Ir
Strut thickness	91 µ (0.0036 in.)	81 µ (0.0032 in.) (2.00–4.00 mm) 91 µ (0.0036 in.) (4.50–5.00 mm)
Polymer coating	BioLinx (C10:C19:PVP = 27:63:10)	No change
Base coating	Parylene C	No change
Drug density	Zotarolimus (~1.6 µg/mm²)	No change
Delivery system	MicroTrac	Resolute Onyx
Balloon material	Fulcrum™	Improved
Platform	RX	No change
Catheter length (cm)	140	No change
Nominal pressure (atm)	9	12 (2.00–5.00 mm)
Rated burst pressure (atm)	16	18 (2.00–4.00 mm) 16 (4.50–5.00 mm)
Crimping technology	Secure Technology	No change
Marker band material	Gold	Platinum iridium

Resolute Onyx™ DES

The Advanced Workhorse

RANGE OF SIZES



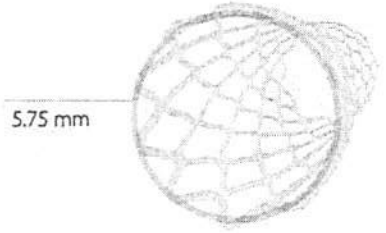
Most deliverable DES,[1] featuring Core Wire Technology

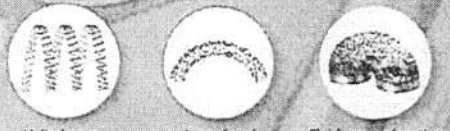
Broadest size matrix to optimise treatment of complex clinical scenarios

Proven long-term safety and efficacy shown in the Global RESOLUTE Program[2]

COMPLE**XLV**

COMPLE**XLV** 4.5- and 5.0-mm sizes are specifically designed to expand treatment options for extra-large vessels and feature the same proven safety profile of Resolute Onyx™ DES.





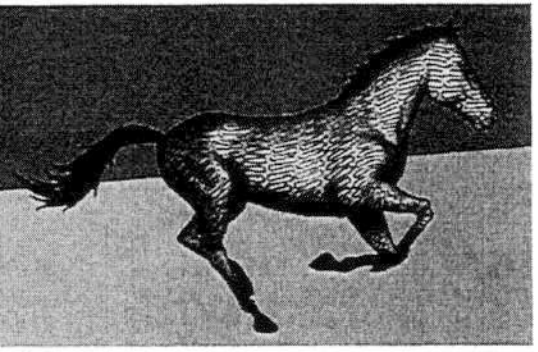
CONTINUOUS SINUSOID TECHNOLOGY

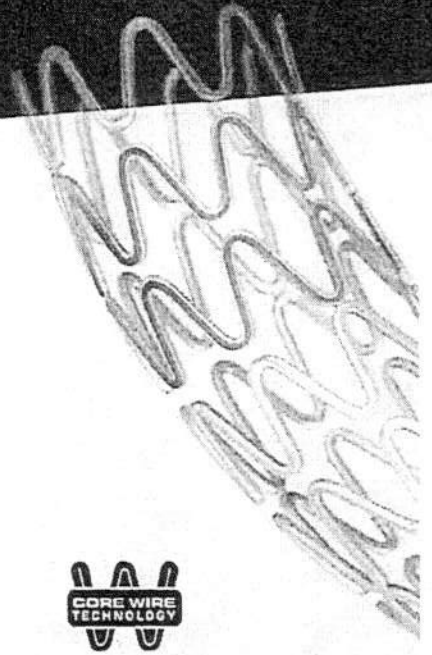
Resolute Onyx DES is manufactured from a single strand of core wire into a continuous sinusoidal wave form to provide a fluid range of motion.

The Most Deliverable DES[3]

Featuring Core Wire Technology

PROCEDURAL SUCCESS



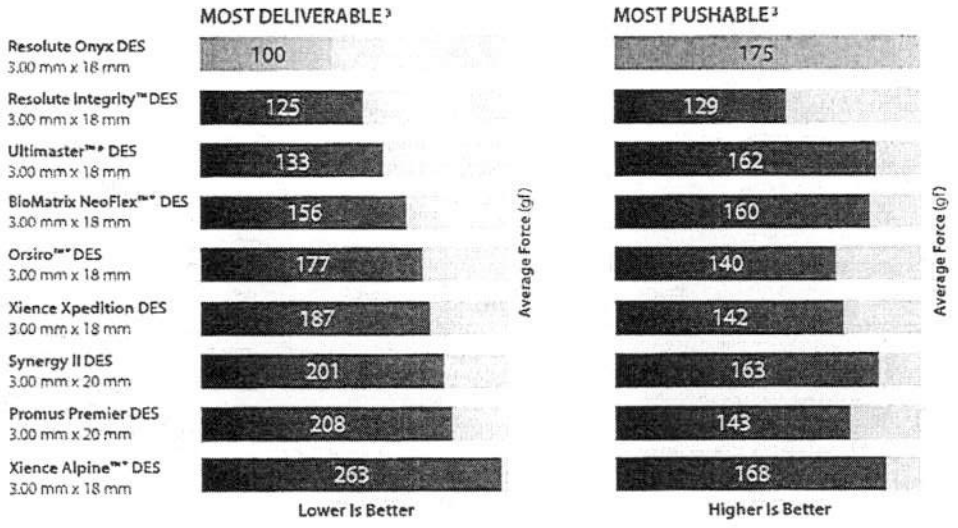


CORE WIRE TECHNOLOGY

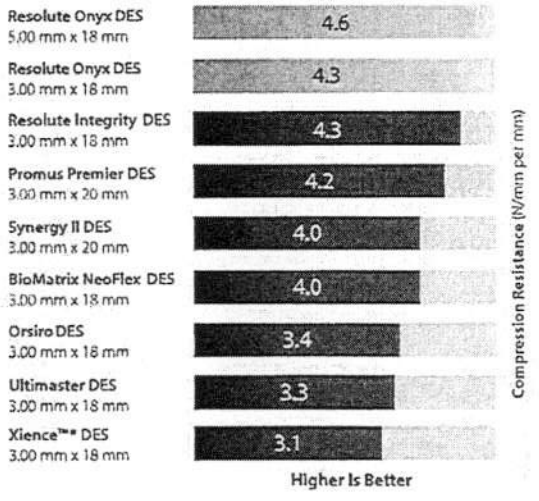
CORE WIRE TECHNOLOGY ENABLES:

- Increased deliverability
- Thinner struts with enhanced radiopacity
- No compromise to structural strength

EVEN GREATER DELIVERABILITY AND PUSHABILITY



SUSTAINED RADIAL STRENGTH

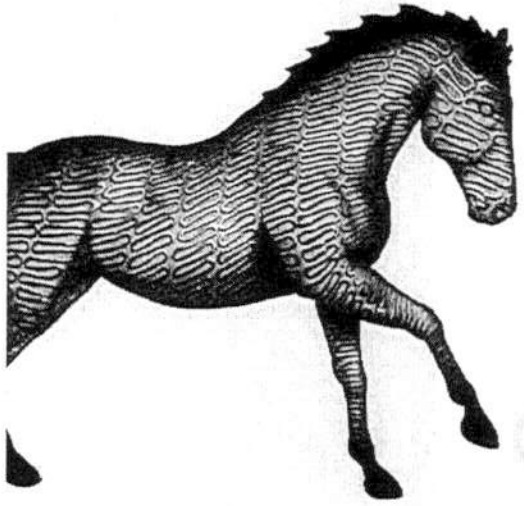


Based on bench test data vs. Promus Premier DES, Synergy II DES, Xience Xpedition DES and Resolute Integrity DES.

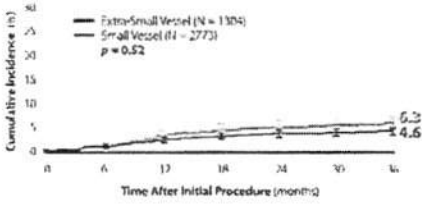
Broadest Size Matrix

To optimise treatment of complex clinical scenarios

COMPLEX CASES



EXCELLENT RESULTS IN PATIENTS WITH EXTRA-SMALL VESSELS[4]



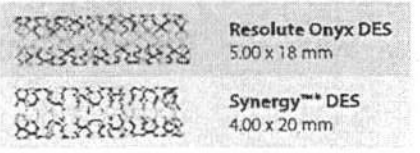
RVD up to 5.0 mm	Diabetes
Long lesions	ACS
CTOs	UA
Total occlusions	Bifurcations
AMIs	DAPT: Low risk of ST after one month
ISR	
Multivessels	

CONSIDERATIONS FOR TREATING EXTRA-LARGE VESSELS

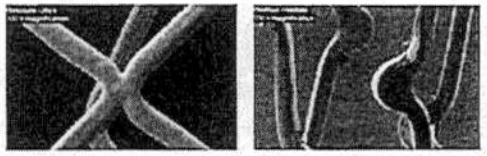
Standard DES treatment has historically involved overexpanding a 4.0-mm stent; however, important considerations exist:

- Radial strength and stent recoil
- Vessel scaffolding
- Foreshortening
- Resistance to longitudinal compression

Maximum labelled overexpansion capabilities
COMPLEXLV offers enhanced scaffolding and less foreshortening.



Impact to DES coating integrity
COMPLEXLV maintains drug-coating integrity even when overexpanded.



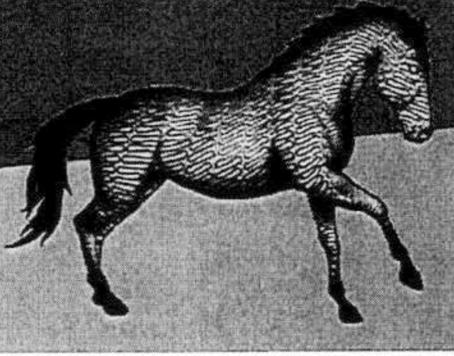
Featuring a 2.0-mm diameter and longer stent lengths

Proven Long-Term Safety and Efficacy

Shown in the Global RESOLUTE Program

SAFETY ASSURED

Comprehensive, unique Global RESOLUTE Program with more than 7500 patients enrolled.

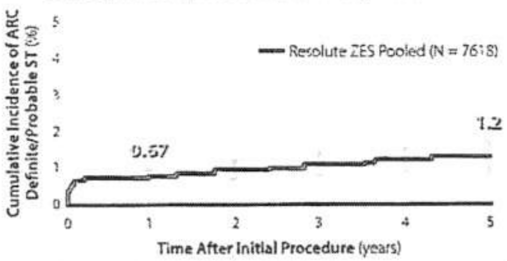


One year data from the RESOLUTE Clinical Program indicates low stent thrombosis rates for those that interrupted or discontinued DAPT any time after one month. While physicians should adhere to current ESC or ACC/AHA/SCAI guidelines for PCI, patients who interrupt or discontinue DAPT medication one month or more after stent implantation are considered at low risk and showed no increased risk for stent thrombosis. Early discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, MI or death.

—DAPT language in CE Mark *IFU*

SUSTAINED SAFETY OF 1.2% ST THROUGH FIVE YEARS IN MORE THAN 7500 PATIENTS[5]

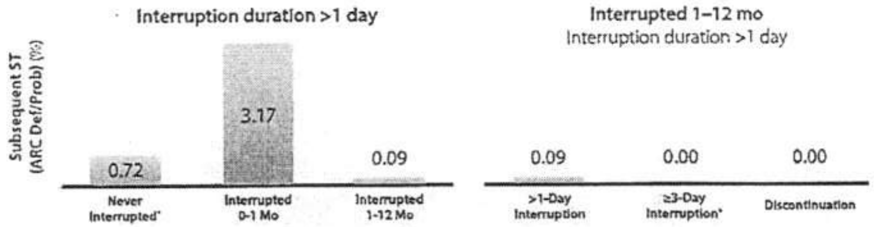
RESOLUTE Pooled Analysis of More Than 7500 Patients Stent Thrombosis (ARC Definite/Probable) at 5 Years



No. at risk	7618	7610	7344	6676	4511	2443
% CI	0.08	0.67	0.84	0.95	1.07	1.20

NO INCREASED RISK FOR ST WITH INTERRUPTION OR DISCONTINUATION OF DAPT AFTER ONE MONTH[6]

Timing of First DAPT Interruption and ST Through 1 Year



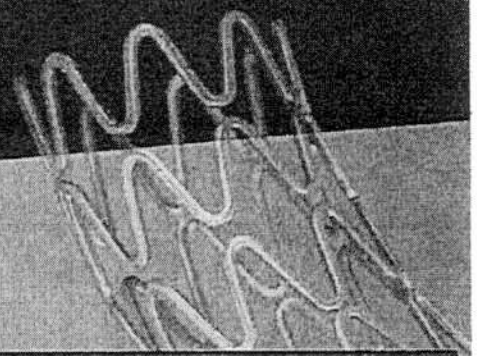
	Never Interrupted*	Interrupted 0-1 Mo	Interrupted 1-12 Mo	>1-Day Interruption	≥3-Day Interruption†	Discontinuation
Patients at risk	5816	221	1094	1094	1059	744
No. of events	42	7	11	1	0	0
Median days to interruption	NA	3	240.5	240.5	242	273

Three-year follow-up was available in almost 5000 patients and showed no increased ST risk in patients interrupting beyond one month[1].
(R-China, R-Japan SVS, R-Asia, R-US 38 mm and China Registry have not completed follow-up beyond one year and will be included in future analyses).

Product Information

RONYX22508X

- RONYX — Product Code
- 225 — Diameter
- 08 — Length
- X — Rapid Exchange



Ordering Information

Stent Diameter (mm)	Stent Length (mm)								
	8	12	15	18	22	26	30	34	38
2.00	RONYX20008X	RONYX20012X	RONYX20015X	RONYX20018X	RONYX20022X	RONYX20026X	RONYX20030X	—	—
2.25	RONYX22508X	RONYX22512X	RONYX22515X	RONYX22518X	RONYX22522X	RONYX22526X	RONYX22530X	RONYX22534X	RONYX22538X
2.50	RONYX25008X	RONYX25012X	RONYX25015X	RONYX25018X	RONYX25022X	RONYX25026X	RONYX25030X	RONYX25034X	RONYX25038X
2.75	RONYX27508X	RONYX27512X	RONYX27515X	RONYX27518X	RONYX27522X	RONYX27526X	RONYX27530X	RONYX27534X	RONYX27538X
3.00	RONYX30008X	RONYX30012X	RONYX30015X	RONYX30018X	RONYX30022X	RONYX30026X	RONYX30030X	RONYX30034X	RONYX30038X
3.50	RONYX35008X	RONYX35012X	RONYX35015X	RONYX35018X	RONYX35022X	RONYX35026X	RONYX35030X	RONYX35034X	RONYX35038X
4.00	RONYX40008X	RONYX40012X	RONYX40015X	RONYX40018X	RONYX40022X	RONYX40026X	RONYX40030X	RONYX40034X	RONYX40038X
4.50	—	RONYX45012X	RONYX45015X	RONYX45018X	RONYX45022X	RONYX45026X	RONYX45030X	—	—
5.00	—	RONYX50012X	RONYX50015X	RONYX50018X	RONYX50022X	RONYX50026X	RONYX50030X	—	—

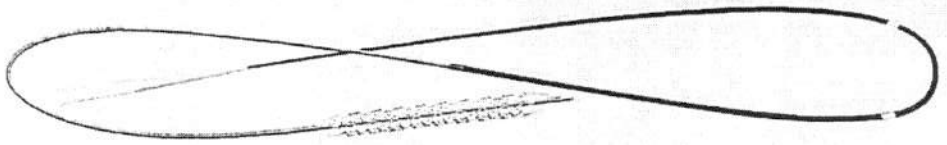
○ Indicates new sizes

Lubricious hydrophilic coating for reduced drag

0.69 mm (2.1 F) proximal shaft

PowerTrac™ technology enhances deliverability

Resilient hypotube for high shaft column strength



Enhanced balloon material improves flexibility and trackability

0.91 mm (2.7 F) distal shaft
4.50–5.00 mm: 1.07 mm (3.2 F)

Platinum iridium marker bands enhance visibility

Reduced catheter profile under the stent enables lower crossing profiles

Compliance Data

Pressure kPa (atm)	Stent Diameter Deployed Stent I.D. (mm)								
	2.00	2.25	2.50	2.75	3.00	3.50	4.00	4.50	5.00
709 (7)	1.85	2.05	2.25	2.45	2.75	3.05	3.60	4.10	4.55
811 (8)	1.90	2.10	2.30	2.55	2.80	3.15	3.70	4.20	4.65
912 (9)	1.90	2.15	2.35	2.60	2.90	3.25	3.80	4.30	4.80
1013 (10)	1.95	2.20	2.45	2.65	2.95	3.35	3.85	4.40	4.90
1115 (11)	2.00	2.25	2.50	2.70	3.00	3.40	3.95	4.45	4.95
1216 (12)	**2.05**	**2.30**	**2.55**	**2.75**	**3.05**	**3.45**	**4.00**	**4.50**	**5.05**
1317 (13)	2.05	2.35	2.55	2.80	3.10	3.50	4.05	4.55	5.10
1419 (14)	2.10	2.35	2.60	2.80	3.10	3.55	4.05	4.60	5.15
1520 (15)	2.10	2.35	2.60	2.85	3.15	3.55	4.10	4.65	5.20
1621 (16)	2.15	2.40	2.65	2.90	3.20	3.60	4.15	**4.70**	**5.25**
1723 (17)	2.15	2.40	2.70	2.90	3.20	3.65	4.20	4.80	5.30
1824 (18)	**2.20**	**2.45**	**2.70**	**2.95**	**3.25**	**3.70**	**4.25**	4.85	5.35
1925 (19)	2.20	2.45	2.75	3.00	3.30	3.75	4.30	–	–
2027 (20)	2.25	2.50	2.75	3.00	3.35	3.80	4.35	–	–
2128 (21)	2.25	2.50	2.80	3.05	3.40	3.80	4.40	–	–
MSID	3.25*	3.25*	3.25*	3.75*	3.75*	4.75*	4.75*	5.75*	5.75*

Nominal pressure | **Rated burst pressure†** | **Maximum stent I.D.**

*Do not postdilate greater than listed value.
†Do not exceed rated burst pressure.

www.medtronic.com | www.theadvancedworkhorse.com
www.medtronicstents.com

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Medtronic

Vs.Ex

Ch.

10 PATIENT SELECTION AND TREATMENT

See also **Section 5.5 - Use in Special Populations**. The risks and benefits described above should be carefully considered for each patient before use of the Resolute Onyx™ System. Factors to be utilized for patient selection should include an assessment of the risk of prolonged anticoagulation. Administration of $P2Y_{12}$ platelet inhibitor is recommended pre-procedure and for at least 6 months in stable ischemic heart disease patients and for at least 12 months in patients with acute coronary syndrome (ACS). In patients at higher risk of bleeding, DAPT discontinuation may be reasonable after 3 months in stable patients or 6 months in ACS patients (see **Section 5.1 - Pre- and Post-Procedure Antiplatelet Regimen**). Aspirin should be administered concomitantly with an approved antiplatelet medication and then continued indefinitely. The safety and effectiveness of the Resolute Onyx stent have not been evaluated in patients at high bleeding risk or those with contraindicated anticoagulation therapy.

11 PATIENT COUNSELING INFORMATION

Physicians should consider the following in counseling the patient about this product:

- Discuss the risks associated with stent placement
- Discuss the risks associated with a zotarolimus-eluting stent implant
- Discuss the risks/benefits issues for this particular patient
- Discuss alteration to current lifestyle immediately following the procedure and over the long term
- Discuss the risks of early discontinuation of the antiplatelet therapy

The following patient materials will be provided to physicians to educate their patients about the options available for treating coronary artery disease and provide contact information to the patient after their stent implant procedure:

- A Patient Guide which includes information on the Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System, coronary artery disease, and the stent implantation procedure.
- A Stent Patient Implant Card that includes patient information, stent implant information and MRI guidelines. All patients should be instructed to keep this card in their possession at all times for procedure/stent identification.

12 HOW SUPPLIED 3.1✓

STERILE: This product is sterilized with ethylene oxide (EO) and is nonpyrogenic. Do not use if the package is opened or damaged. Do not resterilize. If the product or package is opened or damaged, return to Medtronic Returned Goods. Contact your local Medtronic Representative for return information.

CONTENTS: Package contains one (1) Resolute Onyx™ Zotarolimus-Eluting Coronary Stent mounted on either a Rapid Exchange (RX) or an Over-the-Wire (OTW) stent delivery system.

STORAGE: Store in the original container. Store at 25°C (77°F); excursions permitted to 15 - 30°C (59 - 86°F). Use by the "Use By" date noted on the package.

DISPOSAL INSTRUCTIONS: After use, dispose of product and packaging in accordance with hospital, administrative and/ or local government policy.

13 DIRECTIONS FOR USE

13.1 Access to Package Holding Sterile Stent Delivery System

Remove the stent delivery system from the package. Special care must be taken not to handle the stent or in any way disrupt its placement on the balloon. This is most important during catheter removal from packaging, placement over guidewire, and advancement