AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratie de conformitate CE_2
I.2. Declarația de conformitate CE	Declaratie de conformitate CE_1
I.3. Certificatul CE	Certificat CE_Design Examination_2
I.3. Certificatul CE	Certificat CE_Design Examination_1
I.3. Certificatul CE	Certificat CE_Full Quality

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		Resolute Onix								
DM000196111	STENT CORONARIAN CU ELIBERARE DE ZOTAROLIMUS	Resolute Onix	2,5 x 8 mm	RONYX25008X	SUA	MEDTRONIC, INC.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000196131	STENT CORONARIAN CU ELIBERARE DE ZOTAROLIMUS	Resolute Onix	3,0 x 15 mm	RONYX30015X	SUA	MEDTRONIC, INC.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000196108	STENT CORONARIAN CU ELIBERARE DE ZOTAROLIMUS	Resolute Onix	2,25 x 30 mm	RONYX22530X	SUA	MEDTRONIC, INC.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000196121	STENT CORONARIAN CU ELIBERARE DE ZOTAROLIMUS	Resolute Onix	2,75 x 12 mm	RONYX27512X	SUA	MEDTRONIC, INC.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000196107	STENT CORONARIAN CU ELIBERARE DE ZOTAROLIMUS	Resolute Onix	2,25 x 26 mm	RONYX22526X	SUA	MEDTRONIC, INC.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000196096	STENT CORONARIAN CU ELIBERARE DE ZOTAROLIMUS	Resolute Onix	2,0 x 12 mm	RONYX20012X	SUA	MEDTRONIC, INC.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000196110	STENT CORONARIAN CU ELIBERARE DE ZOTAROLIMUS	Resolute Onix	2,25 x 38 mm	RONYX22538X	SUA	MEDTRONIC, INC.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
DM000196115	STENT CORONARIAN CU ELIBERARE DE ZOTAROLIMUS	Resolute Onix	2,5 x 22 mm	RONYX25022X	SUA	MEDTRONIC, INC.	CLASDAC S.R.L.	A07.PS-01.Rg04-5	14-01-2019	
	STENT									

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 84868**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

In respect of:

The design, development and manufacture of sterile Endoluminal Stent Grafts, sterile Securement Devices and Delivery Systems for Endovascular Indications, sterile Vascular Introducer Sheaths, sterile Stent Graft Balloon Catheters, sterile Coronary Stents and Delivery Systems, Sterile Intravascular Catheters and sterile/non-sterile Catheter Systems for Renal Denervation.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 84868

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	Attain Clarity Venogram Balloon Catheter	See CE 593123
N/A	Driver Sprint Rapid Exchange Coronary Stent System	See CE 545439
N/A	Endeavor Resolute Zotarolimus-Eluting Coronary Stent System Resolute Integrity Zotarolimus-Eluting Coronary Stent System	See CE 514336
N/A	Endeavor Sprint Zotarolimus-Eluting RX Coronary Stent System	See CE 86406
N/A	Endurant™ Stent Graft System Endurant™ II Stent Graft System Endurant™ IIs Stent Graft System	See CE 559659
N/A	Euphora Rapid Exchange Balloon Dilatation Catheter	See CE 622066
N/A	Heli-FX™ EndoAnchor™ Systems	See CE 669930
N/A	IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)	See CE 570280

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	IN.PACT Falcon (Paclitaxel-eluting PTCA Balloon Catheter)	See CE 570282
N/A	IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter)	See CE 570281
N/A	Integrity Rapid Exchange Coronary Stent System	See CE 91271
N/A	Micra™ Introducer Sheath with Hydrophilic Coating	See CE 599898
N/A	NC Euphora Rapid Exchange Balloon Dilatation Catheter	See CE 612356
N/A	NC Solarice Rapid Exchange Balloon Dilatation Catheter	See CE 630635
N/A	NC Sprinter Rapid Exchange Balloon Dilatation Catheter	See CE 506473
N/A	Reliant Stent Graft Balloon Catheter	See CE 635936
N/A	Resolute Onyx Zotarolimus-Eluting Coronary Stent System	See CE 618060
N/A	Sentrant Introducer Sheath with Hydrophilic Coating	See CE 595294
N/A	Solarice Rapid Exchange Balloon Dilatation Catheter	See CE 630580
N/A	Sprinter Legend OTW Balloon Dilatation Catheter	See CE 547584

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Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	Sprinter Legend RX Balloon Dilatation Catheter	See CE 525652
N/A	Sprinter Over-the-Wire Balloon Dilatation Catheter	See CE 92065
N/A	Telescope Guide Extension Catheter	See CE 701802
N/A	Valiant Navion™ Thoracic Stent Graft System	See CE 702496
N/A	Valiant Thoracic Stent Graft with the Captivia Delivery System	See CE 554030

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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Supplementary Information to CE 84868

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Medtronic, Inc.
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Class IIb products under the scope of CE 84868		
GMDN #	**Device or Generic Device Group**	**Intended Purpose per IFU**
58893 (Catheter) 35156 (Generator)	Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter & Symplicity G3™ Renal Denervation RF Generator	The Symplicity G3™ Renal Denervation RF Generator when used with the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter is intended to deliver low-level radio frequency (RF) energy through the wall of the renal artery to denervate the human kidney.

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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Supplementary Information to CE 84868

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Minneapolis, MN 55432
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Class IIb products under the scope of CE 84868		
GMDN #	**Device or Generic Device Group**	**Intended Purpose per IFU**
46777	Talent Endoluminal Occluder System	The Talent Endoluminal Occluder System is intended for endoluminal occlusion of the contralateral iliac artery in cases where an abdominal aortic aneurysm is treated with an aorto-uni-iliac stent graft and subsequent femoral-to-femoral bypass procedure

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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Supplementary Information to CE 84868

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Class IIa products under the scope of CE 84868		
NBOG code	**Device or Generic Device Group**	**Intended Purpose per IFU**
MD0106	Confida™ Expandable Sheath	The Confida™ Expandable Sheath is intended to be inserted into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters or devices introduced into the femoral iliac arteries.

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 84868**

Date: **2019-08-22**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Subcontractor:	**Service(s) supplied**
Invatec S.p.A. Via Martiri della Libertà 7 25030 Roncadelle (BS) Italy	**Manufacture**
Medistri SA Rte de L'Industrie 96 1564 Domdidier Switzerland	**ETO Sterilization**
Medtronic B.V. / E.O.C. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	**EU Representative**
Medtronic CoreValve LLC 1851 E. Deere Ave Santa Ana, CA 92705 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No: **CE 84868**

Date: **2019-08-22**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Subcontractor:	**Service(s) supplied**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**Design** **EU Representative** **Manufacture**
Medtronic Mexico EG Carret. Int. Km. 1969 Guad-Nogales Km. 2 85340 Empalme Sonora Mexico	**Manufacture**
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	**Manufacture**
Medtronic Vascular 3576 Unocal Place Santa Rosa California 95403 USA	**Design**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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710 Medtronic Parkway
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USA

Subcontractor:	**Service(s) supplied**
Phoenix DeVentures, Inc. 18655 Madrone Parkway Suite 180 Morgan Hill California 95037 USA	**Manufacture**
Plexus Corp. Pinnacle Hill Kelso TD5 8XX United Kingdom	**Manufacture**
Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone Phase II, 11900 Bayan Lepas Penang Malaysia	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Date: **2019-08-22**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Subcontractor:	**Service(s) supplied**
SSP-SiMatrix, Inc. 1131 North US Highway 93 Victor Montana 59875 USA	**Manufacture**
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	**ETO Sterilization**
Surmodics, Inc. 9924 West 74th Street Eden Prairie Minnesota 55344 USA	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 84868**

Date: **2019-08-22**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Subcontractor:	**Service(s) supplied**
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore, Co. Offaly Ireland	**E Beam Sterilization** **ETO Sterilization**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	**E Beam Sterilization**
Teleflex Medical Annacotty Business Park Annacotty Co. Limerick Ireland	**Manufacture**

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EC Certificate - Full Quality Assurance System
Certificate History

Certificate No: **CE 84868**

Date: **2019-08-22**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
24 August 2004		First Issued.
15 November 2004		Transfer of the following certificates from NSAI:- Q252.322, Q252.407, Q252.426, Q252.427, Q252.428, Q252.467, Q252.480, Q252.587, and Q252.611 D252.587 and D252.407, plus incorporation of Medtronic Vascular Ireland as a subcontract manufacturer.
02 December 2004		Carotid and Coronary Stents and Delivery Systems added to the scope (transfer) Medtronic Mexico (manufacture), and Titan Scan Systems, Nutec Corporation, Sterigenics (Queensbury), Steris Corporation-Isomedix Services (Sandy), Rocialle in Health (Mid Glamorgan UK), and EBIS Iotron added as sub-contract sterilizers.
21 December 2004		PTCA Balloon Dilatation Catheters added to the range of products manufactured (transferred from another Notified Body) and Isotron Ireland Ltd added as sub-contract sterilization site.
19 August 2005		Sterilization sub-contractor name change from Titan Scan Systems to Beam One.
03 April 2006		Addition of Sterigenics UK Ltd, as sterilization sub-contractor.
07 August 2006		Addition of AD)MEDES Schuessler GmbH as a sub-contractor for manufacture.

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Date	Reference Number	Action
11 January 2008	7149866	Subcontractor name change from EBIS Isotron, Harwell to Isotron Harwell. Addition of Isotron plc, Daventry as a subcontractor for E beam sterilization.
03 October 2008	7279045	Addition of Medtronic Mexico EG, Empalme as a subcontractor for manufacture.
14 April 2009	7341499	Correction of the legal name of the Medtronic Mexico facility and postcode for the Isotron PLC, Daventry facility. Addition of the activity of EU Representative for Medtronic Ireland.
13 August 2009	7432878	Certificate renewal. Addition of Accellant Inc as a manufacturing subcontractor, amendment to company name for Isotron PLC, Daventry, and Steris Corporation, Sandy, Utah. Change to address for the subcontractor, Nutek Corporation. Addition of E Beam Sterilization for Isotron Ireland. Rewording of scope for clarification purposes only.
29 July 2010	7546410	Added C.R. Bard, Inc. to the list of significant subcontractors for manufacturing. Extended the scope to include guidewires.
12 October 2011	7730209	Extension to scope to include Catheter Systems for Renal Denervation. Removal of Carotid Stents and Delivery Systems from the scope. Minor amendments to Isotron Daventry and Isotron Tullamore's addresses.

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Date	Reference Number	Action
26 January 2012	7792125	Amendment to significant subcontractors to reflect Isotron's name change to Synergy Health and removal of Isotron Harwell.
25 May 2012	7842435	Amendment to the address format and zip code for the significant subcontractor Medtronic Mexico (Tijuana).
19 December 2012	7915649	Addition of Medtronic B.V. The Netherlands for EU Representative Activities.
22 January 2013	7945194	Extension to scope to include Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems.
28 February 2013	7960715	Addition of Invatec Technology Center GmbH to the list of significant subcontractors for manufacturing activities.
28 March 2013	7943883	Extension to Scope to include Vascular Introducer Sheaths and the addition of Teleflex Medical for manufacturing activities.
16 December 2013	8082854	Addition of Plexus Manufacturing Sdn Bhd, Malaysia and Plexus Corp, UK to the list of significant subcontractors for manufacturing activities.
13 July 2014	8154862	Certificate Renewal. Various updates and changes to the list of significant subcontractors. Correction of the reference number for the reissue dated 19th December 2012 on the certificate history page.

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Date	Reference Number	Action
31 July 2015	8350802	Addition of SSP SiMATrix Inc. as balloon supplier for the Attain Clarity.
01 July 2016	8545838	C. R. Bard, Inc., Medtronic Ardian LLC, Nutek Corporation, Sterigenics NY and Apical Instruments Inc. were removed from the list of significant subcontractors.
09 October 2017	8696759	Certificate scope updated to add the design, development and manufacture of securement devices for endovascular indications.
01 May 2018	8895951	Specify devices covered in this certificate are sterile/non-sterile. Move 'sterile Vascular Introducer Sheaths' up in the scope after securement devices. Remove 'Renal Stents and Delivery Systems' and 'guidewires for diagnostic or interventional procedures' from scope. Correction to certificate history entry #2 from '2014' to '2004'.
06 March 2019	8786554	Traceable to NB 0086.

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710 Medtronic Parkway
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Date	Reference Number	Action
Current	9736517	Certificate Renewal. Added product table per MDP4500 Appendix A. Clarified addresses of subcontractors to exactly align with their ISO certificate name and address. Remove "sterile Iliac Stents and Delivery Systems, sterile Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems" from scope as the Complete SE product (iliac and vascular indications) is no longer manufactured nor in the distribution chain. Remove Assurant Cobalt product (iliac product scope) it is no longer manufactured and the last product builds expired in April 2019. Remove subcontractors – Admedes Schuessler GmbH, Germany, Flextronics Medical, Austria, Sterigenics, Corona, CA, Synergy Health, Ireland related to removed products above. Add subcontractors - Phoenix DeVentures, CA, Sterigenics, Los Angeles, CA, SurModics, MN and Medtronic, Santa Ana, CA related to new Class IIa product Confida Expandable Sheath.

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Medtronic Ireland
Parkmore Business Park West
Galway
Ireland

Holds Certificate Number: **MD 94974**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design and manufacture of vascular devices and heart valve delivery and loading systems. The manufacture of heart therapy/pacemaker delivery systems, biliary stents and delivery systems, nonactive implantable/non-implantable medical devices with drug coating/impregnation, catheter systems for renal denervation, venous occlusion systems, atherectomy systems, and implantable fixation systems. The loading & final assembly of transcatheter pacemaker systems. Provision of analytical test services for Medtronic Corporation facilities/sites.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2005-03-17
Latest Revision Date: 2018-11-15

Effective Date: 2018-11-15
Expiry Date: 2021-08-08

UKAS MANAGEMENT SYSTEMS 003

...making excellence a habit.™

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 94974**

Location	Registered Activities
Medtronic Ireland Parkmore Business Park West Galway Ireland	The design and manufacture of vascular devices and heart valve delivery and loading systems. The manufacture of heart therapy/pacemaker deliverysystems, biliary stents and delivery systems, nonactive implantable/non-implantable medical devices with drug coating/impregnation, catheter systems or renal denervation, venous occlusion systems, atherectomy systems, and implantable fixation systems. The loading & final assembly of transcatheter pacemaker systems. Provision of analytical test services for Medtronic Corporation facilities/sites.
Medtronic, Inc. 710 Medtronic Parkway Minneapolis Minnesota 55432 USA	Corporate Headquarters

Original Registration Date: 2005-03-17

Effective Date: 2018-11-15

Latest Revision Date: 2018-11-15

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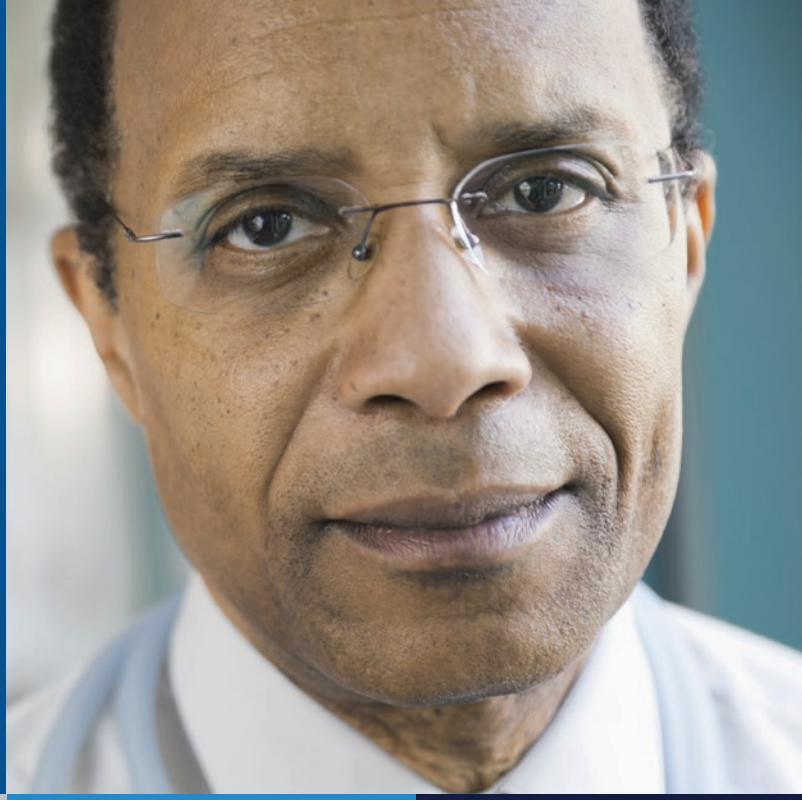
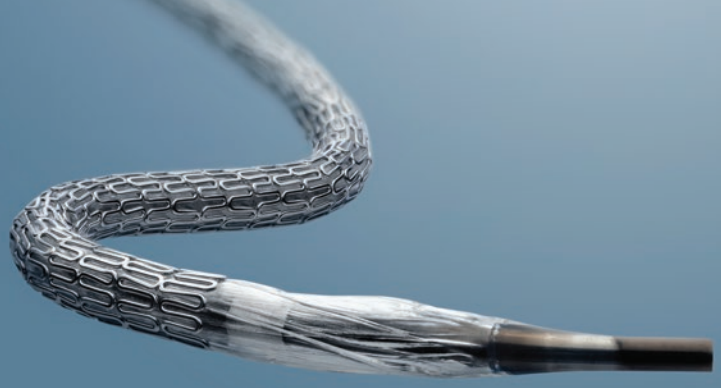
THE ADVANCED WORKHORSE POWERED BY CORE WIRE TECHNOLOGY



Resolute Onyx™
Zotarolimus-Eluting
Coronary Stent System



Including COMPLE**XLV** sizes
4.5mm and **5.0mm**

Medtronic
Further, Together

RESOLUTE ONYX™ DES

THE ADVANCED WORKHORSE

Most deliverable DES[1] featuring Core Wire Technology

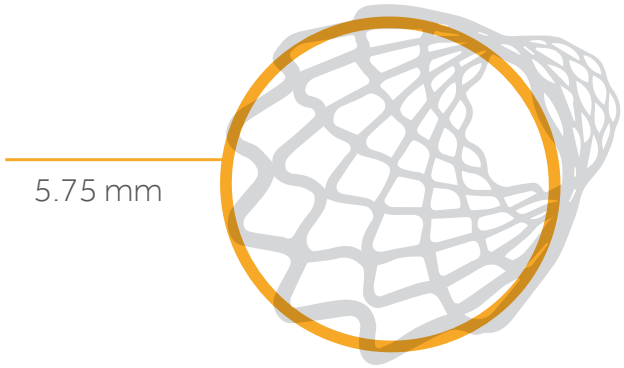
Broadest size matrix to optimise treatment of complex clinical scenarios

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

At Medtronic, we are committed to creating innovative solutions that expand your treatment options. That's why we developed **Resolute Onyx™ DES** — our advanced workhorse coronary stent system to help you treat complex cases.

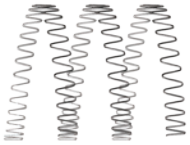
COMPLE**XLV**

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.



Helical wrap

Laser-fused

Fluid range of motion

[1]Based on bench test data vs. Resolute Integrity™ DES, Ultimaster™* DES, BioMatrix NeoFlex™* DES, Orsiro™* DES, Xience Xpedition™* DES, Synergy™* II DES, Promus Premier™* DES, and Xience Alpine™* DES. Bench test data of 3.0-mm stents on file at Medtronic.

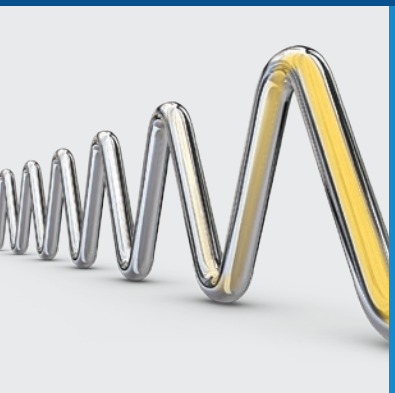
[2]RESOLUTE FIM, RESOLUTE All Comers, RESOLUTE International, RESOLUTE US, RESOLUTE US 38 mm, RESOLUTE Japan, RESOLUTE China RCT, RESOLUTE China Registry, RESOLUTE Asia, RESOLUTE Japan SVS.

THE MOST DELIVERABLE DES[3]

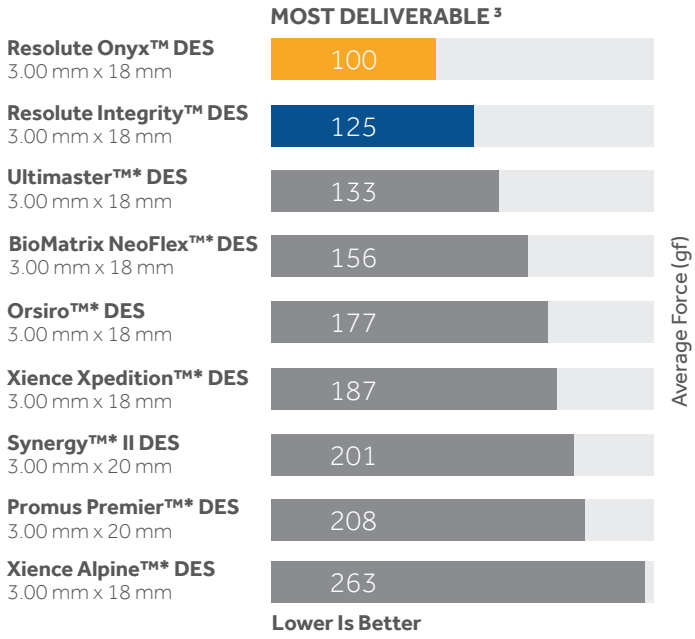
FEATURING CORE WIRE TECHNOLOGY

Core Wire Technology enables:

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

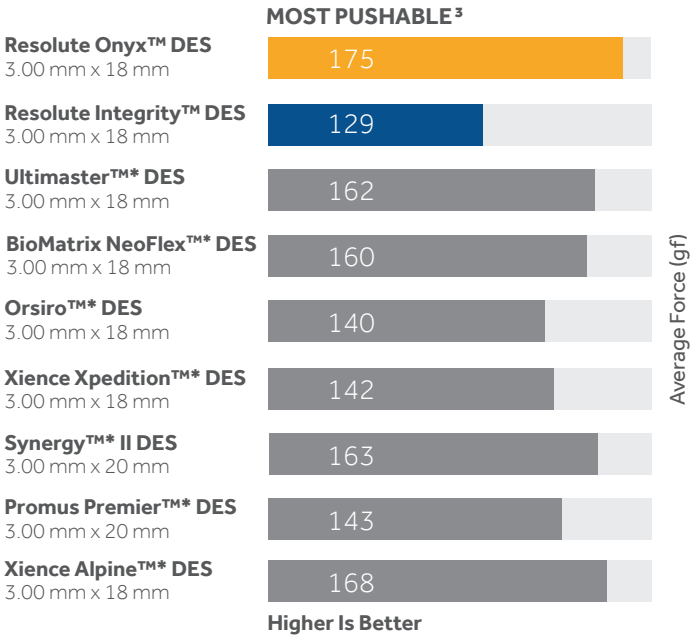


EVEN GREATER DELIVERABILITY

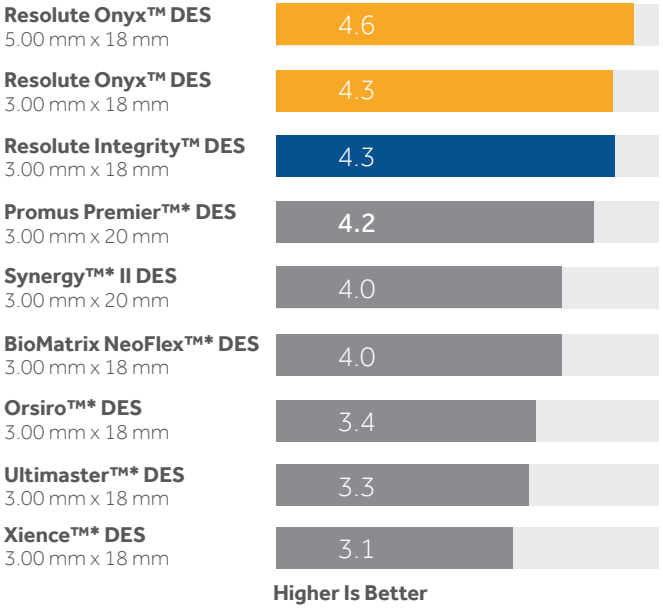


PROCEDURAL SUCCESS

INCREASED PUSHABILITY



SUSTAINED RADIAL STRENGTH

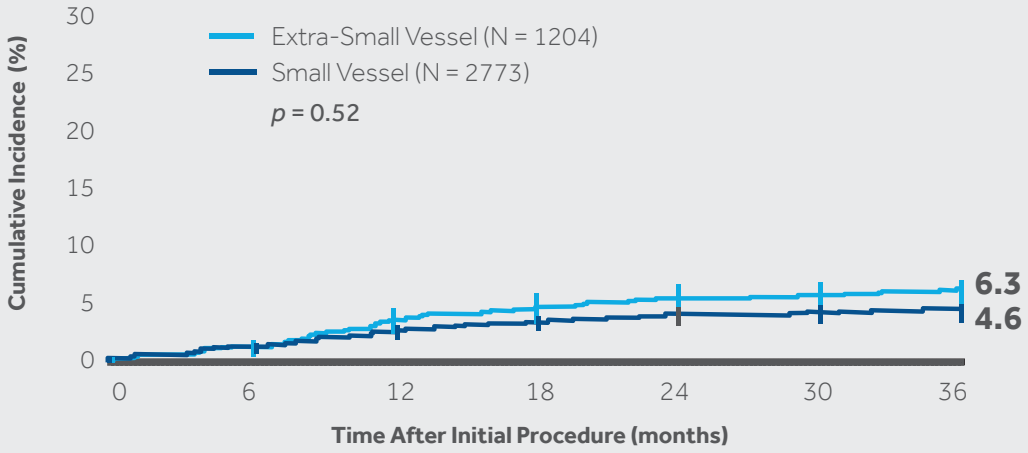


[3]Based on bench test data vs. Resolute Integrity™ DES, Ultimaster™* DES, BioMatrix NeoFlex™* DES, Orsiro™* DES, Xience Xpedition™* DES, Synergy™* II DES, Promus Premier™* DES, and Xience Alpine™* DES. Bench test data of 3.0-mm stents on file at Medtronic.

BROADEST SIZE MATRIX

TO OPTIMISE TREATMENT OF COMPLEX CLINICAL SCENARIOS

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



CE

Small vessels
RVD up to 5.0 mm
Long lesions
CTOs
Total occlusions
AMIs
ISR
Multivessels
Diabetes
ACS
UA
Bifurcations
Left Main

DAPT: Low risk of ST after one month

Please see Page 8 for further discussion

Featuring a 2.0-mm diameter and longer stent lengths

CONSIDERATIONS FOR TREATING EXTRA-LARGE VESSELS

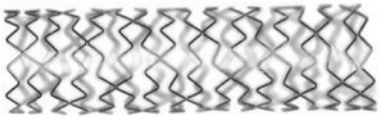
Standard DES treatment has historically involved overexpanding a 4.0-mm stent; however, important considerations exist:

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

Maximum labelled overexpansion capabilities

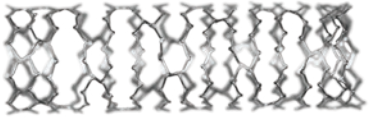
COMPLE**XLV** offers enhanced scaffolding and less foreshortening.

Resolute Onyx™ DES
5.0 mm x 18 mm



Resolute Onyx™ DES overexpanded to 5.75 mm, per the ***IFU.***

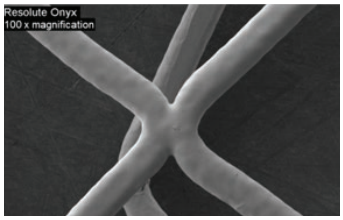
Synergy™* DES
4.0 mm x 20 mm



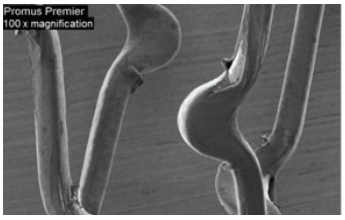
Synergy™* DES overexpanded to 5.75 mm, per the *IFU.*

Impact to DES coating integrity

COMPLE**XLV** maintains drug-coating integrity even when overexpanded.



Resolute Onyx™ DES overexpanded to 5.75 mm, per the *IFU.*



Promus Premier™* DES overexpanded to 5.75 mm, per the *IFU.*

[4]RESOLUTE Pooled—extra-small vessel (RVD ≤2.25 mm) vs. small vessel (RVD >2.25 mm but ≤2.75 mm) stenting TLR at three years. Post-hoc RESOLUTE Pooled analysis was not powered for the analysis shown. RESOLUTE FIM, RESOLUTE All Comers, RESOLUTE International, RESOLUTE US, RESOLUTE US 38 mm, RESOLUTE Japan, RESOLUTE China RCT, RESOLUTE China Registry, RESOLUTE Asia, RESOLUTE Japan SVS

PROVEN LONG-TERM SAFETY AND EFFICACY

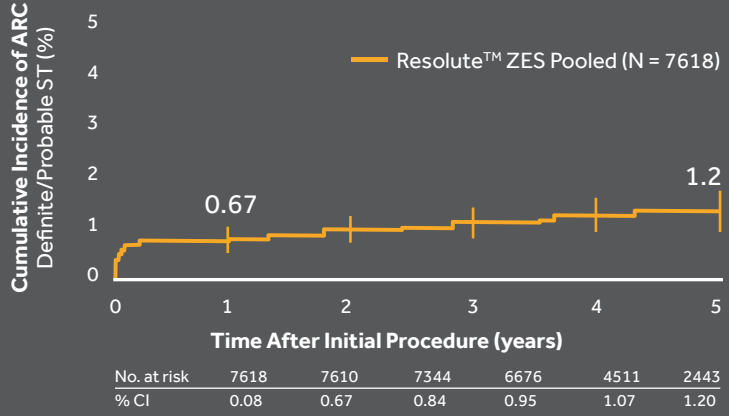
SHOWN IN THE GLOBAL RESOLUTE PROGRAM

" 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]

ST Rate Through 5 Years[6]
RESOLUTE Pooled[6] Analysis



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

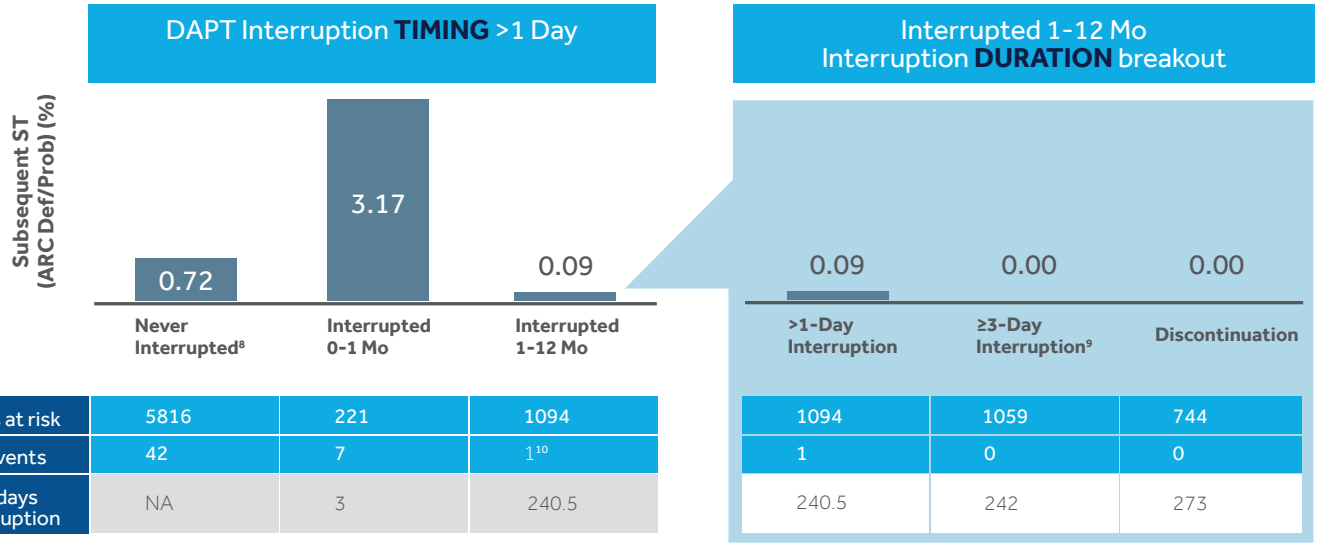
[5]Silber S. Five-year follow-up of safety and efficacy of the Resolute™ zotarolimus-eluting stent: Insights from the RESOLUTE Global Clinical Trial Program in approximately 8000 patients EuroPCR 2015. Post-hoc RESOLUTE Pooled analysis was not powered for the analysis shown.
[6]RESOLUTE FIM, RESOLUTE All Comers, RESOLUTE International, RESOLUTE US, RESOLUTE US 38 mm, RESOLUTE Japan, RESOLUTE China RCT, RESOLUTE China Registry, RESOLUTE Asia, RESOLUTE Japan SVS

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

SAFETY ASSURED

NO INCREASED RISK FOR ST WITH INTERRUPTION OR DISCONTINUATION OF DAPT AFTER ONE MONTH[7]

TIMING OF FIRST DAPT INTERRUPTION AND ST THROUGH 1 YEAR



Patients at risk	5816	221	1094	1094	1059	744
No. of events	42	7	1[10]	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[11]
(R-China, R-Japan SVS, R-Asia, R-US 38 mm and China Registry had not completed follow-up beyond one year and will be included in future analyses).

Bhatt. Relation of stent thrombosis to interruption of dual antiplatelet therapy after Resolute™ zotarolimus-eluting stent Implantation. TCT 2013. Kandzari. Pharmacodynamic considerations and clinical impact of dual antiplatelet therapy interruption after Resolute™ zotarolimus-eluting stent implantation. ACC 2014. Post-hoc RESOLUTE Pooled DAPT analysis was not powered for the analysis shown.

[7]Silber S et al. *Eur Heart J.* 2014;35(29):1949–1956

[8]Including patients with no DAPT interruption except for ST while on DAPT through 12 months.

[9]Three-day cutoff selected because studies have shown that discontinuation of at least three days is necessary for platelet function recovery in most individuals.

[10]Patient with a history of thrombosis was on DAPT at the time of ST event but had interrupted DAPT for two consecutive days prior to the event.

[11]Kirtane. Long-term impact of antiplatelet therapy interruption on ST following PCI with the Resolute™ zotarolimus-eluting stent.

TCT 2013. ESC guidelines recommend DAPT duration of 6–12 months after DES implantation in all patients and one year after ACS, irrespective of the type of implanted stent.

PRODUCT INFORMATION

RONYX22508X

- Rapid Exchange
- Length
- Diameter
- Product Code

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**[12]	**3.25**[12]	**3.25**[12]	**3.75**[12]	**3.75**[12]	**4.75**[12]	**4.75**[12]	**5.75**[12]	**5.75**[12]

Nominal pressure | **Rated burst pressure**[13] | **Maximum stent I.D.**

[12]Do not postdilate greater than listed value.
[13]Do not exceed rated burst pressure.

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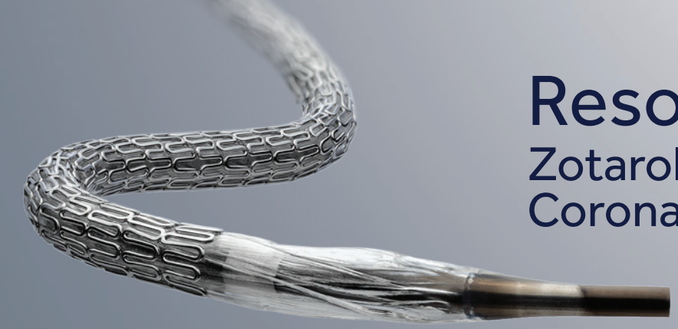
THE ADVANCED WORKHORSE



Resolute Onyx™
Zotarolimus-Eluting
Coronary Stent System

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[1]	3.25[1]	3.25[1]	3.75[1]	3.75[1]	4.75[1]	4.75[1]	5.75[1]	5.75[1]

Nominal pressure | **Rated burst pressure[2]** | **Maximum stent I.D.**

[1]Do not postdilate greater than listed value.
[2]Do not exceed rated burst pressure.

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