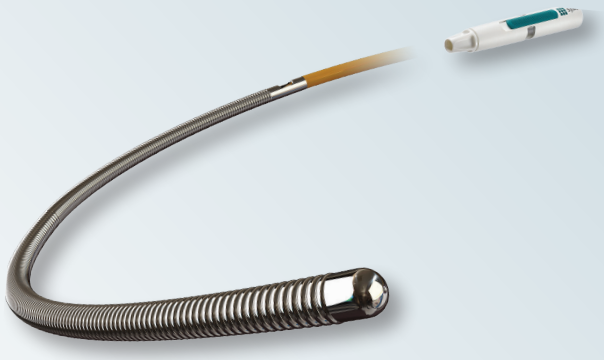
PRESSUREWIRE™ X

Wireless FFR Measurement System



THE WORLD'S ONLY WIRELESS PRESSURE GUIDEWIRE[1-5]

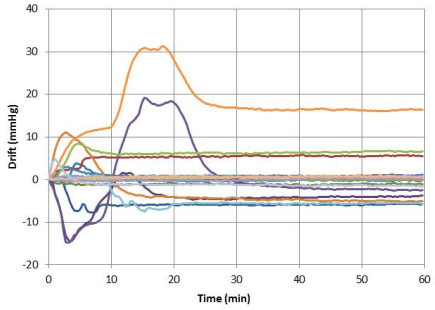
NOW MORE ACCURATE WITH AN IMPROVED DESIGN

- The innovative PressureWire X guidewire is the world's only wireless pressure guidewire for coronary physiology assessment with metrics such as fractional flow reserve (FFR).[1-5]
- This wire now has a new design for the jacket surrounding the pressure sensor, which improves the clinical decisions made using measurements from the wire.
- The soft tip design and hydrophilic coating help navigate tortuous anatomy, enable smoother stent delivery, and improve overall maneuverability. [6-8]

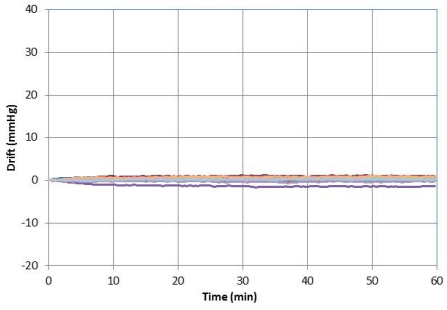
ACCURATE AND RELIABLE

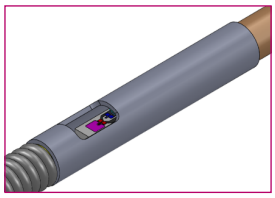
- The new design of the jacket surrounding the pressure sensor improves the accuracy of pressure measurements by reducing acute drift of >2 mmHg by 84%.[10]

1-HOLE DESIGN

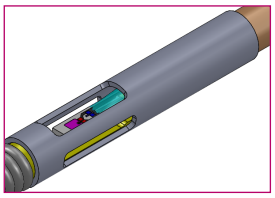


3-HOLE DESIGN





Previous Sensor Jacket with single "window"



Updated Sensor Jacket with multiple, larger "windows"

WIRELESS CORONARY PHYSIOLOGY

- The PressureWire X guidewire (wireless configuration) is the world's only wireless pressure guidewire for FFR assessment.[1-5]

Abbott data on file. Report 90328885.
*Bench testing data designed to simulate the cath lab environment.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY.
Check the regulatory status of the device in areas where CE marking is not the regulation in force.

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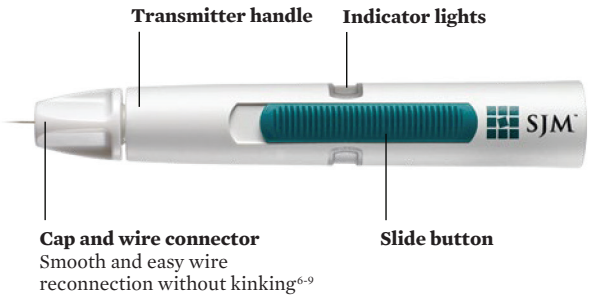
HIGH LEVEL OF HANDLING PERFORMANCE

- Improved shapeability and reshapeability for improved navigation.[9]
- Better shape retention for performance in complex anatomy and for multiple pull-backs.[9]
- More durable[6] soft tip designed to protect the vessel in tortuous anatomy[7] without compromising steerability/trackability.[9]



ORDERING INFORMATION

REORDER NUMBER	DESCRIPTION
C12059	PressureWire X Wireless FFR Guidewire, 175 cm
C12009	PressureWire X Cabled FFR Guidewire, 175 cm

1. Volcano Corp. Verrata‡ guidewire and PrimeWire Prestige‡ Plus guidewire IFUs.
2. Opsens Inc. OptoWire‡ guidewire and OptoWire‡ II guidewire IFUs.
3. ACIST Medical Systems. Navvus‡ Microcatheter IFU.
4. Boston Scientific Corporation. Comet‡ guidewire IFU.
5. Abbott. PressureWire™ X guidewire IFU.
6. Abbott data on file. Report 90205458.
7. Abbott data on file. Report 90205274.
8. Abbott data on file. Report R2542-01.
9. Compared to the previous generation (PressureWire 8 Guidewire); Abbott data on file. Report 90239691.
10. Abbott data on file. Report 90328885.

Abbott International BVBA
Park Lane, Culliganlaan 2B, 1831 Diegem, Belgium, Tel: 32.2.714.14.11

www.Vascular.Abbott

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By Royal Charter

EC Design-Examination Certificate

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

No. **CE 623075**

Issued To: **St. Jude Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

PressureWire Diagnostic Guidewire

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2014-12-18** Date: **2019-04-04** Expiry Date: **2024-04-13**

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EC Design-Examination Certificate

Supplementary Information to CE 623075

Issued To:

St. Jude Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Product: PressureWire Certus, PressureWire Aeris

Model Number	Product Name
C12008	PressureWire Certus, Agile Tip, 175 cm
C12308	PressureWire Certus Agile Tip, 300 cm
C12058	PressureWire Aeris Agile Tip, 175 cm
C12358	PressureWire Aeris Agile Tip, 300 cm

Product: PressureWire X

Model Number	Product Name
PWX175C, C12009	PressureWire X, 175 cm, cabled connection
PWX300C, C12309	PressureWire X, 300 cm, cabled connection
PWX175W, C12059	PressureWire X, 175 cm, wireless connection
PWX300W, C12359	PressureWire X, 300 cm, wireless connection

First Issued: **2014-12-18** Date: **2019-04-04** Expiry Date: **2024-04-13**

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EC Design-Examination Certificate

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55442
USA

Certificate History

Date	Reference Number	Action
18 December 2014	10152648	First Issue. Mirror certificate to CE 620481.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
15 April 2016	10162099	Addition of PressureWire X models.
03 May 2016	10163009	Correction of typographical error in product table.
02 August 2016	10164104	Changes for PressureWire X products: Shelf life extension to 2 years, addition of hydrophilic PEG coating over sensor, changes to labeling and IFU, addition of alternate model numbers.
13 August 2018	8899153	Change to Pressurewire X products: addition of 2 extra windows around pressure sensor to improve fluid flow and reduce drift
05 March 2019	8250541	Traceable to NB 0086.
Current	9686240	Certificate Renewal.

First Issued: **2014-12-18** Date: **2019-04-04** Expiry Date: **2024-04-13**

SJM Declaration of Conformity PressureWire

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:	St. Jude Medical 5050 Nathan Lane North Plymouth, Minnesota 55442 USA
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Guidewire mounted sensor
Product Name(s):	PressureWire Diagnostic Guidewire
Model Number(s):	See Attachment 1.
Classification:	Class III per Annex IX, Rule 7
GMDN Code(s):	15071 Catheter-tip transducer, pressure 35094 Cardiac catheter guidewire, single use
Original CE Mark Date:	See Attachment 1.
Certificate No and expiration date:	Certificate No: CE 597699 – Annex II.3 (FQA) Expiration Date: 15 May 2023 Certificate No: CE 623075 – Annex II.4 (DE) Expiration Date: 13 April 2019
Applicable Quality System Standards:	ISO 13485 and EN ISO 13485:2012
Notified Body:	BSI Kitemark Court Davy Avenue Knowlhill, Milton Keynes MK5 8PP UK
Notified Body Number:	0086
Manufacturing Facilities:	St. Jude Medical Costa Rica LTDA Zona Franca Coyol S.A. Edifico #44B, Calle 0, Avenida 2, Coyol Alajuela Costa Rica

Signature:

Marlene Peterson
Regulatory Affairs Manager

16 May 2019
Issue Date

SJM Declaration of Conformity PressureWire

Attachment 1. PressureWire Model Numbers

Product Description	Model Number	Original CE Mark Date
PressureWire Certus, Agile Tip, 175cm	C12008	18 December 2014*
PressureWire Certus, Agile Tip, 300cm	C12308	18 December 2014*
PressureWire Aeris, Agile Tip, 175cm	C12058	18 December 2014*
PressureWire Aeris, Agile Tip, 300cm	C12358	18 December 2014*
PressureWire X, 175cm, cabled connection	PWX175C	15 April 2016
PressureWire X, 300cm, cabled connection	PWX300C	15 April 2016
PressureWire X, 175cm, wireless connection	PWX175W	15 April 2016
PressureWire X, 300cm, wireless connection	PWX300W	15 April 2016
PressureWire X, 175cm, cabled connection	C12009	2 August 2016
PressureWire X, 300cm, cabled connection	C12309	2 August 2016
PressureWire X, 175cm, wireless connection	C12059	2 August 2016
PressureWire X, 300cm, wireless connection	C12359	2 August 2016

*Date reflects original CE Mark through BSI, as denoted on Annex II.4 certificate, CE 62305. Previously CE marking was through Intertek (Certus and Aeris only) in 2009, and through Dekra (for Certus only) in 2006.

Signature:

Marlene Peterson
Regulatory Affairs Manager

16 May 2016
Issue Date

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Medical
4 Robbins Road
Westford
Massachusetts
01886
USA

Holds Certificate No: **FM 701294**

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

The design, development, manufacture, and servicing of Optical Coherent Tomography Imaging Systems, including embedded software and sterile Imaging Catheters. The distribution of syringes, sterile bags, inflation devices and accessories. Design of Diagnostic Guidewire, Computer, Signal Transmission and Diagnostic software and accessories.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2018-10-01
Effective Date: 2018-10-01
Latest Revision Date: 2018-10-01
Expiry Date: 2021-10-07

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