

SLITTABLE OUTER GUIDE CATHETER

CPS Direct™ Universal 3D

Models DS2C029

Specifications

- The CPS Direct™ Universal slittable Outer Guide Catheters are designed to facilitate left heart lead delivery. They are compatible with other products in the Abbott CPS™ Cardiac Positioning System family — an inter-compatible system of tools designed to give you more control to efficiently and predictably deliver the left heart lead to your vein of first choice.
- Designed to provide reliable coronary sinus access:
 - Excellent torque transmission and soft tip are due to braid-reinforced, multi-durometer PEBAX⁺ material design.
 - Unique SiteMark™ Markers provide 3-D fluoroscopic visibility to determine anterior/posterior location and verify torque transfer.
- Designed to reduce procedural steps during implant:
 - Slittable hub and integrated shaft provide smooth transition during slitting of the catheter.
 - U-channel valve bypass tool simplifies lead delivery.
 - Ergonomic slitter facilitates smooth slitting.
- Designed for removal:
 - Catheter design features Smooth-Slit™ Technology and an ergonomic slitter, which are designed to allow cutting, minimizing the risk of lead dislodgement upon catheter removal.



Physical Specifications

MODEL #	CURVE SHAPE	AVAILABLE LENGTH	OVERALL LENGTH	INNER DIAMETER	OUTER DIAMETER
DS2C029	3D	42 cm	45.7 cm	8.01 F (2.67 mm)	9.90 F (3.30 mm)
Material	Multi-durometer PEBAX ⁺ material reinforced with stainless steel braid wire for a kink-resistant catheter shaft and soft distal tip. Lubricious coating on inner and outer surfaces.				
Marker	Three gold marker bands and two tungsten stripes on distal tip.				

Accessories

INCLUDED
Dilator
2 Valve Bypass Tools

SEPERATELY AVAILABLE	MODEL NUMBER
CPS™ Universal Slitter	DS2A003
CPS Direct™ Valve Bypass Tool	410194

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner

Abbott
15900 Valley View Court, Sylmar, CA 91342
Tel: +1 818 362 6822
Abbott.com

© 2023 Abbott. All Rights Reserved.





EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 014607 0248 Rev. 00

Manufacturer:

**St. Jude Medical
Cardiac Rhythm Management
Division**

15900 Valley View Court
Sylmar CA 91342
USA

**Authorized
Representative:**

St. Jude Medical Coordination Center BVBA
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem,
BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 014607 0248 Rev. 00

Report No.:

713198441

Valid from:

2021-05-14

Valid until:

2026-05-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-05-14



EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 014607 0248 Rev. 00

Classification: III
Device Group: C0503 - CARDIOVASCULAR INTRODUCING SHEATHS, PEEL-AWAY

Basic UDI-DI: 5415067ALP0001D6

Intended Purpose: The CPS Catheter is intended to provide a transvenous conduit for navigation of the coronary venous system anatomy and delivery pathway during cardiac surgery procedures for contrast media, implantable left heart pacing leads, or other delivery tools.

Device(s): CPS Direct™ PL Peelable Outer Guide Catheter
410210, 410211, 410212, 410213, 410214, 410215, 410216,
410217, 410218, 410219, 410220, 410221, 410222, 410223,
410224, 410225

Classification: III
Device Group: C0502 - CARDIOVASCULAR INTRODUCING SHEATHS, VALVULATED

Basic UDI-DI: 5415067ALP0001D6

Intended Purpose: The CPS Catheter is intended to provide a transvenous conduit for navigation of the coronary venous system anatomy and delivery pathway during cardiac surgery procedures for contrast media, implantable left heart pacing leads, or other delivery tools.

Device(s): CPS Aim™ SL Slittable Inner Catheter
DS2N021-59, DS2N021-65, DS2N022-59, DS2N022-65,
DS2N023-59, DS2N023-65, DS2N024-65, DS2N025-65

CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C001, DS2C002, DS2C003, DS2C004, DS2C005, DS2C006,
DS2C011, DS2C012, DS2C013, DS2C014, DS2C015

CPS Aim™ Universal Slittable Inner Catheter
DS2N026-59, DS2N026-65, DS2N027-59, DS2N027-65,
DS2N028-59, DS2N028-65, DS2N029-65, DS2N030-65

The validity of this certificate depends on conditions and/or is limited to the following: ./.

-

Manufacturer:	St. Jude Medical Cardiac Rhythm Management Division
Manufacturer SRN:	US-MF-000010382
Address:	15900 Valley View Court Sylmar, California 91342 USA
Manufacturing Site(s):	St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court Sylmar, California 91342 USA
European Authorized Representative:	SJM Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
European Authorized Representative SRN:	BE-AR-000008417

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Type:	Cardiovascular delivery catheter
Product Trade Name(s):	<ul style="list-style-type: none"> • CPS Direct™ PL Peelable Outer Guide Catheter • CPS Direct™ SL II Slittable Outer Guide Catheter • CPS Aim™ SL Slittable Inner Catheter • CPS Aim™ Universal Slittable Inner Catheter

Model Number(s):	Device Name	Model Numbers
	CPS Direct™ PL Peelable Outer Guide Catheter	410210, 410211, 410212, 410213, 410214, 410215, 410216, 410217, 410218, 410219, 410220, 410221, 410222, 410223, 410224, 410225
	CPS Direct™ SL II Slittable Outer Guide Catheter	DS2C001, DS2C002, DS2C003, DS2C004, DS2C005, DS2C006, DS2C011, DS2C012, DS2C013, DS2C014, DS2C015
	CPS Aim™ SL Slittable Inner Catheter	DS2N021-59, DS2N021-65, DS2N022-59, DS2N022-65, DS2N023-59, DS2N023-65, DS2N024-65, DS2N025-65
	CPS Aim™ Universal Slittable Inner Catheter	DS2N026-59, DS2N026-65, DS2N027-59, DS2N027-65, DS2N028-59, DS2N028-65, DS2N029-65, DS2N030-65
Intended Purpose:	The CPS Catheter is intended to provide a transvenous conduit for navigation of the coronary venous system anatomy and delivery pathway during cardiac surgery procedures for contrast media, implantable left heart pacing leads, or other delivery tools.	
Risk Classification:	Class III	
Classification Rationale:	EU MDR 2017/745, Annex VIII, Chapter III, Rule 6, Bullet 3	
EMDN Code(s):	Device Name	EMDN Code
	CPS Direct™ PL Peelable Outer Guide Catheter	C0503 – Cardiovascular Introducing Sheaths, Peelable
	CPS Direct™ SL II Slittable Outer Guide Catheter	C0502 – Cardiovascular Introducing Sheaths, Valvulated
	CPS Aim™ SL Slittable Inner Catheter	C0502 – Cardiovascular Introducing Sheaths, Valvulated
	CPS Aim™ Universal Slittable Inner Catheter	C0502 – Cardiovascular Introducing Sheaths, Valvulated
Basic UDI-DI:	5415067ALP0001D6	

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Medical Device Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1

Common Specifications Applied:	Not Applicable. No common specifications are available for this type of device.	
STED #	90612379	
Notified Body:	TÜV SÜD Product Services GmbH Ridlerstraße 65 80339 München/Munich Deutschland/Germany ID Number: 0123	
Supporting Certificate(s):	EU Technical Documentation Assessment Certificate (MDR) No: G70 014607 0248 Rev. 00 Expiration Date: May 13, 2026 EU Quality Management System Certificate (MDR) No: G12 014607 0244 Rev. 00 Expiration Date: April 6, 2026	
Original CE Mark Date:	Device Name	Original CE Mark Date (AIMDD)
	CPS Direct™ PL Peelable Outer Guide Catheter	June 2, 2006
	CPS Direct™ SL II Slittable Outer Guide Catheter	September 11, 2009
	CPS Aim™ SL Slittable Inner Catheter	September 10, 2009
	CPS Aim™ Universal Slittable Inner Catheter	May 13, 2013
Conformity Assessment:	EU MDR 2017/745, Annex IX	
Device Photograph:	Not Applicable. Identification and traceability achieved through Model Numbers listed above.	

The products in the below Declaration of Conformity Product List are approved under EU Technical Documentation Assessment Certificate (MDR) No. G70 014607 0248 Rev. 00

Declaration of Conformity Product List

Model No.	Description
410210	CPS Direct™ PL Peelable Outer Guide Catheter
410211	CPS Direct™ PL Peelable Outer Guide Catheter
410212	CPS Direct™ PL Peelable Outer Guide Catheter
410213	CPS Direct™ PL Peelable Outer Guide Catheter
410214	CPS Direct™ PL Peelable Outer Guide Catheter
410215	CPS Direct™ PL Peelable Outer Guide Catheter
410216	CPS Direct™ PL Peelable Outer Guide Catheter
410224	CPS Direct™ PL Peelable Outer Guide Catheter
410217	CPS Direct™ PL Peelable Outer Guide Catheter
410218	CPS Direct™ PL Peelable Outer Guide Catheter
410219	CPS Direct™ PL Peelable Outer Guide Catheter
410220	CPS Direct™ PL Peelable Outer Guide Catheter
410221	CPS Direct™ PL Peelable Outer Guide Catheter
410222	CPS Direct™ PL Peelable Outer Guide Catheter
410223	CPS Direct™ PL Peelable Outer Guide Catheter
410225	CPS Direct™ PL Peelable Outer Guide Catheter
DS2C001	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C002	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C003	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C004	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C005	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C006	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C011	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C012	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C013	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C014	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C015	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2N021-59	CPS Aim™ SL Slittable Inner Catheter
DS2N021-65	CPS Aim™ SL Slittable Inner Catheter
DS2N022-59	CPS Aim™ SL Slittable Inner Catheter
DS2N022-65	CPS Aim™ SL Slittable Inner Catheter
DS2N023-59	CPS Aim™ SL Slittable Inner Catheter
DS2N023-65	CPS Aim™ SL Slittable Inner Catheter
DS2N024-65	CPS Aim™ SL Slittable Inner Catheter
DS2N025-65	CPS Aim™ SL Slittable Inner Catheter
DS2N026-59	CPS Aim™ Universal Slittable Inner Catheter
DS2N026-65	CPS Aim™ Universal Slittable Inner Catheter
DS2N027-59	CPS Aim™ Universal Slittable Inner Catheter
DS2N027-65	CPS Aim™ Universal Slittable Inner Catheter

Model No.	Description
DS2N028-59	CPS Aim™ Universal Slittable Inner Catheter
DS2N028-65	CPS Aim™ Universal Slittable Inner Catheter
DS2N029-65	CPS Aim™ Universal Slittable Inner Catheter
DS2N030-65	CPS Aim™ Universal Slittable Inner Catheter