

Pacel™ Bipolar Pacing Catheter, Ventricular Pacing 60 Degree Curve Torque Control

Product Highlights

- Designed to provide reliable pacing and sensing in the ventricle from the superior vena cava approach
- Precise control without excessive stiffness
- Optimal torque control for challenging anatomy
- Solid core enables user to customize the curve
- 10 cm depth markers to enhance placement
- Smooth, hemocompatible polyurethane surface
- Stainless steel center conductor and electrodes
- Clearly marked terminals
- Shrouded 2 mm pin connector leads

Ordering Information

Shrouded Pin Contents: Pacing Catheter and Pin Adapters (5 units per box)

Exposed Pin Contents: Pacing Catheter (5 units per box)

Kit Contents: Pacing Catheter and Needle Peel-Away Introducer (5 units per box)

Shrouded Pin Reorder Number	Exposed Pin Reorder Number**	French Size	Electrode Spacing (cm)	Usable Length (cm)	Recommended Introducer Size (F)
401765	401664	4	1	110	4
401775	401686	5	2.5	110	5
401766	401665	5	1	110	5
401776	401688	6	2.5	110	6
401767	401666	6	1	110	6
401768	401672	7	1	110	7
N/A	401641 (Kit)	5	1	110	5
N/A	401645 (Kit)	5	2.5	110	5
N/A	401642 (Kit)	6	1	110	6
N/A	401646 (Kit)	6	2.5	110	6



*Allow up to 3 weeks for delivery.

**Not available in countries requiring CE Mark.

Product referenced is approved for CE Mark.

Pacel™ Bipolar Pacing Catheter, Ventricular Pacing with Right Heart Curve Torque Control

Product Highlights

- Designed to provide reliable pacing and sensing in the ventricle from the inferior vena cava approach
- Precise control without excessive stiffness
- Optimal torque control for challenging anatomy
- Solid core enables user to customize the curve
- 10 cm depth markers to enhance placement
- Smooth, hemocompatible polyurethane surface
- Stainless steel center conductor and electrodes
- Clearly marked terminals
- Shrouded 2 mm pin connector leads

Ordering Information

Shrouded Pin Contents: Pacing Catheter and Pin Adapters (5 units per box)

Exposed Pin Contents: Pacing Catheter (5 units per box)

Kit Contents: Pacing Catheter and Needle Peel-Away Introducer (5 units per box)

Shrouded Pin Reorder Number	Exposed Pin Reorder Number**	French Size	Electrode Spacing (cm)	Usable Length (cm)	Recommended Introducer Size (F)
401769	401673	4	1	110	4
401770	401674	5	1	110	5
401771	401675	6	1	110	6
401772	401676	7	1	110	7
N/A	401643 (Kit)	5	1	110	5
N/A	401644 (Kit)	6	1	110	6



*Allow up to 3 weeks for delivery.

**Not available in countries requiring CE Mark.

Product referenced is approved for CE Mark.

EC Design-Examination Certificate

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

No.**CE 569561****Issued To:**

**St. Jude Medical
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA**

In respect of:

Pacel™ Bipolar and Pacel™ Flow Directed Pacing Catheters

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: **2011-03-21**

Date: **2020-04-10**

Expiry Date: **2024-05-26**

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Page 1 of 5

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 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.

EC Design-Examination Certificate

Supplementary Information to CE 569561

Issued To:

St. Jude Medical
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA

Pacel Bipolar Pacing Catheter – Model Numbers

Catalogue Number	Device Name	Model, Type			Intended purpose per IFU	Classification
		Fr. Size	Electrode Spacing (cm)	Catheter Curve Style		
401765	Pacel™ Bipolar Pacing Catheter	4	1	60 Degree Curve	The PACEL™ Bipolar Pacing Catheters are intended for use in intracardiac pacing and/or ECG recording.	Class III
401775		5	2.5	60 Degree Curve		
401766		5	1	60 Degree Curve		
401776		6	2.5	60 Degree Curve		
401767		6	1	60 Degree Curve		
401768		7	1	60 Degree Curve		
401769		4	1	Right Heart Curve		
401770		5	1	Right Heart Curve		
401771		6	1	Right Heart Curve		
401772		7	1	Right Heart Curve		
401773		5	1	Atrial "J" Curve		
401774		6	1	Atrial "J" Curve		

First Issued: **2011-03-21**

Date: **2020-04-10**

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Pacel Flow Directed Pacing Catheter – Model Numbers

Catalogue Number	Device Name	Model, Type			Intended purpose per IFU	Classification
		Fr. Size	Electrode Spacing (cm)	Catheter Curve Style		
401761	Pacel™ Flow Directed Bipolar Pacing Catheter	5	1	Straight	The PACEL™ Flow Directed Bipolar Pacing Catheters are indicated for use in temporary transvenous right ventricular pacing.	Class III
401762 (Kit)*		5	1	Straight		
401763		5	1	Right Heart Curve		
401764 (Kit)*		5	1	Right Heart Curve		

*Kit includes a peel-away introducer with needle.

First Issued: **2011-03-21**

Date: **2020-04-10**

Expiry Date: **2024-05-26**

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Page 3 of 5

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14901 DeVeau Place
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Certificate History

Date	Reference Number	Action
21 March 2011	10119198	First Issue – Transfer from another Notified Body. Certificate Renewal.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
01 February 2016	10160623	Addition of Sterigenics Willowbrook, IL as a sterilizer.
29 February 2016	10161295	Certificate renewal.
10 August 2016	10164740	Change in adhesive for Pacel Flow Directed Pacing Catheters.
05 December 2016	10165172	Addition of St. Jude Medical Plymouth as a physical manufacturing site.
05 March 2019	7780677	Traceable to NB 0086.
15 April 2019	9752171	Addition of Sterigenics US, LLC, Salt Lake City, Utah for ETO Sterilization.
09 December 2019	3098502	Addition of Midwest Sterilization Corporation, Jackson, Missouri USA for ETO Sterilization in chambers 1, 2, 3, 6, and 13.
06 March 2020	3043483	Addition of Steris Temecula, California, USA for ETO Sterilization in chambers 1 and 2. Minor format revision to device tables.

First Issued: **2011-03-21**

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Expiry Date: **2024-05-26**

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Page 4 of 5

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Certificate History

Date	Reference Number	Action
Current	9767651	Certificate renewal. Correction of error in Flow Directed table, 401774 (kit)* should be 401764 (kit)*.

First Issued: **2011-03-21**Date: **2020-04-10**Expiry Date: **2024-05-26**

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Page 5 of 5

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SJM Declaration of Conformity Pacel Bipolar and Flow Directed Pacing Catheter

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 as amended by 2007/47/EC. 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
14901 DeVeau Place
Minnetonka, MN, 55345-2126
U.S.A.

European Representative:

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

Product Type:

Temporary Pacing Catheter

Product Name(s):

Pacel™ Bipolar Pacing Catheter
Pacel™ Flow Directed Pacing Catheter

Model Number(s):

Pacel™ Bipolar Pacing Catheter
401765, 401766, 401767, 401768, 401769, 401770, 401771,
401772, 401773, 401774, 401775, 401776

Pacel™ Flow Directed Pacing Catheter
401761, 401762, 401763, 401764

Classification:

Class III per Annex IX

GMDN Code(s):

47852 (Pacel Bipolar Pacing Catheter)
35854 (Pacel Flow Direct Pacing Catheter)

Original CE Mark Date:


1994*
*EU sales pre-date CE Mark requirements, which were
implemented country by country around 1994.

**(FQA or EC as appropriate) Certificate No
and expiration date:**

Certificate No: CE 569561
Expiration Date: 26 May 2024

Certificate No: CE 548213
Expiration Date: 26 May 2024

Signature:


Blair Schwartz
Sr. Manager, Regulatory Affairs


11 Jan 2021
Issue Date



SJM Declaration of Conformity Pacel Bipolar and Flow Directed Pacing Catheter

Applicable Quality System Standards:	ISO 13485:2016
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Kaynesplein 9 1066 EP Amsterdam The Netherlands
Notified Body Number:	2797
Manufacturing Facilities:	N/A

Signature:


Blair Schwartz
Sr. Manager, Regulatory Affairs

11 Jan 2021
Issue Date