Cool Point Irrigation Pump

Engineered for Control, Safety, and Ease of Use

Control

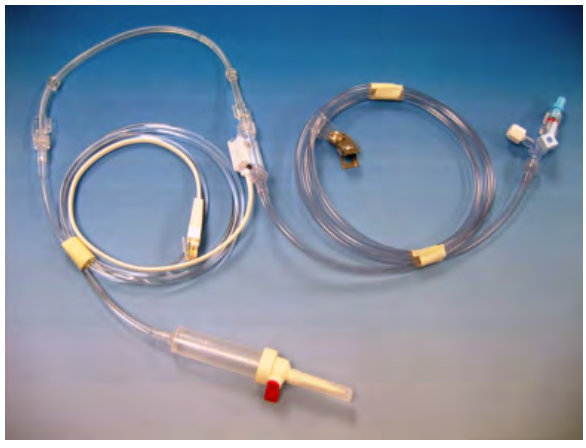
- Direct communication with IBI-1500T11 cardiac ablation generator
- Fully programmable flow rates – up to 40 ml/min*
- Tracks and displays total irrigation volume

Safety

- Exclusive in-line occlusion detection
- Dual bubble detectors:
  - 2 µL air bubble detection
  - Bubble detection diagnostic self-check

Ease of Use

- Plug-and-play use with IBI-1500T11 cardiac ablation generator
- Flow rate displayed on highly visible LED
- Compact size, lightweight design – can be mounted on an IV pole



Cool Point Tubing Set specially designed for easy connection. An in-line occlusion sensor helps ensure safe operation.

Specifications

Mechanism:	Peristaltic
Dimensions:	29 cm x 21 cm (including handle) x 18.5 cm (including pump head) (W x H x D)
Weight:	3.75 kg
Flow Rates:	Low flow: 1 to 5 ml/min (1 ml/min increments)
	High flow: 6 to 40 ml/min (1 ml/min increments)
Priming Flow Rate:	60 ml/min
Air Bubble Detection:	2 µL
Alarms:	Bubble detection; communication lost; door open; pressure sensor not connected; occlusion

Ordering Information

Item Number	Description
85784	Cool Point Irrigation Pump
85786 (Model Number 1779)	Communication cable for the Cool Point Irrigation Pump
85785	Cool Point tubing set (sold individually)

*When the Cool Point irrigation pump is used with Therapy Cool Path irrigated ablation catheters, a maximum flow rate of 17 ml/min is recommended.

Visit our website: sjm.com/irrigatedsystem
For further information, please call:

Product manufactured by Irvine Biomedical, Inc., a St. Jude Medical Company.

Information contained herein for distribution outside of the US only.

ST. JUDE MEDICAL

CE 0086

St. Jude Medical, Inc.
Global Headquarters
One Lillehei Plaza
St. Paul, MN 55117
651 483 2000
Telex: 298453
651 766 3045 Fax

St. Jude Medical Europe, Inc.
The Corporate Village
Avenue Da Vinci laan, 11 - Box F1
B-1935 - Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brazil Ltda.
Rua Frei Caneca, 1380-9 A-CJ91/92
Sao Paulo - SP - Brasil
CEP 01307-002
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Unit 2701-07, COSCO Tower,
Grand Millennium Plaza
183 Queen's Road,
Central, Hong Kong
+852 2996 7688
+852 2956 0622 Fax

GMAF163

EC Certificate - Full Quality Assurance System

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

No. **CE 58528**

Issued To: **Irvine Biomedical, Inc.**
a St. Jude Medical Company
2375 Morse Avenue
Irvine
California
92614
USA

In respect of:

The design, development and manufacture of electrophysiology and radiofrequency ablation catheters, intracardiac catheters used for echocardiography, irrigation pumps, irrigation tubing sets, catheter tip-to-tissue impedance monitoring system, and accessories for cardiac ablation.

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: **2001-05-03** Date: **2020-09-06** Expiry Date: **2024-05-26**

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Supplementary Information to CE 58528

Issued To:

Irvine Biomedical, Inc.
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NBOG code(s)	Device Name	Intended purpose per IFU
Class III		
--	Inquiry™ Luma-Cath™ Diagnostic Catheter	See CE 60202
--	Therapy™ and Therapy™ Dual-8™ Ablation Catheters using one ablating tip electrode with temperature sensors.	See CE 65957
--	Inquiry™, Inquiry™ Afocus, Inquiry™ Optima™ and Inquiry™ Optima™ PLUS Diagnostic Catheters and Inquiry™ Cardioversion and Cardioversion II Catheters	See CE 69920

First Issued: **2001-05-03** Date: **2020-09-06** Expiry Date: **2024-05-26**

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NBOG code(s)	Device Name	Intended purpose per IFU
--	Therapy Cool Path, Therapy Cool Path PLUS, Therapy Cool Path Duo, Therapy Cool Flex, Contact Therapy Cool Flex, Contact Therapy Cool Path, Contact Therapy Cool Path Duo, Therapy Cool Path Triga, Therapy Cool Path Duo Triga, Safire BLU, Safire BLU Duo, Contact Safire BLU and Contact Safire BLU Duo Catheters, Safire Duo Ablation Catheter, MediGuide Enabled and Cool Path Duo Ablation Catheter, MediGuide Enabled	See CE 71046
--	ViewFlex™ Xtra ICE Ultrasound Catheter	See CE 561277

First Issued: **2001-05-03** Date: **2020-09-06** Expiry Date: **2024-05-26**

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NBOG code(s)	Device Name	Intended purpose per IFU
Class IIb		
13215	Cool Point Irrigation Pump	The Cool Point irrigation pump is a peristaltic pump that is intended for use in administration of irrigation solution into the patient through an open irrigated ablation catheter. The Cool Point irrigation pump is intended for use only with the Cool Point tubing set.
Class IIa		
MD 0102	Irrigation Pump Tubing set	The Irrigation Pump Tubing Set is a sterile, single use device which provides access for the administration of fluids from a container.
MD 0102	Cool Point Tubing Set	The Cool Point Tubing Set is a sterile and single use device which provides access for the administration of fluids from a container. This tubing set is intended for use with the Cool Point™ Irrigation Pump only.
Class Is		
MD 0106	CE 85222 Annex V – Electrophysiology Cables	--

First Issued: **2001-05-03** Date: **2020-09-06** Expiry Date: **2024-05-26**

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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 58528**
Date:	**2020-09-06**
Issued To:	**Irvine Biomedical, Inc.** **a St. Jude Medical Company** **2375 Morse Avenue** **Irvine** **California** **92614** **USA**

Subcontractor:	**Service(s) supplied**
Merit Medical Systems Inc 1600 West Merit Parkway South Jordan UT 84095 USA	**Design** **Manufacture** **Regulatory Compliance**
Parter Sterilization Services, LLC 17115 Kingsview Avenue Carson CA 90746 USA	**ETO Sterilization**
St Jude Medical Costa Rica Ltda. Edificio #44, El Coyol Calle 0, Ave. 2, Zona Franca Coyol ALAJUELA Costa Rica	**Manufacture**

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Subcontractor:	**Service(s) supplied**
St. Jude Medical 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA	**Manufacture**
St. Jude Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA	**Manufacture**
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	**EU Representative** **Labelling** **Packaging**

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List of Significant Subcontractors

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Subcontractor:	**Service(s) supplied**
Synergy Health AST, SRL B13.1 Street 4, Avenue 1 El Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 58528**

Date: **2020-09-06**

Issued To: **Irvine Biomedical, Inc.**
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Date	Reference Number	Action
03 May 2001		First Issue (Transfer of Annex V, Section 3.2 certificate from DGM Certificate Nr. 031, subsequently upgraded to an Annex II, Section 3.2 certificate)
04 January 2002		Cardiac ablation generators added to the scope
16 April 2004		Change of address details
09 July 2004		Addition of sub-contractor, NAmSA
04 May 2006		Addition of Edwards Lifesciences, LLC to the list of subcontractors. Certificate Renewal
12 February 2007		Name changed to include "a St. Jude Medical Company"
20 December 2007		Irrigation pumps and tubing sets added to scope. HEI Inc. and Merit Medical Systems Inc added as subcontractors for manufacture.
24 June 2008	7212459	"Intracardiac catheters used for echocardiography" added to the scope. GE Healthcare added to list of subcontractors for manufacture.

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Date	Reference Number	Action
29 July 2009	7430516	Addition of subcontractor, SI. Jude Medical, Minnetonka, MN
28 May 2010	7510842	"Catheter tip-to-tissue impedance monitoring devices" added to the scope. OEM, STERIS Isomedix Services and St. Jude Medical Coordination Center added to the list of significant subcontractors.
15 March 2011	7660787	Certificate Renewal. Correction of history page to add back text reflecting certificate renewal in May 2006. Remove significant subcontractor "GE Healthcare". Reword scope to reflect current activities and devices.
31 October 2011	7731019	Extend the scope to include accessories for cardiac ablation. Add Steris to the list of significant subcontractors for the activity of sterilization. Addition of significant subcontractor St. Jude Medical Cardiovascular Division, Coyol, Costa Rica for manufacturing activities.

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
11 June 2013	8003586	Addition of St Jude Neuromodulation Division to the list of significant subcontractors. Correct the address of the Costa Rica facility.
16 March 2015	8297445	Addition of Packaging & Labelling to activities of St. Jude Medical Coordination Center BVBA.
31 March 2015	8296211	Addition of Synergy Health, Costa Rica as a significant subcontractor for the ETO sterilization of the Inquiry Catheter Family. The following subcontractors have been discontinued and were removed from the list of significant subcontractors: St. Jude Medical Portland, Steris Libertyville, Sterigenics Salt Lake City, Minnetronix Inc, Steris New Jersey , Edwards Lifesciences LL and HEI Boulder.
15 September 2015	8411946	Addition of significant contractor: SJM Plymouth for receiving inspection and release of Cool Point and irrigation pump tubing sets in addition to Irvine Biomedical.
01 April 2016	8481478	Certificate Renewal. Removed Irvine Biomedical / Irvine CA and OEM / Watertown SD from subcontractor list.

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Date	Reference Number	Action
12 December 2016	8632750	Removal of subcontractor NamSA.
17 March 2017	8690925	'Radiofrequency ablation generators' removed from scope.
05 March 2019	7781598	Traceable to NB 0086.
Current	3266661	Certificate Renewal. Product table added.

SJM Declaration of Conformity
Cool Point Tubing Set

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 2007/42/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:	Irvine Biomedical, Inc. a St. Jude Medical Company 2375 Morse Avenue Irvine, CA 92614, USA
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Tubing Set
Product Name(s):	Cool Point™ Tubing Set,
Model and Model Number(s):	85785
Classification:	Class IIa, Rule 2 according to Annex IX of the MDD 93/42/EEC
GMDN Code(s):	44772
Original CE Mark Date:	21 December 2007
EC Certificate No and expiration date:	Certificate No: CE 58528 Expiration Date: 26 May 2024
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 (Traceable to NB number 0086, BSI Reference 7781595)

Signature:

Adam Ettl
Manager, Regulatory Affairs

23 Sep 2020
Issue Date