

Therapy™ Ablation Catheters
 4 & 8 mm Tip Thermocouple
 Quadripolar
 7 F

Standard Ablation Catheters

Product Highlights

- Uni-directional steering
- Thermocouple temperature measurement
- Push/pull handle

Ordering Information

7 F ablation catheter (1 unit per box)

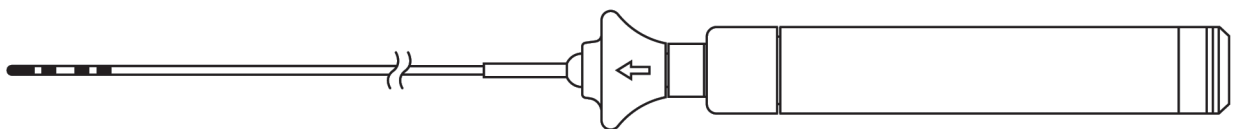
Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Band Electrode (mm)	Curve Type	Usable Length (cm)
83302	1304-7-25-M-TE8	2-5-2	8	2	Medium	110
83306	1304-7-25-L-TE8	2-5-2	8	2	Large	110
83309	1304-7-25-L-TE8A	2-5-2	8	2	Large	110
83311	1304-7-25-XL-TE8A	2-5-2	8	2	X-Large	110
83312	1304-7-25-XL-TE8	2-5-2	8	2	X-Large	110
83404	1304-7-2-M	2	4	2	Medium	110
83405	1304-7-25-M	2-5-2	4	2	Medium	110
83408	1304-7-25-L	2-5-2	4	2	Large	110
83411	1304-7-25-E	2-5-2	4	2	Extended Reach	110
83413	1304-7-2-F	2	4	2	Far Reach	110
83417	1304-7-25-XL	2-5-2	4	2	X-Large	110
83432	1304-7-25-S	2-5-2	4	2	Small	110

Required Catheter Connecting Cable – Page 164

SJM: 85641

Stockert: 85713, 85709

Medtronic: 85711, 85708



Therapy™ Ablation Catheters
 4 & 8 mm Tip Thermistor
 Quadripolar
 7 F

Standard Ablation Catheters

Product Highlights

- Uni-directional steering
- Thermistor temperature measurement
- Compatible with EPT-1000 XP generator
- Push/pull handle

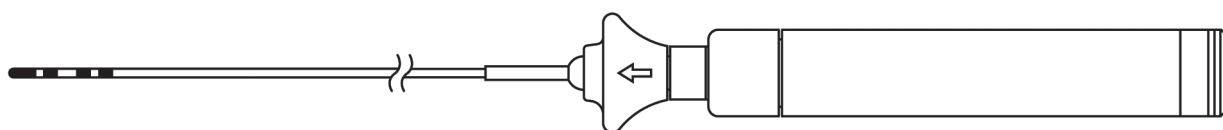
Ordering Information

7 F ablation catheter (1 unit per box)

Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Band Electrode (mm)	Curve Type	Usable Length (cm)
83453	1304-7-25-S-TH	2-5-2	4	2	Small	110
83456	1304-7-25-M-TH	2-5-2	4	2	Medium	110
83459	1304-7-25-L-TH	2-5-2	4	2	Large	110
83462	1304-7-25-XL-TH	2-5-2	4	2	X-Large	110
83477	1304-7-25-L-TE8-TH	2-5-2	8	2	Large	110
83481	1304-7-25-XL-TE8-TH	2-5-2	8	2	X-Large	110

Required Catheter Connecting Cable – Page 164

EPT: 85763



Product Highlights

- Compatible cables for Therapy™ and Safire™ BLU™ Duo catheters to compatible generators

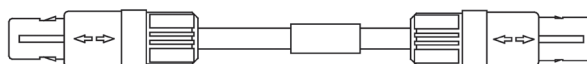
Ordering Information

Reorder Number	Model Number	Length (cm)	Catheter	Generator
85641	1641	250	Therapy™ Series Single Thermocouple/Therapy™ Dual-8™/ Therapy™ Cool Path™/ Therapy™ Cool Path™ Duo/ Therapy™ Cool Flex™/ Safire™ BLU™ Duo	IBI-1500T Series
85644	1641-A	250	Therapy™ Series Single Thermocouple/Therapy™ Dual-8™/ Therapy™ Cool Path™/ Therapy™ Cool Path™ Duo/ Therapy™ Cool Flex™/ Safire™ BLU™ Duo	IBI-1500T Series
85708	1711-MA	250	Therapy™ Series Thermocouple	Medtronic Atakr
85709	1713-WA	250	Therapy™ Series Thermocouple	Stockert Shuttle
85711	1711-M	250	Therapy™ Series Thermocouple	Medtronic Atakr
85713	1713-W	250	Therapy™ Series, Single Thermocouple	Stockert Shuttle
85739	1739-W	250	Therapy™ Dual-8™	Stockert Shuttle
85761	1761-W	250	Therapy™ Series Thermistor; 4 mm tip	Stockert Shuffle
85763	1763-E	250	Therapy™ Series Thermistor; 4 mm tip	EPT-1000 XP
85765	1763-EA	250	Therapy™ Series Thermistor; 4 mm tip	EPT-1000 XP
A402892	1611	250	Contact Enabled™	IBI-1500T Series

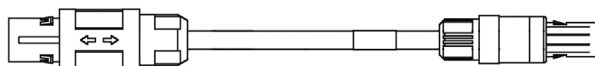
1711-M 1711-MA



1641, 1641-A, 1713-W, 1713-WA,
1739-W, 1761-W, 1763-E, 1763-EA



1611



Atakr is a trademark of Medtronic, Inc.
EPT-1000 TC is a trademark of Boston Scientific, Inc.

EC Design-Examination Certificate

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

No.

CE 65957

Issued To:

**Irvine Biomedical, Inc,
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA**

In respect of:

Therapy™, Therapy™ Dual-8™ and Therapy™ PLUS Ablation Catheters using one ablating tip electrode with and without temperature sensors.

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 0086):

Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2002-05-27**

Date: **2017-05-25**

Expiry Date: **2022-05-26**

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Page 1 of 3

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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 65957

Issued To:

**Irvine Biomedical, Inc,
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA**

Electrophysiology and ablation catheters

Model	Model No:
Therapy™, Therapy™ Dual-8™ and Therapy™ PLUS Ablation Catheters without temperature sensor	12XX (1)-X(2)-XX(3)-X(4)-XX X(5)-BD(6)
Therapy™, Therapy™ Dual-8™ and Therapy™ PLUS Ablation Catheters with temperature sensors (two maximum)	13XX (1)-X(2)-XX(3)-X(4)-XX X(5)-BD(6)

Notes

- (1) – Number of electrodes, from 1 to 14
- (2) – Outside Diameter in French size, from 5Fr to 9Fr
- (3) – Interelectrode spacing, these are variable
- (4) – Curve configuration.
- (5) – Modification Code (specifies usable length, tip/band electrode length, and the number of temperature sensors
- (6) – BD designation will only be present on bi-directional deflection catheters

First Issued: **2002-05-27**

Date: **2017-05-25**

Expiry Date: **2022-05-26**

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Page 2 of 3

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**Irvine Biomedical, Inc,
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA**

Certificate History

Date	Reference Number	Action
27 May 2002	10035311	Original Issue
30 April 2003	10049544	Modifications to existing device
09 July 2004	10059218	Change of address New certificate format
12 February 2007	10083251 10083250	Name change to include "a St. Jude Medical Company" Therapy™ PLUS Catheters added to the scope
24 April 2007	10087839	Renewal and text change in the scope
04 April 2012	10134047	Certificate renewal
28 March 2014	10145858	Correct certificate to add the Therapy Dual-8 name to the scope
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
25 May 2017	10169587	Certificate Renewal

First Issued: **2002-05-27**

Date: **2017-05-25**

Expiry Date: **2022-05-26**

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Page 3 of 3

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A member of BSI Group of Companies.

**SJM Declaration of Conformity
Therapy™, Therapy™ Dual-8™ and Therapy™ PLUS Ablation Catheters**

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:	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:	Electrophysiology and Ablation Catheters
Product Name(s):	Therapy™, Therapy™ Dual-8™ and Therapy™ PLUS Ablation Catheters
Model and Model Number(s):	Therapy™, Therapy™ Dual-8™ and Therapy™ PLUS Ablation Catheters without temperature sensor 12XX ⁽¹⁾ -X ⁽²⁾ -XX ⁽³⁾ -X ⁽⁴⁾ -XX X ⁽⁵⁾ -BD ⁽⁶⁾ Therapy™, Therapy™ Dual-8™ and Therapy™ PLUS Ablation Catheters with temperature sensors (two maximum) 13XX ⁽¹⁾ -X ⁽²⁾ -XX ⁽³⁾ -X ⁽⁴⁾ -XX X ⁽⁵⁾ -BD ⁽⁶⁾
	Notes: (1) – Number of electrode, from 1 to 14 (2) – Outside Diameter in French size, 5Fr to 9Fr (3) – Interelectrode spacing, these are variable (4) – Curve configuration (5) – Modification Code (specifies usable length, tip/band electrode length, and the number of temperature sensors (6) – BD designation will only be present on bi-directional deflection catheters
Classification:	Class III, Rule 7 according to Annex IX of the MDD 3/42/EEC.
GMDN Code(s):	61785
Original CE Mark Date:	27 May 2002
EC Certificate No:	Certificate No: 65957 Expiration Date: 26 May 2022
Applicable Quality System Standards:	ISO 13485:2003



ST. JUDE MEDICAL

M8002511 Ver. J
Declaration of Conformity

Notified Body:

BSI
Kitemark Court
Davy Avenue
Knowlhill, Milton Keynes
MK5 8PP UK

Notified Body Number:

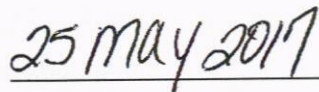
0086

Signature:

Place and Issue Date: Irvine, California US



Kellie Stefaniak
Manager, Regulatory Affairs,



25 May 2017