

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)

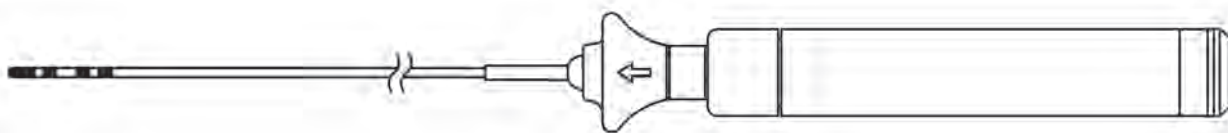
| Reorder Number | Description | Electrode Spacing (mm) | Tip Electrode (mm) | Band Electrode (mm) | Curve Type | Usable Length (cm) |
|----------------|-------------------|------------------------|--------------------|---------------------|----------------|--------------------|
| 83302 | 1304-7-25-M-TE8 | 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

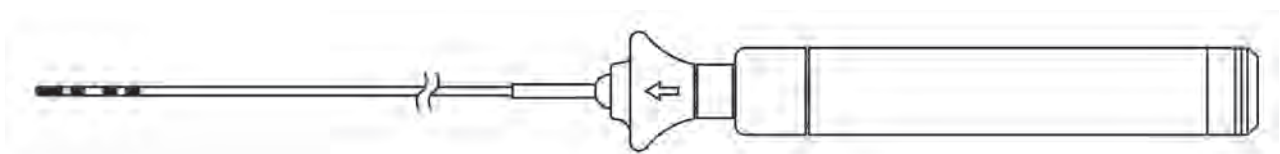
Ordering Information

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



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**

...making excellence a habit.™

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**

...making excellence a habit.™

Page 2 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**

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**

...making excellence a habit.™

Page 3 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.

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 93/42/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:

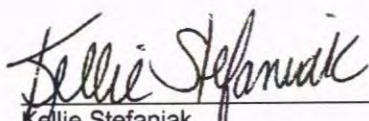
BSI
Kitemark Court
Davy Avenue
Knowlhill, Milton Keynes
MK5 8PP UK

Notified Body Number:

0086

Signature:

Place and Issue Date: Irvine, California US



Kellie Stefaniak
Manager, Regulatory Affairs,

