Inquiry™ Electrophysiology Catheters
Decapolar
5 F

Steerable Diagnostic

Product Highlights

- Variable electrode spacing for pacing and recording
- Multiple curve configurations for ease of placement
- Push/pull handle for steering control
- 1 mm band electrodes

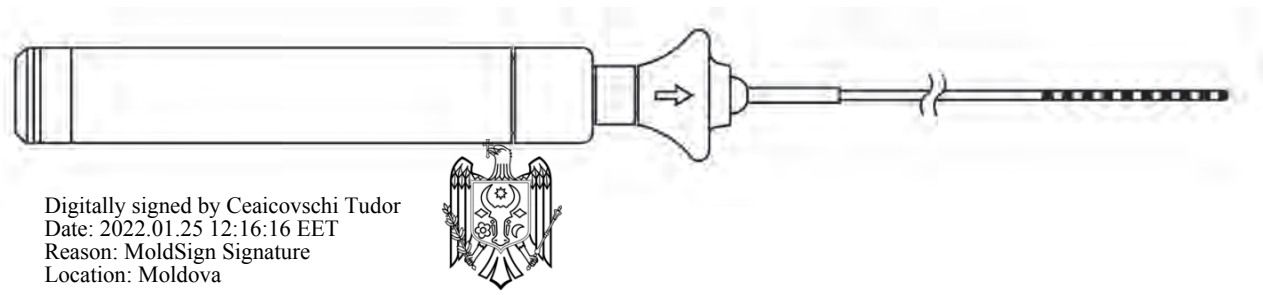
Ordering Information

5 F Decapolar steerable diagnostic catheter (1 unit per box)

Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Curve Type	Usable Length (cm)
81171	1110-5-2-M	2	1	Medium	110
81172	1110-5-25-M	2-5-2	1	Medium	110
81174	1110-5-25-L	2-5-2	1	Large	110
81223	1110-5-2(50)3-XL	2(50)3	1	X-Large	110
81734	1110-5-25-L (soft)	2-5-2	1	Large	110
81735	1110-5-5-L (soft)	5	1	Large	110
81736	1110-5-5(22)5-M/L (soft)	5(22)5	1	Medium/Large	110
81721	1110-5-25-M(SC) (soft)	2-5-2	1	Medium(SC)	110
81730	1110-5-28-M/L (soft)	2-8-2	1	Medium/Large	110

Required Catheter Connecting Cables – Page 122

Reorder Number	Model Number	Description	Length (m)
85954	1910-SA	10-Pin Diagnostic Connecting Cable	1.5
85930	1910-S	10-Pin Diagnostic Connecting Cable	1.5
85942	1910-S	10-Pin Diagnostic Connecting Cable	2.5



Inquiry™ Electrophysiology Catheters
Decapolar
6 F

Steerable Diagnostic

Product Highlights

- Variable electrode spacing for pacing and recording
- Multiple curve configurations for ease of placement
- Push/pull handle for steering control
- Bi-directional Steering model

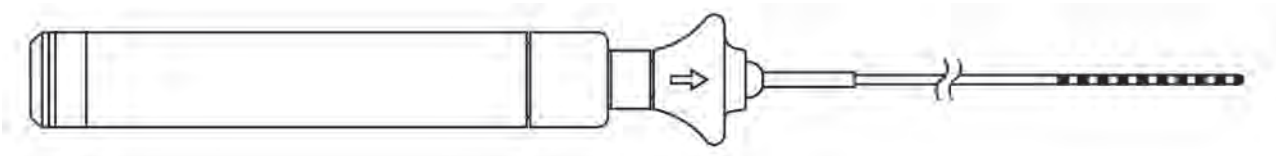
Ordering Information

6 F Decapolar steerable diagnostic catheter (1 unit per box)

Reorder Number	Description	Electrode Spacing (mm)	Curve Type	Usable Length (cm)
81102	1110-6-25-M	2-5-2	Medium	110
81104	1110-6-25-L	2-5-2	Large	110
81105	1110-6-25-XL	2-5-2	X-Large	110
81107	1110-6-5-L	5	Large	110
81520	1110-6-2-XL-TE4BE4	2	X-Large	110
81524	1110-6-2-L-TE4BE4	2	Large	110
87006	1110-6-25-M/L(SOFT)	2-5-2	Medium/Large	110
81945	1110-6-25-L(SOFT)	2-5-2	Large	110
81947	1110-6-5-M/L(SOFT)	5	Medium/Large	110
81504	1110-6-5-M-TE2BE2-BD	5	Medium	110

Required Catheter Connecting Cable – Page 122

Reorder Number	Model Number	Description	Length (m)
85954	1910-SA	10-Pin Diagnostic Connecting Cable	1.5
85930	1910-S	10-Pin Diagnostic Connecting Cable	1.5
85942	1910-S	10-Pin Diagnostic Connecting Cable	2.5



ST. JUDE MEDICAL

bsi.

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 69920**

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

In respect of:

Inquiry™, Inquiry™ Afocus, Inquiry™ Optima™ and Inquiry™ Optima™ PLUS Diagnostic Catheters and Inquiry™ Cardioversion and Cardioversion II 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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2002-09-26** Date: **2017-09-22** Expiry Date: **2022-09-25**

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USA

Diagnostic Catheters
Inquiry™ Fixed Curve Diagnostic Catheters
Model Numbers: $10XX^{(1)}$ -$X^{(2)}$ -$X^{(3)}$ - $X^{(4)}$ - $X^{(5)}$
Inquiry™ Steerable Diagnostic Catheters
Model Numbers: $11XX^{(1)}$ -$X^{(2)}$ - $X^{(3)}$ - $X^{(4)}$ -$X^{(5)}$

Cardioversion Catheters
Inquiry™ Fixed Curve Cardioversion Catheters
Model Numbers: $10XX^{(1)}$ -CV-$X^{(2)}$ -$X^{(3)}$ - $X^{(4)}$ - $X^{(5)}$
Inquiry™ Steerable Cardioversion Catheters
Model Numbers: $11XX^{(1)}$ -CV-$X^{(2)}$ - $X^{(3)}$ - $X^{(4)}$ -$X^{(5)}$

Notes
$XX^{(1)}$ – defines the number of electrodes, from 1 to 30
$X^{(2)}$ – is the outside diameter in French size, from 4Fr to 7Fr
$X^{(3)}$ – is the electrode spacing, these are variable
$X^{(4)}$ – defines the curve configuration. For Cardioversion Catheters, curve configurations include "C", "C1", "SC1", "L" and two additional shapes

First Issued: **2002-09-26** Date: **2017-09-22** Expiry Date: **2022-09-25**

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X(5) – various modifiers including but not limited to: ▪ Useable length is specified if it's not 110cm (from 60 cm to 130 cm) ▪ TE"X" – tip electrode length where "X" is between 1 mm to 4 mm ▪ BE"X" – band electrode length where "X" is between 0.6 mm to 4 mm ▪ POS – Pin out Shrouded ▪ SOFT – Soft tube ▪ AF – AFocus ▪ OPT - Optima ▪ AB – all braided tubing ▪ EB – extended braid tubing ▪ BD – bi-directional steering ▪ DL – double loop ▪ H"X"(40-50 mm nominal) – H-Curve TV Steerable Diagnostic Catheter curve configurations include H, HJ, and four additional shapes
CV designates Cardioversion

First Issued: **2002-09-26** Date: **2017-09-22** Expiry Date: **2022-09-25**

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Certificate History

Date	Reference Number	Action
26 September 2002	10039964	First Issue
21 August 2003	10051238	Addition of Inquiry™ with 0.6 mm band electrodes
09 July 2004	10059218	Change of address New certificate format
20 August 2004	10061093	Inquiry™ Optima™ and Bi-directional catheters added to the scope
23 January 2006	10072850	Addition of Inquiry™ Cardioversion Catheters
13 March 2006	10078316	Inquiry ™ Optima™ PLUS Diagnostic Catheter added to the scope
12 October 2006	10080300	Inquiry Cardioversion II Catheters added to the scope
12 February 2007	10083251	Name change to include "a St. Jude Medical Company"
17 August 2007	10089753	Certificate renewal
27 September 2007	10091579	Removal of the reference 'IBI' throughout the certificate
27 June 2008	10098262	Addition of "All Braid" shaft to the Inquiry™ Catheters. Clarify modification code X(5) to be more specific.
16 September 2008	10098977	Addition of Inquiry™ H-Curve TV Steerable Diagnostic Catheters

First Issued: **2002-09-26** Date: **2017-09-22** Expiry Date: **2022-09-25**

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EC Design-Examination Certificate

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Irvine
CA 92614
USA

Certificate History

Date	Reference Number	Action
27 May 2009	10104367	Expansion of list of defibrillators that are compatible with the Inquiry™ cardioversion catheter 1400-CV and 1400-CV-II cardioversion catheters to include the Medtronic® Lifepak 20 and Philips HeartStart XL biphasic defibrillators
25 September 2012	10136624	Certificate renewal.
21 May 2013	10141030	Addition of St. Jude Medical Costa Rica Ltda as an alternative manufacturing site for the Inquiry Steerable Diagnostic Catheter.
31 March 2015	10154190	Synergy Health, Costa Rica added as a significant subcontractor for the ETO sterilization of the Inquiry Catheter Family.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
Current	8760902	Certificate renewal.

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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
Inquiry™, Inquiry™ AFocus™, Inquiry™ Optima, Inquiry™ Optima™ PLUS Diagnostic Catheters and Inquiry™ Cardioversion and Cardioversion II 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:

Diagnostic Catheters

Product Name(s):

Inquiry™, Inquiry™ AFocus™, Inquiry™ Optima, Inquiry™ Optima™ PLUS Diagnostic Catheters and Inquiry™ Cardioversion and Cardioversion II Catheters

Model and Model Number(s):

Diagnostic Catheters
Inquiry™ Fixed Curve Diagnostic Catheter
$10XX^{(1)} - X^{(2)} - X^{(3)} - X^{(4)} - X^{(5)}$

Inquiry™ Steerable Diagnostic Catheter
$11XX^{(1)} - X^{(2)} - X^{(3)} - X^{(4)} - X^{(5)}$

Cardioversion Catheters
Inquiry™ Fixed Curve Cardioversion Catheter
$10XX^{(1)} - CV - X^{(2)} - X^{(3)} - X^{(4)} - X^{(5)}$

Inquiry™ Steerable Cardioversion Catheter
$11XX^{(1)} - CV - X^{(2)} - X^{(3)} - X^{(4)} - X^{(5)}$

Notes:
$XX^{(1)}$ – defines the number of electrodes, from 1 to 30
$X^{(2)}$ – is the outside diameter in French size, from 4Fr to 7Fr
$X^{(3)}$ – is the electrode spacing, these are variable
$X^{(4)}$ – defines the curve configuration. For Cardioversion Catheters, curve configurations include "C", "C1", "SC1", "L" and two additional shapes

$X^{(5)}$ – various modifiers including but not limited to: • Useable length is specified if it's not 110cm (from 60 cm to 130 cm) • TE"X"- tip electrode length where "X" is between 1 mm to 4 mm • BE"X"- band electrode length where "X" is between 0.6 mm to 4 mm • POS - Pin out Shrouded • SOFT - Soft tube • AF – AFocus • OPT - Optima • AB - all braided tubing • EB - extended braid tubing • BD - bi-directional steering • DL – double loop • H"X"(40-50 mm nominal) – H-Curve TV Steerable Diagnostic Catheter curve configurations include H, HJ, and four additional shapes
CV designates Cardioversion

Classification: Class III, Rule 7 according to Annex IX of the MDD 3/42/EEC.

GMDN Code(s): 46355

Original CE Mark Date: 26 Sep 2002

EC Certificate No: Certificate No: 69920
Expiration Date: 25 Sep 2022

Applicable Quality System Standards: ISO 13485:2003

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

Notified Body Number: 0086

Signature:

Kellie Stefaniak
Manager, Regulatory Affairs

25 SEP 2017
Issue Date