Fast-Cath™ Hemostasis Introducer 12 cm Sheath with Guidewire and Needle

Standard Introducer

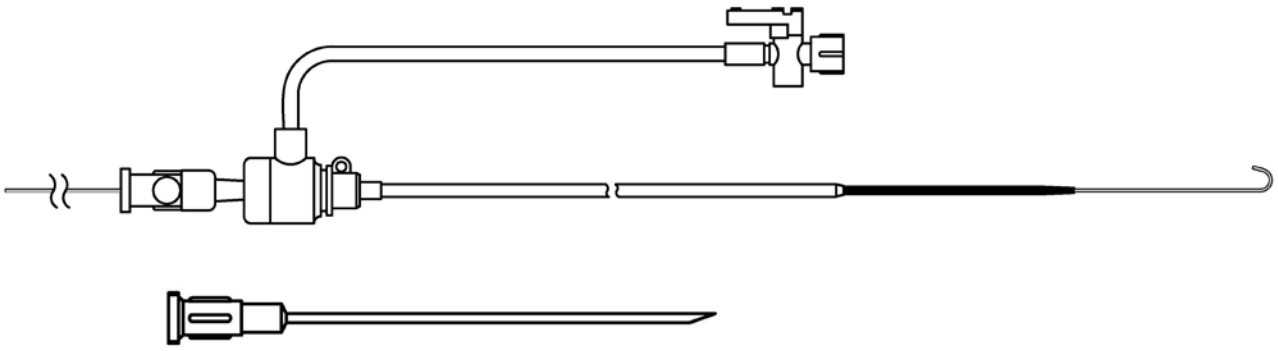
Product Highlights

- Designed as a standard introducer for both diagnostic and interventional catheterizations
- Close tolerance extrusion and proprietary tipping process dramatically improve tracking on a guidewire
- Convenient suture rings to secure sheath during catheter manipulation or during prolonged vascular access
- Patented valve preserves catheter handling characteristics while minimizing backbleeding and air aspiration
- Snap lock feature secures dilator in sheath during insertion

Ordering Information

Contents: Introducer Sheath with Hemostasis Valve, Sideport, Dilator, 50 cm Double Distal .038" Guidewire with "J" and Straight ends and 18 ga. XTW Needle. (5 units per box)

Reorder Number	French Size	Guidewire Diameter (in)	Sheath Length (cm)
406350	5	.038	12
406354	6	.038	12
406358	7	.038	12
406362	8	.038	12
406366	9	.038	12



Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Product referenced is approved for CE Mark.

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MORE CONTROL. LESS RISK.

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 561244**

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

In respect of:

The Design, Development and Manufacturing of sterile Pacing Catheters, Radio Frequency (RF) Ablation Catheters, Introducers and Accessories, Guide Catheters, Guidewires, Resorbable Closure Devices and non-sterile Radio Frequency (RF) Ablation Generators

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **18 May 2010** Date: **11 March 2016** Expiry Date: **14 March 2021**

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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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
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: + 44 845 080 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.

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EC Certificate - Full Quality Assurance System

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 561244**

Date: **11 March 2016**

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

Subcontractor:	**Service(s) supplied**
Kensey Nash Corporation d.b.a. DSM Biomedical 735 Pennsylvania Drive Exton Pennsylvania 19341 USA	**Animal substances** **Manufacture**
Lake Region Medical Ltd. Butlersland New Ross Co. Wexford Ireland	**Manufacture**
Lake Region Medical 340 Lake Hazeltine Drive Chaska MN 55318 USA	**Control of Sterilization** **Manufacture** **Packaging**

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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 561244**
Date:	**11 March 2016**
Issued To:	**St. Jude Medical** **14901 DeVeau Place** **Minnetonka** **Minnesota** **55345-2126** **USA**

Subcontractor:	**Service(s) supplied**
Plexus Corp. 2400 Millbrook Drive Buffalo Grove Illinois 60089 USA	**Manufacture** **Packaging**
Plexus Corp. 55 Jewelers Park Drive P.O. Box 677 Neenah Wisconsin 54957 USA	**Design** **Development**
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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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Certificate No: **CE 561244**

Date: **11 March 2016**

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

Subcontractor:	Service(s) supplied
St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela Costa Rica	**Manufacture**
St. Jude Medical, Puerto Rico LLC Caguas West Industrial Park Caguas 00725 Puerto Rico	**Manufacture**
St. Jude Medical (Atrial Fibrillation Division) 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

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 561244**
Date:	**11 March 2016**
Issued To:	**St. Jude Medical** **14901 DeVeau Place** **Minnetonka** **Minnesota** **55345-2126** **USA**

Subcontractor:	**Service(s) supplied**
St. Jude Medical (Irvine Biomedical) 2375 Morse Avenue Irvine California 92614 USA	**Manufacture**
St. Jude Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA	**Manufacture**
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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Certificate No: **CE 561244**

Date: **11 March 2016**

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

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	**Gamma Sterilization**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	**ETO Sterilization**
STERIS Isomedix Services 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**

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List of Significant Subcontractors

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14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA

Subcontractor:	**Service(s) supplied**
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore Co. Offaly Ireland	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 561244**

Date: **11 March 2016**

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

Date	Reference Number	Action
18 May 2010	7508960	First Issue
21 March 2011	7610650	Transfer from another Notified Body of all the St. Jude Medical Cardiology Division products from the 14901 DeVeau Place, Minnetonka, MN facility. Certificate Renewal
26 April 2012	7816453	Update the scope of the certificate to add RF ablation catheters and RF ablation generators. Also addition of the significant subcontractors for manufacture: SJM AFD Minnetonka and SJM Irvine Biomedical. Significant sutx:ontractor name change from Isotron to Synergy Health Ireland LTD.
22 November 2012	7915693	Addition of St. Jude Medical Costa Rica Ltda. and several locations of Plexus Corp. to the list of significant subcontractors. Name change of Sterigenics located in Gurnee, Ill and West Memphis AR to Sterigenics US LLC.
14 February 2013	7900352	Removal of St. Jude Medical, Mahwah from the list of significant subcontractors.
15 October 2013	8026882	Addition of St. Jude Medical Plymouth as a significant subcontractor for manufacture.
12 June 2014	8154317	Typographical corrections to both Lake Region Medical significant subcontractor listings.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 561244**

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Issued To: **St. Jude Medical**
14901 DeVeau Place
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Date	Reference Number	Action
16 March 2015	8297445	Addition of Packaging & Labelling to activities of St. Jude Medical Coordination Center BVBA.
07 December 2015	8433259	Addition of Sterigenics US, LLC, Willowbrook, IL as a significant subcontractor for ETO sterilization.
11 March 2016	8487290	Certificate renewal. Update of scope. Subcontractors: SJM, Maple Grove removed (facility closed), Kensey Nash Corp. and Synergy Health Ireland address corrections.

ST. JUDE MEDICAL

SJM Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of the Council Directive 93/42/EEC, Annex II, Section 4. 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:	**Introducers**
Product and RO Number:	**Fast–Cath™ Hemostasis Introducer** 406xxx, 407xxx **SJM™ Percutaneous Catheter Introducer** 404xxx
Classification:	Class IIa per Annex IX, Rule 6
GMDN Code(s):	58865
Original CE Mark Date:	1994**
(FQA or EC as appropriate) **Certificate No and expiration date:**	Certificate No: CE 561244 Expiration Date: 14Mar2021
Applicable Quality System Standards:	ISO 13485:2012
Notified Body:	BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP UK
Notified Body Number:	0086

ST. JUDE MEDICAL

SJM Declaration of Conformity

Signature:

14-MAR-2016

Jack Kromenhoek
Manager, Regulatory Affairs

Issue Date

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