Livewire™ Electrophysiology Catheters
Duo-Decapolar (20 electrodes)
7 F

Product Highlights

- Ergonomic handling
- Rotary dial designed for fine tip movements
- Color-coded cables for convenience
- 1 mm band electrodes

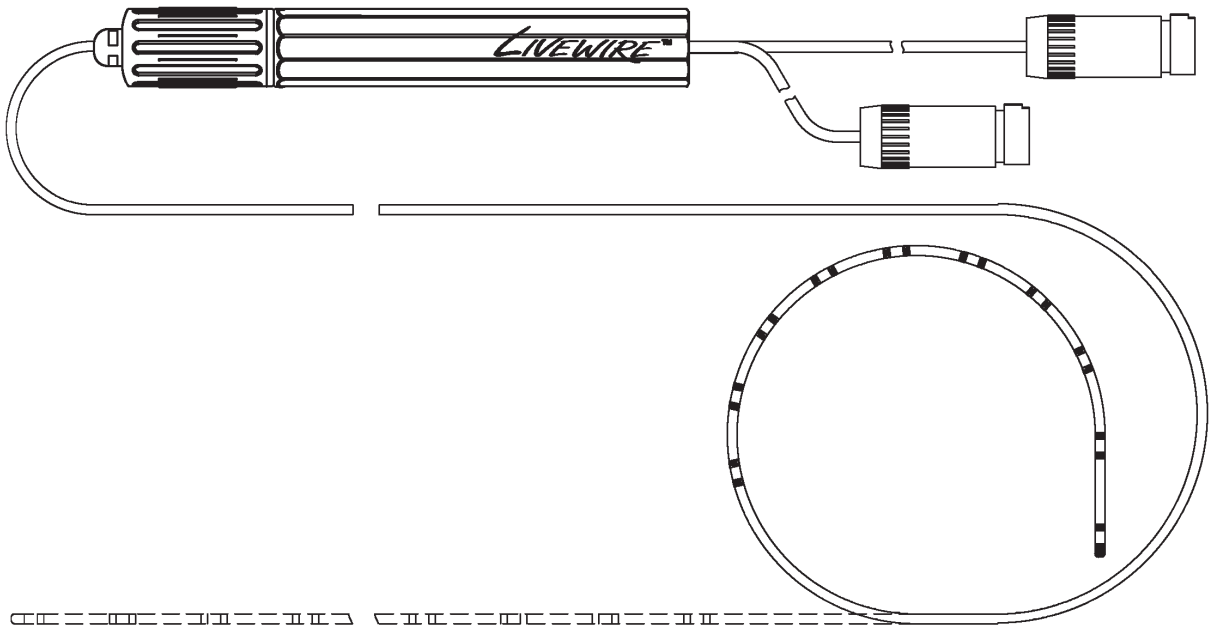
Ordering Information

7 F Duo-Decapolar catheter (1 unit per box) Note: Requires two catheter extension cables

Reorder Number	French Size	Electrode Spacing (mm)	Tip Electrode (mm)	Distal Reach	Usable Length (cm)
401904	7	2-10-2	2	Super Large Curl	95
401905	7	5-5-5	2	Super Large Curl	95
401914	7	2-5-2	2	Super Large Curl	95
401908	7	2-2-2	2	Medium Curl	115

Required Catheter Connecting Cables – Page 123

Reorder Number	Color	Connects these Catheters	Usable Length (cm)
401972	Black	Hexapolar, Octapolar and Decapolar	150
401977	Red	Hexapolar, Octapolar and Decapolar	150
401976	Black	Hexapolar, Octapolar and Decapolar	210



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EC Design-Examination Certificate

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

No. **CE 548275**

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

In respect of:

Livewire™ Electrophysiology Catheter

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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-07-01** Date: **2019-06-25** Expiry Date: **2024-05-26**

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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, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Intended Purpose per IFU

The Livewire™ Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

Product	Model Number	Size (F)	Electrode Spacing (mm)	Tip Electrode Length (mm)	Distal Reach	Usable Length (cm)	Classification
Livewire™ EP Bipolar (2 electrodes)	401786	7	2	2	Large Curl	80	Class III
Livewire™ EP Quadripolar (4 electrodes)	401572	6	2-5-2	2	Medium Sweep	115	Class III
	401576	7	2-5-2	4	Small Sweep	115	Class III
	401577	7	2-5-2	4	Medium Sweep	115	Class III
	401578	7	2-5-2	4	Large Sweep	115	Class III
	401586	7	2-5-2	4	Small Curl	115	Class III
	401587	7	2-5-2	4	Medium Curl	115	Class III
	401588	7	2-5-2	4	Large Curl	115	Class III
	401600	6	2-5-2	4	Medium Sweep	115	Class III
	401603	6	2-5-2	4	Medium Curl	115	Class III

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Product	Model Number	Size (F)	Electrode Spacing (mm)	Tip Electrode Length (mm)	Distal Reach	Usable Length (cm)	Classification
	401606	6	2-5-2	2	Large Sweep	115	Class III
	401647	5	5-5-5	2	Medium Curl	115	Class III
	401648	5	5-5-5	2	Large Curl	115	Class III
	401649	5	2-5-2	2	Medium Curl	115	Class III
	401780	5	5-5-5	2	Medium Sweep	115	Class III
	401781	5	5-5-5	2	Large Sweep	115	Class III
	401933	6	5-5-5	2	Medium Sweep	115	Class III
	401934	6	5-5-5	2	Large Sweep	115	Class III
Livewire™ EP Pentapolar (5 electrodes)	402019	5	5-5-5-175	2	Medium Sweep	115	Class III
	402022	5	5-5-5-175	2	Large Curl CRD-2™	115	Class III

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Product	Model Number	Size (F)	Electrode Spacing (mm)	Tip Electrode Length (mm)	Distal Reach	Usable Length (cm)	Classification
Livewire™ EP Hexapolar (6 electrodes)	401580	7	2-5-2-5-2	2	Medium Sweep	115	Class III
	401653	5	2-5-2-5-2	2	Medium Sweep CRD-2™	115	Class III
	401654	5	5-5-5-5-5	2	Medium Sweep CRD-2™	115	Class III
Livewire™ EP Octapolar (8 electrodes)	401581	7	2-5-2-5-2-5-2	2	Medium Sweep	115	Class III
	401652	5	2-2-2-2-2-2-2	2	Medium Sweep CRD-2™	115	Class III
	401917	6	2-2-2-2-2-2-2	2	Medium Sweep	115	Class III
	401949	6	2-2-2-2-2-2-2	2	Large Sweep	115	Class III
Livewire™ EP Decapolar (10 electrodes)	401575	6	2-5-2-5-2-5-2-5-2	2	Medium Sweep	115	Class III
	401582	7	2-5-2-5-2-5-2-5-2	2	Medium Sweep	115	Class III

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Product	Model Number	Size (F)	Electrode Spacing (mm)	Tip Electrode Length (mm)	Distal Reach	Usable Length (cm)	Classification
	401655	5	2-5-2-5-2-5-2-5-2	2	Extra Large Curl	115	Class III
	401915	6	2-5-2-5-2-5-2-5-2	2	Extra Large Curl	115	Class III
	401923	6	2-2-2-2-2-2-2-2-2	2	Extra Large Curl	115	Class III
	401926	6	2-8-2-8-2-8-2-8-2	2	Extra Large Sweep CSL™ Bi-Directional	115	Class III
	401935	7	2-5-2-5-2-5-2-5-2	2	Extra Large Sweep CSM™	115	Class III
	401938	5	5-5-5-5-5-5-5-5-5	2	Medium Sweep	115	Class III
	401939	5	2-2-2-2-2-2-2-2-2	2	Medium Sweep	115	Class III
	401940	5	2-5-2-5-2-5-2-5-2	2	Medium Sweep	115	Class III

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Product	Model Number	Size (F)	Electrode Spacing (mm)	Tip Electrode Length (mm)	Distal Reach	Usable Length (cm)	Classification
	401941	5	2-8-2-8-2-8-2-8-2	2	Extra Large Curl	115	Class III
	401942	6	2-8-2-8-2-8-2-8-2	2	Extra Large Curl	115	Class III
	401990	5	2-2-2-2-2-2-2-2-2	2	Extra Large Curl	115	Class III
	401991	5	2-5-2-5-2-5-2-5-2	2	Extra Large Curl	115	Class III
	402026	5	2-8-2-8-2-8-2-8-2	2	Large Curl CSL™	115	Class III
	D402070	6	5-5-5-5-5-5-5-5-175	2	Large Curl CSL™	115	Class III
Livewire™ EP Duo-Decapolar (20 electrodes)	401904	7	2-10-2-10-2-10-2-10-2-10-2-10-2-10-2-10-2	2	Super Large Curl	95	Class III

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Product	Model Number	Size (F)	Electrode Spacing (mm)	Tip Electrode Length (mm)	Distal Reach	Usable Length (cm)	Classification
	401905	7	5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5-5	2	Super Large Curl	95	Class III
	401908	7	2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2	2	Medium Curl	115	Class III
	401914	7	2-5-2-5-2-5-2-5-2-5-2-5-2-5-2-5-2-5-2-5-2-5-2-5-2-5-2	2	Super Large Curl	95	Class III
	401918	7	2-20-2-2-2-2-2-2-2-2-2-2-2-25-2-25-2-25-2	2	Super Large Curl	95	Class III

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Product	Model Number	Size (F)	Electrode Spacing (mm)	Tip Electrode Length (mm)	Distal Reach	Usable Length (cm)	Classification
	401932	7	2-8-2-8-2-8-2-8-2-60-2-8-2-8-2-8-2-8-2	2	Super Large Curl	95	Class III
	402032	6	2-4-2-4-2-4-2-4-2-4-2-4-2-4-2-4-2-4-2-4-2	2	Large Curl	115	Class III
Livewire™ EP Spiral HP™ Duo-Decapolar (20 electrodes)	401782	7	2-1.5-1-1.5-1-1.5-1-1.5-1-1.5-1-1.5-1-1.5-1-1.5-1-1.5-1	2	Medium Sweep, Spiral HP™ 15 mm	120	Class III

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Product	Model Number	Size (F)	Electrode Spacing (mm)	Tip Electrode Length (mm)	Distal Reach	Usable Length (cm)	Classification
	401783	7	2-2.5-1-2.5-1-2.5-1-2.5-1-2.5-1-2.5-1-2.5-1-2.5-1-2.5-1	2	Medium Sweep, Spiral HP™ 18 mm	120	Class III

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Certificate History

Date	Reference Number	Action
01 July 2009	10104504	First issue – Transfer from another Notified Body
30 October 2009	10109161	Line extension to add Livewire Pigtail Steerable Electrophysiology Catheter D402051
06 June 2014	10146392	Certificate renewal
10 June 2015	10156225	Tip shaft buckle force product specification change.
01 February 2016	10160623	Addition of Sterigenics Willowbrook, IL as a sterilizer.
19 June 2016	10163123	Changes to product family catalogue numbers.
05 December 2016	10165171	Addition of St. Jude Medical Plymouth as a physical manufacturing site.
05 March 2019	7780627	Traceable to NB 0086.
15 April 2019	9718016	Addition of Sterigenics US, LLC, Salt Lake City, Utah for ETO Sterilization.
Current	9698762	Certificate Renewal and administrative update to product table format per MDP 4500, Appendix A.

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SJM Declaration of Conformity

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 2007/47/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:	St. Jude Medical 14901 DeVeau Place Minnetonka, Minnesota 55345-2126 USA
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Electrophysiology Catheter
Product Name(s):	Livewire™ Electrophysiology Catheter
Model Number(s):	401572, 401575, 401576, 401577, 401578, 401580, 401581, 401582, 401586, 401587, 401588, 401600, 401603, 401606, 401647, 401648, 401649, 401652, 401653, 401654, 401655, 401780, 401781, 401782, 401783, 401786, 401904, 401905, 401908, 401914, 401915, 401917, 401918, 401923, 401926, 401932, 401933, 401934, 401935, 401938, 401939, 401940, 401941, 401942, 401949, 401990, 401991, 402019, 402022, 402026, 402032, D402070
Classification:	Class III, Rule 7 according to Annex IX of the MDD 93/42/EEC
GMDN Code(s):	46355 Cardiac mapping catheter, percutaneous, single-use
Original CE Mark Date:	01-Jul-2009
Certificate No and expiration date:	Certificate No: CE 548275 Expiration Date: 26-May-2024
Applicable Quality System Standards:	EN ISO 13485:2016

Signature:

Blair Schwartz
Regulatory Affairs Manager

09Mar2020
Issue Date: March 9, 2020

ST. JUDE MEDICAL

SJM Declaration of Conformity

Notified Body:

BSI Group The Netherlands B.V.
Say Building
John M. Kaynesplein 9
1066 EP Amsterdam
The Netherlands

Notified Body Number:

2797 (Traceable NB number 0086, BSI Reference 7780627)

Signature:

Blair Schwartz
Regulatory Affairs Manager

09 Mar 2020
Issue Date: March 9, 2020