Peel-Away Introducer
14 cm Sheath
Introducer Kit

5 F – 16 F

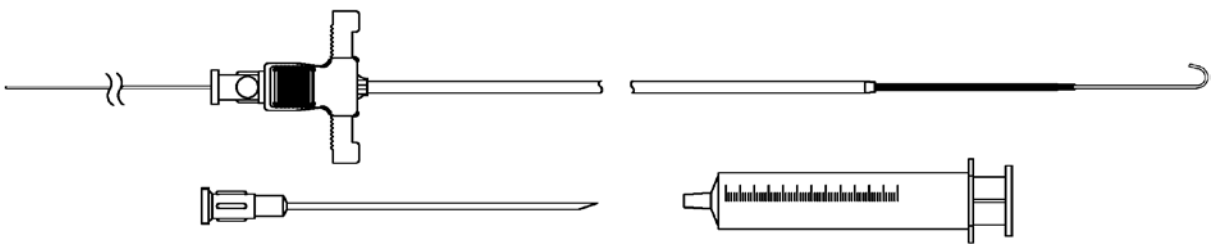
Product Highlights

- Proprietary materials improve insertion characteristics and reduce vessel trauma
- Close tolerance extrusion and proprietary tipping process improves tracking on a guidewire
- Reliable peeling characteristics
- Sheath can be totally occluded without kinking to prevent air inspiration
- Di-Lock™ feature secures dilator in sheath during insertion

Ordering Information

Contents: Peel-Away Sheath, Di-Lock™ Dilator, 12 cc syringe, 18 ga. XTW Needle, and 50 cm Guidewire with 3 mm "J" (5 units per box)

Reorder Number	French Size	Maximum Guidewire Diameter (in)	Sheath Usable Length (cm)
405100	5	.038	14
405104	6	.038	14
405108	7	.038	14
405112	8	.038	14
405116	9	.038	14
405118	9.5	.038	14
405120	10	.038	14
405122	10.5	.038	14
405124	11	.038	14
405128	12	.038	14
405132	13	.038	14
405136	14	.038	14
405144	16	.038	14



U.S. Patent Number 5,098,392

Electrophysiology EMEAC Catalogue
GMAF392EN (October, 2010)

EC Design-Examination Certificate

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

No. **CE 597707**

Issued To: **St. Jude Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

Peel-Away Introducers

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: **2013-05-16** Date: **2018-05-01** Expiry Date: **2023-05-15**

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EC Design-Examination Certificate

Supplementary Information to CE 597707

Issued To:

St. Jude Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Peel-Away Introducer Set

405100, 405104, 405108, 405112, 405116, 405118-405120, 405122, 405124, 405128, 405129, 405132, 405136, 405144, 405145, 405146, 405147, 405149, 405153, 405154, 405254, 405256, 405258, 405259, 405269, 405270, 405400, 405404, 405408, 405412, 405416, 405418, 405420, 405422,405424, 405428, 405444

First Issued: **2013-05-16** Date: **2018-05-01** Expiry Date: **2023-05-15**

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EC Design-Examination Certificate

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Certificate History

Date	Reference Number	Action
16 May 2013	10141164	First Issue. Mirror certificate to CE 576208
14 May 2014	10146050	Addition of St. Jude Medical Plymouth facility as a manufacturing site.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
01 February 2016	10160623	Addition of Sterigenics Willowbrook, IL as a sterilizer.
Current	8903134	Certificate Renewal. Clarification of model number listings.

First Issued: **2013-05-16** Date: **2018-05-01** Expiry Date: **2023-05-15**

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SJM Declaration of Conformity Peel Away Introducer

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 5050 Nathan Lane N Plymouth MN 55442 USA
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Introducer
Product Name(s):	Peel Away Introducer
Model Number(s):	405100, 405104, 405108, 405112,405116, 405118-405120, 405122, 405124, 405128, 405129, 405132, 405136, 405144, 405145, 405146, 405147, 405149, 405153, 405154, 405254, 405256, 405258, 405259, 405269, 405270, 405400, 405404, 405408, 405412, 405416, 405418, 405420, 405422, 405424, 405428, 405444
Classification:	Class III, Rule 7 according to Annex IX of the MDD 93/42/EEC as amended by 2007/47/EC
GMDN Code(s):	*58865*
Original CE Mark Date:	*18 Feb 2013*
EC Certificate No and expiration date:	Certificate No: CE 597707 Expiration Date: 05 May 2023
Applicable Quality System Standards:	EN ISO 13485:2012
Notified Body:	BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP
Notified Body Number:	*0086*

Signature:

Blair Schwartz
Regulatory Affairs Manager

09May18
Issue Date