

Peel-Away Introducer

14 cm Sheath

Introducer Kit

5 F – 16 F

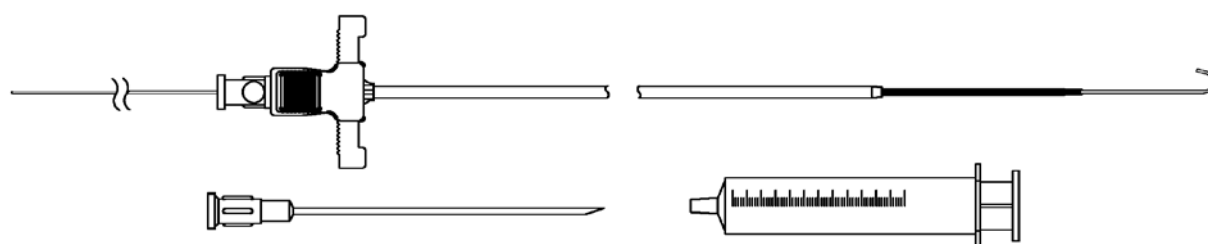
Product Highlights

- 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

EC Design-Examination Certificate

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

No.

CE 597707

Issued To:

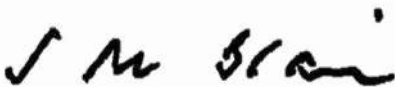
**St. Jude Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA**

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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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.

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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Page 2 of 3

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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**

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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Page 3 of 3

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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
58865

GMDN Code(s):

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
Knowhill
Milton Keynes
MK5 8PP
0086

Notified Body Number:

Signature:


Blair Schwartz
Regulatory Affairs Manager

09 May 18
Issue Date

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Medical Costa Rica Ltda.
Edificio #44
Calle 0, Ave. 2
Zona Franca Coyol
El Coyol, Alajuela
Costa Rica

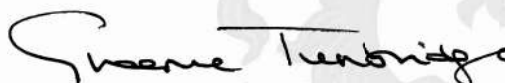
Holds Certificate No:

FM 728657

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacture and distribution of radio-frequency (RF) ablation catheters, electrophysiology (EP) catheters, intracardiac echocardiography catheters, cardiac mapping system accessories, transseptal access system, introducer catheters, vascular closure systems; and the design of cardiac mapping system accessories.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-06

Latest Revision Date: 2022-03-22

Effective Date: 2021-12-14

Expiry Date: 2024-12-13

Page: 1 of 1



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CERTIFICATE



This is to certify that



SANTE
INTERNATIONAL S.A.

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

has implemented and maintains a **Quality Management System**.

Scope:

Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no. 497269 QM15
Valid from 2021-06-16
Valid until 2024-06-15
Date of certification 2021-06-16



DQS GmbH

Markus Bleher
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Romania, Str. Batului nr. 11, 020565 Bucharest - Romania



Annex to certificate
Registration No. 497269 QM15

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

Location

Scope

075906
Sante International SA
Sos. Mihai Bravu nr. 7, bl. P37-P37A,
sector 2
021303 Bucuresti
Romania

Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices. Consulting for state and private medical units.

497270
Sante International SA
Str. Pupitrului, nr. 81,
sect. 3
033036 Bucuresti
Romania

Storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

31050285
Sante International SA
Calea Ghirodei, nr. 36
300327 Timisoara
Romania

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

31050284
Sante International SA
Calea Dorobantilor, nr. 111
400609 Cluj-Napoca
Romania

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

31050283
Sante International SA
Str. Lascar Catargi, nr. 37
700107 Iasi
Romania

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.