Peel-Away Introducer
14 cm Sheath
Introducer Kit

5 F – 16 F

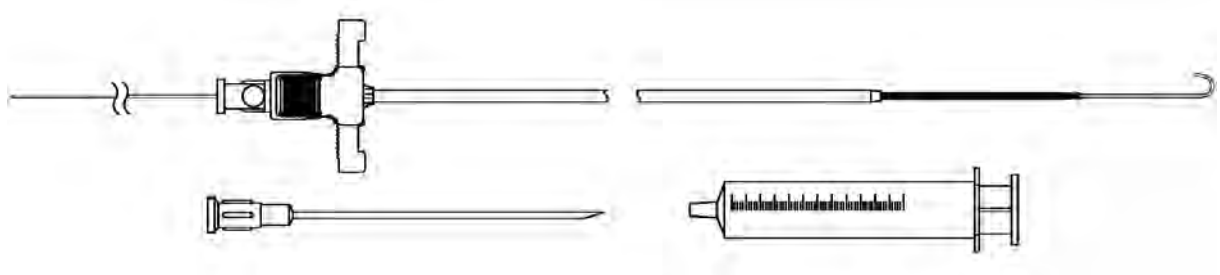
Product Highlights

- 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)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 014607 0256 Rev. 00

Manufacturer:

Abbott Medical
15900 Valley View Court
Sylmar CA 91342
USA

SRN Manufacturer: US-MF-000010383

Authorized Representative:

Abbott Medical
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem,
BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result. Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 014607 0256 Rev. 00

Report No.: 713234168

Valid from: 2023-03-08

Valid until: 2028-03-07

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2023-03-08

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 014607 0256 Rev. 00

Classification:	Class III
Device Group:	C0503 - CARDIOVASCULAR INTRODUCER SHEATHS, PEEL-AWAY
Basic UDI-DI:	5415067PLA0001FY
Intended Purpose:	The Peel Away Introducers are intended to provide a transvenous conduit for the introduction of cardiac leads and catheters into the venous vascular system.
Device(s):	Peel-Away Introducer. Article numbers: 405104, 405108, 405112, 405116, 405118, 405119, 405120, 405122, 405124, 405128, 405129, 405136, 405144, 405145, 405146, 405147, 405149, 405153, 405154, 405254, 405269, 405270, 405404, 405408, 405412, 405416, 405418, 405420, 405422, 405424, 405428
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Rev.	Dated	Report	Description
00	2023-03-08	713234168	Initial issuance

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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TÜV®

Abbott Medical
15900 Valley View Court
Sylmar, CA USA 91342
Tel: +1 818 362-6822

0081901 Rev. A

Declaration of Conformity

Manufacturer:	Abbott Medical
Manufacturer SRN:	US-MF-000010383
Address:	15900 Valley View Court Sylmar, CA 91342 United States of America
Manufacturing Site(s):	Abbott Medical 5050 Nathan Lane Plymouth, Minnesota 55442 United States of America
European Authorized Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
European Authorized Representative SRN:	BE-AR-000008744

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Device Name(s):	Introducers
Product Trade Name(s):	Peel-Away Introducer
Model Number(s):	405104, 405108, 405112, 405116, 405118, 405119, 405120, 405122, 405124, 405128, 405129, 405136, 405144, 405145, 405146, 405147, 405149, 405153, 405154, 405254, 405269, 405270, 405404, 405408, 405412, 405416, 405418, 405420, 405422, 405424, 405428
Intended Purpose:	The Peel-Away Introducers are intended to provide a transvenous conduit for the introduction of cardiac leads and catheters into the venous vascular system.
Risk Classification:	**Class III** as per EU MDR 2017/745 per Annex VIII

Signature: Abbott Digitally signed by CANANCX Date: 2023.05.11 12:48:06 -07'00' Colleen Canan Divisional Vice President, Global Regulatory Affairs, Cardiac Rhythm Management	**May 11, 2023** Issue Date On behalf of Abbott Medical, signed at Sylmar, CA

Abbott Medical
15900 Valley View Court
Sylmar, CA USA 91342
Tel: +1 818 362-6822

0081901 Rev. A

MDR Declaration of Conformity

Risk Classification Rationale:	Annex VIII, Rule 6, 3rd indent
EMDN Code(s):	C0503 - Cardiovascular Introducing Sheaths, peel-away
GMDN Code:	17846
Basic UDI-DI:	5415067PLA0001FY

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1

Common Specifications Applied:	Not Applicable. No common specifications are available for this type of device
Notified Body:	TÜV SÜD Product Services GmbH Ridlerstraße 65 80339 Munich Germany ID Number: 0123
Supporting Certificate(s):	EU Technical Documentation Assessment Certificate (MDR) No: G70 014607 0256 Rev. 00 Expiration Date: 2028-03-07 EU Quality Management System Certificate (MDR) No: G12 014607 0255 Rev. 02 Expiration Date: 2027-08-14
Original CE Mark Date:	May 16, 2013 (MDD)
Conformity Assessment:	EU MDR 2017/745, Annex IX

The signature is applied on page 1

Abbott Medical
15900 Valley View Court
Sylmar, CA USA 91342
Tel: +1 818 362-6822

0081901 Rev. A

MDR Declaration of Conformity

The products in the attached Declaration of Conformity Product List are approved under EC Certificate No: G70 014607 0256 Rev. 00.

Declaration of Conformity Product List

Model No.	Product Trade Name	UDI-DI
405104	Peel-Away Introducer, 6F 14CM	05415067040855
405108	Peel-Away Introducer, 7F 14CM	05415067040879
405112	Peel-Away Introducer, 8F 14CM	05415067040893
405116	Peel-Away Introducer, 9F 14CM	05415067040916
405118	Peel-Away Introducer, 9.5F 14CM	05415067040930
405119	Peel-Away Introducer, 8.5F 14CM	05415067040954
405120	Peel-Away Introducer, 10F 14CM	05415067040978
405122	Peel-Away Introducer, 10.5F 14CM	05415067040992
405124	Peel-Away Introducer, 11F 14CM	05415067041012
405128	Peel-Away Introducer, 12F 14CM	05415067041036
405129	Peel-Away Introducer, 8F 14CM	05415067041050
405136	Peel-Away Introducer, 14F 14CM	05415067041074
405144	Peel-Away Introducer, 16F 14CM	05415067041098
405145	Peel-Away Introducer, 8F CM	05415067041111
405146	Peel-Away Introducer, 8.5F CM	05415067041135
405147	Peel-Away Introducer, 9F CM	05415067041159
405149	Peel-Away Introducer, 10F CM	05415067041173
405153	Peel-Away Introducer, 7F CM	05415067041197
405154	Peel-Away Introducer, 7F 14CM	05415067041210
405254	Peel-Away Introducer, 9F 23CM	05415067041258
405269	Peel-Away Introducer, 7F 23CM	05415067041272
405270	Peel-Away Introducer, 8F 23CM	05415067041296
405404	Peel-Away Introducer, 6F 14CM	05415067041319
405408	Peel-Away Introducer, 7F 14CM	05415067041333
405412	Peel-Away Introducer, 8F 14CM	05415067041357
405416	Peel-Away Introducer, 9F 14CM	05415067041371
405418	Peel-Away Introducer, 9.5F 14CM	05415067041395
405420	Peel-Away Introducer, 10F 14CM	05415067041418
405422	Peel-Away Introducer, 10.5F 14CM	05415067041432
405424	Peel-Away Introducer, 11F 14CM	05415067041456
405428	Peel-Away Introducer, 12F 14CM	05415067041470

The signature is applied on page 1

CERTIFICATE

This is to certify that

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. Bratului 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.

This annex (edition:2021-06-16) is only valid in connection with the above-mentioned certificate.