ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 04 12974 422

Manufacturer:

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Facility(ies):

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

AESCULAP CHIFA Sp. z o.o.
ul. Tysiaclecia 14, 64-300 Nowy Tomysl, POLAND

B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

Product Category(ies):

Coronary stent systems, PTCA catheters, PTA catheters,
PTCA guide wires and sets,
Probes for stimulation and electrophysiology,
Procedure Kits,
Angiography sets, manifolds, guide wires,
single use Right heart pulmonary artery catheters,
Monitoring sets for invasive physiological
pressure measurement,
Introducer sheaths and sets,
Arterial puncture cannulae, arterial catheter sets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713055006

Valid from: 2015-06-16
Valid until: 2020-06-13

642819

Date, 2015-06-18

Hans-Heiner Junker

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

TÜV®

A1 / 04.11

B BRAUN

Konformitätserklärung
Declaration of Conformity

Document-No.:	39.05.646
Revision-No.:	24
Effective Date:	2016-10-11
Page:	1 of 2

Wir | We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung, dass das/die Produkt/e

hereby declare in our own responsibility that the product/s

Inflation Device

Y-Connector, Torquer, PTCA-Zubehör
(Artikelnummern siehe Anlage)

Y-Connector, Torquer, PTCA Accessories
(article numbers see attachment)

mit den Anforderungen der folgenden Richtlinie übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

Council Directive 93/42/EEC of 14th June 1993 concerning Medical Devices

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
nach Anhang V, VII
der oben genannten Richtlinie

Conformity Assessment Procedure
according to annex II (excluding section 4)
according to annex V, VII of the
Council Directive named above

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse Is / Regel 1
Klasse IIa / Regel 2, Regel 5

Classification
according to annex IX of the
Council Directive named above
Class Is / Rule 1
Class IIa / Rule 2, Rule 5

Benannte Stelle
TÜV SÜD Product Service GmbH (ID-Nr. 0123)
Ridlerstraße 65, 80339 München, Deutschland

Notified Body
TÜV SÜD Product Service GmbH (ID-No. 0123)
Ridlerstraße 65, 80339 Munich, Germany

Datum der ersten CE-Kennzeichnung
1999-02-17

Date of first CE-marking
1999-02-17

Gültig bis
2020-06-13

Valid until
2020-06-13

Berlin, 2016-10-11

B. Braun Melsungen AG

i. A.

R. Lorenz
Head of Quality Management

Berlin, 2016-10-11

B. Braun Melsungen AG

i. V.

Dr. B. Jänicke
Head of Regulatory Affairs Management

"TEHNOMEDICA" S.R.L. IDNO 1002600053256

Form: SA-DE03-M-5-1-12-000-4-B-DE/EN

Anlage I / Attachment I

Art.-Nr. REF No.	Artikelbezeichnung	Article description	Klasse Class
622510	Inflation Device	Inflation Syringe 25 ml	IIa
5028901	Inflationsspritze AI25	Inflation Device AI25	IIa
5019602	Y-Konnektor mit Einführhilfe 7,5 cm	Y-Connector with Introducer 7.5 cm	IIa
5021596	Y-Adapter 9,5F Lumen	Y-Adapter 9.5F Lumen	IIa
5021693	Y-Adapter 9,5F Lumen m. Einführhilfe	Y-Connector Single 9.5F	IIa
5020743	Y-Adapter 9,5F doppelt	Y-Adapter 9.5F, double	IIa
5022693	Y-Konnektor Flat Cap m. Einführhilfe	Y-Connector Flat Cap w. Insertion Tool	IIa
5023687	Torquer, rund	Torquer	Is
622511	PTCA-Set	PTCA Kit Inflation Device 25 ml	IIa
5028550	PTCA-Set 2	PTCA-Kit 2	IIa
5028902	PTCA-Set 3	Angiodyn PTCA-Set 3	IIa
5028904	Inflationsspritzenset Bifurkation	Inflation Device Kit Bifurcation	IIa
5028905	PTCA Set 4	PTCA Kit 4	IIa
5014760	UKB Unique Kissing BiBallonadaptor	UKB Unique Kissing BiBallonadaptor	IIa
5017826	Metall Einführhilfe 20G, 7,5 cm	Metal Insert Tool 20G, 7.5 cm	IIa

LNE
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Certification
Médical-Santé
Notified Body N° 0459

ATTESTATION / *CERTIFICATE* **N° 9638 rev. 8**
Délivrée à Paris le 26 avril 2017
Issued in Paris on April 26th, 2017

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

B. BRAUN MEDICAL
204 avenue du Maréchal Juin
92100 BOULOGNE-BILLANCOURT FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Filtres à veine cave

Vena cava filters

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P145907, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P145907, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **April 26th, 2017 (included)**
Valable jusqu'au / *Expiry date :* **July 8th, 2019 (included)**

Laboratoire national de métrologie et d'essais LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

LNE - 9638 rev. 8
Modifie le certificat 9638-7

GMED_b2p3-V3-01-2013

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Certification
Médical-Santé

Addendum au certificat n° 9638 rev. 8
Addendum of the certificate n° 9638 rev. 8
Dossier / *File* N° P145907

Identification des dispositifs / *Identification of devices*

Les produits couverts par ce certificat sont référencés sur la liste des produits authentifiée par le LNE/G-MED en date du 26 avril 2017.
The products covered by this certificate are listed on the manufacturer's list of products authenticated by LNE/G-MED on April 26th, 2017.

Identification des sites et activités / *Identification of locations and activities*

- **204 avenue du Maréchal Juin - 92100 BOULOGNE-BILLANCOURT – France : Siège social – Responsable de la mise sur le marché** / *Headquarters – Legal manufacturer*
- **30 avenue des Temps Modernes - 86360 CHASSENEUIL-DU-POITOU – France : Conception – Fabrication – Contrôle final** / *Design – Manufacturing – Final Control*

LNE/G-MED	0459

Laboratoire national de métrologie et d'essais
LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

"TEHNOMEDICA" S.R.L.

720 DM 0701-31 rev 5 du 28/07/2015

ADD
Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.eumed.fr

B|BRAUN
SHARING EXPERTISE

B. Braun Medical
Société par actions simplifiée
Etablissement de CHASSENEUIL-DU-POITOU
30, avenue des Temps Modernes
86360 CHASSENEUIL-DU-POITOU

IDENTIFICATION DU (DES) DISPOSITIFS / *IDENTIFICATION OF DEVICE(S)*

Filtres à veine cave Vena cava filters			
REFERENCES	**DESIGNATION**	**DIRECTIVE 93/42/CEE**	**EC CERTIFICAT**
04435125	VenaTech® LP Vena cava filter system	Annex II.3 - Annex II.4	n° 9638 - n° 14996
04439985	VenaTech® LP Brachial introducer system (Antecubital)	Annex II.3 - Annex II.4	n° 9638 - n° 14996
04430098	Tempofilter II Vena cava filter system	Annex II.3 - Annex II.4	n° 9638 - n° 8904
04435140	VenaTech® Convertible Vena cava filter system	Annex II.3 - Annex II.4	n° 9638 - n° 10616
04435150	VenaTech® RETRIEVABLE, Vena cava filter system	Annex II.3 - Annex II.4	n° 9638 - n° 26025
04435160	VenaTech® RETRIEVABLE, Brachial introducer system	Annex II.3 - Annex II.4	n° 9638 - n° 26025
04435170	VenaTech® RETRIEVABLE, Vena cava filter retrieval system	Annex II.3 - Annex II.4	n° 9638 - n° 26025

Date : 19/04/2017

LNE/G-MED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits
C Binoche T 26 AVR. 2017
LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

Catherine BOISMENU
Manager, Quality and Environmental Management System and Regulatory Affairs
B.BRAUN Medical

LNE
Le progrès, une passion à partager

Certification
Médical-Santé
Notified Body N° 0459

ATTESTATION / *CERTIFICATE* **N° 10616 rev. 4**
Délivrée à Paris le 19 juin 2017
Issued in Paris on June 19th, 2017

ATTESTATION CE / *EC CERTIFICATE*

Examen CE de la Conception (du produit) / EC Design Examination (of the product)
ANNEXE II point 4 de la directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II section 4 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant / *Manufacturer*

B. BRAUN MEDICAL
204 avenue du Maréchal Juin
92100 BOULOGNE-BILLANCOURT FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Filtre Veine Cave convertible

Convertible Vena Cava filter

Identification du(des) dispositif(s) / *Identification of device(s)*

VenaTech Convertible (GMDN 44864)
Voir addendum

VenaTech Convertible (GMDN 44864)
See addendum

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) P165599, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file(s) referenced P165599, the product(s) complie(s) with the requirements of the directive 93/42/EEC, annex 1

Début de validité / *Effective date :* **June 21st, 2017 (included)**
Valable jusqu'au / *Expiry date :* **June 20th, 2022 (included)**

Laboratoire national de métrologie et d'essais LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

GMED_b2p4-V2-01-2013

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

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Certification
Médical-Santé

Addendum au certificat n° 10616 rev. 4
Addendum of the certificate n° 10616 rev. 4
Dossier / *File* N° P165599

Identification des dispositifs / *Identification of devices*

Filtre Veine Cave convertible
VenaTech™ Convertible (GMDN 44864)
Convertible Vena Cava filter
VenaTech™ Convertible (GMDN 44864)

Se référer au(x) document(s) de / *See document(s) from*

B. BRAUN MEDICAL

authentifié(s) par le LNE/G-MED, le 19 juin 2017 (1 page)
authenticated by LNE/G-MED, dated June 19th, 2017 (1 page)

LNE/G-MED	0459

Laboratoire national de métrologie et d'essais
LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

720 DM 0701-31 rev 5 du 28/07/2015

ADD
Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial S.R.I.
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

B BRAUN

EC DECLARATION OF CONFORMITY
ANNEX

Filtre de veine cave VenaTech® Convertible /
Vena cava filter VenaTech® Convertible

REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	N° CERTIFICAT CE
04435140	VenaTech® Convertible	Annexe II.3 - Annexe II.4	n° 9638 - n° 10616

Date : 07/07/2016

Christelle TROLESE
Adjoint Affaires Réglementaires
B. Braun Medical France – Site Chasseneuil

LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits
C.BRANELLEC 19 JUIN 2017
LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

B BRAUN

B. Braun Medical
204 Avenue du Maréchal Juin
92100 Boulogne-Billancourt
FRANCE

B BRAUN	Form	Document Nr	SA-FR02-M-5-1-14-000-2-G-EN
Chasseneuil	EC DECLARATION OF CONFORMITY STERILE DEVICES	Revision date	18-03-2015
		Creation date	17-11-2006
		Page	1 of 1

EC Declaration of conformity
Déclaration CE de conformité

According to Directive 93/42/EEC concerning Medical Devices
Conformément à la Directive 93/42/CEE relative aux Dispositifs Médicaux et aux articles R5211-1 et suivants du Code de la Santé Publique

Manufacturer : *Fabricant*
B. Braun Medical
204 Avenue du Maréchal Juin
92100 Boulogne-Billancourt
FRANCE

Product Group : *Gamme de produit*
VenaTech® Convertible
Vena cava filter

Manufacturing site : *Site de fabrication*
B.Braun Medical – 30 Avenue des Temps Modernes
86360 Chasseneuil-du-Poitou - FRANCE

Conformity Assessment Procedure:
According to annexes II.3 and II.4 of the Directive 93/42/EEC
Procédure d'évaluation de la conformité : Conformément aux annexes II.3 et II.4 de la Directive 93/42/CEE

Classification : *Classification*
According to annexe IX of the Directive 93/42/EEC
Conformément à l'annexe IX de la Directive 93/42/CEE
Class : III
Classe

Notified Body / Identification number : G-MED / 0459
Organisme Notifié / Numéro d'identification

Address : *Adresse*
1, rue Gaston Boissier – 75724 Paris Cedex 15

We hereby, **B. Braun Medical**, declare under sole responsibility, that the above mentioned product group meets all requirements of the Directive 93/42/EEC concerning medical devices which apply to it.
Nous, par la présente, B. Braun Medical SAS, déclarons sous notre seule responsabilité, que le groupe de produit mentionné ci-dessus répond à toutes les exigences de la directive 93/42/CEE relative aux dispositifs médicaux qui lui sont applicables.

Regulatory Affairs *Affaires réglementaires*	**Quality & Regulatory Affairs** *Qualité et Affaires réglementaires*
Name / *Nom* : C. Trolèse	Name / *Nom* : BOISNEAU C.
Date : 23/06/2017	Date : 23/06/2017
Signature :	Signature :

First issue : 10/10/2008
Date de création

Revision : 23/06/2017
Date de révision

Valid until : 08/07/2019
Valide jusqu'au

"TEHNOMEDICA" S.R.L.

B. Braun Medical
204 Avenue du Maréchal Juin
92100 Boulogne-Billancourt
FRANCE

B BRAUN	Form	Document Nr.	SA-FR02-M-5-1-14-000-3-F-EN
		Revision date	18-03-2015
Chasseneuil	PRODUCT LIST	Creation date	17-11-2006
		Page	1 of 1

EC Declaration of conformity
Déclaration CE de conformité

PRODUCT LIST

Liste de produits

PRODUCT RANGE *Gamme de produit*	VenaTech® Convertible Vena cava filter
Class *Classe* **Sterile / Non sterile** *Stérile / Non stérile*	III Sterile
Intended use *Usage revendiqué*	The VenaTech® Convertible filter is designed to provide effective protection against pulmonary embolism where the patient's risk is permanent. The specificity is that the intraluminal filter elements can be converted to an open configuration.
GMDN code *Code GMDN*	44864

REFERENCE *Référence*	**PRODUCT** *Produit*
See attached product list *Voir la liste de produits jointe*	

Date of first EC-marking (or first lot number) : *Date de premier marquage CE (ou premier numéro de lot)*	Manufacturing lot : H1757600 – H2599840 - H2671340

Regulatory Affairs *Affaires réglementaires*	**Quality & Regulatory Affairs** *Qualité et Affaires réglementaires*
Name / *Nom* : C. Troplèse	Name / *Nom* : Boisnel C.
Date : 23/06/2017	Date : 23-06-2017
Signature :	Signature :

First issue : 10/10/2008
Date de création

Revision : 23/06/2017
Date de révision

"TEHNOMEDICA" S.R.L.

B BRAUN

EC DECLARATION OF CONFORMITY
ANNEX

Filtre de veine cave VenaTech® Convertible /
Vena cava filter VenaTech® Convertible

REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	N° CERTIFICAT CE
04435140	VenaTech® Convertible	Annexe II.3 - Annexe II.4	n° 9638 - n° 10616

Date : 23/06/2017

Christelle TROLESE
Adjoint Affaires Réglementaires
B. Braun Medical France - Site Chasseneuil

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD
Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 11 12974 427

Manufacturer:

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Facility(ies):

AESCULAP CHIFA Sp. z o.o.
ul. Tysiaclecia 14, 64-300 Nowy Tomysl, POLAND

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

B. Braun Medical (Suzhou) Co., Ltd.
No. 128 Changyang Street, Suzhou Industry Park, 215024
Suzhou, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Coronary stent systems, PTCA catheters, PTA catheters,
PTCA guide wires and sets,
Probes for stimulation and electrophysiology,
Procedure Kits,
Angiography sets, manifolds, guide wires,
single use Right heart pulmonary artery catheters,
Monitoring sets for invasive physiological
pressure measurement,
Introducer sheaths and sets,
Arterial puncture cannulae, arterial catheter sets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713067641
Valid from: 2016-01-07
Valid until: 2020-06-13

04052768811233

Date, 2016-01-07

Hans-Heiner Junker

"TEHNOMEDICA" S.R.L. IDNO 1002600053258

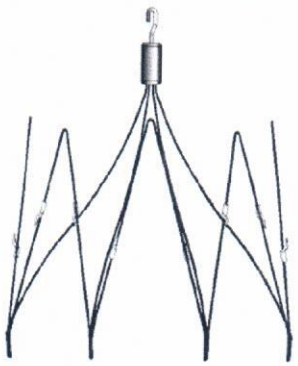
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

A1 / 04.11

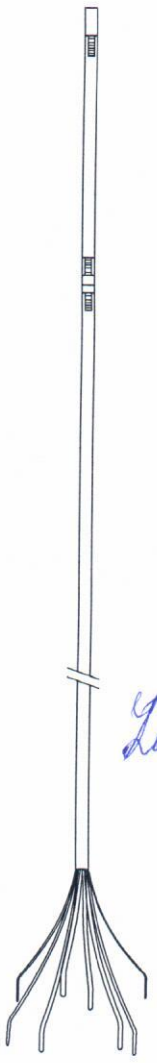
Vena Cava Filters

For protection against pulmonary embolism



Indications:
- contraindications to anticoagulants (severe coagulopathy, thrombocytopenia, hemorrhage, recent brain surgery, recent cranial trauma, ...)
- failure of the anticoagulants treatment (recurrent pulmonary embolism under treatment development of clot in spite of anti-coagulation)
- severe complication of the anticoagulants treatment (intestinal hemorrhage, gastroduodenal ulcer, ...)

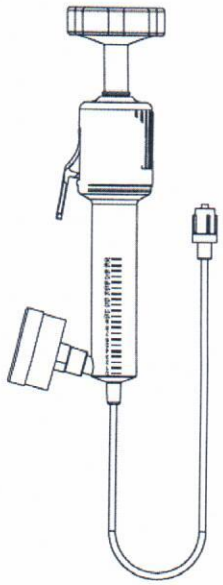
Advantages:
- proven conical design
- long term temporary filter: up to 12 weeks (Tempofilter II)
- made from Phynox, a non-ferromagnetic alloy with excellent MRI compatibilty and X-Ray visibility
- various access sites (VenaTech™ LP and VenaTech™ Convertible)
- small, flexible introducer (VenaTech™ LP)
- compatible with large Vena Cava (VenaTech™ LP and VenaTech™ Convertible)
- may be altered structurally to deactivate filtration (VenaTech™ Convertible)



	Access Site	Code Number	Sales unit-pcs.
Permanent filters			
VenaTech™ LGM 30 D/U	femoral, jugular	**5010519**	1
VenaTech™ LP	jugular, femoral, subclavian	**4435125**	1
VenaTech™ LP brachial Introducer System	brachial	**4439985**	1
VenaTech™ LP Platinum Introducer System	femoral, jugular, subclavian	**4439986**	1
Temporary filter			
Tempofilter II	jugular	**4430098**	1
Convertible filter			
VenaTech™ Convertible	femoral, jugular	**4435140**	1

Accessories for PTCA

INFLATION DEVICES, Y-CONNECTOR, KISSING BIBALLOON ADAPTER



Inflation Device for PTCA

Pressure gauge:
- 90° rotating manometer for „custom" handling
- coded figures from nominal to burst pressures for easy reading

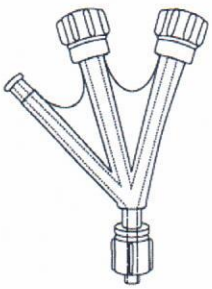
Body and button:
- advanced mechanism for rapid pressure increase, i.e. effective and fa t procedure
- grip design for better handling
- clear material for easy air bubble detection and removal

Handle:
- ergonomic design for optimal handling
- progressive resistance while inflating for pressure feedback

	Code-Number	Sales unit-pcs.
Inflation Device for PTCA, 20 ml/30 atm	5028901	1

Torquer
Torque device for guide wires
- luminescent
- wire grip for all diameters up to 0.022"

Torque device	5023687	10



Y-Connector
For all interventional techniques
- with rotational adaptor and Touhy-Borst-valve
- 9.5F lumen

Y-connector with plastic insertion tool	5021693	10
Double Y-connector with plastic insertion tool	5020743	5

Unique Kissing BiBalloon adaptor
For simultaneous and/or sequential dilatation of bifurcation lesions
- innovative approach for multiple dilatation techniques
- final kissing balloon inflation

Kissing BiBalloon adaptor	5014760	25

Cat 43.

Angiodyn

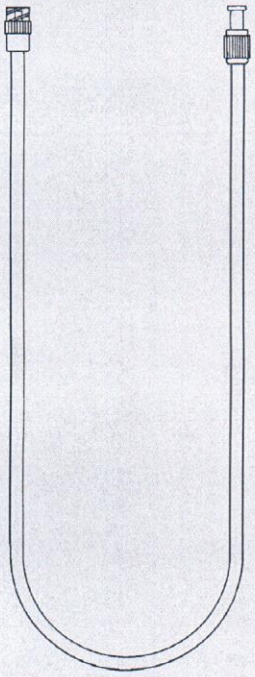
High pressure tubing with / without rotating adaptor

Angiodyn high pressure tubing
– transparent for visual control
– tubing lengths for all needs
– luer lock-fitting male / female

Angiodyn high pressure tubing up to 84 bar (1200 psi)
– braided PUR, very flexible

male / female with rotating adaptor

length cm	inner ø (mm)	outer ø (mm)		
50	1.7	3.6	**5011507**	25
75	1.7	3.6	**5011515**	25
100	1.7	3.6	**5011523**	25
120	1.7	3.6	**5011531**	25
200	1.7	3.6	**5016002**	25



Angiodyn high pressure tubing up to 70 bar (1000 psi)
– PVC, flexible

male / female with rotating adaptor

length cm	inner ø (mm)	outer ø (mm)		
50	2.15	4.75	**5011957**	20
75	2.15	4.75	**5011965**	20
100	2.15	4.75	**5011973**	20
120	2.15	4.75	**5011938**	20
150	2.15	4.75	**5018580**	25

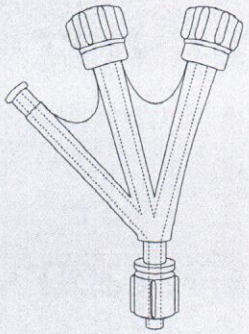
male / female without rotating adaptor

length cm	inner ø (mm)	outer ø (mm)		
50	2.15	4.75	**5018196**	20
75	2.15	4.75	**5018200**	20
100	2.15	4.75	**5018218**	20
120	2.15	4.75	**5018233**	20
150	2.15	4.75	**5014875**	20

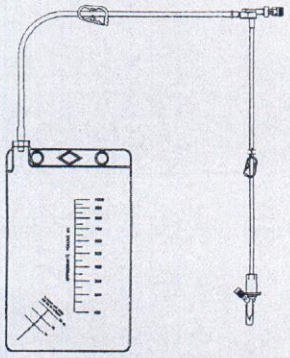
Lot 46

Accessories for PTCA

Y-Connector, PTCA-Set, Fluid Collection System



	Code-Number	Sales unit-pcs.
Y-Connector For all interventional techniques – with rotational adaptor and Touhy-Borst-valve – 9.5F lumen		
Y-connector with plastic insertion tool	**5021693**	10
Double Y-connector with plastic insertion tool	**5020743**	5
Unique Kissing BiBalloon adaptor For simultaneous and/or sequential dilatation of bifurcation lesions - innovative approach for multiple dilatation techniques - final kissing balloon inflation		
Kissing BiBalloon adaptor	**5014760**	25
PTCA-Kit 1 – Y-connector with metal insertion tool – Torquer, luminescent wire grip for all diameters up to 0.022" – Inflation Device for PTCA (622510)		
PTCA-Kit 1	**622511**	1
PTCA-Kit 2 – Y-connector with metal insertion tool – Torquer, luminescent wire grip for all diameters up to 0.022"		
PTCA-Kit 2	**5028550**	10
Bifurcation Kit – Inflation device – Double Y-Connector – Kissing Balloon adaptor – Insertion tool and torquer		
Bifurcation Kit	**5028904**	1



Fluid Collection System – aspiration of liquids (saline solution, contrast media) – secure disposal of aspiration liquid in a closed container (bag) – tubing length to dual check valve: 190 cm – tubing length to container: 180 cm – container volume: 1000 ml		
Fluid Collection System	**5010555**	50

Customized kits on request. Please ask your B. Braun clinical specialist.

Angioplasty Inflation Device

Accurate. Responsive. Consistent.

Highlights:

- 30 ATM luminescent analog pressure gauge accommodates most procedures and registers inflation pressure immediately without decay or drift.
- 25cc clear polycarbonate syringe barrel provides rapid deflation, accommodates large balloon sizes and permits easy debubbling.
- O-ring syringe piston design provides accurate pressure and minimizes pressure decay.
- Winged locking mechanism permits easy deflation at high pressures and engages more threads for stability under high pressure.

For more information or to place an order, contact your B. Braun Interventional Systems Inc. representative or call 1-877-VENA CAV (836-2228)

Ordering Information:

Inflation Device

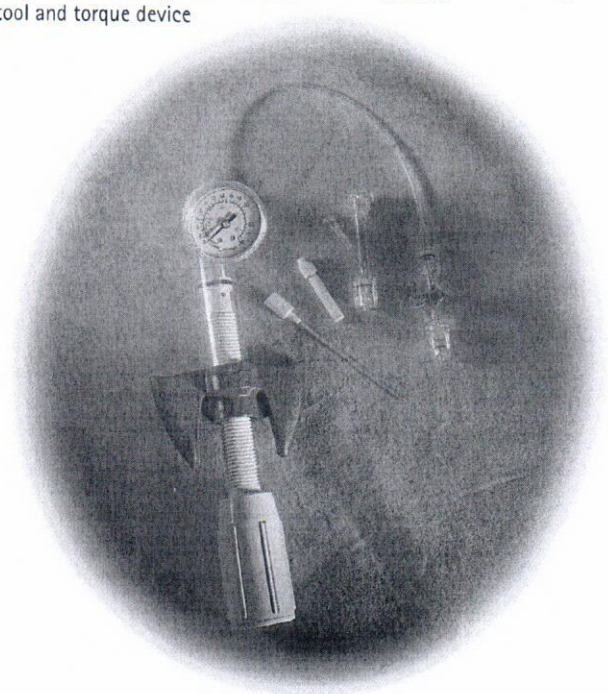
Product Description	REF Number	Case Qty.
Inflation Device	622510	10
Inflation Device Kit with single Y-connector and plastic insertion tool	622511	10

Single (9.5 F lumen) Y-connector

Single Y-connector with metal insertion tool	610400	5
Single Y-connector with plastic insertion tool	610402	5

Y-connector Kits (9.5 F lumen)

Single Y-connector, metal insertion tool and torque device	610420	5
Single Y-connector, plastic insertion tool and torque device	610403	5



B|BRAUN Interventional Systems

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