

Certificate

Production Quality Assurance System Approval Annex V of the Directive on Medical Devices

ECM, Bismarckstr.106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex V of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

intra special catheters GmbH

Oststrasse 2, 66780 Rehlingen-Siersburg, Germany

ECM certifies that the quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex V of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex V of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Report Number

218-15-2018

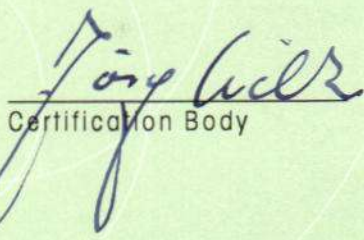
Registered under

Z/15/03696E

Valid until

November 17th, 2020

Aachen, November 18th, 2015


Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-240.10.12

Annex I to Certificate Z/15/03696E

Number of Pages: 1 of 1



Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

| Name of product category | Name of individual type | Nomenclature code ¹ |
|--------------------------|---|--------------------------------|
| Single use devices | Fittings, Adapter | 11-726 |
| Single use devices | Drainage Systems, Pleural | 10-817 |
| Single use devices | Drains, Thoracic | 11-308 |
| Single use devices | Guide Wires | 11-925 |
| Single use devices | Catheters, Introducers | 10-678 |
| Single use devices | Catheters, Vascular, Blood Pressure | 10-689 |
| Single use devices | Catheters, Vascular, Embolectomy/Thrombectomy | 10-714 |
| Single use devices | Catheters, Cardiac, Pericardium Drainage | 10-741 |
| Single use devices | Catheters, Others | 15-209 |
| Single use devices | Catheters, Rinsing | 10-730 |
| Single use devices | Catheters, Vascular, Embolectomy/Thrombectomy, Ballon, Venous | 10-756 |
| Single use devices | Tubing, Suction | 16-779 |
| Single use devices | Strippers, Vein | 13-828 |
| Single use devices | Tubes, Bronchial | 15-322 |
| Single use devices | Tubes, Connecting | 14-188 |
| Single use devices | Valves | 14-325 |
| Single use devices | Manifolds | 15-587 |
| Single use devices | Catheters, Vascular, Infusion, Central Venous | 10-729 |
| Single use devices | Sterile Procedure Packs acc. § 12, MDD | |
| | Casework, General-Purpose | 15-896 |
| | Sterile Procedure Packs acc. § 12, MDD | |

Special terms of validity:

In case of class I products or sterile procedure packs acc. to article 12 (3) of the Directive 93/42/EEC the intervention of ecm is limited to aspects of manufacture concerned with securing and maintaining sterile conditions respectively the conformity with the metrological requirements.

¹ UMDNS Code is optional

Certificat

Aprobarea sistemului de asigurare a calitatii in productie
Anexa V a Directivei Dispozitivelor Medicale

Sigla **ecm**

ECM, Bismarckstr. 106, 52066 Aachen, inregistrata la CE sub numarul 0481, prin prezenta, declara ca a fost efectuata o inspectie a sistemului de asigurare a calitatii mentionat mai jos, conform Anexei V a Directivei 93/42/CEE.

Prezentul certificat a fost eliberat in beneficiul
intra special catheters GmbH
Oststrasse 2, 66780 Rehlingen-Siersburg, Germania

ECM certifica faptul ca sistemul de asigurare a calitatii, in baza caruia sunt fabricate produsele enumerate in anexa 1 a prezentului certificat sunt fabricate conform cerintelor Anexei V a Directivei 93/42/CEE privind dispozitivele medicale.

Prezentul certificat este valabil exclusiv pentru produsele mentionate mai sus. Conditiiile speciale de valabilitate sunt descrise in anexa 1 a prezentului certificat.

Toate modificarile substantiale ale asigurarii calitatii sau a produselor enumerate, care pot afecta conformitatea cu Anexa V a Directivei 93/42/CEE trebuie comunicate catre ECM si vor constitui obiectul unei evaluari separate.

Numar raport audit
218-15-2018

Numar de inregistrare
Z/15/03696E

Valabil pana la
17 Noiembrie 2018

Aachen, 18 Noiembrie 2015

(Semnatura indescifrabila)
Organ de certificare



Anexa I la Certificatul Z/15/03696E

Numar de pagini: 1 din 1

Prezentul certificat este valabil pentru dispozitivele mentionate mai jos:

| Denumirea categoriei de produse | Denumirea tipului individual | Cod nomenclatura |
|---------------------------------|--|------------------|
| Dispozitive de unica folosinta | Fitinguri, adaptor | 11-726 |
| Dispozitive de unica folosinta | Sisteme de drenare, pleurale | 10-817 |
| Dispozitive de unica folosinta | Drenuri, toracice | 11-308 |
| Dispozitive de unica folosinta | Fire de ghidaj | 11-925 |
| Dispozitive de unica folosinta | Catetere, introductoare | 10-678 |
| Dispozitive de unica folosinta | Catetere, vasculare, tensiune arteriala | 10-689 |
| Dispozitive de unica folosinta | Catetere, vasculare, embolectomie/trombectomie | 10-714 |
| Dispozitive de unica folosinta | Catetere, cardiace, drenaj pericardial | 10-741 |
| Dispozitive de unica folosinta | Catetere, altele | 15-209 |
| Dispozitive de unica folosinta | Catetere, curatare | 10-730 |
| Dispozitive de unica folosinta | Catetere, vasculare, embolectomie/trombectomie, balon, venos | 10-756 |
| Dispozitive de unica folosinta | Tubulatura, aspiratie | 16-779 |
| Dispozitive de unica folosinta | Benzi, vena | 13-828 |
| Dispozitive de unica folosinta | Tuburi, bronhiale | 14-188 |
| Dispozitive de unica folosinta | Valve | 14-325 |
| Dispozitive de unica folosinta | Robineti | 15-587 |
| Dispozitive de unica folosinta | Catetere, vasculare, perfuzie, sistem venos central | 10-729 |
| | Pachete pentru proceduri sterile conform art.12 DDM | |
| Dispozitive de unica folosinta | Casete, de uz general | 15-896 |
| | Pachete pentru proceduri sterile conform art.12 DDM | |

Conditii speciale de valabilitate:

In cazul produselor din clasa I sau a pachetelor pentru proceduri sterile conform art.12 (3) din Directiva 93/42/CEE, interventia ecm este limitata la aspectele de fabricatie aferente asigurarii si mentinerii conditiilor sterile, respectiv a conformitatii cu cerintele metrologice.

Codul UMDNS este optional.



products



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The background of the entire page is a high-quality photograph of medical catheters. In the upper half, a long, thin, clear catheter with a blue-tinted hub is shown against a light blue background. In the lower half, a similar catheter is shown, but with a prominent red, cylindrical, knurled connector attached to its hub. Next to this red connector is a small, white, hexagonal plastic cap. The entire scene is reflected on a glossy surface, creating a clear mirror image of the objects below. The text 'Arterial Seldinger Catheters' is centered in the middle of the image, overlaid on the white background strip.

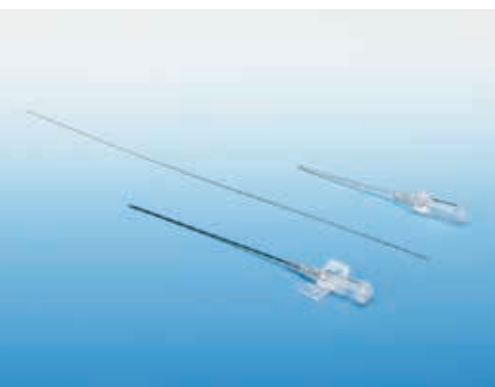
Arterial Seldinger Catheters

6 Arterial Seldinger Catheters

MICROSELD®

Radiopaque arterial catheter for measurement and diagnosis

MICROSELD® is suited for non-traumatic puncture of peripheral arteries for safe and complication-free positioning. It can be applied for any operation where a continuous blood pressure monitoring in anaesthesia and internal medicine is required and vessel damage or bleeding is to be eliminated, especially for arteria radialis, arteria brachialis and arteria femoralis. MICROSELD® is also suited for monitoring of the heart function, circulation and lung function control as well as for sampling of blood gas. The used biocompatible Teflon material avoids deposition of any kind of blood ingredients such as fibrin, erythrocytes and leucocytes. For this reason MICROSELD® - PTFE is particularly suited for long-term-monitoring of the catheter over 48 hours. But also the MICROSELD®-PEBAX has a big flexibility area, an excellent moving fortune and a good chemical resistance. It is produced without softeners.



Content

- Micro-catheter with flexible wings
- Puncture needle with transparent handle
- Safety guide wire with flexible tip 3 cm

| REF | Length x Size | French Size | Material |
|---------|----------------|-------------|----------|
| 302 042 | 4 cm x 0,7 mm | 2 | PTFE |
| 302 062 | 6 cm x 0,7 mm | 2 | PTFE |
| 302 063 | 6 cm x 1,0 mm | 3 | PTFE |
| 302 083 | 8 cm x 1,0 mm | 3 | PTFE |
| 302 113 | 11 cm x 1,0 mm | 3 | PTFE |
| 302 153 | 15 cm x 1,0 mm | 3 | PTFE |
| 302 084 | 8 cm x 1,3 mm | 4 | PTFE |
| 302 114 | 11 cm x 1,3 mm | 4 | PTFE |
| 302 154 | 15 cm x 1,3 mm | 4 | PTFE |
| 302 204 | 20 cm x 1,3 mm | 4 | PTFE |
| 302 115 | 11 cm x 1,7 mm | 5 | PTFE |
| 302 205 | 20 cm x 1,7 mm | 5 | PTFE |
| 305 063 | 6 cm x 1,0 mm | 3 | Pebax |
| 305 083 | 8 cm x 1,0 mm | 3 | Pebax |
| 305 113 | 11 cm x 1,0 mm | 3 | Pebax |
| 305 114 | 11 cm x 1,3 mm | 4 | Pebax |

Box: 20 pcs.

Other lengths and sizes on enquiry.

MICROSELD®-VENT

Radiopaque arterial catheter for measurement and diagnosis

As MICROSELD®, MICROSELD®-VENT is also suitable for non-traumatic puncture of peripheral arteries for safe and complication-free positioning. Additionally, it is provided with a proximal valve which occurs blood escapes and contamination by disconnection. MICROSELD®-VENT has an insertion device to protect the valve membrane.



Content

- Micro-catheter with flexible wings, made from biocompatible PTFE
- Puncture needle with transparent handle
- Safety guide wire with flexible tip 3 cm

| REF | Length x Size | French Size |
|---------|----------------|-------------|
| 307 063 | 6 cm x 1,0 mm | 3 |
| 307 083 | 8 cm x 1,0 mm | 3 |
| 307 113 | 11 cm x 1,0 mm | 3 |
| 307 114 | 11 cm x 1,3 mm | 4 |

Box: 20 pcs.

Other lengths and sizes on enquiry.



Venous Seldinger Catheters

Central Venous Catheters

All catheters consists of high flexible thin-walled polyurethane which ensures very high flow rates. It is anti-thrombogenic and biocompatible. At body temperature it gets very soft, swims in the vessel and reduces clearly the risk of phlebitis. The catheters are equipped with extremely soft-tip. A perforation of the vein or damage of the intima are excluded practically. All intra-catheters have a cm-marking. The X-ray-opaque material offers an extremely high X-ray-ability. The catheter clips offer a safe and fast fixation.



Content

- Catheter with clamp
- Ultra sharp puncture needle
- Guide wire in advancer with flexible J-tip and one hand handling
- Dilator
- 5ml LL-syringe
- Additional fixation clip
- Further components on enquiry*

Advantages of the multilumen catheters:

- Due to only one puncture and the separated lumen providing several accesses, different indications are possible, partly also simultaneous.
- continuous or intermittent drug infusions
- CVP monitoring
- Short- or long-term hyperalimentation
- Likewise, incompatible drugs or solutions can be infused separately in a quick and safe way, also administration of viscous or high-volume fluids.
- Liquid gift with high flow rates in emergency
- Blood sampling and administration of blood products

| REF | Size | Length |
|-------------------------|------|--------|
| VENOSELDT 1lumen | | |
| 331 092H | 24 G | 9 cm |
| 331 132H | 24 G | 13 cm |
| 331 130H | 20 G | 13 cm |
| 331 200H | 20 G | 20 cm |
| DUOCATH 2lumen | | |
| 332 014 | 4 F | 15 cm |
| 332 024 | 4 F | 20 cm |
| 332 015 | 5 F | 15 cm |
| 332 025 | 5 F | 20 cm |
| 332 017 | 7 F | 15 cm |
| 332 027 | 7 F | 20 cm |
| 332 037 | 7 F | 30 cm |
| 332 028 | 8 F | 20 cm |

Box: 10 pcs. (Hardblister)

| REF | Size | Length |
|--------------------------|-------|--------|
| 331 208H | 18 G | 20 cm |
| 331 206H | 16 G | 20 cm |
| 331 204H | 14 G | 20 cm |
| 331 304H | 14 G | 30 cm |
| TRILUCATH 3lumen | | |
| 323 085 | 5.5 F | 8 cm |
| 323 015 | 5.5 F | 13 cm |
| 323 017 | 7 F | 16 cm |
| 323 027 | 7 F | 20 cm |
| 323 037 | 7 F | 30 cm |
| QUADROCATH 4lumen | | |
| 334 028 | 8.5 F | 20 cm |

Other lengths and sizes on enquiry.

Catheters For Hemodialysis

Hemodialysis catheters are catheters that provide temporary vascular access for hemodialysis until a permanent access is available or until another type of dialysis therapy is substituted. The multiple lumen catheters contain two large bore lumen that are connected to the dialysis machine to form a complete circuit for the removal and return of the patient's blood during treatment. intra offers two- and three-lumen catheters for subclavian-jugular-femoral application. The radiopaque, thermosensitive and anti-kinking PUR-material with a blue soft-tip guarantees a high biocompatibility. It is extremely smooth and has a non-thrombogenic surface. The catheters are semirigid at room temperature and get softer when reaching body temperature thus minimizing the possibility of vessel wall injuries. It allows also the catheter to remain for extended periods in the body. The catheters are intended for percutaneous introduction using the Seldinger Technique. The catheter can be changed using the existing puncture.



Content

- Catheter with soft tip, clips and fixation aid
- Seldinger Cannula 18G - 7 cm
- Guide wire in advancer with flexible J-tip and one hand handling
- Dilator
- 5ml LL-syringe
- Further components on enquiry*

| REF | | Size | Length |
|-----------------------------------|----------|------|--------|
| DUOCATH 2lumen | | | |
| 332 112 | Straight | 12 F | 16 cm |
| 332 212 | Straight | 12 F | 20 cm |
| Box: 10 pcs. (Hardblister) | | | |

Other variations (3lumen catheter / pre-curved / curved extension lines) and lengths on enquiry.

*

R – Guiding Syringe
D – Blade
N – Nitinol Guide Wire
F – Hypodermic Needle
Y – Y-Needle

For example:

332 027 with a Blade and a Nitinol Guide Wire is the article number: 332 027DN
331 092H with a Guiding Syringe is the article number: 331 092HR

12 Venous Seldinger Catheters

Thermodilution

Multilumen catheter for measuring and monitoring cardiac output and for continuous infusion, blood sampling and blood gas analysis. The catheter is made of radiopaque polyurethane. The marker rings have an interval of 10 cm from distal. The enclosed syringe for inflation of the balloon corresponds to the balloon capacity. The symmetrical balloon is made of Latex and individually checked on pressure resistance and leakages.



| REF | Length | French Size |
|------------------------------|--------|-------------|
| INTRATHERMODIN 2lumen | | |
| 250 115 | 110 cm | 5 |
| INTRATHERMODIN 3lumen | | |
| 252 116 | 110 cm | 6 |
| 252 117 | 110 cm | 7 |
| INTRATHERMODIN 4lumen | | |
| 440 117 | 110 cm | 7 |

Box: 5 pcs.

Other sizes (5 - 7 French) on enquiry.

In dependence of specification a minimum order quantity of 30 pcs. is requested.

A collection of medical catheters and tubing, including a blue catheter with a green connector, a white catheter with a blue connector, and a blue catheter with a white connector. The catheters are coiled and arranged on a light blue background.

Accessories For Seldinger Catheters, Measurement And Infusion

Introducer - INTRADESILET®

We provide kits including dilator with precision shaped tip, radiopaque sheath, both made of medical PP/PE, with homogeneous transition from dilator to sheath, puncture needle 18 G, guide wire with flexible, straight or J-tip. The INTRADESILET®-INTRADUCER includes an haemostatic valve and a sideport with stopcock. INTRADESILET®-PEEL is especially designed for the displacement of the introducer-set without changing the localization of the introduced catheter (permanent pacing leads, balloon catheters, drainage catheters, ...). The risk of kinking or traumatic effects at the insertion point is minimized by it's optimized design.



| REF | French Size | Sheath Length | Dilator Length | Guide wire | Needle | |
|---------|-------------|---------------|----------------|----------------|-------------|------------|
| 300 505 | 5 | 12 cm | 18 cm | 0.035" - 45 cm | 18 G - 7 cm | Standard |
| 300 506 | 6 | 12 cm | 18 cm | 0.035" - 45 cm | 18 G - 7 cm | Standard |
| 300 507 | 7 | 12 cm | 18 cm | 0.035" - 45 cm | 18 G - 7 cm | Standard |
| 300 508 | 8 | 12 cm | 18 cm | 0.035" - 45 cm | 18 G - 7 cm | Standard |
| 300 607 | 7 | 14 cm | 18 cm | 0.035" - 45 cm | 18 G - 7 cm | Peel |
| 300 608 | 8 | 14 cm | 18 cm | 0.035" - 45 cm | 18 G - 7 cm | Peel |
| 300 609 | 9 | 14 cm | 18 cm | 0.035" - 45 cm | 18 G - 7 cm | Peel |
| 300 610 | 10 | 14 cm | 18 cm | 0.035" - 45 cm | 18 G - 7 cm | Peel |
| 300 805 | 5 | 11 cm | 15.5 cm | 0.035" - 50 cm | 18 G - 7 cm | with valve |
| 300 806 | 6 | 11 cm | 15.5 cm | 0.038" - 50 cm | 18 G - 7 cm | with valve |
| 300 807 | 7 | 11 cm | 15.5 cm | 0.038" - 50 cm | 18 G - 7 cm | with valve |
| 300 808 | 8 | 11 cm | 15.5 cm | 0.038" - 50 cm | 18 G - 7 cm | with valve |

Box: 10 pcs.

Guide wires

All guide wires are made of stainless steel with exactly rounded tip. They are available with fixed or movable core. The tip is flexible at one or both ends, with straight or J-tip.

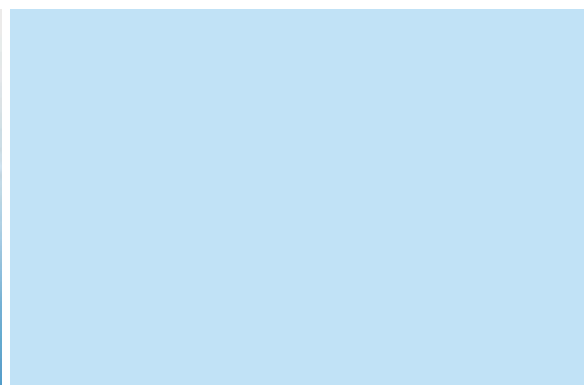
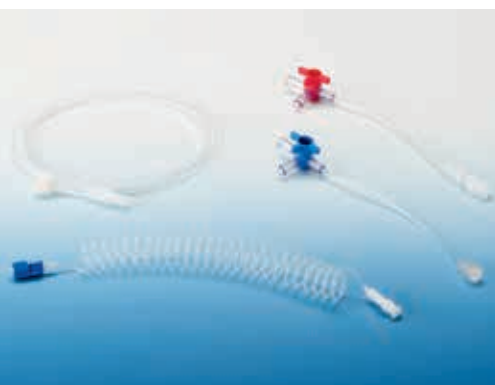
| REF | Size | Length | Type |
|---------|------------------|--------|------------------------|
| 470 075 | 0.035" / 0.89 mm | 70 cm | Straight |
| 470 155 | 0.035" / 0.89 mm | 150 cm | Straight |
| 471 075 | 0.035" / 0.89 mm | 70 cm | J-Tip |
| 471 155 | 0.035" / 0.89 mm | 150 cm | J-Tip |
| 472 155 | 0.035" / 0.89 mm | 150 cm | J-Tip - PTFE coated |
| 472 156 | 0.038" / 0.96 mm | 150 cm | J-Tip - PTFE coated |
| 473 155 | 0.035" / 0.89 mm | 150 cm | Straight - PTFE coated |
| 473 156 | 0.038" / 0.96 mm | 150 cm | Straight - PTFE coated |

Box: 50 pcs.

Other lengths and sizes for guide wires and introducers on enquiry.

CONNECATH

The connection line is made of PE (polyethylene) or medical PVC with precision lumen for blood pressure measurement and blood sampling. No hydrothermal changes. No leakages due to line distortions.



| REF | Size/Length | Other spec. |
|---------------|--------------------------|-------------|
| PE | | |
| 401 xxx (m/f) | 2.0 x 1.0 mm / 10-200 cm | 14 bar |
| 402 xxx (m/f) | 3.0 x 1.8 mm / 10-200 cm | 14 bar |
| Box: 50 pcs. | | |

| REF | Size/Length | Other spec. |
|-------------------------------|----------------------|---------------|
| Connecath with stopcock (PVC) | | |
| 451 015 | 2.5 x 1.5 mm / 15 cm | Red, 2.5 bar |
| 452 015 | 2.5 x 1.5 mm / 15 cm | Blue, 2.5 bar |
| 452 070 | 2.5 x 1.5 mm / 70 cm | Blue, 2.5 bar |

Other sizes and lengths on enquiry. Lengths from 10-200cm. The last 3 figures correspond to the length, i.e. 401 030 for 30 cm

STOPCOCKS

The intra-stopcock is suitable for normal infusion use and accurate frequency measurement. It is transparent, lipid-resistant, resistant against cytostatica and pressure-resistant till 2.0 bar. The luer-lock-connector provides a fast and sure connection.

| REF | Description |
|--------------|----------------------------|
| 611 010 | 2-way-stopcock, LL |
| 621 311 | 3-way-stopcock, white 360° |
| Box: 50 pcs. | |

| REF | Description |
|---------|---------------------------|
| 621 312 | 3-way-stopcock, red 360° |
| 621 313 | 3-way-stopcock, blue 360° |

Accessories

| REF | Description |
|-----------------|--|
| 630 001 | Filter, 96 h Gelmann with LL connectors 0.2 µm |
| 630 002 | Lipid Filter with LL connectors 1.2 µm |
| Box: on enquiry | |

| REF | Description |
|---------|---|
| 011 000 | Tubing adaptor, variable connection adaptor |
| 801 001 | Change adaptor, male/male rotating LL |
| 801 002 | Change adaptor, female/female |

Manifold / Manifold Systems

The manifold is a one-piece moulding production and has a holding plate for easy and secure attachment to the IV pole with a special clamp. They are transparent, lipid-resistant and pressure-resistant till 2 bar. The stopcock handles are with different colours to differentiate the monitoring lines. If needed also available in one colour.

Our manifold systems can be composed to the customer's specific requirements, also as systems including filters, three-way-stopcocks, etc. They are transparent and pressure-resistant till 2 bar. Extension tubes are available male/female or male/male combinations in different lengths.



| REF | Description |
|---------|--|
| 701 030 | 3-way m/f luer-lock with one lateral male port, all other ports female |
| 701 050 | 5-way m/f luer-lock with one lateral male port, all other ports female |
| 701 130 | 3-way f/f luer-lock all ports female |
| 701 150 | 5-way f/f luer-lock all ports female |

Box: 50 pcs.

intra-tumescence-kit

Distributor system for subcutaneous application of thinned down local anesthetic solutions.

The Tumescence-Local-Anesthesia (TLA) is a regional anesthesia of the skin and of subcutaneous fat tissue by a direct infiltration of big volumes of a thinned local anesthetic. The thought, to combine the introduction of fluid with anesthetic means, that during this intervention you can do without risk full general anesthesia, which is normally needed with siphoning greases. The intra-tumescence-kit was specially conceived as distributor system to inject large amounts of thinned solution (up to 6 liters), i.e. with Liposuctions. By parallel use of several cannulas, connected to intra-Tumescence-Set, the duration of infiltration gets abbreviated. The liquid at the single cannulas is promoted with a relatively low speed. This is to avoid a too quick print construction, which gets frequent of patients as felt unpleasantly.

| REF | Description |
|---------|--|
| 713 999 | 3-gang Kit, m/f with colored cock and connected infiltration lines (75 cm) |

Box: 50 pcs.

Further versions on enquiry

The background of the slide features a collection of medical devices. At the top, a long, thin blue catheter is coiled. Below it, several colored wires (red, black, blue) are connected to a blue plastic junction box. In the lower half, there are two blue-handled catheters with long, thin shafts and metal tips, and a separate blue catheter with a shorter shaft. The entire scene is set against a light blue background with soft shadows.

Electrophysiology

Intralektrode Bipolar

Bipolar Semi-Floating pacing lead in 4,5 and 6 French for temporary stimulation of the heart especially in emergency cases of bradycardial arrhythmias or for recording intracardiac ECGs. Intralektrode can be positioned quickly, easy and safely and the advantages are good pushability, excellent torque control and positional - stability. Intralektrode can be easily user preformed or ordered in traditional shapes. Spacing and sizes of the electrodes can be changed individually upon request.

Advantages:

Easy and safe positioning, constant torque control, radiopaque, length bending, high positional-stability, user preformability.



Content

Intralektrode bipolar

- 1 bipolar temporary pacing lead, 110 cm
- 1 Introducer Set (over the needle sheath)

Intralektrode with balloon

- 1 bipolar, temporary pacing lead with balloon, 110 cm
- 1 syringe for balloon

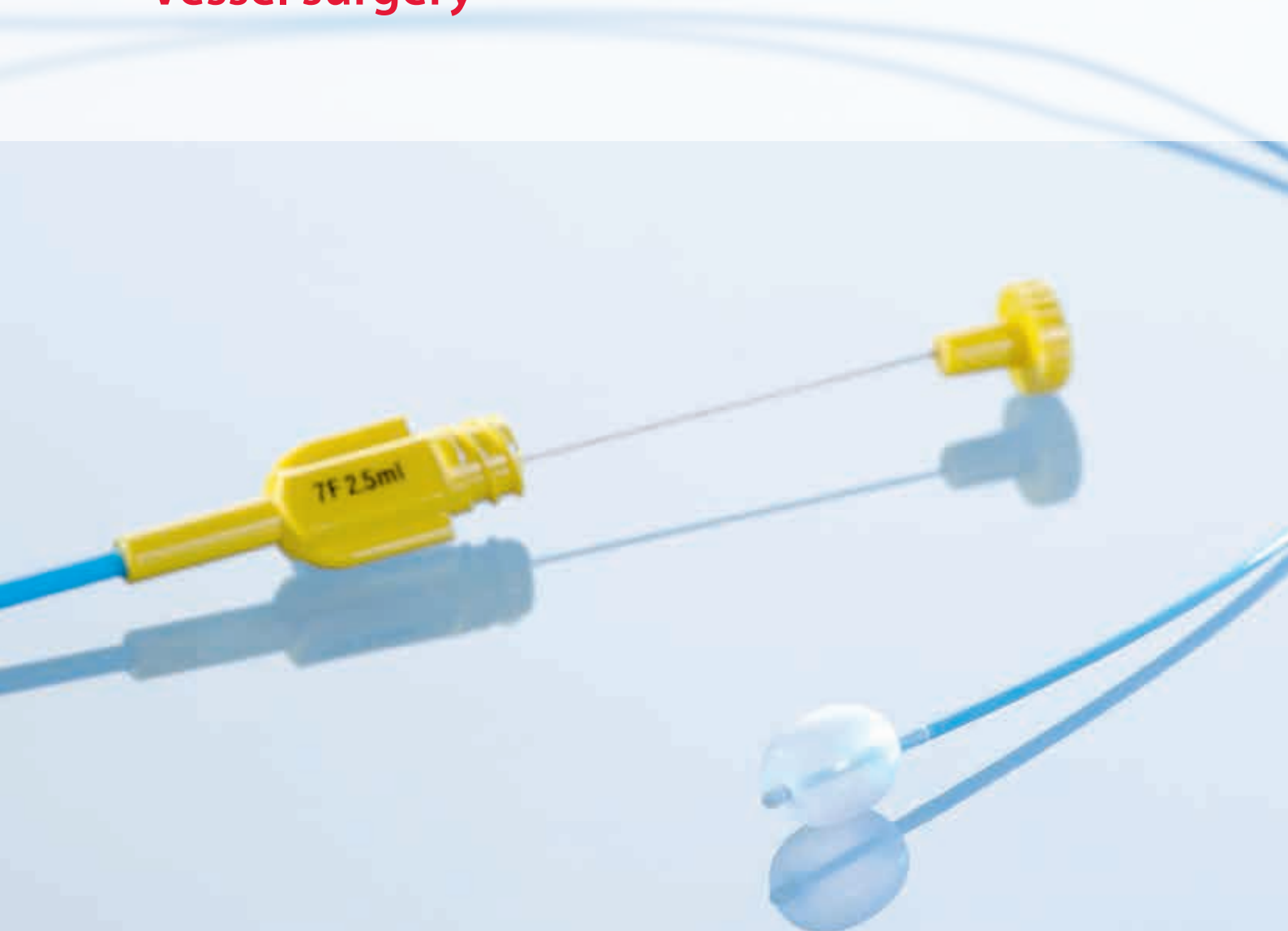
| REF | French Size | Tip |
|-----------------------------------|-------------|----------|
| Intralektrode bipolar | | |
| 022 244M | 4 | C-Type |
| 022 245M | 5 | C-Type |
| 022 246M | 6 | C-Type |
| Box: 5 pcs. | | |
| Intralektrode with balloon | | |
| 052 225 | 5 | Straight |
| Box: 5 pcs. | | |

Electrodes in straight version or with J-Type on enquiry.

Electrodes in size of 7F on enquiry.

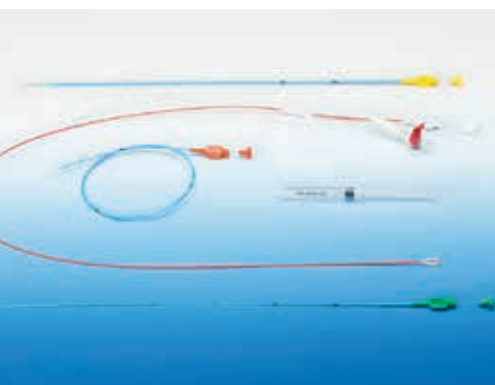


Vessel surgery



Balloon catheters

The catheter is made of flexible radiopaque Polyamid with latex balloon and has an inside, removable steel mandrin for difficult vessel constitution. It has a soft tip to avoid vessel perforation. The balloon capacity is adapted to the corresponding lumen. The catheter sizes are colour-coded for easy identification and has marker rings at 10 cm intervals. The length of 40 cm is especially adequate for elimination of thrombi out of cannula dialysis. The double lumen catheter with a length of 80 cm can be delivered in sizes 5 to 7 French. The catheter is distal open and has at proximal end a sideport with flexible line for balloon filling. The biliary catheter is used to remove biliary stones and ductal debris intraoperatively. The flush catheter (without balloon) is designed for irrigation after successful embolectomy, thrombectomy or bile-duct-operation.



| REF | French Size | Size | Length | Color | Balloon capacity (ml) | Balloon size |
|-----------------------------|-------------|--------|--------|-------------|-----------------------|--------------|
| Embolectomy Catheter | | | | | | |
| 100 240 | 2 | 0.7 mm | 40 cm | Transparent | 0.15 | 4 mm |
| 100 260 | 2 | 0.7 mm | 60 cm | Transparent | 0.15 | 4 mm |
| 100 340 | 3 | 1.0 mm | 40 cm | Green | 0.20 | 6 mm |
| 100 380 | 3 | 1.0 mm | 80 cm | Green | 0.20 | 6 mm |
| 100 440 | 4 | 1.3 mm | 40 cm | Red | 0.75 | 8 mm |
| 100 480 | 4 | 1.3 mm | 80 cm | Red | 0.75 | 8 mm |
| 100 540 | 5 | 1.7 mm | 40 cm | White | 1.50 | 10 mm |
| 100 580 | 5 | 1.7 mm | 80 cm | White | 1.50 | 10 mm |
| 100 680 | 6 | 2.0 mm | 80 cm | Blue | 2.00 | 12 mm |
| 100 780 | 7 | 2.3 mm | 80 cm | Yellow | 2.50 | 14 mm |
| 100 880 | 8 | 2.7 mm | 80 cm | Brown | 3.00 | 16 mm |

Sterilization by gamma radiation

Box: 5 pcs.

Other types and sizes on enquiry.

Thrombectomy catheter

| | | | | | | |
|---------|----|--------|-------|-------|------|-------|
| 110 680 | 6 | 2.0 mm | 80 cm | Blue | 1.50 | 12 mm |
| 110 880 | 8 | 2.7 mm | 80 cm | Brown | 2.25 | 13 mm |
| 111 080 | 10 | 3.3 mm | 80 cm | Grey | 4.00 | 19 mm |

Box: 10 pcs.

Double lumen catheter with balloon

| | | | | | | |
|---------|---|--------|-------|--------|------|-------|
| 120 580 | 5 | 1.7 mm | 80 cm | White | 0.90 | 10 mm |
| 120 680 | 6 | 2.0 mm | 80 cm | Blue | 1.40 | 11 mm |
| 120 780 | 7 | 2.3 mm | 80 cm | Yellow | 1.60 | 12 mm |

Sterilization by gamma radiation

Box: 5 pcs.

Occlusion catheter / Biliary catheter with balloon / Flush catheter without balloon

On enquiry

Disposable-Vein-Stripper

Flexible Nylon wire - High tensile strength of the wire | Practical Handle - Free From Torsions and kinkings

The high flexibility of the nylon wire facilitates the passage of venous valves and minimizes the number of incisions. The smooth wire guarantees easy and atraumatic passage within the veins as well as quick and problem-free shedding of the stripped veins. Thus the extended varices can be quickly controlled for tributary venous vessels and these can be searched specifically and then ligated. One of the important features of the nylon wire is its high tensile strength. A broad handle ensures an effective and thus strength and time-saving stripping of veins. The handle may be set up at any end, distal or proximal, just before stripping. The disposable instrument is free of torsions and kinkings from prior operations. This warrants atraumatic and time-saving application.



Anterograde and retrograde stripping

The special designed olives, which can be clipped on each wire end after wire-passage through the vein, enable a retrograde as well as an anterograde stripping, independent from distal or proximal access.

Four sizes in one instrument

The vein stripper may be provided with four various olives of 6, 9, 12, 15 mm diameter. Thus stripping varices of different sizes will be possible with one single instrument which means cost reducing.

Technical data

Length of the wire: 100 cm

Sizes of the olives: 6, 9, 12 + 15 mm Ø

| REF | Description |
|---------|--------------|
| 103 100 | With 1 wire |
| 103 200 | With 2 wires |

Box: 10 pcs.

The background of the slide features a close-up, shallow depth-of-field photograph of medical equipment. In the foreground, a hand is holding a blue and white connector, likely part of a drainage system. Behind it, several long, thin, metallic catheters or needles are visible, some with clear plastic hubs and others with blue components. The overall color palette is light blue and white, giving it a clinical and professional appearance.

Thoracic Drainage - Pleural Puncture - Accessories

PNEUMOCATH® / NEO-PNEUMOCATH

Thin and radiopaque drainage in slide-in cover with marker rings, three-way-stopcock with suction connection tube for drainage of air and/or fluid in the pleural cavity, as well as in all emergency situations where the application of a surgical suction drainage might come too late or is quite a risk. Due to its small size and easy handling, the Pneumocath® thoracic drain is particularly valuable in paediatrics. The NEO-PNEUMOCATH® with its enlarged lumen, offers a new and improved technique for drainage in the thoracic cavity. It is also a valuable device for simplifying the Bülow suction method and other trocar methods. A high degree of safety is ensured by compatibility of the material and an Heimlich-valve (PNEUMOVENT®) with fixed LL-mechanism ensures more security. The catheter permits sterile, fast and safe handling without any additional aids.



Content

Basic equipment consisting of:

- Suction catheter with protective cover
- Puncture needle and three-way-stopcock with tube adapter

Features of the kits according to the declaration

| REF | PNEUMOCATH | Stitch length Needle | Catheter Length | Catheter Size |
|--------------|---|-------------------------|-----------------|---------------|
| 503 001 | PNEUMOCATH® for adults | 85 mm | 500 mm | 8 F (2.7 mm) |
| 503 002 | PNEUMOCATH® for children | 65 mm | 400 mm | 8 F (2.7 mm) |
| 503 003 | PNEUMOCATH® for prenaturs and newborns | 55 mm | 300 mm | 6 F (2.0 mm) |
| 503 201 | PNEUMOCATH® fix-adapter for adults | 85 mm | 500 mm | 8 F (2.7 mm) |
| Box: 20 pcs. | | | | |
| 503 401 | PNEUMOCATH® Kit consisting of <ul style="list-style-type: none"> • Basic equipment • 50 ml syringe • Collecting bag 2.0 ltr. with 90 cm tube | 85 mm | 500 mm | 8 F (2.7 mm) |
| 503 501 | PNEUMOCATH® Kit consisting of <ul style="list-style-type: none"> • 503 401 but with • Heimlich valve (Pneumovent®) | 85 mm | 500 mm | 8 F (2.7 mm) |
| Box: 10 pcs. | | | | |
| REF | NEO-PNEUMOCATH® | Stitch length Needle | Catheter Length | Catheter Size |
| 503 011 | NEO-PNEUMOCATH® for adults | 85 mm | 500 mm | 10 F (3.2 mm) |
| 503 211 | NEO-PNEUMOCATH® for adults with fix-adapter | 85 mm | 500 mm | 10 F (3.2 mm) |
| 503 012 | NEO-PNEUMOCATH® for children | 65 mm | 400 mm | 10 F (3.2 mm) |
| Box: 20 pcs. | | | | |
| 503 014 | NEO-PNEUMOCATH® emergency model with fix-Adapter in Hardblister | 85 mm | 500 mm | 10 F (3.2 mm) |
| Box: 10 pcs. | | | | |
| 503 111 | NEO-PNEUMOCATH® Kit consisting of <ul style="list-style-type: none"> • Basic equipment • Suction tube 180 cm • Heimlich valve (Pneumovent®) • Skin fixation plate | 85 mm | 500 mm | 10 F (3.2 mm) |
| Box: 6 pcs. | | | | |
| 503 711 | NEO-PNEUMOCATH® Seldinger Technik <ul style="list-style-type: none"> • Catheter with stopcock and adapter (open tip) • Puncture needle 18G – 7cm, Dilator 9F and Guide wire 0.035" – 70cm | / | 500 mm | 10 F (3.2 mm) |
| Box: 20 pcs. | | | | |

Box: 20 pcs.

Other kits conforming customer's requests on enquiry.

PNEUMOCATH® - Intrasplit

New thoracic drainage system with intrasplit-cannula for drainage of pathological accumulation of air and/or fluid in the pleural cavity. Fast, simple and safe handling. The thin drain is to insert through a new intrasplit-cannula. As this is a closed system including a three-way-stopcock already connected, a subsequent connection to an adaptor is not required. After a successful puncture and placement of the thoracic drain into the pleural cavity, the puncture needle is withdrawn, the sterile slide-in cover is removed by splitting it open and the intrasplit cannula is also removed by splitting. The variable adaptor can be connected with the suction lines.



ONKO-PNEUMOCATH®

A new, improved technique for intercostal drainage to facilitate the aspiration method by Bülow. The catheter provides sterile and reliable manipulation without further auxiliary instruments.

Indications:

Pathicological accumulation of air and/or liquid in the pleural cavity, especially for malign intrapleural effusion or intended pleurodesis.

Advantages:

Stabilisation of the catheter extrathoracically and in the area of the thoracic wall by wrapping catheters, self-adhesive fixation panel, suitable connection tube, double safeguard at the three-way-stopcock by two-point-fixation.

| REF | | Stitch length Needle | Catheter Length | Catheter Size |
|--------------|--|-------------------------|-----------------|---------------|
| 505 001 | PNEUMOCATH® with intrasplit-cannula and already connected stopcock | 85 mm | 500 mm | 8 F (2.7 mm) |
| Box: 20 pcs. | | | | |
| 503 015 | ONKO-PNEUMOCATH® Kit consisting of <ul style="list-style-type: none"> • Basic equipment • Wrapping catheter anti-kink tube • Skin fixation plate • Suction tube 180 cm | 110/85 mm | 500 mm | 10 F (3.2 mm) |

Box: 10 pcs.

THORACENTESIS / Pleural-Puncture-Kits

Kits for pleural puncture in case of:

- Pneumothorax
- Pleurodesis
- Aspiration of any effusions (i.e. ascites)

They consist of a puncture cannula with catheter (over the needle).

Besides the straight version, the combined models with self-locking-seal and sideport, are particularly well suited for pleurodesis applications. Special possibility for infusion of drugs with subsequent optional suction. Reliable handling by stopcock and a flexible silicon tube. All models have a lateral eye on the distal end of the catheter.

The models with Veress-Needle offers an additional protection against injuries.



| REF | Description |
|---------------------|--|
| 503 021 | Thoracentesis (14 G – 10 cm) straight version |
| 503 019 | Thoracentesis (14 G – 8.5 cm) for adults with side port |
| 503 119 | Thoracentesis-Ascites-Puncture Kit consisting of <ul style="list-style-type: none"> • Thoracentesis for adults with sideport (14 G – 8.5 cm) • Syringe 50-60 ml LL • Collecting bag 2.0 ltr. LL with 90 cm tube |
| 010 050 | Veress-Needle (2.1 x 120 mm) with stopcock |
| 503 061 | Thoracentesis Kit with Veress-Needle (1.8 x 120 mm) and <ul style="list-style-type: none"> • Collecting bag 2.0 ltr. LL with 90 cm tube • Stopcock • Syringe 50-60 ml LL • 75 cm extension line |
| 503 060 | Thoracentesis Kit with Veress-Needle (2.1 x 120 mm) and <ul style="list-style-type: none"> • Collecting bag 2.0 ltr. LL with 90 cm tube • Stopcock • Syringe 50-60 ml LL • 75 cm extension line |
| 503 025 | Pleural-Puncture-Kit consisting of <ul style="list-style-type: none"> • Thoracentesis (14 G – 8 cm) with puncture needle, 2-way-stopcock and syringe (5 ml) |
| Box: 20 pcs. | |
| 503 022 | Pleural-Puncture-Kit consisting of <ul style="list-style-type: none"> • Thoracentesis (14 G – 10 cm), straight version • Collecting bag 2.0 ltr. LL with 90 cm tube • Stopcock • Syringe 50-60 ml LL • 75 cm extension line |

Box: 10 pcs.

Other kits conforming customer's requests on enquiry.

Accessories

intra special catheters offers suitable accessories for all thoracic catheters, such as Heimlich-type drainage valves PNEUMOVENT® (with LL-connections or also tube connections), various variable adaptors (with or without stopcock), a special fixation plate to adapt three-way stopcocks, as well as suction tubes with silicone adaptors.



| REF | Description |
|---------------------|--|
| 504 001 | Pneumovent® with LL-connection |
| 504 002 | Pneumovent® with tube connection |
| 503 010 | Connection tube to connect the thin drains to bigger systems |
| 503 050 | Suction tube 50 cm, male/silicone adaptor |
| 503 180 | Suction tube 180 cm, male/silicone adaptor |
| 010 002 | Collecting bag 2.0 ltr. with 90 cm tube |
| Box: 20 pcs. | |
| 011 000 | Variable adaptor without stopcock |
| 011 001 | Variable adaptor with stopcock for NEO-PNEUMOCATH® (10 F) |

Box: 50 pcs.

All collecting bags with back valve and bottom valve.

A collection of medical catheters and connectors, including blue and clear plastic tubing, metal catheters, and connectors, arranged diagonally across the frame. The background is a light blue gradient.

Special Products

PERICARDIAL ASPIRATION KIT

Aspiration set to puncture the pericardium by a Pigtail catheter

The catheter has additionally to the distal port 8 side holes for secretion suction, as well as a device for stretching the pigtail tip to make the inserting process easier.



| REF | Description |
|--------------|---|
| 509 045 | Pigtail catheter 5 F, 45 cm with three-way-stopcock 18 G Seldinger cannula 7 cm Guide wire J-tip 90 cm x 0.032" with insertion aid Suction bag 2.0 ltr. with LL-adaptor and 90 cm suction tube |
| 509 095 | Pigtail catheter 5 F, 90 cm 18 G Seldinger cannula 7 cm + 19 cm Dilator 6F - 10 cm Guide wire J-tip 150 cm x 0.032" with insertion aid |
| Box: 5 pcs. | |
| 010 002 | Collection bag 2.0 ltr. with 90 cm tube |
| Box: 20 pcs. | |

Other lengths and sizes on enquiry.

High Pressure Lines

Disposable stopcocks, manifolds and pressure catheter for angiography and other pressure measurements in the high pressure range up to 1.200 psi (85 kg/cm²) in PVC or PUR.



| REF | Description |
|-----|-------------|
|-----|-------------|

High pressure stopcocks

On enquiry

High pressure manifolds

On enquiry

High pressure connecting lines

| | |
|---------|--|
| 714 075 | 75 cm length, PVC, rigid adapter, LL, m/f, 1200 PSI |
| 714 120 | 120 cm length, PVC, rigid adapter, LL, m/f, 1200 PSI |
| 716 075 | 75 cm length, PVC, rotating male adapter, LL, m/f, 1200 PSI |
| 716 120 | 120 cm length, PVC, rotating male adapter, LL, m/f, 1200 PSI |

Box: 20 pcs.

PUR-lines with rigid or rotating adapter on enquiry.

Endovenous Laser Therapy

Varicose veins pose a problem to approx. 15-30% of the adult population, increasing with age. In mild cases patients are bothered by the unaesthetic appearance of varicose veins. Severe cases are associated with pain, inflammation and in rare cases open wounds. Following needle positioning an introducer is easily inserted into the vein by Seldinger technique. After insertion of a laser fibre the treatment can begin. With the laser fibre in correct position of the saphenofemoral junction (determined by ultrasound) you are ready to deliver the first laser pulse. The laser energy will result in permanent thermal damage to the vein wall. The laser treatment is performed along the entire length of the varicose vein and will result in a complete and permanent occlusion of the vein. After a treatment of 30 – 45 minutes the patient can return to normal activity level.



Advantages of the method:

- minimal risk of side effect
- better aesthetic results compared to other methods
- no post-op downtime for patients
- fast out-patient procedure
- only local anaesthesia
- cost-effective solution

We offer special introducers for bare fibers and radial fibers.

The kit contains the catheter, a puncture needle, dilator und guide wire.

| REF | Description | Catheter-Specifications | ID (mm) |
|---------------------------------------|----------------------|--|---------|
| Introducers for bare fibers. | | | |
| 331 704 | Catheter Kit | 6F – 70 cm/with extension line, blue soft tip | 0,92 |
| 331 004 | Catheter Kit | 6F – 100 cm/with extension line, blue soft tip | 0,92 |
| 330 705S | Catheter Kit | 5F – 70 cm; stiff, no extension | 1,05 |
| 330 005S | Catheter Kit | 5F – 100 cm; stiff, no extension | 1,05 |
| Box: 25 pcs. | | | |
| 330 705S2 | Catheter/long packed | 5F – 70 cm; stiff, no extension | 1,05 |
| 330 005S2 | Catheter/long packed | 5F – 100 cm; stiff, no extension | 1,05 |
| Box: 10 pcs. | | | |
| 010 015 | Lock-Adapter | | |
| Box: 50 pcs. | | | |
| Introducers for radial fibers. | | | |
| 300 806 | Introducer Kit 6 F | | |
| 300 807 | Introducer Kit 7 F | | |
| Box: 10 pcs. | | | |

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Information

All products are delivered **sterile** (ethylene oxide), if not otherwise described.

The products are for **single use only**, if not otherwise described.

Most of intra-products are **latex-free**. But for some products of our range it's not possible to do without.

This is for the following products:

| | | |
|--|---|-------------------------------|
| Flow-directed balloon-tipped catheter (Intrathermodin) | → | Balloon from Latex |
| Pneumovent® valve | → | Inside lying valve from Latex |
| Catheters for vessel surgery (Embolectomies) | → | Balloon from Latex |

Company profile

The company intra special catheters GmbH was founded in 1977. Since then, we have provided our customers worldwide with special catheters for anaesthesiological wards and departments of internal medicine, intensive care and emergency medical care, cardiology and pneumology, which offer the users numerous benefits thanks to their optimum range of safety features included and their consistently high quality.



More than ever before, the success of a product is defined by its high and consistent quality. Therefore, we put our faith in qualified staff and are committed to highly advanced production premises. Of course all our products are manufactured and sterilized in accordance with GMP. Hence, only materials of highest purity and quality are used.

Our competence is the result of long years of experience. We take up new challenges by facing them with prompt technological developments. We believe that no product is so good that it could not be further improved. That is why innovation work is carried out in cooperation with physicians from research, universities and hospitals.

intra products are used in various fields of medicine; both in pneumology, where special catheters are used to remove pathological accumulations of air and/or fluid within the pleural cavity, and in intensive care as well as cardiology for invasive measurement of arterial/venous or pulmonary pressures. Of course, we offer adequate accessories for all our special products.

Our enterprise is certified in compliance with the international standards ISO 13485 and Annex II / V according to guideline 93/42/EEC. intra products bear the CE mark of the European Commission.

Certificate

Quality Assurance

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2012.



Through an audit performed on behalf of

intra special catheters GmbH

Oststrasse 2, 66780 Rehlingen-Siersburg, Germany

it could be demonstrated that a quality assurance system

according to

DIN EN ISO 13485:2012

"Medical devices – Quality management systems – Requirements for regulatory purposes"

for the

**development, manufacturing and
distribution of medical devices**

has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number
218-15-1028

Registered under
Z/15/03697E

Valid until
November 17th, 2018

Aachen, November 18th, 2015


Certification Body

Certificat

Asigurarea calitatii

Sigla ecm

ecm Zertifizierungsgesellschaft fuer Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germania, prin prezenta, declara ca a fost efectuata o inspectie a sistemului de asigurare a calitatii mentionat mai jos, conform cerintelor standardului DIN EN ISO 13485:2012.

In cadrul unei proceduri de audit, efectuata in beneficiul
intra special catheters GmbH
Oststrasse 2, 66780 Rehlingen-Siersburg, Germania

S-a demonstrat ca a fost stabilit si implementat un sistem, de asigurare a calitatii
conform DIN EN ISO 13485:2012

“Dispozitive medicale – sisteme de asigurare a calitatii –
Cerinte de reglementare

pentru : dezvoltarea, fabricarea si distributia dispozitivelor medicale.

Prezentul certificat este valabil in conditiile raportului de audit mentionat. Toate modificarile substantiale ale asigurarii calitatii trebuie comunicate catre ECM si vor constitui obiectul unei evaluari separate.

Numar raport
218-15-1028

Numar de inregistrare
Z/15/03697E

Valabil pana la
17 Noiembrie 2018

Aachen, 18 Noiembrie 2015

(Semnatura indescifrabila)
Organ de certificare

