

products



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The image features a light blue background with several medical catheters. One catheter is positioned horizontally across the top, with its clear plastic hub on the left and a thin, curved wire extending to the right. In the lower right quadrant, there is a red, cylindrical catheter hub with a clear plastic connector, and a white, dome-shaped cap. Another catheter is visible in the bottom left corner, extending diagonally. The overall aesthetic is clean and clinical.

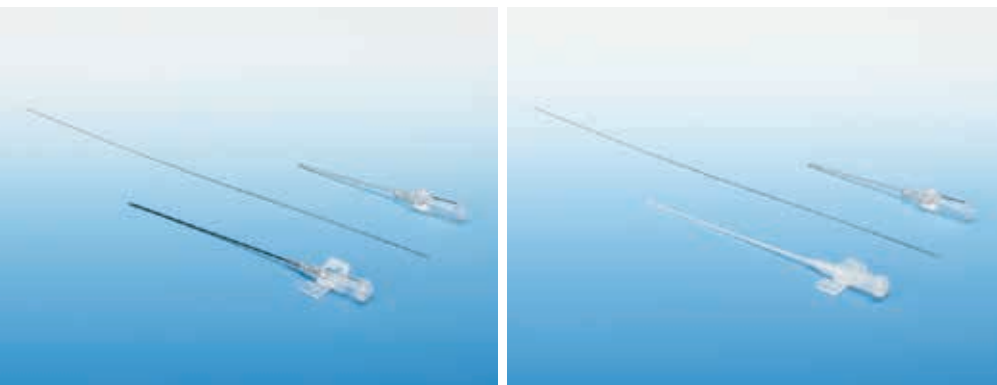
Arterial Seldinger Catheters

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.



Venous Seldinger Catheters

Central Venous Catheters

All catheters consists of high flexible thin-walled polyurethane which ensures very high flow rates. It is anti-thrombogen 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		
331082H	24 G	8 cm
331132H	24 G	13 cm
331130H	20 G	13 cm
331200H	20 G	20 cm
DUOCATH 2lumen		
332 084	4 F	8 cm
332 014	4 F	15 cm
332 015	5 F	15 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
331208H	18 G	20 cm
331206H	16 G	20 cm
331204H	14 G	20 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

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.

Sales in European Union only.

The image shows a collection of medical catheters and accessories. In the foreground, there are several light blue and white catheters with different connectors. One prominent catheter has a large, white, multi-lumen connector at the bottom left. Another catheter has a green connector at the top. The catheters are coiled and arranged on a light-colored surface. The background is slightly blurred, showing more medical equipment.

**Accessories For Seldinger Catheters,
Measurement And Infusion**

12 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.

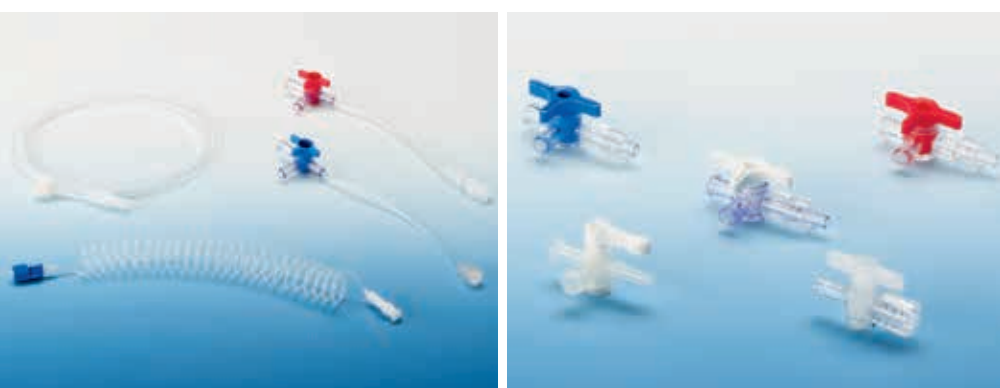


REF	French Size	Sheath Length	Dilator Length	Guide wire	Needle	
300 505	5	12 cm	18 cm	0.035" - 45 cm	18 G - 7 cm	Standard
300 506	6	12 cm	18 cm	0.035" - 45 cm	18 G - 7 cm	Standard
300 507	7	12 cm	18 cm	0.035" - 45 cm	18 G - 7 cm	Standard
300 508	8	12 cm	18 cm	0.035" - 45 cm	18 G - 7 cm	Standard
300 607	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.

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.	REF	Size/Length	Other spec.
PE			Connecath with stopcock (PVC)		
401 xxx (m/f)	2.0 x 1.0 mm / 10-200 cm	2 bar	451 015	2.5 x 1.5 mm / 15 cm	Red, 2.5 bar
402 xxx (m/f)	3.0 x 1.8 mm / 10-200 cm	2 bar	452 015	2.5 x 1.5 mm / 15 cm	Blue, 2.5 bar
Box: 50 pcs.			452 070	2.5 x 1.5 mm / 70 cm	Blue, 2.5 bar

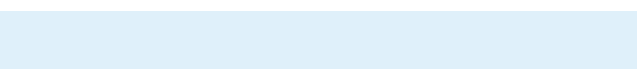
Other sizes and lengths on enquiry. Lengths from 10-200cm. The last 3 figures correspond to the length, i.e. 401 030 for 30 cm

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	REF	Description
611 010	2-way-stopcock, LL	621 312	3-way-stopcock, red 360°
621 311	3-way-stopcock, white 360°	621 313	3-way-stopcock, blue 360°
Box: 50 pcs.			

Accessories



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.

The image displays various medical catheters and components against a light blue background. At the top, a long, thin, blue catheter is curved. Below it, a red catheter with a red handle and a black catheter with a black handle are visible. In the lower half, there are two larger catheter assemblies with blue handles and clear plastic housings, and a smaller blue catheter tip. The text 'Electrophysiology' is centered in red.

Electrophysiology

Intraelektrode 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. Intraelektrode can be positioned quickly, easy and safely and the advantages are good pushability, excellent torque control and positional - stability. Intraelektrode 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

Intraelektrode bipolar

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

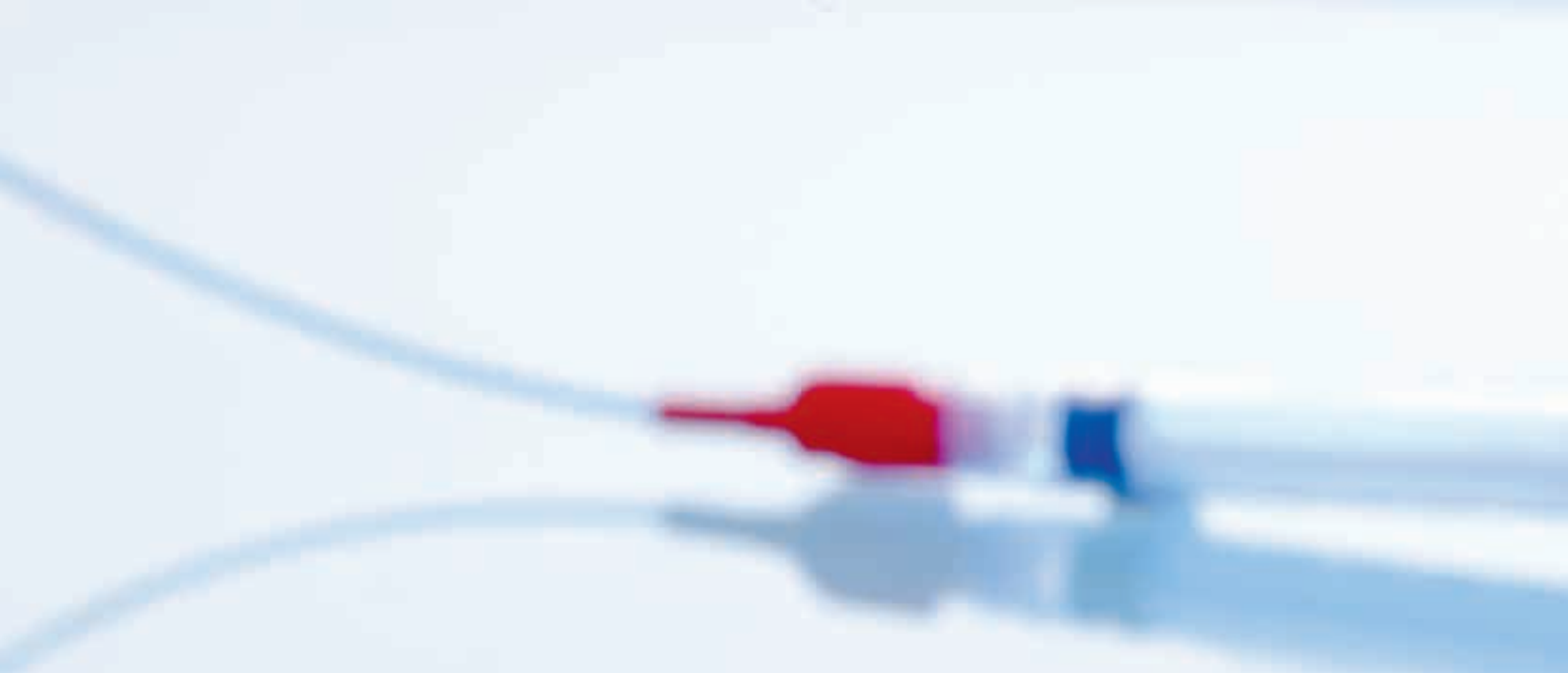
Intraelektrode with balloon

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

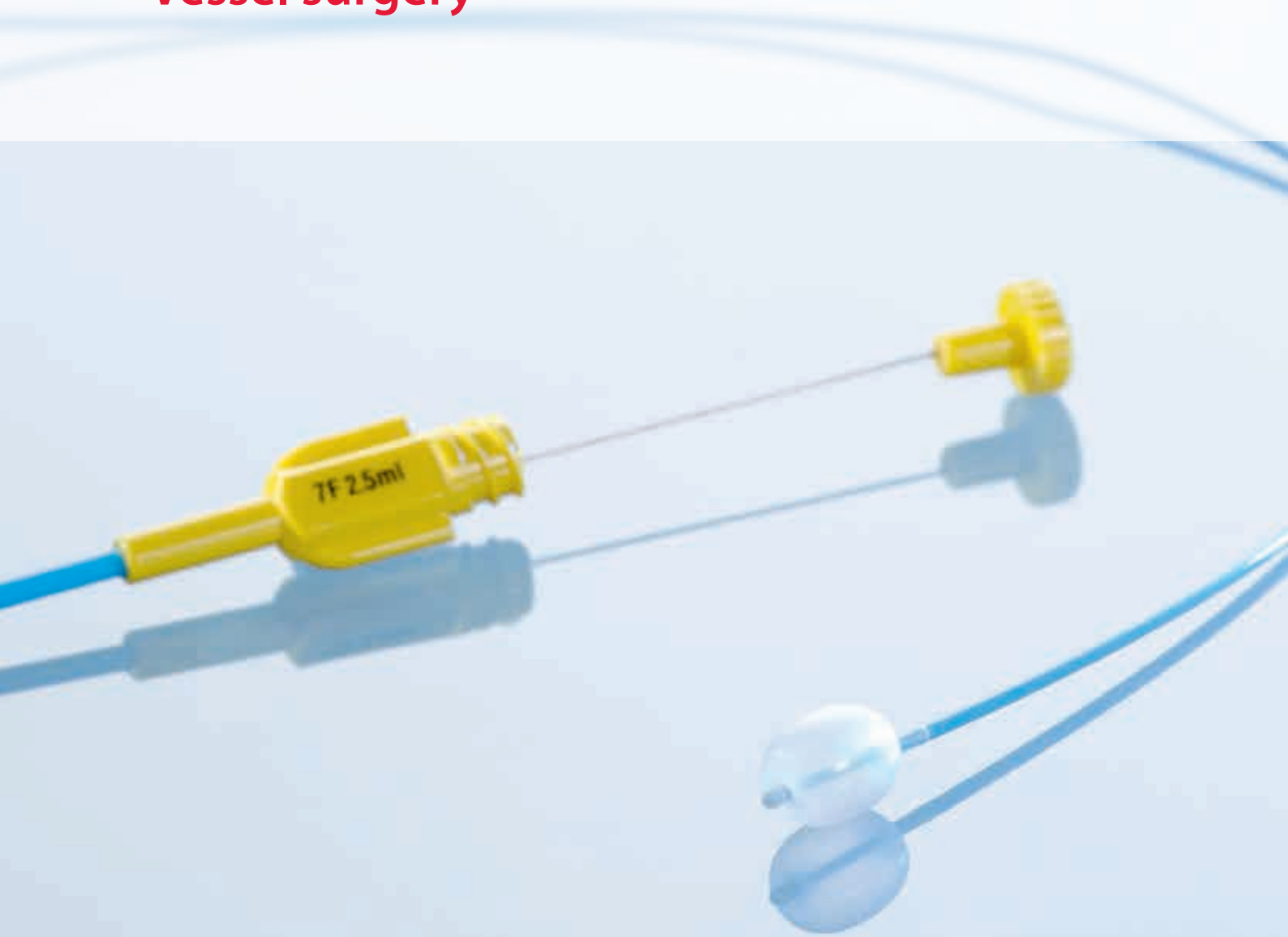
REF	French Size	Tip
Intraelektrode bipolar		
022 244M	4	C-Type
022 245M	5	C-Type
022 246M	6	C-Type
Box: 5 pcs.		
Intraelektrode with balloon		
052 225	5	Straight
Box: 5 pcs.		

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

Electrodes in size of 7F on enquiry.

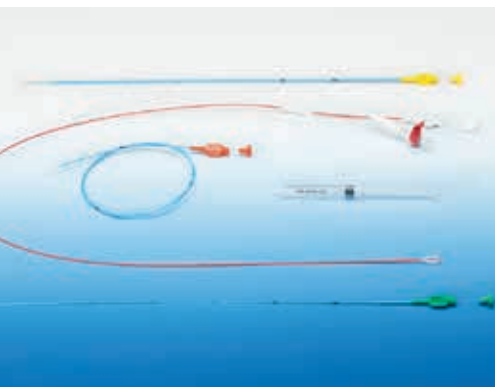


Vessel surgery



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	0.70	8 mm
100 480	4	1.3 mm	80 cm	Red	0.70	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	3.50	16 mm

Sterilization by gamma radiation

Box: 5 pcs.

Other types and sizes on enquiry.

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.

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 image shows various medical instruments used for thoracic drainage and pleural puncture. In the foreground, there are several catheters and needles. One prominent catheter has a blue handle and a clear, graduated tube. Another catheter has a clear handle and a blue connector. A hand is visible on the right side, holding one of the catheters. The background is a light blue gradient with a blurred image of a long, thin tube.

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)
503 014	NEO-PNEUMOCATH® emergency model with fix-Adapter in Hardblister	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
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 (2.0 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
010 045	Collecting bag 1.5 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.



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.

010 045 Collection bag 1.5 ltr. with 90 cm tube

Box: 20 pcs.

Other lengths and sizes 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.

010 015	Lock-Adapter
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Box: 50 pcs.

Introducers for radial fibers.

300 806	Introducer Kit 6 F
300 807	Introducer Kit 7 F

Box: 10 pcs.

Further versions on enquiry

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300 ...	12	471 ...	12	503 061	23		
302 ...	6	472 ...	12	503 111	23		
305 ...	6	473 ...	12	503 119	23		
		503 001	22	503 180	24		

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 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 V according to guideline 93/42/EEC. intra products bear the CE mark of the European Commission.

THORACATH®
Thoracentesis / Pleural / Ascites Puncture Kit



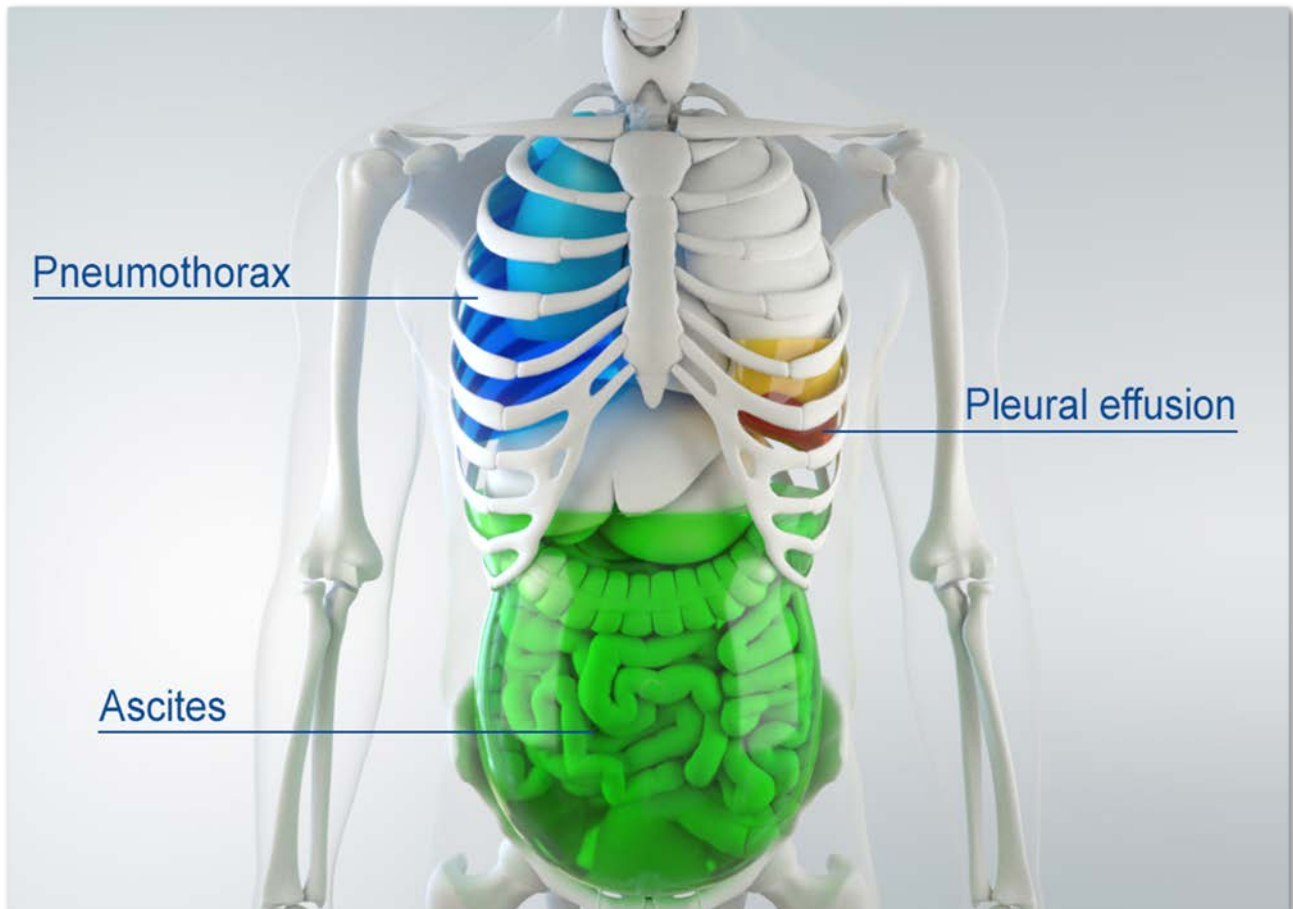
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1. Intended Purpose

1.1 Indications and medical purpose

The THORACATH® Drainage Catheters are used to aspirate unwanted effusions of all kinds from the pleural cavity (pleural effusion), from the abdominal cavity (ascites) or to remove air or gases from the pleural cavity (pneumothorax (spontaneous, traumatic, iatrogenic)). Pleural puncture (thoracentesis) and ascites puncture (paracentesis) can be used for diagnostic or therapeutic purposes. The aims of the application are to initiate further therapeutic measures, in the case of thoracentesis, among other things, to restore the physiological pressure conditions of the pleural cavity and to relieve symptoms, and in the case of ascites puncture, among other things, to relieve symptoms by draining free fluids (ascites).



1.2 Contraindications

1.2.1 Pleural puncture

There are no absolute contraindications, especially in case of vital (life-threatening) indication. It is at the discretion of the attending Healthcare Professional to assess this.

Relative contraindications:

- Unwilling uncooperative patient
- Coagulopathy / haemorrhagic diathesis
- Anticoagulation

- Severe decompensation
- Infections / inflammations (e.g. infections of the pleural cavity, Flordid skin infections in the area of the puncture site)
- Restricted access route to the pleural cavity (e.g. adhesions in the pleural space, malformation of the cardiac vessels, Altered anatomy of the chest wall)
- Chylothorax
- Emphysema of the lung

1.2.2 Ascites puncture

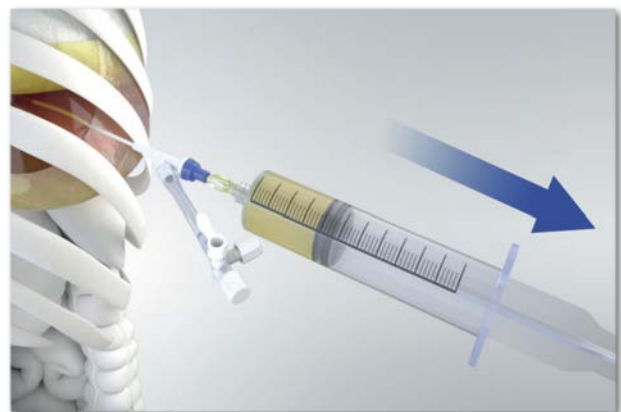
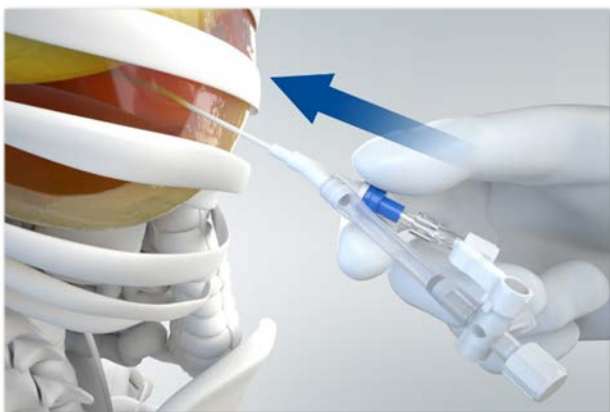
There are no absolute contraindications, especially in case of vital (life-threatening) indication. It is at the discretion of the attending physician to assess this.

Relative contraindications:

- Unwilling, uncooperative patient
- Coagulopathy / haemorrhagic diathesis
- Anticoagulation
- Severe decompensation
- Infections / inflammations (e.g. peritonitis, flordid skin infections in the area of the puncture site)
- Restricted access route to the abdominal cavity as well as pathological anatomical conditions that make catheter placement difficult (e.g. massively dilated intestinal loops, pronounced organomegaly, hydronephrosis, pregnancy, intestinal adhesions to the abdominal wall)
- decompensated liver cirrhosis
- presence of chambered ascites
- clinically detectable fibrinolysis

1.3 Product description

The THORACATH® Drainage Catheters are made of PE (polyethylene) tubing and have different connectors at the end (e.g. Luer-Lock or three-way-stopcock). The catheter itself has 2-4 lateral holes at the distal catheter tip to prevent blockages and to optimise drainage. The models with lateral connection and three-way-stopcock have a self-locking valve that closes after removal of the puncture needle inserted into the catheter, thus ensuring protection against aspiration of air during the procedure.



1.4 Intended users and patient population

The product may only be inserted, applied and removed by Healthcare Professionals, i.e. by qualified physicians or by qualified medical personnel under the instruction of a qualified physician.

Of particular importance are the procedures in anaesthesia, intensive care, internal medicine, surgery and emergency medicine and for all other patients with the listed indications and where the user with the required qualifications considers this necessary.

The medical device can be used on both adults and children without any fundamental distinction as to age, anatomy or physiology, taking into account the contraindications. The anatomical and physiological conditions of the patient must be checked by the attending Healthcare Professional before using the product.

1.5 Application duration

The product is only suitable for transient (< 60 minutes) use.

1.6 Single use

The product is not reusable. It is a single use product.

1.7 Classification

Product group: Drainage Systems, Pleural

UMDNS: 10-817

Catheter: Class IIa (Rule 6)

Kit: Sterile procedure pack according to article 12 of the Council Directive 93/42/EEC

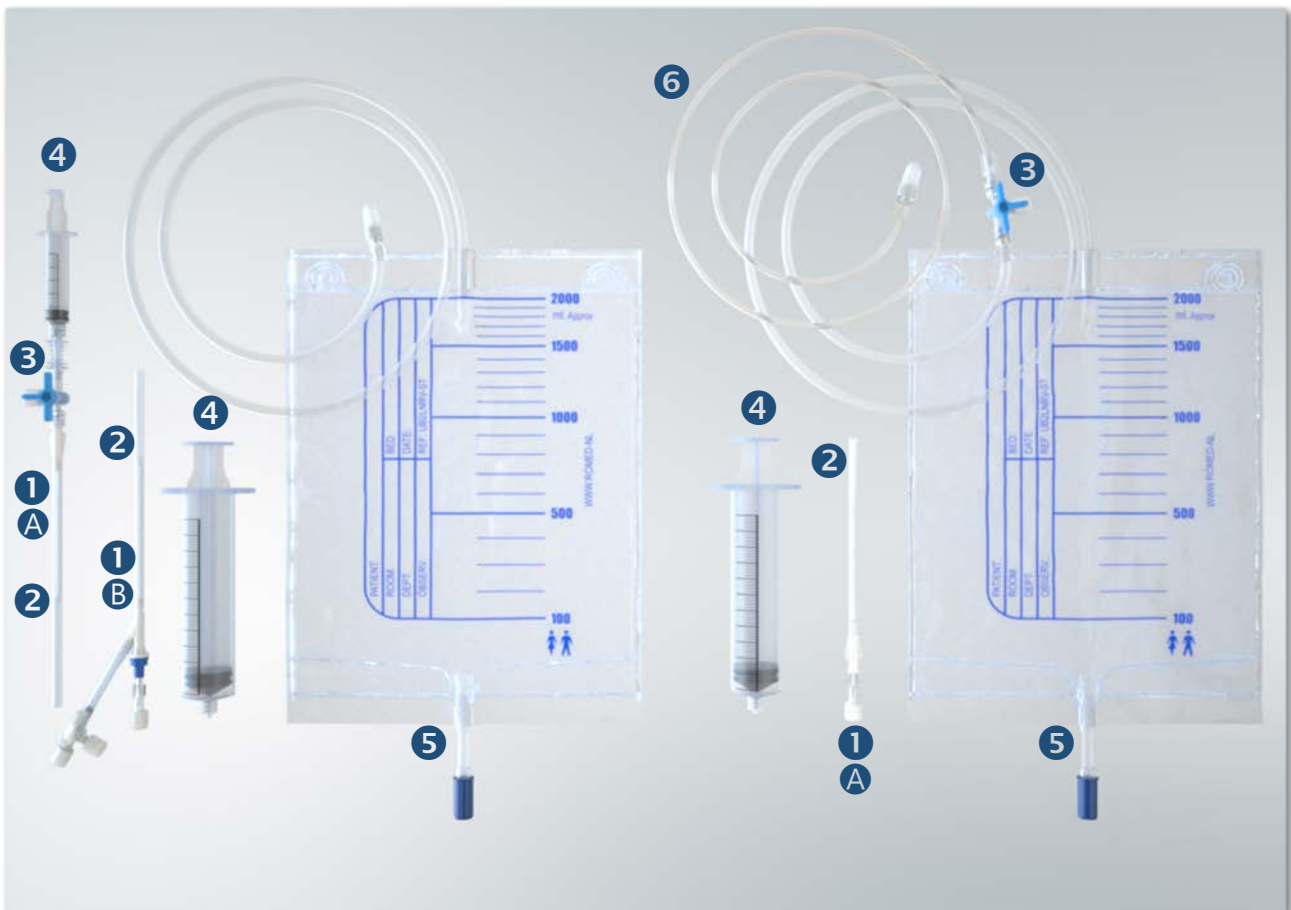
2. Packaging Content

2.1 Primary packaging content

- ① 1: Radiopaque PE-catheter with protective caps in appropriate numbers in:
 - Ⓐ - straight version without sideport or
 - Ⓑ - Y-version with side port including three-way-stopcock
- ② 1: Puncture needle inserted into the catheter including protective tube

2.2 Possible additional packaging contents

- ③ 1: Three-way-stopcock
 - ④ 1: Syringe
 - ⑤ 1: Collection bag
 - ⑥ 1: Connecting tube
- Possibly further components



3. Device and Material Specifications

Table 1: Product variants and article numbers

REF	Catheter OD / Length	Catheter ID	Needle Length	Needle OD / ID	Type
Thoracentesis Kit					
503 019	14 G (2.1±0.04mm) – 88±0.5mm	1.6 ±0.04mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	With sideport
503 019A	14 G (2.1mm) – 90±1.0mm	1.6mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	With sideport
503 021	14 G (2.1±0.04mm) – 104±0.5mm	1.6 ±0.04mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	Straight
503 021A	14 G (2.1mm) – 105±1.0mm	1.6 mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	Straight
Pleural Puncture Kit					
503 022	14 G (2.1±0.04mm) – 104 ±0.5mm	1.6 ±0.04mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	Straight
503 022A	14 G (2.1mm) – 105±1.0mm	1.6mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	Straight
503 022V	14 G (2.1±0.04mm) – 104±0.5mm	1.6 ±0.04mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	Straight
503 022VA	14 G (2.1mm) – 105±1.0mm	1.6mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	Straight
503 025	14 G (2.1±0.04mm) – 74±0.5mm	1.6 ±0.04mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	Straight
503 025A	14 G (2.1mm) – 75±1.0mm	1.6mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	Straight
Ascites Puncture Kit					
503 119	14 G (2.1±0.04mm) – 88±0.5mm	1.6 ±0.04mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	With sideport
503 119A	14 G (2.1mm) – 90±1.0mm	1.6mm	135 ±2.0mm	1.48 (±0.02) x 1.0 mm (±0.04)	With sideport

Articles with the suffix A may differ in individual specifications such as materials.

Table 2: Material components of the Thoracentesis / Pleural / Ascites Catheters

Product / Component	Material (I)	Material (II)	Type of contact
Catheter (straight version)			
Catheter tube	LDPE	LDPE	invasive (in the body, no direct contact with circulating blood)
Connection (LL-Adapter)	HDPE	HDPE	outside the body; skin contact possible
Screw cap	PP	ABS	outside the body; skin contact possible
Catheter (Y-version with side port including three-way-stopcock)			
Catheter tube	LDPE	LDPE	invasive (in the body, no direct contact with circulating blood)
Y-connector (1) Valve attachment (2) Upper part (3) Membrane	HDPE PP Silicone	HDPE HDPE Silicone	(1)(2) outside the body; skin contact possible (3) No direct body contact
Tube (sideport)	Silicone	PVC	outside the body; skin contact possible
Three-way-stopcock (1) Body (2) Adapter (LL) (3) Core handle	PC PC HDPE	PC PC HDPE	outside the body; skin contact possible
Screw cap	PP	ABS	outside the body; skin contact possible

Table 3: Material components of the Thoracentesis / Pleural / Ascites Kits

Product / Component	Material (I)	Material (II)	Type of contact
Three-way-stopcock (1) Body (2) Adapter (LL) (3) Core Handle	PC PC HDPE	PC PC HDPE	outside the body; skin contact possible
Puncture needle (1) Canula (2) Grip of needle (3) Protection tube	Stainless steel PC PP	Stainless steel PC PP	invasive (in the body, no direct contact with circulating blood)
Collection bag (1) Bag (2) Tube (3) Adapter (LL) (4) Bottom drain valve	PVC, DEHP PVC ABS PVC, LDPE	PVC, DEHP PVC ABS PVC, LDPE	outside the body; skin contact possible
Connecting tube (1) Tube (2) Adapter (LL) (3) Protection cap	PVC ABS LDPE	PVC ABS (mLL) PVC (wLL) PE	outside the body; skin contact possible
Syringe (5 ml / 50 - 60 ml) (1) Case (2) Plunger rod (3) Piston plug (50-60ml) (3) Piston plug (5ml)	PP PP Rubber Synth. rubber	PP PP Polyisoprene Synth. rubber	outside the body

4. Packaging and Sterilization

The products are packed in peel pouches, placed in cartons of 10 or 20 pieces.

The sets are sterilized with ethylene oxide according to a method validated at the physical and microbiological level. The usability period is a maximum of 5 years from the date of sterilization. Depending on the components used, a shorter shelf life may be possible, but not less than 3 years. The specific shelf life is indicated on the product label.

5. Storage and Handling Instructions

The storage and handling instructions are given on the label of the product and in the instructions for use.

6. Quality Assurance

The quality of the products is guaranteed by inspections at all levels of production. All intra products are produced and packaged in controlled atmosphere zones.

Final inspection takes place at packaging level.

7. Regulatory Requirements

7.1 General

The Medical Device Regulation (EU) 2017/45 (MDR) has been in force since 26.05.2021 and has thus replaced the Medical Device Directive 93/42/EEC (MDD). According to Article 120 MDR, the transitional provisions apply until 26.05.2024, of which use is made for the named medical device. The implementation of the MDR is currently in progress and will take place within the mentioned period for the named medical device.

intra special catheters complies with the requirements of the MDR - (EU) Regulation 2017/745 and maintains the certificate according to the Medical Device Directive 93/42/EEC under the certification by TÜV NORD CERT GmbH (CE 0044) until 26.05.2024. intra special catheters also maintains a quality management system according to EN ISO 13485. Within the framework of the quality management system, all regulatory requirements relevant for the product group are implemented and maintained and monitored for revisions.

7.2 Implemented regulatory requirements

Medical Device Law Implementation Act (<i>german</i> MPDG)	C	DIN EN ISO 11737-2	C*
Medical Devices EU Adaptation Act (<i>german</i> MPEUAnpG)	C	DIN EN ISO 11135	C*
Medical Devices User Notification and Information Ordinance (<i>german</i> MPAMIV)	C	DIN EN ISO 10993-1	C
MDR (EU) Regulation 2017/745	C	DIN EN ISO 10993-5	C
MDD Directive 93/42/EEC	C	DIN EN ISO 10993-7	C
DIN EN ISO 13485	C	DIN EN ISO 10993-10	R
DIN EN ISO 14971	C	DIN EN ISO 10993-11	R
DIN EN ISO 20417	C	DIN EN ISO 10993-12	C*
DIN EN ISO 15223-1	C	DIN EN ISO 10993-16	R
DIN EN 868-2	C*	DIN EN ISO 10993-17	R
DIN EN 868-3	C*	DIN EN ISO 10993-18	C
DIN EN 868-4	C*	DIN EN ISO 80369-7	C
DIN EN 868-5	C*	DIN EN ISO 20697	C
DIN EN ISO 11607-1	C*	DIN EN ISO 14644-1	C*
DIN EN ISO 11607-2	C*	DIN ISO 2859-1	R
DIN EN 556-1	C*	DIN EN 62366-1	R
DIN EN ISO 11737-1	C*	ISO/TR 20416	R

Overview of abbreviations

"C" (*Compliance*)

Regulatory requirements that are mandatory

"R" (*Reference*)

Regulatory requirements that are not mandatory but serve as a reference

" * "

Regulatory requirements that are applied by subcontractors within the scope of the service to be provided