THORACATH®
Thoracentesis / Pleural / Ascites Puncture Kit

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Content

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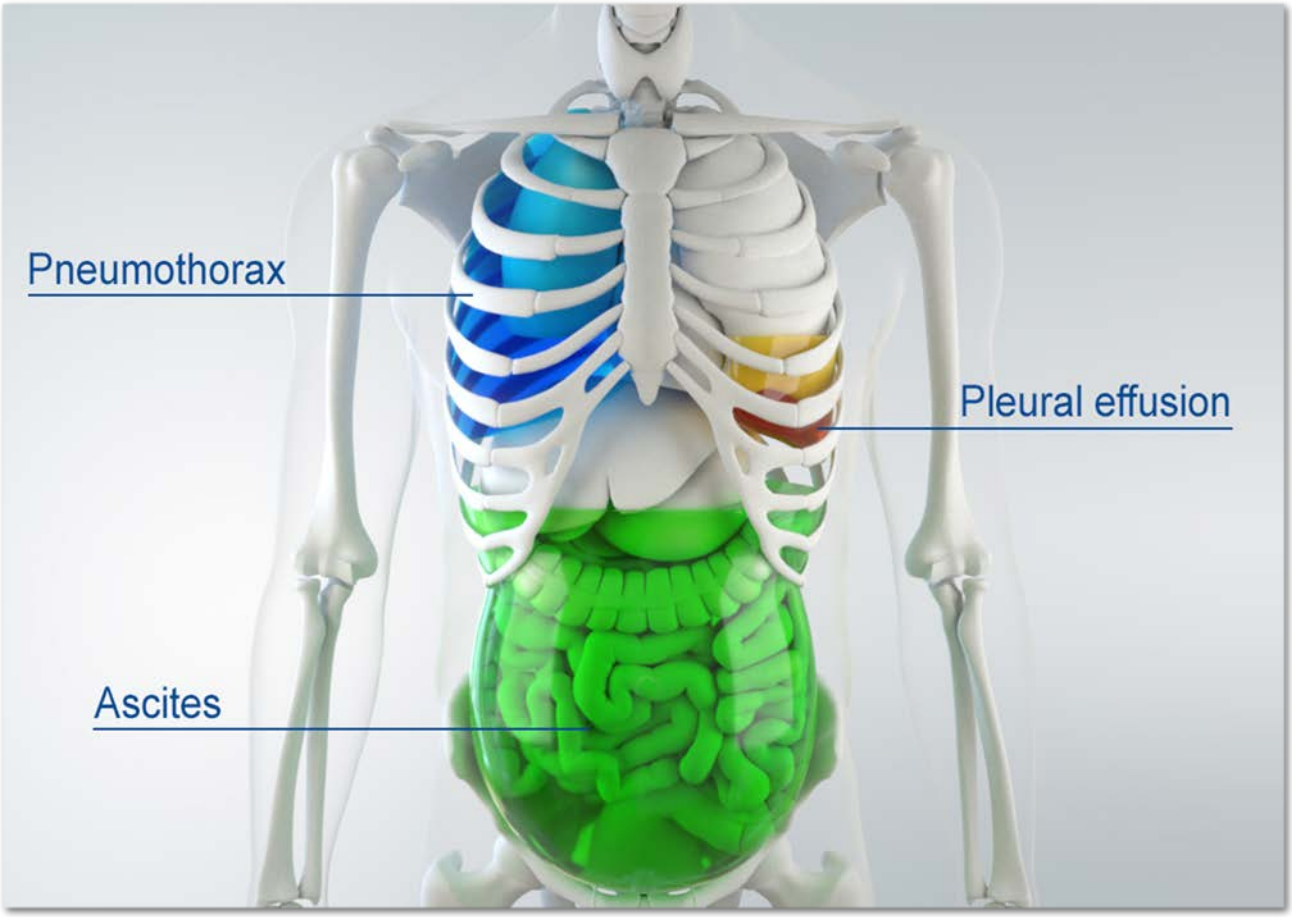
1. Intended Purpose

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, Florid 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

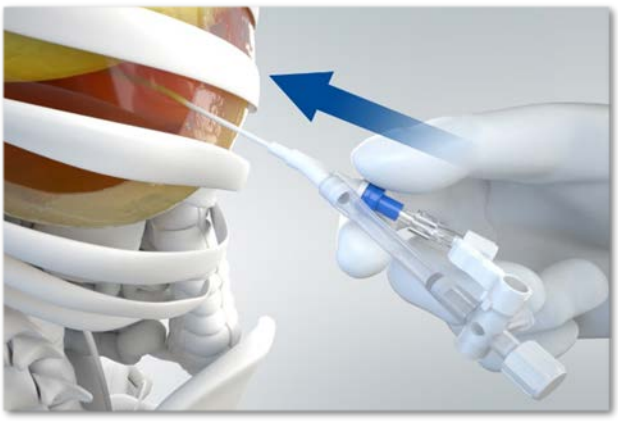
There are no absolute contraindications, especially in case of vital (life-threatening) indication.
It is at the discretion of the attending physician to assess this.

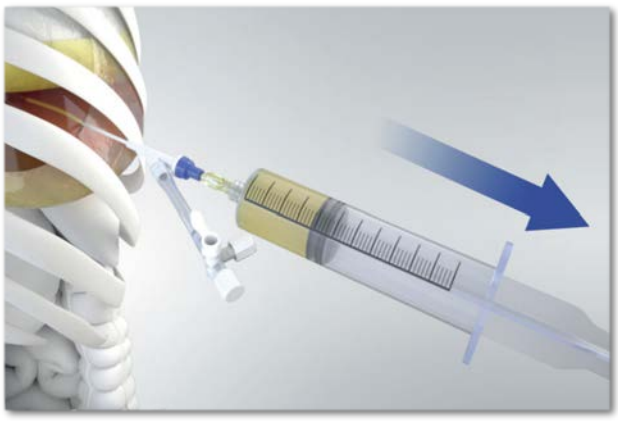
Relative contraindications:

- Unwilling, uncooperative patient
- Coagulopathy / haemorrhagic diathesis
- Anticoagulation
- Severe decompensation
- Infections / inflammations (e.g. peritonitis, florid 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

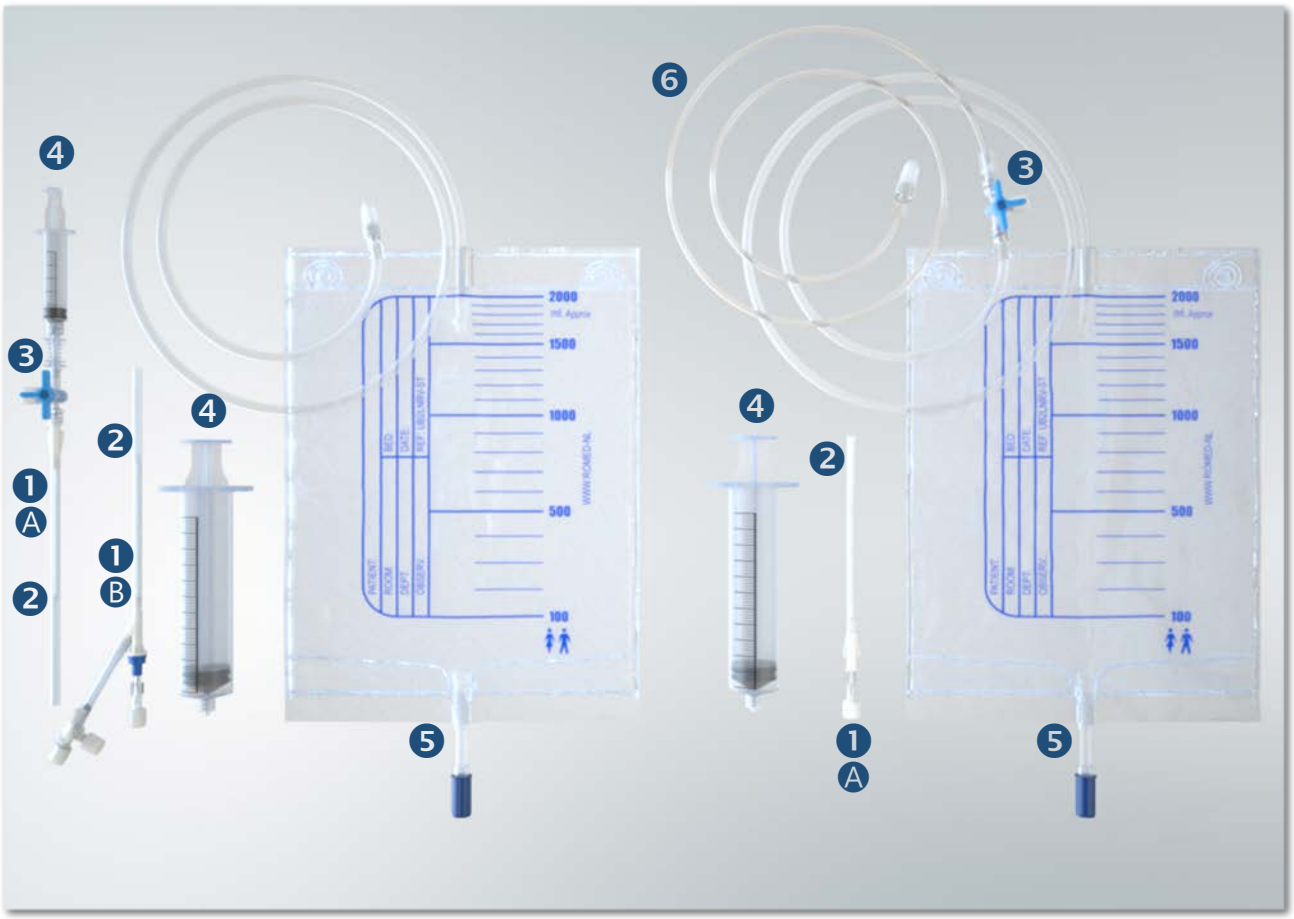
2.1 Primary packaging content

❶ 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

❷ 1: Puncture needle inserted into the catheter including protective tube

2.2 Possible additional packaging contents

❸ 1: Three-way-stopcock
❹ 1: Syringe
❺ 1: Collection bag
❻ 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.

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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.

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7.2 Implemented regulatory requirements

Medical Device Law Implementation Act (*german* MPDG)	C	DIN EN ISO 11737-2	C*
Medical Devices EU Adaptation Act (*german* MPEUAnpG)	C	DIN EN ISO 11135	C*
Medical Devices User Notification and Information Ordinance (*german* 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*

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