(en) Instructions for use

Thoracentesis / Pleural / Ascites Catheter
Thoracentesis / Pleural / Ascites Puncture Kit

Read the instructions for use carefully before application!

Primary packaging content:

1: Radiopaque PE-catheter with protective caps in appropriate numbers in:
- straight version without sideport (→ Fig. 1: ❶ / ❷) or
- Y-version with side port including three-way-stopcock (→ Fig. 1: ❸)

1: Puncture needle inserted into the catheter including protective tube *(only included in STBE*)*

Possible additional packaging contents:

1: Three-way-stopcock
1: Syringe (→ Fig. 1: ❹)
1: Collection bag (→ Fig. 1: ❺)
1: Connecting tube (→ Fig. 1: ❻)
Possibly further components

The contents of the packaging and the specifications of the individual components are indicated on the packaging and the label.

Valid for:

503 019 503 019A 503 021 503 021A 503 022 503 022A	503 022V 503 022VA 503 025 503 025A 503 119 503 119A	**STBE***	503 019E 503 019EA 503 020E 503 020EA 503 021E 503 021EA	CE 0044
STBE* = Sterile procedure pack acc. to Article 12 of the Council Directive 93/42/EEC concerning Medical Devices Notified Body: TÜV NORD CERT GmbH CE 0044			The article numbers with *E* or *EA* consist exclusively of the **non sterile** catheter mentioned above. All points applicable to the catheter in these instructions for use apply to these articles. In these instructions for use, contents are addressed which apply to the use of the catheter in combination with a puncture needle and other components. These points should be observed when using the product.	

Indications and Medical Purpose:

The thoracentesis / pleural / ascites puncture catheters / kits 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).

Application duration:

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

Contraindications 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 pleural puncture:

It is necessary to weigh the benefit against the risk by the user!
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

Contraindications 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 ascites puncture:

It is necessary to weigh the benefit against the risk by the user!
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;

Intended user and patient target group:

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.

⚠ General notes and precautions:

- **The product is to be used exclusively sterile!**
  If the product is unsterile, the information enclosed with the product must be taken into account.
  The instructions described in these instructions for use apply in any case.
- The product may only be used under absolutely aseptic conditions.
- The product may only be used in accordance with the intended purpose described.
- The medical methods and procedures described in this manual for use do not reflect all accepted medical practices nor are they a substitute for the experience and judgment of the physician in treating his or her patients.
- Users must be aware of the risks, complications and undesirable side effects associated with pleural and ascitic puncture procedures, including but not limited to the risks, complications and side effects listed in this Instructions for Use.
- Improper handling can damage the catheter (e.g. piercing the catheter) with the consequence that parts of the catheter could remain in the patient and cause him/her harm.
- Do not use damaged products or products from damaged packaging, as this could result in the product no longer functioning properly, parts getting into the patient's body or the sterile barrier system no longer being intact with the consequence that sterility is no longer guaranteed.
- Do not use products that have exceeded the expiry date on the sterile packaging (label).
- When using additional or other components that are not included in the packaging, care must be taken to ensure safe and firm connection, compatibility with the components contained in the packaging, as well as the instructions of the respective manufacturers.
- The connections may have become loose due to transport and storage or procedures during the sterilization process. Check all connections before use and tighten the connections if necessary.
- In case of treating pregnant women, the use of the product must be checked by a doctor before application.
- The medical device is intended for single use only and is not allowed to be resterilized. In case of reuse or resterilization, it cannot be guaranteed that biological, physical, chemical and functional properties of the device are still given. Reuse or resterilization may lead to malfunction of the product, which in turn may lead to injury, illness or death of the patient.
- If a **malfunction** of the medical device occurs, the application must be stopped immediately and the manufacturer must be informed. Defective products must be kept and sent to the manufacturer for investigation.
- **Serious incidents** related to the medical device must be reported immediately to the manufacturer and the competent authorities, and the products must be kept and sent to the manufacturer for investigation.

⚠ Possible side effects:

- Potential allergic reaction to the material of the catheter (polyethylene with barium sulphate) or to the material of the puncture needle (stainless steel).

⚠ Possible risks, complications and further notes on pleural puncture:

- Malposition of the pleural drainage:
  1. Insertion too deep: The drainage causes chest or shoulder pain when pressure is applied to the parietal pleura; in addition, the drainage function is impaired.
  2. Extrathoracic malposition: The drainage has slipped past the rib and is now in the subcutaneous or submuscular tissue. This is noticeable by the fact that the fluid column in the drainage system no longer moves in breath-synchronous.
  3. Intrapulmonary malposition: This malposition is especially possible with adhesions and represents a lung injury.
  4. Injury to intercostal nerves and vessels running along the lower edge of each rib.
     Recommendation: The chest drain should always be placed at the upper edge of the rib in order not to injure the nerves and vessels.
- Sagging of the tubes / suction reduction:
  Make sure that the tubes do not sag, as liquids or secretions collect in the loops (syphon), which reduces the suction.

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- Infections / inflammations (e.g. at the puncture site, intrapleural wound infection)
- Skin emphysema
- Injury to intra-abdominal or intrathoracic organs (visceral injuries) (e.g. heart, lungs, lung parenchyma, diaphragm), intrapleural injury or nerve damage.
- Bleeding
- Circulatory problems when aspirating large amounts of pleural effusion
- Pneumothorax in case of incorrect use
- In the case of pleural drainage, a suction of -10 to -20 cm H_2O on the patient is sufficient for suction as well as for maintaining the intrapleural pressure. Unless clinically necessary, negative pressures greater than -50 cm H_2O should not be applied to the patient. A lower suction level may be necessary when used on children and newborns. It is recommended to apply a suction of -5 to -10 cm H_2O to the patient in children and newborns. Too much suction during drainage may cause severe pain, lung injury, injury to surrounding blood vessels, syncope, or re-expansion edema.

Alternative treatment options:

- For effusions < 100 ml in the pleural cavity, drug therapy should be considered as an alternative treatment option.
- For effusions in the pleural cavity: Thick fluids may cause blockages of the catheter and the puncture cannula. In this case, the use of larger diameter drains is recommended (e.g. PNEUMOCATH®).
- Alternatively, the use of a minithoracotomy in combination with upstream imaging for exploration of the pleural cavity can provide essential information about the intrathoracic findings, with the possibility of placing a drain immediately.

⚠ Possible risks, complications and further notes on ascites puncture:

- Sagging of the tubes / suction reduction:
  Make sure that the tubes do not sag, as liquids or secretions collect in the loops (syphon), which reduces the suction.
- Bleeding
- Restricted access route into the abdominal cavity filled with ascites due to enlarged organs (e.g. hepatosplenomegaly, cystic kidneys), tumours, pregnancy or strongly filled hollow organs (e.g. air-filled intestinal loops in ileus, intestinal adhesions to the abdominal wall, urinary bladder atony, urinary outflow obstruction).
- Injuries to abdominal organs (resulting in e.g. abdominal wall abscess after intestinal perforation).
  Recommendation: Ultrasound-guided punctures to avoid organ injuries
- Syncope
- Infections (e.g. peritonitis)
- Fistula formation
  Recommendation: Use an appropriate puncture technique to avoid fistula formation.
- Hepatorenal syndrome (can be triggered e.g. by massive decompression puncture)
- Prophylactic leakage of ascites through the stitch canal
  Recommendation: Can be prevented by positioning the patient on the side opposite the stitch canal, choosing an oblique stitch canal, draining the ascites completely or, if necessary, using a tobacco bag suture.
- In cases of decompensated cirrhosis and pre-existing clouding of consciousness, draining excessive volumes of ascites may worsen the clinical situation.

Application steps:

1. Open the packaging and remove the components (→ Fig. 1).
2. Carefully remove the protective tube from the puncture needle (→ Fig. 2 / 3 / 4).
3. Check the mobility between the catheter and the puncture needle by gently rotating the needle without retracting it (→ Fig. 5 / 6 / 7).

⚠ **Attention!**
The ground needle tip is not allowed to disappear into the catheter and be pushed forward again, as there is a risk of the needle damaging the catheter (e.g. piercing the catheter or abrading the material from the inside of the catheter) and thus causing the catheter to leak or plastic particles to enter the patient! In models with a sideport, there is also a risk of the membrane leaking (→ Fig. 8 / 9).

4. Close the three-way-stopcock in the catheter direction for models with sideport (→ Fig. 10).
5. Determine the puncture site depending on the indication and the previously determined localization of the medium to be aspirated (e.g. by imaging procedures).
6. Disinfect the puncture site and administer local anaesthesia.

⚠ **Attention!**
Use only alcohol or iodine-based disinfectants. Other disinfectants may weaken the material on contact with the catheter, which could affect the catheter properties. This may lead to leaks or air aspiration.

7. Perform the puncture by advancing the catheter with the needle in place (→ Fig. 11).
   An ultrasound examination can be helpful for exact positioning.
8. Once the catheter is placed in the desired location, a sample can be taken through the needle (→ Fig. 12 / 13).
9. Slowly retract the needle from the catheter (→ Fig. 14).

⚠ **Attention!**
After the needle has been withdrawn from the catheter, it is not allowed to be advanced again as there is a risk of the needle damaging the catheter (e.g. piercing the catheter or abrading the material from the inside of the catheter) and thus causing the catheter to leak or plastic particles to enter the patient! In models with a sideport, there is also a risk of the membrane leaking (→ Fig. 15).

10. Check the position of the catheter by imaging procedures if necessary.
11. A connection tube, a three-way-stopcock, a syringe LL, a collection bag can be connected. To prevent air from entering the thoracic cavity and thus another pneumothorax, a Pneumovent® valve according to Heimlich can also be attached (→ Fig. 16).

⚠ **Attention!**
Close the bottom drain valve of the collection bag before use!

12. For models with sideport and three-way-stopcock, the three-way-stopcock must now be opened accordingly (→ Fig. 17).
13. These models also offer the option of alternating use of the two ports of the three-way stopcock, e.g. for flushing the catheter, suction or connection of a manometer for pressure measurement.
14. Secure the catheter to the patient's body in such a way that the catheter cannot come loose from the tight connection (→ Fig. 18) and start the application.
15. When the application is complete, release the fixation and hold the catheter firmly (→ Fig. 19).
16. Carefully withdraw the catheter from the patient and protect the puncture site immediately afterwards (e.g. with gauze swab and dressing) (→ Fig. 20).

⚠ **Attention!**
Immediate closure of the puncture site (e.g. with gauze swab and dressing) is essential to avoid a recurrence of a pneumothorax and infections.

Disposal:

After use, the product must be disposed of in accordance with infectious waste regulations or national or regional regulations.

Excluding of liability:

Due to the biological differences of the patients, the effectiveness cannot be fully guaranteed. As we have no control over the conditions of use, diagnosis and indication as well as application and use of the product, we can neither guarantee success nor can we exclude the occurrence of side effects.
intra special catheters GmbH accepts no liability for damage or injury of any kind resulting from improper use, reuse or modification of the product.

Explanations:

The symbols used on the packaging and on the label have the following meanings:

	Manufacturer	STERILE EO	Sterilized with ethylene oxide		For single use only
	Date of manufacture		Do not resterilize		Protect from sunlight
REF	Article number		Do not use if packaging is damaged		Protect from moisture
LOT	Lot / Batch number		Attention	10°C 35°C	Temperature limitation
	Can be used until		Follow instructions for use	PHT DEHP	Product contains DEHP
				LATEX	Latex free

Further information on the application and training of the product can be obtained from the contact details provided.

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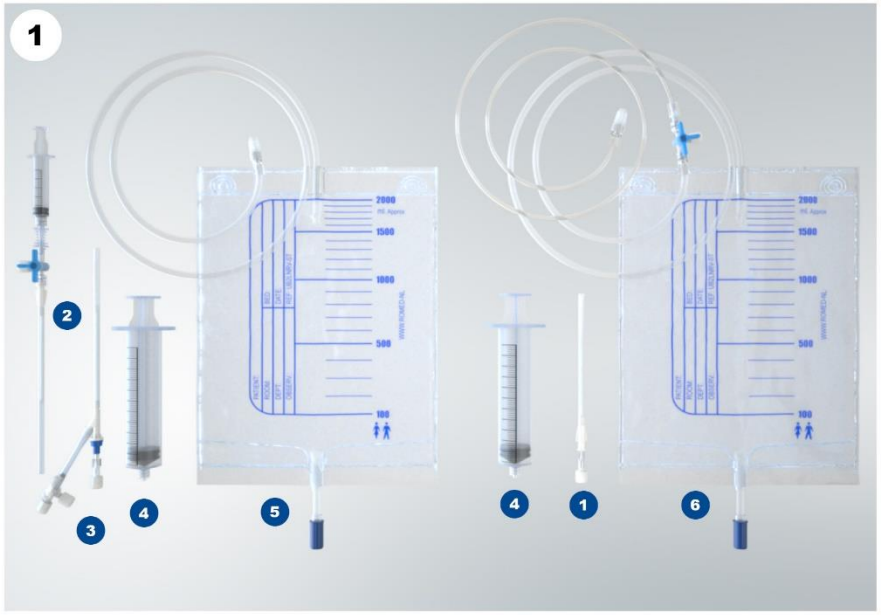

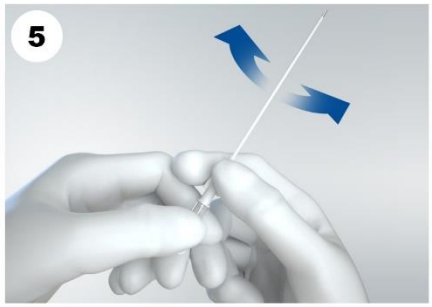

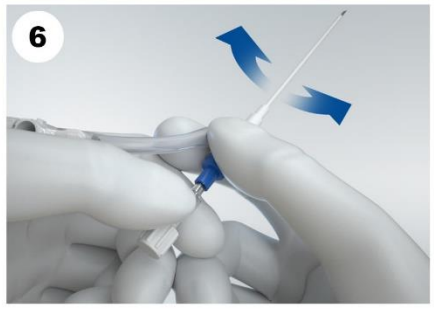

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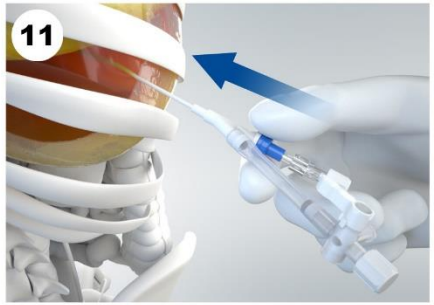

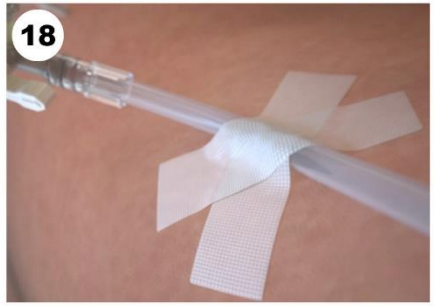

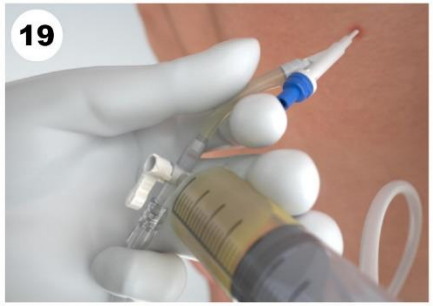

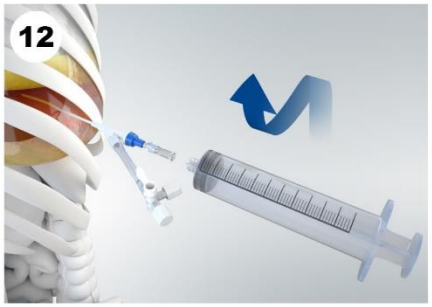

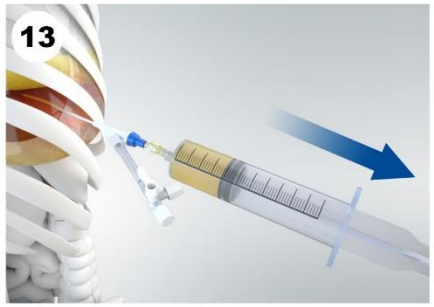

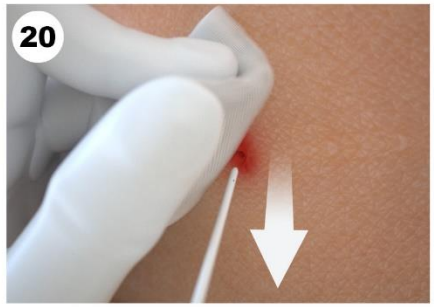

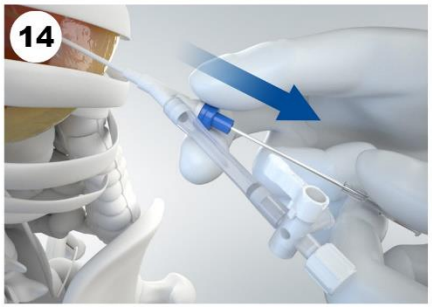

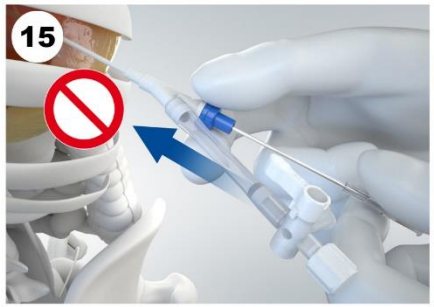

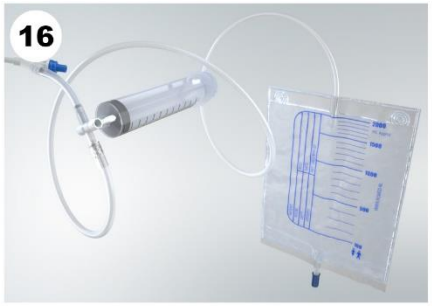

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