# *(en) Instructions for use* PNEUMOCATH® / NEO-PNEUMOCATH® / THORACATH®

**Read the instructions for use carefully before application!**

## Primary packaging content:

1: Radiopaque PE-catheter with ring marks, inserted into a puncture cannula with sterile sheath (→ Fig. 1: ❶) and
1: Three-way-stopcock with connected step adapter (only for standard version) (→ Fig. 1: ❷) or
1: Fix adapter with integrated three-way-stopcock and connected step adapter (only Fix version) (→ Fig. 1: ❸)

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

## Valid for:

| | | | | | |
|---|---|---|---|---|---|
| 503 001 | 503 011 | 503 201 | 503 001E | 503 011E | 503 211E |
| 503 002 | 503 012 | 503 211 | 503 002E | 503 012E | |
| 503 003 | 503 014 | 90001 | 503 003E | 503 201E | |
| **Sterile** | | | **Non sterile** | | |

## Indications and Medical Purpose:

The PNEUMOCATH® drainage catheters are used to aspirate unwanted effusions of all kinds from the pleural cavity (pleural effusion (e.g. haematothorax, pleural empyema, chylothorax)), to remove air or gases from the pleural cavity (pneumothorax (spontaneous, traumatic, iatrogenic)) or for pleurodesis. Pleural puncture (thoracentesis) can be used for diagnostic or therapeutic purposes. The aims of the application are to initiate further therapeutic measures and, among other things, significantly to restore the physiological pressure conditions of the pleural cavity and to relieve symptoms or, in the case of pleurodesis, to obliterate the pleural leaves in order to prevent a recurrence of effusion.

## Application duration:

The product is only suitable for short term (< 30 days) use.

## Contraindications:

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:

*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); Emphysema of the lung

## 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, pneumology (pulmology), 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. Shearing off 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:

- The terms "adults", "children" and "newborns" in the product description are to be understood as an orientation. Which product (size) is most suitable for the patient must be checked by the Healthcare Professional before use according to the anatomical and physiological conditions of the patient.
- 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.
- Before each drainage procedure, the position of the catheter must be checked!
- 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.
- 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

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- 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.
- If there are appropriate indications and recurrent accumulations of fluid or air in the pleural cavity, if the drainage is prolonged or has been completed, a thoracoscopy or thoracotomy may be useful to determine the cause and to treat the problem. 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.

## 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. Check the mobility between the catheter and the puncture needle by gently rotating the needle (→ Fig. 3).
4. Close the three-way-stopcock in the catheter direction (Off-position in the direction of the metal tube connection from the three-way-stopcock) (→ Fig. 4 / 5).
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 rotary advancement. This eliminates the need for a puncture incision (→ Fig. 6).
   An ultrasound examination can be helpful for exact positioning.
8. When the pleural cavity is reached:
   a) air may escape from the sheath and the sheath may visibly contract if the pleural pressure is negative (→ Fig. 7).
   b) the sheath may fill with air or effusion if the pleural pressure is positive (→ Fig. 8).
9. Push the pleural drain provided with lateral eyes into the chest wall in the desired length, but at least until the double mark on the catheter disappears in the puncture cannula (→ Fig. 9 / 10).
10. Pull the puncture needle together with the sterile sheath back over the pleural drain which needs to be fixed with the other hand (→ Fig. 11).

⚠ **Attention!**
**Never withdraw the catheter through the needle as there is a risk that the catheter will be sheared off by the needle or that material of the catheter will be abraded and thus the catheter will leak or plastic particles may get into the patient! (→ Fig. 12)**

11. Attach the catheter (e.g. with adhesive plaster) to the skin (→ Fig. 13).

⚠ **Attention!**
- **Immediately after the catheter has been placed, it must be temporarily fixed so that it cannot be pulled into the pleural cavity by a possible negative pressure!**
- **The temporary fixation may only be released when the final fixation of the catheter is ensured (see point 15).**

12. Clamp the pleural drain with thumb and index finger of one hand and remove the distal plug with the other hand (→ Fig. 14).

13.

| **a) Standard version only:** | **b) Fix version only:** |
|---|---|
| Connect the three-way-stopock with the changeover tap so that it points in the direction of the metal tube connection (closing position of the catheter) (→ Fig. 15).<br>**Attention: The catheter must be pushed as far as possible onto the metal mandrel of the three-way stopcock. The catheter must be held at the end to avoid kinking the tube. Afterwards, it is essential to check that the catheter is firmly seated on the metal mandrel (→ Fig. 16).** | Insert the catheter into the fix adapter until shortly before the mark (no further than 5 mm from the blue mark) into the opening of the blue cap of the fixed adapter (→ Fig. 17 / 18).<br>Tighten the blue cap of the fix adapter and check the attachment (→ Fig. 19). |

14. A connection tube, a three-way-stopcock, a syringe LL, a collection bag can be connected for the purpose of drainage, instillations or flushes. To prevent air from entering the thoracic cavity, and thus another pneumothorax, a Pneumovent® valve according to Heimlich can also be attached. In addition, there is also the possibility of connecting a manometer for pressure measurement (→ Fig. 20).

⚠ **Attention!**
**Close the bottom drain valve of the collection bag before use!** (→ Fig. 21) Different variations of the valve are possible.

15. Fix the catheter in a suitable place. The catheter must be fixed in such a way that it cannot come loose from the connection on the patient's body (→ Fig. 22 / 23).

⚠ **Attention!**
**Only after this fixation may the attachment from point 11 be released.**

16. If necessary, check the position of the catheter by imaging procedures.
17. Start the application.
18. When the application is complete, release the fixation and hold the catheter firmly.

⚠ **Attention!**
**Be sure to hold the catheter firmly during and after loosening the fixation so that it cannot be pulled into the pleural space by any negative pressure! (→ Fig. 24)**

19. Carefully withdraw the catheter from the patient and protect the puncture site immediately afterwards (e.g. with gauze swab and dressing) (→ Fig. 25).

⚠ **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.**

Depending on the suction applied, the drain allows up to 0.2 litres of liquid per minute to be sucked out.

## 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 | MR | MR unsafe – Do not use in MR fields |
| | | | | 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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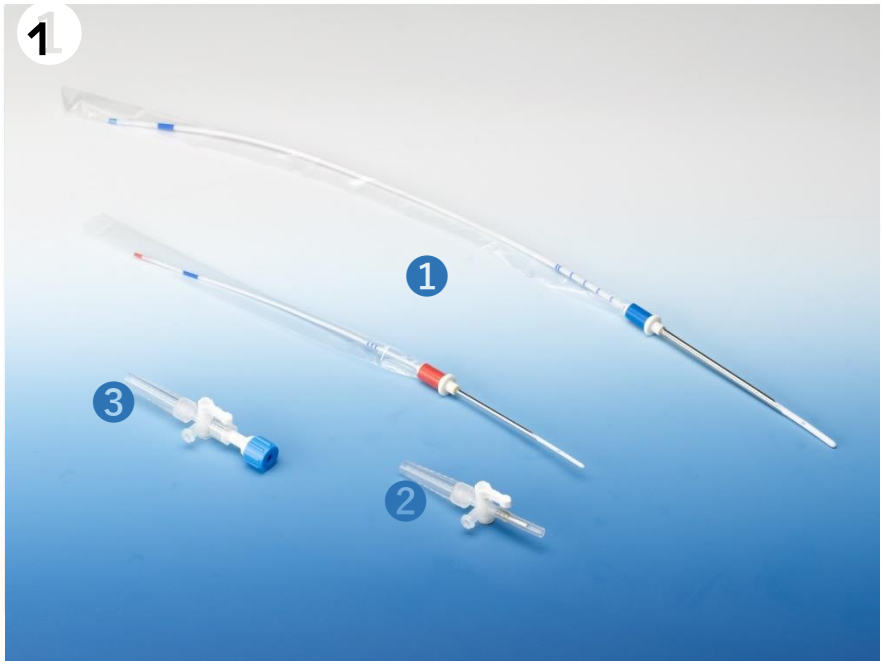


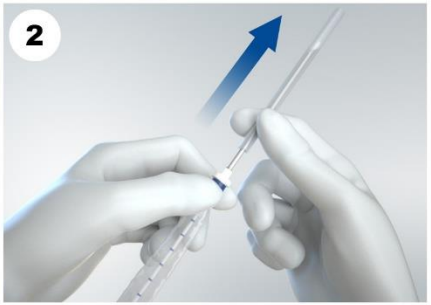


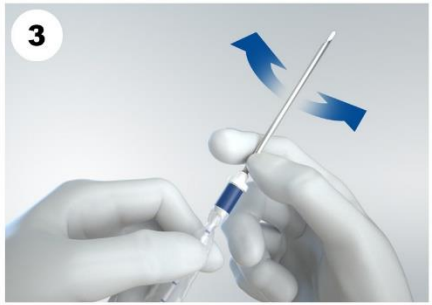


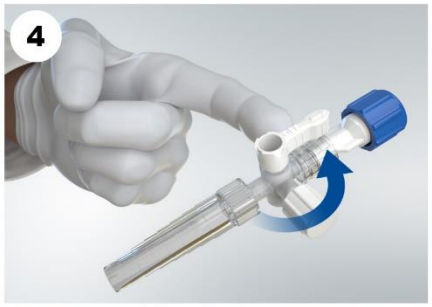


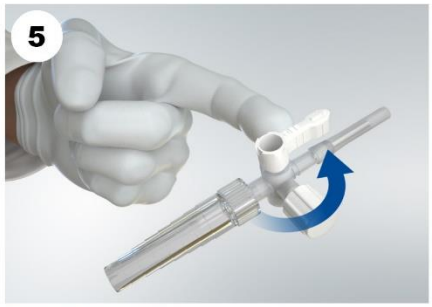


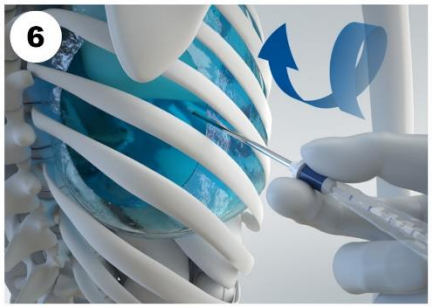


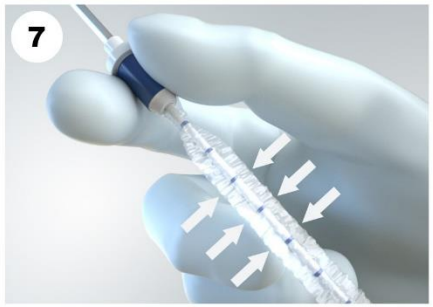


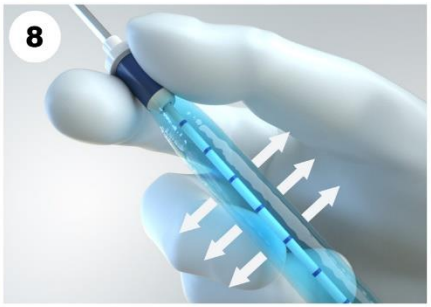


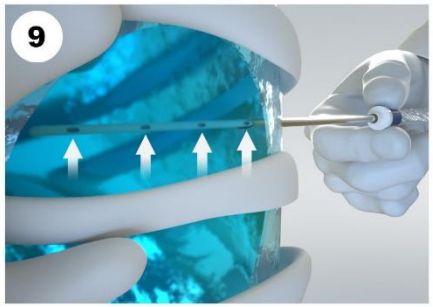


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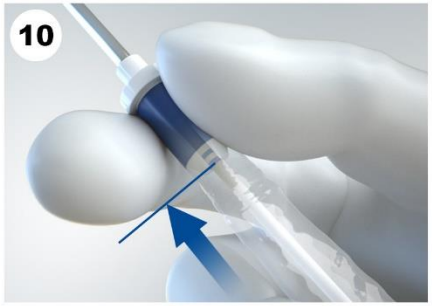


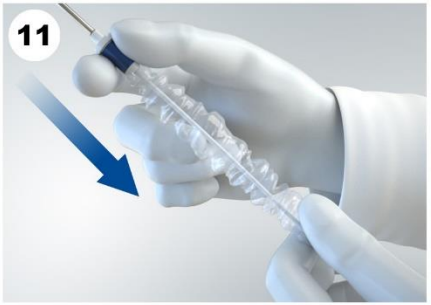


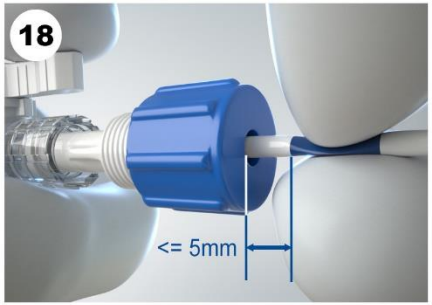


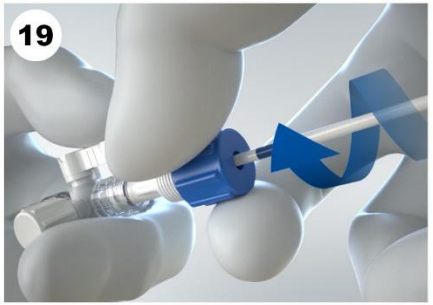


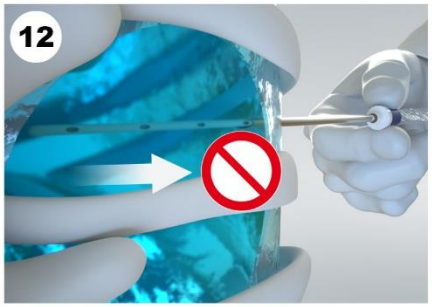


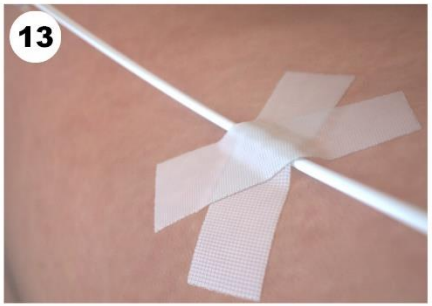


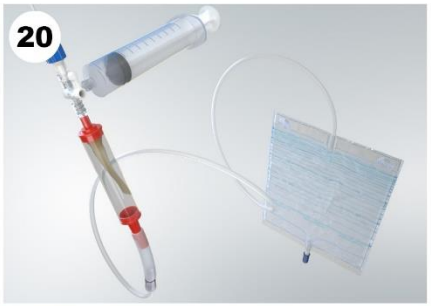


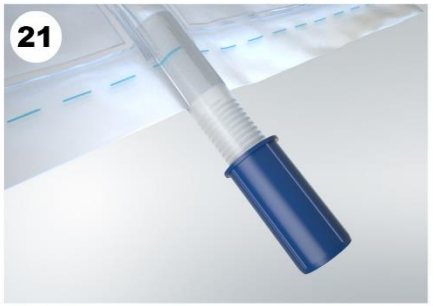


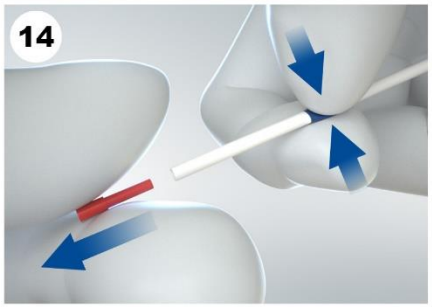


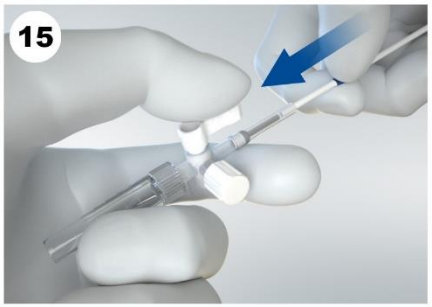


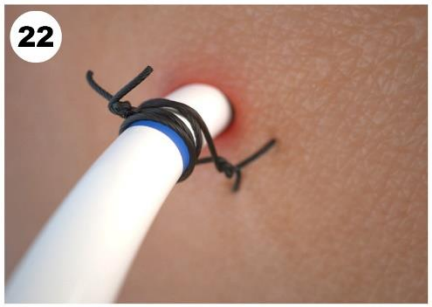


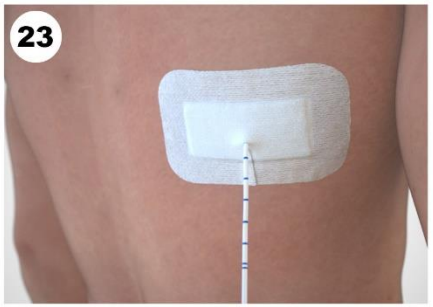


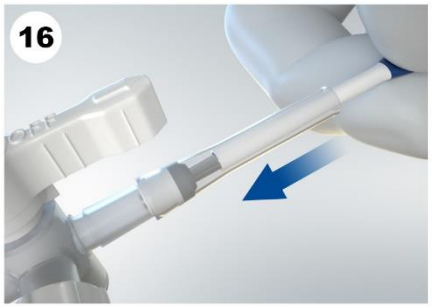


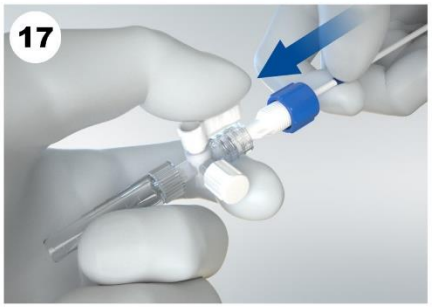


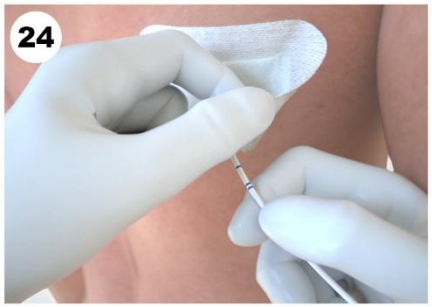


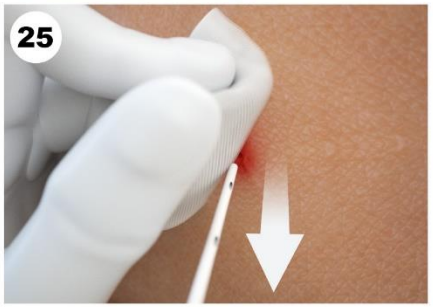


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