

Packaging Symbols Explained

REF Article number

LOT Lot/ Batch number



Protect from sunlight



Protect from moisture



Temperature limitation



Can be used until



For single use only

STERILE | EO Sterilized by ethylene oxide



Do not use if sterile barrier system of the product or its packaging is damaged



Manufacturer



Date of manufacture



Do not re-sterilize.



Follow instructions for use



MR unsafe - Do not use in MR fields

intra
special catheters

SURIMEX

Surgical Import Export Distributor

Drainage

Neo-Pneumocath catheter
Neo-Pneumocath connector

Instructions for Use

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Product Description

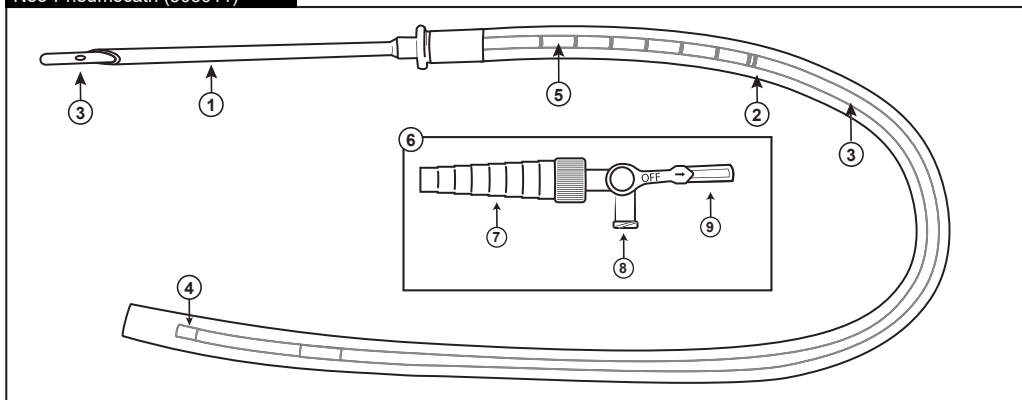
Neo-Pneumocath is a radiopaque PE-catheter with ring marks, inserted into a puncture cannula with a sterile sheath. Including a 3-way-stopcock with suction connected step adaptor.

Intended purpose: drainage catheters are used for short-term (<30 days) puncture of the pleural cavity to remove air and/or fluid (such as blood, pus, exudate etc.) and for pleurodesis.

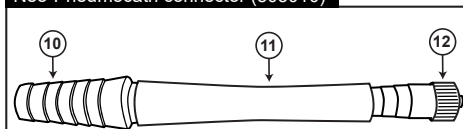
Indications: Pneumothorax, Pleural Effusion, Pleural empyema, Chylothorax, Haemothorax.

- | | | | |
|-----------------------|---------------------------|-----------------------|-----------------------|
| ① Introduction needle | ④ Catheter tip (blue) | ⑦ Universal connector | ⑩ Universal connector |
| ② Protective sheath | ⑤ Catheter distal markers | ⑧ Luer lock end | ⑪ Tube |
| ③ Catheter | ⑥ 3 way stopcock | ⑨ Metal tip | ⑫ Luer-lock adaptor |

Neo-Pneumocath (503011)



Neo-Pneumocath connector (503010)



To connect the Neo-Pneumocath connector to a larger suction system

1. Remove universal connector (7) from the 3 way stopcock (6)
2. Connecting Luer-lock adaptor (12) to 3 way stopcock (6)
3. Attach larger tube (leading to suction system) over the universal connector (10) of the connecting piece.

Relative Contraindications

Coagulopathy, Pulmonary emphysema, Adhesions of the lung to the thoracic wall after surgical interventions on the thorax, Skin infections.

Recommendation: In complicated cases, a thoracoscopy can provide essential information about the intrathoracic findings before a thoracic drainage is applied in order to avoid injury to the lung or other thoracic structures.

Intended user and patient target group

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

General instructions

The product may only be used according to its intended purpose. The introduction, use and removal of the product may only be carried out by qualified physicians or under their instructions.

- The medical methods and procedures described in this instruction for use do neither reflect all medically accepted practices, nor do they replace the experience and judgement of a physician in the treatment of his patients.
- Do not use damaged products, products from damaged packaging or products that have exceeded the expiry date on the sterile packaging (label).
- The connections may have become loose during transport and storage or by processes during sterilization. Please check all connections before use and tighten them.
- When using additional components that are not included in the kit, make sure that the connections are secure and firm and follow the instructions of the relevant manufacturers. Such components can be connected to the supplied three-way stopcock via the connected step adaptor or the female Luer-Lock connection.

Special instructions

Avoid contact of the catheter with acetone, ethanol and disinfectants as this could lead to weakening of the material, leakage or air aspiration.

- Before each drainage procedure the position of the catheter must be checked!

Never pull the catheter through the needle!

Immediately after placement of the catheter, it must be fixed in place (e.g. with adhesive tape) so that it cannot be pulled into the pleural space by any negative pressure!

Application notes

1. Open the packaging and take out the components.
2. Remove the protective tube of the needle
3. Check that the catheter slides well in the puncture needle.
4. Close the three-way-stopcock in direction of the catheter.
5. Specify the puncture site.
6. Perform local disinfection and anaesthesia.
7. Rotating advance of the wide lumen needle makes a stitch incision unnecessary.
8. When the pleural space is reached:
 - a) air may escape from the sheath and the sheath may visibly contract if the pleural pressure is negative.
 - b) the sheath may fill with air or effusion if the pleural pressure is positive.
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.
10. Pull the puncture needle together with the sterile sheath back over the pleural drain which needs to be fixed with the other hand.
11. Attach the catheter (e.g. with adhesive plaster) to the skin. Attention: The fixation must not be released until the final fixation of the catheter is ensured.
12. Clamp the pleural drain with thumb and index finger of one hand and remove the distal plug with the other hand.
13. Connect the three-way-stopcock with the changeover tap so that it points in the direction of the metal tube connection (closing position of the catheter). **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.
14. It is possible to attach a syringe with "Luer-Lock" connection to the three-way stopcock or to connect a suction pump hose to the three-way-stopcock for the purpose of drainage, instillation or flushing. It is also possible to connect a manometer for pressure measurement. **Attention:** Never apply negative pressures greater than -50 cm H₂O to the pleural space, because of the risk of pulmonary oedema and severe pain.
15. A Heimlich PNEUMOVENT-valve can also be fitted in order to prevent air from entering the thoracic cavity and thus a further pneumothorax.
16. 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. **Attention:** Only after this fixation may the attachment from point 11 be released.
17. Check the position of the catheter by x-ray control. Depending on the suction applied, the drain allows to suck up to 10 litres of air or 0.2 litres of liquid per minute.

Warning for reuse

The medical device is intended for single use only. In the event of reuse, it cannot be guaranteed that the biological, physical, chemical and functional properties of the product are still present. Reuse or reesterilization may result in malfunction of the product, which in turn may result in injury, illness or death of the patient.

Disposal

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

Further Information

- **Serious incidents** related to the medical device must be reported immediately to the manufacturer and the competent authority.
- 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 inspection.

Exclusion of liability

Due to the biological differences of the patients, the efficacy cannot be fully guaranteed. Since we have no control over the conditions of use, diagnosis and indication, use and application of the product, we can neither guarantee its success nor can we exclude the occurrence of side effects. **intra special catheters GmbH** does not assume any liability for damages or injuries of any kind caused by improper use, reuse or modification of the product.