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KIT FOR THORACENTESIS AND PARACENTESIS

INSTRUCTIONS FOR USE

APPLICATION :

Used to remove liquid of residuals extracts from the patient with a view to;

- **Thoracentesis,** to decrease symptoms due to pleural discharge, in this case called TORASET or TORAMATIC
- **Paracentesis**, in order to drain the peritoneal fluid, in this case called PARASET

PERFORMANCE CHARACTERISTICS:

The hourly diuresis measurement system « Misuro™ » is characterised by:
The thoracentesis and paracentesis kits are waterproof systems characterized by:

- The ability to adapt to different hypodermic thicknesses thanks to the various ranges of SF needle gauges (14-16-19G × 55mm or 80mm) which are non-cytotoxic, non-toxic for the intracutaneous or systemic and non-sensitizing
- The ability to favor delicate and fragile tissues thanks to the atraumatic Veress needle (15G×100mm) which is biocompatible, non-cytotoxic, non-irritating, non-sensitizing and does not cause systemic toxicity
- The ability to perform a safe puncture that minimizes the risk of venous trauma thanks to the Angiocath needle (14G×133mm) characterized by a catheter with thermo-modeled bevel (triple bevel)
- The ability to correctly position the atraumatic catheter needle (16G×15mm) thanks to the thin-walled triple sharpened stylet which releases both internally and externally at the correct distance between the needle cut and the start of the catheter
- The ability to flow fluid through the system from the peritoneal or pleural cavity to the syringe and to the collection bag through 3-way stopcocks or Y-connector (3-way)
- The ability to prevent the backflow of the aspirated liquid towards the syringe and the needle by the non-return valves positioned at the level of the tubing
- The ability to ensure the uninterrupted passage of fluid to the syringe and to the collection bag
- The ability to collect fluid and meter it through collection bags and prevent backflow of this fluid from the bag into the tubing.

MODE OF USE :

1. Wash your hands thoroughly and open the confection.
2. Determine the location of the pleural discharge or the cavity to be treated using standard diagnostic methods such as percussion, radiology or ultrasound.
3. The site where the needle should be inserted should be chosen to avoid vascular and nerve structures lying in the intercostal space adjacent to the lower edge of the ribs (for thoracentesis) or under the skin (in paracentesis view).
4. Disinfect the part of the skin concerned.
5. It is possible to inject a local anesthetic under the skin.

TORASET-PARASET MODELS

1. Wash your hands thoroughly and open the packaging.
2. Put on a pair of sterile gloves (not supplied as equipment).
3. Provide a sterilized place on which to place the components found in the kit.
4. Remove the protective cap from the needle
5. Introduce the needle and make sure you have reached the desired cavity. If you do not penetrate to the desired depth, it is advisable to withdraw the needle and check the location of the pouring using diagnostic methods (for the use of needle with cannula it is necessary that after insertion, the internal metal cannula is extracted).
6. Connect the needle to the extension and the syringe to the three-way stopcock.
7. Position the stopcock to have a direct needle-syringe suction flow using the practical indications embossed on the stopcock.
8. Perform the suction
9. When the syringe is full, orient the valve so as to have the syringe - bag flow, then drain the liquid which will go directly into the collection bag.
10. If necessary, repeat the suction operation several times

TORAMATIC MODEL (equipped with one-way valves)

1. Wash your hands thoroughly and open the packaging.
2. Put on a pair of sterile gloves (not supplied as equipment).
3. Provide a sterile place to place the components from the kit.
4. Remove the protective cap from the needle
5. Introduce the needle, ensuring that the desired cavity is reached. If the desired depth is not penetrated it is advisable to withdraw the needle and check the location of the pour using diagnostic methods.
6. Connect the needle to the extension and perform aspiration.
7. When the syringe is full, empty it. The liquid will go directly into the collection pocket thanks to a system of one-way valves.
8. If necessary, repeat the suction operation several times.

TORASET-VER, TORAMATIC-VER and PARASET-VER MODELS (equipped with a Veress needle)

1. Wash your hands thoroughly and open the packaging.
2. Put on a pair of sterile gloves (not supplied as equipment).
3. Provide a sterile place to place the components from the kit.
4. Remove the protective cap from the needle
5. If necessary, program using the stopper, located on the outer cannula of the needle, the desired depth of penetration (the reference notches are 1 cm apart).
6. insert the needle into the desired cavity, taking care that the internal cannula retracts completely, checking the positioning with the help of the red indicator located on the transparent connector. When the red indicator returns to the initial position the internal cannula has been released and is in the working position (in the cavity).
7. Connect the syringe to the three-way stopcock (for TORASET and PARASET models) while for TORAMATIC models the syringe is already connected.
8. Carry out the suction as indicated for the two TORASET models - PARASET and TORAMATIC.
9. If necessary, repeat the suction operation several times.

SPARE BAG FOR TORASET AND PARASET MODELS

1. Position the stopcock to have a direct needle-syringe suction flow using the practical indications embossed on the stopcock.
2. Detach the used bag from the stopcock through the Luer connection.
3. Connect the spare bag in the same position and continue the aspiration procedure as indicated for the two TORASET models – PARASET and TORAMATIC

WARNINGS:

- Use reserved for qualified healthcare professionals. BioService Tunisie declines all responsibility for damage caused to the patient in the event of improper use of the device, misuse or in the event of use by persons who do not have the required qualifications.
- Visual verification of the integrity of the packaging is necessary before opening.
- When handling the device, always use aseptic technique and good skin preparation to reduce the risk of infection.
- Always check the correct connection of the needle and syringe.
- Do not use the device for permanent drainage. Discard immediately after the therapeutic thoracentesis or paracentesis procedure.
- Do not use the bag for infusions.
- Do not, under any pretext, return the aspirated liquid.
- Do not try to fill the pocket beyond the maximum capacity.
- Make sure that the probe allows an even flow of the liquid.
- Do not put the bag on the ground, as this is certainly a risk of infection and malfunction of the device.
- The patient should be informed of the course of the procedure and the possible risks before starting.
- EtO sterilized; Sterilization is guaranteed provided the packaging is intact.
- Do not re-sterilize
- Single-use medical device, single patient, reuse can cause infections either for the patient or for the user of the device.
- Non-pyrogenic
- Expiry date: 5 years with the packaging in good condition and kept under normal storage conditions (Kept in its packaging in a cool, dry place.). Avoid exposure to light and high temperatures. The temperature should be between 5°C and 40°C.
- For staff safety, when required by hospital regulations or by the department, it may be necessary to use sterile gloves, masks and protective goggles (Caution: these accessories are not supplied with the device).
- Putting the capsules back on the needles should be considered a dangerous operation. Percutaneous injection with contaminated needles can cause serious illnesses such as hepatitis, AIDS or other infectious diseases. If you prick yourself with a contaminated needle, report it immediately to a nurse and follow established procedures.
- Any serious incident occurring in connection with the device should be notified to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.
- Dispose of the device after use in accordance with the regulations in force.
- Do not use this device for premature babies, infants, newborns and children under 10 kg.

MANUFACTURER INFORMATION :

- First put on the market: 2014
- Code and date of revision: 8450590000 rev 04 of 10/2022
- Certification Institution number CE 0459
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CE 0459 STERILE EO

EC REP

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