REDAX™

EN

SPIRAL DRAIN™
KARDIA SPIRAL
Round Fluted Drain

INSTRUCTIONS FOR USE

DESCRIPTION

The SPIRAL DRAIN and KARDIA SPIRAL drains consist of:

- a portion of tube, in radiopaque white silicone, provided with grooves. This exclusive design guarantees effective drainage due to the capillarity principle and decreases the probability of tube occlusion following pulling and/or twisting.
- a portion of transparent silicone tube, connected to the radiopaque end following an atraumatic profile, through which it is possible to connect to closed drainage systems by gravity or by suction.

The KARDIA SPIRAL version differs from the SPIRAL DRAIN version due to the presence of a double depth marker for positioning.

Depth markings (single or double, depending on the model), positioned at the end of the radiopaque end, facilitate the positioning and removal of the drains themselves. All drains are supplied in different sizes and are available with or without a steel Trocar needle. All the configurations foresee the packaging in double sterile wrapping and contain special fittings for the connection to the collection devices.

INTENDED FOR USE

The drains are intended for short-term use, in clinical cases, which require the evacuation of liquids accumulated in natural and/or newly formed cavities following surgery. They are suitable for use in conjunction with gravity or suction drainage systems.

Depending on the size of the tube, this device can be used in adult, pediatric and neonatal patients.

Note: These devices can be used in safe conditions only in the applications and in the manner indicated in this instruction sheet, in accordance with the type of product itself. The manufacturer denies all liability arising from misuse and any use different from that indicated herein. **The procedure must be performer by trained personnel, specialized in anatomical landmarks, safe technique, and potential complications.**

SUGGESTIONS FOR USE

How to place the drain

1. Before placing the drain, carefully choose the type, location and size needed. These parameters depend on the type of surgery, the patient's physiology and the surgeon's experience.
2. Using aseptic technique, carefully remove the sterile chest drain from the protective wrap.
3. Place the drain into the wound following an aseptic procedure. In products equipped with a trocar needle, use the latter according to the usual positioning technique, proceeding from the inside of the wound outwards.
4. Use the depth markings on the drain for correct positioning.
5. Secure the drainage with a skin stitch or band-aid.
6. Connect the positioned tube to the selected drainage system according to the methods indicated in the respective instruction sheet. In the case of drains equipped with a Trocar needle, cut the Trocar needle and dispose of it before connecting to the drainage system. If necessary, it is possible to use the fitting included in the package, in the models where it is provided, to make the connection to the drainage system.
7. It is recommended to secure the connector connection to the drain tube and also to the catheter by means of tape.

Drain removal

1. Remove the tape or any other fasteners and secure the catheter with a clip to prevent air from entering the chest cavity.
2. In case of use with a suction collection system, deactivate the vacuum.
3. Disconnect the collection system while keeping the round proximal end of the drain clamped.
4. Remove the catheter. During this phase it is important to avoid air leaks and to immediately apply a dressing and/or suture to the wound.

CONTRAINDICATIONS

There are no known contraindications.

GENERAL INSTRUCTIONS

The product is sterile if the packaging is intact. Single use, disposable product. Reuse can lead to performance alterations and risks of cross-contamination. Dispose of after each single use, do not reuse. Avoid exposure to high temperatures and ultraviolet light during storage. For the disposal and dismantling of the device, it is necessary to take appropriate precautions and comply with the legal provisions in force on biological hazardous waste.

WARNINGS / PRECAUTIONS

1. **Before inserting the drains, identify the insertion point and choose the correct size.**
2. **The choice of drain size is based on the type of pathology and surgery and on the experience of the surgeon.**
3. **It is absolutely forbidden to tamper with the drain and/or make additional holes with any tool. Only the reduction of the length of the fluted section is allowed, provided that the operation is carried out with a clean cut, without tears or burrs, and that the remaining section is not less than 15 cm, in order not to reduce the drainage capacity.**
4. **After removal, ensure that the drain is intact as this is an essential condition to prevent any drainage fragments generated by accidental lacerations from remaining inside.**
5. **It is recommended not to use the drain for a period longer than 29 days.**
6. **After positioning the device, ensure that the fluted portion is fully embedded within the wound and that the connections are tight.**
7. **It is not recommended to use drains with high vacuum bottles.**
8. **The device must be removed by hand, pulling gently and avoiding sudden maneuvers. Avoid using metal tools such as clamps or devices that could break the device.**
9. **If the device remains on site for very long periods, it may become difficult to remove. Be extremely careful during removal operations.**
10. **Do not use roller clamps or other metal devices, abrasive tools (such as cotton balls or gauze) for silicone tubesmilking. The use of these tools can cause damage to the drainage surface by reducing its mechanical strength.**
11. **Do not use any alcoholic or aggressive liquid to lubricate the surface of the tubes before milking procedure.**
12. **Redax strongly recommend using Vaseline cream or oil or any other non-aggressive lubricant to facilitate tube removal.**
13. **Depending on their CH/Fr, catheters are compatible with various connectors available on the market (in addition to those present in the package). Be sure to check compatibility with the accessory you want to use before using it on a patient.**
14. **All connections must be firmly taped to minimize the risk of accidental detachment**
15. **Properly dispose of sharps in sharps container in accordance with state/Osha standards for blood borne pathogens and/or institutional policy.**

STERILE - Ethylene oxide sterilized

MATERIALS USED

Biocompatible and Haemocompatible silicone.

MEDICAL DEVICE NOT MADE WITH NATURAL RUBBER LATEX

X ray contrast

Date of issue of the last version:
see: (REV .: XX-XXXX)

CE 0123

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