REDAX™

EN

COAXIAL SMART DRAIN
ROUND FLUTED DRAIN

INSTRUCTIONS FOR USE

DESCRIPTION

SMART DRAIN drains with round fluted profile with coaxial internal lumen, are made from pure biocompatible silicone, and consist of:

- a single section of silicone tube at the distal end of which the profile is provided with grooves that allow for effective drainage based on the principle of capillarity and help mitigate tube occlusion following pulling and/or twisting.
- The fluted section is provided with a coaxial round lumen which allows, in case of lung surgery, for separate evacuation of the air from the thoracic cavity taking it out directly from the distal end of the tube by means of the special holes. The same round lumen and the external grooves form a "double" profile that increases liquid evacuation efficiency even in case of cardiac surgery and abdominal surgery.
- The fluted section converges, without discontinuity, in the proximal part of the round profile catheter, through which it is possible to connect to closed systems of drainage by gravity or by suction.
- The perfect regularity of the diameter makes the device suitable for use in laparoscopy and thoracoscopy. Transition between the grooved and the round profile is made quickly in order to prevent the formation of small diameter ducts that could be blocked by clots.

  Depth markings, graduated from the end of the fluted end, facilitate the placement and removal of the drains themselves.

  The drains are available in two sizes (24 and 28 CH/Fr) and in two versions of different lengths to better adapt to the clinical needs and the anatomy of the site to be drained.

INTENDED FOR USE

The drains are intended for short-term use, in clinical cases that require the evacuation of air and/or liquids accumulated in natural and/or newly formed cavities following surgery. They are suitable for use in conjunction with gravity or suction drainage systems. The catheters can be used in adults and adolescents (from 13 to 18 years for females; from 15 to 18 years for males).

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 coaxial 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 coaxial drain into the wound following an aseptic procedure based on the protocols and habits in use at the hospital.
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. If necessary, you can use the fitting included in the package to connect to the drainage system.

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 by keeping the round proximal end of the coaxial 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.

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 make additional holes with any tool. Only the reduction of the length of the distal section is authorized, provided that the operation is performed with a clean cut, free of tears or burrs, and that the remaining perforated section is not less than half the original length, 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. **The device must be removed by hand, pulling gently and avoiding sudden maneuvers. Avoid using metal tools such as pliers or devices that could cause the device to break.**
8. **If the device remains on site for very long periods, it may become difficult to remove. Be extremely careful during removal operations.**
9. **Do not use roller clamps or other metal devices, abrasive tools (such as cotton balls or gauze) for silicone tubes milking. The use of these tools can cause damage to the drainage surface by reducing its mechanical strength.**
10. **Do not use any alcoholic or aggressive liquid to lubricate the surface of the tubes before milking.**
11. **Redax strongly recommend using Vaseline cream or oil or any other non-aggressive lubricant to facilitate tube removal.**
12. **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.**
13. **All connections must be firmly taped to minimize the risk of accidental detachment.**

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.

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

Redax S.p.A.
Via Galileo Galilei,18
Poggio Rusco (MN) Italy

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