REDAX™

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THORACIC CATHETER

INSTRUCTIONS FOR USE

DESCRIPTION

The thoracic catheter is a sterile, single use, disposable device. Made of silicone, it is available in both straight and right angle versions, in different sizes. The proximal end of the catheters has an oblique cut to facilitate insertion. Each catheter features a radiopaque line to allow for radiographic visualization. There are depth markings, starting from the end of the perforated section, which facilitate insertion and removal. The product is supplied in sterile packaging.

INTENDED FOR USE

The catheter is intended for use in clinical cases that require the drainage of air and/or fluids from the pleural cavity and/or mediastinum. Thoracic catheters are used in symptomatic patients whose pleural cavity has been invaded by air, fluid or pus, in patients with intrathoracic hemorrhage, and in patients undergoing post-thoracic surgery or cardiac surgery. Thoracic catheters are usually connected to a chest drainage system for the collection and drainage of fluid, and/or air from the pleural or mediastinal cavities, following injury or surgical procedures. Alternatively, they can be connected to a sealing or suction device.

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

Note: This device 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 catheter.

1. Using an aseptic technique, carefully remove the sterile thoracic catheter from the protective wrapping.
2. Create another incision, in addition to the main incision.
3. The catheter is inserted into the pleural cavity through the thoracic opening and its proximal end is extracted through the second incision, made in the chest wall.
4. Once the catheter is properly positioned, connect it to a sealed device, suction source, or chest drainage device. The oblique cut end allows insertion through the proximal end of the catheter, which can subsequently be used for connection to the collection, sealing or suction system.
5. It is recommended to secure the connector connection to the drain tube and also to the catheter by means of tape.
6. An appropriate surgical technique should be employed to secure the catheter to the patient's chest wall.

Removal of the catheter.

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 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.

GENERAL INSTRUCTIONS

Do not use if the package has been opened or damaged. Read this instruction sheet carefully before using the product. Single use, disposable product. Reuse can lead to performance alterations and risks of cross-contamination.

CONTRAINDICATIONS

There are no known contraindications.

STERILE - Ethylene oxide sterilized

The product is sterile if the packaging is intact. 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 FOR USE

1. **The right angle catheter was designed to be placed between the chest wall and the lung; the 90° angle has the function of preventing the catheter from resting against the lung.**
2. **Before inserting the thoracic catheter, identify the point of insertion into the chest wall and choose the correct catheter size. Air drainage catheters are usually placed in the anterior upper area, while fluid drainage catheters are placed in the posterior lower area.**
3. **The choice of device size is based on the physician's preference and the expected extent of drainage.**
4. **At the time of removal it is necessary to avoid air leaks and to immediately apply dressings to the wound.**
5. **Do not tamper with the device in any way or make additional holes with the aid of cutting equipment.**
6. **In case of suture fixation, carefully avoid suturing the tube itself or perforating it with needles or cutting edges. Avoid overly tight sutures as these may cause the device to break.**
7. **After positioning the device, make sure that the perforated section is completely included within the wound and that the connections are perfectly sealed.**
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. **After removal, check that the device is intact as this is an essential condition to prevent fragments caused by accidental tearing from remaining in the cavity.**
11. **It is recommended not to use the device for longer than 29 days.**
12. **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.**
13. **Do not use any alcoholic or aggressive liquid to lubricate the surface of the tubes before milking procedure.**
14. **Redax strongly recommend using Vaseline cream or oil or any other non-aggressive lubricant to facilitate tube removal.**
15. **Depending on their Ch/Fr, catheters are compatible with various connectors on the market. Be sure to check compatibility with the accessory you want to use before using it on a patient.**
16. **All connections must be firmly taped to minimize the risk of accidental detachment.**

MATERIALS USED

Biocompatible and Haemocompatible silicone.

MEDICAL DEVICE NOT MADE WITH NATURAL RUBBER LATEX

X ray contrast

Date of issue of the date:
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Redax S.p.A.
Via Galileo Galilei,18
Poggio Rusco (MN) Italy

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