Prymax Surg
Thoracic Drainage Catheter

DEVICE DESCRIPTION:
It is a flexible plastic tube that is inserted through the chest wall and into the pleural space or mediastinum. The major components of the thoracic Drainage Catheters are; Tubing, Pull Connector & Step Connector.

Available sizes

12 FG to 36 FG, Straight and Curved

Drawing of product:

CONTENTS:
Step connector

MATERIAL USED:
Poly vinyl chloride, Acrylonitrile butadiene styrene

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INTENDED PURPOSE:

INTENDED USE: A thoracic drainage catheter is intended to drain the thoracic cavity during the surgery

INTENDED USER: The device is intended to be used only by a qualified medical professional.

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender

INDICATIONS:

Pneumothorax, Pleural effusion, Empyema, Hemothorax, Chylothorax, Postoperative thoracic, cardiac, or esophageal surgery, or after a thoracoscopic procedure, Chemical pleurodesis.

CONTRAINDICATIONS:

The Doctor's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Anticoagulation of a bleeding dyscrasia.
- Systemic anticoagulation.
- Small, stable pneumothorax (may spontaneously resolve).
- Empyema caused by acid-fast organisms.
- Loculated fluid accumulations
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS

CLINICAL BENEFITS:

- Chest tube can be effective at draining fluid and air from pleural space.
- The withdrawal of thoracic drainage has been found to be comfortable, safe and well tolerated by patients.
- The radiopaque catheter martial enhances the radiopaque visualization during X-ray.

PERFORMANCE CHARACTERISTICS

- Catheterisation success rate
- Experience of discomfort and pain

INSTRUCTIONS FOR USE:

- Open the product in sterile environment.

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- Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- Peel open the package and remove the thoracic catheter using sterile technique. Product include a packaging that must be removed from the catheter prior to patient use.
- Sedate or anesthetize the patient and restrain in lateral recumbency.
- Identify the landmarks for the skin preparation: caudal border of scapula to the last rib. The insertion site is midway along the line drawn from the top of the last rib to the point of the flexed elbow.
- Infuse local anesthetic at this site just off the front of the rib and deep enough to reach the pleura.
- Have an assistant grasp the skin of the shoulder and pull it forward. Then make a small incision over the denervated intercostal site.
- Using direct puncture technique, advance the catheter off the introduction needle stylet and into the desired position in the thoracic cavity.
- As you remove the introduction needle stylet, clamp off the catheter with a pair of hemostats.
- Attach the drainage catheter to a multi-functional connection set.
- Release the skin and anchor the catheter by walking a needle off the periosteum of the rib and pass a suture through the intercostal fascia. Tie a loose stitch with a tight knot off three or four throws. Then anchor the tube to the thread with an anchoring stitch.
- Check that air has been evacuated and seal the catheter at the skin with a purse string. Apply a gauze pad with antibiotic ointment (optional) over the site.
- Apply an occlusive dressing with an adhesive cranial band, leaving the suction end exposed
- Users should be familiar with thoracic surgical procedures and techniques before using thoracic catheters. Only qualified healthcare practitioners should insert, manipulate and remove thoracic catheters.
- The insertion technique, location and catheter size are at the discretion of the physician to optimize drainage efficiency. Care must be taken when inserting the thoracic catheter to avoid puncturing the lung and/or other organs.
- The thoracic catheter should be secured properly in place to avoid accidental dislodgement or removal.
- Patient tube connections, insertion site and catheter patency should be checked regularly to confirm proper operation.

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- Care should be taken during catheter removal from the patient to avoid damaging the catheter.

WARNING & PRECAUTIONS:

- Follow universal precautions when inserting and securing the catheter.
- Taper tip PVC catheters must be cut at the distal end on the "bubble" of the catheter following insertion to assure a secure proper fit to the chest drainage patient connector.
- The eyelets of the catheter must remain inside the thoracic cavity at all times during patient use.
- The use of this product is restricted to a qualified doctor or a surgeon trained in the techniques of vascular catheterizations.
- Read all the information mentioned in instruction for use. Failure to do so may result in severe patient injury or death. The product should be used according to the instructions for use.
- The product is guaranteed, sterile till the package has not been opened or damaged within the expiry date.
- Do not use if the sterile pack is opened or damaged.
- Sterile, Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.
- Caution: Care should be taken during catheter insertion, fixation and removal to avoid accidental or intentional cutting, suturing to or puncturing of the thoracic catheter as tearing of the catheter may result, causing device failure, patient injury, illness or death

ADVERSE EFFECTS:

- Pulmonary Infection, Accidental dislodgement, Pain, Biliary pleurisy, Subcutaneous emphysema, Failure to drain and Vasovagal reactions.

RE-USE HAZARDS:

- Transmission of infection from one patient to another.

PACKAGING:

- The device is packed in paper Pouch, which is further packed in inner carton & master carton.

STERILIZATION:

- Device is EO sterilized, and sterilization is done in-house.

STORAGE CONDITION:

- Temperature Limit: 15^{o}C to 40^{o}C.

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DEVICE SHELF LIFE: 3 Year

Country Code: 356

DISPOSAL

- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:

- In case of any serious adverse event please report the same to info@prymaxhealthcare.com & gloizou@compliancems.com.au.
- Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

GOODS RETURN POLICY

Refer to the company's return good policy.
Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818.

SYMBOLS USED ON PRODUCT LABEL

Lot number

Do not re-use

Sterilized by Ethylene Oxide

Manufacturing date

Use-by date

Caution

Non-pyrogenic

Do not resterilize

Catalogue number

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Manufacturer

Storage Temperature Range

Conformité Européenne

Do not use if package is damaged

Consult instructions for use

Single Sterile Barrier System

UDI Carrier

Medical Device

Country of Manufacturer

Manufactured By:

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Haryana, INDIA -121001
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