

Prymax Perfusion

Sucker

DEVICE DESCRIPTION:

Prymax Healthcare supplies Sucker in the form of adult and pediatric versions. Pediatric Sucker is smaller in size as compare to adult. Sucker has a tapered SS rod for better positioning during suction. The tip of the Sucker has multiple holes for suctioning and connector is provided at the distal end of the device so that the Sucker could be attached the tubing of Suction pump.

AVAILABLE SIZES:

Adult & Paediatric

Drawing of product:



MATERIAL USED:

Stainless Steel, Acrylonitrile butadiene styrene

INTENDED PURPOSE:

INTENDED USE: - Cardiac Suckers are used to clear the surgical site of excess blood or Fluid. It Can be used passively or as a retractor.

INTENDED USER: Qualified doctor or surgeon.

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

INDICATIONS:

Invasive and surgically invasive procedures

CONTRAINDICATIONS:

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- Patients in whom there is a general surgical risk. The suction instruments are used exclusively by medical personnel specially trained in the surgical technique.
- The selection of the appropriate suction instrument is the responsibility of the experienced user.
- Suction instruments are not intended specifically for monitoring, diagnosing, checking or correction of a defect in the heart or central circulatory system in direct contact with these parts of the body.
- Suction instruments are not to be used in direct contact with the central nervous system
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

Clinical Benefits:

- Suctioning can help reduce the risk of infection and complications by keeping the surgical site clean and free of debris.
- Suction devices can help surgeons get a better view of the surgical field.
- Suctioning can help surgeons perform surgery more quickly and efficiently, which can reduce the patient's recovery time.
- Emergency suctioning can be life-saving in a variety of respiratory emergencies.
- Suctioning can help manage chronic respiratory conditions like chronic obstructive pulmonary disease (COPD)
- Suctioning can help manage airway trauma, such as a blow to the throat, an object lodged in the throat, or a recent internal injury.

Performance Characteristics:

Un-interrupted suction

INSTRUCTION FOR USE:

- Open the product in sterile environment.
- Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- The sucker's low-profile suction tube is equipped with a connector and fluted tip.
- Connect to suction tubing with the connector end of the device.
- Put the Sucker to the patient where suction is needed and start suction.
- Occlude the device's finger hole (suction control hole) to increase suction.
- When device becomes occluded with surgical debris, remove from suction and pass stylet through the device, repeat if necessary.
- If required, the catheter may be bent gently to suit application.

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WARNINGS & PRECAUTIONS:

- The use of this product is restricted to a qualified doctor or a surgeon trained in the technique.
- 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

ADVERSE EFFECTS:

Hypoxemia, Increased arterial blood pressure & heart rate and Cardiac arrhythmia

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°C to 40°C.

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.

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Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818.

SYMBOLS USED ON PRODUCT LABEL

SYMBOLS USED ON PRODUCT LABEL		
LOT	②	STERILE
Lot number	Do not re-use	Sterilized by Ethylene Oxide
Manufacturing date	Use-by date	Caution
Non-pyrogenic	STERRINGE Do not resterilize	REF Catalogue number
Manufacturer	Storage Temperature Range	Conformité Européenne
Do not use if package is damaged and	consult Instructions for Use	Consult instructions for use
Single Sterile Barrier System		MD Medical Device
UDI		356
UDI Carrier		Country of Manufacturer



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