Prymax Perfusion

Mister Blower

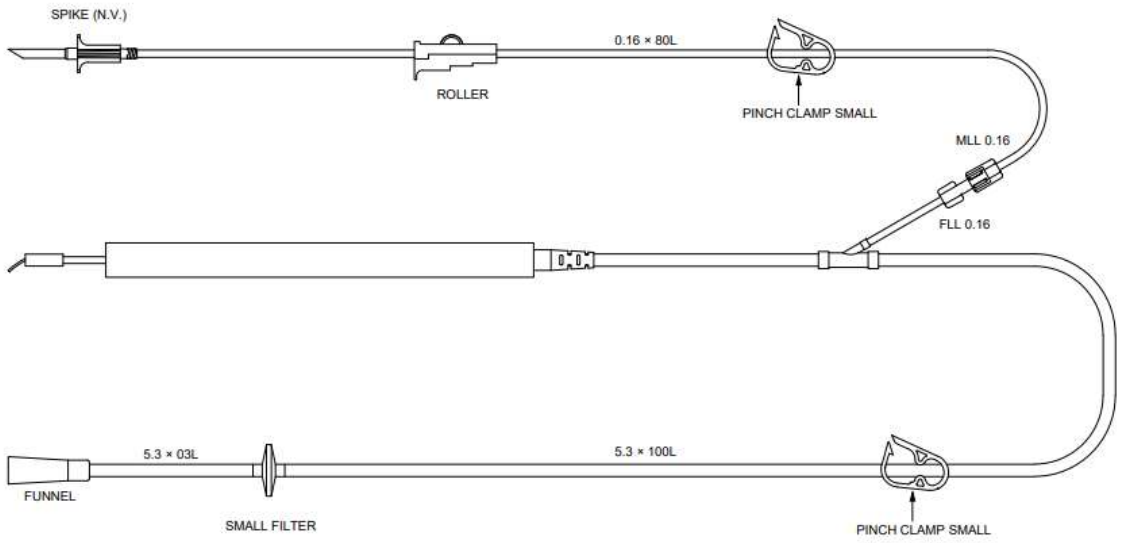
DEVICE DESCRIPTION:

Prymax Healthcare supplies Mister Blower with or without tubing. A standard device contains one tubing for water supply and another tubing for gas supply. Junction at where water and gas met each other, resulted in producing the mist. Device contains a straight SS rod with a handle for easy use.

Available Configuration

With or without tube

Drawing of product:



MATERIAL USED:

Polycarbonate, Poly vinyl chloride, Acrylonitrile butadiene styrene, Poly propylene, Polyoxymethylene

INTENDED PURPOSE:

INTENDED USE:- Mister Blower is intended to clear an anastomotic site for improved visibility by providing controlled delivery of CO2 and saline during surgery

INTENDED USER: Qualified medical professional.

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

INDICATIONS:

- Device is intended for use during procedures when a wound or surgical site must be cleared by non-contact means for improved visibility at the site.

CONTRAINDICATIONS:

This device is not designed, sold, or intended for use except as indicated.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

Clinical Benefits:

- Plastic handle with malleable metal wand
- Roller clamp to control the flow

PERFORMANCE CHARACTERISTICS:

- Prevention of endothelial damage

INSTRUCTIONS FOR USE:

1. Open the product in sterile environment.
2. Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
3. Connect the tubing to a regulated source of CO_2. It is recommended that the regulator be set to no more than 50 psi.
4. Close the pinch clamp on the IV tubing. Aseptically connect the IV spike to a new bag of sterile saline and place in pressure cuff. Inflate the cuff to approximately 150mm Hg. Open the pinch clamp and adjust sterile saline flow to 1-5 mililiters per minute using the roller clamp on the IV tubing.
5. Adjust the irrigation mist as needed by making adjustments to either the roller clamp on the IV tubing or to the flow volume controller on the mister blower hand piece.
6. Bend the malleable shaft to the desired shape to easily access the surgical site.
7. Hold the tip 5cm-15cm from the surgical site to be visualized. Adjust the distance as needed to clear the site. Use caution when moving the tip closer than 3 cm to the surgical site. DO NOT ALLOW TIP TO CONTACT TISSUE.

WARNING & 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.

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- 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:

- Endothelial damage, Ventriclular fibrillation & Air embolism

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.

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 401181

SYMBOLS USED ON PRODUCT LABEL

Lot number


Do not re-use

Sterilized by Ethylene Oxide

Prepared by:	Approved By:


Manufacturing date


Use-by date


Caution


Non-pyrogenic

Do not resterilize

Catalogue number


Manufacturer

Storage Temperature Range

Conformité Européenne


Do not use if package is damaged


Consult instructions for use


Single Sterile Barrier System

Medical Device

UDI Carrier

Country of Manufacturer


Manufactured By:

Prymax Healthcare LLP.,
53/17,Industrial Area NIT, Faridabad,
Haryana, INDIA -121001
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