Prymax Perfusion

Arterial Filter

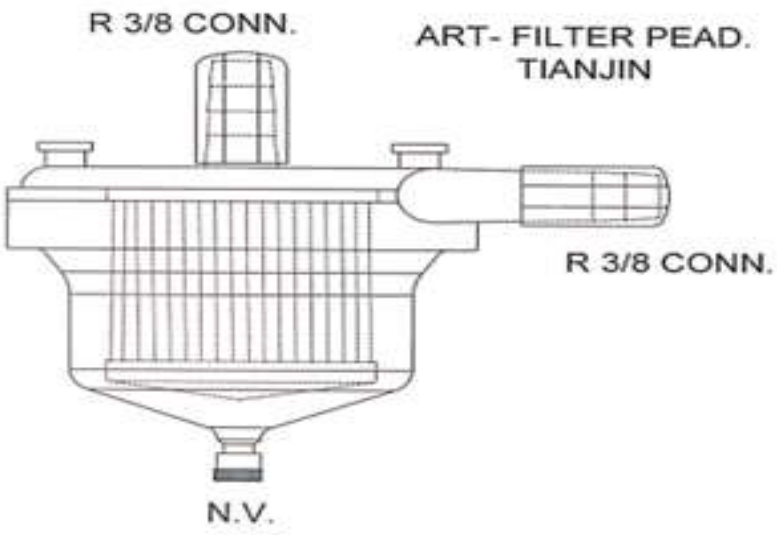
DEVICE DESCRIPTION:

Arterial filters are inserted into the arterial line, which connects the patient's blood vessels to the CPB machine. They trap particles larger than a certain size, usually around 40–60 microns, to prevent them from entering the CPB machine and damaging the patient's organs.
The device is single use, non-toxic, pyrogen-free, supplied sterile. Sterilized by ethylene oxide.

AVAILABLE CONFIGURATIONS:

Adult, Pediatric, Infant, With loop, Without loop

DRAWING OF PRODUCT:



MATERIAL USED:

Polycarbonate, Polyester

INTENDED PURPOSE:

INTENDED USE: The device is indicated to be used in all Cardiopulmonary bypass procedures for the removal of microemboli greater than 40 micron in size, incluiding gas emboli, fat emboli and aggreates composed of plateletes, damaged red blood cells, bone chips from sternotomy, flakes of PVC tubing and other debris, from the arterial line.

INTENDED USER: Qualified medical professional.

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

INDICATIONS:

- Device is indicated for use in surgical procedures requiring extracorporeal support

CONTRAINDICATIONS:

- This device is not designed, sold, or intended for use except as indicated.
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

Clinical Benefits:

- Arterial filters prevent air bubbles and other harmful particles from entering the circulation system

PERFORMANCE CHARACTERISTICS:

- Kink resistant tubing
- Maximum blood flow in the Adult Arterial filter
- Priming volume

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.
- Provide a filter bypass line to be used in the event an alternate flow path is required.
- Secure tubing to filter ports with band clamps located behind port barbs.
- A vent line with a check valve and three-way tap should be installed between filter vent port and oxygenator or another unpressurised location for continuous, automatic venting.
- If a check valve is not installed, position filter so that it will be bellow patient's midline and at or below level of oxygenator during use.
- Orient filter in mounting bracket with inlet port horizontal & uppermost, the outlet port vertical & down.
- After filter is installed in arterial line, with vent uppermost and closed, clamp inlet tubing between filter and Y-Connector, prime rest of the circuit through bypass line at a flow of between 3-5 L / min.
- While maintaining flow open the went line allow filter to fill. When liquid reaches top of the filter remove inlet clamp completely and clamp bypass line.
- Remove filter from mounting bracket invert and tap with heel of your palm or rubber and of a percussion hammer to help dislodged any bubbles on downstream side of filter.

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CAUTION/WARNING

- 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:
Bleeding, Blood clot (thromboembolism), Infection, Loss of blood in hands, feet or legs (limb ischemia), Anaphylactic reaction, Blood damage & haemolysis and Hyperglycaemia

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.

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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

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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