Prymax Perfusion

Perfusion Tubing Set

DEVICE DESCRIPTION:

Perfusion tubing set or Cardioplegia Adapters are comprised of various configurations of clear manifold connections in either straight, Y-shaped, or 4-way connections which are joined by appropriate lengths of clear, flexible tubing. Depending upon configuration, the cardioplegia Adapter may contain a vent port adapter with female luer lock, a tapered tubing adapter, tubing clamps, and/ or male and/ or female luer lock connectors. Depending upon configuration cardioplegia adapters are one way, two ways and three way. Cardioplegia adapter one way makes a smooth transition from a cardioplegia administration line to a perfusion catheter.

The "Y" Adapter can be used to simultaneously connect both cardioplegia administration and suction lines to the same catheter allowing the surgeon to switch between the two modes of operation. The "Y" Adapter also allows cardioplegia solution to be recirculated up to the point of connection to the catheter thus insuring infusion of a uniform temperature solution.

Two way and three-way adapter is a convenient adapter that has the capability of delivering cardioplegia solution to an aortic root catheter, as well as perfusing up to three vein grafts.

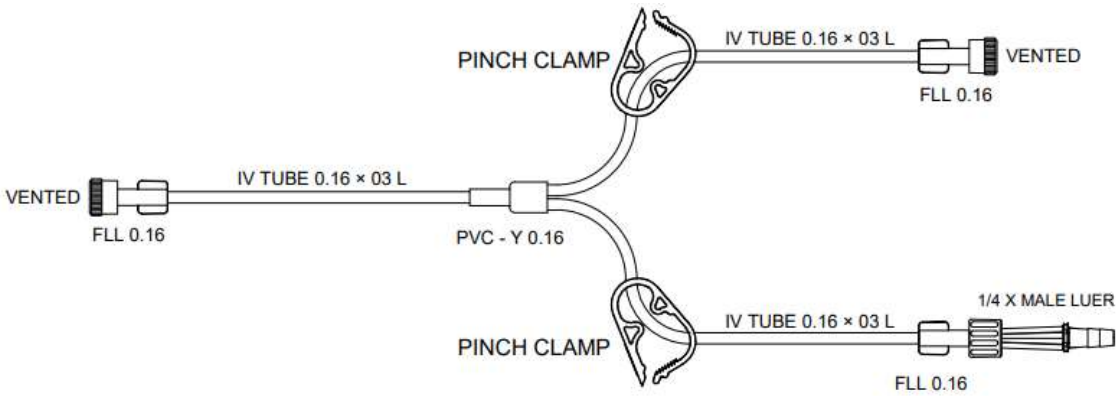
device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

Available Configuration

Perfusion tubing set One/Two/Three way cardioplegia adaptor

Device is also available with perfusion conector

Drawing of product:



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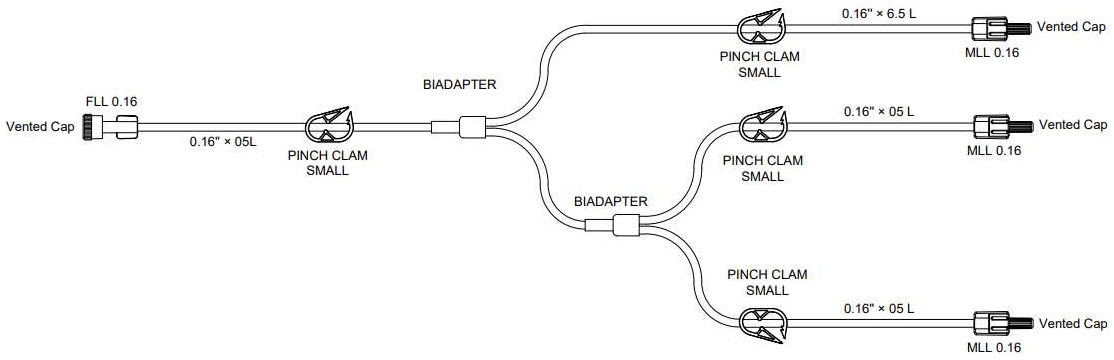

MATERIAL USED:
Poly vinyl chloride, Polycarbonate, Acrylonitrile butadiene styrene, Polyoxymethylene

INTENDED PURPOSE:
INTENDED USE:- Cardioplegia Adapters are intended for use as adapters for connecting cardioplegia administration tubing to cardioplegia delivery catheters.

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:
Cardioplegia Adapter is intended for use in the delivery of cardioplegia solutions to the aortic root and vein grafts or directly to the coronary arteries and vein grafts. When used with the vent line, the adapter can be used for aspiration of the aortic root.

- Remove the set from the package using a sterile technique.
- Make all the connections using an aseptic technique.
- Connect the set to the oxygenator, heat exchangers, filters and other components in accordance with the specific instructions for use.
- Secure the connections with clamps.
- Prime the circuit in accordance with the instructions for use of the circuit components.
- Ensure that there are no air bubbles in the circuit and the components.
- Ensure that there are no leaks.
- Initiate the bypass in accordance with the instructions for use of the oxygenator and following good perfusion practice.

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:

The device does not have a direct clinical benefit however, it is used during extracorporeal circuit surgery procedures to alleviate the diseased conditions related to heart which are life-threatening.

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The performance characteristics of the device includes:

- Kink resistant tubing

INSTRUCTIONS 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.
- Using care not to contaminate the sterile product ,remove adapter from its sterile pouch and place into the sterile field.
- Check the packing and expiry date before use.
- Check the adapter for patency and any storage or shipping damage.
- Attach the adapter to the male luer lock on the cardioplegia delivery set patient line.
- Using sterile technique, securely connect the cardioplegia delivery set connector(s) to the appropriate cardioplegia administration line(s) and cardioplegia catheter.
- Prime the adapter with cardioplegia solution and de-air using standard procedures.
- Using proper surgical technique, Introduce and secure the perfusion catheter. Remove the introducer needle and immediately attach the catheter to one branch of the adapter.
- When all the air has been removed, Cardioplegia solution may be administered

CAUTION/WARNING

- All adapters should be inspected for storage and shipping damage prior to use. Kinked or distorted parts may lead to obstruction or disruption of blood flow and should not be used.
- Prymax Healthcare Does not recommend a particular technique for the use of this device.
- The steps contained in the IFU are for information purposes only. Each surgeon should evaluate their appropriateness according to individual patient condition and his or her medical training and experience.
- 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, Infection & Blood damage

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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 4011818.

SYMBOLS USED ON PRODUCT LABEL

Lot number


Do not re-use

Sterilized by Ethylene Oxide

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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 and consult Instructions for Use		Consult instructions for use
Single Sterile Barrier System		Medical Device
UDI Carrier		Country of Manufacturer

Manufactured By:

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