Prymax Angi

High Pressure Tubing

DEVICE DESCRIPTION:
High Pressure line is used for high pressure monitoring and for connection between syringe infusion pump and patient. High pressure line is used to inject contrast media and the other medical solutions during PTCA procedure, PCI procedure. These medical-grade tubes are used for cardiovascular procedures. They have a flexible oxygen hose with 1200 psi pressure resistance and are sterilized using ETO.

Available sizes:
10-200 cm

Drawing of product:

MATERIAL USED:
Poly urethane, Poly Carbonate

INTENDED PURPOSE:
INTENDED USE: High pressure tubing is the tubing to carry the fluid / contrast media to the patient during angiography procedure.

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:
Angioplasty & Angiography

Prepared by:	Approved By:

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:

- High-pressure tubing is a vital part of the angiography procedure because it allows a contrast agent to be injected into a patient's blood vessels under high pressure. This helps to make blood vessels visible so that doctors can diagnose and treat blood vessel conditions

PERFORMANCE CHARACTERISTICS:

- Pressure resistance

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.
- Open the undamaged sterile pouch in sterile area.
- Remove the caps. Connect the female luer end to the manifold. Connect the male luer end toward the patient via suitable device
- Make sure that entire system is de-aired before use.

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.
- 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:

Infection, Access site complication, Thrombosis & Aneurysm/Pseudo aneurysm

RE-USE HAZARDS:

Transmission of infection from one patient to another.

PACKAGING:

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The device is packed in 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.

COUNTRY CODE: 356

DEVICE SHELF LIFE: 3 Year

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

Prepared by:	Approved By:

Manufacturer

Storage Temperature Range

Conformité Européenne

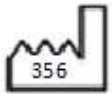
Do not use if package is damaged and

Consult instructions for use

Single Sterile Barrier System

Medical Device

UDI Carrier



Country of Manufacturer

Manufactured By:

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