Prymax Angi

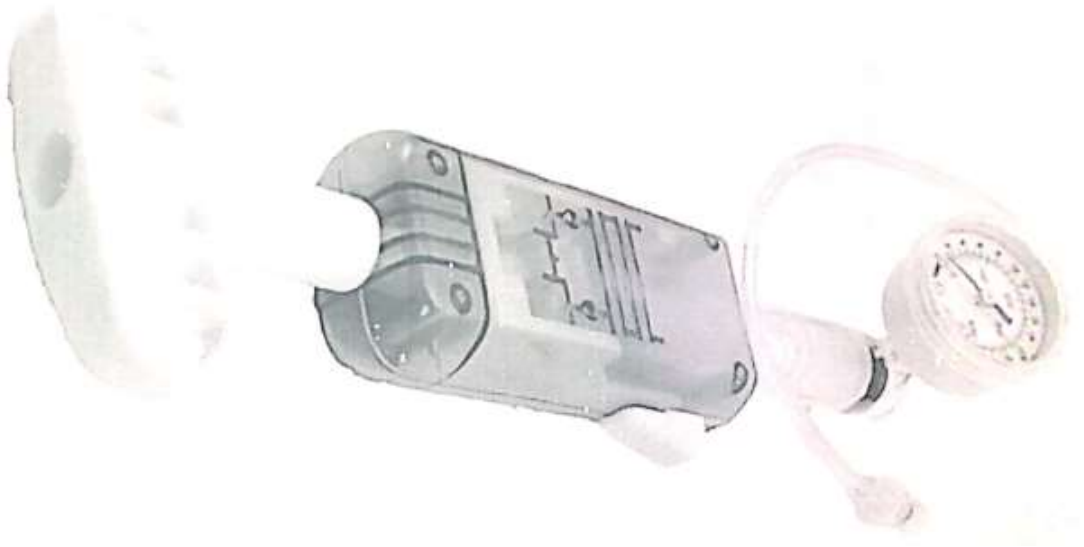
Inflation Device

DEVICE DESCRIPTION:
An inflation device specifically designed for dilation balloons. This inflation device is a 20 ml disposable device capable of producing a maximum pressure of 30 ATM.

AVAILABLE VARIANTS:

Straight type, Gun type

Drawing of product:



MATERIAL USED:
Poly Carbonate, Acrylonitrile-butadiene-styrene, Polyurethane

INTENDED PURPOSE:
INTENDED USE: Inflation Device is used to inflate & deflate the balloon and measure the pressure within the balloon during the PTCA 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.

Prepared by:	Approved By:

INDICATIONS:

Percutaneous transluminal coronary angioplasty

CONTRAINDICATIONS:

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

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS

Clinical Benefits:

- Inflation devices help minimize risks and ensure patient comfort by providing consistent pressure regulation and accurate measurement.
- Inflation devices help improve procedural efficiency by facilitating proper vessel dilation, accurate stent deployment, or controlled fluid administration.

PERFORMANCE CHARACTERISTICS:

Accurate pressure control

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 device is designed for maximum application pressure of 30 bars.
- Hold the device and push the buttons forward to deactivate the lock.
- By keeping the lock in deactivated position, pull the plunger handle back to fill the radiography solution into the device.
- Release the button to activate the lock.
- Plunger handle can not be pushed or pulled unless the lock is deactivated
- Remove air by pushing plunger handle.
- Connect the Male Luer of Inflation Device to the balloon catheter. Secure the connection. Follows the indications and instructions for balloon catheter procedure as prescribed by the manufacturer.
- Once the balloon catheter is positioned, screw the plunger handle in clockwise direction to increase the pressure and thus, for inflation of the balloon.
- Screwing the plunger handle in anti-clockwise direction will reduce the pressure and thus, for deflation of the balloon.

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.

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- 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.
- Always follow the manufacturer's directions accompanying the balloon dilation catheter for instructions for use, maximum balloon inflation pressure, precautions, and warnings for that device. Troubleshooting: User Paramedic staff should be aware & able to troubleshoot the certain complications that may occur during the application of the product such as; He/she should be careful while performing the balloon angioplasty to avoid rupturing or dissecting the vessel wall.

ADVERSE EFFECTS:
Vascular damage, Air embolism

RE-USE HAZARDS:
Transmission of infection from one patient to another.

PACKAGING:
The device is packed in Header 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.

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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

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
www.Prymaxhealthcare.com

EC REP:

Compliance Management Solutions Europe LTD
2 Bulgaria Str. ,2850 Petrich, Bulgaria
E-mail: gloizou@compliancems.com.au
Contact No.: **+61 4 33 124266**

Prepared by:	Approved By: