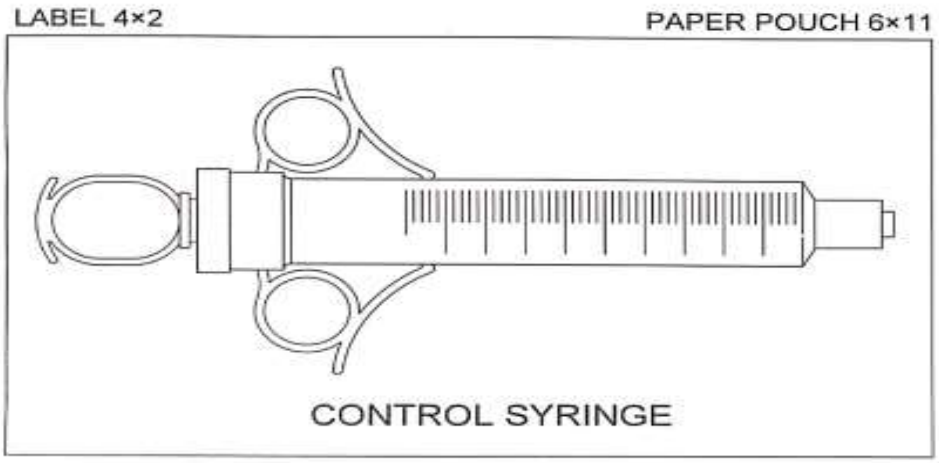
Prymax Angi

Control Syringe

DEVICE DESCRIPTION:
Control Syringes used during various cardiology procedures. Control syringes are specially designed for ease of use. The plunger tip and barrel are designed for consistent movement and smooth rotator action. The enhanced graduation markings increase legibility. The clear polycarbonate design allows for enhanced visual inspection, and the enlarged reservoir stop is specially designed to decrease the possibility of air infusion.

AVAILABLE SIZES:
10, 12 and 20 ml

Drawing of product:



MATERIAL USED:
Polycarbonate. High Density Poly Ethylene, Acrylonitrile-butadiene-styrene

INTENDED PURPOSE:
INTENDED USE: Control syringe is a hand controlled device used to inject contrast media 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:

Prepared by:	Approved By:

Angiography

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:

- Control syringe medical device designed for precise and accurate medication administration.
- Its transparent barrel and ergonomic grip ensure precise dosing and easy handling. With its versatility, it can be used for various injections, including subcutaneous, intramuscular, and epidural.
- The syringe features a Luer lock tip and minimal dead space, effectively reducing air bubbles and enabling compatibility with catheters.

PERFORMANCE CHARACTERISTICS:

- Clear Barrel: Provides exceptional clarity and smooth as glass feel
- Solid Plunger Body: Maintains stability and durability under pressure
- Rotating luers : Allow for flexibility and confidence in luer connection
- Safety Space: Intended to minimize the potential of air bubbles introduced in to the catheter

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.
- Push the plunger in to barrel to expel air out.
- Connect the male luer lock to the manifold assembly & secure all connections.
- Flush the system to ensure free flow channel.
- Once manifold connection is done push the plunger to ensure forwarded flow of the contrast media to initiate Angiography procedure.

WARNING & PRECAUTIONS:

- Do not use if the sterile pack is opened or damaged.
- The use of this product is restricted to a qualified doctor or a surgeon trained in the techniques of vascular catheterizations.
- 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

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for use.

- The product is guaranteed, sterile till the package has not been opened or damaged within the expiry date.
- 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

RE-USE HAZARDS:

Transmission of infection from one patient to another.

PACKAGING:

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.

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

Prepared by:	Approved By:

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.

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Haryana, INDIA -121001
www.Prymaxhealthcare.com

EC REP:

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