Prymax Angi

Introducer Needle

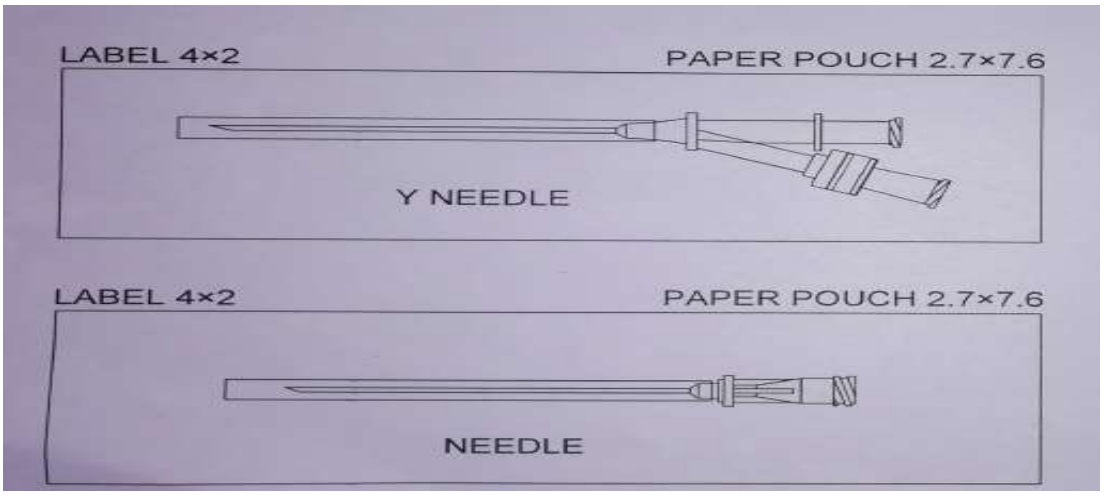
DEVICE DESCRIPTION:

The Introducer Needle allows access to the vascular system for the introduction of a guidewire to facilitate catheter placement. The Introducer Catheter over Needle is intended to puncture the skin to gain access to the vascular system and, after removal of the introducer needle, allows passage of a spring wire guide into the vessel.

AVAILABLE SIZES:

17, 18, 20, 21 G
Straight & Y type

Drawing of product:



MATERIAL USED:

Stainless steel, Poly carbonate, poly propylene

INTENDED PURPOSE:

INTENDED USE: Puncture Needle / Introducer Needle is a device indicated to use to create an incision in the skin or vessel to facilitate other devices to enter into the body.

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.

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INDICATIONS:

Catheterization, Angiography, Angioplasty, Anesthesia, Biopsy

CONTRAINDICATIONS:

- A known or suspected obstruction in the vessel or target anatomy
- Distorted anatomy due to congenital heart disease
- Significant chest or spine deformity
- Inability to lie flat
- Ongoing anticoagulation
- Previous intra-atrial septal patch
- Known or suspected atrial myxoma
- Myocardial infarctions within the last two weeks
- Unstable angina
- Recent cerebral vascular accident (CVA)
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS

Clinical Benefits:

Stabilization, Reduces tissue damage, Guides navigation, Obtains biopsy samples

PERFORMANCE CHARACTERISTICS:

- Easy insertion
- Compatible with guide wire

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.
- To be pre-decided to use. Short or Long, 18, 20, 21 & 18G Y type as per user's protocol.
- Connect the proximal port of Puncture needle to a syringe.
- Ensure that the connection is secured properly and free of air bubble.
- Flush with saline to prime the device.
- Target the selected vessel and insert in to it to make passage to enter through it.

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

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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:
Accidental dural puncture, Needle breakage

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.
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

UDI Carrier

Medical Device

Country of Manufacturer

Manufactured By:

Prymax Healthcare LLP.,
53/17, Industrial Area NIT, Faridabad,
Haryana, INDIA -121001

EC REP:

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