Prymax Angi

Introducer Sheath

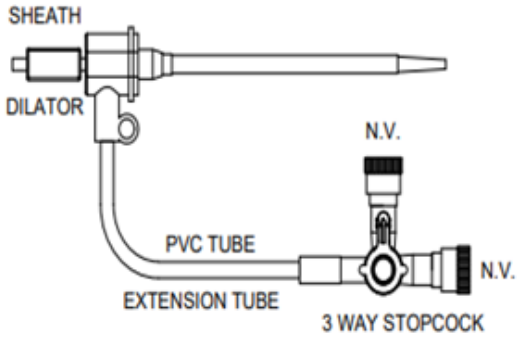
DEVICE DESCRIPTION:

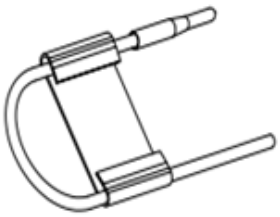
Prymax Healthcare supplies introducer sheath for femoral as well as radial access. The introducer sheath for femoral access is available in different sizes ranging from 4 FR to 11 FR with a length of 11 cm, whereas the introducer sheath for radial access is available in different sizes ranging from 4FR to 6FR with length of 7 cm.

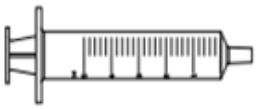
Available Sizes:

Scalpel – 11 number										
Sheath					**Dilator**		**Needle**		**Guidewire J**	
Size	**Color**	**OD (mm)**	**ID (mm)**	**Length (cm)**	**Size (G)**	**Length (cm)**	**Size (G)**	**Length (cm)**	**Size (inch)**	**Length (cm)**
Femoral										
4 F	Violet	2.28	1.49	11	4 F	15.0	21	4.0	0.018	45
5 F	Grey	2.64	1.85	11	5 F	15.0	21	4.0	0.018	45
5 F	Grey	2.64	1.85	11	5 F	15.0	18	7.0	0.035	45
6 F	Green	2.94	2.15	11	6 F	15.0	18	7.0	0.035	45
7 F	Orange	3.25	2.41	11	7 F	15.0	18	7.0	0.035	45
8 F	Blue	3.58	2.74	11	8 F	15.0	18	7.0	0.035	45
9 F	Black	3.96	3.07	11	9 F	15.0	18	7.0	0.035	45
10 F	Fuchsia	4.29	3.40	11	10 F	15.0	18	7.0	0.035	45
11 F	Yellow	4.72	3.75	11	11 F	15.0	18	7.0	0.035	45
Radial										
4 F	Violet	2.28	1.49	7	4 F	13.3	21	4.0	0.025	45
5 F	Grey	2.64	1.85	7	5 F	13.3	21	4.0	0.025	45
6 F	Green	2.94	2.15	7	6 F	13.3	21	4.0	0.025	45

Drawing of product:







CONTENTS:

- One Introducer Needle
- One Guide Wire
- One Scalpel
- One Dilator
- One Syringe

MATERIAL USED:

Fluorinated ethylene propylene (FEP), Acrylonitrile butadiene styrene (ABS), Silica gel, Polyvinylchloride (PVC), Stainless steel, Poly carbonate (PC), Polypropylene (PP), Stainless steel/Nitinol, Polyethylene (PE), Thermoplastic elastomers (TPE).

INTENDED PURPOSE:

INTENDED USE: Introducer Sheath is intended to provide access and to facilitate percutaneous introduction of guide wires, catheters and other devices into the femoral and radial arteries while maintaining hemostasis during diagnostic and interventional procedures.

INTENDED USER**:** The device is intended to be used only by a qualified doctor or surgeon.

INTENDED PATIENT POPULATION**:** All patient population irrespective of age and gender.

INDICATIONS:
This device is indicated during the diagnostic and interventional procedure of the percutaneous coronary interventions.

CONTRAINDICATIONS:
Introducer Sheath is contraindicated in patient with allergic/hypersensitive to materials used in the device.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:
The device does not have a direct clinical benefit however, it is used during percutaneous interventional procedures to alleviate the diseased conditions related to heart which are life-threatening. The device provides access to other devices used during PCI, while maintaining hemostasis.

The performance characteristics of the device includes:

- Sheath insertion time

INSTRUCTIONS FOR USE:

- **PRE-PREPARATION:**
  - Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
  - Open the product in sterile environment.
  - Make that the dilator fits easily through the introducer sheath.
  - Position patient as appropriate for insertion site.
  - Disinfect the skin and prepare venipuncture site.
  - Drape venipuncture site.

- **INTRODUCER SHEATH PREPARATION:**
  - Flush the dilator, introducer sheath, and extension tube with heparinized or suitable isotonic intravenous fluid.

- **INTRODUCER SHEATH PLACEMENT:**
  - Insert introducer needle with syringe into artery and aspirate. Assure a good flow of venous blood is established.
    PREACUATION. Always confirm the needle placement in desired vessel before going to the next step.
  - Remove syringe and advance the guide wire through introducer needle into the blood vessel till the require depth.
  - Advancement of "J" tip may require a gentle rotating motion. Straighten the "J" tip by retracting the guide wire into the advancer. When the tip is straightened, the guide wire is ready for insertion. Centimeter marks are referenced from "J" end. One band indicates 10 cm, two bands 20 cm, and three bands for 30 cms.
    WARNING: Carefully introduce guidewire, since mechanical damage can be caused to the guidewire during insertion or removal, resulting in guidewire damage.
  - Gently withdraw and remove the introducer needle, while holding the guidewire in position.

WARNING: In case guidewire must be removed while the needle is inserted, remove both together to prevent needle damage.

- Maintain firm grip on guide wire at all time. Use centimeter markings on guide wire to adjust indwelling length.
  WARNING: Although the incidence of guide wire failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the wire.
- Use the tip of the scalpel #11, against the guide wire to enlarge the sheath entry site.
- Insert the dilator tip through the valve and completely into the sheath until the dilator hub comes in contact with the hemostatic valve. This ensures that the tapered portion of the dilator is beyond the end of the sheath. Push to click the dilator hub into the valve head.
- Advance the dilator-sheath assembly over the guidewire as an assembly unit; do not allow dilator to back out of the sheath while advancing. Stop advancement of the assembly if there is resistance. Investigate the cause of resistance before proceeding. Carefully advance the assembly until it is at the desired location. Advance dilator-sheath assembly with a twisting motion to avoid damage to the sheath or vessel.
- Hold the sheath steady and maintain the guidewire position while withdrawing the dilator from the sheath, over the guidewire until it is completely removed with the guidewire.
  WARNING: To minimize the risk of possible vessel wall perforation do not leave dilator in place.
- If resistance is encountered when attempting to remove the guide wire after sheath placement, the guide wire may be kinked around the tip of the catheter within the vessel. In such a circumstance, pulling back the guide wire may result in guide wire breakage due to undue force being applied. If resistances encountered, withdraw the sheath relative to the guide wire about 2-3 cm and remove the guide wire.
- Verify that the entire guide wire is intact upon removal.
- Flush and connect extension tube to appropriate lines as necessary.
- The sheath is ready for advancing the catheter or other interventional medical device.
- Dress the incision site per hospital or departmental protocol.
- Check sheath and dressing regularly for evidence of sheath movement, interrupted flow rates, leakage, security of all connection and signs of infection.

- **REMOVAL PROCEDURE:**
  - Remove dressing, if applicable.
    PRECAUTION: To minimize the risk of cutting sheath, do not use scissors to remove dressing.
  - Withdraw catheter or other interventional medical device from sheath.
  - Remove sheath slowly, pulling it parallel to the skin. As sheath exits the site, apply pressure with a gauze or as per the procedures followed by the hospital.
  - Upon removal of the sheath, inspect it to make sure that the entire length has been withdrawn.
  - Discard the sheath as per the instructions given in this IFU.

WARNING & PRECAUTIONS:

- 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 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.
- Do not use excessive force when introducing guidewire or dilator-sheath assembly as this can lead to vessel perforation, bleeding, or component damage or breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained, and further consultation requested.
- Always flush/aspirate the device as per the instruction given in this IFU.
- Pre-dilation may be required when introducing a sheath- dilator assembly through scar tissue.
- Remove the needle first. Never pullback or withdraw the guide wire back from the Needle because this may result in shearing of the guide wire.
  - Tap the vessel assembly tightly.
- When the sheath will remain in a vessel for an extended period, consider using a continuous drip of heparinized or suitable isotonic intravenous fluid under pressure administered through the extension tube connection.

ADVERSE EFFECTS:
The known adverse events associated with the use of Introducer Sheath includes: radial artery occlusion (RAO), radial arterial spasm (RAS), bleeding/hematoma and vascular complications such as vessel perforation, arterial dissection, pseudoaneurysm, arteriovenous fistula, and local hematoma.

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

PACKAGING:
The device is packed in Blister sealed with Tyvek paper, inner carton & master carton.

STERILIZATION:
Device is EO sterilized, and sterilization is done in-house.

STORAGE CONDITION:
Temperature Limit: 15^0C to 40^0C.

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
Date of manufacture	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 instruction for use		Consult instructions for use
Single Sterile Barrier System		Medical Device
UDI-DI carrier		

Manufactured By:

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