Prymax Cathe

Arterial Catheter Kit
Device Description:

Arterial Catheterization is a routine and standard procedure in intensive care settings, emergency rooms, and the operating room. This procedure entails the insertion of a catheter into the peripheral artery lumen to facilitate a one-time or frequent arterial blood sampling to assess oxygenation and acid-base status, as well as for hemodynamic monitoring through the evaluation of various patterns of arterial waveforms. Device is available from 16 Ga to 22 Ga with extension/ without extension.

Available Sizes:

Catheter type	Lumen	Dilator	Guide Wire	Needle	w/o Dilator	With Dilator
					Part No.	Part No.
16 Ga x 16cm with Extn.	5fr	7 Fr	0.032-0.035 x50-60 cm	17/18 Ga, 7cm	PAC-16G16	PAC-16G16D
16 Ga x 16cm without Extn.	5fr	7 Fr	0.032-0.035 x50-60 cm	17/18 Ga, 7cm	PACW-16G16	PACW-16G16D
16 Ga x 20cm with Extn.	5fr	7 Fr	0.032-0.035 x50-60 cm	17/18 Ga, 7cm	PAC-16G20	PAC-16G20D
16 Ga x 20cm without Extn.	5fr	7 Fr	0.032-0.035 x50-60 cm	17/18 Ga, 7cm	PACW-16G20	PACW-16G20D
18 Ga x 08cm with Extn.	4fr	5 Fr	0.025x50 cm	18 Ga, 7cm	PAC-18G08	PAC-18G08D
18 Ga x 08cm without Extn.	4fr	5 Fr	0.025x50 cm	18 Ga, 7cm	PACW-18G08	PACW-18G08D
18 Ga x 10cm with Extn.	4fr	5 Fr	0.025x50 cm	18 Ga, 7cm	PAC-18G10	PAC-18G10D
18 Ga x	4fr	5 Fr	0.025x50	18 Ga, 7cm	PACW-	PACW-

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10cm without Extn.			cm		18G10	18G10D
18 Ga x 15cm with Extn.	4fr	5 Fr	0.025x50 cm	18 Ga, 7cm	PAC-18G15	PAC-18G15D
18 Ga x 18cm with Extn.	4fr	5 Fr	0.025x50 cm	18 Ga, 7cm	PAC-18G18	PAC-18G18D
18 Ga x 18cm without Extn.	4fr	5 Fr	0.025x50 cm	18 Ga, 7cm	PACW-18G18	PACW-18G18D
20 Ga x 04cm with Extn.	3fr	4 Fr	0.021x 35-50 cm	20 Ga, 4cm	PAC-20G04	PAC-20G04D
20 Ga x 04cm without Extn.	3fr	4 Fr	0.021x 35-50 cm	20 Ga, 4cm	PACW-20G04	PACW-20G04D
20 Ga x 06cm with Extn.	3fr	4 Fr	0.021x 35-50 cm	20 Ga, 4cm	PAC-20G06	PAC-20G06D
20 Ga x 06cm without Extn.	3fr	4 Fr	0.021x 35-50 cm	20 Ga, 4cm	PACW-20G06	PACW-20G06D
20 Ga x 08cm with Extn.	3fr	4 Fr	0.021x 35-50 cm	20 Ga, 4cm	PAC-20G08	PAC-20G08D
20 Ga x 08cm without Extn.	3fr	4 Fr	0.021x 35-50 cm	20 Ga, 4cm	PACW-20G08	PACW-20G08D
20 Ga x 20cm with Extn.	3fr	4 Fr	0.021x 35-50 cm	20 Ga, 4cm	PAC-20G20	PAC-20G20D
20 Ga x 20cm without Extn.	3fr	4 Fr	0.021x 35-50 cm	20 Ga, 4cm	PACW-20G20	PACW-20G20D
22 Ga x 04cm with Extn.	2fr	4 Fr	0.018x 35-50 cm	20 Ga, 4cm	PAC-22G04	PAC-22G04D
22 Ga x 04cm	2fr	4 Fr	0.018x 35-50 cm	20 Ga, 4cm	PACW-22G04	PACW-22G04D

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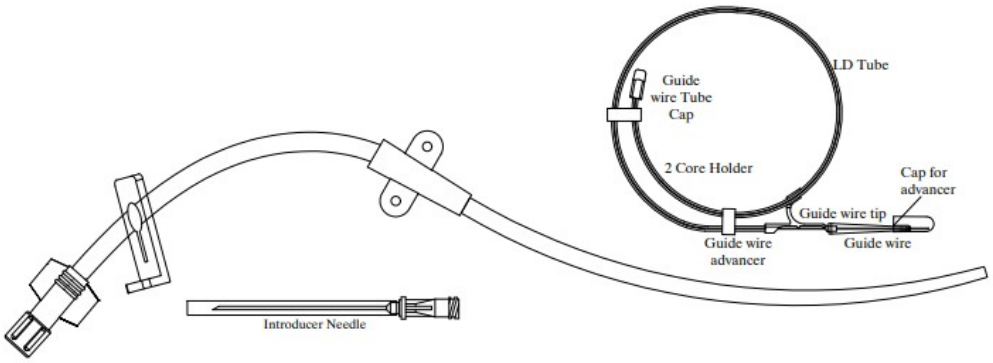
without Extn.						
22 Ga x 06cm with Extn.	2fr	4 Fr	0.018x 35-50 cm	20 Ga, 4cm	PAC-22G06	PAC-22G06D
22 Ga x 06cm without Extn.	2fr	4 Fr	0.018x 35-50 cm	20 Ga, 4cm	PACW-22G06	PACW-22G06D
22 Ga x 08cm with Extn.	2fr	4 Fr	0.018x 35-50 cm	20 Ga, 4cm	PAC-22G08	PAC-22G08D
22 Ga x 08cm without Extn.	2fr	4 Fr	0.018x 35-50 cm	20 Ga, 4cm	PACW-22G08	PACW-22G08D
22 Ga x 20cm with Extn.	2fr	4 Fr	0.018x 35-50 cm	20 Ga, 4cm	PAC-22G20	PAC-22G20D
22 Ga x 20cm without Extn.	2fr	4 Fr	0.018x 35-50 cm	20 Ga, 4cm	PACW-22G20	PACW-22G20D

Drawing of product:



CONTENTS:

- One Catheter
- One Guide Wire
- One Introducer needle
- One Dilator (If supplied)

MATERIAL USED:

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Poly Urethane (PU), Polypropylene (PP), Acrylonitrile-butadiene-styrene (ABS), Nitinol/Stainless Steel (SS), Poly carbonate (PC), Low Density Polyethylene (LDPE)

INTENDED PURPOSE:

INTENDED USE: An arterial catheter is a thin, hollow tube that is placed into an artery (blood vessel) in the wrist, groin, or other location to measure blood pressure more accurately than is possible with a blood pressure cuff. This is often called an “art line” in the intensive care unit (ICU). The catheter can also be used to get blood samples when it is necessary to frequently measure the levels of gases (oxygen and carbon dioxide) in the bloodstream. Blood for other lab tests may also be drawn at times

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:

Arterial Catheter Kit is used for invasive monitoring of blood pressure and blood sampling using the Seldinger technique

CONTRAINDICATIONS:

- Absence of collateral circulation (eg. Local infection)
- Distorted anatomy (eg, previous surgical interventions, congenital malformations)
- Active Raynauds Disease
- Thrombo angiti sobliterans (Buerger disease)
- Burns
- Aneurysm
- Stent or synthetic vascular graft
- Allergic/hypersensitive to materials used in the device.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

Clinical Benefits:

- Allows continuous ‘beat-to-beat’ blood pressure monitoring. This is useful in patients who are likely to display sudden changes in blood pressure (e.g. vascular surgery).
- Allows accurate blood pressure readings at very low pressures, for example in shocked patients.
- Allows close blood pressure monitoring for a long period of time e.g. ICU patients. Intra-arterial blood pressure monitoring avoids the trauma of repeated cuff inflations.

Performance Characteristics:

- Catheterisation success rate

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	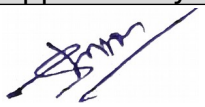

- Experience of discomfort and pain

INSTRUCTION FOR USE:

Pre-preparation:

- 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.
- Position patient as appropriate for insertion site.
- Disinfect the skin and prepare venepuncture site.
- Drape venipuncture site.

Catheter Preparation:

- Flush lumen with normal saline for injection to establish patency and prime catheter.
- Clamp or attach injection caps to extension line to contain saline with lumen.
  Warning: Air embolism can occur if air allowed to enter a arterial access device or artery. Do not leave open needles or uncapped/unclamped catheters in arterial puncture site. Use only securely injection caps connections with any arterial access device to guard against inadvertent disconnection.

Procedure:

- Raise a skin wheal by intradermal or subcutaneous infiltration of local anesthetic, if desired.
- Perform venipuncture using the thin wall needle. Presence of blood in the clear flash-back hub verifies placement of the needle in the artery. If blood flow is not adequate, aspirate to establish desired flow. (Repositioning of thin wall needle may be necessary.
- Insert the introducer needle at the desired landmark while gently withdrawing the plunger of the syringe.
- Insert the flexible end of the guide wire into the thin wall needle and gently advance 5-10 cm into the artery. It may be necessary to gently rotate the guide wire to successfully advance it into the artery. Avoid vigorous manipulation of the guide wire to prevent shearing of the guide wire or damage to the vessel. If gentle rotation fails to transverse the obstruction, remove the needle and guide wire simultaneously and select another insertion site. MAINTAIN FIRM GRIP ON GUIDE WIRE AT ALL TIMES. DO NOT WITHDRAW THE GUIDE WIRE BACK THROUGH THE THIN WALL NEEDLE AS THIS MAY RESULT IN SHEARING OF THE GUIDE WIRE.
- Remove the needle proximally, leaving the guide wire in the artery.
- If desired, a small skin nick may be made to widen the insertion site.
- Thread the arterial catheter over the guide wire and advance it into the artery using a rotation motion; maintain a firm grip on the proximal end of the guide wire at all times.

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	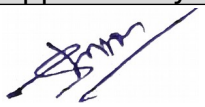

- Hold catheter in desired position and remove guide wire proximally.
- Connect a syringe to connector of catheter and aspirate to ensure flow.
- Remove syringe and connect the catheter hub to selected monitoring line.
- Suture catheter in place. DO NOT PLACE SUTURE ON CATHETER TUBING AS THIS MAY RESTRICT FLOW THROUGH CATHETER OR DAMAGE TUBING.
- Follow hospital protocol for puncture site dressing and maintenance.
- POSITION OF THE ARTERIAL CATHETER, FOLLOWING PLACEMENT, SHOULD BE ESTABLISHED BY IMAGING TECHNIQUES
- Apply pressure at site after catheter is removed per institutional policies and procedures.

WARNINGS & PRECAUTIONS:

- Do not use the product if the package is damaged or open.
- The procedure must be performed by trained personnel, well versed in anatomical landmark, trained for safe Techniques and aware of potential complications.
- The physician should be aware of possible complications may occur during Arterial and Venous insertion.
- Product must not be resterilized. The re-sterilization of the device will alter mechanical and chemical properties, inappropriate of intended use and also increase the EO residue on device
- Do not alter or modify any part of the kit.
- 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.
- Air embolism can occur if air is allowed to enter a Artery. Do not leave open needles or uncapped/ unclamped catheters in artery. Use only secured injection caps connections.
- If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.
- Never pull back or withdraw the catheter while the needle is in place. This could damage the wire on the needle bevel.
- Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation, bleeding, or component damage.

ADVERSE EFFECTS:

- Bruising or bleeding where the doctor inserted the catheter
- Nausea, itching, or hives from any contrast dye (and more uncommonly, an allergic reaction or kidney damage)
- Blood clot or blood vessel damage
- Infection
- Arrhythmia, or abnormal heart rhythm (usually temporary)

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	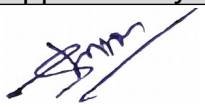

RE-USE HAZARDS:
Transmission of infection from one patient to another.

PACKAGING:
The device is packed in paper 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: 15ºC to 40ºC.

Country Code: -356

DEVICE SHELF LIFE: 5 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 goods 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

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Manufacturer

Storage Temperature Range

Conformité Européenne

Do not use if package is damaged and consult instructions for use

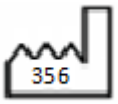
Instructions for Use

Consult

Single Sterile Barrier System

Medical Device

UDI Carrier



Country of Manufacturer

Manufactured By:

Prymax Healthcare LLP.,
Solutions Europe LTD
53/17,Industrial Area NIT, Faridabad,
Haryana, INDIA -121001
gloizou@compliancems.com.au
www.Prymaxhealthcare.com

EC REP:

Compliance Management

2 Bulgaria Str. ,2850 Petrich, Bulgaria
E-mail:

Contact No.: **+61 4 33 124266**

Prepared by:	Approved By: