en Instructions for Use

Accura Kit – Percutaneous access Set

BLUENEEM®
Clinicians Trust. Patients Wellbeing

Percutaneous Access Set (6Fr)

- 6Fr Introducer Sheath with obturator and metal stiffener
- 21 G x 15 cm Chiba needle
- 0.018-inch x 60 cm cope mandril wire

Micropuncture Kit (4 & 5Fr)

- Introducer sheath with obturator
- 21 G x 7 cm cannulated needle
- 0.018-inch x 40 cm cope mandril wire

Intended Purpose

Used for single puncture percutaneous access to facilitate placement of 0.035 or 0.038-inch diameter Guide wire for interventional radiology procedures for a period of up to 60 minutes.

Indications For Use & Contraindications

Indicated to be placed before placement of drainage catheter percutaneously in liver for biliary drainage / in the abdominal or thoracic cavity for drainage of clear or infected fluid collection / abscess / in kidney for renal drainage or other interventional percutaneous access procedures. This device is contraindicated in the presence of conditions which create unacceptable risk during percutaneous access procedures.

Potential Complications

Potential complications include but not limited to Perforation of a vessel or viscus, Laceration of a vessel or viscus, Bleeding, Wire or catheter embolism, Extravasation, Hematoma, Haemothorax, Hydrothorax, Inflammation, necrosis or scarring, Risks normally associated with percutaneous interventional procedures, Pain in region, Skin infection, Edema and Malposition.

Warnings And Precautions

- This device is intended single use only. Do not use if product is damaged or expired, reuse and resterlization of this device leads to loss in structural integrity and performance. It can cause serious infections and harm to the patient.
- This device is intended for use by trained physicians or healthcare professionals who were trained in interventional procedures and this device should not be used without comprehensive knowledge of the indications, techniques and risks of the procedure.
- Do not use force to advance any component if resistance is encountered during placement or removal. Standard techniques to be applied.
- Use package supplied accessories only. On completion of the procedure, dispose off the device as per local regulatory guidelines for bio-hazardous medical waste disposal.
- Activate the hydrophilic coating on the surface of introducer sheath before use for better results.

Instructions For Use

1. Introduce the 21G needle in to the vessel, duct or cavity based on the interventional procedure requirement.
2. Confirm the needle position by aspiration. (For 2-part needle remove the inner stylet to aspirate). Advance 0.018-inch nitinol Cope mandril wire through the lumen of needle. On positioning at wire at desired site, remove the needle cannula.
3. Activate the hydrophilic coating and advance introducer sheath assembly over 0.018-inch wire (remove the metal stiffener is found assembled with introducer sheath) and advance up to desired location up to main duct/vessel or cavity.
4. Now remove the plastic obturator leaving cope mandril wire in position. Confirm the position of sheath and remove 0.018-inch wire. Now introduce 0.035 or 0.038-inch wire through the lumen of introducer sheath up to desired site and remove the sheath maintaining the wire in position for further interventions and device placements.

Target Population Group

Adult male and females who requires access to desired anatomical sites while performing percutaneous interventional procedures of placement of devices.

Supply and Storage

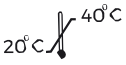
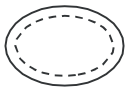
The device is packed in such a way that, all contents assembled in tray and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20^{O}C to 40^{O}C and away from direct sunlight.

Report Any Serious Incident

If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Symbol Glossory And Definations

Standard Reference:
ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

	Do not resterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barriersystem with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription

- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.

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