

# IFU of ARTERIAL CANNULA

## Arterial Cannula with Wings (On/Off Switch)

Manufactured by Mais India Medical Devices Pvt. Ltd.

### DEVICE DESCRIPTION:

Arterial Cannula is a sterile, non-pyrogenic, disposable (single use), over the needle, single lumen peripheral catheter, which specifically is intended for insertion into the radial artery and is indicated for patients requiring arterial pressure monitoring and serial arterial blood gas determinations. Arterial Cannula hub has an integral on/off flow control device to prevent back-flow and blood spillage, a luer-lock connection for accessory attachment, and wings to facilitate securement. The flow control device is operated by a positive action by moving a red button to or from a position allowing flow through the device. The catheter tubing is polytetrafluoroethylene (PTFE), which is widely accepted as nonreactive and resistant to a broad range of drugs. The sealed unit packs are sterilized using Ethylene Oxide (EO) gas and are given a shelf life of 5 years from the date of sterilization.

### INTENDED PURPOSE:

Arterial Cannula Product is intended for use only with:

- Arterial pressure monitoring.
- Serial arterial blood gas determinations.

### CLINICAL BENEFITS :

- Provides short term arterial access to facilitate arterial blood pressure monitoring to aid in patient treatment, management, and diagnosis.
- Provides short term arterial access to facilitate the ability to collect serial arterial blood gas determinations to aid in patient treatment, management and diagnosis.

### CONTRAINDICATIONS:

None known.

### GENERAL WARNINGS :

- Intended for use only with: - Arterial pressure monitoring.
- Serial arterial blood gas determinations.
- For proper use, clinicians must be familiar with and trained in the use of the Arterial Cannula with the flow control device.
- Observe standard infection control precautions on all patients.
- Aseptic technique, proper skin preparation and continued protection of the insertion site are essential.
- Examine the catheter insertion site frequently.
- Follow hospital/institutional policies and procedures on recommended

indwell time for arterial cannula. DO NOT exceed 30 days.

- Non-Pyrogenic. Sterile, do not use if the unit package is opened or damaged.
- This product does not contain natural rubber latex. PVC free. DEHP free.
- Arterial catheters inserted in emergency situations where sterile technique could be compromised should be replaced within 48 hours.
- Ensure the placement location of the Arterial Cannula does not prevent collateral flow to the extremity.
- Do not attempt to re-insert a partially or completely withdrawn needle into the cannula. If arterial puncture is unsuccessful discard both needle and cannula.
- Immediately dispose of any needles keeping the needlepoint away from the body and fingers at all times.
- Report needlestick injuries immediately and follow established facility protocol.
- Exposure to blood, either through percutaneous puncture with a contaminated needle or via mucous membranes, may lead to serious illness such as hepatitis, HIV, AIDS, or other infectious diseases.
- Re-use may lead to infection or other illness/injury.
- Potential complications related to the insertion and use of Arterial Cannula include but are not limited to: abscess, air embolism, arterial irritation or necrosis, blood exposure, blood loss / leakage, blood stream infection, bruising, catheter breakage / embolization, choking, clean and contaminated needle stick injury, death, delay or interruption of treatment, discomfort, edema, hematoma, hemorrhage, localized infection, particulate infusions, permanent ischemic damage, pseudoaneurysm, thrombosis and unsuccessful arterial insertion.
- Arterial pressure monitoring.
- Serial arterial blood gas determinations.

### GENERAL PRECAUTIONS :

- If the switch (red) is moved forward the fluid pathway is closed. A positive click is felt. If the switch (red) is moved backwards the fluid pathway is opened.
- If sutures are used to secure the cannula, only suture through the eyelets in the wings.
- When the cannula is not in use for infusion or aspiration, the flow control device must be switched off and a suitable luer cap locked into the hub.
- Do not bend the needle while using the product.
- Do not use scissors at or near the insertion site.
- Use only with ISO compliant Luer connections. Non-ISO compliant Luer connections may cause leakage.

- EU Only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.

### INSTRUCTIONS:

- **CANNULA INSERTION:** Remove the needle cover in a straight outward motion and inspect the cannula unit.
- Position the needle bevel and flow control device upwards.
- Insert the needle through the skin, insert the cannula into the artery, either by direct threading or by the transfixing method as described here.
- When the needle has punctured the posterior wall of the artery it should be partially withdrawn, held by the hub, while holding the wing of the cannula to keep it stationary.
- Bring the cannula back until blood return indicates that the cannula tip is in the lumen of the artery.
- Advance the cannula into the artery, at the same time drawing the needle back.
- Once the needle has been completely withdrawn the switch (red) can be pushed forward to close off the cannula.
- Connect the extension lines or monitoring kits.
- Open the switch (red) for operation. After checking successful cannulation by aspirating blood, flush the system with saline.
- Secure the cannula with a sterile dressing.

### STORAGE CONDITIONS:

Store in a Cool & Dry Place.

Keep away from sunlight

### SHELF LIFE:

5 Years

### LIFETIME:

Short-term (continuous use for between 60 minutes - 30 days).

















### TYPE OF STERILIZATION:






EO sterilization.


### NOTICE TO USERS AND/ OR PATIENTS:

Any serious incident that has occurred in relation to the device, should be reported to the Manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

**EXPLANATION OF SYMBOLS USED:**

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Single sterile barrier system (Indicates a single sterile barrier system)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Non-pyrogenic (Indicates a medical device that is non-pyrogenic)		Keep dry (Indicates a medical device that needs to be protected from moisture)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details: +91 8527589990 Fax No.: 0124 4047533 Email ID: info@maisindia.com Website:www.maisindia.com

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Country of manufacture (To identify the country of manufacture of products)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	This way up		

 **Manufactured by:**  
**Mais India Medical Devices Pvt. Ltd.**  
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