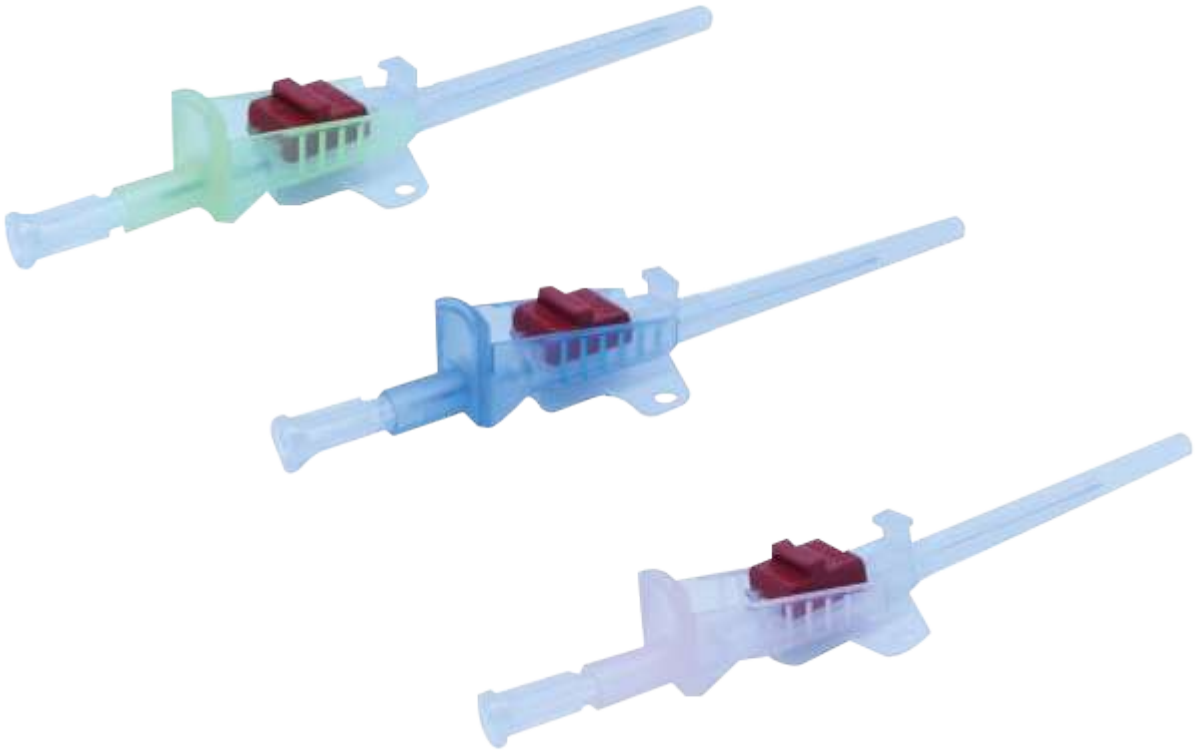
medbar®

Arterial Cannulas



REF 304

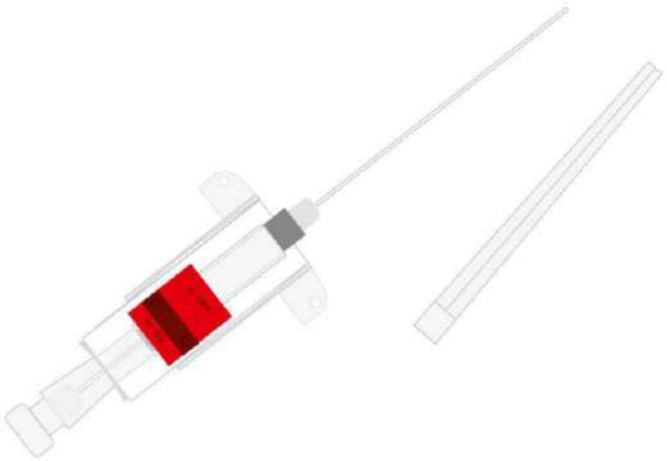
STERILE EO

CE 2292

Arterial Cannulas

Intended Use

- Used primarily for hemodynamic monitoring of the cardiovascular system.
- Used for blood gas monitoring.



Components of The Product

Medbar brand Arterial Cannula consists of :

- Body,
- Needle Holder,
- Filter,
- Filter Holder,
- Needle,
- Switch,
- Cannula,
- Needle Cover.

Product Features

- Atraumatic needle tip: specifically designed to minimize injurious effects or trauma.
- Easily fixed onto the skin with soft wings.
- Built in air embolism protection: blood back-flow and blood contamination are also avoided with the on/off switch.
- The flow-block mechanism can be used easily with one hand.
- 18 G --> 1.30 mm x 45 mm (80 ml/min).
- 20 G --> 1.10 mm x 45 mm (50 ml/min).
- 22 G --> 0.90 mm x 33 mm (30 ml/min).

Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class IIA sterile medical device.
- Manufactured under ISO 13485 Quality Management System standard.
- Notified Body: UDEM LTD A.Ş. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 34893

Sterilization

- Sterilized with Ethylene Oxide.
- Validated for ISO 11135 standard.

Shelf Life

- 5 years.

Biocompability

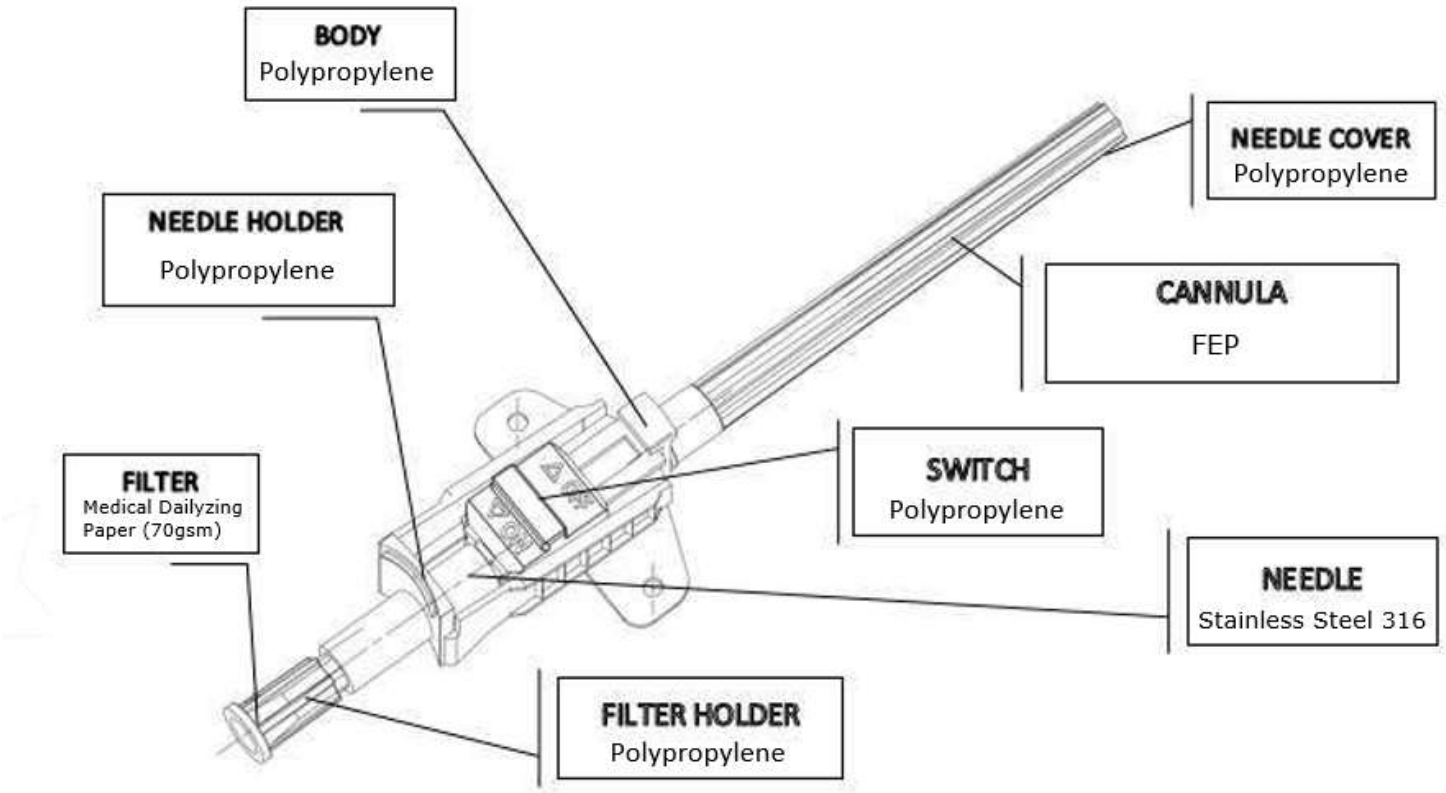
- Selections of tests for interactions with blood for Arterial Cannulas to EN ISO 10993-4.
- Tests of hemolysis, complement activation and coagulation to the ISO 10993-4:2009-10 Part 4.
- Cytotoxicity of eluates according to the DIN EN ISO 10993-5:2009-10 Part 5.
- Ethylene Oxide sterilization residuals tests according to EN ISO 10993-7:2008.
- Tests for irritation and sensitization according DIN EN ISO 10993-10:2010-12 Part 10.
- Tests for irritation and delayed-type hypersensitivity according to the DIN EN ISO 10993-10.
- In-vitro Pyrogen Test (IPT) according EN ISO 10993-11.
- The product does not incorporate a substance of a human blood derivative, animal originated tissues, phthalates,medicinal product, latex, radioactive material and electromagnetic waves.

REF NO	PRODUCT NAME	STERILIZATION	PACKAGING
304 01	Arterial Cannula (20 G)	EO	50 pcs inner box/500 pcs outer box
304 02	Arterial Cannula (18 G)	EO	Box Dimensions: 28*6423,5 cm
304 03	Arterial Cannula (22 G)	EO	Box Weight Gross: 4,613 KG

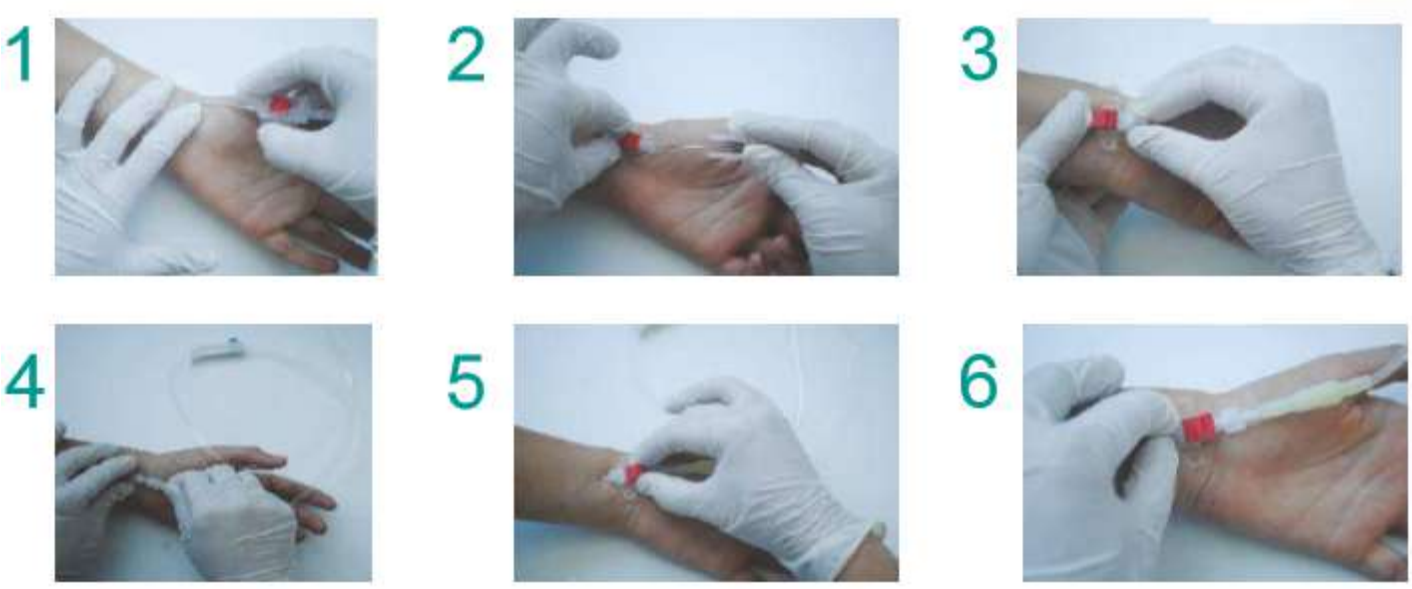
Arterial Cannulas

Technical Drawing

Arterial Cannulas



Arterial Cannula



- Remove the needle cover in a straight outward motion and inspect the cannula unit.
- Position the needle bevel and flow control device upwards.

1 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 car
- Bring the cannula back until blood return indicates that the cannula tip is in the lumen of the artery.

2 Advance the cannula into the artery, at the same time drawing the needle back.

3 Once the needle has been completely wihdrawn the switch (red) can be pushed forward to close off the cannula .

4 Connect the extension lines or monitoring kits.

5 Open the switch (red) for operation.

6 After checking successful cannulation by aspirating blood, flush the system with saline. Secure the cannula with sterile dressing.

Notes

- When the switch is moved forward, fluid path is closed.
- A positive click is felt.
- When the switch is moved backwards, fluid path is opened.
- When cannula is not used for infusion or aspiration purposes, flow control device should be closed and a suitable hydrophobic cover must be installed to the core.
- Hospital / institution protocols and procedures must be followed for the proposed arterial cannula injection time.

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