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PureFlex Arterial Cannulae – Important Safety Information

RAXXX-XX

INDICATIONS:

The arterial cannulae are intended to be used as perfusion cannulae to return arterial blood from the extracorporeal circuit to the patient during cardiopulmonary surgery for periods of up to six hours.

CONTRAINDICATIONS:

The cannulae are for use only as indicated. Not recommended use in diseased or abnormal cannulation sites.

GENERAL WARNINGS:

- The User should carefully check the device during set-up and priming for leaks. Do not use if any leak is detected.
- The device must be used in accordance with the instructions for use provided in this manual.
- For use by professionally trained personnel only.
- Proper surgical procedure and technique is the responsibility of the attending medical professional (physician). This guideline is furnished for informational purposes only. Each surgeon must evaluate the appropriate use of this device, case by case, based upon medical training, experience, and the type of surgical procedure employed.
- Sorin Group Italia is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- Keep dry. Store at room temperature.
- Always give and maintain a correct dose and accurate monitoring of the anticoagulant before, during and after the bypass.
- For single use and for single-patient use only. During use the device is in contact with human blood, body fluids, liquids or gases for the purpose of eventual infusion, administration or introduction into the body, and due to its specific design it cannot be fully cleaned and disinfected after use.
- Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, the reuse increases the probability of product failure (integrity, functionality and clinical effectiveness).
- Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.
- The device must not undergo any further processing.
- Do not resterilize.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.
- The device must only be used if STERILE.
- Do not use if sterile packaging is damaged, unsealed, or has been exposed to moisture or other conditions that would compromise the sterility of the device.
- Check the expiry date on the label attached. Do not use the device after the date shown.
- The device must be used immediately after opening the sterile packaging.
- The device must be handled aseptically.

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- Carry out a visual inspection and carefully check the device before use.
- Transport and/or storage conditions other than those prescribed may have caused damage to the device.
- Do not use solvents such as alcohol, ether, acetone, etc.: as contact may cause damage to the device.
- For further information and/or in case of complaint contact SORIN GROUP
- ITALIA or the authorised local representative.

For professional use. Please visit www.sorinmanuals.com to find instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Consult your labeling.

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