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Health innovation that matters

Pediatric Cannulae – Important Safety Information

A272-XX; BA272-XX; A900-XX; BA900-XX
V132-XX; BV132-xx; V122-XX; BV122-XX; V900-XX; BV900-XX

INDICATIONS:

The Pediatric cannulae are intended for use in pediatric patients in both the venous and the arterial line of the extracorporeal circuit:

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

The Venous cannulae are intended to be used to cannulate the major venous vessels during cardiopulmonary surgery for periods of up to six hours

CONTRAINDICATIONS:

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

"B" preceding the part number on the product label indicates that the device is PC coated, currently Sorin Group Italia is not aware of any contraindications to the use of this coated device.

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 Sorin Group Italia is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- Do not expose to temperatures below 0°C (32°F) or above 60°C (140°F).
- 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).
- If on the label is present the symbol then the device contains Phthalates. Considering the nature of contact with the body, the limited duration of contact and the number of treatments per patient, the amount of phthalates which might be released from the device does not raise specific concerns about residual risks. Further information is available on request from Sorin Group Italia.
- 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.

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- The device must only be used if sterile.- For further information and/or in case of complaint contact SORIN GROUP ITALIA or the authorised local representative.
- 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.
- 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 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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