LivaNova

Health innovation that matters

FlexFlow Venous Cannula – Important Safety Information

200-200

INDICATIONS:
The FlexFlow™ Venous Cannula is intended for use as a venous drainage cannula during cardiopulmonary bypass for up to 6 hours.

CONTRAINDICATIONS:
The FlexFlow™ Venous Cannula is not designed, sold or intended for use other than indicated.

GENERAL WARNINGS:
This device is only intended to be used by professionally trained personnel. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. These instructions are furnished for informational purposes only. Each surgeon must evaluate the appropriate use of this device, case by case, based on medical training, experience, and the type of surgical procedure employed.

- 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 at the end of use. Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, reuse increases the probability of product failure (integrity, functionality and clinical effectiveness).
- Do not use this device if package is damaged or opened.
- Never use a device if it is beyond its expiration date.
- Do not use this device if it shows signs of damage, e.g., crimps, kinks, or crushed areas.
- This cannula is for short term use only (<6 hours).
- Do not cut or alter the cannula in any way. Cutting the cannula could release particulate matter which may be thrombogenic or embolic and may render the device unusable.
- Removal should always be done under visualization.
- Handle with care after use as the product may be contaminated with blood and/or body fluids. Dispose of in accordance with applicable regulations in the country of use.
- DO NOT REUSE. DO NOT RESTERILIZE.
- If used on children, pregnant or nursing women, be aware that this device contains di (2-ethylhexyl) phthalate (DEHP) and/or di-n-hexyl phthalate (DnHP) which are presently classified in the European Union as toxic to reproduction. The amount of phthalate which might be released from the device does not raise specific concerns about the residual risks.

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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