LivaNova

Health innovation that matters

REVOLUTION Centrifugal Blood Pump – Important Safety Information

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.
- The device is intended to be used by professionally trained personnel. - 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 administer 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 resterilise.
- 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.
- For further information and/or in case of complaint contact SORIN GROUP ITALIA or the authorised local representative.

CAUTIONS:

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- Currently, no contraindications relating to use of the systems equipped with Ph.I.S.I.O. treated components is known to SORIN GROUP ITALIA.

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