LivaNova

Health innovation that matters

BMR1900™ Ph.I.S.I.O.® – Important Safety Information

WARNINGS:

- 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.
- Keep dry. Store at room temperature.
- 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.
- Do not resterilise.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.
- 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.
- The user should carefully check the BMR1900™ Ph.I.S.I.O. ® before set-up and use. Do not use if package is open or damaged. Transportation may cause structural and functional damage. Integrity and proper performance is not guaranteed if the BMR1900™ Ph.I.S.I.O.® has been damaged during transport.
- Do not let organic solvents such as alcohol, or anesthetic agents, such as isofluorane, come into direct contact with the reservoir bag. These agents may jeopardize structural integrity.
- The internal surface of the system is Ph.I.S.I.O. coated; currently, no contraindications relating to use of the systems equipped with Ph.I.S.I.O. treated components is known to SORIN GROUP ITALIA.
- 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
- 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.

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.

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Mini BYPASS Bag – Important Safety Information

WARNINGS:

- The MINI BYPASS BAG cannot be used as collapsible venous reservoir directly on the venous line.
- It is recommended to strictly monitor the platelets activation conditions. There are various factors that can have effects on platelets activation leading to the formation of clots in the device, which may obstruct or block the blood flow at the MINI BYPASS BAG outlet. These factors include:
  - A high amount of air or other gases (e.g. CO2) mixed with the aspirated blood.
  - Platelet activation due to prolonged dwelling of blood in the bag.
  - Coagulation disorders in the patient.
- If the presence of the above listed factors is suspected, a cardiotomy reservoir should be used to collect the aspirated blood.
- In certain particular and unusual circumstances (high blood volume, bag almost full, successive bag collapse and swelling) the filter mesh may collapse towards the outlet connector. This may temporarily limit the flow from the bag outlet connector. Should this occur, it is advisable to pull the bag outlet connector downwards.
  - Constantly monitor the presence of air in the bag and remove it through the purge line located in the upper part of the bag.

CAUTIONS:

- The internal surface of the system is Ph.I.S.I.O. coated; currently, no contraindications relating to use of the systems equipped with Ph.I.S.I.O. treated components is known to SORIN GROUP ITALIA.