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Health innovation that matters

INSPIRE 6F M OXY MODULE PH.I.S.I.O. w / IAF and INSPIRE 8F M OXY MODULE PHISIO w / IAF – 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.
- For use by professionally trained personnel only
- SORIN GROUP 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 correct anticoagulant dosage before, during and after the bypass and provide its correct monitoring.
- 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. Due to its specific design the device 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).
- Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.
- The device and its accessories must be handled applying sterile techniques.
- The device must not undergo any further processing.
- Do not resterilize.
- Use of phospolipidic drugs in the priming fluid or their infusion in the patient during the case, might facilitate the hydrophylization (plasma breakthrough) of the microporous membrane.
- 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 obstruct secondary vent port (fig.1, ref.12) of gas outlet cap. Secondary vent port is an additional safety against accidental positive pressure build-up in the gas compartment. Blockage of all gas outlet connectors and openings could cause pressurization of the gas compartment thus the formation of gaseous emboli in to the blood stream.
- Do not create negative pressure in the oxygenator blood compartment in any possible ways. Microporous membrane does allow blood compartment air embolization in case blood path pressure becomes lower in respect to gas path pressure.
- Inspire 6F M upper point should always be positioned at least 5 cm below the minimum operating level of the venous reservoir used in conjuction with it.
- Inspire 6F M must be used with its dedicated brackets.
- Only purge/recirculation lines preconnected to Inspire 6F M allow adequate operations.
- In case pump console is moved during use make sure that no lines such as gas, blood and water lines are pulled.
- When using the device in conjunction with other CPB devices, always consider that the most restrictive of all flow rate range and time duration indications reported on the IFUs will set the limits for all the devices constituting the CPB system.
- For further information and/or in case of complaint contact SORIN GROUP or the authorised local representative.

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CAUTIONS:

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- Inner surfaces of the system are Phisio coated, currently SORIN GROUP is not aware of any contraindications to the use of this coated device.

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.