

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 use. Do not use if damaged or uncomplete.
- 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.
- For multiple use and multiple patient use: during use the device may accidentally come in contact with human blood or body fluids. The device has to be cleaned and disinfected at the end of each use. Reuse on other patients might cause cross-contamination, infection and sepsis if not properly cleaned and disinfected.
- The device must not undergo any further processing.
- Do not steam sterilize. Do Not Gamma Sterilize. Do not ETO sterilize.
- Do not machine wash. Do not dip the device into washing solutions.
- Illustrated Inspire disposable devices must be used with their dedicated holders and squeezer as illustrated in the present directions for use.
- In case pump console is moved during use make sure that the device does not undergo shocks and damages.
- For further information and/or in case of complaint contact SORIN GROUP or the authorised local representative.

CAUTIONS:

- Accessories provided with the device are meant to be used with the device itself to facilitate positioning and set-up on the Heart Lung Machine.
- Brackets shall be cleaned after each use. Only hand cleaning with a soft cloth is allowed.
- To achieve adequate cleaning and avoid damage or alterations of the bracket, use water, mild soap and other detergents commonly available in the operating room and used for surface cleaning.
- The bracket is maintenance free except lubrication of moving parts.
- 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.