

## **INSPIRE HVR HARD SHELL VENOUS RESERVOIR PH.I.S.I.O. and INSPIRE HVR START HARD SHELL VENOUS RESERVOIR – Important Safety Information**

### **WARNINGS:**

- The user should carefully check the device for leaks during set-up and priming. 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.
- 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.
- Inspire HVR should always be positioned with its minimum operating level at least 5 cm above the upper point of the oxygenator used in conjunction with it.
- An auxiliary/cardiotomy reservoir port allows bypassing regular cardiotomy function in case cardiotomy filter ability is impaired.
- The auxiliary/cardiotomy port must always be kept sealed unless its specific use is needed. Unnecessary non monitored use may entrain air into the reservoir especially in VAVD conditions.
- During Inspire HVR operation constantly check that the blood level does not fall below the minimum operating level. Level below the minimum operating value may induce air embolism to the oxygenator and to the patient.
- The use of a blood level detector is recommended.
- "Filtered" and "unfiltered" ports allow the administration of fluids and medicaments.
- Drugs which must be administered at low doses should be diluted with saline solution so that they can fully run into the extracorporeal circulation.
- It is recommended to administer all fluids through the filtered ports, even if this should result in a slight delay in the fluid reaching the circulation.
- The Inspire HVR used with vacuum must be carefully used following the instructions "USE OF ACTIVE VENOUS DRAINAGE WITH VACUUM" of this user's manual in paragraph N.
- When using the venous reservoir for post-operative chest drainage carefully follow the instructions in "USE FOR POST-OPERATIVE CHEST DRAINAGE" of this user's manual at paragraph O.
- The special positive and negative overpressure valve built into the Inspire HVR ensures optimal intra- and post-operative performance of the system. The valve is activated and

vents positive pressure higher than +5 mmHg (0.7 kPa/ 0.007 bar / 0.1 PSI) and negative pressure lower than -200 mmHg (-26.7 kPa / -0.27 bar / -3.86 PSI). DO NOT OCCLUDE THE VALVE ORIFICE FOR ANY REASON WHATSOEVER.

- Inspire HVR venous reservoirs must be used with its dedicated holder.
- 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.

## **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.
- Do not push on the over/under safety valve as it can be displaced or its ability to properly work might be impaired.

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.