

INSPIRE HVR DUAL DUAL HARD SHELL VENOUS RESERVOIR PH.I.S.I.O. – 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 DUAL 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.
- When the special blood sequestration valve is down (sequestration mode active), Inspire HVR DUAL becomes a twin reservoir device allowing physical separation of systemic non activated blood from suction activated blood. The two sections work independently and blood is separately stored.
- When the special blood sequestration valve is up (sequestration mode inactive) Inspire HVR DUAL behaves like a regular single chamber venous/cardiectomy reservoir. Blood and medicaments of all kinds are mixed and no discrimination of activated blood takes place.
- Blood sequestration valve may be brought to open and closed position during the clinical procedure according to blood volume shifts and to clinical practice.
- An auxiliary/cardiectomy reservoir port allows bypassing regular cardiectomy function in case cardiectomy filter ability is impaired.
- The auxiliary/cardiectomy 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.
- It is a must to refer to Inspire HVR DUAL volume scales by discriminating from SEQUESTER MODE situations (valve down) to REGULAR MODE situations (valve up). Inspire HVR DUAL is equipped with a dual system of volume scales allowing correct volume reading in all working situations.
- During Inspire HVR DUAL operation constantly check that the blood level of the venous non activated blood section 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.

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.