

INSPIRE SVR 1200 SOFT SHELL VENOUS RESERVOIR PHISIO – 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 SVR 1200 should always be positioned with its inner outlet port profile at least 5 cm above the upper point of the oxygenator used in conjunction with it.
- Do not exceed 73 mmHg maximum operating pressure.
- A cardiotomy reservoir port allows the connection of a stand alone cardiotomy reservoir that will allow suction blood handling.
- The cardiotomy line must always be long enough to allow a safety syphon to guard against accidental air intake in case of no suction flow.
- During bypass constantly check that the volume inside Inspire SVR 1200 does not fall below the minimum operating value. Volume below the minimum operating value will make the SVR 1200 collapse in case of venous flow decrease.
- In case active volume control of SVR 1200 is required, the squeezer must be mounted before the procedure.
- The use of a bubble detector is recommended.
- 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 enter the extracorporeal circulation.
- Inspire SVR 1200 venous reservoirs must be used with its dedicated holders and optional squeezer.
- 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:

- SVR 1200 volume can be measured only when its squeezer is in place.
- The Inspire SVR 1200 may not fully collapse if overstretched or if operating in ipothermic conditions.
- It is advisable to set the squeezer to an approx. volume less than 350 ml only during priming volume recovery phase prior bypass, and during patient's weaning phase at the termination of bypass.
- The squeezer must not be set to an approx. volume below 350 ml during bypass conditions. Macro and micro (GME) air handling ability of Inspire SVR 1200 might be affected.
- A padded protection is guarding against accidental shocks when the SVR1200 is packaged into a PTS tray. Remove the padded protection from the top of the Inspire SVR 1200 prior to removing Inspire SVR 1200 from the PTS packaging and before set-up and use.
- 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.