

## **INSPIRE VBT 8 VENOUS BUBBLE TRAP – 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 ITALIA is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- Keep dry. Store at room temperature.
- Always apply 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 and due to its specific design it 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 purge line 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 VBT 8 must be used in a closed loop, active venous drainage system and does not normally include a venous reservoir. Care must be taken to strictly monitor the pump rpm, delivery flow rate and circuit/patient pressures such that, in case of massive blood loss or low blood loss, the pump can be adjusted accordingly.
- The use of roller pump as main pump is not allowed.
- Do not use Inspire VBT 8 in pulsatile flow conditions.
- High vacuum pressures can be generated in the venous line due to cannulae manipulation/movement, flow obstructions including kinking of the venous line, etc. It is highly recommended that the negative pressure at the inlet of the Inspire VBT 8 is monitored in order to avoid situations of excessive negative pressure at the venous inlet of the device. It is imperative that the maximum allowable negative pressure limit of  $-1 \text{ mH}_2\text{O} / -73.5 \text{ mmHg} / -9.8 \text{ KPa}$  in the venous line is never exceeded. If the venous inlet pressure exceeds this limit, reduce the pump flow rate, then identify and resolve the problem creating the high negative pressure.
- The positive pressure inside the blood compartment shall not exceed  $1 \text{ mH}_2\text{O} / 73.5 \text{ mmHg} / 9.8 \text{ KPa}$ .
- Do not operate the pump with the centrifugal pump inlet clamped. A negative non controlled pressure would be generated.
- The use of the Air Purge Control (APC) with Inspire VBT 8 is highly recommended.
- The use of the Electric Remote Clamp (ERC) and a bubble sensor at the outlet of the Inspire VBT 8 is highly recommended.
- Inspire VBT 8 should always be placed at a level not higher than the patient.

- The venous bubble trap must always be placed in a higher position in respect to the centrifugal pump.
- Arrange the surgical cannula in such a way that air is not aspirated into the venous line. Entry of massive air into the Inspire VBT 8 could cause the device to deprime and release air to the pump.
- Inspire VBT 8 can only be used with the devoted holder.
- For further information and/or in case of complaints contact SORIN GROUP ITALIA or the authorised local representative.

## **CAUTIONS:**

- Inner surfaces of the Inspire VBT 8 are Ph.I.S.I.O. coated; currently SORIN GROUP ITALIA is not aware of any contraindication to use of systems having components treated with Ph.I.S.I.O.
- Holder 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 holder, use water, mild soap and other detergents commonly available in the operating room and used for surface cleaning.
- The holder is maintenance free.

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.