

## Cardioplegia Delivery Systems – Important Safety Information

### WARNINGS:

- The device must be used in accordance with these instructions for use. - The device is intended for professional use.
- SORIN GROUP ITALIA accepts no responsibility for problems caused by negligence or improper use.
- FRAGILE: handle with care
- Do not exceed a inlet water pressure of 300 kPA (3 bar/43.5 psi).
- Keep dry. Store at room temperature.
- 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 after use. Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, the 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 contains phthalates. Considering the nature of contact with the body, the limited duration of contact and the number of treatments per patient, the amount of phthalates which might be released from the device does not raise specific concerns about residual risks. Further information is available on request from Sorin Group Italia.
- Do not subject to further treatments.
- Do not resterilize.
- After use, dispose of the device in accordance with the applicable regulations in the country of use.
- The device must only be used if STERILE.
- It is recommended that a cold agglutinin test be performed with the patient's blood before using the set. The temperature of cardioplegic solution should not be lower than the cold agglutination temperature if the test shows the cold agglutinin to be haemolytic.
- Do not allow the cardioplegic solution bags to empty completely.
- When used in conjunction with membrane oxygenators, to avoid introducing air into the circuit:
  - do not start cardioplegia pump until arterial pump is on
  - do not stop arterial pump until cardioplegia pump is off
  - arterial pump flow must always exceed cardioplegia pump flow.
- For further information and/or in case of complaint, contact SORIN GROUP ITALIA or your local authorised representative.



Health innovation that matters

**CAUTIONS:**

- 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.

## CSC14 and Helios Cardioplegia Heat Exchangers – 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 a correct dose and accurately monitor the anticoagulant before, during and after the bypass.
- 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 must not undergo any further processing.
- Do not resterilize.
- After use, dispose of the device in accordance with the applicable regulations in force in the country of use.
- The maximum pressure in the blood compartment must not exceed 100 KPa (1 bar/14.5 Psi).
- The water pressure in the heat exchanger must not exceed 200 KPa (2 bar/29 Psi).
- The water temperature must not exceed 42°C (107.6°F).
- CSC14 and its accessories must be handled using sterile techniques. - CSC14 can only be used with an appropriate HSC holder (fig.2).
- Make sure that the main pump flow always exceeds that of the cardioplegia pump.
- The device contains phthalates. Considering the nature of body contact, the limited contact duration and the number of treatments per patient, the amount of phthalates which might be released from the device do not raise specific concerns about residual risks. Further information is available on request from Sorin Group Italia.
- Only use the device if it is STERILE.
- It is recommended that a cold agglutinin test be performed with the patient's blood before using the set. The temperature of cardioplegic solution should not be lower than the cold agglutination temperature if the test shows the cold agglutinin to be haemolytic.
- Do not allow the cardioplegic solution bags to empty completely.
- For further information and/or in case of complaints contact SORIN GROUP ITALIA or the authorised local representative.



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#### **WARNINGS FOR HELIOS:**

- The device must be used in accordance with the instructions for use provided in this manual.
- The device is intended to be used by professionally trained personnel.
- SORIN GROUP ITALIA is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- Keep dry. Store at room temperature.
- 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 after use. Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, the reuse increases the probability of product failure (integrity, functionality and clinical effectiveness).
- Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.

#### **CAUTIONS:**

- 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.