

D100 KIDS ALL MODELS and D101 KIDS ALL MODELS – Important Safety Information

WARNINGS:

- The User should carefully check the device during set-up and priming for leaks. Do not use if leaks are 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 accurate monitoring of 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 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 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.
- 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.
- For further information and/or in case of complaint contact SORIN GROUP ITALIA or the authorised local representative.

CAUTIONS:

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- The internal surface of the system is Ph.I.S.I.O. coated; currently, no contraindications relating to use of the systems equipped with Ph.I.S.I.O. treated components is known to SORIN GROUP ITALIA.

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.

D 901 LILLIPUT 1 ALL MODELS, D 902 LILLIPUT 2 ALL MODELS and D 920 TWIN RESERVOIR – Important Safety Information

WARNINGS:

- 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.
- 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
- Always apply and maintain a correct dose and accurate monitoring of the anticoagulant before, during and after the bypass.
- The device must not undergo any further processing.
- Do not reesterilise.
- 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.
- For further information and/or in case of complaint contact **SORIN GROUP ITALIA** or the authorised local representative.

ONLY ON D 920 TWIN RESERVOIR

- Do not expose to temperatures below 0°C (32°F) or above 60°C (140°F). - Keep dry.
- Never exceed 100 mmHg (1.93 psi, 13.33 kPa, 133 mbar) of negative pressure when aspirating blood. Excessive vacuum can generate hemolysis.
- Use a safety valve on the vacuum line to avoid exceeding the above mentioned pressures.



Health innovation that matters

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