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# Dideco & Sorin Perfusion Tubing Systems – Important Safety Information

**WARNINGS:**

- Only use the unit if it is STERILE.
- 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 administer 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 resterilise.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.
- Sterility is guaranteed only if the sterile packaging is not wet, opened, damaged or broken. Do not use the device if sterility cannot be guaranteed.
- Check the expiry date on the label attached. Do not use the device after the date shown.
- The device must be used immediately after opening the sterile packaging.
- The device must be handled aseptically.
- Carry out a visual inspection and carefully check the device before use. Transport and/or storage conditions other than those prescribed may have caused damage to the device.
- Do not use solvents such as alcohol, ether, acetone, etc.: as contact may cause damage to the device.
- Do not allow halogenated liquids such as Halothane and Fluothane to come into contact with the polycarbonate housing of the device. This could cause damage which may compromise the integrity and proper functioning of the device.
- The instructions for use of individual components should be read and understood also.
- Carefully read and follow the instructions for use of the manufacturer of the Heart Lung Machine (HLM) in use regarding tubing specifications and installation.
- Handle all tubing carefully to avoid damaging it.

- The user is responsible for any changes made either to the set or to the procedure that may affect the function of the set.
- Carefully check for leaks before and during use. Leaks may cause loss of sterility, loss of perfusate, or air emboli. Should leakage be observed before or during use, re-tighten or replace the leaking component following good perfusion practice. The use of an arterial filter or bubble trap is recommended to reduce the possibility of transmitting gaseous emboli to the patient when used in accordance with manufacturers instructions.
- If the set contains a pre-bypass filter, it must not be exposed to blood or other cellular fluids and must be removed before initiating bypass.
- The effectiveness of myocardial cooling may only be ascertained by the measurement of myocardial temperature.

**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.

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# Phtalates – Important Safety Information

**WARNINGS:**

- 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).
- 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

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# PH.I.S.I.O coating - Important Safety Information

**WARNINGS:**

- The blood to be treated should contain anticoagulant. Always apply and maintain a correct dose and accurate monitoring of the anticoagulant before, during and after the bypass.
- The PH.I.S.I.O. coated devices should not be used longer than 6 hours. Contact with blood for longer periods is not advised.
- Read all warnings of the Instruction for use related to the specific device.