

Sorin Group Cardio Accessories, DIDEKO CARDIOACCESSORIES – Important Safety Information

WARNINGS:

- The device must only be used if 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.
- 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.
- If on the label is present the symbol then 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
- 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.
- For further information and/or in case of complaint contact SORIN GROUP ITALIA or the authorised local 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.