LivaNova

Health innovation that matters

D905 EOS ECMO – Important Safety Information

INDICATIONS:

The D905 EOS ECMO is intended for use in an extracoporeal circuit as a device to replace the function of the lungs (transfer of oxygen and removal of carbon dioxide) in order to control the arterial/venous temperature during extended respiratory support applications (i.e. ECMO). The blood to be treated should contain anticoagulant. The D905 EOS ECMO should not be used longer than 5 days. Contact with blood for longer periods is not advised. The D905 EOS ECMO should be used in combination with medical devices listed in section L (Medical devices for use with the D905 EOS ECMO).

CONTRAINDICATION:

No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions. Do not use the device for any purpose other than indicated.

WARNINGS:

1. The device must be used in accordance with the instructions for use provided in this manual.
2. The device is intended to be used by professionally trained personnel.
3. SORIN GROUP ITALIA is not responsible for problems arising from inexperience or improper use.
4. FRAGILE, handle with care.
5. Do not expose to temperatures below 0°C (32°F) or above 60°C (140°F).
6. Keep dry.
7. Always give and maintain a correct dose and accurate monitoring of the anticoagulant before, during and after the bypass. The risk of total systemic anticoagulation must be weighed against the benefits of extracorporeal support when this device is considered.
8. Technical complications during long-term use are generally due to ineffective anticoagulation, which reduces oxygenator efficiency. Procedures lasting >6 hours should include monitoring of blood compartment pressure drop, whole blood coagulation time, inspection for thrombus formation and system component wear.
9. 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).
10. Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.
11. The device must not undergo any further processing.
12. Do not resterilise.
13. After use, dispose of the device in accordance with applicable regulations in force in the country of use.
14. The device must only be used if sterile.
15. This device does not allow the administation of anaesthetic gases (i.e. isofluorane) to the patient.
16. This device is Phosphorylcholine (Ph.I.S.I.O.) coated; currently SORIN GROUP ITALIA is not aware of any contraindication to the use of systems
having components treated with Phosphorylcholine.For further information and/or in case of complaint contact SORIN GROUP ITALIA or the authorised local representative.

LivaNova

Health innovation that matters

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.