

EVO SYSTEM – Important Safety Information

WARNINGS:

Introduction (Chpt 1)

- In accordance with regulations, the occluder is used for controlled regulation of the venous blood flow for extracorporeal perfusion. The occluder is only intended for use in combination with the S5/C5 System during extracorporeal perfusion. Any use beyond this specification is not in accordance with the regulations. LivaNova Deutschland GmbH will not assume any liability for damage in such a case. Usage in accordance with regulations also includes compliance with the operating instructions, as well as routine maintenance
- The occluder has been designed according to current state-of-the-art technology and accepted safety standards. Although this may be the case, danger may arise for the patient, the user or for other equipment during operation.
- The occluder must not be operated near explosive materials.
- The occluder may only be used when in running technical order and according to regulations and
- the operating instructions. Be sure to take note of any cautions or warnings.
- The operating instructions must be available close to the machine at all times. Incomplete or illegible operating instructions must be replaced immediately.
- Also applicable to the occluder in combination with the S5/C5 System (overall system): According to European Directive 93/42 EEC and the national standards based on this directive, the occluder must be subjected to a regular maintenance check by an authorised service representative. The maintenance check must be performed after every 1000 operating hours or at least every 12 months, whichever comes first.
- In addition to the operating instructions, the relevant legal, general and binding regulations concerning the prevention of accidents must be observed.
- In order to take situations into account which are clinic-specific and outside of normal routine, e.g. certain working procedures, the operating instructions must be supplemented with relevant instructions (supervision and registration requirements, etc).
- An S5/C5 System is required to operate the occluder. You will find details of the firmware inside the front cover and in the separate operating instructions for the S5/C5 System.
- Only authorized service technicians may upgrade the relevant firmware.
- If modifications affecting safety or machine performance are noticed when the occluder is not in use in the O.R., shut down the machine immediately and have it checked by an authorised service technician.
- Do not perform any modifications or extensions to the occluder, unless they have been tested and approved by LivaNova Deutschland GmbH. LivaNova Deutschland GmbH cannot assume liability or responsibility for unauthorised modifications or changes.
- Keep the occluder clean. Doing so will prevent malfunctions due to dirt.
- Only PVC tubing may be inserted into the occluder.
- Never insert your finger(s) into the occluder to avoid injuries.
- The safety instructions for the overall system in which they are being used apply to the occluder at all times.
- The occluder is only intended for use with the S5/C5 System.

- Prior to working with the S5/C5 System, the user must have thoroughly read the separate operating instructions and have become familiar with the machine functions!
- The occluder and the S5/C5 System must only be operated when being continually monitored by a trained user. Noncompliance with this responsibility of monitoring the equipment can result in a danger to the patient! The safety features of the S5/C5 System (alarm signals etc.) are intended to be a support for the user and do not free him from the responsibility to continuously and conscientiously monitor the system.
- Prior to working with the occluder, the user must have thoroughly read the operating instructions and have become familiar with the functions of the unit.
- Monitor the perfusion process continuously, so that you are able to correct the occluder to adapt to a given situation at any time.
- For safety reasons, keep a conventional surgical clamp ready and ensure that the venous line is accessible.
- Make sure that the occluder flap and the inserted tube are clearly visible.
- The inserted tubing must be suited for a pressure of at least 500 mmHg.
- To calibrate the occluder, the temperature of the inserted tube must be $+22\text{ °C} \pm 2\text{ °C}$.
- In an open perfusion system, the occluder must only be used when the S5/C5 System level monitoring is active.
- Modifications or extensions to the occluder, as well as accessories or spare parts which have not been tested and approved by LivaNova Deutschland GmbH may have negative effects on the safety and function of the system. LivaNova Deutschland GmbH cannot accept any liability or responsibility.

Operations (Chpt5)

- Only the PVC tube sizes listed in the menu may be used with the occluder (see also Chapter 7.1.1 „Dimensions, weights, operating conditions“ on page 7.1).
- In an open perfusion system, the occluder must only be used when the S5/C5 System level monitoring is active. For information on activating level monitoring, please refer for the separate operating instructions of the S5/C5 System.

Routine maintenance (Chpt 6)

Regular maintenance and care are important factors for the operation of the occluder as they result in

- ▶ increased operational safety,
 - ▶ lower susceptibility to failure, and
 - ▶ increased service life for all components
- Completely disconnect the occluder from the S5/C5 System, before carrying out routine maintenance work.
 - Do not fail to observe the regulations concerning routine maintenance in these operating instructions, as well as the prescribed maintenance intervals for the S5/C5 System.
 - Comply with the separate operating instructions for all accessories.
 - Use recommended cleaning agents.

- Wear protective gloves when disconnecting used tubing sets and disposables.
- Routine maintenance work must only be performed by qualified personnel.
- Repair work on the occluder must only be carried out by authorised service technicians. Only original spare parts from LivaNova Deutschland GmbH are to be used in order to guarantee the safe functioning of the occluder.

Cleaning:

- Use only lint-free cloths, which have been moistened with water and will not disintegrate.
- Rub the machine dry.
- Always wipe off spills (blood etc.) from the occluder as quickly as possible.
- To avoid biological contamination and corrosion, the surface of the occluder must be cleaned with a mild detergent after each use.
- Never use detergents containing oil or grease.
- Never use cleaning agents containing acetone, as these can cause damage to the plastics or the lacquered surfaces.
- If possible, avoid using cloths that generate static charging (polyester or similar synthetics).
- Liquids must not enter the housing (do not use sprays).

Disinfecting:

- Use only alcohol-based hospital-grade hand disinfectants.
- Only use lint-free cloths moistened with disinfectant.
- Again ensure that no liquids enter the machine housing.

Cleaning and disinfecting the mast holder:

The instructions and information concerning the cleaning and disinfection of the overall system apply to the mast holder at all times. In addition:

Ensure that the clamping lever is secured before cleaning and disinfecting.

- Make sure that no liquid enters the joint of the mast holder. Loosen the clamping lever if necessary. Use compressed air to blow out the joint carefully or leave the joint to dry.

Check the function of the mast holder and swivel arms after cleaning and disinfecting.

CAUTIONS:

- When opening fast clamp connectors: Hold the mounted components in place, before opening a fast clamp connector

- Securing the cables and the tubings is a prerequisite for the safe transport and operation of the S5/C5 System. This will prevent the machine rolling over a cable and/or a cable/tube being pulled out unintentionally.
- The control unit may only be connected to the system slots on the S5 System.

Operations (Chpt5)

- Read this entire chapter carefully before using the occluder for the first time.
- To enable correct measurement and display of the cross-sectional change, occlude calibration must be performed before every use.
- Note: Once calibration has taken place, the tubing position in the occluder must not be changed. If the position of the tubing pinched during calibration is changed, this could affect other measurement values
- In this situation, the occluder can also be used without calibration and operation be continued with increased care and attention. Full opening and closing (0 and 100%) is assured. Because there has been no calibration, all the other set value displays (from 1 to 99%) may differ from the value actually measured

Routine maintenance (Chpt 6)

- The instructions for routine maintenance, which are given in the following sections, are part of the operating conditions for the occluder.

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.