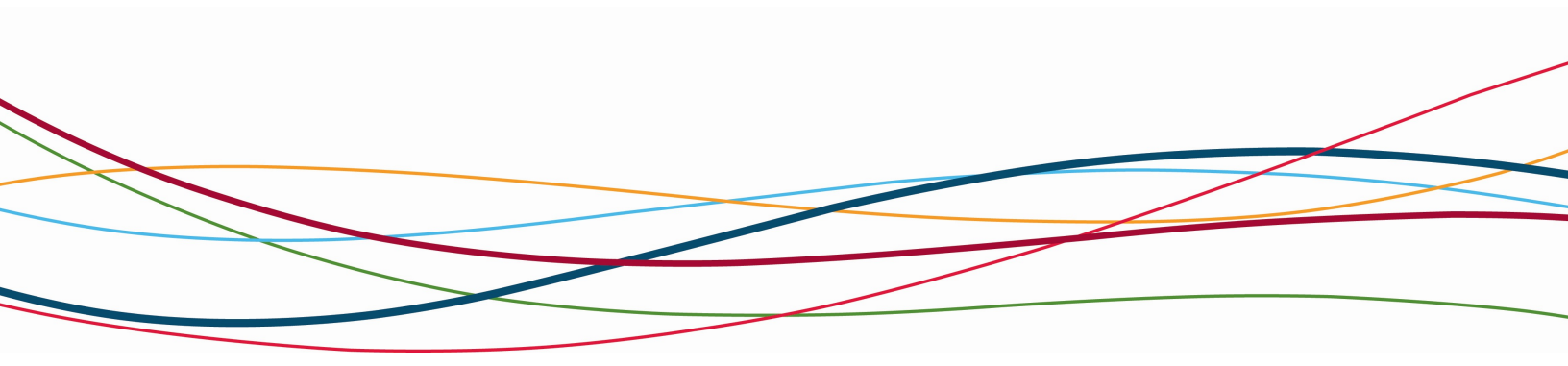




Extracorporeal Life Support (ECLS) Adult E-VAD Tubing Pack Instructions For Use



English



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SUPPLIED STERILE AND READY FOR USE — DO NOT USE IF PACKAGING IS DAMAGED OR ANY STERILE SEALS ARE BROKEN.

1 Description

The ECLS Adult E-VAD Tubing Pack (for use with CentriMag™) is a priming set designed to be used with the CentriMag™ Extracorporeal Ventricular Assist Device [E-VAD] (blood pump) to facilitate priming & de-airing of the tubing & pump while maintaining sterility of the circuit in the sterile field. The ECLS Adult E-VAD Tubing Pack (for use with CentriMag™) is sterilised with ethylene oxide.

2 Intended Use / Indications

This ECLS Adult E-VAD Tubing Pack is indicated for use only with the CentriMag™. The ECLS Adult E-VAD Tubing Pack (for use with CentriMag™) is not designed, sold, or intended for use except where indicated.

3 Duration of Use

The ECLS Adult E-VAD Tubing Packs are intended for clinical use of up to 6 hours.

4 Contraindications

The ECLS Adult E-VAD Tubing Pack (for use with CentriMag™) is contraindicated for patients who are unable or unwilling to be treated with appropriate anticoagulants such as heparin. Do not use protamine before or during the ECLS support of patients undergoing heparin mediated anticoagulation.

5 Storage

Even with correct storage the tubing packs have a limited shelf life. Please pay attention to the expiry date on the device packaging. The device has to be stored in a dry, frost-free area and protected from direct solar or UV light. Storage temperatures are detailed on the product label.

6 Tubing Specifications

Tubing Specifications to include data from TPSS sheets.

Tubing Specifications						
Product Code	Priming/Blood Volume (ml)	Duration of use/ Lifetime (Hours)	Max Pressure (mmHg)	Clinical Flow Rate Limits (L/min)	All Component Flow Rate Limits (L/min)	All Components Priming Flow Rate limits (L/min)
CME90048	1323.235	360	750	0-8.0	0-3.0	0-3.0
CM1752	1464.995	6	750	0-8.0	0-3.0	0-3.0

Information relating to tubing specifications detailed below is to be made available at the point of use.

7 Side Effects

There are no known side effects.

8 Risk

Healthcare professionals experienced in the intended use should be fully aware of how ECLS Tubing Packs work, thus decreasing the risk of incorrect use.

9 Warnings

- Instructions for use and manuals for all related CentriMag™ System elements (Console, Motor & E-VAD) should be read prior to using the ECLS Adult E-VAD Tubing Pack (for use with CentriMag™), hereafter referred to as the 'tubing pack'.

- Possible side effects related to the tubing pack include, but are not limited to: infection, mechanical failure, leakage, embolism, neurologic dysfunction, end organ dysfunction, bleeding. These are potential side effects with mechanical circulatory support systems.
- Ensure that the tubing pack and the blood pump have been de-bubbled & primed properly prior to use to minimise the risk of air reaching the patient.
- It is intended that systemic anti-coagulation be utilised while the tubing from this circuit is in use. Anti-coagulation levels should be determined by the physician based on risks & benefits to the patient.
- The tubing pack is designed to be operated only with the CentriMag™ blood pump. There is no safety or performance data known to Thoratec Switzerland GmbH which establishes compatibility of any other manufacturer's devices or components to this tubing pack.
- The CentriMag™ blood pump must be handled in an aseptic manner until primed and connected to this tubing pack priming circuit.
- Do not operate the CentriMag™ blood pump with its inlet clamped as a negative pressure will be generated into the system and air bubbles may be formed inside.
- Monitor the red stripe outlet tubing for air because the CentriMag™ blood pump, similar to other centrifugal pumps, will pump air. Stop infusion if air enters the priming circuit as gaseous emboli may be introduced into the patient, with attendant risk of death or severe bodily injury.

10 Cautions

- This tubing pack is designed for use in an operating environment. While the priming circuit does not require a sterile field for preparation & priming, care must be taken to maintain sterility of selected components.
- This device should only be used by persons thoroughly trained in extra-corporeal circulation procedures.
- This tubing pack is supplied sterile in an unopened & undamaged package. Inspect the tubing pack & packaging carefully prior to use. Do not use if the package or components have been dropped or damaged.
- This tubing pack is intended for single use only (to avoid cross contamination). Do not re-sterilise. Re-sterilisation by any means may cause severe damage to the device or its components. Dispose of safely after single use to avoid risk of infection.
- Attach tubing in such a manner as to prevent kinks or any restrictions that may alter flow, and in a manner that does not bend or fracture the barbed tubing ports & connectors. Extend the tubing beyond the second barb on the connectors.
- Monitor carefully for any signs of occlusion throughout the circuit.
- Do not use excessive force to install the tubing on the CentriMag™ blood pump as damage to the blood pump & 3/8" pump connectors may occur.
- Take care to prevent damage to the CentriMag™ pump & tubing pack connectors when setting up and de-airing the E-VAD & priming circuit.
- Always have a spare ECLS Adult E-VAD Tubing Pack (for use with CentriMag™) readily available.

11 Pre-Use Checklist

1. Verify that all the items listed in the table below are provided inside the ECLS Adult E-VAD Tubing Pack (for use with CentriMag™) packaging.

Item	Contents Description
1	Table Tray containing sterile Inlet & Outlet E-VAD lines.
2	E-VAD Inlet Tubing (Blue Stripe 3/8 x 3/32 PVC Tubing).
3	E-VAD Outlet Tubing (Red Stripe 3/8 x 3/32 PVC tubing).
4	E-VAD tubing Pack 1000 mL soft shell reservoir.
5	E-VAD tubing Pack fill line (1/4 x 1/16 PVC tubing with prime spike & clamp).
6	20 mL Syringe to assist air venting.

2. Check the expiration date and integrity of the sterile circuit packaging prior to use (do not use if date has expired).

12 Circuit Set-up & Priming

1. Remove the ECLS Adult E-VAD Tubing Pack (for use with CentriMag™) from the correx box & tyvek / breather bag. Do not remove the sterile tubing from inside the A.V Loop Tray—this will maintain tubing sterility while the circuit is being primed.
2. If needed, add an appropriate anticoagulant such as heparin to a 1 litre bag of sterile injectable saline and hang on a drip stand. Hang the reservoir bag using the green loop at a slightly lower level to that of the saline bag.
3. Wearing sterile gloves, remove the blood pump from its packaging and, while maintaining sterility of the exposed connectors, connect the capped blue stripe line from the A.V Tray to the top inlet port of the pump.
4. As above, connect the capped red stripe line from the A.V Tray to the side outlet port of the pump. Ensure A.V Tray is held horizontal to assist de-airing.
5. Fully close the white clamp on the prime line to this tubing pack reservoir bag. Pierce the bag of saline with the circuit prime line spike.
6. Clamp the blue stripe inlet & red stripe outlet lines approximately 2 cm from the reservoir bag with tubing clamps.
7. Open the white clamp on the prime line, allowing the reservoir bag to fill with anti-coagulated saline through the priming port on the bottom of the bag.
8. Once the reservoir bag is full, close off the white clamp and gently release the tubing clamp on the blue stripe line first, allowing the circuit to slowly fill with fluid. Once it has found a level, gently release the tubing clamp on the red stripe line allowing the rest of the circuit to fill through.
9. Encourage air bubbles in the circuit & pump through the red stripe line and back into the reservoir. Vent any built up air in the reservoir through and out of the 1-way valve & tap on the top of the reservoir.
10. Once the circuit is fully wetted through, place the pump into the motor drive and secure with the retaining screw on the side—this will ensure a correct and flat placement of the pump.
11. Using the CentriMag™ console, slowly increase pump speed to initiate flow, allowing the last remaining air bubbles in the circuit to be removed and purged from the reservoir bag.
12. Once the circuit is completely free of air the pump can be stopped and both the blue stripe inlet & the red stripe outlet tubes, can be clamped between the reservoir bag & A.V Tray with 2 pairs of tubing clamps.
13. When securely clamped, both lines can be cut between the tubing clamps, and the reservoir bag can be discarded as the circuit is now ready for connection to the patient.

13 Circuit Connection to Patient

1. Carefully remove the 3 gas tapes securing the lid to the A.V Tray.
2. Remove the lid and allow the tubing inside the tray to be removed by a person within the sterile field.
3. The sterile tubing should be clamped and cut to an appropriate length, discarding any excess tubing from the sterile field.
4. Follow the instructions provided in the CentriMag™ blood pump IFU for proper insertion and placement for the inlet & outlet cannula.
5. Position this tubing pack's blue stripe inlet tubing next to the ventricular / atrial cannula and the tubing pack's red stripe outlet tubing next to the arterial cannula. The tubing can now be cut to its final length. Ensure that the clamp is placed distal from the point at which it will be cut.
6. Connect the tubing pack's red stripe outlet tubing to the arterial cannula and the tubing pack's blue stripe inlet tubing to the ventricular / atrial cannula, ensuring the connection is bubble free. A bulb syringe full of saline may be used to continuously irrigate whilst the connections are made.
7. Remove all clamps from the circuit, with the exception of the clamp on the blood pump red stripe outlet tubing.
8. Connect the flow probe to the tubing according to the instructions provided in the CentriMag™ Console Operating Manual.

CAUTION

Do not hit or strike the pump with hands or instruments. Shock may cause damage to the device, which can lead to malfunction.

WARNING

Do not reverse the inlet & outlet cannula connections. Reversal of inlet & outlet will limit effective circulatory support.

WARNING

Do not operate the pump with its inlet clamped as a negative pressure would be generated and air bubbles may be formed in the blood.

WARNING

If leaks or other anomalies are found on the pump, connectors or any part of the circuit, remove and replace —repeating the above steps to prime.

WARNING

Massive air entry into the pump will cause the pump & circuit to de-prime and blood flow to stop. Clamp the red stripe outlet tubing and stop the pump. Remove air prior to resuming circulation.

WARNING

Ensure that the pump & circuit have been de-bubbled and primed properly to minimise the risk of air reaching the patient.

14 Disposal

After use, ECLS Tubing Packs must be disposed in accordance with applicable clinical and local regulations in force in the country of use.

15 Explanation of Symbols

Do Not Re-Use		Use By	
Date of Manufacture		Fragile handle with care	
Manufacturer		Keep dry	
Do Not Re-Sterilise		Addition of number to determine how many products are in the packaging.	
Do Not Use if Packaging is Damaged		Keep away from sunlight	
Temperature limitation		EC Authorised Representative	EC REP
Sterilised Using Ethylene Oxide	STERILE EO	CH Authorised Representative	CH REP
Medical Device	MD	CE Mark	CE
Consult Instruction for Use		Language Symbol – assigned as required	en it es
Single Sterile Barrier System		Importer	
Single Sterile Barrier System with Protective Packaging Outside		Lot Number	LOT
Catalogue Number	REF		

16 Further Information

All serious incidents relating to this product should be reported to Chalice Medical Ltd or Sales Representative and the Competent Authority of the Member State in which the user and/or patient is established. The report can be made by email to quality@chalicemedical.com.

A product associated with an incident must not be disposed immediately after use. If the product is to be returned for any reason, please seek prior approval from Chalice Medical Ltd. If the product is contaminated, it is the responsibility of the User to adequately prepare and label the product for return shipment. The shipping address for returns is the Manufacturer's address. It is encouraged to electronically record the Unique Device Identifier (UDI) of products that are supplied.

The following information is available upon request: the sterilisation method and the list of the materials of the blood pathway. Along with a physical copy of the IFU a QR code is provided on the product packaging to allow users to obtain a PDF version of the IFU. For further information or additional copies of the IFU, they can be obtained from enquiries@chalicemedical.com.

17 Economic Operator Contacts

EC Importer



EC Authorised Representative



Prinses Margrietplantsoen 33 – Suite 123
595 AM The Hague
The Netherlands

CH Authorised Representative & Importer



18 Warranties and Statement of Commitments

The manufacturer guarantees that the products have been manufactured, sterilised, and packaged according to the MDR Regulations 2017/745.

All components produced are thoroughly tested before being packaged. The manufacturer is obliged to replace any product that is found to be damaged at the time of shipment. Products with defects must be returned to the investigation. Due to non-controlling factors, i.e., transmission, storage and user behavior, the manufacturer can not guarantee that the product is not defective.

The manufacturer can not be held liable for damages caused by the use or misuse of the product for purposes other than those for which it is intended. The manufacturer is not liable for any damage resulting from repeated sterilization or re-use of the product.

19 Limitation of Liability

Translations are performed to be the best of our knowledge. We accept no liability for translation errors, even if the translation has been carried out by us or on our account. Only the original English text remains binding.



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