

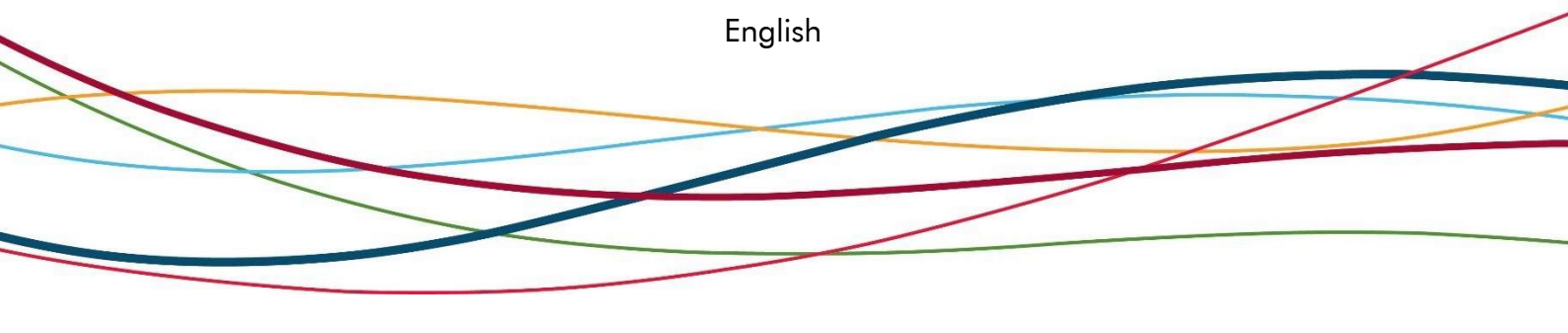


Extracorporeal Life Support (ECLS) Tubing Pack

Instructions for Use



English



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Important Information

Please read Instructions for Use (IFU), prior to use in a clinical setting. The information contained within this booklet is for guidance only. There is a wide variety of perfusion techniques, it is the responsibility of the user to determine the appropriate application method.

This IFU only relates to the ECLS Tubing Pack.

The IFU of individual components which may be contained or used in conjunction with the ECLS Tubing Pack such as membrane oxygenators, reservoirs, filters, heat exchangers, haemoconcentrators must be carefully read and observed. This is available upon request, from enquiries@chalicemedical.com.

1 Intended Use

ECLS Tubing Packs are intended to be used for extracorporeal life support (ECLS) procedures, including extracorporeal membrane oxygenation (ECMO), cardiopulmonary bypass (CPB) and ventricular assist devices (VAD) procedures and circuits.

This instructions for use cover the following categories of ECLS Tubing Packs:

- Bypass Tubing Pack (Coated/ Uncoated)
- ECMO Tubing Pack (Coated/ Uncoated)
- Bypass Tubing Pack including Oxygenator (Coated/ Uncoated)
- ECMO Tubing Pack including Oxygenator (Coated/ Uncoated)
- Ancillary Components
- Cardiopulmonary Bypass System Priming Set

ECLS Tubing Packs enable the connection of a variety of functional components or medical devices into one complete circuit.

ECLS Tubing Packs are supplied sterile and intended for single use only.

2 Treatment Population

ECLS Tubing Packs are intended for use within all patient populations, including neonatal, infant, paediatric, and adult patients. ECLS Tubing Packs are designed and manufactured for the intended population in mind.

3 Indications

ECLS Tubing Packs are indicated for a broad range of ECLS procedures for a wide range of medical conditions, both acute and chronic.

4 Contraindications

Do not use for any other purposes other than indicated.

ECLS Tubing Packs containing silicone pump-boot/ raceway (for use with peristaltic roller pump) are NOT for use in extracorporeal membrane oxygenation (ECMO).

Do not use protamine before or during the ECLS support of patients undergoing heparin mediated anticoagulation.

5 Duration of Use

ECLS Tubing Packs are intended for clinical use of up to 6 hours.

Tubing Packs intended for ECMO are intended for clinical use up to 15 days.

Usage beyond these timeframes is at the discretion of the user and should be based on a benefit-risk analysis. This is considered to be off-label use.

6 Further Description

ECLS Tubing Packs are only intended to be used by trained healthcare professionals.

ECLS Tubing Packs are manufactured as standard or according to user specifications. The product codes and description can be located on the product packaging.

ECLS Tubing Packs can be used in combination with other devices and accessories provided that they are CE marked. This is at the discretion of the user.

ECLS Tubing Packs are supplied sterile, latex free and sterilised by ethylene oxide.

7 Tubing Specifications

Tubing Specifications					
Intended Use	Internal Diameter (in)	Internal Diameter (mm)	Wall Thickness (in)	Wall Thickness (mm)	Tubing Cross-Sectional Area (mm)
Main Circuit (Blood/ Gas Tubing)	1/2	12.70	1/8	3.20	126.68
	1/2	12.70	3/32	2.40	126.68
	3/8	9.50	1/8	3.20	70.88
	3/8	9.50	3/32	2.40	70.88
	3/8	9.50	1/16	1.60	70.88
	1/4	6.35	3/32	2.40	31.67
	1/4	6.35	1/16	1.60	31.67
	3/16	4.75	1/16	1.60	17.72
Ancillary Tubing Lines	1/8	3.20	1/16	1.60	8.04
	1/8	3.20	1/32	0.80	8.04
	N/A	2.90	N/A	1.30	6.61
	N/A	3.50	N/A	1.00	9.62
	N/A	4.80	N/A	1.00	18.10
	N/A	2.00	N/A	1.00	3.14

As Chalice Medical ECLS Tubing Packs are bespoke medical devices, the priming volume/ blood volume of each product is provided to the user with the signed customer drawing approval form alongside the product drawing, maximum pressure, and flow rate limitations for the device. The individual authorising the signing of the customer drawing approval form assumes responsibility for this information being available at point of use. An additional Tubing Pack Specification Sheet is included with each device to ensure the information is available at point of use.

Where the priming volume of specific tubing lines is required, the following equation is used to calculate the blood volume of tubing used:

$$\text{Tubing Volume} = \text{Tubing Cross-Sectional Area} \times \text{Tubing Length} \div 1000 \text{ (millilitres)}$$

Patient Specifications and Tubing Maximum Flow Rates			
Internal Diameter (in)	Maximum Flow Rate (L/min)	Patient Population	Estimated Patient Weight (kg)
1/2	8	Adult	>40
3/8	8	Adult/Paediatric	16-40
1/4	3	Infant/ Paediatric	4.5-16
3/16	1.4	Neonatal	<4.5

Tubing length and dimensions are provided to all customers during product approval. Blood Pathway Dimensions will always be displayed with inner diameter x wall thickness; other numbers dictate length in centimetres (cm).

8 Side Effects

There are no known side effects.

9 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.

10 Warnings

- Check expiry date on the product label prior to use. Do not use if date has expired.
- Check integrity of sterile packaging before use. Do not use if sterile packaging or product is opened or damaged.
- Sterility can only be guaranteed if packaging has not been opened or damaged in any way.
- ECLS Tubing Packs are intended for single use only.
- Do not reuse. Reuse of a single use device may create a risk of cross-contamination or infection.
- Do not re-sterilise.
- Before use, visually inspect ECLS Tubing Packs for any damage.
- If zip ties are not secured correctly, a leak can occur. All zip ties must be secured tightly such that the connection does not move. Before and during use, ensure all connections made with the ECLS Tubing Packs are correct and secure, to alleviate any possibility of leaking.
- Air must be removed from within the circuit before clinical use to reduce the risk of air embolism.
- If phthalates are present within ECLS Tubing Pack, the DEHP symbol is detailed on the product label.
- Ensure adequate use of anticoagulants throughout the duration of use with regular monitoring. In the event of coagulation, stop treatment and replace the device.
- Do not kink the tubing of the circuit.
- Do not use the device beyond the technical limits imposed by this Instruction. Improper use outside the parameters of this instruction relieves the manufacturer of any responsibility for the consequences for the patient or third parties.
- In the event of allergic reactions or sensitization affecting patients while using the device, stop treatment immediately.
- In the instance of damaged devices or packaging, expired shelf-life, devices used over hours of operation, device leaks, the coagulation phenomena, or any persistent adverse performance characteristics, stop treatment and replace the medical device.
- After use, ECLS Tubing Packs are to be disposed of according to appropriate regulations.
- **The pressure of the blood circuit must not be higher than 750 mmHg (105 Pa), unless lower maximum pressures are recommended for attached devices or components.**

Warning - ECLS Tubing Packs containing one-way valve for ECMO and VAD

- A one-way valve must be removed from long term support circuits including circuits used for ventricular assist devices (VAD) and extracorporeal membrane oxygenation (ECMO) before the circuit is used clinically.
- A one-way valve may be used within the priming circuit to aid the removal of air, but these must be removed prior to connecting the circuit to the patient.
- A one-way valve, if used clinically within long term support circuits could allow thrombus to develop within the valve area. This is due to low anticoagulation levels used within the clinical application of these circuits.

Warning - ECLS Tubing Packs containing one-way valve for CPB

- One-way valves can be used in CPB circuits within the vent sucker lines. This is to reduce the possibility of incorrect directional use by the operator of the vent pump. If this does occur, without the one-way valve within the vent tubing line, air could enter a patient's circulatory system.

Warning - ECLS Tubing Packs containing stainless steel spiral

- A circuit with the stainless-steel spiral must be de-bubbled before use.
- A circuit with the stainless-steel spiral must be used within 6 hours of de-bubbling the circuit.
- The stainless-steel spiral may start to corrode when used for more than 6 hours when in contact with a cardioplegia solution.

Warning – ECLS Tubing Packs containing silicone pump-boot (for use with peristaltic roller pump)

Risks associated with use include:

- Spallation
- Leaching
- Haemolysis
- Tubing rupture

11 Shelf Life

The shelf life of ECLS Tubing Packs is a maximum of 1 year. The shelf life can be found on the product label.

12 Storage and Handling

Even with correct storage, ECLS 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.

13 Disposal

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

14 Explanation of Symbols

Do not re-use		Use by	
Date of manufacture		Fragile handle with care	
Manufacturer		Consult instruction for use	
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		Sterilised using ethylene oxide	
Keep dry		Components containing DEHP	
Language symbol – assigned as required		EC authorised representative	
Medical device		Importer	
CE mark		Single sterile barrier system with protective packaging outside	
Serial number		Single sterile barrier system	
Lot number/ batch code		Single sterile barrier system with protective packaging inside	
Catalogue Number		Consult electronic Instructions for Use	
Non-pyrogenic: Indicates a medical device which is non-pyrogenic			

15 Further Information

All serious incidents relating to this product should be reported to Chalice Medical Ltd, or a 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.

16 Economic Operator Contacts

EC Authorised Representative



MedEnvoy Global B.V

Prinses Margrietplantsoen 33 – Suite 123
2595 AM The Hague
The Netherlands

EC Importer



T.: +49 (0) 04120-70679-0

17 Warranty and Liability Statement

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

Chalice Medical Ltd warrants that all reasonable care has been taken during manufacture of this product. Products are carefully checked before being packaged. The manufacturer's obligation is to replace any products, which it determines were defective at the time of shipment. Faulty products must be returned for investigation. Because of factors that are out of the manufacturer's control i.e., shipping, storage and handling by the user, the manufacturer cannot guarantee that a product is without faults. The manufacturer can therefore not be made liable for damages, resulting from use or misuse of the product other than as intended. The manufacturer is not liable for any damages caused by re-sterilisation or re-use of the product.



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CD1586A

Rev: 10.1 – 2025/06

