

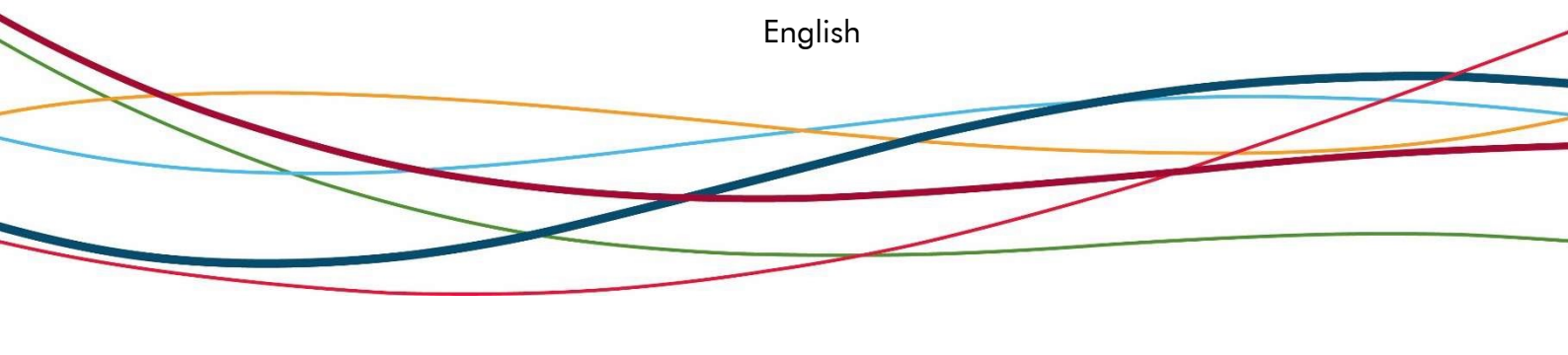


Extracorporeal Life Support (ECLS) Tubing Pack

Including Haemoconcentrator
Instructions for Use



English



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Important Information

Please read the 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, and it is the responsibility of the user to determine the appropriate application method.

1. Description

The ECLS Tubing Pack including Haemoconcentrator comes pre-connected. The tubing enables the connection of a variety of functional components or medical devices into one complete circuit. The haemoconcentrator removes plasma, water, and electrolytes from diluted blood across a semipermeable membrane.

2. Intended Use

During extracorporeal life support (ECLS), blood from a high-pressure arterial line in a cardiopulmonary bypass (CPB) circuit is passed through a haemoconcentrator. As the blood passes through the haemoconcentrator, plasma, water, and electrolytes are removed from diluted blood across a semipermeable membrane. Waste products are removed into a waste bag. Once haemoconcentration has been achieved, blood is returned via a venous line to the low-pressure venous system.

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

3. Treatment Population

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

4. Indications

ECLS Tubing Packs including Haemoconcentrators are indicated for use in a cardiopulmonary bypass circuit.

5. Contraindications

There are no known contraindications if ECLS Tubing Packs including Haemoconcentrators are used as described in accordance with this IFU. Do not use protamine before or during ECLS support of patients undergoing heparin mediated anticoagulation. Do not use for any other purposes other than indicated.

6. Duration of Use

ECLS Tubing Packs including Haemoconcentrators are intended for clinical use of up to 6 hours. It is recommended to replace ECLS Tubing Packs including Haemoconcentrators after this duration.

7. Further Description

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

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

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

8. 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).

9. Side Effects

There are no known side effects.

10. Risk

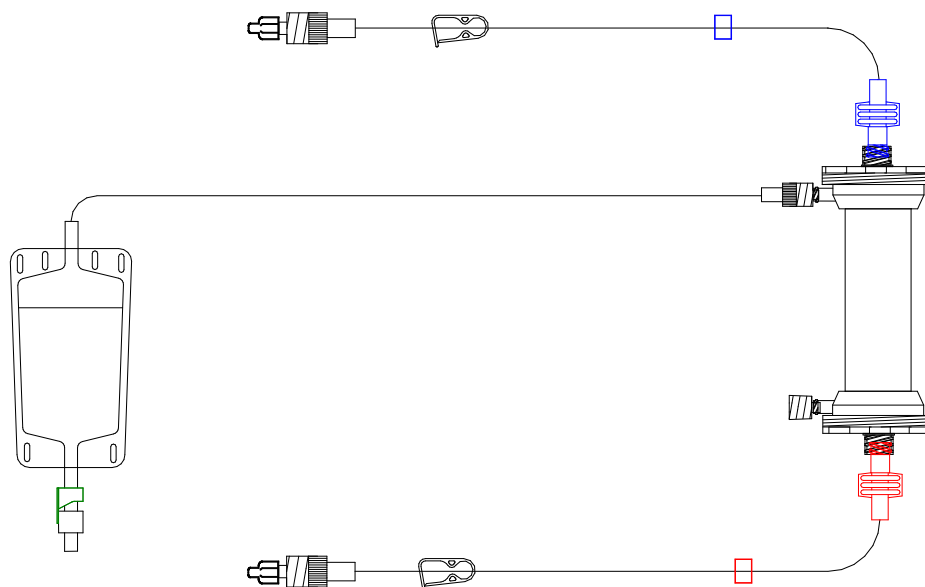
Healthcare professionals experienced in the intended use should be fully aware of how ECLS Tubing Packs including Haemoconcentrators function, thus decreasing the risk of incorrect use.

11. Technical Data

11.1 Technical Features

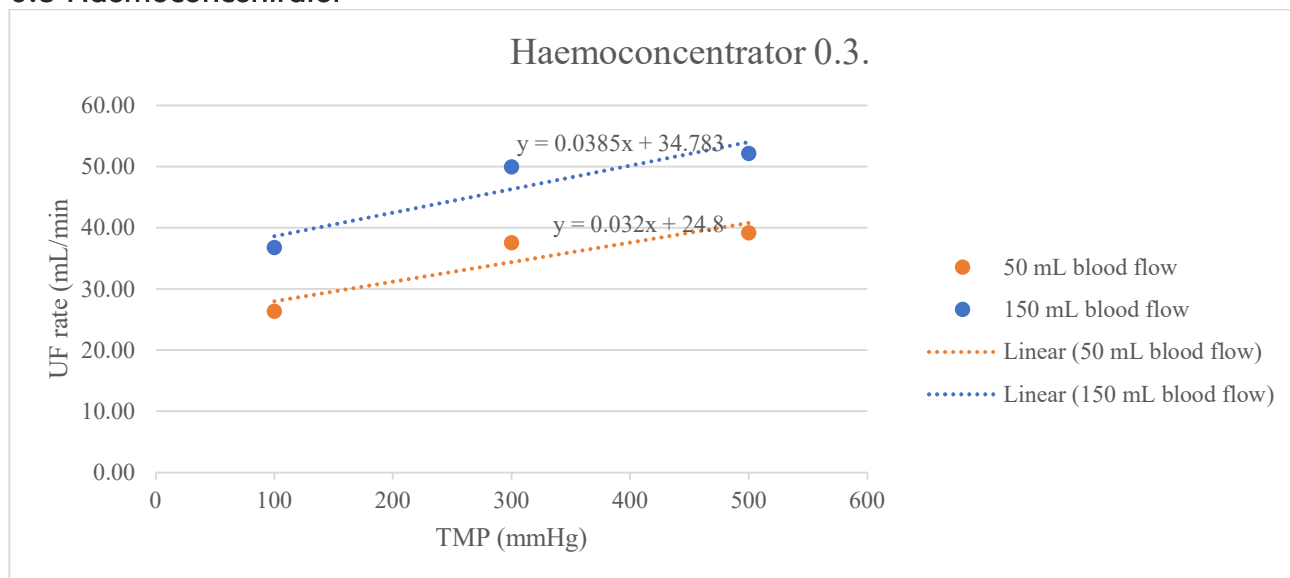
Intended use	Paediatric	Adult/ Paediatric	
Hollow fibre material	Polyethersulfone (PES)/ HIGH FLUX Purema®		
Membrane area/filtering surface (m²)	0.3	0.7	1.2
Fibre internal diameter (µm)	200		
Fibre external diameter (µm)	260		
Fibre wall thickness (µm)	30		
Fibre length (mm)	140		225
Number of fibres	3,600	9,300	9,300
Cartridge/ filter housing inner diameter (mm)	24	38	32
Volume of the blood compartment (mL)	28	73	119
Priming blood volume (mL)	28	73	119
Max blood flow (mL/min)	150	300	400
Minimum blood flow (mL/min)	50	100	100
Max transmembrane pressure (mmHg)	500		
Potting compound	Polyurethane		
Cartridge housing material	Polycarbonate (PC) / Copolyester – BPA Free		
Cartridge blood ports/cap material	Polycarbonate (PC) / Copolyester – BPA Free		
Cartridge blood connectors (cap)	Twist lock		
Cartridge filtrate/dialysate connectors (housing)	Female Luer Lock		
Unit total length (mm)	180	180	265
Average ultrafiltration rate (mL/h/mmHg)	14	32	55
Albumin sieving coefficient (%)	0.11		0.12
Average pressure drop of the blood compartment (mmHg)			
Minimum Flow Rate	12.20	10.60	15.80
Maximum Flow Rate	24.00	24.40	52.40

11.2 Sample diagram of an ECLS Tubing Pack including Haemoconcentrator

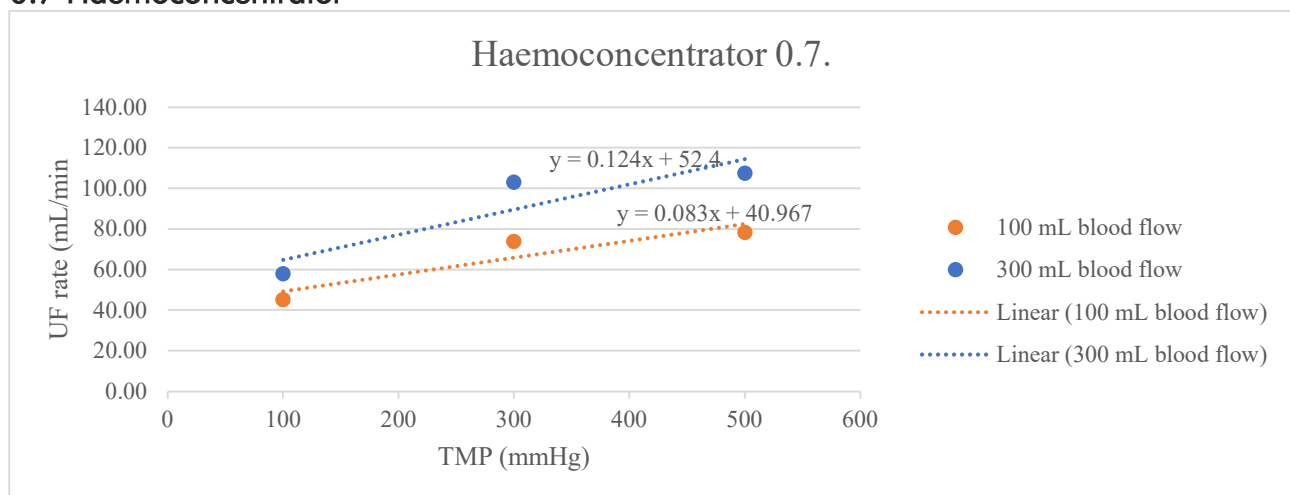


11.3 Ultrafiltration Coefficients

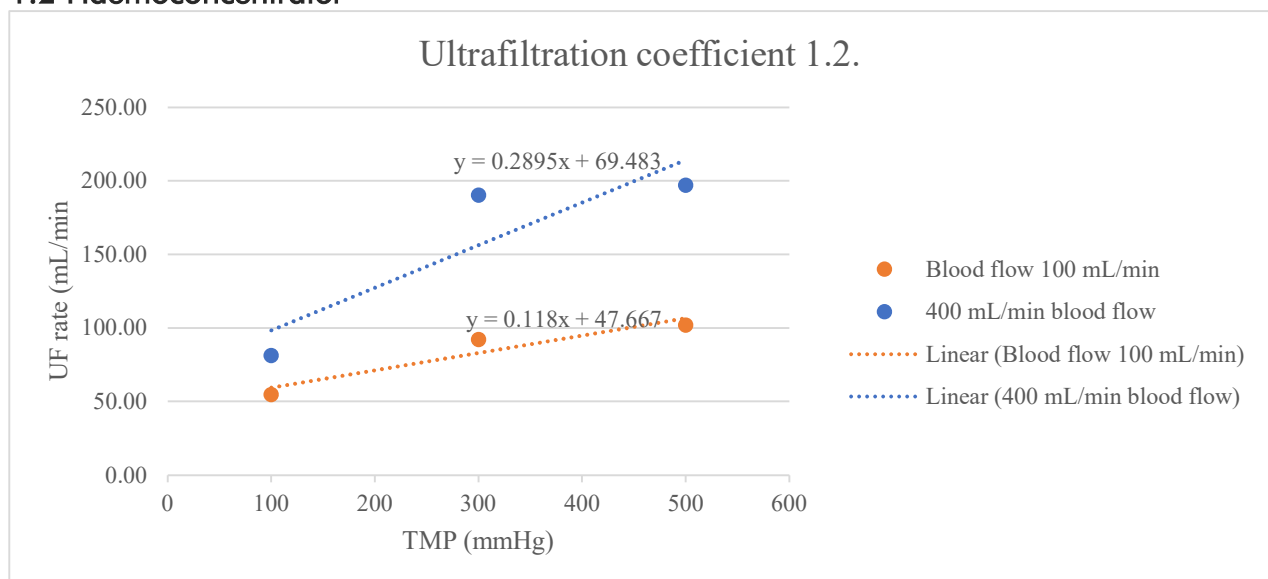
0.3 Haemoconcentrator



0.7 Haemoconcentrator



1.2 Haemoconcentrator



12 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 including Haemoconcentrators 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 including Haemoconcentrators for any damage.
- Before and during use, ensure all connections made with ECLS Tubing Packs including Haemoconcentrators are correct and secure, to alleviate any possibility of leaking.
- The flow within the device may differ from the flow displayed on any connected devices.
- Air must be removed from within the circuit before clinical use to reduce the risk of air embolism. It is recommended that an air detector be used if deemed necessary by the healthcare professional.
- If phthalates are present within ECLS Tubing Packs including Haemoconcentrators, the DEHP symbol is detailed on the product label.
- Increased pressure could be due to coagulation within the device. The flow rate should not drop below the recommended minimum flow rate for duration of use.
- Ensure adequate use of anticoagulants throughout the duration of use with regular monitoring. In the event of coagulation, stop treatment and replace the device.
- After use, ECLS Tubing Packs including Haemoconcentrators are to be disposed of according to appropriate regulations.
- Do not kink the tubing of the circuit.
- Do not use the device beyond the technical limits imposed by this IFU. 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 6 hours of operation, device leaks, coagulation, or any persistent adverse performance characteristics such as pink colour in the ultrafiltrate, stop treatment and replace the medical device.
- 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.

13 Application

Preparation

- Check the product integrity. If concerned, do not use the product, and contact the manufacturer.
- Using strict aseptic technique, remove the package and protection and immediately secure the product within the cardiopulmonary bypass circuit.
- Ensure all connections are secure and tight, to alleviate any possibility of leaking.
- Ensure the waste bag is attached and the bag empty valve is closed.

Priming

- Prime the circuit taking into consideration the technical features of the device and the instructions provided for any attached devices, flushing the circuit through with a 2000 mL bag of saline.

Treatment

- Connect the arterial (red) line of the haemoconcentrator to a high-pressure arterial line within the circuit.
- Connect the venous (blue) line of the haemoconcentrator to a low-pressure venous line within the circuit.
- Unclamp the arterial line and make sure the venous return line is unrestricted. Blood should now be flowing through the haemoconcentrator.

End of treatment and disposal

- When the adequate volume of blood to be treated is reached or the medical professional desires to stop treatment, start the appropriate process for end of treatment as per the instructions on the control unit.
- In the blood return phase, administer 500 mL of saline solution to the patient through the arterial line.
- Once the procedure is complete, disconnect the patient from vascular access and dispose of the device as per the section below.

14 Shelf Life

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

15 Storage and Handling

Even with correct storage, ECLS Tubing Packs including Haemoconcentrators have a limited shelf life. Please pay attention to the expiry date on the product label. ECLS Tubing Packs including Haemoconcentrators must be stored in a dry, frost-free area and protected from direct solar or UV light until use. Storage temperatures are detailed on the product label.

16 Disposal

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

17 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			

18 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 of 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
- 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.

Further information or additional copies of the IFU can be obtained from enquiries@chalicemedical.com.

19 Economic Operator Contacts

EC Authorised Representative



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

EC Importer



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

20 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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