BRAILE

LIFE-SAVING TECHNOLOGIES

Instructions for Use

TUBING SET

ECMO

2024-02 Rev.0

SUMMARY

READ INSTRUCTIONS BEFORE USE

Model: Tubing Set ECMO Adult (code 617327)

1. DESCRIPTION

The Tubing Set ECMO consists of pre-assembled tubing lines, connectors and accessories consisting of medical grade, non-toxic, biocompatible and non-pyrogenic materials.

It is used in an ECMO system. The venous line connects to a venous cannula and transports the patient's venous blood to the centrifugal pump, which pumps the blood to the oxygenator through the centrifugal line. The oxygenated blood is returned to the patient through the arterial line, which connects to the arterial cannula.

All the Tubing Set ECMO surfaces in contact with blood are treated with the biocompatible coating, named BRCoating, composed of water produced by reverse osmosis, Polyethylene glycol 300 and recombinant human albumin*. This solution coats the inner surface of the product, reducing the interaction of the blood with it.

Figure 1 - Tubing Set ECMO Adult

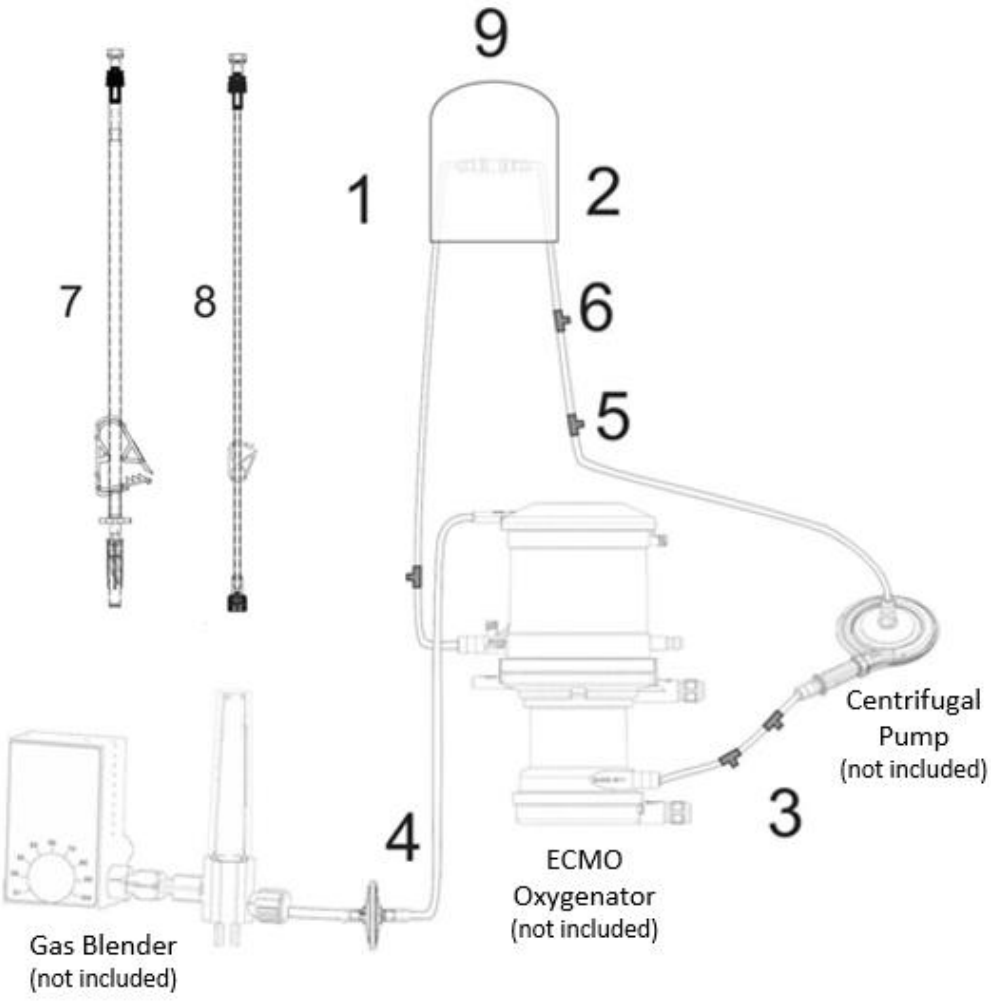
*Recombinant human albumin it is not derived from Animal or Human sources.

1.1. Graphic images

We find in the Tubing Set ECMO the following lines:

- ECMO Arterial Line
- ECMO Venous Line
- Centrifugal Line
- Oxygen Line
- Serum Line
- MF Extender Line
- Accessories Line (3-way stopcock)

Figure 2 shows the layout of the circuit with Tubing Set ECMO Adult.



1. ECMO Arterial Line
2. ECMO Venous Line
3. Centrifugal Line
4. Oxygen Line
5. Connector *Prime* 1
6. Connector *Prime* 2
7. Serum Line
8. Extender MF
9. Sterile Case

Figure 2 - ECMO circuit with Tubing Set ECMO Adult

1.2. Technical Specifications

Table 1 - Technical Specifications

Material		
Tubes	PVC DEHP FREE	
Connectors	Polycarbonate	
Protective covers (Caps)	Polyethylene	
3-way stopcock	Polycarbonate	
Coating	BRCoating	
Performance		
Maximum Blood flow rate	7.0 L/min	
Blood inlet maximum pressure	152 kPa (1,140 mmHg)	
Priming volume (Static)	500 ± 10 ml	
Line	**Diameter x Wall Thickness x Size**	**Identification**
Venous Line	3/8” x 3/32” x 270cm	Sterile Case – Blue Cap
Arterial Line	3/8” x 3/32” x 260cm	Sterile Case – Red Cap
Centrifugal Line	3/8” x 3/32” x 50cm	Double Blue Cap
Oxygen Line	1/4” x 1/16” x 200cm	Double Green Cap
Serum Line	1/4” x 1.5mm x 150cm	Needle / Male luer Connector
MF Extender Line	4.3mm x 0.65mm x 15cm	Male / Female luer connector

Disclosable information: Information on blood cell damage, data tolerances and Leaching.

If during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

2. PRESENTATION

The Tubing Set ECMO Adult is sterile (sterilized by Ethylene Oxide - ETO) and non-pyrogenic. In its primary packaging, the product is packed in Tyvek paper envelope and polyethylene film. In its secondary packaging, the Tubing Set ECMO Adult is packed in a cardboard box. The instruction for use accompanies the product, in the secondary packaging.

3. INTENDED PURPOSE

The Tubing Set ECMO Adult is intended to provide a conduit for saline solution, blood and gases during extracorporeal membrane oxygenation (ECMO) technique in extracorporeal life support (ECLS) procedure. Braile does not specify the maximum period of use of the Tubing Set ECMO Adult, nor the ideal time to change it. The decision on whether to replace the product rests with the medical team.

4. INDICATION FOR USE

The Tubing Set ECMO Adult is indicated for the extracorporeal membrane oxygenation (ECMO) technique in the extracorporeal life support (ECLS) procedure in patients with cardiac and/or respiratory failure.

The Tubing Set ECMO Adult is for use with patients when required blood flow rate (cardiac output) will not exceed 7L/min.

This device shall only be used by properly trained and qualified personnel.

5. CONTRAINDICATIONS

The tubing set **cannot** be used in the raceway of a roller pump.

The product is contraindicated to perform other functions that are not determined by the indication for use, or when, in the opinion of the medical team, its use is contrary to the best benefits for the patient.

6. CLINICAL BENEFITS

Enabling extracorporeal life support (ECLS) procedure that require extra corporeal membrane oxygenation (ECMO) by using blood circuits including this device.

7. ADVERSE EFFECTS

Use of this medical device may cause: Pressure drop, Hemolysis, Blood Loss, Inflammatory reaction, Embolism, Infection Organ and tissue failure; Septic Shock, Kidney Failure, Heart attack, Permanent damage; Death.

8. INSTRUCTION FOR USE

It is recommended to use the Braile Biomédica Tubing Set ECMO Adult with devices from the Braile Biomédica brand, listed in Table 2.

Table 2 - Compatible devices (sold separately)

Description	Code
Membrane Oxygenator Oxyprime ECMO Adult	617320
Centrifugal Pump Safira Centriflux with BRCoating	616322

***** Braile Biomédica cannot guarantee the compatibility between products from other manufacturers and, consequently, their safety and effectiveness.

8.1 Circuit Assembly

a. Open the sterile packaging using aseptic techniques.

b. Remove the set of tubes and hang the sterile case up on a high support.

c. Remove the ECMO oxygenator and fix it in its support.

d. Remove the centrifugal pump and place it in its coupling on the ECMO device.

e. Connect the ECMO arterial line from the tube set to the arterial outlet of the oxygenator.

f. Connect the ECMO venous line from the tube set to the blood inlet of the centrifugal pump.

g. Connect the centrifugal line of the tube set between the blood outlet of the centrifugal pump and the blood inlet of the oxygenator.

h. Remove the centrifuge from the device coupling and hang it up through the tubes.

i. Connect the oxygen line of the tube set between the gas inlet of the oxygenator and the gas blender of the ECMO device.

j. Connect the 3-way stopcock of the tube set to the luer connectors of the prime connectors 1 and 2 of the tube set venous line.

k. Connect the serum lines to the prime connectors 1 and 2, through the 3-way stopcock, and then connect to a serum bag with two openings for serum infusion set.

l. Connect the oxygenator's recirculation line between the bubble-trap connector and recirculation.

m. Connect an MM extender of the oxygenator between the bubble-trap connector stopcock and the prime connector 2.

n. Place a tube clamp between the prime connectors 1 and 2. Open the flow regulating clamps of the serum lines 1 and 2.

o. According to the team routine for pressure measurements, set up 3-way stopcocks in the luer connectors of the circuit.

p. Connect water lines from the ECMO device to water connectors in the oxygenator.

8.2 Prime Filling

a. Allow the serum to flow through serum line 1, filling a centrifugal pump and oxygenator by means of gravity. Check that the oxygenator recirculation line and bubble-trap are open.

b. With a centrifugal pump and oxygenator filled, close the oxygenator's recirculation lines and bubble-trap.

c. Place the centrifugal pump on the ECMO device coupling and start rotation.

d. When the entire circuit is filled and free of bubbles, close serum lines 1 and 2 and remove the clamp between them.

e. Stop the rotation of the console, disconnect the serum lines from the prime connectors 1 and 2. Close the luer with a sterile luer cover. Make sure there are no air bubbles in the body of the luer.

f. Remove the MM extender from the stopcock of the bubble-trap connector and cap with a sterile luer cover.

g. Keep a clamp on the arterial line and another on the venous line.

8.3 Start of ECMO

h. Remove the clamps from the venous line.

i. Increase the ECMO device rotation speed to 1700rpm.

j. Remove the clamp from the arterial line simultaneously with the increase in rotation.

k. Adjust the blood flow according to the patient's need.

l. Start the gas flow and adjust to the desired gas flow to blood flow ratio (0.5: 1 - 1: 1 - 2: 1).

8.4 ECMO control

- Monitor the performance of the oxygenator by periodic blood gas analysis.
- Monitor the patient clotting status by periodically analyzing TCA.
- Monitor the pressure gradient of the oxygenator periodically.
- Control the blood temperature by regulating water temperature, ECMO device heater, which circulates in the oxygenator heat exchanger.

Problems and solutions	
low pO_2	Increase O_2%
high pO_2	Reduce O_2%
low pCO_2	decrease gas flow
high pCO_2	Increase gas flow

8.5 End of ECMO

a. Decrease the rotation of the ECMO device, and consequently blood flow.
b. Clamp the arterial and venous lines simultaneously.
c. Close the gas flow.
d. Stop the rotation of the ECMO device.
e. Turn off heating / water flow of the ECMO device.

9. WARNINGS

- Read the instructions before use;
- Single use product. Therefore, do not re-sterilize or reuse the product. There are no data to support the sterility, pyrogenicity and functionality of devices after reprocessing;
- Reprocessing prohibited. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device (leaks);
- Do not use non-sterile products - they must be sterile before use;
- Do not use the product after the expiry date;
- Do not use the product if it is damaged or the packaging is broken;
- Before use, the product must be checked for proper operation and to ensure the model is suitable for its intended purpose;
- Product intended exclusively for medical use;
- The product should only be used by people specially trained on ECMO techniques.
- The procedure and the correct application of the product are the responsibility of the doctor who performs the treatment;
- The product must not be used under conditions that contradict its technical specifications, under penalty of loss of performance or accidents. It is up to the person responsible for using the product to check in advance whether the technical specifications meet the needs of the procedure to be performed;
- Always use aseptic techniques when handling the product after opening;
- Avoid any impacts during transport or use;
- Do not use the product in case of doubt;
- The product should be used immediately after opening the package. After use, dispose of safely as medical waste according to health institution policies. The product is biohazardous as it is contaminated with blood;
- Pressure at the blood inlet of the tubing set should not exceed 152kPa (1,140 mmHg). Pressure greater than that may cause leaks or damage to the device;
- Before stopping the centrifugal pump, clamp the arterial line distal to the oxygenator (the patient's side). Improper clamping may causa back-flow or migration of gaseous

emboli into the blood side;

10. PRECAUTIONS

- It is recommended that you check the product carefully before use. The operation of the product packaging may be affected by transport. It is not possible to guarantee full operation of the product when transport damage occurs. If the product has been dropped or crushed, it cannot be used and must be replaced with a new product;
- Always keep a spare unit of the product during the procedure;
- The manufacturer is not responsible for damage resulting from lack of experience, misuse or failure to follow the instructions for use;
- During the procedure, blood anticoagulation protocol should be adopted;
- Protamine should not be used in patients before or during extracorporeal circulation;
- It is necessary to provide correct heparinization and accurate monitoring of the anticoagulation status before, during or after extracorporeal circulation;
- Check all circuit connections in advance to prevent any leaks;
- Remove all air from the extracorporeal circuit before the start of ECMO using the circuit prime procedure;
- It is recommended to start the procedure immediately after filling with prime in order to minimize the period of microbiological contamination, precipitation of the filling solution;
- Do not make changes to the product;
- Do not use the product if not all connectors are protected with a protective cover. The protective covers must be retained immediately before use;
- Regularly monitor the patient to identify side effects of cardiopulmonary bypass (e.g., infections, hemolysis, post-perfusion syndrome and organ damage);
- Regularly monitor the patient clotting status (e.g., activated clotting time and partial thromboplastin time). The anticoagulation control protocol is the responsibility of the responsible user;
- Broken and / or leaking connectors must be replaced;
- Tube metal clamps should be available;
- During transport of patient, avoid leaving the tubes hanging, excessive forces, bumps and kinks;
- To collect samples, avoid creating bubbles in the circuit;
- Monitor collection and recirculation lines to prevent clots;
- The maximum blood flow of the tubing set model used must not be exceeded;
- Whenever the Arterial Pump is stopped (zero flow), the gas flow must be closed

(zero flow), under the risk of gas embolism;

- Do not use solvents such as alcohol, ether, acetone, liquid anesthetics by inhalation (for example: Halothane, Enflurane, etc.), as these can damage the product;

11. STORAGE AND TRANSPORT

The product in its original packaging must be stored in a clean, dry, weather-free environment and at temperatures above -10ºC and below 40ºC. For its transportation, it should never be refrigerated, frozen or exposed to temperatures above 40ºC.

12. PRODUCT DISPOSAL

After use, follow the **safe disposal procedure, item 12.1,** to safely dispose of the device. Product and packaging disposal must comply with the hospital and / or local government policy. The product must be disposed of only in hospital / infectious waste. The product is biohazardous as it is contaminated with blood.

12.1 Safe Disposal Procedure

Warning: Wear gloves to carry out this process, there is a risk of contamination.
Note 1: It is not necessary to disconnect the bloodlines tubes.

a. Detach the centrifugal pump and set aside on a secure surface.
b. Position a surgical field below the oxygenator to avoid wetting the floor, clamp the water lines near the oxygenator's water inlet/outlet connectors, and, disconnect the lines, set the pipes aside on a safe surface.

Note 2: For the next steps, use the disposal waste for contaminated products.

c. Remove the oxygenator from the support (holder) and discard it carefully.
d. Discard the centrifugal pump and pump line.
e. Discard the remaining lines.

13. SHELF-LIFE

The Tubing Set ECMO ADULT is valid for 2 years after the sterilization date, considered sterile only if the package has not been violated. Check the validity date on the label of the product package.

14. WARRANTY

Braile Biomédica Indústria, Comércio e Representações Ltda, certifies that the product has been manufactured with due care, with good quality materials, and is warranted for manufacturing defects pursuant to the Brazilian Consumer Protection Code. It further clarifies that if the product is violated by unauthorized or unqualified personnel, the warranty will be void. The manufacturer states that any other warranty expressly or implicitly granted by others shall not be valid. The use of the product is restricted to doctors or qualified and trained technicians under the supervision of the responsible physician, who are familiar with the procedures for using the product, being their responsibility said use. The manufacturer will not be responsible for any damage resulting from product misuse.

Braile Biomédica Ltda also states that the right to complain about the product will be governed by the provisions contained in Article 26 of the Brazilian Consumer Protection Code (Law 8.078 / 90). No agent, employee, representative, or distributor of the Braile Biomédica Ltda has the authority to change or amend what is described herein, assume or bind the Braile Biomédica Ltda to any other liability or warranty in connection with this product.

This product was developed and manufactured based on legal and regulatory requirements, and under strict quality control, aiming at managing potential risks of its use, in order to minimize them within safe limits. However, Braile Biomédica cannot ensure that the product is totally free from the likelihood of failure, so that its use must respect all precautions, restrictions, warnings, special care and relative instructions for use, as well as must be constantly and carefully monitored.

15. MANUFACTOR INFORMATION

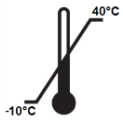
Manufactured by:

Braile Biomédica Indústria Comércio e Representações Ltda
CNPJ N°: 52.828.936/0001-09
Av. Presidente Juscelino Kubitschek de Oliveira, 1505 – Jardim Tarraf I
CEP: 15091-450
São José do Rio Preto – São Paulo

Imported and distributed by:

Mars Medical
Landhausstrasse 46
70190, Stuttgart – Germany
Tel: +49 1751938653
Email: info@marsmedical.de

16. SYMBOLS DESCRIPTION

	Manufacturer		Use-by date
	Catalog Number		Sterile
	Serial Number		Sterilized using ethylene oxide
	Batch Code		Do not use if packaging is damaged
	Date/ Country Manufacture		Fragile, handle with care
	Non-pyrogenic		This way up
	Consult Instructions for Use or electronic instructions for use		Stacking limit
	Temperature limit		Recyclable
	Keep dry		Medical Device
	Keep away from sunlight		Do not re-use
	Unique Device Identifier		Do not resterilize
	CE Mark		Authorized representative in the European Union

17. LABEL TEMPLATE

Braile Biomédica Indústria Comércio e Representações Ltda.
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CE 2797

EC REP

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E-Mail: info@marsmedical.de

TUBING SET ECMO ADULT

Description (Model): XXXXXX
Package Content: 01 unit of Tubing set ECMO Adult / 01 Instruction for Use
Contains 1 unit destined to medical application

ANVISA Registration nº: 617327
Technical Name: Tubing Set
Technician in Charge: Vladimir D. A. Ramirez – CRF-SP 09010

Read instructions before use
Single use product / Prohibited reprocessing

Indications, Precautions, Warnings, Instructions of Use, Preservation Cares*.
* Please refer to leaflet insert "INSTRUCTIONS OF USE".

REF XXXXXX SN XXXXXX LOT XXXXXX

BR YYYY/MM/DD UDI

YYYY/MM/DD

STERILE STERILE EO

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MD

The external package has the following informations

The product must be stored and transported in its original packaging, in a clean, dry, weather-free environment and at a controlled temperature.