BRAILE

LIFE-SAVING TECHNOLOGIES

Instructions for Use

Cardiopulmonary bypass

TUBING SET

BRCoating

2024-02 Rev.0

SUMMARY

READ INSTRUCTIONS BEFORE USE

Model: Tubing Set Adult BRCoating	(code 622286)
Tubing Set Pediatric BRCoating	(code 622298)
Tubing Set Infant BRCoating	(code 622290)
Tubing Set infant 1500 BRCoating	(code 622294)
Tubing Set Newborn BRCoating	(code 622302)

1. DESCRIPTION

The Tubing Set BRCoating consists of a kit of tubes, connectors and accessories made of medical grade, non-toxic, biocompatible and non-pyrogenic materials. The product consists of the following lines: cava, arterial, pump, aspirators, serum, oxygen, recirculation, arterial filter, extensor and accessory.

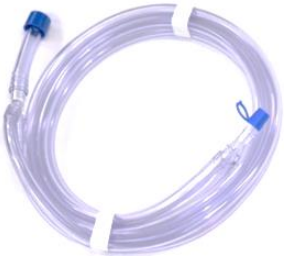
The tubing set is treated with the biocompatible coating, named BRCoating, composed of water produced by reverse osmosis, Polyethylene glycol 300 and recombinant human albumin*. This solution coats the inner surface of the product, reducing the interaction of the blood with it.

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

1.1. Graphic images

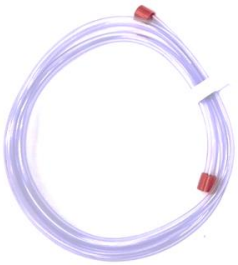
Figure 1 - Tubing Set BRCoating

Table 1 - Components of the tubing Set



Venous Line (Double Cava)

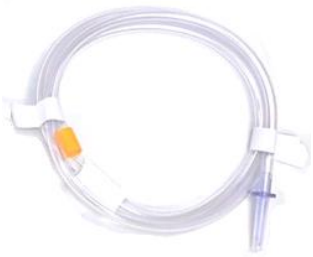
Venous Line (Single Cava)



Arterial Line

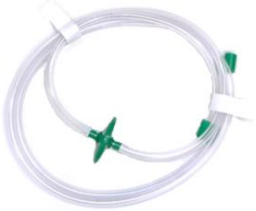
Pump Line

Aspirator Line



Serum Line

Arterial Filter Line

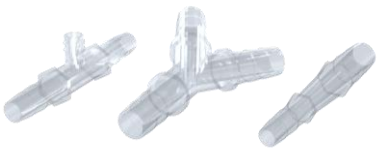


Oxygen Line

Recirculation Line

Extensor Line

Nylon Cable Tie (accessory)



Connectors (accessory)

3-way Stopcock (accessory)

1.2. Technical Specifications

Table 2 - Technical Specifications

Line / Model	Adult	Pediatric	Infant	Infant 1500	Newborn
Double Cava	3/8” x 250cm	3/8” x 250cm	1/4” x 250cm	1/4” x 250cm	3/16” x 250cm
Single Cava	1/2" x 250cm	1/2" x 250cm	3/8” x 250cm	1/4” x 250cm	1/4” x 250cm
Arterial Line	3/8” x 250cm	3/8” x 250cm	1/4” x 200cm	1/4” x 200cm 3/16” x 200cm	3/16” x 200cm
Pump Line	3/8” – 1/2” – 3/8” 100x65x120cm	3/8” – 1/2” – 3/8” 100x65x120cm	1/4” – 3/8” – 1/4” 100x65x120cm	1/4” – 1/4” – 1/4” 100x65x120cm	1/4” – 1/4” – 3/16” 100x65x120cm
Aspirator Line (3x)	1/4” – 3/8” – 1/4” 250x65x150cm	1/4” – 3/8” – 1/4” 250x65x150cm	1/4” – 3/8” – 1/4” 250x65x150cm	1/4” – 1/4” – 3/16” 250x65x150cm	1/4” – 1/4” – 3/16” 250x65x150cm
Aspirator Line (small) (2x)	1/4” – 3/8” – 1/4” 250x32x150cm	1/4” – 1/4” – 1/4” 250x32x150cm	1/4” – 3/8” – 1/4” 250x32x150cm	-	-
Serum Line	1/4" x 1500cm	1/4" x 1500cm	1/4" x 1500cm	1/4" x 1500cm	1/4" x 1500cm
Arterial Filter Line	3/8” x 60cm	3/8” x 60cm	1/4” x 60cm	1/4” x 60cm	3/16” x 60cm
Oxygen Line	1/4" x 200cm	1/4" x 200cm	1/4" x 200cm	1/4" x 200cm	1/4" x 200cm
Recirculation Line	1/4" x 60cm	1/4" x 60cm	1/4" x 60cm	-	-
Accessory Line	3/8” x 100cm	3/8” x 100cm	3/8” x 50cm	4.3mm x 40cm	4.3mm x 40cm
Extensor Line 1	1/8” x 60cm	1/8” x 60cm	3mm x 40cm	3/16” x 15cm	3/16” x 15cm
Extensor Line 2	4.3mm x 40cm	4.3mm x 40cm	-	-	-
Connectors	1/2" x 1/2” 3/8” x 1/2" 1/2" x 1/2" Luer 3/8” x 3/8” Luer 1/4” x 1/4” Luer 1/4” x 1/4” x 1/4” 1/2" x 3/8” x 3/8”	1/2" x 1/2” 3/8” x 1/2" 1/2" x 1/2" Luer 3/8” x 3/8” Luer 1/4” x 1/4” Luer 1/4” x 1/4” x 1/4” 1/2" x 3/8” x 3/8”	3/8” x 3/8” Luer 3/8” x 1/4” 1/4” x 1/4” 1/4” x 1/4” x 1/4” 3/8” x 1/4” x 1/4”	3/16” x 1/4” 1/4” x 1/4” 1/4” x 1/4” Luer 3/16” x 3/16” Luer 1/4” x 1/4” x 1/4” 3/8” x 1/4” x 1/4”	3/16” x 1/4” 1/4” x 1/4” 1/4” x 1/4” Luer 3/16” x 3/16” Luer 3/16” x 3/16” x 3/16” 1/4” x 3/16” x 3/16”
Accessories	(3) 3Way Stopcock Cable Tie T-18R Cable Tie T-30R	(3) 3Way Stopcock Cable Tie T-18R Cable Tie T-30R	(3) 3Way Stopcock	(3) 3Way Stopcock	(3) 3Way Stopcock

Table 3 - Tube diameter and wall thickness

Tube Diameter	Wall thickness
PVC 1/2"	3/32”
PVC 3/8"	3/32”
PVC 1/4"	1/16”
PVC 3/16"	1/16”
PVC 4.3mm	0.65mm
Silicon 1/2"	3/32”
Silicon 3/8"	1/16”
Silicon 1/4"	1/16”

Disclosable information: Information on blood cell damage, data tolerances, 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 BRCoating 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, Tubing Set BRCoating is packed in a cardboard box. The instruction manual accompanies the product, in the secondary packaging.

3. INTENDED PURPOSE

The Tubing Set BRCoating is intended to provide a conduit for saline solution, blood and gases when interconnecting components of the bypass circuit during cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

4. INDICATION FOR USE

The Tubing Set BRCoating is intended to be used for patients who need surgical procedures requiring cardiopulmonary bypass (CPB).

The Tubing Set BRCoating is for use with patients when required blood flow rate (cardiac output) will not exceed:

Tubing Set Adult BRCoating: 7L/min

Tubing Set Pediatric BRCoating: 3L/min

Tubing Set infant BRCoating: 2L/min

Tubing Set Infant 1500 BRCoating: 1.5L/min

Tubing Set Newborn BRCoating: 0.8L/min

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

5. CONTRAINDICATIONS

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 surgical procedures that require cardiopulmonary bypass 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 Tubing Set BRCoating with devices from the Braile Biomédica brand, listed in Table 4.

Table 4 - Compatible devices (sold separately)

Reservoir Model	Description	Code
Tubing Set Adult BRCoating code 622286)	Membrane Oxygenator Adult BRCoating	622375
	Membrane Oxygenator Oxyprime 7000 BRCoating	622383
	Membrane Oxygenator Oxyprime Duo	618949
	Blood Reservoir Venous 4000 BRCoating	622383
	Blood Reservoir Cardiotomy 4000 BRCoating	622272
	Centrifugal Pump Safira Centriflux with BRCoating	616322
Tubing Set Pediatric BRCoating (code 622298)	Membrane Oxygenator Pediatric BRCoating	622266
	Blood Reservoir Venous 4000 BRCoating	622258
	Blood Reservoir Venous 2000 BRCoating	622262
	Blood Reservoir Cardiotomy 4000 BRCoating	622272
	Blood Reservoir Cardiotomy 2000 BRCoating	622277
Tubing Set Infant BRCoating (code 622290)	Membrane Oxygenator Infant BRCoating	622257
	Blood Reservoir Venous 2000 BRCoating	622262
	Blood Reservoir Cardiotomy 2000 BRCoating	622277
Tubing Set infant 1500 BRCoating (code 622294)	Membrane Oxygenator Infant 1500 BRCoating	622261
	Blood Reservoir Venous 500 BRCoating	622267
	Blood Reservoir Cardiotomy 500 BRCoating	622279
Tubing Set Newborn BRCoating (code 622302)	Membrane Oxygenator Newborn 800 BRCoating	622271
	Blood Reservoir Venous 500 BRCoating	622267
	Blood Reservoir Cardiotomy 500 BRCoating	622279

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

8.1 Assembly of Bloodlines

a. Remove the sterile tubes from the plastic wrap and place them on the Extracorporeal Circulation Pump Tray.

Note 1: The dimensions of the tubes must be in accordance with the size (body surface) of the patient.
Note 2: The tubes must remain sterile during handling.

b. Connect the cava (venous) line of the Tubing Set to the venous inlet of the Blood Reservoir and the Venous Cannula(s).

Note 3: Consult the Blood Reservoir and Venous Cannula instructions for use before starting to assemble the circuit.

c. Connect the recirculation line to the recirculation connectors of the Oxygenator and Blood Reservoir

Note 4: Consult the Oxygenator instructions for use before starting to assemble the circuit

d. Connect the pump line to the blood outlet connector of the Blood Reservoir and to the blood inlet connector of the Oxygenator heat exchanger.
e. Connect the arterial line to the blood outlet connector of the Oxygenator or to the arterial blood outlet connector of the Arterial Blood Filter and to the Arterial Cannula

Note 5: Consult the Arterial Cannula and arterial blood filter instructions for use before starting to assemble the circuit.

f. Connect the oxygen line to the Oxygenator gas inlet connector and to the Gas Mixer/Flowmeter, observing the correct flow direction in the Oxygen Filter.

Note 6: Consult the Gas Mixer/Flowmeter instruction manual before starting to assemble the circuit.

g. Connect the aspirator lines to the inlet connectors for Blood Reservoir aspirators and surgical aspirators.

h. Connector to the serum line to the solution bag and the 1/4" inlet of the Venous Reservoir.

i. Check all connections, and for safety, secure them with the clamps that come with the Set of Tubes for Extracorporeal Circulation

8.2 Priming Procedure

a. Connect the Arterial line to the venous line connector, forming a closed circuit to circulate the prime solution.

b. Connect the serum line to the fast-priming port on the blood reservoir (Venous or cardiotomy).

Note 7: If a cardiotomy reservoir is being used, the serum line must be connected to the fast-priming connector of the blood reservoir cardiotomy.

Note 8: For next step, adequate amount of priming must be available.

c. Connect the needle connector of the serum line to the priming solution bag and position it above the reservoir.

d. After filling in the complete circuit, circulate the priming solution until the air bubbles in the components (Reservoir, centrifugal pump, oxygenator, arterial filter and de tubes) are completely eliminated;

Note 9: Refer to the priming procedure of the instructions for use for these components.

e. Stop the arterial pump, clamp the arterial line and the venous line;

f. To start cardiopulmonary bypass, connect venous line and arterial line to the venous and arterial cannulas, respectively, making sure there are no air bubbles at the connection points, and adjust the perfusion parameters according to the team's standard protocol.

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 cardiopulmonary bypass (CPB) 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;
- When using the centrifugal pump on the arterial line, clamp the arterial line distal to the oxygenator (the patient's side) before stopping the pump. 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 CPB using the circuit prime procedure;
- 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;
- To ensure optimal operation of the oxygenator, additional devices or connections are required. Read the instructions for use carefully before using the device, ensuring that all necessary parts are available before use;
- The maximum blood flow of the tubing set model used must not be exceeded;
- Monitor the suction pressure in the venous line, check if luer connections and 3-way valves are closed to avoid embolism in the line;
- 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 10: It is not necessary to disconnect the bloodlines tubes.
Note 11: This safe disposal procedure serves the cardiopulmonary bypass circuit and its main components (Tubing Set, Oxygenator, Blood Reservoir Venous/Cardiotomy and centrifugal pump). For specific components, follow instructions that come with the device in question.

a. Remove the aspirators lines from the roller of the heart-lung machine and set them aside on a secure surface.
b. Remove the pump line from the roller of the heart-lung machine or, if using a centrifugal pump, detach it and set aside on a secure surface.
c. 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 12: For the next steps, use the disposal waste for contaminated products.
Note 13: Always handle the Venous Reservoir and the Cardiotomy Reservoir in an upright position to avoid blood overflow through the top cover.

d. Remove the oxygenator and venous reservoir from their respective holders and discard it carefully.
e. Remove the Cardiotomy reservoir from the holder and discard it carefully.
f. Discard the remaining lines, including the centrifugal pump line if used.

13. SHELF-LIFE

The Tubing Set BRCoating is valid for 3 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

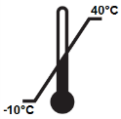
Manufactured by:

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
E-Mail: 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.
Av. Presidente Juscelino Kubitschek de Oliveira, 1505 - Jardim Tarraf I
CEP 15091-450 - São José do Rio Preto - SP - Brasil
Fone: +55 17 2136-7000 SAC: 0800 707 20 50
CNPJ: 52.828.936/0001-09 www.braile.com.br

CE 2797

EC REP

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

TUBING SET BRCOATING

Description (Model): XXXXXX
Package Content: 01 unit of Tubing Set **#model** BRCoating / 01 Instruction for Use
Contains 1 unit destined to medical application

ANVISA Registration nº: XXXXX
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 STERILIZE

40°C -10°C MD

braile.com.br/en/produtos/cemark products

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.

40°C -10°C 10