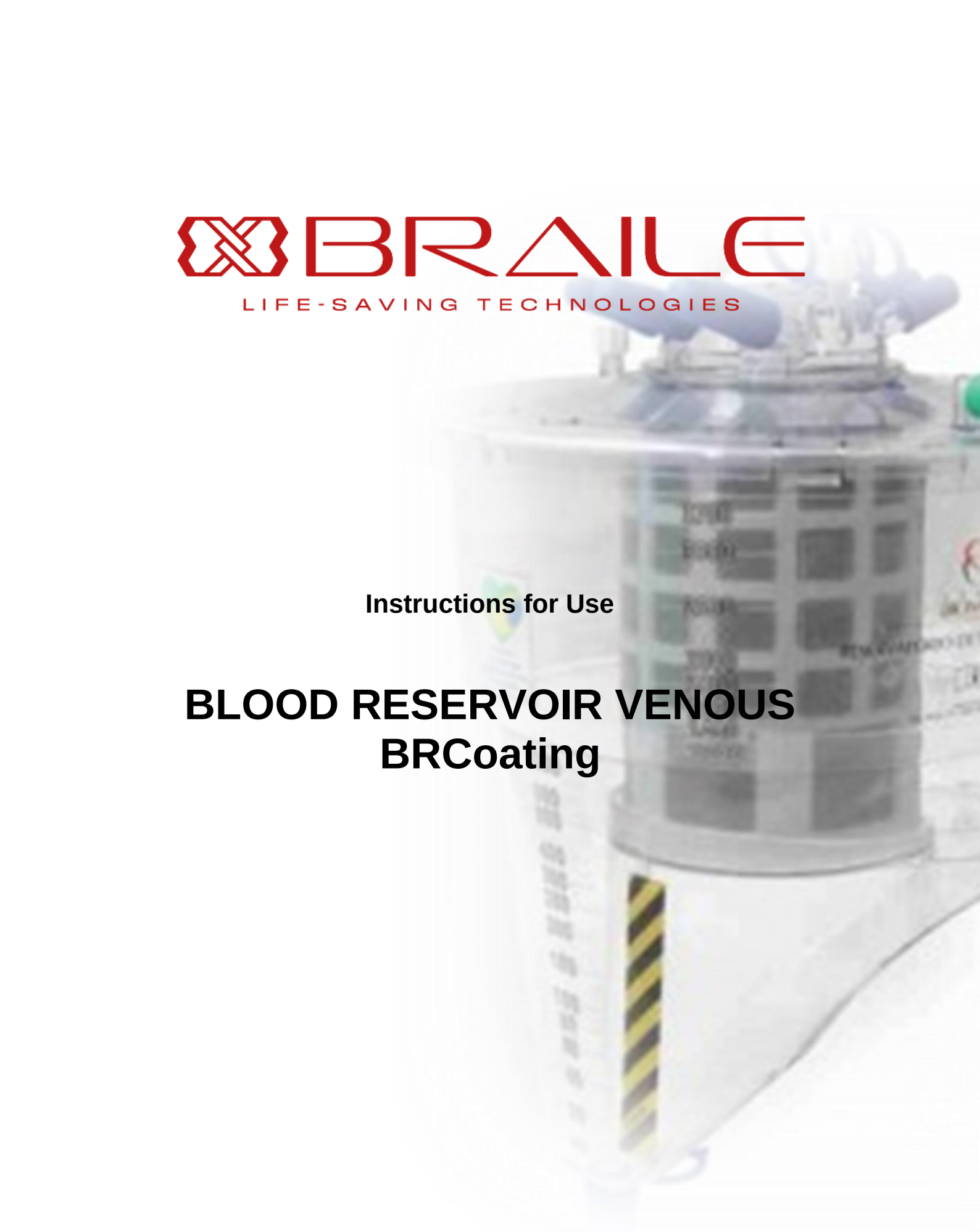
BRAILE

LIFE-SAVING TECHNOLOGIES



Instructions for Use

BLOOD RESERVOIR VENOUS BRCoating

2024-02 Rev.0

SUMMARY

READ INSTRUCTIONS BEFORE USE

Models: Blood Reservoir Venous 4000 BRCoating (code 622258)
Blood Reservoir Venous 2000 BRCoating (code 622262)
Blood Reservoir Venous 500 BRCoating (code 622267)

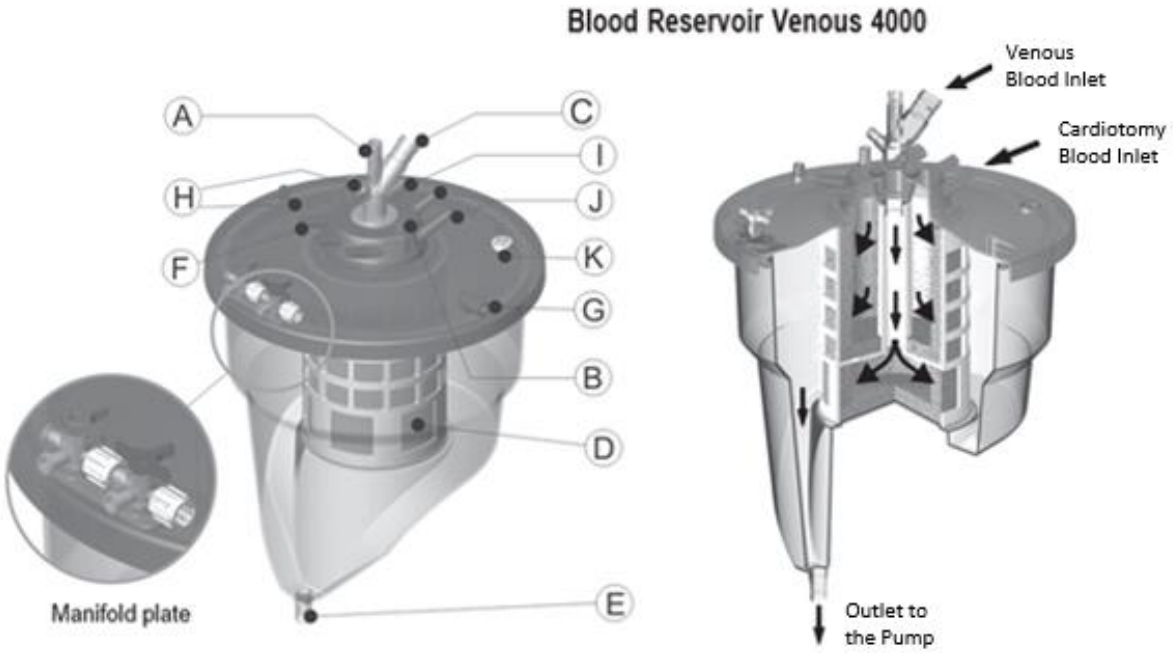
1. DESCRIPTION

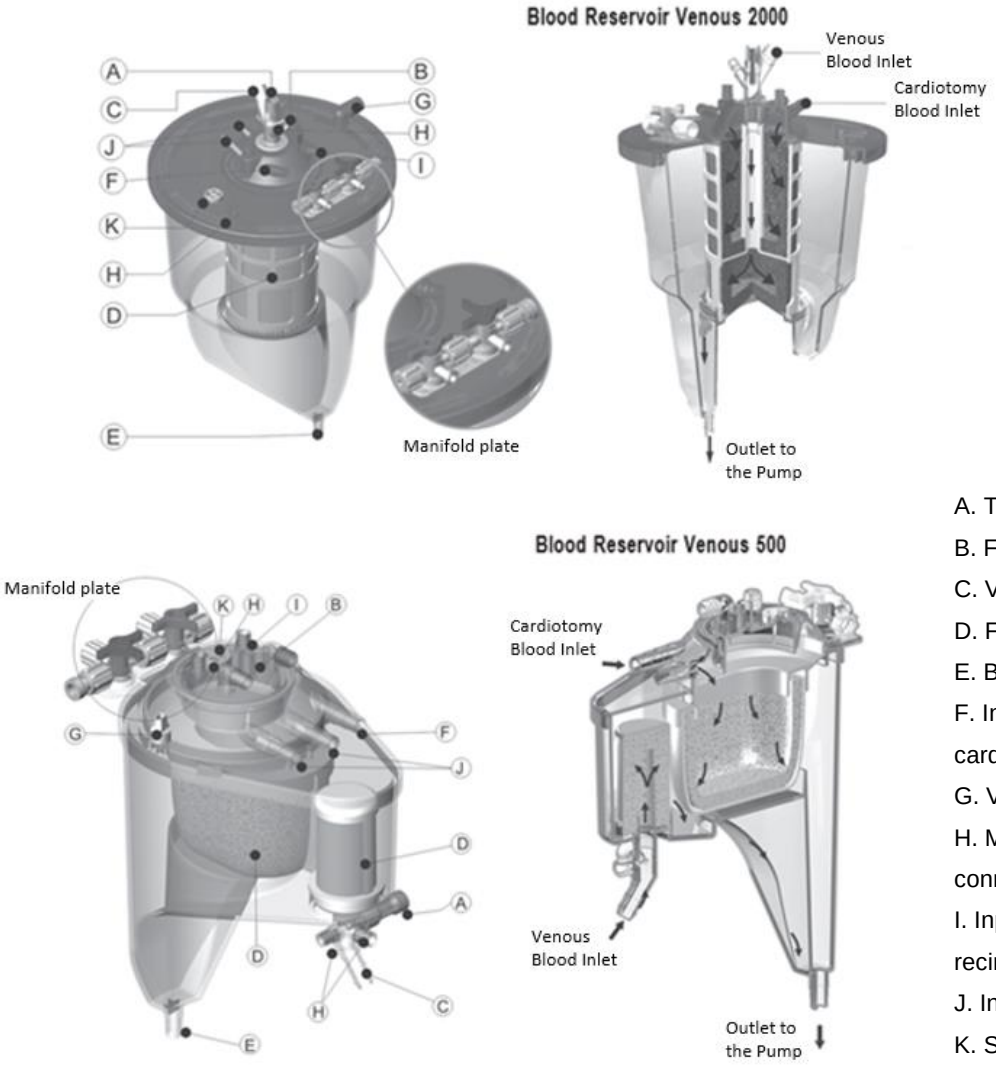
The Blood Reservoir Venous is made in polycarbonate, it has a spinning lid for better positioning of the connectors, safety valve, volumetric scale and siliconized polyurethane filter coated by a polyester screen, which enables the burst of bubbles and blood filtering. The product comes prepared for vacuum drainage and all the components are made with material appropriate for medical-pharmaceutical applications sterilizable in Ethylene Oxide (ETO).

All reservoir 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, creating a biopassive layer, reducing the interaction of the blood with it.

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

1.1. Graphic images





A. Temperature sensor
B. Fast priming connector
C. Venous input connectors
D. Filter
E. Blood output connector
F. Input connectors for cardiotomy
G. Vent / Vacuum connector
H. Medication / Sample injection connector
I. Input connector for recirculation
J. Input connector for aspirators
K. Safety valve

Figure 1 – Blood Reservoir Venous BRCoating

Table 1 - Compatibility table between Reservoirs and supports (Sold Separately)

Device	Support (Holder)	Description	Code
Blood Reservoir Venous 4000 BRCoating (622258)		Reservoir Support BRV/BRC-4000	132125
Blood Reservoir Venous 2000 BRCoating (622262)		Support for CPB mod II	205753
Blood Reservoir Venous 500 BRCoating (622267)		Support for CPB mod V	228398

1.2. Technical Specifications

Table 2 - Technical Specifications

Model	4000	2000	500
Material	Polycarbonate	Polycarbonate	Polycarbonate
Max blood flow	7 L/min	2.5 L/min	0.8 L/min
Maximum volume	3700 ml	2000 ml	450 ml
Minimum volume	150 ml	125 ml	25 ml
Volume of permeabilization	260 ± 10ml	85 ± 10ml	13 ± 2ml
Maximum vacuum	-75 mmHg	-50 mmHg	-50 mmHg
Anti-foam material	Polyurethane	Polyurethane	Polyurethane
Filtering material	Polyester	Polyester	Polyester
Venous filtering	150 ± 5 µm	150 ± 5 µm	245 ± 5 µm
Cardiotomy filtering	150 ± 5 µm	150 ± 5 µm	200 ± 5 µm
Safety valve	One way	One way	One way
Venous input connector	1/2”	3/8”	1/4”
Input connectors for cardiotomy	3/8”	1/4”	1/4”
Input connector for aspirators	1/4”	1/4”	1/4”
Blood outlet connector	3/8”	1/4”	1/4”
Fast priming connector	Luer lock	Luer lock	1/4”
Vent / Vacuum connector	1/4”	1/4”	3/16”
Medication / Sample injection	Luer lock	Luer lock	Luer lock
Recirculation input connector	1/4”	1/4”	Luer lock

Disclosable information: Information on blood cell damage, data tolerances, Air handling capability, Anti-foam characteristics, Filtration efficiency 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 Blood Reservoir Venous BRCoating is sterile (sterilized by Ethylene Oxide - ETO) and non-pyrogenic. In its primary packaging, the product is packed in Tyvek paper envelope. In its secondary packaging, the Blood Reservoir Venous BRCoating is packed in a cardboard box. The instructions for use accompany the product, in the secondary packaging.

3. INTENDED PURPOSE

The Blood Reservoir Venous BRCoating is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during cardiopulmonary bypass (CPB) procedures up to 6 hours in duration. The Blood Reservoir Venous BRCoating is also intended for use during vacuum-assisted venous drainage (VAVD) procedures.

The Blood Reservoir Venous BRCoating is also intended for use after surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement.

4. INDICATION FOR USE

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

The Blood Reservoir Venous BRCoating is for use with patients when required blood storage volume and flow rate (cardiac output) is up to:

Blood Reservoir Venous 4000 BRCoating: 3700 ml and 7 L/min

Blood Reservoir Venous 2000 BRCoating: 2000 ml and 3 L/min

Blood Reservoir Venous 500 BRCoating: 500 ml and 0.8 L/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, Blood Loss, Inflammatory reaction, Infection Organ and tissue failure; Permanent damage; Death.

8. INSTRUCTION FOR USE

It is recommended to use the Blood Reservoir Venous with devices from the

Braile Biomédica brand, listed in Table 3.

Table 3 - Compatible devices (sold separately)

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

a. Place the Blood Reservoir Venous in the proper support (see Table 1), ensuring that the support and the device are properly secured.

Note 1: The Blood Reservoir Venous should always be positioned above the Membrane Oxygenator and below the Blood Reservoir Cardiotomy.

b. Adapt the Blood Reservoir Venous position to facilitate connections, spinning the rotation lid or adjusting the support.
c. Connect the cava lines (venous) of the Tube Set to the venous input to the Blood Reservoir Venous and clamp it.

Note 2: Consult the instructions for use of the Tubing Set before beginning the circuit assembly.

d. Connect the pump line of the Tubing Set to the blood outlet to the Blood Reservoir Venous and clamp it.
e. Connect the recirculation line of the Membrane Oxygenator to the Blood Reservoir Venous.

Note 3: Consult the instructions for use of the Membrane Oxygenator before beginning the circuit assembly.

f. Connect the aspiration lines of the Tube Set to the inputs to the aspirators of the Blood Reservoir Venous.

Note 4: When the Blood Reservoir Cardiotomy is used (always positioned over the Blood Reservoir Venous), the aspiration lines should be connected to the inputs for aspirators of the Blood Reservoir Cardiotomy, and the blood outlet of the Blood Reservoir Cardiotomy should be connected to the cardiotomy entry of the Blood Reservoir Venous, according to the instructions for use of the Blood Reservoir Cardiotomy.

g. Make the remaining connections (three-way taps, extensor tubes, etc.) required for the Blood Reservoir Venous and prepare the remaining of the CPB circuit according to instructions from the manuals of the Membrane Oxygenator, Blood Filter, and remaining accessories that are being used.

8.2 Priming Procedure

a. In the priming procedure of the CPB circuit, introduce the solution through the connectors on the Venous Reservoir cover intended for rapid priming, so that the solution passes through the reservoir filter.

Note 5: When the Cardiotomy Reservoir is used, the priming solution must be introduced through the Cardiotomy Reservoir, as directed in the product instructions for use.

b. Carry out the priming procedure of the other parts of the CPB circuit according to the instructions in the Oxygenator, Blood Filter and other circuit accessories instructions for uses.
c. Before starting the infusion, make sure that all devices and tubes in the CPB circuit are free from air bubbles and leak points.

Note 6: For vacuum drainage, it is recommended to use a Cardiotomy Reservoir for aspirated blood and a Venous Reservoir for vacuum drained venous blood, in addition to paying attention to the volume control of the Venous Reservoir.

Note 7: To use vacuum drainage, the hospital vacuum line must be connected to the Vent/Vacuum connector of the reservoir and respect the maximum vacuum pressure established for the product. It is recommended to use a Vacuum Monitor for pressure control.

8.3 Emergency Reservoir Venous Replacement

In case of failures or leaks in the Blood Reservoir Venous, the procedure below must be followed to replace the unit:

a. Remove the reserve reservoir from the packaging and check its integrity.

b. Clamp the arterial and venous (cava) lines.

c. Stop rotation in the heart-lung machine.

d. Stop rotation of the aspirator's pumps;

e. Close gas flow.

f. Close the pump line, near the outlet connector of the reservoir.

g. In case of using a Blood Cardiotomy Reservoir, clamp the cardiotomy line. If the aspirators are connected directly to the Blood Venous Reservoir, clamp the aspirator lines.

h. Close every other line that's in use (recirculation, extensors, etc..).

i. Remove the reservoir to be replaced from the support and replace with the new one.

j. Remove the venous (cava) line from the reservoir to be replaced and connect it to the new one.

k. Remove the aspirators or cardiotomy lines from the reservoir to be replaced and connect to the new one.

l. Remove the pump line from the outlet blood connector of the reservoir to be replaced and connect to the new one.

m. Remove the others lines from the reservoir to be replaced and connect to the new one.

n. Fill the minimum volume of the Blood Reservoir Venous with priming solution through the rapid priming connector;

o. Remove all the clamps and open the lines: Aspirators, Cardiotomy, recirculation, extensors, etc.

p. Make sure there are no bubbles in the circuit.

q. Remove the clamp of arterial and venous (cava) line.

r. Turn on the pumps and the gas flow and restart the perfusion.

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 and filtration failures);

- 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.
- Do not use the product in case of doubt.
- 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.
- Transport and store the product in a clean, dry environment, away from harsh weather conditions and in a temperature above -10ºC and below 40ºC.

10. PRECAUTIONS

- It is recommended that you check the product carefully before use. The integrity 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.
- 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.
- Monitor the suction pressure in the venous line, check if luer connections and 3-way valves are closed to avoid embolism in the line.
- Always position the Blood Reservoir Venous below the patient level.
- Do not use solvents such as alcohol, ether, acetone, liquid anesthetics by inhalation (for example: Halothane, Enflurane, etc.), as these can damage the product.
- Avoid excessive efforts or squeezing while connecting syringes, 3-way stopcock, tubes or any other device to the connectors of the Blood Reservoir Venous.
- Prevent sudden variation in the blood level of the Blood Reservoir Venous.
- During the perfusion, the minimum blood volume should be respected (minimum work level) specified, under risk of a gas embolism occurring.
- For vacuum drainage, the use of a Blood Reservoir Cardiotomy is recommended for the aspirate blood and a Blood Reservoir Venous for vacuum drained venous blood, as well as attention in the volume control of the Blood Reservoir Venous.
- In the use of the vacuum drainage, the max vacuum pressure determined for the product should be respected (see technical product specifications).

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 8: It is not necessary to disconnect the bloodlines tubes.

Note 9: 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 10: For the next steps, use the disposal waste for contaminated products.

Note 11: 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 Blood Reservoir Venous 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

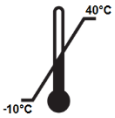
Landhausstrasse 46

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.
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CE 2797

EC REP

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

BLOOD RESERVOIR VENOUS BRCOATING

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

ANVISA Registration nº: XXXXX
Technical Name: Blood Reservoir
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

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