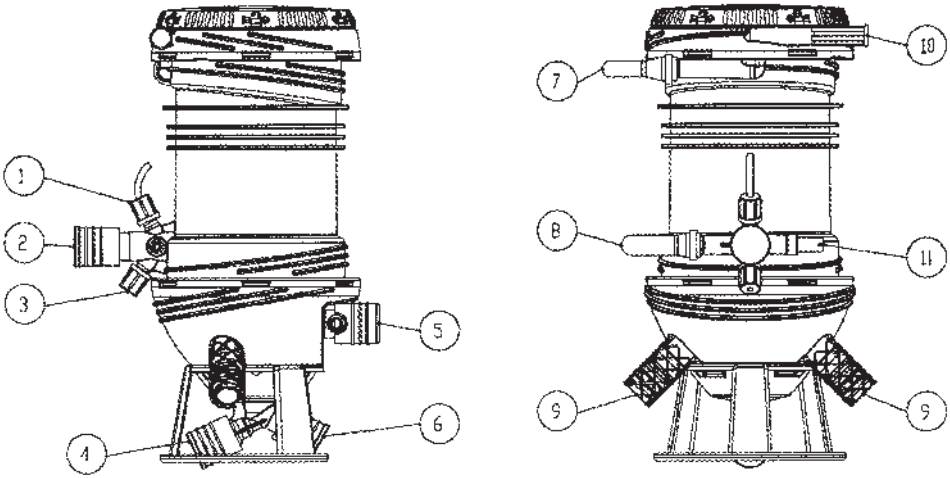
TRILLY PAEDIATRIC AF

Oxygenating device for extracorporeal circulation in cardio surgery

INSTRUCTION FOR USE

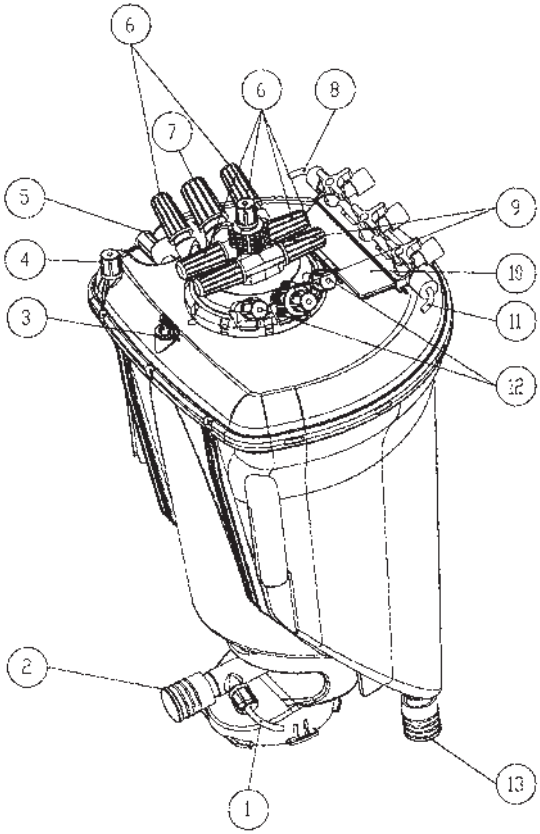
EUROSETS
EVERY LIFE MATTERS

Figure 1 – Trilly Paediatric AF oxygenator



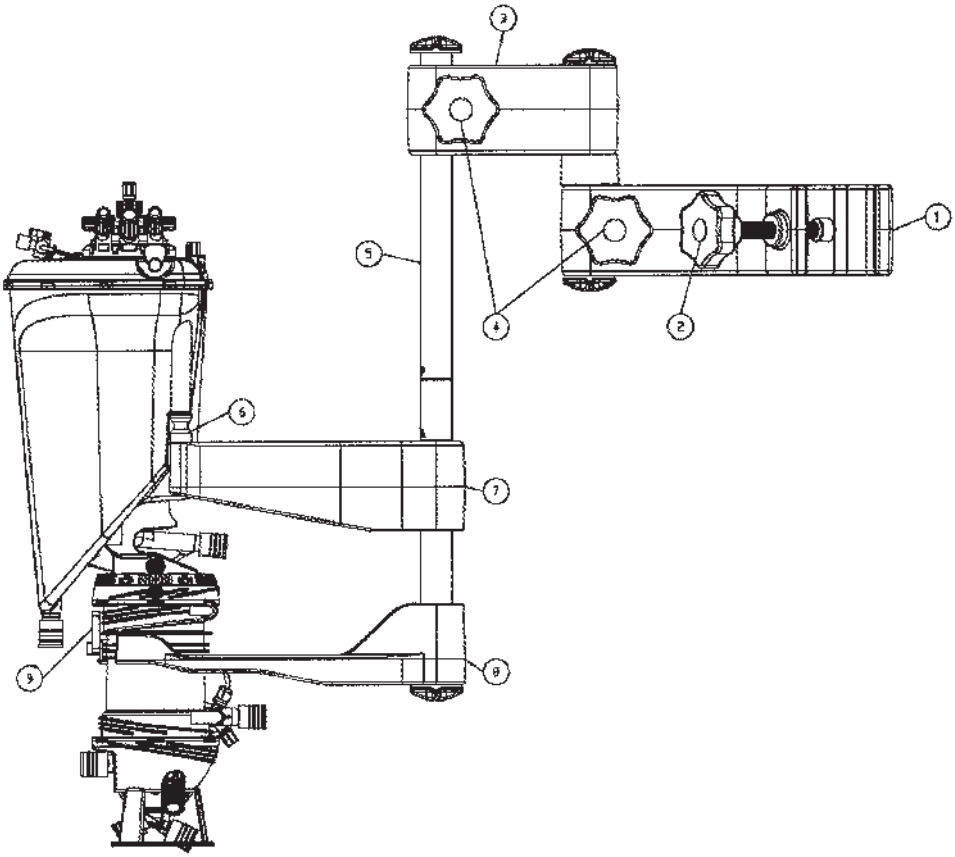
1	Arterial blood sampling port, female luer lock, with one-way valve
2	Arterial blood outlet, 3/8" (9.53 mm)
3	Pressure port, female luer lock
4	Venous temperature probe port
5	Gas outlet, 3/8" (9.53 mm)
6	Venous blood inlet, 3/8" (9.53 mm)
7	Air purge line, 1/4" (6.35 mm)
8	Cardioplegia port, 1/4" (6.35 mm)
9	Water Hansen fitting (inlet/outlet)
10	Gas inlet, 1/4" (6.35 mm)
11	Arterial temperature probe port

Figure 2 – Trilly Paediatric AF cardiotomy/venous reservoir



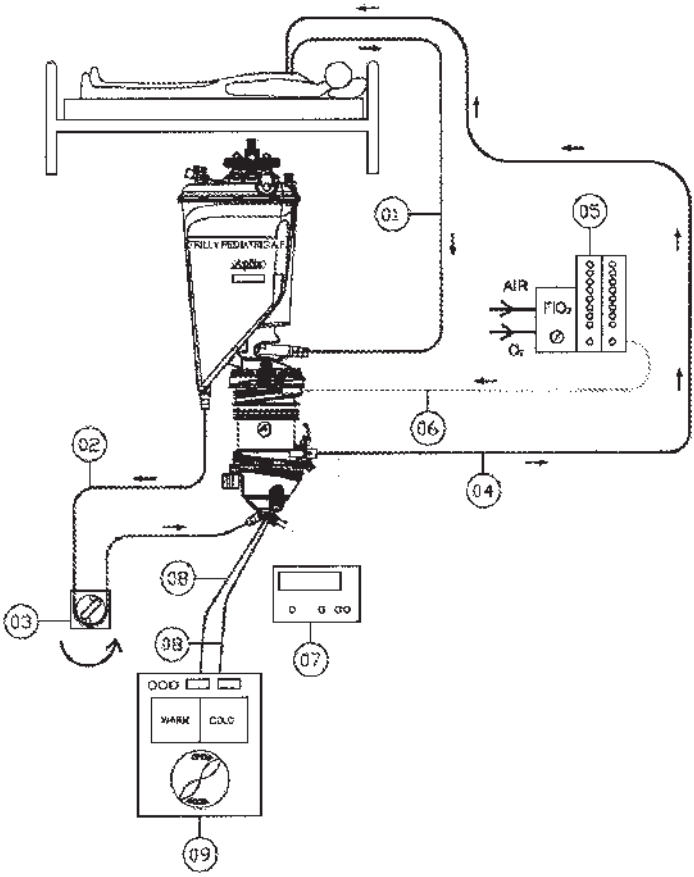
1	Venous blood sampling port, female luer lock
2	Venous blood inlet port (VENOUS RETURN), 3/8" (9.53 mm)
3	Pressure relief valve
4	1 x unfiltered female luer lock port
5	VENT/VACUUM port (VAVD technique)
6	6 x 1/4" (6.35 mm) filtered ports
7	1 x 3/8" (9.53 mm) filtered port
8	Arterial sampling line
9	2 x female POS lock filtered ports (ISO 8838) reducible to female luer lock
10	Sampling manifold
11	Venous sampling line
12	2 x female luer lock filtered ports
13	Venous blood outlet port, 3/8" (9.53 mm)

Figure 3 – Trilly Paediatric AF assembly on holder



1	Console pole clamp
2	Console pole clamp knob
3	Height and rotation arm
4	Holder knobs (height and rotation adjustment)
5	Holder pole
6	Cardiotomy/Venous Reservoir arm pin
7	Cardiotomy/Venous Reservoir arm
8	Oxygenator arm
9	Oxygenator locking lever

Figure 4 – Example of circuit system including Trilly Paediatric AF



1	VENOUS LINE
2	PUMP LINE
3	BLOOD PUMP
4	ARTERIAL LINE
5	GAS MIXER
6	GAS INLET LINE
7	TEMPERATURE MONITOR
8	WATER LINES (IN/OUT)
9	HEATER-COOLER UNIT

DESCRIPTION

TRILLY PAEDIATRIC AF is a microporous hollow-fibre membrane oxygenator consisting of a gas exchange module with an integrated heat exchanger and an integrated 38µm arterial filter that ensures arterial blood filtration with removal of microaggregates and microemboli.
TRILLY PAEDIATRIC AF also has a hard-shell cardiotomy/venous reservoir that can be connected to the aspirators, designed to allow venous drainage of the patient's blood, making use of both the hydrostatic load offered by the difference in height between the patient and the reservoir and the vacuum-assisted technique (VAVD).
TRILLY PAEDIATRIC AF hard-shell cardiotomy/venous reservoir is fitted with a pressure relief valve.
TRILLY PAEDIATRIC AF is coated with PC coating. The PC coating improves the blood compatibility of the device by reducing platelet adhesion on the coated surface.
The device is single use, non-pyrogenic, supplied **STERILE** and individually packed. Sterilised by ethylene oxide.

TECHNICAL FEATURES

OXYGENATOR MODULE

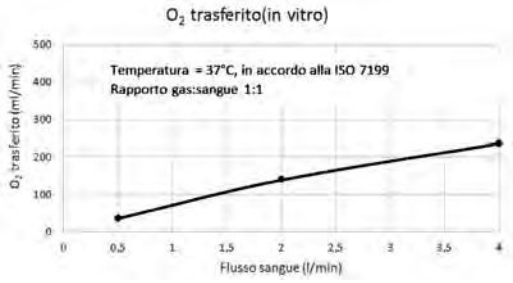
Recommended blood flow range	0.5 - 3.5 l/min	
Reference blood flow (AAMI standard)	4 l/min	
Recommended gas flow range	0.25 - 7 l/min	
Max blood pressure	750 mmHg (100 kPa)	
Max water pressure	1500 mmHg (200 kPa)	
Membrane type	Microporous polypropylene	
Membrane surface area	1.10 m^2	
Heat exchanger surface area	0.04 m^2	
Arterial filter pore size	80 µm	38 µm
Arterial filter surface area	200 cm^2	225 cm^2
Air-handling capability	≥ 95%	
Static priming volume (oxygenator module + heat exchanger)	130 ml	
Residual blood volume	39 ml	

Ports

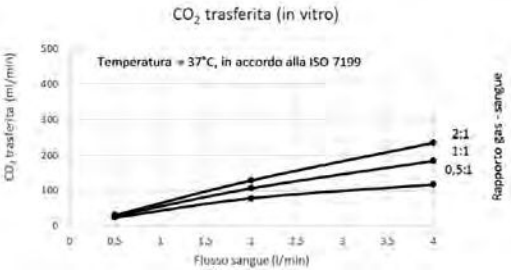
Oxygenator venous inlet	3/8" (9.53 mm)
Oxygenator arterial outlet	3/8" (9.53 mm)
Oxygenator gas inlet	1/4" (6.35 mm)
Oxygenator gas outlet	3/8" (9.53 mm)
Water ports	1/2" Hansen coupling
Arterial/Venous temperature probe ports	YSI Series 400 fitting
Arterial sampling port	female luer lock with one-way valve
Cardioplegia line port	1/4" (6.35 mm)
Air-purge line port	1/4" (6.35 mm)
Blood Pressure drop monitoring port on arterial outlet	female luer lock

Performance Data

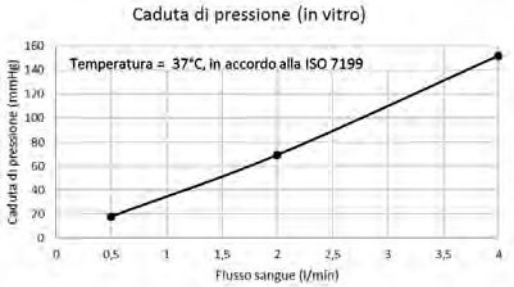
Oxygen transfer rate



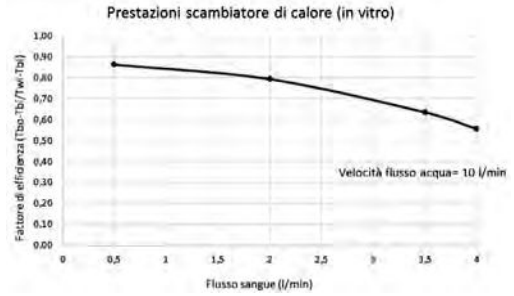
Carbon dioxide transfer rate



Blood side pressure drop



Heat exchanger performance factor *R*



Materials

Housing	Polycarbonate (PC)
Microporous hollow fiber membrane	Polypropylene (PP)
Filtering media	Polyester (PET)
Potting	Polyurethane (PU)
Heat exchanger	Stainless steel
Seals	Thermoplastic Elastomer - Stirene - Butilene - Etilene - Stirene (SEBS)
Caps and adapters	Polypropylene (PP), Thermoplastic Elastomer - Stirene - Butilene - Etilene - Stirene (SEBS)
Biocompatible coating	Phosphorylcholine (PC)

Technical data1 available on request

Gas pathway pressure drop at max. blood: gas flow rates: 3.5 l/min: 7 l/min
Blood cell damage
Particle release

[1] The data include the applicable tolerances.

HARD-SHELL CARDIOTOMY/VENOUS RESERVOIR

Max. Blood Volume Capacity	2.5 l
Max. Operating Volume	2.2 l
Min. Operating Volume	100 ml (@ 3.5 l/min) 50 ml (@ 2 l/min) 30 ml (@ 0.5 l/min)
Blood Flow Range	0.5-3.5 l/min
Dynamic Priming (Hold up) Volume	55 ml @ 3.5 l/min
Volume scale tolerance	± 10%
Filtration	
Pore size	40 µm + 80 µm
Efficiency	≥98% at 40 µm
Pressure relief valve	
Positive pressure	5.3 mmHg
Negative pressure	-75.2 mmHg
Max negative reservoir pressure	
Negative pressure	-75.2 mmHg
Ports	
Venous blood inlet port	3/8" (9.53 mm)
Luer lock at venous inlet	1 x female luer lock
Cardiotomy turret (360° rotatable) filtered ports	6 x 1/4" (6.35 mm) 1 x 3/8" (9.53 mm) 2 x female luer lock 2 x female POS lock (ISO 8838) reducible to female luer lock
VENT/VAACUM port	1 x 1/4" (6.35 mm)
Unfiltered luer lock	1 x female luer lock
Sampling manifold	Arterial blood sampling line (red handle stopcock) Venous blood sampling line (blue handle stopcock) Additional sampling/injection port (white handle stopcock)
Venous blood outlet port	3/8" (9.53 mm)
Materials	
Housing parts (reservoir and lid)	Polycarbonate (PC)
Filtering media	Polyester (PET), Polypropylene (PP)
Defoamer	Silicone treated Polyurethane (PU)
Seals	Thermoplastic Elastomer - Stirene - Butilene - Etilene - Stirene (SEBS)
Caps and adapters	Polycarbonate (PC), Polypropylene (PP), Thermoplastic Elastomer - Stirene - Butilene - Etilene - Stirene (SEBS)
Biocompatible coating	Phosphorylcholine (PC)
Technical data[2] available on request	
	Blood cell damage Air-handling capability Antifoam characteristics Break-through volume

CONVENIENCE KIT ADAPTERS

Cardioplegia line port adapter	1 x male POS lock (ISO 8837) / 1/4" (6.35 mm)
Other adapters	3 x 3/8" (9.53 mm) / 1/4" (6.35 mm)
Venous return extension line	3/8" (9.53 mm) / 3/8" (9.53 mm)

[2] The data include the applicable tolerances.

INTENDED USE AND INDICATIONS FOR USE

TRILLY PAEDIATRIC AF is intended for use in extracorporeal perfusion circuit during cardiopulmonary bypass in cardiac surgery to oxygenate and remove carbon dioxide from the blood and regulate the blood temperature.
TRILLY PAEDIATRIC AF, being integrated with arterial filter, enables filtration of arterial blood with removal of microemboli and microaggregates larger than 38 µm.
TRILLY PAEDIATRIC AF is equipped of a hard-shell cardiotomy/venous reservoir intended to collect, store and filter venous and cardiotomy suctioned blood during cardiopulmonary bypass procedure.
The hard-shell cardiotomy/venous reservoir is also intended for use during vacuum-assisted venous drainage (VAVD) procedures.
The blood to be treated should contain anticoagulant.
TRILLY PAEDIATRIC AF is a PAEDIATRIC oxygenator.
TRILLY PAEDIATRIC AF should not be used for more than 6 hours. Contact with blood for longer periods is not advised.
TRILLY PAEDIATRIC AF should be used in combination with the medical devices listed in section "MEDICAL DEVICES FOR USE WITH TRILLY PAEDIATRIC AF".

CONTRAINDICATIONS

Do not use the device for any purpose other than indicated.
Do not use if air leaks are observed during priming or operation, this may result in air embolism to the patient and/or fluid/blood loss.

RISKS AND SIDE EFFECTS

The possible risks and side effects of the TRILLY PAEDIATRIC AF include:

- haemolysis,
- adverse blood / tissues reaction,
- coagulation/complement activation, platelet dysfunction,
- thrombosis,
- gaseous embolism,
- thromboembolism,
- blood loss,
- haemodilution,
- infection.

SAFETY INFORMATION

Information to draw the user's attention to potentially dangerous situations and to ensure correct and safe use of the device is indicated in the text as follows:

WARNING
Indicates serious adverse reactions and potential safety hazards for the practitioner and/or the patient, which may occur during proper use or misuse of the device and also the limitations of use and the measures to be adopted in such cases.

CAUTION
Indicates that the user must take every possibly precaution for safe and effective use of the device.
The following is general safety information for the operator preparing to use the device. Specific safety information is also given in the instructions for use where this information is relevant for correct operation.

WARNINGS

- **⚠ Carefully read the instructions before use.**
- **Store in a dry place between 0°C (32°F) and 40°C (104°F).**
- **FRAGILE, handle with care.**
- **Single-use device. Do not reuse. Do not clean or resterilize the device for subsequent reuse.**
- **Improper reuse may cause transfusion reactions, cross-infection and alteration of device performance.**
- **For use by professionally trained personnel only.**
- **The device must be used in accordance with these instructions. EUROSETS cannot be held responsible for damage deriving from inexperience or improper use.**
- **Carefully check the device seal during priming and operation. Any leakage may give rise to loss of sterility, blood leakage, gaseous embolism. If you notice leakage during priming or operation, replace the defective device following good perfusion practices.**
- **During use, a spare TRILLY PAEDIATRIC AF oxygenator must always be available.**
- **The connection lines must be correctly connected in order to prevent any potential tube constriction or occlusion which may lead to reduced blood and/or water and/or gas flow.**
- **Before the cardiopulmonary bypass, administer to the patient an adequate dosage of anticoagulant, and adjust dosage through**

monitoring during and after the bypass.
- **It is recommended not to expose the blood to a temperature lower than 18°C (64°F) and higher than 37°C (99°F).**
- **To safely apply a vacuum to the device, carefully read section "USE OF THE ACTIVE VENOUS DRAINAGE WITH VACUUM (VAVD)".**
- **The special pressure relief valve on the cardiotomy/venous reservoir allows to discharge positive pressures higher than 5.3 mmHg (0.7 kPa) and negative pressures lower than -75.2 mmHg (-10 kPa).**
- **The extracorporeal circulation shall be carefully and continuously checked throuhout the cardiopulmonary bypass procedure.**
- **After use, dispose of the device in accordance with the regulations in force on biologically hazardous waste in the country of use.**
- **For further information and/or in case of a complaint, contact EUROSETS or an authorised local representative.**

SET UP

1) POSITIONING THE HOLDER

Position the TRILLY PAEDIATRIC AF holder on the pump stand and secure it by means of the knob found at the end of the carrying arm.

Verify that the holder is in the right position (see Oxy Adult/Paediatric Holder Instructions for use for two different height holder positions).

2) SECURING TRILLY PAEDIATRIC AF ON THE HOLDER

WARNINGS
- **Check the expiry date on the label. Do not use the device after this date.**
- **The device has been sterilized by ethylene oxide and is non-pyrogenic. Its sterility and integrity are guaranteed only if the package is intact.**
- **Carefully inspect the device before use. Do not use it if the package is wet, open or damaged, if the device is visibly damaged or if the protective caps are not in place.**
- **The device must be used immediately after opening the sterile package.**
- **The device must be handled aseptically.**
- **Do not use solvents such as alcohol, ether, acetone, etc., as contact may cause damage to the device.**
- **Do not allow halogenated liquids such as Halothane and Fluothane to come into contact with the polycarbonate housing of the device. This would cause damage which may compromise the integrity and proper functioning of the device.**
- **Avoid that the ports accidentally come into contact with lubricating agents which may encourage accidental disconnection.**

Secure TRILLY PAEDIATRIC AF on the holder.

Check that TRILLY PAEDIATRIC AF fits perfectly and fully into place with the holder support inserts in the two housing holes and check that the oxygenator is securely in place in the support jaws.

Check and, if necessary, tighten the connections of the lines connected to the oxygenator.

Only in this condition it will be possible to secure TRILLY PAEDIATRIC AF by turning the fastening lever anticlockwise, until block is achieved.

3) THERMOCIRCULATOR SET UP

Connect the water tubes to the TRILLY PAEDIATRIC AF Hansen fittings (indifferently to the water inlet or outlet).

WARNINGS
- **The water temperature at the heat exchanger inlet must not exceed 42°C (108°F).**
- **The water pressure in the heat exchanger must not exceed 1500 mmHg (200 kPa).**

4) CHECK THE HEAT EXCHANGER

WARNING
- **Check the heat exchanger by recirculating water inside the heat exchanger for a few minutes. The integrity of the unit is guaranteed if there are absolutely no leaks from the water compartment.**

5) CIRCUIT CONNECTIONS

WARNINGS:
- **All the connections downstream of the pump must be secured by means of ties.**
- **Remove the label (labelled with "Remove before use") and the yellow cap from the VENT/VACUUM port.**
- **Before use remove from the pressure relief valve the yellow tab (labelled with "Remove before use").**
- **The action of the pressure relief valve does not prevent from excessive negative pressure in the reservoir caused by sudden abnormal high vacuum level (i.e. vacuum regulator device failure).**

- **Do not for any reason occlude the external access hole of pressure relief valve.**
- **Do not occlude the gas escape port to avoid that pressure achieved into the gas side compartment becomes higher than pressure into the blood site compartment.**

VENOUS LINE: Connect a 3/8" venous line to the port on the venous reservoir marked "VENOUS RETURN".
The Venous Return port can be rotated through 150° to find the most convenient position for the venous tube.
ASPIRATION LINES: After removing the protective caps from the filtered inlet ports on the top of the cardiotomy/venous reservoir (composed of 6 x 1/42 inlets, 1 x 3/8" inlet, 2 x female luer lock and 2 x POS lock reducible to female luer lock) connect the aspiration lines end and rotate the turret orienting the filtered inlets towards the suction pumps.
ARTERIAL LINE: Remove the red cap on the arterial outlet of the oxygenator marked "ARTERIAL OUTLET" and connect a 3/8" line.
PUMP LINE: The pump segment must be fitted between the venous reservoir outlet port and the oxygenator venous inlet port taking account of the pump rotation direction.

CAUTION
CARDIOPLEGIA LINE: If oxygenated blood is necessary for blood cardioplegia, connect the TRILLY PAEDIATRIC AF cardioplegia blood line to the cardioplegia circuit.

6) SAMPLING MANIFOLD
The arterial/venous sampling manifold is positioned on the venous reservoir lid and is already connected to the sampling points.
If you wish to take samples from a more remote position, remove the manifold from the fastening guide, fit it on the dedicated holder and unwind the tubing provided. In this position, arterial/venous sampling can be performed in a radius of about 1 meter.

WARNINGS:
- **The female luer arterial sampling port, located over the arterial outlet port, pre-connected with sampling manifold, cannot be used as outlet pressure measurement port due to the presence of integrated one-way valve.**
- **Blood pressure monitoring can be performed by connecting to the luer lock located under the arterial port.**
- **Male luer locks not supplied with EUROSETS products may damage the one-way valve positioned in the oxygenator arterial sampling luer lock.**

7) CONNECTING THE TEMPERATURE PROBES
The arterial temperature probe port is positioned near the arterial outlet, while the venous temperature probe port is opposite to the oxygenator venous inlet.

8) CLOSING THE PURGE AND CARDIOPLEGIA LINES
Connect the purge line to the turret; close the clamp on the cardioplegia line and the clamp on the purge line.
Connect the cardioplegia line to the cardioplegia kit.

9) CONNECTING THE GAS LINE
Remove the green cap from the gas inlet port marked "GAS INLET" and connect the 1/4" gas line.
Ensure that the gas supply is from a suitable air/oxygen mixer such as Sechrist or a system with similar technical features.
The special configuration of the "GAS ESCAPE" port prevents potential occlusion of the gas outlet.
A capnograph can be attached to this port.

CAUTION
The "GAS ESCAPE" system has been designed to avoid any possible risk of occluding the gas outlet, which would cause immediate passage of air into the blood compartment.
The user should check for occlusions in tubing during set up.

PRIMING AND RECIRCULATION PROCEDURE

WARNINGS
- **Do not apply the vacuum during this procedure.**
- **Do not use alcohol-based priming solution, as this would compromise proper functioning of the oxygenator module.**

1) KEEP THE GAS FLOW OFF
2) KEEP THE OXYGENATOR PURGE LINE CLOSED
Check that the purge line clamp is closed.
3) CLOSE VENOUS AND ARTERIAL LINES

Clamp the venous line leading from the patient.
Clamp the arterial line a few centimetres away from the oxygenator arterial outlet port.

4) CHECK THE HEAT EXCHANGER

Verify again the integrity of the heat exchanger, paying particular attention to possible water leaks.

5) PRIME THE VENOUS RESERVOIR

Secure all the aspiration lines with clamps.
Fill the cardiotomy/venous reservoir with sufficient liquid to ensure that the intended hematocrit is obtained, taking into account that:

- The static priming volume of the oxygenator is 130 ml.
- The 3/8" tube capacitty is 72 ml/m.

Clamp the cardiotomy/venous reservoir outlet.

6) CIRCUIT PRIMING

WARNINGS

- **The pressure in the blood compartment of the oxygenator module must not exceed 750 mmHg (100 KPa).**
- **Do not occlude the gas escape port to avoid that pressure achieved into the gas side compartment becomes higher than pressure into the blood site compartment.**
- **The pressure in the blood compartment must always be higher than that in the gas compartment. This is to prevent the formation of gas emboli in the blood compartment.**
- **It is always advisable to use a pre-bypass filter during priming.**

Remove the pump segment of the arterial pump head and position it at the same height as the cardiotomy/venous reservoir.
Slowly open the clamp at the reservoir outlet and fill the tube, gradually lowering it with respect to the level in the cardiotomy/venous reservoir, so that it is completely filled and all the air is sent to the oxygenator.
The oxygenator module is hence completely filled by gravity. When TRILLY PAEDIATRIC AF is full, position the pump segment in the arterial pump.

7) OPEN THE VENOUS AND ARTERIAL LINES

Remove the clamps from the venous and arterial lines and increase the flow rate to 1000 ml/min.

8) OPEN THE PURGE LINE

Check that the purge line is connected to the turret of the cardiotomy/venous reservoir.
Increase the arterial pump speed to the maximum flow rate.
Open the purge line of the oxygenator module in order to evacuate the air towards the reservoir.
Ensure the filling and the de-bubbling of the cardioplegia line.

9) PURGE THE AIR CONTAINED IN THE CIRCUIT

During this phase it is necessary to tap the entire circuit in order to facilitate the removal of microbubbles from the tube walls. After some minutes in which the flow is maintained at a high rate, all air will be evacuated.

10) PRIME THE SAMPLING MANIFOLD

Prime the sampling lines (arterial/venous) until all the air has been evacuated. Turn the stopcock selectors of the sampling manifold so as to fill automatically the arterial and venous line.

11) CLOSE THE PURGE LINE / PURGING / RECIRCULATION LINE

After 3-5 minutes of circulation at high flow, all the residual air will have been evacuated and the purge line can be closed.
The particular configuration of the upper potting (inclined potting) will allow all the air contained in the upper area of the oxygenator module to automatically evacuate.

12) CLOSE THE VENOUS AND ARTERIAL LINES

After having verified the absence of air inside the circuit, stop the pump and clamp the venous and arterial line.

WARNINGS

- **Do not use pulse flow during priming.**
- **Sudden changes in flow rate during priming can pull air across the membrane into the blood pathway.**
- **Check the correct dosage of anticoagulant in the system before starting the bypass.**
- **EUROSETS recommends using the pump speed regulator to reduce or slowly stop the arterial flow.**
- **Do not use the pump on/off switch until the pump speed is zero.**
- **Do not turn off the heater-cooler.**
- **If the cardioplegia line has been connected, make sure that all the air has been evacuated.**
- **Do not apply negative pressure to the coronary outlet.**
- **Negative pressures in the blood**

compartment might cause the formation of gaseous microemboli.

INITIATING BYPASS

1) OPENING THE ARTERIAL AND VENOUS LINES

First remove the clamp from the arterial line and then the clamp from the venous line. Start bypass with a blood flow appropriate for the patient's size.

Constantly check the blood level in the cardiotomy/venous reservoir.

If performing vacuum-assisted drainage (VAVD), check that all the ports are closed and apply the vacuum to the cardiotomy/venous reservoir.

2) CHECKING PROPER FUNCTIONING OF THE HEAT EXCHANGER

Check the temperature of the venous and arterial blood.

3) SELECTING THE APPROPRIATE GAS FLOW

The product has characteristics which offer the possibility of treating a wide range of patients.

The regulation of gas, blood and FiO_2 flows in normothermia must be performed according to the table below.

Blood flow ml/min	**FiO_2 %**	**Gas:Blood flow**
<1500	50	1:1
1500 – 2500	60-70	1:1
>2500	70-80	1:1

After initiating cardiopulmonary bypass, check the content of gas in the blood with a blood gas analysis and make any necessary corrections.

WARNINGS

- **Always open the gas flow after the blood flow. The gas blood flow ratio must never exceed 2:1.**
- **Do not occlude the gas escape port to avoid that pressure achieved into the gas side compartment becomes higher than pressure into the blood site compartment.**
- **The pressure in the blood compartment must always be higher than that in the gas compartment. This is to prevent the formation of gas emboli in the blood compartment.**
- **During the heating and cooling phases, pay attention to the rate of temperature increase and decrease (gradient).**

4) BLOOD GAS ANALYSIS

After a few minutes of bypass, measure the gas content in the blood. Depending on the values found, adjust as follows:

High pO_2	==>	decrease FiO_2
Low pO_2	==>	increase $FiO2_2$
High pCO_2	==>	increase gas flow
Low pCO_2	==>	decrease gas flow

DURING BYPASS

1) CHECKING THE VENOUS RETURN

If a higher venous return flow is necessary, lower both the oxygenator and the cardiotomy/venous reservoir respect to the patient's position.

With vacuum assisted drainage, the vacuum applied to the cardiotomy/venous reservoir must be adjusted in order to obtain adequate venous return.

WARNINGS

- **The ACT (Activated Coagulation Time) must always be greater than or equal to 480 seconds in order to ensure adequate anticoagulation of the extracorporeal circuit.**
- **If administration of anticoagulant to the patient is necessary use the luer port of the central stopcock on the sampling manifold.**
- **The cardiotomy/venous reservoir minimum operating volume is 100ml at 3.5 l/min, 80ml at 2 l/min and 30ml/min at 0.5 l/min. To allow sufficient reaction time in case of sudden venous flow stop, preventing gaseous emboli passing to the patient, it is recommended to maintain the operating level at the double of the minimum operating volume.**
- **If performing sampling during vacuum assisted drainage, please read carefully.**
- **Perform sampling only when the pump is running, otherwise the blood pressure in the compartment would drop and might lead to the formation of air bubbles.**

2) ARTERIAL SAMPLING

Turn all stopcock to allow the blood re-circulation thanks to the arterial pressure. Insert a sampling syringe into the arterial stopcock luer and draw at least 10 ml of blood prior to take the arterial sample. Return the collected blood in the central stopcock luer and proceed to the arterial sampling. Collect the blood sample through the syringe. Close the arterial stopcock before removing the syringe. Return the blood residual from gas analysis in the central stopcock luer. Ensure to turn all stopcock to allow the blood re-circulation at the end of the operation.

3) VENOUS SAMPLING

Ensure that the arterial stopcock is closed, and so not communicating with the venous line. Insert a sampling syringe into the venous stopcock luer and draw at least 10 ml of blood prior to take the venous sample.Turn the venous sampling stopcock and proceed to the venous sampling with another syringe. Return the collected venous blood in the central stopcock luer. Return the blood residual from gas analysis in the central stopcock luer. Ensure to turn all stopcock to allow the blood re-circulation at the end of the operation.

4) DRUGS INJECTION

Insert the medication syringe into the luer port of the central stopcock. Open the central and venous stopcocks and inject the drug into the manifold and venous sample line.

Close the central stopcock to the medication syringe and allow drug wash through the stopcock manifold from arterial to venous blood. Turn the stopcocks to the closed position when the drug has been delivered to the venous line.

5) LOW FLOW RECIRCULATION

(Hypothermia associated with circulatory arrest)

WARNINGS

If performing vacuum-assisted drainage, please adhere strictly to the following:

a) reduce the gas flow rate to less than 500 ml/min,

b) open the purge line of the arterial filter or the arterial-venous loop,

c) reduce the flow rate of the arterial pump to 1000 ml/min and clamp the venous reservoir inlet line,

d) clamp the oxygenator arterial line after the recirculation loop and recirculate at a maximum flow rate of 1000 ml/min throughout the patient's circulatory arrest,

e) to restart bypass after circulatory arrest, open the venous and arterial lines and slowly increase the blood flow,

f) close the recirculation line used and adjust the gas flow.

Resume the arterial pump flow to the value previously setted.

In case of vacuum-assisted drainage, increase the negative pressure in cardiotomy/reservoir, to reach an adequate drainage flow.

If you need to add priming solution to the venous reservoir, use the 1/4" ports, the luer locks or the POS locks located on the turret of the cardiotomy/venous reservoir.

Perform sampling only when the pump is running, otherwise the blood pressure in the compartment would drop and might lead to the formation of air bubbles.

WARNING

For the low flow recirculation, do not use the purge line, because it doesn't allow the recirculation of oxygenator module.

6) CONTINUOUS AIR PURGING

If air continuously arrives at the oxygenator, hold the clamp of the purge line partially open so as to eliminate the air (this procedure however entails a drop in flow rate to the patient, proportional to the clamp opening, the arterial pump flow rate and the arterial pressure).

TERMINATING BYPASS

This must be carried out depending on the condition of each individual patient. Act as follows:

1) Turn off the gas flow.
2) Turn the heater-cooler off.
3) Slowly reduce the arterial flow to zero, at the same time closing the venous line.
4) Clamp the arterial line.
5) Open the arterial / venous recirculation line or the purge line.
6) Increase the arterial flow rate to 1000 ml/min.

CAUTION

If extracorporeal circulation has to be restarted, maintain a minimum blood flow inside TRILLY PAEDIATRIC AF (maximum 1000 ml/min).

Check that the cardioplegia circuit connected to the coronary outlet is properly clamped.

CAUTION

We recommend that you disconnect the venous reservoir from the oxygenator module when the same is still on the holder (press the release button and rotate counterclockwise the blue ring, indicated by the lock open).

RECOVERING THE BLOOD VOLUME AFTER BYPASS

1) Recover all the blood contained in the venous line into the cardiotomy/venous reservoir as soon as the surgeon has removed the cannula from the

patient's vena cava.
2) Perfuse through the aortic cannula as required by the patient's condition, slowly decreasing the level in the cardiotomy/venous reservoir.
3) If desired, blood in the oxygenator may also be returned by adding clear prime to the venous reservoir when the blood in the reservoir as reached minimum value. Pump the prime slowly (minimum flow ~50 ml/min) through the oxygenator ensuring that the reservoir never be emptied.
4) When the cardiotomy/venous reservoir is nearly empty, stop the arterial pump and clamp the arterial line.

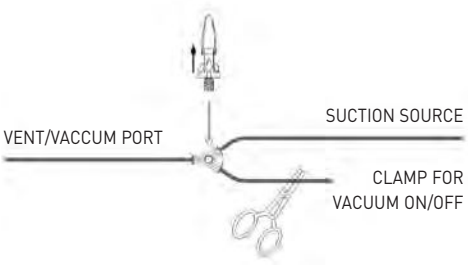
USE OF THE ACTIVE VENOUS DRAINAGE WITH VACUUM (VAVD)

The device can be used for vacuum-assisted drainage as it is fitted with a pressure rilef valve.
To safely apply a vacuum to the device, carefully read the instructions for use in this point.

CONNECTING THE VACUUM LINE

If performing venous drainage using the vacuum technique, the vacuum line must be connected to the port marked "VENT/VACUUM PORT" after removing the label and yellow protection cap.
Connect the Eurosets connection kit (VAVD) to it.
Connect the other end of the line to a vacuum regulator equipped with a condensation trap.

CONNECTION LINE TO THE ASPIRATION SOURCE FOR THE VAVD (Vacuum Assisted Venous Drainage).



WARNINGS

- **Do not apply the vacuum during PRIMING AND RECIRCULATION PROCEDURE.**
- **It is recommended not to exceed -75.2 mmHg (-10 KPa) when applying negative pressure to the cardiotomy/venous reservoir.**
- **Periodically check functioning of the vacuum regulating device and the degree of vacuum.**

If is necessary to interrupt vacuum application, remove one of the leakproof caps on the cardiotomy/venous reservoir and remove clamp from the collecting line to the suction source for the VAVD tecnique.
In case of vacuum-assisted drainage (VAVD), re-insert leakproof cap on the cardiotomy/venous reservoir and re-insert the clamp on the collecting line to the suction source.

WARNING
CARDIOTOMY/VENOUS RESERVOIR MANAGEMENT

- **If you wish to change from vacuum-assisted drainage to conventional venous drainage, suspend the vacuum application by detaching the vacuum line so that the venous reservoir is brought back to atmospheric pressure.**

CAUTION

During the vacuum-assisted venous drainage procedure pay attention to involuntary opening of the luer locks or ports positioned on the turret, as this causes a reduction of the vacuum in the reservoir; open the ports only when fluids need to be sent to the venous reservoir and only for the time necessary for this operation.

USING THE CARDIOTOMY/VENOUS RESERVOIR FOR POST-OPERATIVE AUTOTRANSFUSION

To use the cardiotomy/venous reservoir for post-operative autotransfusion, proceed as follows:
1) Disconnect the purge lines.
2) Disconnect the arterial sampling line from the sampling manifold.
3) Separate the venous reservoir from the oxygenating module by pressing the release button and simultaneously turning the blue ring counterclockwise (shown by the open padlock).
4) Separate the venous reservoir from the oxygenator by opening the latch and twist the reservoir clockwise holding oxygenator stationary.
5) Close all the ports of the cardiotomy/venous reservoir used during bypass, including the vent port of the venous reservoir.
6) Connect a line and a vacuum regulator to the vent port marked "VENT/VACUUM PORT" of the

cardiotomy/venous reservoir.

WARNING

- **Periodically check functioning of the vacuum regulating device and the degree of vacuum.**

TRILLY PAEDIATRIC AF REPLACEMENT

A spare device must always be available during perfusion.
After 6 hours of use with blood or if the perfusionist is of the opinion that the conditions are such that the safety of the patient may be compromised (insufficient oxygenator performance, leaks, abnormal blood parameters, etc.), replace the oxygenator following the instructions below

CAUTION

Use a sterile technique throughout the replacement procedure.

1) Suspend the application of vacuum to the cardiotomy/venous reservoir (when vacuum-assisted drainage has been used).
2) Turn off the gas flow.
3) Close the venous return line using two clamps (5 centimetres apart).
4) Stop the arterial pump and close the arterial line using two clamps (5 centimetres apart) near the oxygenator.
5) Turn off the thermocirculator, clamp and remove the water lines.
6) Disconnect the gas line, all the monitoring and sampling lines, and the aspiration lines.
7) Cut the venous return line and the arterial line at the point between the two clamps, leaving a sufficient length of tubing to allow reconnection.
8) Remove TRILLY PAEDIATRIC AF from the holder and remove the pump segment from the arterial pump.
9) Place a new TRILLY PAEDIATRIC AF on the holder. Connect all the lines (venous line to the cardiotomy/venous reservoir, arterial and gas lines to the oxygenator, pump segment of the cardiotomy/venous reservoir to the oxygenator, and possible vacuum line to the cardiotomy/venous reservoir.

WARNING

- **In this phase, keep the venous and arterial lines clamped.**

10) Connect the water lines, turn on the thermocirculator and check the integrity of the new TRILLY PAEDIATRIC AF.
11) Fill the cardiotomy/venous reservoir of the new TRILLY PAEDIATRIC AF with priming solution through one of the turret ports (1/4" or 3/8").
12) Prime the new TRILLY PAEDIATRIC AF and evacuate the micro air bubbles as described in the priming and recirculation procedure.
13) Check all the connections and secure them with clamps.
14) Remove the clamps from the venous and the arterial lines, close the purge line and restart the bypass.
15) Turn on the gas flow and adjust gas flow rate as required.
16) The residual blood in the replaced cardiotomy/venous reservoir may be recovered by connecting the outlet to the 3/8" inlet on the turret of the new cardiotomy/venous reservoir.
17) The blood contained in the oxygenator and in the heat exchanger may be recovered by connecting the arterial line outlet to the 3/8" inlet on the turret of the new cardiotomy/venous reservoir.

Replacing only the oxygenator module

1) Suspend the application of vacuum to the cardiotomy/venous reservoir.
2) Close the gas flow and disconnect the gas line.
3) Clamp the venous return line.
4) Stop the arterial pump and close the arterial line with two clamps (5 centimetres apart) near the oxygenator.
5) Close the oxygenator inlet line near the oxygenator module port with two clamps (5 centimetres apart).
6) Turn off the thermocirculator, clamp and remove the water lines.
7) Close the purge clamp and the cardioplegia line using a metal clamp where necessary.
8) Cut the lines at the point between the two clamps.
9) Make sure that the sampling manifold is closed and disconnect the arterial sampling line being careful not to contaminate the luer lock of the sampling manifold (i.e. by connecting it to a female luer lock positioned on the top of the reservoir).
10) Remove all the other monitoring lines.
11) Cut the oxygenator inlet line and the arterial line at the point between the two clamps, leaving a

sufficient length of tubing to allow reconnection.
12) Turn the holder fastening knob.
13) Press the release button and rotate counterclockwise the blue ring (indicated by the lock open).
14) Remove the oxygenator module.
15) Position a new oxygenator module on the holder.
16) Connect the oxygenator inlet line and the arterial line to the oxygenator module.
17) Connect and turn on the thermocirculator.
18) If possible, connect the reservoir to the oxygenator module by turning the blue ring nut (shown with the padlock closed).
19) Connect the purge line to the turret of the cardiotomy/reservoir; reconnect the cardioplegia line.
20) Connect the gas line, the arterial sampling line and all the monitoring lines.
21) Remove the clamp from the venous line.
22) Open the recirculation line (filter purge or arteriovenous loop), fill the oxygenator module by means of the arterial pump, eliminate the air in the module by opening the purge line in sequence, and recirculate at a maximum flow rate of 1000 ml/min.
23) Close the recirculation line remove the clamp from the arterial line and start the new bypass.
24) Close the purge line and reconnect the cardioplegia circuit if necessary.
25) Restore the vacuum in the cardiotomy/venous reservoir if using the vacuum-assisted drainage technique.

MEDICAL DEVICES FOR USE WITH TRILLY PAEDIATRIC AF

There are no contraindications for use of any heating/cooling system (thermocirculator).
At present EUROSETS is not aware of any contraindication to use of the device with occlusive pumps or centrifugal pumps. The use of other types of pumps must be agreed with EUROSETS.
The circuit connections must be made using tubes of a diameter compatible with the dimensions of the ports on the device (3/8", 1/4").
Eurosets recommended to always use the convenience kit, included for each oxygenator, consisting of 3 x 3/8"-1/4" reducers ports, 1 x cardioplegia adapter and 1 x venous return extension.
Use Sechrist or a system with similar technical features as air/oxygen mixer.
Eurosets recommends the use of YSI temperature probes.
When using the vacuum-assisted drainage technique, it is recommended to use the specific Eurosets connection lines between the cardiotomy/venous reservoir and the vacuum regulator.

LIMITED WARRANTY

These warranty conditions are in addition to any statutory rights of the purchaser pursuant to applicable law.
EUROSETS warrants that all reasonable care has been taken in the manufacture of this medical device as required by the nature of the device and the use for which the device is intended.
EUROSETS warrants that the medical device is capable of functioning as indicated in these instructions for use when used in accordance with them by a qualified user and before any expiry date indicated on the packaging.
Nonetheless, EUROSETS cannot guarantee that incorrect diagnosis or therapy and/or the particular physical and biological characteristics of an individual patient do not affect the performance and effectiveness of the device with damaging consequences for the patient, even though the specified instructions for use have been respected.
EUROSETS, whilst emphasizing the need to adhere strictly to the instructions for use and to adopt all the necessary precautions for proper use of the device, cannot assume any responsibility for any loss, damage, expense, incidents or consequences arising directly or indirectly from improper use of this device.
EUROSETS undertakes to replace the medical device in the event that it is defective at the time of placing on the market or, if shipped by EUROSETS, at the time of delivery to the end user, unless such defect is attributable to the purchaser.
The above replaces all other warranties on sale and/or functionality.
No EUROSETS representative, dealer, distributor or intermediary or any other industrial or commercial organisation is authorised to make any claim or provide additional warranties other than those expressly stated herein.
EUROSETS declines all responsibility for any modifications to the Warranty Conditions and the information/instructions for use expressly stated herein.
The purchaser undertakes to comply with the terms

of this warranty and agrees, in the event of a dispute or litigation with EUROSETS, not to make claims based on alleged or proven changes or alterations made to the warranty by anyone contrary to and/or in addition to what has been agreed upon herein.
The relationship between the parties to the contract (even if not stipulated in writing) for which this warranty is granted, as well as any dispute related thereto or connected therewith, as well as any relationship or dispute regarding this warranty, its interpretation and execution, nothing excluded and/or reserved, are exclusively governed by Italian legislation and jurisdiction.
Any disputes shall exclusively be settled by the Court of Modena (Italy).

CE 0123

Tento produkt je opatřen značkou CE / Dieses Medizinprodukt verfügt über die CE-Markierung / Το παρόν ιατροτεχνολογικό προϊόν φέρει τη σήμανση CE / This medical device bears the CE marking / Este producto sanitario dispone de la marca CE / Ce dispositif médical est marqué CE / Questo dispositivo medico è marcato CE / Dit medisch hulpmiddel is voorzien van de CE-markering / Este dispositivo médico tem marcação CE / Este dispositivo médico tem marcação CE / Данный медицинский прибор имеет маркировку CE

VYSVĚTLENÍ SYMBOLŮ POUŽITÝCH NA ŠTÍTCÍCH / BEDEUTUNG DER AUF DEN ETIKETTEN VERWENDETEN SYMBOLE / ΕΠΕΞΗΓΗΣΗ ΤΩΝ ΣΥΜΒΟΛΩΝ ΠΟΥ ΧΡΗΣΙΜΟΠΟΙΟΥΝΤΑΙ ΣΤΙΣ ΕΤΙΚΕΤΕΣ / EXPLANATION OF THE SYMBOLS USED ON THE LABELS / EXPLICACIÓN DE LOS SÍMBOLOS UTILIZADOS EN LAS ETIQUETAS / EXPLICATION DES SYMBOLES UTILISÉS SUR LES ÉTIQUETTES / SPIEGAZIONE DEI SIMBOLI USATI SULLE ETICHETTE DEL DISPOSITIVO / VERKLARING VAN DE SYMBOLEN DIE OP DE ETIKETTEN GEBRUIKT WORDEN / EXPLICAÇÃO DOS SÍMBOLOS UTILIZADOS NAS ETIQUETAS / EXPLICAÇÃO DOS SÍMBOLOS USADOS NAS ETIQUETAS DO DISPOSITIVO / ОБЪЯСНЕНИЕ СИМВОЛОВ, ИСПОЛЬЗУЕМЫХ НА ЭТИКЕТКАХ

Výrobce / Hersteller / Κατασκευαστής / Manufacturer / Fabricante / Fabricant / Produttore / Fabrikant / Fabricante / Fabricante / Изготовитель

Datum výroby / Herstellungsdatum / Ημερομηνία παραγωγής / Date of manufacture / Fecha de fabricación / Date de fabrication / Data di produzione / Productiedatum / Data de produção / Data de produção / Дата изготовления

Použijte do data (datum spotřeby) / Verwendbar bis (Verfallsdatum) / Οριακή ημερομηνία κατανάλωσης (ημερομηνία λήξης) / Use by-date (expiry date) / Fecha límite de uso (fecha de caducidad) / Utiliser avant la date (date de péremption) / Data limite per il consumo (data di scadenza) / Gebruiken voor datum (houdbaarheidsdatum) / Data limite para o consumo (prazo de validade) / Data limite para o consumo (prazo de validade) / Дата истечения срока действия (срок годности)

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Křehké, manipulujte opatrně / Vorsicht! Zerbrechlich, mit Vorsicht handhaben! / Εύθραυστο, χειριστείτε με προσοχή / Fragile, handle with care / Frágil, manejar con cuidado / Fragile, manipuler avec soin / Fragile, maneggiare con cura / Breekbaar,voorzichtig behandelen / Frágil, manipular com cuidado / Frágil, manusear com cuidado / Хрупкий товар, обращаться с осторожностью

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0°C 32°F 40°C 104°F Teplotní limit / Temperaturbereich / Όριο θερμοκρασίας / Temperature limit / Límites de temperatura / Limite de température / Limite di temperatura / Temperatuurgrens / Limite de temperatura / Limite de temperatura / Температурный предел
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Upozornění / Vorsicht / Προσοχή / Caution / Precaución / Attention / Attenzione / Pas op / Atenção / Atenção / Внимание

Nepyrogenní dráha kapaliny / Fließweg, pyrogenfrei / Μη πυρετογόνος οδός υγρών / Non-pyrogenic fluid path / Trayectoria de fluidos no pirogénicos / Chemin de fluide non pyrogène / Percorso fluido non pirogeno / Pyrogeenvrij vloeistofpad / Percurso de fluido não pirogénico / Percurso de fluido não pirogênico / Непирогенный канал жидкости

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EVERY LIFE MATTERS

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