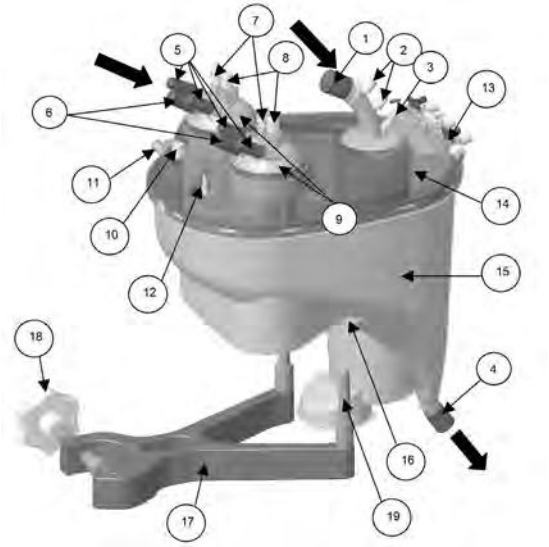
HORIZON CVR

Cardiotomy/Venous Reservoir
for extracorporeal circulation in cardio surgery

INSTRUCTION FOR USE

EUROSETS
EVERY LIFE MATTERS

Figure 1 – HORIZON CVR Cardiotomy/Venous Reservoir (flow direction indicated by bold arrows)

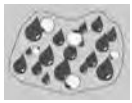
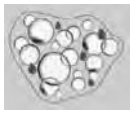


1	Venous blood inlet port (VENOUS RETURN) 360° rotatable
2	2 female luer lock ports on venous blood inlet
3	Temperature probe port on venous blood inlet
4	Venous blood outlet port
5	2 x 1/4" (6.35 mm) filtered ports on each cardiotomy
6	1 x 3/8" (9.53 mm) filtered port on each cardiotomy
7	1 x female luer lock filtered port on each cardiotomy (for use also as Quick prime port)
8	1 x female filtered POS lock (ISO 8838) reducible to female luer lock on each cardiotomy
9	2 x cardiotomy turrets 360° rotatable
10	1 x unfiltered female luer lock port
11	VENT/VACUUM port (VAVD technique)
12	Pressure relief valve
13	Sampling manifold
14	Reservoir lid
15	Reservoir housing
16	Recess for holder
17	Holder
18	Knob
19	Holder pin

A. DESCRIPTION

HORIZON CVR is a hard-shell cardiotomy/venous reservoir integrated with two cardiotomy filters, designed to allow venous drainage of the patient's blood, both through the hydrostatic load (height difference between the patient and the reservoir) and the vacuum-assisted venous drainage (VAVD) technique. The device is fitted with a pressure relief valve. The reservoir's inner contact surfaces are coated with A.G.I.L.E. (Advanced Generation Inert Layer E.C.C.) system, based on Phosphoriylcoline (PC), improving the device blood compatibility by reducing platelet adhesion on the coated surface.
The device is single-use, non-pyrogenic, supplied **STERILE** and individually packed. Sterilised by ethylene oxide.

B. TECHNICAL FEATURES

Max. Blood Volume Capacity		4500 ml
Max Operating Volume		4500 ml
Min. Operating Volume		150 ml up to 5 l/min 200 ml from 5 to 8 l/min
Blood Flow Range		Venous Flow: 0.5-8 l/min Cardiotomies: max. 2.5 l/min (each) Combined venous and cardiotomies flow: max. 8 l/min
Dynamic Priming (Hold up) Volume		
	Venous Filter	250 ml @ 8 l/min
Volume scale tolerance		± 10% for volumes ⩽ 500 ml ± 5% for volumes > 500 ml
Filtration		
Venous	Pore size	80 µm
	Efficiency	⩾90% at 80 µm
Cardiotomies	Pore size	40 µm
	Efficiency	⩾90% 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		1/2" (12.7mm) – 360° rotatable
Luer lock at venous inlet		2 x female luer lock
Venous temperature probe port at venous inlet		YSI Series 400 fitting
Intracavitary cardiotomy turret (360° rotatable) ports (mainly blood with limited amount of air)		2 x 1/4" (6.35 mm) 1 x 3/8" (9.53 mm) 1 x female luer lock 1 x female POS lock (ISO 8838) reducible to female luer lock
Extracavitary cardiotomy turret (360° rotatable) ports (mainly air with limited amount of blood)		2 x 1/4" (6.35 mm) 1 x 3/8" (9.53 mm) 1 x female luer lock 1 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)

Adapters	
Venous blood inlet port adapter	1 x 1/2" (12.7mm) / 3/8" (9.53 mm)
Cardioplegia adapter	1 x POS lock male (ISO 8837) with 1/4" (6.35 mm) connector
Other adapters	1 x 3/8" (9.53 mm) / 1/4" (6.35 mm) 1 x 1/4" (6.35 mm) / female luer lock 1 x 3/8" (9.53 mm) / female luer lock
Materials	
Housing parts (reservoir and lid)	Polycarbonate (PC)
Filtering media (venous and cardiotomies)	Polyester (PET), Polypropylene (PP)
Defoamer (venous and cardiotomies)	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[1] available on request	
	Blood cell damage
	Air-handling capability
	Antifoam characteristics
	Break-through volume

[1] The data include the applicable tolerances.

C. INTENDED USE AND INDICATIONS FOR USE

HORIZON CVR hard-shell cardiotomy/venous reservoir is intended to be used in an extracorporeal perfusion circuit to collect, store and filter venous and cardiotomy suctioned blood during routine cardiopulmonary bypass procedures up to 6 hours in surgery. The hard-shell cardiotomy/venous reservoir is also intended for use during vacuum-assisted venous drainage (VAVD) procedures.
HORIZON CVR is indicated for use on adult patients undergoing extracorporeal circulation during cardiopulmonary bypass procedures. HORIZON CVR should not be used for more than 6 hours. Contact with blood for longer periods is not advised. HORIZON CVR should be used in combination with the medical devices listed in section N (Medical devices for use with HORIZON CVR).

D. CONTRAINDICATIONS

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

E. RISKS AND SIDE EFFECTS

The possible risks and side effects of the HORIZON CVR include:

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

F. 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.

CAUTIONS
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 ECC. Any leakage may give rise to loss of sterility, blood leakage, gaseous embolism. If a leakage during priming or ECC is noticed, replace the defective device following good perfusion** practices.
- **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 gas flow.**
- **To safely apply a vacuum to the device, carefully read section L of these instructions for use.**
- **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).**
- **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.**

CAUTION

- Follow an anticoagulation protocol and monitor anticoagulation before, during and after the bypass.

The benefit of using an extracorporeal support must be weighed against the risk of systemic anticoagulation and it must be prescribed by a physician. Maintain adequate anticoagulation before and during the procedure.

- Federal law (USA) restricts this device to sale by or on the order of a physician.

G. SETUP

1) POSITIONING THE HOLDER

Position the HORIZON CVR 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 Adult/Paediatric Oxygenators Holder Instructions for Use for two different height holder positions).

2) SECURING HORIZON CVR 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 connectors accidentally come into contact with lubricating agents which may encourage accidental disconnection.**

Secure HORIZON CVR on the holder.

Check that HORIZON CVR fits perfectly and fully into place with the holder support inserts in the two housing holes.

3) CONNECTING THE CIRCUIT

WARNINGS

- **All the connections downstream of the pump**

must be secured by means of ties.

- **Remove the yellow label (labelled with "Remove before use") and the yellow cap from the VENT/VACUUM connector.**
- **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.**

VENOUS LINE: Connect a 1/2" venous line to the reservoir venous inlet port marked "VENOUS RETURN".

The venous inlet port can be rotated through 360° 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, connect the ends of the aspiration lines and turn the turret orienting the filtered inlets towards the suction pumps.

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.

Connect the oxygenator purge line to the top of HORIZON CVR (turrets).

4) SAMPLING MANIFOLD

The arterial/venous sampling manifold is positioned on the venous reservoir lid.

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. After perfoming artero/venous sampling, Eurosets recommends to maintain the three stopcocks of the manifold in the open position thus to allow an artero/venous loop during ECC, permitting a representative sampling of the perfusion status.

CAUTION

The user should check for occlusions in tubing during set up.

5) CONNECTING THE TEMPERATURE PROBE

The venous temperature probe port is positioned on the venous inlet port of the reservoir.

6) CONNECTING THE VACUUM LINE

If performing vacuum-assisted drainage (VAVD), please read carefully section L of these instructions for use.

H. PRIMING 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 device.**

1) CLOSE THE VENOUS LINE

Clamp the venous line leading from the patient.

2) PRIME THE VENOUS RESERVOIR

Close all the aspiration lines with clamps and secure with ties all aspiration lines connected to the turrets. Fill the cardiotomy/venous reservoir with sufficient priming solution to ensure that the intended hematocrit is obtained, taking into account that:

- the 3/8" tube capacity is 72 ml/m;
- the 1/2" tube capacity is 127 ml/m.

Eurosets suggests to perform priming through one of the cardiotomy turret ports.

Clamp the cardiotomy/venous reservoir outlet.

3) PRIME THE OXYGENATOR, FOLLOWING THE INSTRUCTIONS FOR USE OF THE OXYGENATOR IN USE

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. Once oxygenator is completely filled, position the pump segment in the arterial pump and start recirculation.

WARNING

- **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.**

I. 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), please read carefully section L of these instructions for use.

J. 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.

If performing vacuum-assisted drainage (VAVD), please read carefully section L of these instructions for use.

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 connector of the central stopcock (white handle) on the sampling manifold.**
- **The cardiotomy/venous reservoir minimum operating volume is 200 ml at 8 l/min and 150 ml at 5 l/min. Minimum operating volume is yellow highlighted on the reservoir volume graduated scale. 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.**
- **It is recommended to monitor the cardiotomy/venous reservoir volume using a reservoir level sensor.**

2) CARDIOTOMY/VENOUS RESERVOIR MANAGEMENT

If performing vacuum-assisted drainage (VAVD), please read carefully section L of these instructions for use. If you need to add priming solution to the venous reservoir, use the 1/4" or the luer-lock or the Pos-lock ports located on the turrets of the cardiotomy/venous reservoir.

WARNING

- **If you wish to change from vacuum-assisted drainage to conventional venous drainage please read carefully section L of these instructions for use.**

K. TERMINATING BYPASS

This must be carried out depending on the condition of each individual patient.

CAUTION

If extracorporeal circulation has to be restarted, maintain a minimum blood flow inside HORIZON CVR reservoir.

L. BLOOD RECOVERY 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 has reached the minimum volume. Pump the prime slowly 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.

M. USE OF THE VACUUM-ASSISTED VENOUS DRAINAGE TECHNIQUE (VAVD)

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

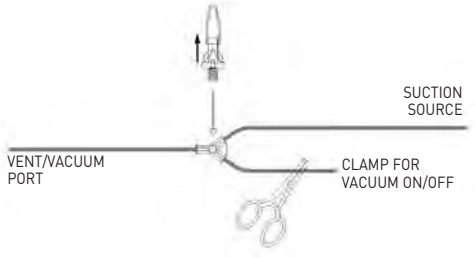
1) CONNECTING THE VACUUM LINE

If performing venous drainage using the vacuum-assisted technique (VAVD), the vacuum line must be connected to the VENT/VACUUM port. Ensure that label and yellow protection cap have been removed from VENT/VACUUM port.

Connect the Eurosets VAVD connection kit (figure

2) to it.
Connect the other end of the line to a vacuum regulator equipped with a condensation trap.

Figure 2 – Connection line to the aspiration source for VAVD



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.**

2) INITIATING BYPASS

OPENING THE ARTERIAL AND VENOUS LINES

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

3) DURING BYPASS

CHECKING THE VENOUS RETURN

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

LOW FLOW RECIRCULATION

In all cases that are expected a circulatory arrest and the opening of a shunt between the arterial and venous circuit, to maintain blood on the move, it is necessary to stop the vacuum application.
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 technique.
Resume the arterial pump flow to the value previously set. In case of vacuum-assisted drainage, re-insert leakproof cap on the cardiotomy/venous reservoir and re insert the clamp on the collecting line to the suction source. Gradually increase the negative pressure to reach an adequate blood drainage.

CARDIOTOMY/VENOUS RESERVOIR MANAGEMENT

WARNING
- **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 connectors positioned on the turrets, as this causes a reduction of the vacuum in the reservoir; open the connectors only for the time necessary for the operation required.**

4) USING THE CARDIOTOMY/VENOUS RESERVOIR FOR POST-OPERATIVE AUTOTRANSFUSION (Vacuum)

Connect a line and a vacuum regulator to the VENT/VACUUM port of the cardiotomy/venous reservoir.

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

5) HORIZON CVR REPLACEMENT

1) Suspend the application of vacuum to the cardiotomy/venous reservoir (when vacuum-assisted drainage has been used).
2) Disconnect all connections lines from the HORIZON CVR.
3) Place a new HORIZON CVR on the holder. Connect all the lines (venous line to the cardiotomy/venous reservoir, pump segment of the cardiotomy/venous reservoir to the oxygenator, and possible vacuum line to the cardiotomy/venous reservoir).

6) MEDICAL DEVICES FOR USE WITH HORIZON CVR

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.

N. 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.
4) Close all the ports of the cardiotomy/venous reservoir used during bypass, including the VENT/VACUUM port.
5) If performing vacuum-assisted drainage (VAVD), please read carefully section L of these instructions for use.

WARNING

- **When using the cardiotomy/venous reservoir for post-operative autotransfusion, pay attention when administering protamine because excessive dosage may cause thrombus formation in the cardiotomy/venous reservoir.**

O. HORIZON CVR 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 performance, leaks, abnormal blood parameters, etc.), replace the cardiotomy/venous reservoir following the instructions below.

CAUTION

Use a sterile technique throughout the replacement procedure.

1) If performing vacuum-assisted drainage (VAVD), please read carefully section L of these instructions for use.
2) Turn the main pump and the suction pump off.
3) Close the venous return and the blood outlet lines, using two clamps (5 centimetres apart).
4) Cut the venous return and the blood outlet lines in the section between the two clamps, leaving a sufficient length of tubing to allow reconnection.
5) Remove all the sampling lines, the suction lines, and in any case all the connection to the HORIZON CVR cardiotomy/venous reservoir.
6) Remove HORIZON CVR from the holder.
7) Place a new HORIZON CVR on the holder. Connect all the lines (inlet, outlet, other connection lines, vacuum line, sampling lines, etc.).
8) Verify all connections and secure with ties.
9) Prime New HORIZON CVR as described in Section G Prime Procedure.
10) Remove the clamps from the venous and the arterial lines, close the oxygenator purge line and restart the bypass.
11) 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.

P. MEDICAL DEVICES FOR USE WITH HORIZON CVR

The device can be integrated into any perfusion system.

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").

When using the vacuum-assisted drainage (VAVD), please read carefully section L of these instructions for use.

Eurosets recommends the use of YSI 400 series temperature probes.

Q. 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, explicit or implicit, written or verbal, including warranties of merchantability and fitness for purpose.

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 / 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 / Ez az orvostechnikai eszköz CE jelöléssel van ellátva / Questo dispositivo medico è marcato CE / Dit medisch hulpmiddel is voorzien van de CE / Ten wyrób medyczny nosi oznakowanie CE / Este dispositivo médico tem marcação CE / Acest dispozitiv medical poartă marcajul 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 / A CÍMKÉKEN HASZNÁLT SZIMBÓLUMOK MAGYARÁZATA / SPIEGAZIONE DEI SIMBOLI USATI SULLE ETICHETTE DEL DISPOSITIVO / VERKLARING VAN DE SYMBOLEN DIE OP DE ETIKETTEN GEBRUIKT WORDEN / OBJAŚNIENIE SYMBOLI NA ETYKIETACH / EXPLICAÇÃO DOS SÍMBOLOS UTILIZADOS NAS ETIQUETA / EXPLICAȚIA SIMBOLURILOR UTILIZATE PE ETICHETE / ОБЪЯСНЕНИЕ СИМВОЛОВ, ИСПОЛЬЗУЕМЫХ НА ЭТИКЕТКАХ

Výrobce / Hersteller / Κατασκευαστής / Manufacturer / Fabricante / Fabricant / Gyártó / Produttore / Fabrikant / Producent / Fabricante / Producător / Изготовитель

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

Použijte do data / Verwendbar bis / Ορισκή ημερομηνία κατανάλωσης / Use by-date / Fecha límite de uso / Utiliser avant la date / Lejárat napja / Data limite per il consumo / Gebruiken voor datum / Użyć przed / Data limite para o consumo / Data limită pentru consum / Дата истечения срока действия

LOT Kód šarže / Batchnummer / Κωδικός παρτίδας / Batch code / Código de lote / Code de lot / Gyártási tételszám / Codice lotto / Batchcode / Kod partii / Código do lote / Cod lot / Код партии

REF Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Catalogue number / Número de catálogo / Numéro du catalogue / Katalógusszám / Numero catalogo / Catalogusnummer / Numer katalogowy / Número catálogo / Număr catalog / Номер по каталогу

STERILE EO Sterilizováno etylenoxidem (Sterilní) / Mit Ethylenoxid sterilisiert (steril) / Αποστειρωμένο με αιθυλενοξείδιο (στείρο) / Sterilized using ethylene oxide (Sterile) / Esterilizado utilizando óxido de etileno (estéril) / Stérilisé à l'oxyde d'éthylène (stérile) / Etilén-oxiddal sterilizált (steril) / Sterilizzato con ossido di etilene (sterile) / Gesteriliseerd m.b.v. ethyleenoxide (steriel) / Wysterylizowano tlenkiem etylenu (sterylny) / Esterilizado com óxido de etileno (estéril) / Sterilizat cu oxid de etilenă (steril) / Стерилизовано с использованием этиленоксида (Стерильно)

Nesterilizujte / Nicht erneut sterilisieren / Μην επαναποστειρώνετε / Do not resterilize / No volver a esterilizar / Ne pas restériliser / Nem újrasterilizálandó / Non risterilizzare / Niet opnieuw steriliseren / Nie sterylizować ponownie / Não reesterilizar / A nu se resteriliza / Не подходит для повторной стерилизации

Nepoužívejte, pokud je obal poškozený / Nicht verwenden, wenn die Verpackung beschädigt ist / Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά / Do not use if package is damaged and consult instructions for use / No utilizar si el embalaje está dañado / Ne pas utiliser si l'emballage est endommagé et consulter le mode d'emploi / Ne használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Niet gebruiken als de verpakking beschadigd is / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se utiliza dacă ambalajul este deteriorat / Не использовать, если упаковка повреждена

Tímto směrem nahoru / Oben / Αυτή η πλευρά προς τα πάνω / This way up / Este lado arriba / Haut / Állítva szállítandó / Tenere rivolto in alto / Deze zijde omhoog / Góra, nie przewracać / Manter virado para cima / Păstrați orientat în sus / Верх упаковки

Křehké, manipulujte opatrně / Vorsicht! Zerbrechlich, mit Vorsicht handhaben! / Εύθραυστο, χειριστείτε με προσοχή / Fragile, handle with care / Frágil, manejar con cuidado / Fragile, manipuler avec soin / Törékeny / Fragile, maneggiare con cura / Breekbaar,voorzichtig behandelen / Ostrożnie kruche / Frágil, manipular com cuidado / Хрупкий товар, обращаться с осторожностью / Fragil, a se manipula cu atenție

Udržujte v suchu / Vor Nässe schützen / Να φυλάσσεται σε ξηρό μέρος / Keep dry / Mantener seco / Garder au sec / Csapadéktól óvni / Conservare in un luogo asciutto / Droog bewaren / Chronić przed wilgocią / Conservar em um lugar seco / A se păstra la loc uscat / Плохо переносит влажность

Chraňte před zdroji slunečního světla - Chraňte před teplem / Von Sonnenlichteinfall fernhalten - Von Hitzequellen fernhalten / Μακριά από πηγές ηλιακού φωτός - Μακριά από θερμότητα / Keep away from sunlight sources - Keep away from heat / Mantener alejado de la luz solar directa - Mantener alejado del calor / Tenir à l'abri du soleil - Tenir à l'écart de la chaleur / Napfénytől távol tartandó - Hőtől távol tartandó / Tenere lontano dalla luce solare - Tenere lontano da fonti di calore / Uit de buurt houden van warmtebronnen - Uit de buurt houden van warmte / Przechowywać z dala od źródeł światła słonecznego - Przechowywać z dala od źródeł ciepła / Manter afastado da luz solar - Manter afastado de fontes de calor / A se proteja de lumina solară - A se păstra departe de surse de căldură / Хранить вдали от источников солнечного света - Хранить вдали от источников тепла

0°C 32°F 40°C 104°F Teplotní limit / Temperaturbereich / Όριο θερμοκρασίας / Temperature limit / Límites de temperatura / Limite de température / Hőmérsékletkorlátok / Limite di temperatura / Temperatuurgrens / Przestrzegać zakresu temperatur / Limite de temperatura / Limite de temperatură / Температурный предел
0°C (32°F) - 40°C (104°F)

Nepoužívejte opakovaně / Nicht wiederverwenden / Μην επαναχρησιμοποιείτε / Do not reuse / No reutilizar / Ne pas réutiliser / Egyszeri használatra / Non riutilizzare / Niet hergebruiken / Nie używać ponownie / Não reutilizar / A nu se reutiliza / Не подходит для повторного использования

Přečtěte si návod k použití / Gebrauchsanweisung beachten / Ανατρέξτε στις οδηγίες χρήσης / Consult instructions for use / Consulte las instrucciones de uso / Consulter les instructions pour l'utilisation / Olvassa el a használati útmutatót / Consultare le istruzioni per l'uso / Voor gebruik de instructies lezen / Uwaga, przeczytać instrukcję użytkowania / Consultar as instruções para a utilização / Citiți instrucțiunile de utilizare / Ознакомьтесь с инструкцией по эксплуатации

Upozornění / Vorsicht / Προσοχή / Caution / Precaución / Attention / Figyelem / Attenzione / Pas op / Uwaga / Atenção / Atenție / Внимание

Nepyrogenní dráha kapaliny / Fließweg, pyrogenfrei / Μη πυρετογόνος οδός υγρών / Non-pyrogenic fluid path / Trayectoria de fluidos no pirogénicos / Chemin de fluide non pyrogène / Nem pirogén folyadék vezeték / Percorso fluido non pirogeno / Pyrogeenvrij vloeistofpad / Ścieżka płynu, niepirogenny / Percurso de fluido não pirogénico / Linie de fluid apirogenă / Непирогенный канал жидкости

Nepyrogenní / Pyrogenfrei / Μη πυρετογόνο / Non-pyrogenic / No pirogénico / Apyrogène / Nem pirogén / Non pirogenico / Pyrogeenvrij / Non-pyrogenic / Não pirogénico / Apirogen / Непирогенно

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