XENIOS

# iLA MEMBRANE VENTILATOR

## PROCEDURE DESCRIPTION


novalung


**IF QUESTIONS, PROBLEMS OR FAULTS ARISE WHILE USING THE iLA MEMBRANE VENTILATOR**

**please contact our XENIOS clinical support, giving the batch description and serial number of the product.**

**The 24/7 XENIOS clinical support team will be happy to assist you with your clinical questions around the clock.**

**Call us. Day and night. +49 7131 2706 345**

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# 1 GENERAL

Solutions for respiratory failure – that is our philosophy. Innovative therapies provide lung protection beyond current protective ventilation standards. We can offer doctors and nursing staff new therapeutic approaches which concentrate on regeneration of the lungs and therefore can improve the outcome of the patient in cases of acute and chronic respiratory failure.

## 1.1 Preliminary remarks

The iLA Membrane Ventilator is an extrapulmonary respiratory system that breathes for the patient outside the body and hence focuses on protecting the lungs. It is used to eliminate carbon dioxide and is supplied with blood from the heart like a natural organ. The exchange of gases is performed via a plasma-tight heparin-coated diffusion membrane which is connected arterio-venously via two NovaPort one KI femoral single lumen cannulas. The iLA Membrane Ventilator can be used on patients for up to 29 days.

## 1.2 Indications

The iLA Membrane Ventilator is used for sustained (> 6 hours) but temporary support of gas exchange in the human lung. Clinical application of the iLA Membrane Ventilator is indicated in the following situations:

**All clinical situations where adequate gas exchange and in particular adequate $CO_2$ elimination is not possible when lung-protective ventilation is applied strictly.**

**Examples of such cases are:**

- ARDS of intra- or extrapulmonary genesis
- Exacerbated COPD
- Bronchopleural fistulas
- Bridge to lung transplantation
- Protective ventilation in the case of elevated intracranial pressure

**All clinical situations where a patient is required to make increased efforts for spontaneous breathing or when failure of the breathing pump is imminent.**

**Examples of such cases are:**

- Exacerbated COPD
- (Difficult) weaning

**The use of the CRRT connector allows simultaneous extracorporeal renal replacement therapy or plasmapheresis.**

## 1.3 Prerequisites

The use of the iLA Membrane Ventilator is subject to certain conditions. The hemodynamic situation must be stable with the possibility of compensating an acute arterio-venous shunt. The mean arterial pressure (MAP) should usually be at least 60 mmHg to prevent gas transfer within the membrane. Primary oxygenation failure must be excluded in all cases, i.e. the $PaO_2/FiO_2$ ratio should normally be ≥ 70.

In case there is a need for additional oxygenation support the XENIOS console is available, which in addition to $CO_2$ removal can meet any need for extracorporeal gas exchange. With four membranes of varying sizes the XENIOS console can be configured to meet individual requirements to reduce or replace invasive mechanical ventilation.

## 1.4 Contraindications

**Use of the iLA Membrane Ventilator is contraindicated in the following situations**

- Heparin-induced thrombocytopenia (HIT) or known negative reactions to heparin
- Severe cardiac dysfunction (e.g. shock)
- Relative: femoral, arterial vessel diameter ≤ 5.1 mm
- Relative: serious peripheral arterial occlusive disease (PAOD)

## 1.5 24/7 XENIOS clinical support

Our primary mission is to optimize the patient outcome. Our objective is also to increase the safety of operator and patient. To this end we offer 24/7 XENIOS clinical support service. This team consists of experts trained in intensive care medicine who offer telephone and on-site support for your clinical application around the clock. The first clinical applications are always accompanied by the 24/7 XENIOS clinical support team.

**CALL US. DAY AND NIGHT.**
**+49 7131 2706 345**

## 1.6 XENIOS ACADEMY

Please note that the XENIOS ACADEMY offers accredited advanced training courses for physicians and nursing staff in the exact use and application of the iLA Membrane Ventilator.

**DETAILS on course content, dates and registration are available at XENIOS ACADEMY on our website:**
**www.xenios-campus.com**

## 1.7 Setup of the iLA Membrane Ventilator

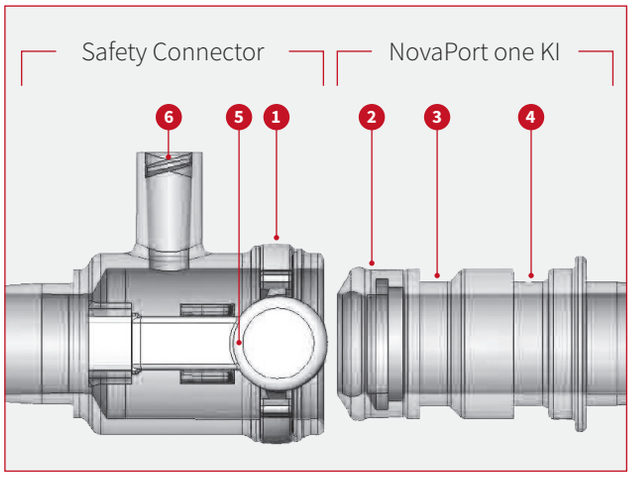
The iLA Membrane Ventilator consists of a membrane ventilator with two blood tubings which is connected to the patient's bloodstream via a specially developed Safety Connector on the NovaPort one KI femoral cannulas. The direction of the blood flow is determined by the color-coded connectors.

Mount the NovaFlow clamp-on transducer on the outlet tubing between the CRRT connector and the patient.

**All blood contact surfaces of the iLA Membrane Ventilator are covered with the x.ellence coating (contains heparin).**

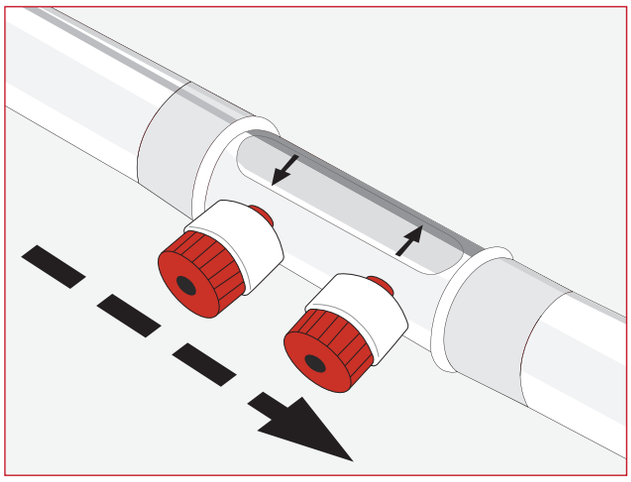
**The Safety Connector ensures that the NovaPort one KI cannulas are securely connected:**

1. Locking ring
2. Seal
3. 1. click stop
4. 2. click stop
5. Release mechanism
6. Luer lock port

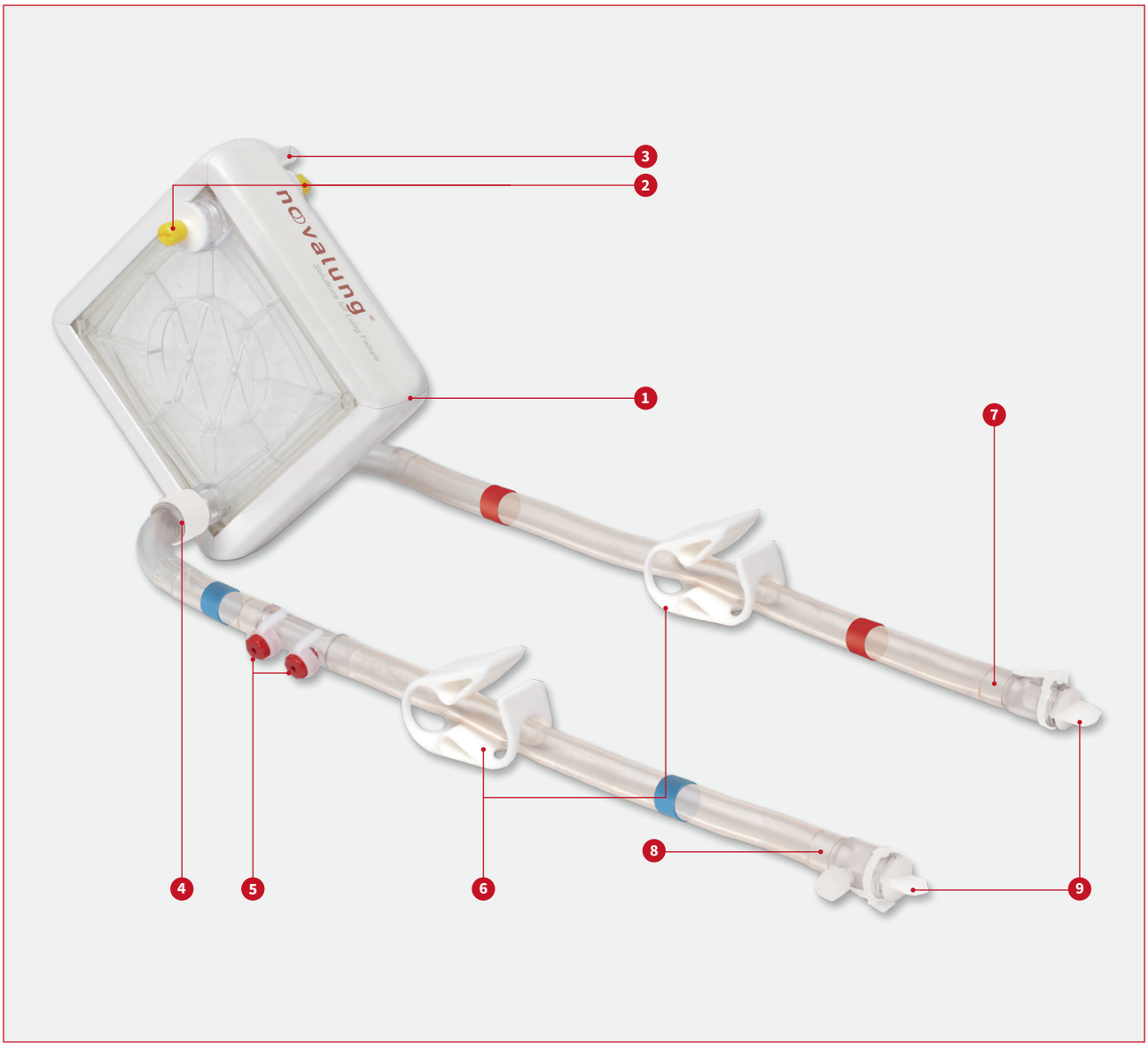



**CRRT Connector for the direct connection of a continuous renal replacement therapy.**

- Suitable for all continuous renal replacement therapies (CRRT) with blood flows up to 500 ml/min.
- Gentle for the patient as additional vascular access is not required.



## 1.8 System overview




1. Membrane Ventilator
2. Deairing
3. Oxygen port
4. 360° rotatable curve connectors
5. CRRT connectors
6. Safety clamps
7. Blood in (artery)
8. Blood out (vein)
9. Safety Connectors

# 2 HANDLING

This section describes step by step how to use the iLA Membrane Ventilator in clinical applications. These instructions cannot replace familiarisation training by our clinical support team and user training at the XENIOS ACADEMY but are intended as an additional aid.

## 2.1 Using the iLA Membrane Ventilator

*Fig. 1*

**Remove the iLA Membrane Ventilator** from the packaging and check that no parts are missing. Ensure that the red Luer caps on the CRRT ports are tightened. To do so, remove the white safety clips, tighten the Luer caps and then replace the safety clips.

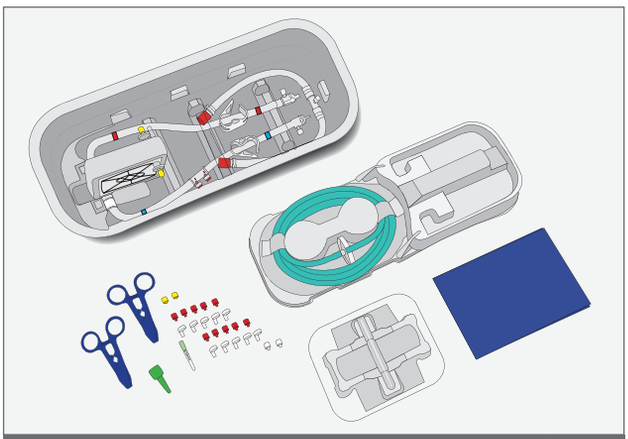


*Fig. 1*

*Fig. 2*

**Connect the priming line** to the open ends of the iLA Membrane Ventilator without twisting it. Make sure that the soft seals at the tip are not twisted. We recommend wetting with a sterile solution prior to connection.

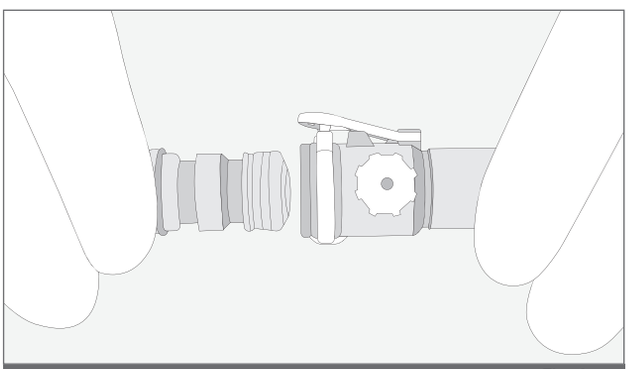


*Fig. 2*

*Fig. 3*

**Deair the iLA Membrane Ventilator** by filling the system passively without pressure with a crystalloid solution.

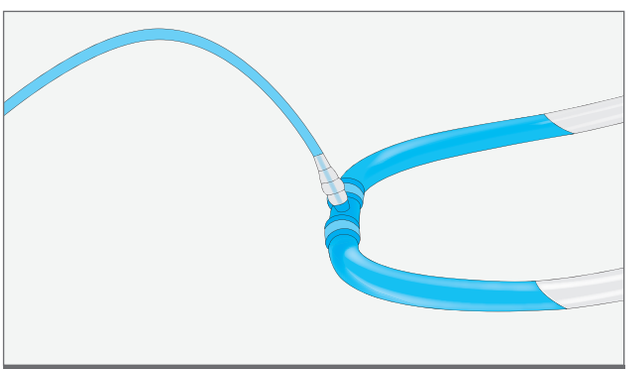


*Fig. 3*

*Fig. 4*

**Open the deairing ports** of the iLA Membrane Ventilator and take care that the deairing ports are the highest point of the system.

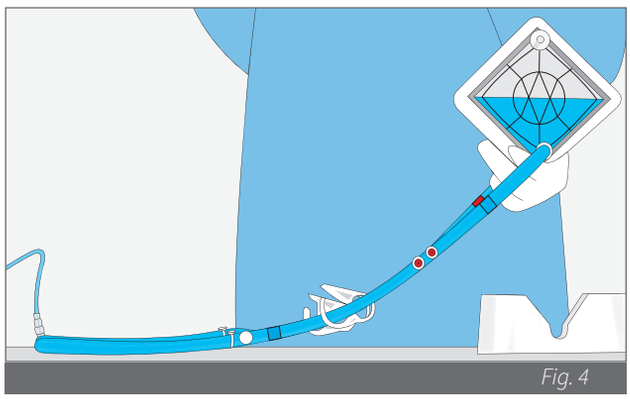


*Fig. 4*

*Fig. 5*

**Hit all four sides** of the iLA Membrane Ventilator firmly with the palm of your hand to ensure that any remaining air is expelled from the system.

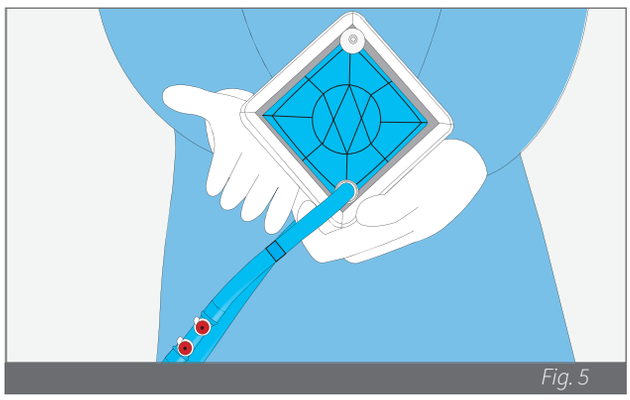


*Fig. 5*

*Fig. 6*

**Place the iLA Membrane Ventilator** in the included holder.

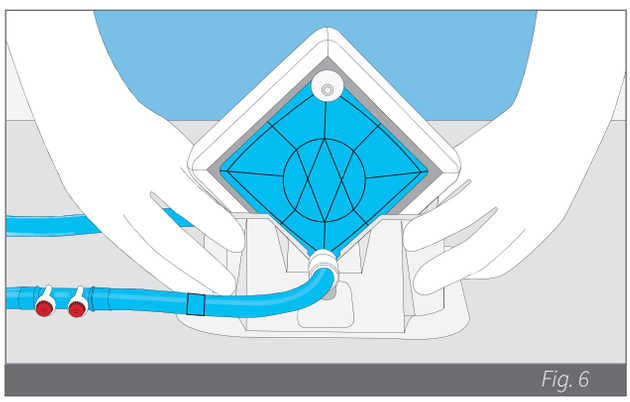


*Fig. 6*

*Fig. 7*

**Then secure the tubing ends** at the inlet and outlet of the iLA Membrane Ventilator with the safety clamps.

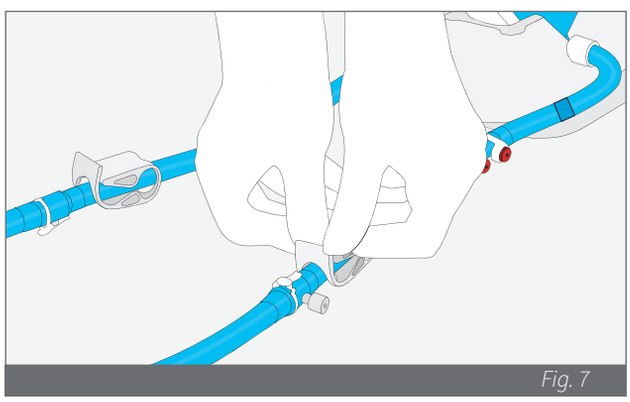


*Fig. 7*

*Fig. 8*

**Remove the selected NovaPort one KI cannulas** from their packaging.

*Fig. 8*

**We recommend the following NovaPort one KI combinations* depending on the size of the arterial vessel:**

| Ø Artery | Arterial cannula | Venous cannula |
|---|---|---|
| ≥ 6 mm | 15 Fr (5 mm) / 90 mm | 17 Fr (5.7 mm) / 140 mm |
| 5.2 mm – 5.9 mm | 13 Fr (4.3 mm) / 90 mm | 15 Fr (5 mm) / 140 mm |

*Fig. 9*

**Locate the femoral bifurcation** by ultrasound and perform venipuncture on the front of the vessel above the bifurcation.

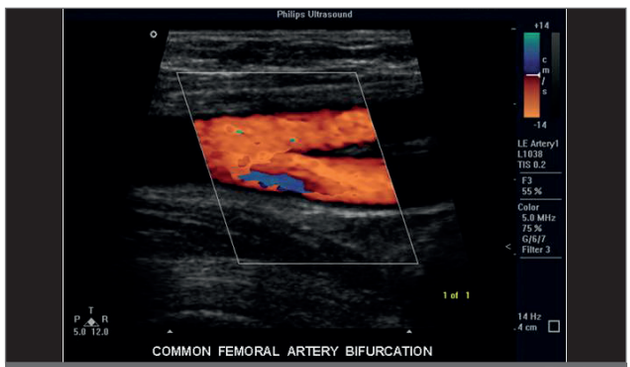


*Fig. 9*

*Fig. 10 -11*

**Insert the NovaPort one KI single lumen cannulas** into the femoral artery by using Seldinger technique and one femoral vein (bilateral insertion is preferred to unilateral insertion, to avoid possible complications during decannulation). The insertion wire must be held steady by an assistant so that the NovaPort one KI cannula can be threaded over the wire without encountering resistance. This minimizes the risk of damaging the wall of the vessel.

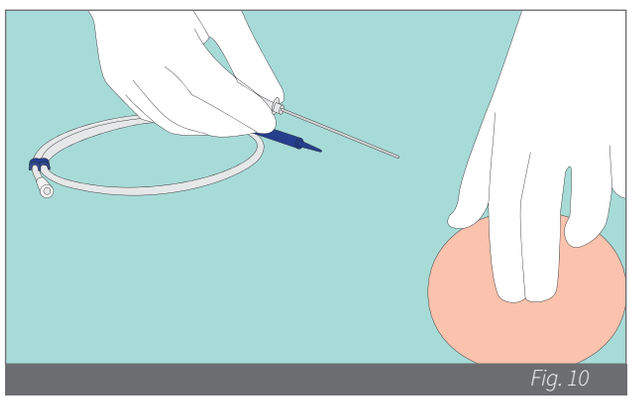


*Fig. 10*

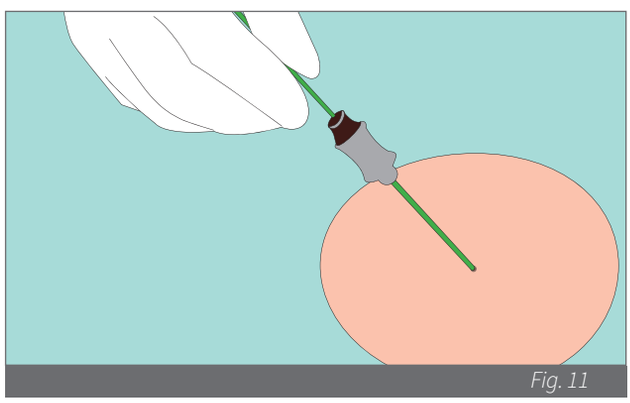


*Fig. 11*

*Individual variations in the case of adipositas (artery 140 mm), borderline cardiovascular situations (artery 13 Fr, vein 15 Fr also if artery ≥ 6 mm).

*Fig. 12*

**Insert the NovaPort one KI cannula** until the black line is at the skin level.

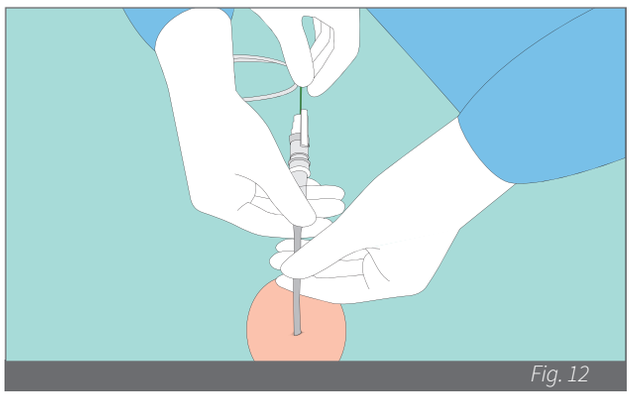


*Fig. 12*

*Fig. 13*

**Remove the wire** and retract the dilator to the third marking. Then rinse with 20 ml heparinized (20 IE/ml) crystalloid solution via the Luer connector. When doing this hold the vent plug and the dilator (with the aid of an assistant). Clamp the NovaPort one KI cannulas above the wire-reinforcement using the clamp provided, while the last milliliters of crystalloid solution are flowing in.

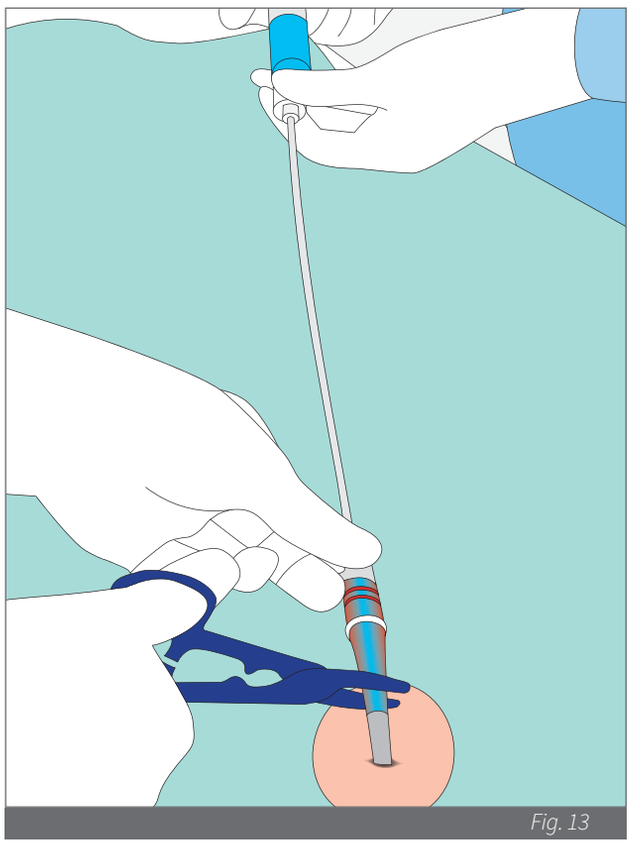


*Fig. 13*

*Fig. 14*

**Remove the dilator** and the vent plug fully.

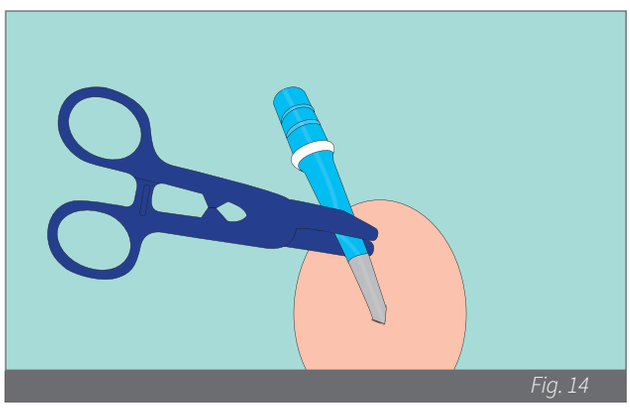


*Fig. 14*

*Fig. 15*

**Remove the priming line** by pressing the release mechanisms. Afterwards place the iLA Membrane Ventilator in the holder between the patient's thighs, taking into account the intended direction of blood flow through the iLA Membrane Ventilator.

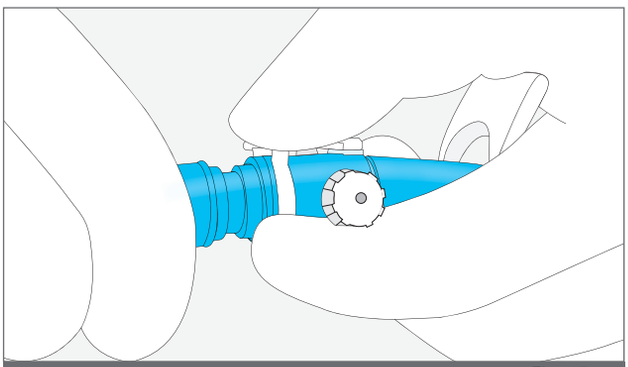


*Fig. 15*

*Fig. 16-17*

**We recommend wetting the silicon seal of the Novalung Safety Connector for better lubrication.**

**Connect the Novalung Safety Connector** without twisting it by gently turning it to the first click stop (see Section 1.6).

**Never force the connectors together. If you cannot connect the parts easily, disconnect and try again.**

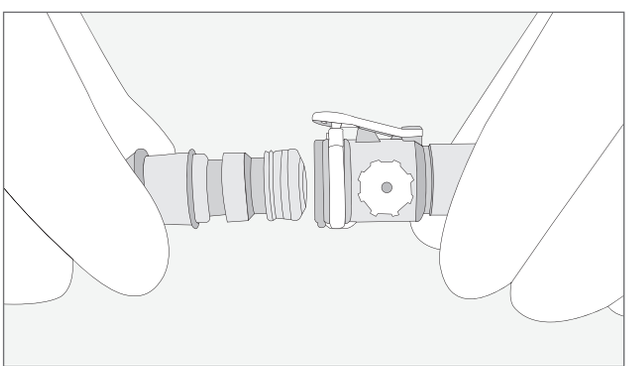


*Fig. 16*

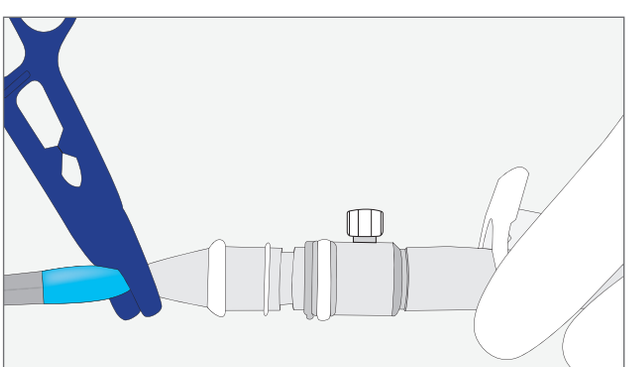


*Fig. 17*

*Fig. 18*

**Deair the connectors** using the blunt cannula provided by filling with crystalloid solution via the Luer connector.

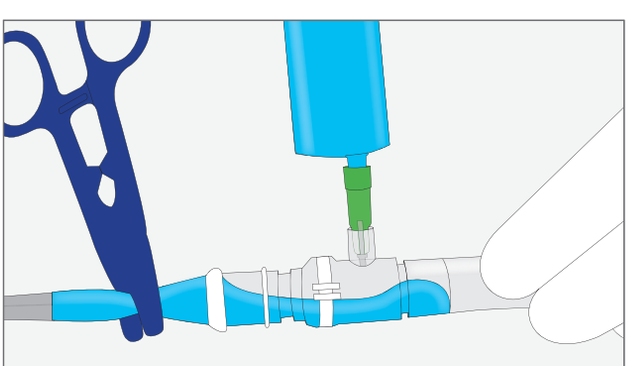


*Fig. 18*

*Fig. 19*

**Close the Luer connector** with the white cap after fully deairing the system.

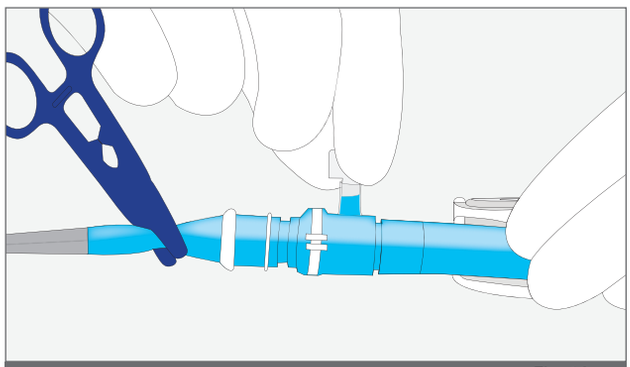


*Fig. 19*

*Fig. 20*

**Release the safety clamps** holding the tubing on the iLA Membrane Ventilator and push the connectors together to the second click stop. Check that the connectors are firmly in place.

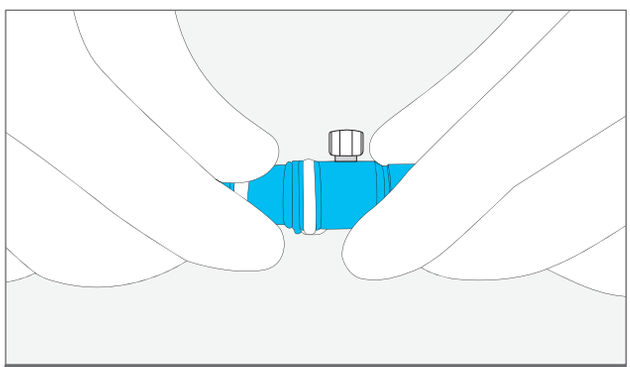


*Fig. 20*

*Fig. 21*

**Check if the system** still contains residual air. Small amounts of air can be released via the deairing ports by opening the AV shunt.

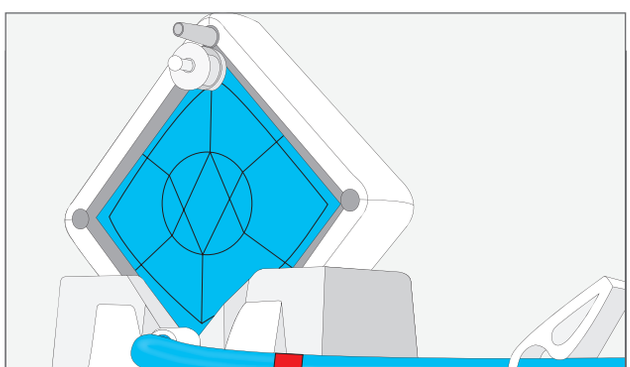


*Fig. 21*

*Fig. 22*

**Connect the NovaFlow clamp-on transducer** to the venous (outlet) tube. Check the flow direction (arrow) of the blood flow.

**Place the sensor** between the CRRT connector and the patient to ensure monitoring of the complete system.

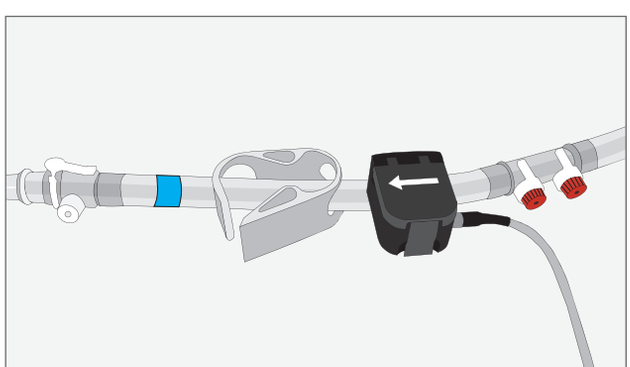


*Fig. 22*

*Fig. 23*

**Set the zero point** of the NovaFlow c Ultrasonic Flowcomputer monitor with the system filled with crystalloid solution. If you need to set the zero point again while the system is running (e.g., if the measured values are implausible) the blood flow must be stopped using the tubing clamp (venous) and the zero point must be set in accordance with the instructions for use of the NovaFlow c Ultrasonic Flowcomputer monitor (this must be done quickly due to the risk of thrombosis).

*Fig. 23*

*Fig. 24*

**First remove the venous clamp** from the venous NovaPort one KI cannula, then **slowly increase blood flow by releasing the arterial clamp** over 1-2 minutes. During this procedure always check bl ood pressure.

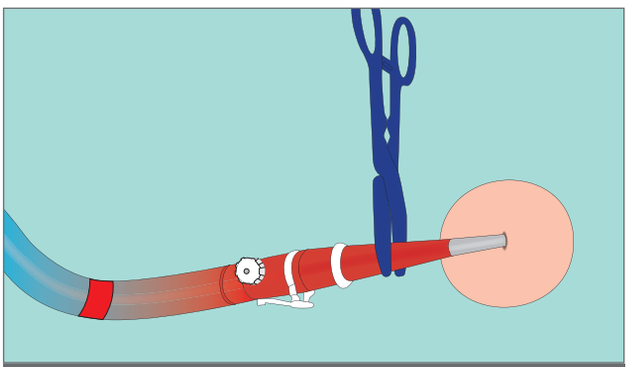


*Fig. 24*

*Fig. 25*

**Suture and attach the cannulas** with adhesive bandages in order to avoid dislocating.

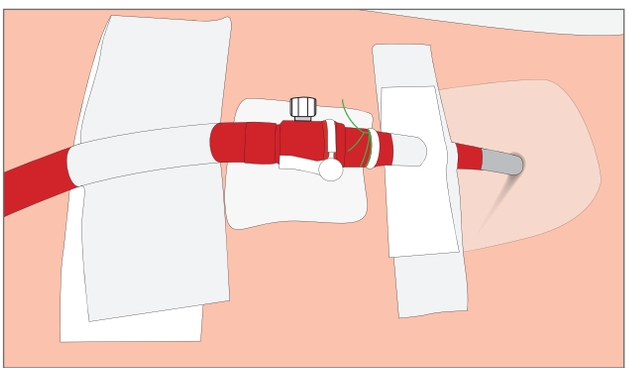


*Fig. 25*

**For patient safety set the alarm to ± 300 ml from the current blood flow. Blood flow < 500 ml/min is not acceptable.**

*Fig. 26*

**Close the deairing ports** with the yellow Luer caps after fixation. Make sure first that the system is filled completely with blood. Then connect the oxygen tube to the gas inlet port. Increase the gas flow as follows: Up to the first 4 l/min $O_2$ the gas flow should be increased in steps of maximum 1 l/min every 20 min. Then increase in steps of maximum 2 l/min every 20 min up to a maximum of 10 l/min. If the patient is being ventilated invasively, reduce the settings for mechanical ventilation to maximum protection levels.

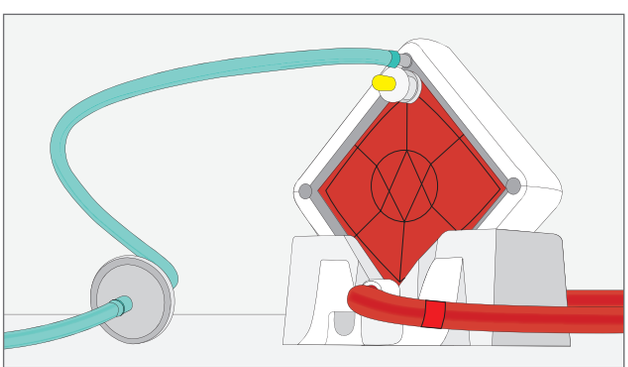


*Fig. 26*

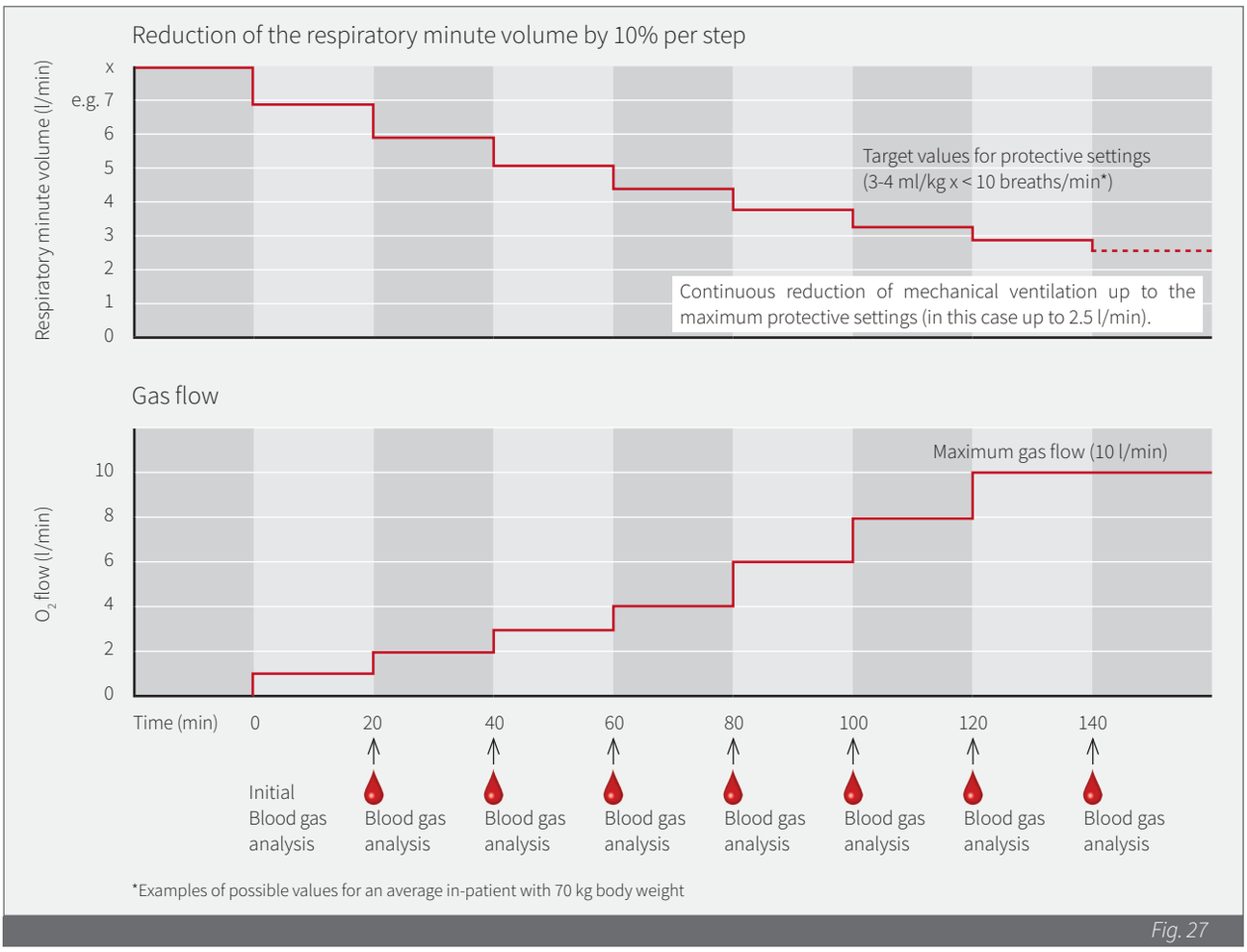
*Fig. 27*

**During the adjustment phase (adaptation of the ventilator settings due to the therapy with the iLA Membrane Ventilator) please consider the following points:**

- Proceed in steps as shown in the graph above.
- In this step only make changes that reduce ventilation; avoid making changes that can influence oxygenation.
- Avoid derecruitment – when reducing the respiratory rate compensate for any reduction of intrinsic PEEP (due to the reduction of air trapping) by increasing the extrinsic PEEP.
- Maintain the mean airway pressure.
- Prioritize the reduction of VT; proceed in steps towards a target value of 3 - 4 ml/kg IBW.
- Avoid reducing $PaCO_2$ too quickly because of the potential risk of cerebrovascular incidents and a resulting decrease in perfusion (s. *Fig. 27).*

**When reducing systemic oxygenation consider the following:**

- The increase in mixed venous saturation may potentially mitigate hypoxic pulmonary vasoconstriction and this can lead to an increase of the intrapulmonary shunt volume.
- Other causal factors which impair the oxygenation must be excluded.
- If applicable stop increasing the sweep gas flow and observe the gas exchange situation. Usually there will be a redistribution of the blood after a few hours, so that the sweep gas can be increased according to the protocol.
- Alternatively the sweep gas flow must be used that offers the best compromise between lung protective ventilation settings and oxygenation.




*Examples of possible values for an average in-patient with 70 kg body weight

*Fig. 27*

## 2.2 General guidelines on running operation

**Ensure that the iLA Membrane Ventilator is monitored continuously when in use by trained personnel.**

- Disconnection can cause rapid loss of blood from the system. Therefore the patient will require professional monitoring and the blood flow should be measured continuously using the NovaFlow Ultrasonic Flowcomputer on the venous (outlet) line after the CRRT connector.
- Non-humidified oxygen should be used as sweep gas with a maximum flow of 10 l/min.
- The iLA Membrane Ventilator must be flushed 3 times daily to rinse out condensate. The gas flow is raised to 15 l/min plus half a turn of the regulating wheel (to add up to approx. 25 l/min) for 1 sec. The initial settings should be returned to immediately afterwards.
- For reasons of patient safety and to avoid clotting in the membrane, visible, and even small amounts of air must be evacuated as quickly as possible from the iLA Membrane Ventilator via the deairing ports.
- In order to avoid potential fat deposits on the membrane, aliphatic medicines (e.g. propofol) and dietary fats should be kept to a minimum with laboratory monitoring of blood lipids. If fat deposits become visible, diet and sedation should be adapted to maintain functionality of the membrane.
- The iLA Membrane Ventilator must be positioned in full view and resting on the holder provided, below the heart level and directly on the mattress.
- Care should be taken to ensure that the NovaPort one KI cannulas and tubing are secured with plasters (see Section 2.1, Fig. 25).
- During CPR the AV shunt must be closed. Clamp the tubing of the iLA Membrane Ventilator on both sides using the safety clamps.

**Caution: Ventilation settings must be adjusted: If possible place heparin plugs in both NovaPort one KI cannulas directly after stopping the blood flow so that they can be used again later. Afterwards the iLA Membrane Ventilator must be replaced.**

- The arterial cannulated leg must be kept warm in order to avoid impacting the microcirculation. Regular checks for clinical signs of circulatory disturbance are essential as well as corresponding monitoring of the extremity (continuous transcutaneous measurement of oxygen saturation, foot pulse checks).

### HEMODYNAMICS

- A mean arterial pressure of 60 mmHg normally should be maintained to avoid the risk of a gas leakage.
- The blood flow should be greater than 1 l/min. Lower values can be tolerated for short periods (drop in performance, increase in the risk of clotting and risk of air leaks on the blood side). A flow less than 0.5 l/min is not acceptable.

### ANTICOAGULATION

- Anticoagulation must be adapted to the individual situation of the patient. Since the whole system (iLA Membrane Ventilator, NovaPort one KI cannulas) is already heparinised, we recommend low-dose heparinisation with a target PTT ≥ 55 sec. On occasion an extended PTT is required, e. g. in acute septic cases. (fibrinogen ≥ 4 g/l – > PTT ≥ 75 sec.).
- If heparin cannot be administered (e.g. severe bleeding), the life cycle of the iLA Membrane Ventilator may be shortened.

## 2.3 Connecting the CRRT circuit

*Fig. 28*

**The blood flow must be restored as quickly as possible after connection of the CRRT circuit (thrombosis risk).**

1. Blood inlet (artery)
2. Blood outlet (vein)
3. Blood flow direction

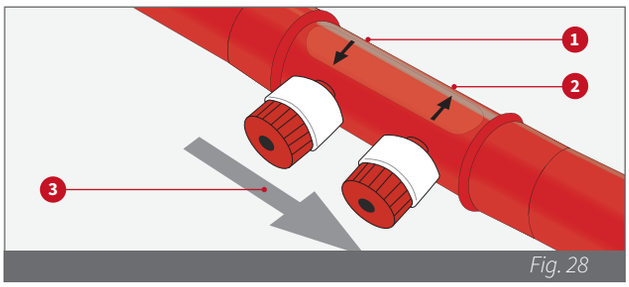


*Fig. 28*

**Remove the white safety clips** from the caps. The blood flow direction for the connection is indicated by arrows on the connector.

*Fig. 29*

**Clamp off blood flow** on both sides of the CRRT connector, immediately prior to connection.

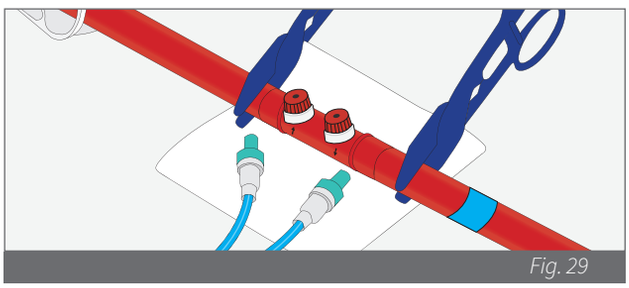


*Fig. 29*

*Fig. 30*

**Release all clamps** (CRRT circuit and iLA tubing) and start the pump of the CRRT machine.

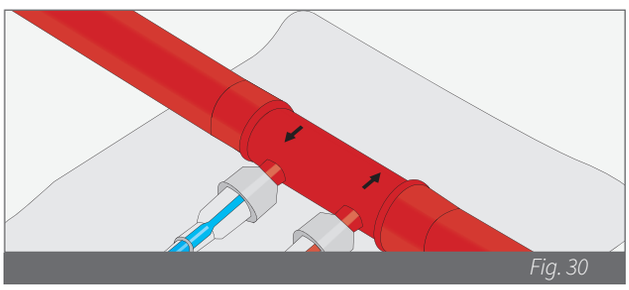


*Fig. 30*

## 2.4 Removal of the CRRT circuit

*Fig. 31*

**Clamp off blood flow** on both sides of the CRRT connector immediately prior to disconnection.

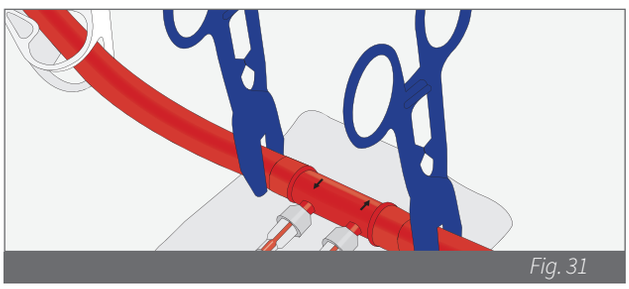


*Fig. 31*

*Fig. 32*

**Use the red Luer caps** supplied with the iLA Membrane Ventilator to seal the CRRT connector (to ensure a complete seal of the connector cone, otherwise thrombosis risk) and secure with the white safety clips.

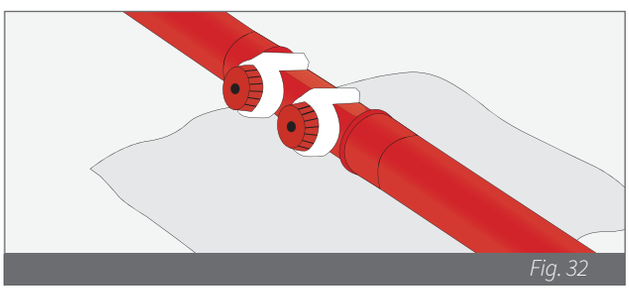


*Fig. 32*

## 2.5 Replacing the iLA Membrane Ventilator

**The iLA Membrane Ventilator should only be replaced during operation if a failure occurs or a fault is detected or when the recommended maximum 29 days use comes to an end.**

**It is important that the highest aseptic standards are maintained when replacing the iLA Membrane Ventilator.**

Maintain the blood and gas flow of the iLA Membrane Ventilator attached to the patient until the replacement iLA Membrane Ventilator is deaired and ready for use (see Section 2.1, *Fig. 1-7*). Depending on the remaining capacity of the iLA Membrane Ventilator that is to be replaced, and on the patient's condition, it may be necessary to adjust the ventilation settings to avoid an increasing respiratory acidosis.

*Fig. 33*

**Place the required equipment** next to the new iLA Membrane Ventilator: 2 clamps; 500 ml crystalloid solution; an infusion system; a 20 ml syringe with crystalloid solution for rinsing the arterial NovaPort one KI cannula.

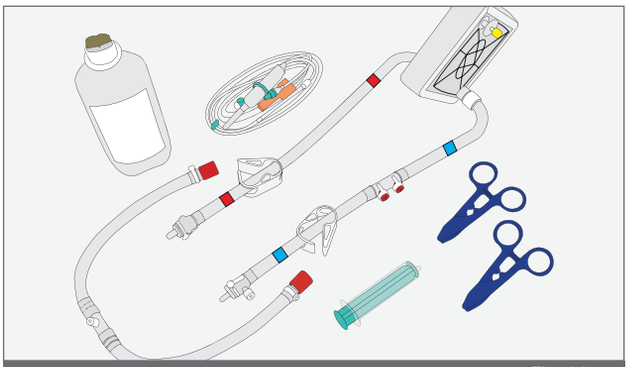


*Fig. 33*

**Fill the new iLA Membrane Ventilator** as described in Section 2.1, *Fig. 2-7*. Then disconnect the NovaFlow Ultrasonic Flowcomputer and remove the oxygen tube and any adhesive tape (for fixation) from both tubing segments of the iLA Membrane Ventilator.

*Fig. 34*

**Clamp the arterial NovaPort one KI cannula** at the cone, and the tubing of the iLA Membrane Ventilator at a short distance from the Safety Connector.

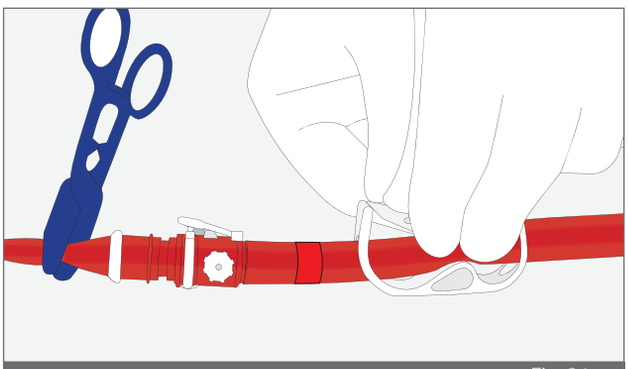


*Fig. 34*

*Fig. 35*

**Remove the white Luer lock caps** on the Safety Connector and place the 20 ml syringe on the Luer connector. Then retract the Safety Connector to the first click stop.

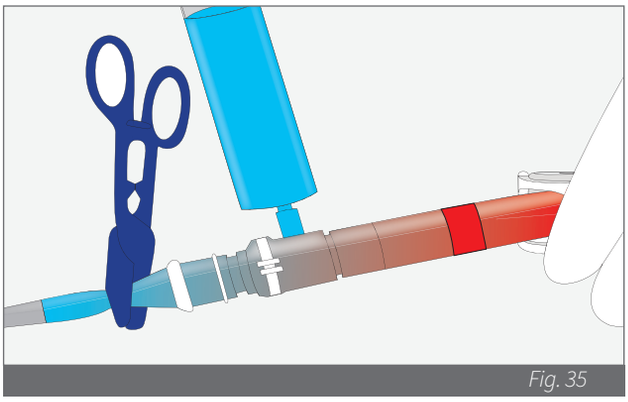


*Fig. 35*

*Fig. 36*

**Open the tubing clamp** of the NovaPort one KI cannula and rinse it with 20 ml crystalloid solution. At this point pay attention to air that may be inside the connector.

**Perform the following steps** shown in *Fig. 37 to Fig. 38* when the blood volume of the iLA Membrane Ventilator is to be retransfused to the patient before changing the membrane. Otherwise rinse the venous NovaPort one KI cannula as described above and continue as shown in *Fig. 34.*

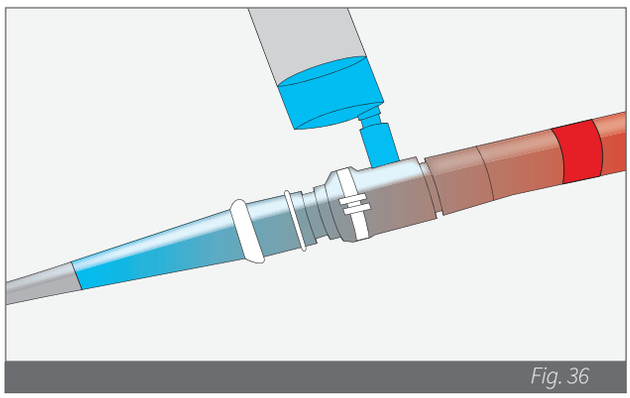


*Fig. 36*

*Fig. 37*

**Clamp the arterial NovaPort one KI cannula** again and connect the Luer connector to the infusion system. Open the safety clamps after the Safety Connector.

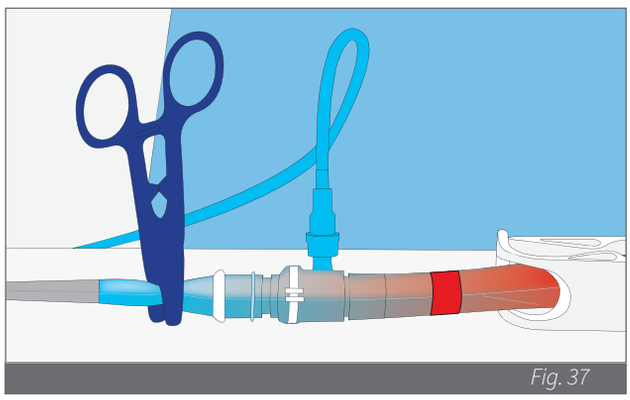


*Fig. 37*

*Fig. 38*

**Rinse the iLA Membrane Ventilator** with a crystalloid solution until all the blood in the iLA Membrane Ventilator has been transferred back to the patient. Then clamp the venous NovaPort one KI cannula and the venous tubing.

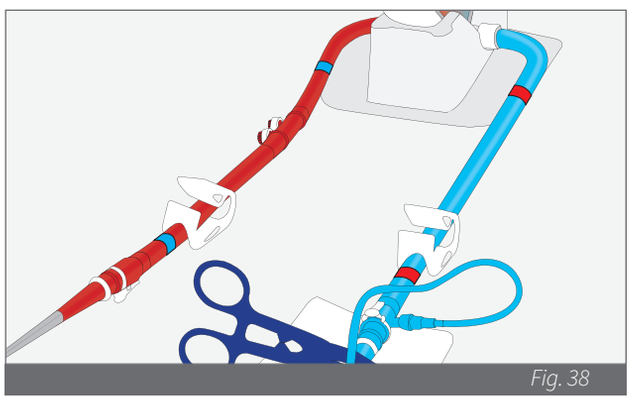


*Fig. 38*

*Fig. 39*

**Disconnect the tubing ends** from the used iLA Membrane Ventilator. Release the Safety Connector and remove the iLA Membrane Ventilator.

**Attach the new iLA Membrane Ventilator** to the NovaPort one KI cannulas (as described in Section 2.1, *Fig. 16-25*).

**When the blood is allowed to flow again it may be necessary to reduce the sweep gas flow, depending on the residual performance capacity of the iLA Membrane Ventilator that was replaced.**

**Monitor blood and gas flow rates** carefully. Monitor the operation of the iLA Membrane Ventilator as soon as possible by blood gas analyses.

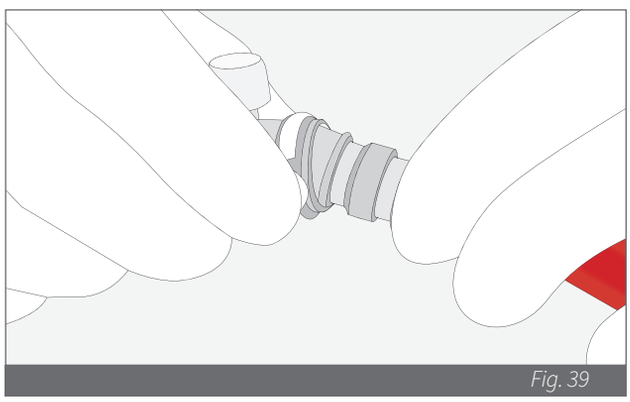


*Fig. 39*

**Possible unwanted drop in the $CO_2$ partial pressure due to improved performance of the new membrane!**

## 2.6 Weaning from the iLA Membrane Ventilator

**During weaning please pursue the following instructions:**

- If possible the patient should be weaned from mechanical ventilation before weaning from the iLA Membrane Ventilator. This can then be used to relieve the patient of the work of breathing. Training and rest phases can be created by varying the gas flow.
- Ventilation should focus on protective ventilation. A reduction in invasiveness of ventilation should always take precedence over the reduction of the gas flow via the iLA Membrane Ventilator. Spontaneous breathing should be encouraged as early as possible.
- Reduce the sweep gas flow in steps, analogous to the initial increase, by 1-2 l/min to 0; the $PaCO_2$ should change by less than 10%. This should not cause over-exertion of the patient's breathing pump.
- Therapy with the iLA Membrane Ventilator can be continued in principle to support the patient's breathing when weaning from mechanical ventilation (see Section 1.2).
- There should be evident recovery of the lungs.
- $FiO_2 < 0.5$.
- Normalisation of inspiratory pressure level.
- Normalisation of gas exchange.
- The patient should be able to initiate spontaneous breathing.

## 2.7 Removing the iLA Membrane Ventilator

Correct disconnection of the iLA Membrane Ventilator is as important as the ventilation process itself. In certain clinical situations a different procedure may be preferred. In these cases contact the XENIOS Clinical Support.

**When disconnecting the device please observe the following instructions:**

- Therapy with the iLA Membrane Ventilator should not be ended until there has been a sufficiently long period without gas flow (usually at least 6 hours) and where the blood gas values are satisfactory and protective ventilation parameters are maintained.
- Continuous application of heparin should be discontinued for a sufficient period before therapy with the iLA Membrane Ventilator is ended (PTT monitoring). After removing the NovaPort one KI cannulas appropriate manual compression of the vessels must be maintained for a sufficient period to prevent arterial bleeding. Afterwards use a compression device. The hip joint of the patient must be immobilized usually for at least 12 hours afterwards.

**If the cannulas are placed on one side only, consider the following points:**

- Theoretically there is a risk of formation of an AV fistula.
- If both NovaPort one KI cannulas are not removed at essentially the same time there is a potential risk of thrombus formation in the NovaPort one KI cannula remaining in the vessel.

# 3 TROUBLESHOOTING

The following complications can arise when using the iLA Membrane Ventilator. For the management, we recommend the following steps.

### BLEEDING AT THE PUNCTURE POINT

This is a general complication which occurs in percutaneous puncturing of large vessels. In order to reduce the risk we recommend a gentle puncture and adaptation of the current anticoagulation treatment where necessary.

**Steps:**

- Monitor clotting parameters and adjust where ecessary.
- Consider a break from administering heparin.
- Check the intravascular position of the NovaPort one KI cannulas.
- Consider a surgical inspection and intervention at the puncture point.

### ACCIDENTAL DISCONNECTION AND DISLOCATION

In order to avoid this risk, check that the Safety Connector of the NovaPort one KI cannula is firmly closed before operating and set appropriate alarm settings (current blood flow ± 300 ml) for the NovaFlow Ultrasonic Flowcomputer.

**Steps:**

- Please observe the notes on fixation of the NovaPort one KI cannulas.
- Clamp blood inflow and outflow cannulas immediately to avoid further loss of blood.
- If a NovaPort one KI cannula has been dislocated, place a new NovaPort one KI cannula.
- When required (in particular where the blood flow has ceased for some time due to disconnection) also replace the iLA Membrane Ventilator.
- While therapy with the iLA Membrane Ventilator is interrupted, no extracorporeal elimination of $CO_2$ takes place. Mechanical ventilation must be adjusted during this period.
- If the venous NovaPort one KI cannula is disconnected, a clinical examination for signs of gas embolism should be performed immediately.

### HEPARIN INDUCED THROMBOCYTOPENIA

This is an absolute contraindication for use of the iLA Membrane Ventilator since the surfaces of the system are coated with heparin. If there is a suspicion of HIT the system should not be used to avoid any risk.

**Steps:**

- Discontinue therapy with the iLA Membrane Ventilator.
- Adjust mechanical ventilation.
- Treat HIT according to current therapy guidelines

### THROMBUS FORMATION IN THE iLA MEMBRANE VENTILATOR

Sufficient blood flow and adequate anticoagulation will reduce this risk. In addition an accumulation of gas in the membrane lung should be avoided or removed.

**Steps:**

- Check the gas exchange function.
- Adjust anticoagulation if necessary.
- Remove any gas bubbles from the system.

### THROMBUS FORMATION IN TUBING

We recommend sufficient blood flow and adequate anticoagulation to avoid this risk.

### ISCHAEMIA IN THE ARTERIAL VESSEL

Selecting the cannula as described below will help to prevent this risk. Selecting an incorrect size of the NovaPort one KI cannula and anatomical or biological variables can contribute to ischaemia in the extremities.

**Steps:**

- If necessary interrupt therapy with the iLA Membrane Ventilator or use smaller NovaPort one KI cannulas.

**We recommend the following NovaPort one KI combinations* depending on the size of the arterial vessel:**

| Ø Artery | Arterial cannula | Venous cannula |
|---|---|---|
| ≥ 6 mm | 15 Fr (5 mm) / 90 mm | 17 Fr (5.7 mm) / 140 mm |
| 5.2 mm – 5.9 mm | 13 Fr (4.3 mm) / 90 mm | 15 Fr (5 mm) / 140 mm |

**The following measures are required to keep the risk of a temporary or persistent ischaemia with the threat of loss of the extremity to a minimum:**

- Select the correct size of NovaPort one KI cannula based on a sonographic check of the vessel diameter and vessel condition.
- Do not use this procedure on patients with previous circulatory problems.
- Regular visual inspection of the extremity.
- Regular clinical examination of the extremity.
- Pulsoximetry on the extremity with the arterial cannula.
- Keep extremity warm at all times.

## INFILTRATION OF GAS IN THE BLOODSTREAM

Under extreme conditions (very high pressure on the gas side, very low pressure on the blood side) it is possible that gas could infiltrate the bloodstream.

**The following measures should be taken to avoid this risk:**

- Limitation of the sweep gas to the maximum allowed flow rate of 10 l/min.
- Use non-humidified oxygen.
- Avoid blockages in the sweep gas outlet.
- Use the holder provided for the iLA Membrane Ventilator.
- Always position the iLA Membrane Ventilator below heart level.
- Regular visual checks for air inclusions in the iLA Membrane Ventilator.
- The lower alarm limit for the NovaFlow Ultrasonic Flowcomputer should be set no lower than 300 ml below the current blood flow or 1 l/min.
- The mean arterial pressure must be maintained above 60 mmHg in order to maintain an optimal sweep gas/blood pressure gradient and hence prevent a direct transfer of gas.

**Steps to follow when gas is sucked into the venous tubing:**

- Act immediately!
- Block the venous return immediately.

**Steps to follow when gas collects in the iLA Membrane Ventilator (air trap):**

- Ensure that the iLA Membrane Ventilator is positioned vertically.
- If necessary, increase the venous return resistance by placing a clamp and open the deairing ports to deair accumulated gas. Ensure that the blood flow does not drop below 1 l/min.
- If gas accumulates: Identify the cause and replace the iLA Membrane Ventilator if the gas cannot be eliminated as described above.

## DETERIORATION OF HEMODYNAMICS

Opening the arterio-venous shunt can lead to a deterioration in the circulatory condition of patients with limited hemodynamics. These patients must be monitored especially carefully. Release of the blood flow through the system must always be performed slowly and arterial blood pressure must be monitored permanently during start-up. Pre-existing shock is a contraindication.

## INFECTION AT THE PUNCTURE POINT

The risk of infection can be reduced by ensuring sterile working conditions and limiting manipulations to a minimum.

## HYPOCAPNIA

This risk can be reduced by careful and gradual adaptation of the ventilator. In particular a gradual increase in the gas flow via the iLA Membrane Ventilator at the beginning of therapy must be monitored continuously (see Section 2.1, *Fig. 27*).

**Steps:**

- Immediately reduce the minute volume on the ventilator or rather adjust the sweep gas flow to the current situation.

*Individual variations in the case of adipositas (artery 140 mm), borderline cardiovascular situations (artery 13 Fr, vein 15 Fr also if artery ≥ 6 mm).

### REDUCED GAS EXCHANGE PERFORMANCE OF THE iLA MEMBRANE VENTILATOR

If there is a suspicion of a loss in functionality, interrupt the sweep gas flow (two minutes, no longer) and check the performance of the iLA Membrane Ventilator using blood gas analyses. If the $CO_2$ rises by > 20% from the initial value or if the spontaneous respiratory frequency of the patient increases, it can be assumed that the iLA Membrane Ventilator is functioning correctly. Possible causes of reduced gas exchange are insufficient perfusion of pseudomembranes (biofilm) for example due to lipids, fibrinogen and coagulant products. The issue can be resolved by replacing the iLA Membrane Ventilator.

### WHITE FILM ON THE BLOOD SIDE OF THE iLA MEMBRANE VENTILATOR

These are generally lipid deposits which can shorten the life cycle of the system.

**Steps:**

- Reduce fat intake of the patient and administration of medicine dissolved in lipids to an acceptable minimum. Blood lipids should not exceed the upper standard value.
- As soon as a loss in function occurs, replace the iLA Membrane Ventilator.

### YELLOW FILM ON THE BLOOD SIDE OF THE iLA MEMBRANE VENTILATOR

These are generally fibrin deposits which can shorten the life cycle of the system.

**Steps:**

- If fibrinogen is above the standard value extend the PTT ≥ 75 sec. if possible.
- As soon as a loss in function occurs, replace the iLA Membrane Ventilator.

### INSUFFICIENT BLOOD FLOW

Insufficient blood flow will limit the performance of the iLA Membrane Ventilator and encourages clotting processes in the iLA Membrane Ventilator. With flow rates under 1 l/min a loss in function (increased clotting tendency) is to be expected. A reduction in flow will not lead to an acute closure of the membrane. If the circulatory situation of the patient is normal, blood flows under 1 l/min are an indication of a mechanical perfusion problem. The blood flow should not drop below 0.5 l/min.

**Steps:**

- Check if there is a blockage (for example, a kink in a NovaPort one KI cannula or lumen displacement of the cannula tip); if so, reposition the cannula (as described in Section 2.1, *Fig. 10-12*).
- In order to maintain sufficient perfusion pressure, the MAP should be greater than 60 mmHg.

# 4 PRACTICAL EXAMPLES

The following examples are intended as an orientation guide when using the iLA Membrane Ventilator. They do not replace the need for a careful medical diagnosis, nor do they limit doctors‘ therapeutic freedom. They describe certain clinical situations where the use of the iLA Membrane Ventilator can be a useful option. Practical guidelines are given for each indication. For individual questions please contact the 24/7 clinical support.

## 4.1 Acute Respiratory Failure

### DIAGNOSIS EXAMPLES

- Acute Respiratory Failure (ARF)
- Acute Respiratory Distress Syndrome (ARDS)

### PARAMETERS FOR DIAGNOSIS

- Limited gas exchange:
  - Hypercapnia (in excess of permissive hypercapnia)
  - pH < 7.2
  - Hypoxemia ($PaO_2/FiO_2$ should not be below 70)
- Non-protective ventilation
- Parameters outside the following limits:
  - VT ≤ 6ml/kg IBW
  - Pmax ≤ 30 mbar
  - Pressure amplitude ≤ 15 mbar
  - Respiratory rate ≤ 25/min
  - No intrinsic PEEP/air trapping
  - pH ≥ 7.2 (permissive hypercapnia is acceptable as long as it has no impact on the patient’s overall situation)
- Adjuvant therapeutic measures (e.g. forced proning therapy (upper body upright, 135°/180°), active respiratory gas climatization, volume/catecholamine therapy, etc.) are optimized.

### THERAPY OBJECTIVES

- Consistent implementation and/or continuation of pulmonary protective ventilation.
- Reduction of respiratory acidosis ($CO_2$ elimination and normalisation of pH value).
- Secondary improvement in oxygenation.

### SPECIAL NOTES

- All mechanical ventilation is potentially harmful for the pulmonary tissue and can induce ventilator associated lung injury (VALI). Early introduction of therapy using the iLA Membrane Ventilator and early implementation of protective ventilation strategies are therefore more beneficial than continuation of conventional mechanical ventilation outside accepted protective ventilation parameters.
- Simultaneous reduction in the minute volume is required. Target parameters: e.g. respiratory frequency 5-10 breaths/min, VT 3-4 ml/kg IBW.
- A reduction in $SpO_2$ during therapy with the iLA Membrane Ventilator can be caused by a weakening of the hypoxic pulmonary vasoconstriction through the venous admixture of oxygenated blood.
- Normalisation of the pH can lead to an improvement in the effectiveness of catecholamines.
- In order to improve oxygenation or optimise protective ventilation, it should be ascertained whether additional high frequency oscillation ventilation (HFOV) or the possibility of apnoic oxygenation (CPAP) is indicated.

## 4.2 Muscular exhaustion

### DIAGNOSIS EXAMPLES

- COPD exacerbation
- Difficult weaning from the ventilator or muscular weakness after long-term ventilation.
- Critical care polyneuropathy or muscular weakness in cases of neuromuscular disease.

### PARAMETERS FOR DIAGNOSIS

- Airway occlusion pressure P 0.1 > 5 mbar.
- Clinical signs of dyspnea, tachypnea, motor agitation, reduction in vigilance, circulatory problems.
- Progredient hypercapnia during (assisted) spontaneous breathing/NIV/NPPV.
- Progredient global respiratory insufficiency.

### THERAPY OBJECTIVES

- Reduction of respiratory effort.
- Support and maintenance of spontaneous breathing, hence avoiding intubation or reintubation.
- Prevention of ventilator associated lung damage.
- Earliest possible extubation.
- Ventilation support after extubation.

### SPECIAL NOTES

If required, oxygenation in such cases can be performed using a CPAP system while the iLA Membrane Ventilator maintains ventilation.

- The required respiratory effort of the patient can be regulated by the control of the sweep gas flow. Intermittent pauses are possible.
- Patients undergoing mechanical ventilation should first be weaned from the ventilator and then from the iLA Membrane Ventilator.

## 4.3 Regulation of intracranial pressure

### DIAGNOSIS EXAMPLES

Regulation of $PaCO_2$ and consequently of the intracranial pressure despite continuation implementation of lung-protective ventilation, e.g. in cases of

- Cerebrocranial trauma
- Intracranial invasion
- Cerebral hemorrhage
- Cerebral oedema

### PARAMETERS FOR DIAGNOSIS

- ICP too high, CPP too low in the individual case.
- Possibly in combination with hypercapnia/ respiratory acidosis.

**Continue lung-protective ventilation or apply stricter standards than the following:**

- VT ≤ 6 ml/kg IBW
- Pmax ≤ 30 mbar
- Pressure amplitude ≤ 15 mbar
- Respiratory rate ≤ 25/min
- No intrinsic PEEP/air trapping
- pH ≥ 7.2 (permissive hypercapnia is acceptable as long as it has no impact on the patient's overall situation)

### THERAPY OBJECTIVES

- ICP reduction through normalisation/reduction of $PaCO_2$.
- Prevention of VALI/VILI.

## 4.4 Terminal respiratory failure

### DIAGNOSIS EXAMPLES

**Hypercapnic, respiratory insufficiency based on:**

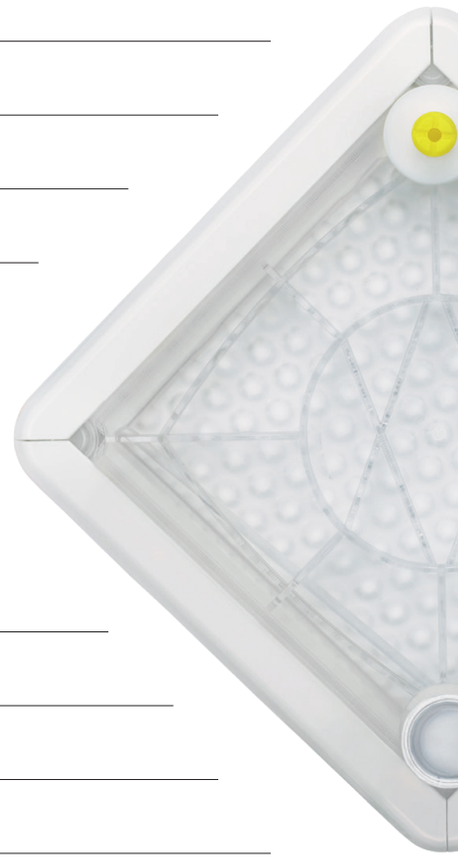
- Pulmonary fibrosis
- Muscular exhaustion with terminal pulmonary disease
- Lung emphysema

### PARAMETERS FOR DIAGNOSIS

- Indication for mechanical ventilation.

### THERAPY OBJECTIVES

- Bridge to lung transplantation
- Prevention of intubation
- Early extubation
- Maintenance of spontaneous breathing
- Maintenance and recovery of muscular respiratory function
- Reduction of respiratory effort before and after transplant
- Survival of the patient




XENIOS AG is a medical device company with the three brands, novalung, i-cor and medos, that run on a single XENIOS platform. This platform enables next-generation therapies for lung and heart failure. No other company except XENIOS AG is offering lung and heart therapies on one single platform.

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