LENUS *pro*®

Information for patients

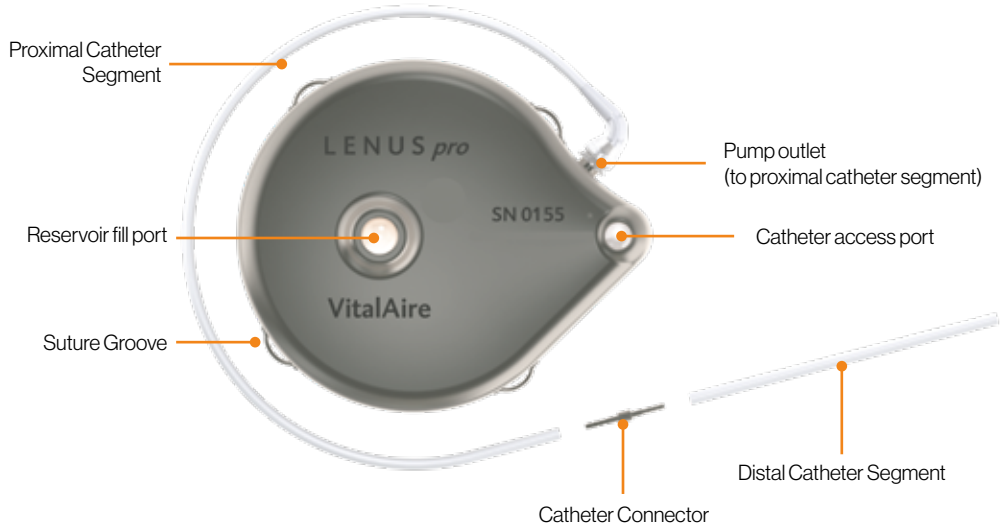
Dear Patient,

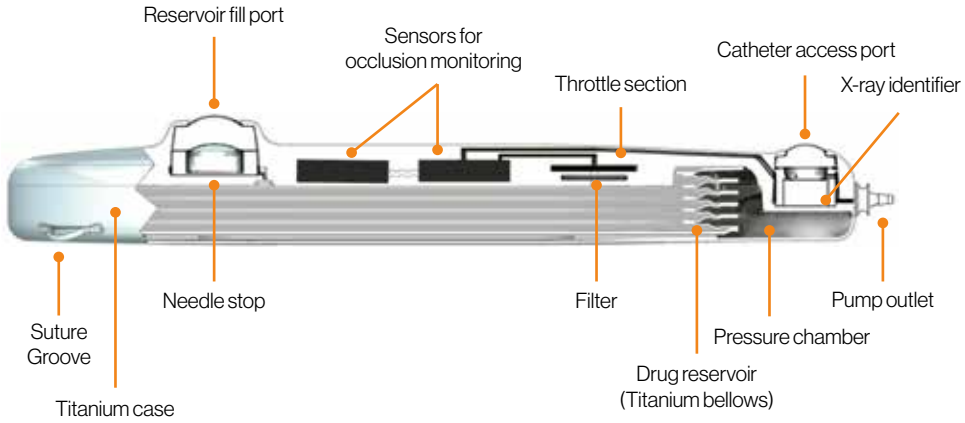
During your hospital visit you were provided with detailed information about continuous intravenous infusion of medication via an implanted LENUS *pro*® implantable infusion pump.

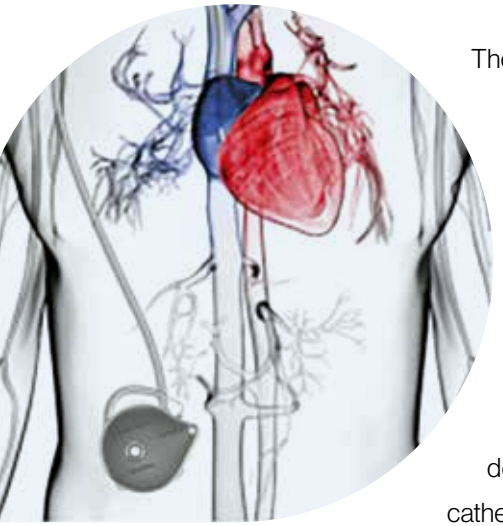
The LENUS *pro*® infusion pump enables continuous intravenous application of Remodulin for the treatment of pulmonary arterial hypertension (PAH).

The LENUS *pro*® is a gas-operated infusion pump with a fixed flow rate.

The drug reservoir consists of a titanium bellows which is compressed by a drive gas at a constant pressure. The drive pressure is 2.5 bar relative at a body temperature of 37 °C. This constant pressure delivers the drug at a steady flow rate.







The infusion pump is implanted subcutaneously (i.e. under the skin) in the upper abdomen.

From the pump, a catheter runs subcutaneously up to the collarbone area. From there, it runs inside a large vein leading to the heart, terminating just before the right atrium. The drug is delivered continuously via this central vein catheter.

Implantation of the infusion pump is planned and performed individually. Your hospital will inform you about the implantation procedure (your hospital stay, the nature and duration of the procedure, and other important aspects).

The drug reservoir in the infusion pump is filled and emptied via the filling port, which has a self-sealing silicone septum. The filling port is located in the middle of the pump and stands slightly proud of the surface.

Things to note during your therapy with the LENUS *pro*® implantable infusion pump

1. Occlusion alarm

The LENUS *pro*® implantable infusion pump continuously monitors the drug flow and automatically detects any interruption, e.g. through kinking or occlusion (blockage) of the catheter.

If the catheter is occluded (partially or completely), the infusion pump sounds an audible alarm. The alarm sequence consists of 8 individual signals at 1-second intervals, followed by a 10-second pause, after which the sequence repeats.

8 individual signals *10 s pause* *8 individual signals* *10 s pause*

If the pressure in the catheter drops below the alarm trigger level (i.e. if a kink is only temporary or some other cause of occlusion is removed), the alarm automatically stops. In other words, the alarm sequence will repeat for as long as the alarm state continues or until the cause of the alarm is resolved. Even if the cause of the alarm/the catheter occlusion is not resolved, after 18 hours the alarm will stop and the alarm system will go into energy-saving standby mode.

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- If the alarm on your infusion pump sounds, you must immediately contact your treating physician or go directly to your treating hospital.
- If you go to your treating hospital, take your replacement pump and consumables (including medication) with you. You should also have your treatment documents, such as your Patient Card, to hand.

If the infusion pump emits a continuous alarm signal, this indicates that the battery for the alarm function is exhausted.

This can happen if the alarm has repeatedly sounded for an entire 18-hour alarm period.

In such an event, your treating physician must decide whether to replace the pump.

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Never ignore the alarm on your LENUS *pro*® implantable infusion pump. If the catheter is occluded or kinked, the pump cannot deliver the medication.

2. Refilling the Infusion pump

Depending on the size of the pump (the size of the drugreservoir) and the pump-specific flow rate, your treating physician will need to refill your pump every 2–4 weeks.

After each refill, your treating physician will arrange your next refill appointment and record it in your Patient Card. Refill appointments are scheduled so that at least 2 ml of drug volume are still present in the reservoir on the refill date. If the drug volume in the reservoir is less than 2 ml, the flow rate will drop sharply. This can lead to a reduction or complete interruption of the infusion, thereby jeopardising your treatment.

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- It is therefore extremely important that you always keep your refill appointments. If special circumstances mean that you are unable to keep an appointment, you should contact your treating physician as soon as possible to arrange an earlier appointment. Please be aware that your infusion pump can only be refilled at your treating hospital.

- The refilling of the pump, including puncturing of the filling port, may only be performed using the filling set approved by the manufacturer. Please monitor this accordingly.

3. Factors influencing the flow rate

The following factors influence the flow rate:

- Changes in body temperature (e.g. fever of any duration, extended periods of sunbathing)
- Changes in air pressure (e.g. when flying or spending time in high-altitude regions)

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- Inform your treating physician if you have a fever or if there are any other circumstances that are causing, or have caused, an increase in body temperature. It may be necessary for your doctor to schedule an earlier refill appointment.

- Inform your treating physician of any planned activities that may affect your body temperature or where there may be changes in air pressure.

- Inform your treating physician of any travel plans, especially involving air travel.

4. Treatment documents

After your infusion pump has been implanted, you will receive an Implant Card.

The Implant Card contains your personal details, the contact details of the treating hospital and treating physician, and all therapy-relevant information about the infusion pump. In addition, the Implant Card is used to record all the necessary details of past refills as well as your next refill appointment.

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- Please ensure that all documents are always complete and up to date, especially your Implant Card.
- Please ensure that the physician updates your Implant Card each time the infusion pump is refilled.
- Always carry your treatment/pump documents with you, including your Implant Card.

5. Compatibility with medical procedures

The LENUS *pro*® implantable infusion pump is not compatible with all medical procedures (or no information on compatibility is available due to a lack of testing). It is, however, fully compatible with defibrillation, diagnostic ultrasound and high-frequency surgery.

Avoid the following examination or treatment procedures:

Procedure	Notes
Therapeutic ultrasound	The infusion pump should not be exposed to therapeutic ultrasound as the sound waves could be amplified by the metal components in the device, potentially causing injury. ✕
Diathermy	Since the effects of diathermic treatment on the infusion pump and pump users are not known, this procedure should not be used in the immediate vicinity of the pump. ✕

Check with the infusion pump manufacturer before the following examination or treatment procedures are carried out:

Procedure	Notes
CT scan	Before conducting a CT scan, the physician should contact the manufacturer or supplier of the infusion pump to check compatibility with the procedure. If you have been told you need a CT scan, please inform your treating physician as soon as possible. !
MRI	The infusion pump has not been tested for compatibility with MRI. To check compatibility, your physician should contact the manufacturer or supplier. !

6. If you would like to travel

In addition to body temperature, changes in air pressure when flying or spending time in high-altitude regions can affect the flow rate of the pump. It may therefore be necessary to reschedule refill appointments.

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- Inform your treating physician of your travel plans so a new refill appointment can be made. Ask your treating physician about the infusion pump documentation you need to take with you when travelling.
- Always carry your Implant Card with you. You should also ensure that the information about your pump in your Implant Card is always complete and up to date.
- Before travelling, check the availability of medical services at your destination to ensure your treatment is not jeopardised if you have a problem with your pump.
- Regardless of the destination and duration of your journey, always take your back-up supplies (replacement pump, consumables and medication).
- Magnetic security gates can trigger the alarm on the pump. To avoid this, present your Implant Card to the security personnel.

7. General precautions when using the infusion pump

- Avoid pressing or prodding the infusion pump through the skin. This can cause the pump to move and the catheter can become kinked or detached.
- Avoid physical activities that may damage the implant or the implant site.
- Inform all other treating physicians that you have an implanted infusion pump.
- Inform your treating physician of any planned medical examinations.
- Any form of intervention in the infusion pump may only be carried out by your treating hospital. However, if it is not possible for your regular treating physician or hospital to refill your pump due to exceptional circumstances, it is essential that the physician performing the refill should consult your regular treating physician during or immediately before/after the refill to discuss any potential abnormalities, flow rate changes and/or any necessary dosage adjustments.

8. What you should pay particular attention to

- If you experience burning pain at the pump pocket or along the catheter route, inform your treating physician immediately so the necessary action can be taken. These symptoms may indicate catheter dislocation or extravasation.

- If the alarm on your infusion pump sounds, you should immediately contact your treating physician or go directly to your treating hospital.

- Inform your treating physician immediately of any unusual symptoms or reactions.

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