



VivereX™ patient information



Introduction

VivereX™ system is a medical therapeutic device which apply controlled negative pressure to the wound bed. VivereX™ system includes a non-sterile single use battery powered device and should be used with a sterile NPWT dressing set. VivereX™ is equipped with necessary safety visual indicators and performs Negative Pressure Wound Therapy (NPWT) by a continuous mode. VivereX™ device is intended to be used for ten days for one patient, which means no risk for cross contamination. Applying negative pressure results in transferring wound exudate to the NPWT dressing. The NPWT dressing contains of 5 layers and is designed to manage the wound exudate in two different mechanisms, by which VivereX™ system increases dramatically the dressing life time:

- The absorbent layer of the dressing absorbs some of the secretion.
- The dressing allows evaporation of the rest of the wound secretion.

What does VivereX™ do?

VIVEREX™ provides suction known as Negative pressure wound therapy (NPWT) which draws out excess fluid from a wound and protects the incision or wound.

How does VivereX™ work?

VivereX™ consists of an NPWT pump connected to an absorbent gentle adhesive dressing.

The dressing is applied to the wound bed and extra adhesive strips are placed over the outside edge to help hold the dressing in place. When the pump is turned on, air is pulled out of the dressing and excess fluid from the wound will start to enter the dressing. The dressing helps to prevent bacteria from entering the wound. It may also improve blood flow to the wound which will help it to heal.



INSTRUCTION TO USE VIVEREX™ DEVICE:

1. Insert two AA batteries into the battery compartment on the back side of the VivereX™ device, in the correct orientation (1). Alkaline batteries are recommended. Do not use rechargeable battery, the device will not work. All indicators flash twice indicating the device is ready to use. Secure the battery compartment cover.
2. Twist luer connectors together to connect the dressing tube to VivereX™ device (2).
3. Use extension tube if a longer distance between dressing and the device is required.
4. Ensure the tube is free from kinks and not blocking the flow between the dressing and VivereX™ device.
5. Press the power button on the front of the VivereX™ device to start the device. The green indicator starts to flash, indicating that the device is on.
6. The device can be heard functioning while contraction of the dressing confirms the start of NPWT.
7. The leak indicator flashes if the dressing is not sealed (refer to section 20 for troubleshooting). VivereX™ will turn off if the leak is not adequately solved within 30 seconds.
8. Keep VivereX™ in a place close to the patient, where the patient can easily monitor the status of LED indicators e.g. using the belt holder to hang the device on their pocket, outer garments, or belt.
9. VivereX™ will automatically stop functioning ten days after start date.
 - Note: The dressing should be removed as soon as possible or VivereX™ should be replaced with a new one.
10. To turn off the device, press the power button.
11. If you require any assistance in setting up, using or maintaining the VivereX™ system, or if any unexpected alerts or fault are encountered, please contact Sunmedic.

WILL IT BE PAINFUL?

The first time the VivereX™ pump is turned on, you may feel a slight pulling or drawing sensation. If you experience any pain, please speak to your nurse or doctor for advice.

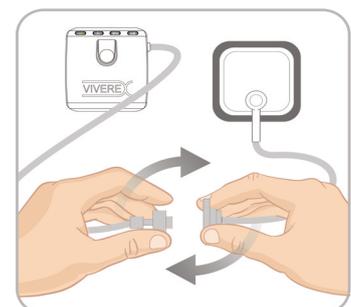


Taking shower with VivereX™ dressing:

Press the power button to put the device in «Off» mode and disconnect VivereX™ and keep the device in a safe place.

The end of the dressing's tube should be facing down, to prevent water entering the tube and should not be submerged in water or sprayed.

After showering reconnect the device using the luer lock and press power button to turn the device to «On» mode. Ensure that the green indicator flashes, the dressing is contracted and no yellow indicator is active.



WHEN TO CHANGE THE DRESSING?

A common wear time for a silicone dressing is three to seven days. This period of time reduces in case of wound infection or excessive wound secretion. The dressing should be changed in accordance with following guidelines:

- When the «change dressing» indicator is turned «On».
- When the wound exudate has reached or is close to the suction port as in (b) and (c).
- When there is repeated sign of leak which has been difficult to solve.

Dressing properly positioned and is acceptable to be left in place (a)



Will the dressing changes hurt?

Some people may experience slight discomfort during dressing changes, specifically during cleaning of the wound, depending on the type and position of the wound. If you feel any discomfort, please contact your healthcare giver.

Can you move around while on the therapy?

Patients using VivereX™ can move around but this will depend on recommendations provided by your healthcare giver.

When you are asleep

Make sure that the VivereX™ pump is placed somewhere safe and cannot be pulled off a table or cabinet onto the floor during sleep.

HOW DO I KNOW IF THE VIVEREX™ SYSTEM IS WORKING?

While the VivereX™ pump is working correctly a green light located at the left top of the device will flash continuously. The dressing should have a slightly wrinkled appearance and feel firm to the touch.



WHAT HAPPENS IF THE VIVEREX™ VISUAL INDICATORS STARTS FLASHING?

The VivereX™ system has a visual indicator for “Low Battery” and “Leak”. These issues are easily solved, for example:

“**Leak indicator is flashing**” – A significant leak exits. NPWT is not established.

The unit will be turned off after 30s. If NPWT has not been established due to air leak, the unit will automatically restart after one hour.

Check dressing's border and smooth out if any creasing is observed and check and secure tube-unit connectors.

Press power button to restart the unit.



“Normal function and Battery indicator flash”

The unit is functioning normal but the battery power is too low.
Replace batteries during one day or as soon as possible

“BATTERY INDICATOR ALONE FLASHES”

Replace the batteries within few hours, preferably immediately.
Press power button to restart the therapy.



When will I need a new pump?

The pump is designed to stop working after ten days after initially started. After this time, it will stop and will not restart even with new batteries. Negative pressure therapy is not being applied at this point so healthcare giver will need to apply a new VivereX™ therapy system if needed.

The pump will look like this when it has come to the end of its life.

Call your healthcare giver immediately if:

You notice a change in the colour or amount of the fluid in the dressing, for example:

- If it changes from clear to cloudy or bright red.
- You see the dressing fill rapidly with blood.
- Your wound looks more red than usual or has a foul smell.
- The skin around your wound looks reddened or irritated.
- The dressing feels or appears loose.
- You experience pain.
- The yellow indicator is flashing.