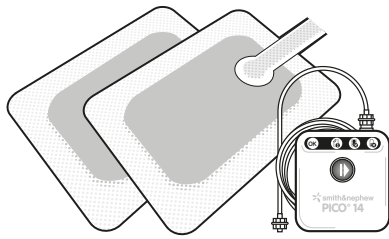




Information for Patients and Caregivers



smith&nephew PICO[®] 14 Single Use Negative Pressure Wound Therapy System User Manual



Pump noise level is below 35dB



System lasts up to 14 days



Pump has high tolerance to air leaks



Dressing full indicator



Airlock layer helps maintain negative pressure across the dressing



80% of exudate managed through evaporation



Indicated for low to moderate exuding wounds



Silicone gel adhesive dressing



Dressing is showerproof

The PICO[®] 14 Single Use Negative Pressure Wound Therapy System is intended for use by or on the direction of a trained and licensed physician in accordance with these instructions for use. **Contact a healthcare professional right away if you are unsure as to the correct use of the PICO 14 System.**

1. Indications

PICO 14 Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 14 Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
 - Venous leg ulcers – the PICO 14 System can be used in combination with graduated compression therapy in the management of venous leg ulcers.
- Flaps and grafts
- Closed surgical incisions

When used on closed surgical incisions, PICO 14 Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections for high risk patients in Class I and II wounds
- Post-operative Seroma
- Dehiscence

2. Contraindications

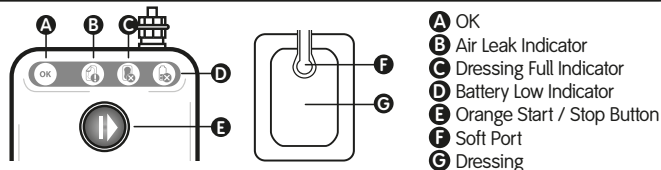
The PICO 14 System is contraindicated for:

- Patients with malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life).
- Previously confirmed and untreated osteomyelitis.
- Non-enteric and unexplored fistulas.
- Necrotic tissue with eschar present.
- Exposed arteries, veins, nerves or organs.
- Exposed anastomotic sites.

The PICO 14 System should not be used for the purpose of:

- Emergency airway aspiration.
- Pleural, mediastinal or chest tube drainage.
- Surgical suction.

3. Description



The PICO 14 System is a device that provides suction to a wound to promote wound healing. When the PICO 14 pump is turned on, air is pulled out of the dressing and excess fluid will start to enter the dressing.

The PICO 14 System has visual indicators to let you know when there is an issue. The PICO 14 System does not contain any audible alerts. Dressings should be checked frequently (See *Does your dressing look full?*). Carry the pump so that the status can be checked frequently. If the air leak, dressing full or battery low indicators illuminate, consult the troubleshooting section.

4. Important Information

⚠ Pump Placement Warning

The PICO 14 pump contains a MAGNET. **Keep the PICO 14 pump at least 4 inches (10 cm) away from other medical devices at all times.** As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices. See Section 5 Magnet Warning.



5. Warnings



Magnet Warning

The PICO 14 pump contains a MAGNET. As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices. The PICO 14 pump must be positioned at least 4 inches (10cm) away from other medical devices that could be affected by magnetic interference.

These include but are not limited to:

- Implantable Cardioverter-defibrillator (ICD)
- Pacemakers
- Insulin Pumps
- Shunt Valves
- Neurostimulators
- Cochlear Implants

THIS WARNING APPLIES AT ALL TIMES TO ALL USERS.

This applies to both Patients and Caregivers. You must keep the PICO 14 pump at least 4 inches (10cm) away from other devices:

- If you have an electronic medical device and are helping take care of somebody else using the PICO 14 System.
- If you are wearing the PICO 14 pump in a public area where you may come in close contact with someone else who has an electronic medical device.
- Do not attempt to change the dressing. Dressings should only be changed by a healthcare professional.
- Excessive bleeding is a serious risk with the application of suction to wounds, which may result in death or serious injury. Carefully monitor your dressing for any excessive bleeding. If sudden or increased bleeding is observed, immediately disconnect the PICO pump but leave the dressing in place and seek immediate medical assistance.
- If defibrillation is required, only remove the dressing if it is positioned in a location that will interfere with defibrillation.
- The PICO 14 System contains small parts which could represent a choking hazard for young children. Keep out of the reach of children.
- The PICO 14 System is unsuitable for use in areas where there is danger of explosion (e.g. oxygen rich environments such as Hyperbaric oxygen unit).
- **MR Unsafe.** You must remove the PICO 14 pump from the dressing before entering the MRI suite. Do not bring the PICO 14 pump into the MRI scan room. The device presents a projectile hazard.
- The PICO 14 System is not suitable for use in the presence of flammable anesthetic mixture with oxygen or nitrous oxide.
- PICO dressings should only be applied, changed and removed by a healthcare professional.
- At all times care should be taken to ensure that the pump, tubing and connectors do not:
 - Lie in a position where they could cause pressure damage to the patient.
 - Trail across the floor where they could present a trip hazard or become contaminated.
 - Present a risk of strangulation or a tourniquet to the patient.
 - Rest on or pass over a source of heat.
 - Become twisted or trapped under clothing or bandages so that the air-path delivering negative pressure is blocked.
- Keep the PICO 14 System away from pets, pests and other animals that could damage it.
- Do not attempt to dismantle or modify the PICO 14 System.

6. Precautions

- Regularly monitor the PICO dressing. If the dressing appears full or there is fluid around the Soft Port contact your healthcare professional right away.
- Do not let the pump get wet. Protect it from the sources of fluid e.g. from incontinence or spillages. Do not use the PICO 14 pump if it is wet or has previously been wet.
- Do not take the pump apart.
- Do not cut the tubing between the pump and dressing. Avoid pulling on the tubing or soft port.
- The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if the PICO 14 pump is near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment or metal detectors.
- The PICO 14 System is intended for use in both a hospital and homecare setting. The system can also be used in aircraft, train and boat transportation. Special care must be taken regarding pump positioning when in close proximity to other people (see magnet warning).
- During transport there is a potential for radio frequency interference that could affect the PICO 14 System performance. If the PICO 14 pump malfunctions, replace batteries. If not corrected, contact your healthcare professional right away to replace the system.
- If pain, reddening, odor, sensitization or a sudden change in the volume or color of wound fluid occurs during use, contact your healthcare professional right away.
- If the PICO 14 System is being used on a skin graft, visually inspect the status of the system regularly to ensure that therapy is continually applied and a seal is maintained.
- The PICO 14 System does not contain audible alerts. Carry the PICO 14 pump so it is accessible and can be checked routinely.
- When showering, disconnect the PICO 14 pump from the dressing. Ensure the end of the dressing tubing faces downwards so water does not enter the tube.

7. Technical Information

| Storage and Transport Conditions | |
|----------------------------------|---|
| Temperature | 41°F - 77°F (-13°F to +41°F allowable for up to 7 days) |
| Relative Humidity | 10 – 75% |
| Atmospheric Pressure | 700 to 1060 mbar |
| Operating Conditions | |
| Temperature | 41°F - 104°F |
| Relative Humidity | 10 – 95% |
| Atmospheric Pressure | 700 to 1060 mbar |
| Pump Information | |
| Ingress Protection Rating | IP22 |
| Battery Type | 2 x AA 1.5V (LR6 / FR6) |

8. How do I know if the PICO 14 pump is working?



Green 'OK' indicator flashes

While the PICO 14 pump is powered on the OK indicator will flash green. The system is functioning correctly. Regularly check the condition of the dressing by referring to *Does your dressing look full?* If dressing looks full or blocked, contact a healthcare professional right away.

9. How do I know if the PICO 14 pump is pumping down?



Green 'OK' and Orange 'Leak' indicators flash

The pump is working to achieve therapy but has not reached the intended pressure.

Depending on the size of the wound the pump may take up to 100 seconds to establish therapy.

Check condition of dressing by referring to *Does your dressing look full?* If dressing is not full or blocked then no action is required. If dressing looks full or blocked contact a healthcare professional right away.

10. Changing the batteries

If the battery low indicator flashes, the batteries on the PICO 14 pump will require changing. To change the batteries:

1. Remove the back cover from the PICO 14 pump to access the battery compartment.
2. Remove the used batteries and dispose of in accordance with local regulations.
3. Insert new AA batteries in the orientation indicated inside the battery compartment.
4. Replace the back cover. Following this all four indicators should illuminate for 3 seconds.

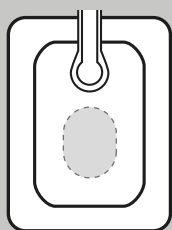
11. Showering and bathing

Light showering is permissible; however, the PICO 14 pump should be disconnected and placed in a safe location where it will not get wet. Disconnect the pump from the dressing by untwisting the connectors. The PICO dressing should not be exposed to a direct spray or submerged in water. While disconnected, ensure the end of the tube from the dressing faces down so that water does not enter the tube. After showering and bathing the PICO 14 pump should be reconnected to the dressing and restarted by pressing the orange button.

12. Does your dressing look full?

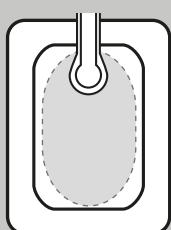
Patients and caregivers should not attempt to change or apply dressings. Dressings should only be changed by a healthcare professional.

If your dressing looks similar to this, you should leave the dressing

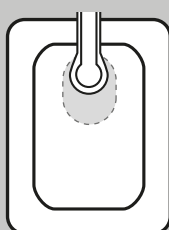


It is acceptable to be left in place

If your dressing looks similar to either or both of these you must contact your healthcare professional right away



Dressing is full



Soft port may be blocked with fluid

13. Troubleshooting

| Indicator Status | What could be the problem? | How to solve |
|--|--|---|
| All indicators off | The pump is in standby. The pump has completed its course of therapy. The batteries are dead. | Therapy has been paused. Press the orange button to resume therapy. Pressing the orange button will not restart therapy. Contact your healthcare professional right away. If the pump has not yet completed its course of therapy, replace the batteries. |
| Green 'OK' and Orange 'Battery low' indicators flash | System is functioning properly but the batteries are low. | Replace the batteries (see changing the batteries) then press the orange button to restart therapy. |
| Orange 'leak' indicator flashes | An air leak has been detected. Therapy is not being applied. (Note: the pump will automatically try to restart therapy after 1 hour). | 1. Smooth down the dressings and strips to remove any creases. 2. Ensure that the tube connectors have been twisted together securely. 3. Press the Orange button to restart the pump. |
| Orange 'leak' and Orange 'battery low' indicators flash | An air leak has been detected and the batteries are low. Therapy is not being applied. (Note: the pump will automatically try to restart therapy after 1 hour). | 4. If the air leak remains the Orange leak indicator will flash again after approximately 65 seconds (depending on the size of the wound). 5. If the battery low indicator is flashing, replace the batteries (see changing the batteries), then press the orange button to restart therapy. |
| Orange 'dressing full' indicator flashes | Dressing is full or there is a blockage. Therapy is not being applied. (Note: the pump will automatically try to restart therapy after 1 hour). | Contact healthcare professional right away |
| Orange 'dressing full' and orange 'battery low' indicators flash | Dressing is full or there is a blockage and the battery is low. Therapy is not being applied. (Note: the pump will automatically try to restart therapy after 1 hour). | |
| All indicators solidly illuminated | A pump error has been detected. The pump can no longer apply therapy. | |

14. Glossary of symbols

| | |
|---|---|
| Follow instructions for use | EU: Not for general waste |
| OK Pump is functioning properly | International classification |
| Warning: The PICO 14 pump contains a MAGNET . The PICO 14 pump must be positioned at least 4 inches (10cm) away from other medical devices that could be affected by magnetic interference. As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices. See Section 5 Magnet Warning. | Defibrillation-proof type BF applied part |
| MAGNET | MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment |
| STERILE | Product is sterilised by Ethylene Oxide |
| Air leak detected | Non-Sterile |
| Dressing change needed | Caution |
| Low battery | Do not use if the package is damaged |
| Start/pause/resume therapy | Storage temperature |
| System lasts 14 days | Manufacturer |
| Pump lasts 14 days | Date of manufacture |
| Rx only | Consult instructions for use |
| Single Use. Do not reuse. | Keep product out of sunlight |
| LOT | Keep dry |
| | Relative humidity limits |
| | Atmospheric pressure limits |
| | Patient and Caregiver |
| | CE Mark |

15. Contact Information

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