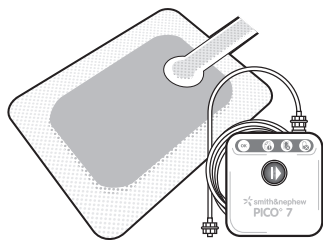




Information for Patient and Caregiver



smith&nephew
PICO[®] 7

Single Use
Negative Pressure
Wound Therapy System
Patient and Caregiver
User Manual

PICO[®] 7 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 7 system.**

1. Indications

PICO 7 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 7 Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting.

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehiscent wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

2. Contraindications

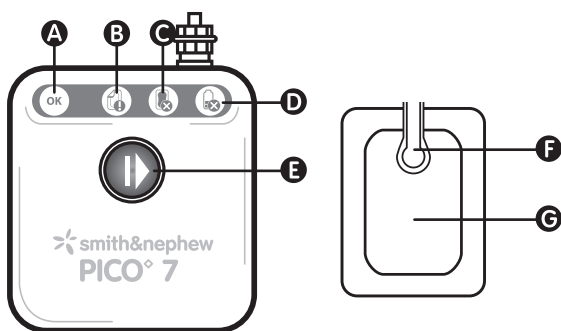
PICO 7 is contraindicated for:

- 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

PICO 7 should not be used for the purpose of:

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

3. Description



- | | |
|----------------------------------|-----------------------------------|
| A OK | E Orange Start/Stop Button |
| B Air Leak Indicator | F Soft Port |
| C Dressing Full Indicator | G Dressing |
| D Battery Low Indicator | |

PICO 7 is a device that provides suction to a wound to promote wound healing. When PICO 7 is turned on, air is pulled out of the dressing and excess fluid will start to enter the dressing.

PICO 7 has visual indicators to let you know when there is an issue. PICO 7 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 7 pump contains a **MAGNET**.

Keep the PICO 7 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 7 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 7 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 7 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 7 system.
- If you are wearing the PICO 7 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 system contains small parts which could represent a choking hazard for young children. Keep out of the reach of children.
- PICO 7 is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).
- **MR Unsafe.** You must remove the PICO 7 pump from the dressing before entering the MRI suite. Do not bring PICO 7 into the MRI scan room. The device presents a projectile hazard.
- PICO 7 is not suitable for use in the presence of flammable anesthetic mixture with oxygen or nitrous oxide.

5. Warnings (continued)

- PICO 7 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.

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 PICO 7 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 PICO is near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment or metal detectors.
- The PICO 7 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 PICO 7 performance. If the PICO 7 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 a healthcare professional right away.
- If PICO 7 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.
- PICO 7 does not contain audible alerts. Carry PICO so it is accessible and can be checked routinely.
- When showering, disconnect PICO 7 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 Environment	
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. Activating the PICO pump



- Press Orange Button to activate pump.
- The green 'OK' indicator and orange 'leak' indicator will start to flash together.
- The pump may take up to 65 seconds to establish therapy, during this time you will hear the pump.

If after this time the orange 'leak' indicator continues to flash without the 'OK' indicator, consult the troubleshooting section.

9. How do I know if PICO is working?



Green 'OK' indicator flashes

While PICO is powered on the OK indicator will flash green.

The system is functioning correctly and delivering negative pressure. Regularly check the condition of the dressing by referring to Section 12 Does your dressing look full? 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 PICO will require changing. To change the batteries:



- Remove the back cover from the PICO 7 pump to access the battery compartment.
- Remove the used batteries and dispose of in accordance with local regulations.
- Insert new AA batteries in the orientation indicated inside the battery compartment. Following this all four indicators should briefly illuminate.
- Replace the back cover.
- Press the orange button to restart therapy.

11. Showering and bathing

Light showering is permissible; however, the PICO 7 pump should be disconnected and placed in a safe location where it will not get wet.

Before showering and bathing

Press the orange button to stop therapy. Disconnect the pump from the dressings by untwisting the connectors.

While disconnected

PICO dressings should not be exposed to a direct spray or submerged in water. Ensure the ends of the tubing attached to the dressing faces down so that water does not enter the tube.

After showering or bathing

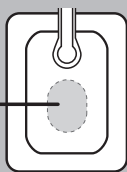
Reconnect the dressing to the pump by twisting the connectors together. Press the orange button to resume therapy.

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.

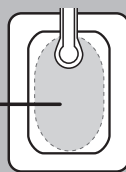
If your dressing looks similar to this, you should leave the dressing.

It is acceptable to be left in place.

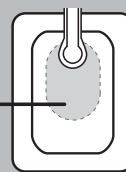


If your dressing looks similar to either or both of these you must contact your healthcare professional right away.








Dressing is Full.



Soft port may be blocked with fluid.



13. Troubleshooting

Indicator status	What could be the problem?	How to solve
 <p>All indicators off</p>	<p>The pump is in standby.</p> <p>The pump has completed its course of therapy.</p> <p>The batteries are dead.</p>	<p>Therapy has been paused. Press the Orange button to resume therapy.</p> <p>Pressing the Orange button will not restart therapy. Contact your healthcare professional right away.</p> <p>Replace the batteries (see changing the batteries) then press the Orange button to restart therapy.</p>
 <p>Green 'OK' and Orange 'battery low' indicators flash</p>	<p>System is functioning properly but the batteries are low.</p>	<p>Replace the batteries (see changing the batteries) then press the Orange button to restart therapy.</p>
 <p>Orange 'leak' indicator flashes</p>	<p>An air leak has been detected. Therapy is not being applied. (Note: the pump will automatically try to restart therapy after 1 hour).</p>	<ol style="list-style-type: none"> 1. Smooth down the edge of 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. 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.
 <p>Orange 'leak' and Orange 'battery low' indicators flash</p>	<p>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).</p>	
 <p>Orange 'dressing full' indicator flashes</p>	<p>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).</p>	
 <p>Orange 'dressing full' and orange 'battery low' indicators flash</p>	<p>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).</p>	
 <p>All indicators solidly illuminated</p>	<p>A pump error has been detected. The pump can no longer apply therapy.</p>	
		<p>Contact your healthcare professional right away.</p>

14. Glossary of symbols



Follow instructions for use

OK

Pump is functioning properly



Warning: The PICO 7 pump contains a MAGNET. The PICO 7 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.



Air leak detected



Dressing full indicator



Low battery



Start/pause/resume therapy



System lasts up to 7 days

Rx only

Caution: Federal (USA) law restricts this device to sale by or on order of a physician



Single Use. Do not reuse.



Test symbol of TUV Rheinland with approval for INMETRO Brasil

LOT

Lot number



EU: Not for general waste



International classification



Defibrillation-proof type BF applied part



MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment



Product is sterilized by Ethylene Oxide



Caution



Do not use if the package is damaged



Storage temperature



Manufacturer



Date of manufacture



Consult instructions for use



Keep product out of sunlight



Keep dry



Relative humidity limits



Atmospheric pressure limits



CE Mark

15. Contact information



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Date of issue 12/2020