1. Indications

PICO 7 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 systems are 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)
- 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 site.
- PICO 7 should not be used for the purpose of:
  - Emergency airway aspiration.
  - Pleural, mediastinal or chest tube drainage.
  - Surgical suction.

3. Description

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.

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. Failure to do so can cause the other medical device to fail which can result in serious harm including death.

See Section 5 Magnet Warning

5. Warnings

Magnet Warning

The PICO 7 pump contains a MAGNET that can cause other medical devices in close proximity to fail, leading to serious harm including death. The PICO 7 pump must be positioned at least 4 inches (10 cm) away from other medical devices that could be affected by magnetic interference. These include but are not limited to:
- Implantable Cardioger-detibrillator (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 (10 cm) away from other devices:
- If you have an electronic 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.

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.
- 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/Transport Environment

| Temperature | 4°F - 77°F (-20°C to +25°C) |
| Relative Humidity | 10 – 75% |

Atmospheric Pressure

700 to 1060 mbar

Operating Environment

| Temperature | 4°F - 104°F (-20°C to +40°C) |
| Relative Humidity | 10 – 95% |
| Atmospheric Pressure | 700 to 1060 mbar |

Battery Protection

IP22

Battery Type

2 x AA 1.5V (LR6/FR6)
8. 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. Regularly check the condition of the dressings by referring to Section 12 Does your dressing look full?
  If dressing looks full or blocked contact a healthcare professional right away.

9. How do I know if PICO® 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 65 seconds to establish therapy.
  Check condition of dressing by referring to Section 12 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 PICO® will require changing.
  To change the batteries:
  1. Remove the back cover from PICO® to access the battery compartment.
  2. Replace the used batteries and dispose of them 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® 7 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. Whilst disconnected, ensure the ends of the tube from the dressing faces down so that water does not enter the tube.

12. Does your dressing look full?
- If your dressing looks similar to this, you should leave the dressing.

13. Troubleshooting

<table>
<thead>
<tr>
<th>Indicator status</th>
<th>What could be the problem?</th>
<th>How to solve</th>
</tr>
</thead>
<tbody>
<tr>
<td>All indicators off</td>
<td>The pump is in standby.</td>
<td>Therapy has been paused. Press the Orange button to resume therapy.</td>
</tr>
<tr>
<td>Green 'OK' and Orange 'Battery low' indicators flash</td>
<td>The pump has completed its course of therapy. The batteries are dead.</td>
<td>Replace the batteries (see changing the batteries) then press the Orange button to restart therapy</td>
</tr>
<tr>
<td>Orange 'Leak' indicator flashes</td>
<td>System is functioning properly but the batteries are low.</td>
<td>An air leak has been detected. Therapy is not being applied. (Note: the pump will automatically try to restart therapy after 1 hour).</td>
</tr>
<tr>
<td>Orange 'Leak' and Orange 'battery low' indicators flash</td>
<td>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).</td>
<td>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.</td>
</tr>
<tr>
<td>Orange 'dressing full' indicator flashes</td>
<td>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).</td>
<td>If the air-leak remains the Orange-leak indicator will flash again after approximately 65 seconds (depending on the size of the wound).</td>
</tr>
<tr>
<td>Orange 'dressing full' and orange 'battery low' indicators flashes</td>
<td>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).</td>
<td>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</td>
</tr>
<tr>
<td>All indicators solidly illuminated</td>
<td>A pump error has been detected. The pump can no longer apply therapy.</td>
<td>Contact your healthcare professional right away.</td>
</tr>
</tbody>
</table>

14. Glossary of symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>OK</td>
<td>Pump is functioning properly</td>
</tr>
<tr>
<td>Warning: The PICO® 7 pump contains a MAGNET that can cause other medical devices in close proximity to fail, leading to serious harm including death. The PICO® 7 pump must be positioned at least 4 inches (10cm) away from other medical devices that could be affected by magnetic interference. See Section 5 Magnets Warning</td>
<td></td>
</tr>
<tr>
<td>Air leak detected</td>
<td></td>
</tr>
<tr>
<td>Low battery</td>
<td></td>
</tr>
<tr>
<td>Start/pause/resume therapy</td>
<td></td>
</tr>
<tr>
<td>System lasts up to 7 days</td>
<td></td>
</tr>
<tr>
<td>Pump lasts up to 7 days</td>
<td></td>
</tr>
<tr>
<td>Single Use. Do not reuse.</td>
<td></td>
</tr>
<tr>
<td>Lot number</td>
<td></td>
</tr>
<tr>
<td>Do not incinerate</td>
<td></td>
</tr>
<tr>
<td>International classification</td>
<td></td>
</tr>
<tr>
<td>Defibrillation-proof type BF applied part</td>
<td></td>
</tr>
<tr>
<td>MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment. The PICO® 7 is MR Unsafe. Do not bring PICO® 7 into the MRI scan room. The device presents a projectile hazard.</td>
<td></td>
</tr>
<tr>
<td>Product is sterilized by Ethylene Oxide</td>
<td></td>
</tr>
<tr>
<td>Caution: Federal (USA) law restricts this device to sale by or on order of a physician</td>
<td></td>
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<td></td>
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</tbody>
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15. Contact Information

<table>
<thead>
<tr>
<th>UNITED STATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith &amp; Nephew, Inc., 5600 Clearfork Main Street, Suite 600 Fort Worth, TX 76109 Customer care centre: 1-817-900-4000</td>
</tr>
</tbody>
</table>

For more information on electromagnetic immunity and electromagnetic emissions see: www.mypico.com or ask your Smith & Nephew representative for a hard copy.