Warranty

The PICO 7 pump contains a MAGNET. Keep the PICO 7 pump at least 4 inches (10 cm) away from other medical devices that at times. Failure to do so can cause the other medical device to fail which can result in serious harm to the patient.

See Section 5 Magnet Warning.

4. Important information

Pump Placement Warning

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1. Description

The PICO 7 consists of a pump and sterile dressing. The PICO 7 pump maintains negative pressure wound therapy at 80 mmHg (nominal) to the wound surface. Exudate is managed by the pump. The combination of suction and wet/dry dressing allows for pressure to be maintained throughout the therapy. The PICO 7 dressing kit is intended for use for up to 7 days without a dressing change. For moderate exuding wounds the PICO 7 dressing kit is intended for use for up to 7 days without a dressing change. For moderate exuding wounds the PICO 7 dressing kit is intended for use for up to 7 days without a dressing change. For moderate exuding wounds the PICO 7 dressing kit is intended for use for up to 7 days without a dressing change.

2. Indications for use

PICO 7 is indicated for patients who would benefit from a suction device negative pressure wound therapy to promote wound healing via removal of negative pressure wound therapy of exudates and infectious materials.

a. Chronic
b. Acute

3. Contraindications

PICO 7 is contraindicated for:

a. Patients with malignancy in the wound bed or margins of the wound present in the history.

b. Patients with severe coagulopathy, disseminated intravascular coagulation or in the history.

c. Patients with severe anticoagulant use.

d. Patients with severe sepsis.

e. Patients with severe organ failure.

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See Section 5 Magnet Warning.
8.4. Use of PICO dressings with filters

PICO dressings are compatible with standard glue and foam filters. Used in traditional negative pressure wound therapy where this is clinically appropriate—e.g., for example on a defect wound. When a filter is used, the filter is placed on the dressing therapy should be changed 2 to 3 times a week, according to local protocol and as per the manufacturer’s instructions. Gauze should loosely fit the surface of the wound. Avoid over packing.

8.5. Use of PICO dressings with non-adherent layers

PICO dressings may be used over the top of a non-adherent layer if required, for example over a skin graft. On infected wounds or wounds at risk of infection, ACTICOAT™ Flex may be used under PICO dressings.

8.6. To remove a dressing

1. Remove the pump from the dressing by unlatching the orange button - all indicators will turn off.
2. Remove the pump from the dressing by unlatching the connections.
3. Remove the PICO dressing by stretching the fixation strips away from the skin. Lift the dressing at one corner and peel back until it has been fully removed.
4. The PICO dressing and fixation strips should be disposed of as clinical waste in accordance with local protocol.
   The batteries should be removed from the pump, and both batteries and pump disposed of according to local regulations.

For additional information on disposal requirements see: www.mypico.com or speak to your Smith & Nephew representative.

12. Safety of PICO 7
When used in accordance with the manufacturer’s instructions, PICO 7 complies with the General Requirements for Safety of Medical Electrical Equipment (IEC 60601-1). PICO 7 is intended for uncontrollable environments e. g. home use (IEC60601-1-11).

13. Electromagnetic compatibility of PICO 7
PICO 7 has been tested and found to comply with the limits for medical devices to IEC 60601-1-2-400 ed. 4th edition. These limits and test levels are intended to provide reasonable protection against harmful interference when PICO 7 is used in typical medical installation and uncontrolled environments inside the home or hospital. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. For additional information on electromagnetic and Interference, please visit www.mypico.com or ask your Smith & Nephew representative for a handbook.

Guidance and manufacturer’s declaration – electromagnetic immunity
PICO 7 is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

14. Troubleshooting
PICO 7 has visual indicators to let the user know when there is an issue. PICO 7 does not contain audio alerts. The pump should be carried so that it is accessible and the patient/healthcare professional can check the status routinely in case there is a fault or in case of damage.

15. Cautions
This manual is not intended as a guarantee or warranty. It is intended only as a guide for medical questions please consult a physician. The product must be used in accordance with this user manual and all applicable labeling.

PICO 7 is packed in the UK with individual components being made in: Germany, UK, China, Mexico and Malaysia. On delivery, the pump should be checked for damage and stored in a dry environment.

16. System variants
PICO 7 Single Use Negative Pressure Wound Therapy System

In use: Pumps & Pumps clip - China

System lasts up to 7 days

Device includes: 1 single dressing, 1 pump & pump clip, 1 dressing refill pack, 1 fluid management pack, 1 set of fixation strips, 1 carrying case, 1 patient user guide, 1 complete system. The pump clip is made in the following countries: Fixation Strips – Origin as marked: Made in the following countries: China, Mexico, China, Mexico, China.

17. Glossary of symbols
- Follow instructions for use
- International classification
- Pump is functioning properly
- Air leak detected
- Dressing changed
- Drainage needed
- Therapy finished
- Therapy started
- Therapy complete
- Pipeline
- Alarm
- Health care professional
- CAHAR
- Do not use in a general setting

Recommended separation distances between portable and mobile RF communications equipment and the device
PICO 7 is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The customer or the user of this device should ensure that the device is not located in a region that will cause interference.

SEPARATION DISTANCE (in cm) BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICES AND THE PICO 7 DEVICE

<table>
<thead>
<tr>
<th>Distance (cm)</th>
<th>Equipment/Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Portable and mobile RF communication devices</td>
</tr>
<tr>
<td>100</td>
<td>PC/iPad/iPod devices</td>
</tr>
</tbody>
</table>

NOTES: 1.0, 900 and 800 MHz (WLAN) bandwidth can be increased in high frequency range, large appliance needs.

Technical information, including the distances and recommendations, can be found on www.mypico.com.