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Smith Nephew PICO 7 PICO Single Use Negative Pressure Wound Therapy Systems User Manual

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Systems User Manual

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Smith Nephew PICO 7 PICO Single Use Negative Pressure Wound Therapy Systems



Product Information

Product Name

PICOTM Fluid Management Pack

Manufacturer:

Smith & Nephew

Description:

The PICOTM Fluid Management Pack is a single-use negative pressure wound therapy system that manages exudate through a combination of absorption and evaporation of moisture through the outer film. The pack contains a pump with a magnet, which must be kept at least 4 inches (10cm) away from other medical devices at all times to avoid disruption of nearby medical devices' operation.

Product Usage Instructions

1. **Positioning:** Keep the PICO 7, 7Y & 14 pumps at least 4 inches (10cm) away from other medical devices at all times. This applies to both patients and caregivers.
2. **Monitoring:** If pain, reddening, odor, sensitization, or a sudden change in the volume or color of the wound fluid occurs during use, contact your healthcare professional immediately.
3. **Dressing Change:** The PICO dressing is intended to be used for up to 7 days on low-exuding wounds and up to 4 days on moderate-exuding wounds. Low exuding wounds are considered to be up to 0.6g of liquid exudate/cm² of wound area/24 hours, and moderately exuding wounds are considered to be up to 1.1g of liquid exudate/cm² of wound area/24 hours. The frequency of dressing changes can be affected by multiple factors such as wound type, wound size, rate or volume of exudate, orientation, or environmental conditions.
4. **Indications for Use:** PICOTM Fluid Management packs are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as they may promote wound healing via the removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include surgical site infections, seromas, and dehiscence.
5. **Contraindications:** There are no contraindications for PICOTM Fluid Management packs.

Description

PICO dressings are packaged sterile and are for single use only. The PICO dressing manages exudate through a combination of absorption and evaporation of moisture through the outer film.

The PICO dressing is intended to be used for up to 7 days on low-exuding wounds. For the treatment of moderate exuding wounds, the dressing is intended to be used for up to 4 days.

Low-exuding wounds are considered to be up to 0.6g of liquid exudate/cm² of wound area/24 hours. Moderate exuding wounds are considered to be up to 1.1g of liquid exudate/cm² of wound area/24 hours. 1g of exudate is approximately equal to 1ml of exudate.

The frequency of dressing changes can be affected by multiple factors such as wound type, wound size, rate or volume of exudate, orientation or environmental conditions.

Indications for use

PICO Fluid Management packs are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as they may promote wound healing via the removal of low to moderate levels of exudate and infectious materials.

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehiscent wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
 - Venous Leg Ulcers – PICO 7 and PICO 14 Systems can be used in combination with Graduated Compression Therapy in the management of Venous Leg Ulcers.
- Flaps and grafts
- Closed surgical incisions

PICO Fluid Management packs are suitable for use both in a hospital and homecare setting.

For indications relating to reduction in the incidence of surgical site infections, seroma and dehiscence refer to the respective PICO System user manual.

Contraindications

The PICO 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 System should not be used for the purpose of:
- Emergency airway aspiration.
 - Pleural, mediastinal or chest tube drainage.
 - Surgical suction.

PICO 7 & 14 Systems with graduated compression therapy

The PICO 7 and PICO 14 Systems with graduated compression therapy may be used to manage venous ulcerations.



For more information refer to the respective PICO System user manual.

Important information

Pump Placement Warning

The PICO 7, 7Y & 14 pumps contain a MAGNET. Keep

the PICO 7, 7Y & 14 pumps at least 4 inches (10cm) away from other medical devices at all times. As with all electrical medical equipment, failure to maintain an appropriate distance may disrupt the operation of nearby medical devices.

(see Section 6 Magnet Warning)

Warnings

Magnet Warning

The PICO 7, 7Y & 14 pumps contain

a MAGNET. As with all electrical medical equipment, failure to maintain an appropriate distance may disrupt the operation of nearby medical devices. The PICO 7, 7Y & 14 pumps 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, 7Y & 14 pumps 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, 7Y & 14 Systems.
- If the patient is wearing the PICO 7, 7Y or 14 pump in a public area where they may come in close contact with someone else who has an electronic medical device.

Certain patients are at high risk of bleeding complications which, if uncontrolled, could potentially be fatal. Patients must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately disconnect pump, leave the dressing in place, take appropriate measures to stop bleeding and seek immediate medical assistance. Hemostasis must be achieved before applying the dressing, although the use of anticoagulants does not deem a patient inappropriate for treatment with the PICO System. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that may increase the risk of bleeding, if disrupted. Frequent assessment must be maintained throughout the therapy.

At all times care should be taken to ensure that the pump, tubing and connectors do not:

- Lie in a position where it could cause pressure damage to the patient.
- Trail across the floor where it could present a trip hazard or become contaminated.
- Present a risk of strangulation or a tourniquet to patients.
- Rest on or pass over a source of heat.
- Become twisted or trapped under clothing or bandages so that therapy is blocked.

Sharp edges or bone fragments in a wound must be covered or removed prior to using the PICO System due to the risk of puncturing organs or blood vessels while under negative pressure wound therapy.

In the event that defibrillation is required, remove the dressing if it is positioned in a location that will interfere with defibrillation.

The PICO System has not been studied on pediatric patients. Patient size and weight should be considered when prescribing this therapy.

The PICO Systems contain small parts which could represent a choking hazard for young children. Keep out of the reach of children.

The PICO System is not suitable for use in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.

PICO dressings should only be applied, changed or removed by a healthcare professional.

Each PICO dressing (including Multisite) must be used to dress one wound only.

Precautions

1. Precautions should be taken in the following types of patients who are at high risk of bleeding complications:
 - Receiving anticoagulant therapy or platelet aggregation inhibitors or actively bleeding.
 - Having weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to; anastomoses, infection, trauma or radiation.
 - Suffering from difficult wound hemostasis.
 - Untreated for malnutrition.
 - Non-compliant or combative.
 - Suffering from wounds in close proximity to blood vessels or delicate fascia.
2. 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.
3. Where the PICO System is used to bolster skin grafts, it is important to visually inspect the system regularly, especially in the first week of treatment to ensure that negative pressure wound therapy is continually applied and a seal is maintained.
4. Where PICO dressings are used on infected wounds, more frequent dressing changes may be required. Regular monitoring of the wound should be maintained to check for signs of infection.
5. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing or the use of negative pressure wound therapy on ischemic limbs does not compromise circulation.
6. Although PICO dressings can be used under clothing/bedding, it is important that occlusive materials e.g. film dressings, are not applied over the pad area of the dressing as this will impair the intended evaporation of moisture through its outer layer.
7. The PICO dressing should not be covered by rigid immobilization devices or casts which might apply excessive pressure and cause tissue injury at the wound site, especially where the tubing enters the dressing.
8. Prolonged placement of rigid or opaque materials over the PICO dressing may prevent the regular inspection and assessment of the wound, and disrupt scheduled or required dressing changes.
9. Where PICO dressings are used on patients with fragile skin, a skin protectant such as NO-STING SKIN-PREP™ should be used on areas of skin where fixation strips are to be applied. Inappropriate use or repeated application of fixation strips may otherwise result in skin stripping.
10. Do not use PICO dressings with oil-based products such as petrolatum as it may compromise establishing an effective seal.
11. The use of negative pressure wound therapy presents a risk of tissue ingrowth into foam when this is used as a wound filler. When using foam filler with the PICO System, tissue ingrowth may be reduced by using a non-adherent wound contact layer or by increasing the frequency of dressing changes.
12. The PICO System may be used in conjunction with surgical drains provided the dressing is not placed over tubing where it exits the skin. Any surgical drain should be routed under the skin away from the edge of the dressing and function independently of the PICO System.
13. When showering the PICO pump should be disconnected from the dressing. Whilst disconnected, ensure the end of the tubing attached to the dressing is facing down so that water does not enter the tube.
14. The PICO dressing should only be used with PICO pumps.
15. Do not alter or cut tubing configuration or pull on the tubing or soft port.
16. Do not cut the PICO dressing pad as this may lead to loss of negative pressure wound therapy application.
17. Always ensure that the PICO dressing is positioned centrally over the wound. The soft port should be positioned uppermost on intact skin and not extend over the wound so that the risk of fluid collecting around the soft port and potentially blocking the therapy is minimized.
18. The PICO System is single-use only. Use of any part of this system on more than one patient may result in cross-contamination that may lead to infection.
19. High temperatures and humidity may reduce wear times of PICO dressings.
20. When applying dressings next to one another, ensure the dressing borders do not overlap.

Adverse Reactions

Excessive bleeding is a serious risk associated with the application of suction to wounds which may result in death or serious injury. Careful patient selection, in view of the above-stated contraindications, warnings and precautions is essential. Carefully monitor the wound and dressing for any evidence of a change in the blood loss status of the patient. Notify the healthcare professional of any sudden or abrupt changes in the volume or the color of the exudate.

Instructions for use

Guidance on wound suitability

PICO dressings should be used on wounds which

fit comfortably within the area of the pad, observing precautions on soft port positioning (on intact skin and not extending over the wound). PICO Multisite dressings are designed to enhance conformability when dressing in awkward anatomical areas. Each PICO dressing (including Multisite) must be used to dress one wound only. As a guide:

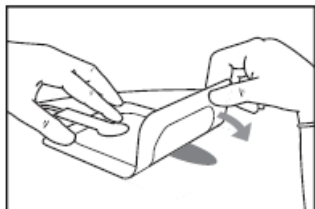
Depth – Wounds greater than 0.5cm (1/4 in.) in depth are likely to require a foam or gauze negative pressure wound therapy filler to ensure adequate treatment of all the wound surface. Wounds must not contain exposed arteries, veins, nerves or organs (see Section 3 – Contraindications). Wounds treated with the PICO 7Y System should generally be no more than 2cm (4/5 in.) in depth. Wounds treated with the PICO 7 System or PICO 14 System should generally be no more than 4.5 cm (1 3/4 in.) in depth.

Exudate – The PICO System is intended for use on wounds where the level of exudate is low (up to of liquid exudate/cm² of wound area/24 hours) to moderate (up to 1.1g of liquid exudate/cm² of wound area/24 hours). 1g of exudate is approximately equal to 1ml of exudate. When used on a moderately exuding wound, the size of the wound should generally be no more than 25% of the dressing pad area.

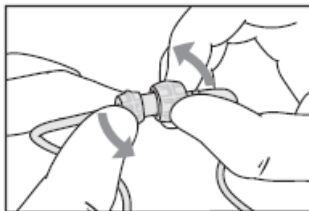
Application

The dressing should only be applied by a healthcare professional.

1. Remove any excess hair to ensure close approximation of the dressing to the wound. If necessary, irrigate the wound with sterile saline and pat the wound dry.
2. Using a clean technique, peel off the first release handle and place the dressing centrally over the wound to reduce the chance of wound fluid coming into contact with the soft port. Ensure the dressing lies flat to the wound and the surrounding skin. The port should be uppermost from the wound (depending on the patient's primary position), placed on intact skin and not extending over the wound to prevent fluid pooling around the soft port and blocking the therapy. Remove the other remaining handle(s) and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure the border is not creased.

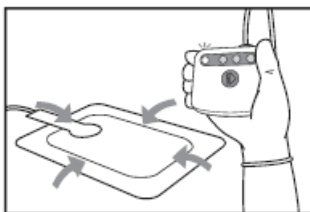


3. Once the dressing is in place, remove the pump and the batteries from the tray.
Warning: The PICO 7, 7Y & 14 pumps contain a MAGNET. Keep the PICO 7, 7Y & 14 pumps at least 4 inches (10 cm) away from other medical devices at all times. (See Section 6 Magnet Warning)
4. The direction in which the batteries should be placed is indicated inside the battery compartment. Insert the batteries. Replace the cover. Following this all four indicators should illuminate for 3 seconds.
5. Join the pump to the dressing tubes by twisting together the connectors. The soft tube can be directly connected



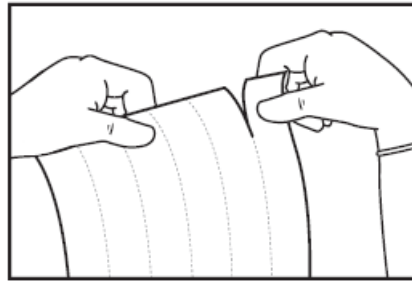
to the pump if long tubing is not required.

6. Press the orange button to start the application of therapy. For any information or troubleshooting refer to the



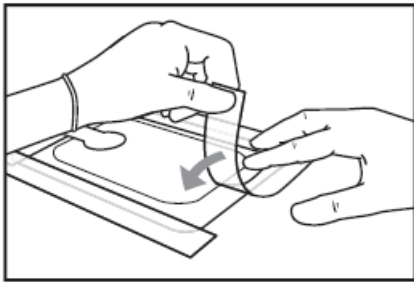
respective PICO System user manual.

7. If using NO-STING SKIN-PREP prior to application of the fixation strips (see Section 7. Precautions), wipe the



area surrounding the dressing and allow skin to dry.

8. Apply the fixation strips all the way around the dressing border. Remove top carrier on the strip after each one has been applied. These strips maintain the seal over the wear time of the dressing. In awkward areas, it may be useful to apply the strips to help achieve a seal prior to switching on the pump. Place each strip so that it overlaps the dressing border by approximately 1cm (2/5 in.). Ensure tubing is not twisted or trapped between



clothing.

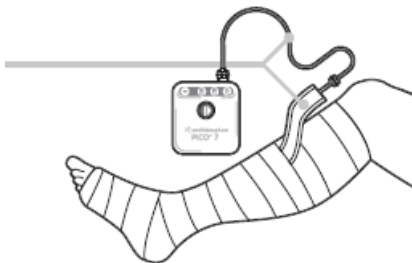
Please note that if at any time the fixation strips are removed, the dressing should also be replaced.

If desired, gel patches may be applied in addition to the fixation strips to help achieve or maintain a seal.

Use of PICO 7 & 14 Systems with graduated compression therapy

When using either PICO 7 & 14 Systems with graduated compression therapy you must comply with indications and contraindications for both the PICO System and the graduated compression therapy product. The PICO 7 & 14 Systems can be used with compression for the management of venous leg ulcerations.

Ensure all tubing including flat soft port tubing is not in contact with skin. When using compression therapy ensure the flat soft port tubing runs over the top of the first layer and beneath subsequent layers.



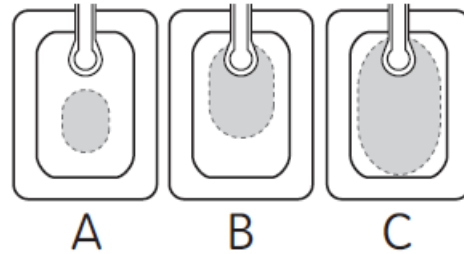
In a clinical study using the PICO Single Use Negative Pressure Wound Therapy System with compression therapy in venous leg ulcers, device-related adverse events included maceration, increase in ulcer size, blistering, and irritation. Care should be taken when combining these therapies, and consider more frequent wound monitoring. Please discontinue combination use if maceration or increase in wound size is observed.

Dressing change

Dressings should only be changed by a healthcare professional.

1. Dressings should only be changed in line with standard wound management guidelines, typically every 3-4 days. At the healthcare professional's discretion, a PICO dressing may be left in place for up to 7 days. More frequent dressing changes may be required depending on the level of exudate, condition of the dressing, wound type/size, orientation of the dressing, environmental considerations or other patient considerations; e.g. when the PICO System is used on infected wounds.
2. Inspect the PICO dressing regularly. If the dressing appears ready for changing (see diagrams A-C), press the orange button and disconnect the dressing from the pump. The fixation strips should be stretched away from the skin and the dressing lifted at one corner and peeled back until it has been fully removed. Apply another dressing as per Section 9.2. Application, connect to the pump and press the orange button to reinitiate the therapy.
 - A Dressing properly positioned and is acceptable to be left in place

- B Dressing requires change – Port may block with fluid



- C Dressing requires change – Absorbent area is full

3. The PICO dressing should be disposed of as clinical waste.

Use of PICO dressings with fillers

PICO dressings are compatible with standard gauze and foam fillers used in traditional negative pressure wound therapy where this is clinically appropriate

- for example on a defect wound. When a filler is used, the filler and the PICO dressing should be changed 2 to 3 times a week, according to local clinical protocol and manufacturer's instructions. Gauze should loosely fill to the surface of the wound. Avoid overpacking.

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 Antimicrobial Barrier Dressing may be used under PICO dressings.

Dressing removal

Follow these instructions for dressing removal:

1. Stop the PICO pump by pressing the orange button – All indicators will turn off.
2. Remove the pump from the dressing by untwisting the connectors.
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. Dispose of the PICO dressing and fixation strips as clinical waste.

Showering and bathing

Light showering is permissible; however, the PICO pump should be disconnected (see Section 7. Precautions) and placed in a safe location where it will not get wet. The PICO dressing should not be exposed to a direct spray or submerged in water. Whilst disconnected, ensure the end of the tubing attached to the dressing is facing down so that water does not enter the tube.

General use

During use of your PICO dressing, for any information or troubleshooting on your pump refer to the respective PICO System user manual.

PICO dressing compatibility with other diagnostic procedures

PICO pumps and PICO dressings are compatible with defibrillation.

If in the event that defibrillation is required, remove the dressing and pump if it is positioned in a location that will interfere with defibrillation.

PICO dressings are MRI-compatible, however, the PICO pumps are not MRI-compatible.

PICO dressings are not compatible with hyperbaric oxygen (HBO).

For compatibility information for the PICO pump, refer to the respective PICO System user manual.

Cautions

This user 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. Smith & Nephew Medical Limited,

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This product may be covered by one or more US patents. See www.smith-nephew.com/patents

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UNITED STATES Smith & Nephew, Inc.,

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System variants

PICO Fluid Management Pack

For use with PICO Single Use Negative Pressure Wound Therapy Systems

5 x individually packaged dressings, secondary fixation strips

- 10cm x 20cm / 3.9in. x 7.9in. 66022022
- 10cm x 30cm / 3.9in. x 11.8in. 66022023
- 10cm x 40cm / 3.9in. x 15.7in. 66022024
- 15cm x 15cm / 5.9in. x 5.9in. 66022025
- 15cm x 20cm / 5.9in. x 7.9in. 66022026
- 15cm x 30cm / 5.9in. x 11.8in. 66022027
- 20cm x 20cm / 7.9in. x 7.9in. 66022028
- 25cm x 25cm / 9.8in. x 9.8in. 66022029
- Multisite 15cm x 20cm / 5.9in. x 7.9in. 66022020
- Multisite 20cm x 25cm / 7.9in. x 9.8in. 66022021

Glossary of symbols

Warning: The PICO 7, 7Y & 14 pumps contain a MAGNET. The PICO 7, 7Y & 14 pumps 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 an appropriate distance may disrupt the operation of nearby medical devices. See Section 6 Magnet Warning.



Single Use. Do not reuse.



EU: Not for general waste.



Product is sterilised 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.



Lot number.



CE Mark.

Documents / Resources



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User Manual

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