PICO 7
Clinical guidelines

smith&nephew
PICO° 7
Single Use Negative Pressure Wound Therapy System
Supporting healthcare professionals for over 150 years
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Smith & Nephew has an extensive portfolio of wound care products and therapies that cover all major aspects of managing a wide range of wound types. It is a well-established principle that wounds are managed across a continuum of healing and require different therapies at each step in the continuum. Smith & Nephew offers negative pressure wound therapy (NPWT) as part of a complete range of wound care products to use along a patient’s journey towards healing. The key to deciding which product to use at each stage of the continuum is to identify the barriers to healing along with a treatment goal to combat those issues.1,2

NPWT is widely adopted as a standard treatment for patients with both acute and chronic wounds.3 A variety of formats are now available, and, as the wound progresses along the continuum, a switch from one format to another may be the most appropriate course. NPWT has been shown to be cost effective when used appropriately.4,5 Knowledge of when NPWT is most appropriate and when alternative therapies may be more appropriate is vitally important to maintain the efficient use of resources while not negatively affecting wound outcomes.3,6,7

Negative pressure wound therapy involves the application of controlled levels of sub-atmospheric (negative) pressure to a wound or closed surgical incision. The systems described in these guidelines consist of a disposable suction pump to generate negative pressure and a variety of wound dressing kits to deliver the therapy to the wound site. The benefits of NPWT for open wounds in progression towards wound healing go well beyond drainage management. Studies have shown that NPWT improves granulation tissue formation, may decrease bacterial burden, protects from the outside environment, promotes moisture balance within the wound bed, and may decrease the frequency of dressing changes.3

Additionally NPWT is now a widely accepted therapy for use on closed surgical incisions. Incisional NPWT (iNPWT) is the process of applying sub-atmospheric pressure to a closed surgical incision with the primary objective of preventing surgical site complications (SSCs). These may include complications such as seroma, surgical site infection, dehiscence, and prolonged drainage. iNPWT has multiple mechanisms of action that can help improve the speed, strength and quality of incisional wound closure.5,6,8,9,10,11,12,13 iNPWT synergistically delivers a multi-modal mechanism of action by protecting the incision from external contamination, reducing the lateral tension to the incision, reducing edema, improving perfusion, and it may reduce the likelihood of seroma and hematoma formations.9,10
Wound bed preparation

Wound bed preparation has been defined as the process of removing the barriers to healing. Removal of these barriers is thought to allow the wound repair process to progress.\(^1,2\)

The Tissue, Infection, Moisture and Edge (epithelial margin) “TIME” scheme is a useful way of identifying and removing barriers to healing.

Wound bed preparation represents a combination of both scientific knowledge and practical skill; its application can help correct abnormalities in acute and chronic wounds and stimulate or progress the healing process.\(^1\) To optimize the use of negative pressure wound therapy, it is essential that clinicians ensure wound bed preparation is achieved prior to, during and after therapy.\(^7\)

**TIME principles of wound bed preparation\(^2\)**

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue nonviable or deficient</td>
<td>Defective matrix and cell debris</td>
<td>Restore wound base and ECM proteins</td>
</tr>
<tr>
<td>Infection or inflammation</td>
<td>High bacterial counts or prolonged inflammation</td>
<td>Low bacterial counts and controlled inflammation</td>
</tr>
<tr>
<td>Moisture imbalance</td>
<td>Desiccation or excess fluid</td>
<td>Restore cell migration, maceration avoided</td>
</tr>
<tr>
<td>Edge of wound non-advancing or undermined</td>
<td>Non-migrating keratinocytes</td>
<td>Stimulate keratinocyte migration</td>
</tr>
<tr>
<td></td>
<td>Non-responsive wound cells</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Debridement</td>
<td>Biologicals agents</td>
</tr>
<tr>
<td></td>
<td>Antimicrobials</td>
<td>Adjunct therapies</td>
</tr>
<tr>
<td></td>
<td>Compression</td>
<td>Debridement</td>
</tr>
</tbody>
</table>

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Optimization of NPWT in open wounds

The effective use of NPWT relies on thorough assessment of the patient, the wound, and development of a plan for how the wound might be closed. When to debride and when to start and stop NPWT are keys to an effective treatment plan.14,15

Debride wound

**Effective debridement may:**
- Reveal extent of tissue damage
- Reduce biochemical imbalance, senescent cells16
- Reduce bacterial burden15
- Reduce odor
- Optimize healing potential16

**Consequences of ineffective debridement are:**
- Potential for delayed healing
- Potential for infection
- Physical barrier preventing accurate assessment
- Reduced patient Quality of Life (QoL)
- Psychological aspects

Optimize wound closure – mechanisms of action3

- Remove exudate
- Assist in wound contraction
- Stimulate granulation tissue
- Protect from outside contaminants
- Increase vascular perfusion

- May reduce wound bioburden
- Remodel connective tissue matrix
- Encourage maturation of epithelial cells
- Maintain a moist wound environment

Know when to stop or change treatment

- Established goal of therapy has been met 3,14
- No improvement or reduction in wound volume has been documented consecutively for 2 weeks16
- Individual patient characteristics and wound considerations may vary clinical decisions in regards to whether to continue or discontinue NPWT14

Foam

Gauze
Wound assessment

NPWT treatment depends heavily upon the quality of the clinical wound assessment. The wound should have a detailed assessment at the initiation of the NPWT treatment regime and with every dressing change thereafter. The following areas should be addressed with every wound assessment:

Wound size: length, width, depth
- NPWT has the ability to assist with removal of interstitial fluid and sloughy necrosis. With the removal of the space filling materials, the volume of the wound may increase slightly. This will likely happen within the first few dressing changes, especially if the wound is in the inflammatory phase of wound healing.

Granulation tissue: amount and description
- Healthy granulation tissue should be beefy red and not bleed easily. No trauma should occur to the granulation tissue with dressing removal. A non-adherent dressing or a contact layer may be used to reduce pain or where the risk of tissue ingrowth is present.

Epithelialization: amount and description
- Epithelialization is thin and often noted to be shiny or silver in appearance and may be hard to see. The new cells are very fragile. If undermining is present, it is important to fill the undermined areas with gauze or foam to prevent the edges from rolling under.

Necrotic tissue: type and amount
- The use of NPWT in wounds with necrotic tissue with eschar present is contraindicated.
- Necrotic tissue is devitalized tissue and often appears black or brown, hard and dry. Soft or boggy necrotic tissue should be assessed for infection.
- NPWT, along with the autolytic environment established by the Transparent Film, may result in a decrease in necrotic slough.

Slough
- Slough is necrotic or devitalized tissue that is yellow in appearance and can be dry or moist.

Exudate: type, amount and consistency
- Assess wound exudate for type, amount, color and consistency. Evaluate the wound exudate for consistent characteristics with the wound type and the anticipated exudate. Significant changes in exudate warrant a reassessment of the wound.

Odor: present/absent, description
- It is important to note that body fluids that have been contained in a sealed system for an extended period of time may likely have an unpleasant odor. This odor is not a direct indication of wound infection. Remove dressing and cleanse wound per facility protocol. If odor persists, assess for wound infection, and if required, treat and increase frequency of dressing changes until odor is under control. The use of an antimicrobial wound contact layer may be used to reduce bacterial burden.
Optimization of NPWT in closed incisions

The effective use of iNPWT relies on thorough assessment of the patient, the incision, and the preparation of the surgical site.

- Determine if patient has risk factors for SSCs that may warrant the use of iNPWT
- Ensure skin surrounding incision is clean and dry
- If using a skin protectant, allow it to thoroughly dry
- Determine length of time for iNPWT therapy

Optimize wound closure – mechanisms of action for iNPWT

- Protect the incision from external contaminants
- Reduce lateral tension to the incision
- May help reduce edema
- May help improve perfusion
- May help reduce seroma and hematoma formations

Know when to stop or change treatment

- Established goal of therapy has been met (ex. Incision is intact with no drainage and the epithelium is closed).
- Incision does not respond to iNPWT, consider additional applications or other treatment modalities.
PICO™ 7 Single Use Negative Pressure Wound Therapy System
Description

PICO® 7 consists of a pump and sterile dressing(s). The PICO 7 pump maintains negative pressure wound therapy at -80 mmHg (nominal) to the wound surface. Exudate is managed by the dressing through a combination of absorption and evaporation of moisture through the outer film. 

The PICO 7 dressing kit is intended to be used for up to 7 days on low exuding wounds. For moderate exuding wounds the system is intended to be used for up to 4 days. For 7 days use on moderate exuding wounds additional dressings will be required (available for purchase separately).

Low exuding wounds are considered to be up to 0.6g of liquid exudate/2cm of wound area/24 hours. Moderate exuding wounds are considered to be up to 1.1g of liquid exudate/2cm 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. Additional dressings are available to purchase separately, as required.

Indications for use

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. Examples of 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

PICO Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.
Contraindications

The use of PICO™ 7 is contraindicated in the presence of:

- 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.

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.

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

5. Warnings

1. **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 (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 the patient is wearing the PICO 7 pump in a public area where they may come in close contact with someone else who has an electronic medical device.

2. 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 discontinue therapy, leave dressing in place, take appropriate measures to stop bleeding and seek immediate medical assistance.

3. Hemostasis must be achieved before applying the dressing, although the use of anticoagulants does not deem a patient inappropriate for treatment with PICO 7. 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.

4. At all times care should be taken to ensure that the pump and tubing does 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 the negative pressure is blocked.

5. Sharp edges or bone fragments in a wound must be covered or removed prior to using PICO 7 due to risk of puncturing organs or blood vessels while under negative pressure.

6. In the event that defibrillation is required, disconnect the pump from the dressing prior to defibrillation. Remove the dressing if it is positioned in a location that will interfere with defibrillation.

7. **MR Unsafe.** The PICO 7 pump is not MRI compatible. 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.
8. PICO® 7 has not been studied on pediatric patients. Patient size and weight should be considered when prescribing this therapy.

9. PICO 7 is unsuitable for use in areas where there is danger of explosion (e.g., hyperbaric oxygen unit).

10. The system contains small parts which could represent a choking hazard for young children. Keep out of the reach of children.

11. PICO 7 is not suitable for use in the presence of flammable anesthetic mixture with oxygen or nitrous oxide.

12. PICO 7 dressings should only be applied, changed, or removed by a healthcare professional.

13. Each PICO 7 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.
   - Noncompliant 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.

3. Where PICO 7 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 7 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. PICO 7 does not contain audible alarms. The pump should be carried so that it is accessible and the patient/healthcare professional can check the status routinely.

7. Although PICO 7 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.

8. The PICO 7 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.

9. Prolonged placement of rigid or opaque materials over the PICO 7 dressing may prevent the regular inspection and assessment of the wound, and disrupt scheduled or required dressing changes.

10. Where PICO 7 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.
11. Do not use PICO™ 7 dressings with oil-based products such as petrolatum as it may compromise establishing an effective seal.

12. 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 PICO 7, tissue ingrowth may be reduced by using a non-adherent wound contact layer or by increasing the frequency of dressing changes.

13. PICO 7 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 7 System.

14. The pump must be protected from sources of fluid e.g. from incontinence or spillages. Discontinue PICO 7 use if fluid ingress is observed.

15. When showering the PICO 7 pump should be disconnected from the dressing. While disconnected, ensure the end of the tubing attached to the dressing is facing down so that water does not enter the tube.

16. Do not take the pump apart.

17. The PICO 7 dressing should only be used with PICO 7 pumps.

18. Do not alter or cut tubing configuration or pull on the tubing or soft port.

19. Do not cut the PICO 7 dressing pad as this may lead to loss of negative pressure wound therapy application.

20. Always ensure that the PICO 7 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.

21. The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if PICO 7 is near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment or metal detectors.

22. CT scans and x-ray have the potential to interfere with some out of the x-ray or scanner range. If the pump has been taken into the CT scan or x-ray range, check that the system is functioning correctly following the procedure.

23. The PICO 7 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.

24. High temperatures and humidity may reduce wear times of PICO 7 dressings.

25. 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).

26. 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 to replace the system.

27. 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 exudate.
Instructions for use

Guidance on wound suitability

PICO 7™ 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 7 Multisite dressings are designed to enhance conformability when dressing awkward anatomical areas. PICO 7 dressings (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 surfaces. Wounds treated with the larger dressing sizes of the PICO 7 system should generally be no more than 2cm (4/5 in.) in depth.

**Exudate** – PICO 7 is intended for use on wounds where the level of exudate is low (up to 0.6g of liquid exudate/2cm of wound area/24 hours) to moderate (up to 1.1g of liquid exudate/2cm 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.

Management of open wounds
(see wound selection guide section for further information)

- Intended for use on wounds with low to moderate levels of exudate.
- Not intended for use on complex wounds with extensive undermining or tunneling. Complexity of the wound refers to the characteristics of the wound and not specific to wound etiology.
- When used on a moderately exuding wound, the size of the wound should generally be no more than 25% of the dressing pad area.

Incision management – closed surgical incisions
(see wound selection guide section for further information.)

Surgical procedures – NPWT is indicated for patients considered to be at risk for surgical site complications.

- Choose dressing size slightly larger than incision or wound length to allow the port to be positioned above or lateral to the incision to minimize exposure of port to wound drainage.
- If excessive exudate is present and/or large volume incisional drainage is anticipated, consider the use of traditional NPWT until fluid noted is low to moderate and then transition the patient to PICO 7.
- NO-STING SKIN-PREP™ may be used on intact skin surrounding the incision. It is important to allow the NO-STING PREP to dry completely before dressing application.
Split thickness skin graft (STSG)/Skin substitutes

- PICO™ 7 may be utilized over STSG/skin substitutes.
- Choose dressing size slightly larger than graft to allow the port to be positioned above the graft to minimize exposure of port to wound drainage.
- Generally a non-adherent layer is applied over the graft prior to PICO 7 application.
- Depending on the contour of the graft site additional filler may be utilized to stabilize the graft.
- PICO 7 has a continuous set pressure of nominal -80mmHg.
- Monitor dressing and pump functionality frequently.

Product application

1. The dressing should only be applied by a healthcare professional. 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 central release handle and place the dressing centrally over the wound to reduce the chance of wound fluid coming into contact with the port. 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 port and blocking the negative pressure. Remove the other handle and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.

3. Once the dressing is in place, remove the pump and the batteries from the tray. Insert the batteries. Replace the cover. Following this all four indicators should illuminate for 3 seconds.

4. Join the pump to the dressing by twisting together the tubing connectors. Press the orange button to start the application of negative pressure. The green light will start to flash.

   Depending on the size of the wound, the pump should take up to 65 seconds to establish negative pressure wound therapy.

   If after 65 seconds the system has not established negative pressure wound therapy, the amber air leak light will illuminate. To troubleshoot refer to section.

5. If using NO-STING SKIN-PREP™ prior to application of the fixation strips (see Precautions), wipe the area surrounding the dressing and allow skin to dry.

6. Apply the fixation strips to each of the four sides of the dressing. 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 (1/2 in.).

   Do not apply fixation strips directly over white PICO pad. 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.

   PICO 7 does come with extra extension tubing if needed.
## Pump status and troubleshooting

PICO™ 7 has visual indicators to let the user know when there is an issue. PICO 7 does not contain audible 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.

<table>
<thead>
<tr>
<th>Display/indicator status</th>
<th>Possible cause</th>
<th>Comments/troubleshooting</th>
</tr>
</thead>
<tbody>
<tr>
<td>All indicators off</td>
<td>The pump is in standby.</td>
<td>NPWT is paused. Press the orange button to restart NPWT.</td>
</tr>
<tr>
<td></td>
<td>The pump has completed its course of NPWT.</td>
<td>Pressing the orange button will not restart NPWT. Healthcare professional to apply new pump and dressing if further NPWT is required.</td>
</tr>
<tr>
<td></td>
<td>The batteries have depleted.</td>
<td>If the pump has not yet completed its course of NPWT, replace the batteries.</td>
</tr>
<tr>
<td>Green “OK” and orange “leak” indicators flash</td>
<td>The pump is working to achieve NPWT but has not reached the intended pressure.</td>
<td>Wait up to 65 seconds. Assess whether NPWT has been established.</td>
</tr>
<tr>
<td>Green “OK” indicator flashes</td>
<td>System is functioning properly. No issues.</td>
<td>The pump may be heard running occasionally as it maintains the negative pressure. This is normal.</td>
</tr>
<tr>
<td>Green “OK” and orange “battery low” indicators flash</td>
<td>System is functioning properly but the batteries are low.</td>
<td>Replace the batteries and press the orange button to restart therapy.</td>
</tr>
<tr>
<td>Orange “leak” indicator flashes</td>
<td>A high air leak has been detected. NPWT is not being applied.</td>
<td>Smooth down the dressing and strips to remove any creases. Press the orange button to restart therapy. If the air leak remains, the orange “leak” indicator will flash again after approximately 60 seconds. Ensure that the tube connectors have been twisted together securely. Press the orange button to restart NPWT. The green OK indicator and orange air leak indicator will start to flash together (indicates pump working to re-establish NPWT). Depending on the size of the wound, the pump should take up to 65 seconds to re-establish NPWT. If the air leak remains, the orange “leak” indicator will flash again after approximately 65 seconds. If the air leak persists, contact healthcare professional.</td>
</tr>
<tr>
<td>Display/indicator status</td>
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<tr>
<td>----------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Orange “leak” and orange “battery low” indicators flash</td>
<td>A high air leak has been detected and the batteries are low. NPWT is not being applied.</td>
<td>Resolve the air leak according to instructions detailed in the brochure. Also replace the batteries and press the orange button to restart therapy.</td>
</tr>
<tr>
<td></td>
<td>Note: the pump will automatically try to restart NPWT after 1 hour.</td>
<td></td>
</tr>
<tr>
<td>Orange “dressing full” indicator flashes</td>
<td>Dressing is saturated or filter is blocked. NPWT is not being applied.</td>
<td>Healthcare professional to replace the dressing with a new one and press the orange button to restart NPWT.</td>
</tr>
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<td></td>
<td>Note: the pump will automatically try to restart NPWT after 1 hour.</td>
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<tr>
<td>Orange “dressing full” and orange “battery low” indicators</td>
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<td></td>
<td>Note: the pump will automatically try to restart NPWT after 1 hour.</td>
<td></td>
</tr>
<tr>
<td>All indicators solidly illuminated</td>
<td>A pump error has been detected. The pump can no longer apply NPWT.</td>
<td>Healthcare professional to apply a new pump and dressing.</td>
</tr>
</tbody>
</table>
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™ 7 dressing may be left in place for up to 7 days. The orange dressing full indicator on the pump will flash if it detects a full dressing or blocked filter. 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 PICO 7 is used on infected wounds. Additional dressings for PICO 7 are available for purchase separately.

2. Inspect the PICO dressing regularly. If the dressing appears ready for changing (see diagram above), 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, connect to the pump and press the orange button to reinitiate the therapy.

3. Based on dressing change frequency, further dressings may be required.

4. The PICO 7 dressing should be disposed of as clinical waste.

5. The pump life ends and it automatically stops functioning at 7 days (all the indicators will turn off at this point). The batteries should be removed from the pump; and both batteries and pump disposed of according to local regulations.

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

Ensuring a good seal – assessing for leaks

- After application, firmly run your fingers around the perimeter of the dressing pad and silicone border.
- Assess for wrinkling and smooth down wrinkles in the silicone border prior to the application adhesive anchoring strips.
- If placing PICO™ 7 in areas of complexity (i.e., skin folds, digits, contours), use of a gel strip or other wound care products may be used to create a tight seal. Adhesive strips may be needed to seal difficult areas.
- When placing PICO 7 in close proximity to drains, isolate the drains using gel strip or other wound care supplies.
- Ensure that the connector between the pump and dressing are securely and tightly attached.

Protecting intact skin and minimizing the risk of skin blistering

1. Position dressing tubing port above the wound towards patient’s head.
2. Position dressing over wound, incision, or graft placing pad area down first.
3. Starting at the middle gently smooth silicone border to periwound area and work towards ends. Avoid applying any tension to border during application. If concerned about applying tension, may lift up and reapply silicone border to release any possible tension.
4. Connect to PICO 7 pump and ensure air tight seal, may reposition to minimize creases and/or leaks.
5. Once seal is achieved, apply anchoring strips – avoid using any tension during application. To prevent blistering of skin, NO-STING SKIN PREP™ may be used under adhesive strips. Always allow NO-STING SKIN PREP to dry completely prior to dressing application.

Closed surgical incision management

- When applying over a curved area such as an elbow or knee, flex the joint 15-30 degrees to prevent tension on the skin and allow for range of motion.
- To aid in application, snip or cut the silicone boarder up to but not into the pad to allow for contouring of the dressing in difficult areas or when external hardware is present.
Use with fillers and wound contact layers

The PICO® 7 System is compatible with standard gauze and foam fillers used in traditional NPWT where this is clinically appropriate – for example on a defect wound. When a filler is used, the filler and the PICO 7 dressing should be changed 2 to 3 times a week, according to local clinical protocol and manufacturer’s instructions. Gauze should be moistened with saline or sterile water prior to application and loosely fill to the surface of the wound. Foam should be cut to fit within the margins of the wound bed. Avoid over packing of wound fillers.

PICO 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 Silver-Coated Antimicrobial Dressings may be used under PICO.

ACTICOAT Flex may be kept on for 3 days in combination with NPWT. The products featured herein have different indications and study populations. Smith & Nephew makes no representations or claims of any kind related to increased clinical efficacy in using the products in combination. When PICO is used on an infected wound more frequent dressing changes may be required. Regular monitoring of the wound should be maintained to check for signs of infection. ACTICOAT Flex 3 is not intended to provide sole treatment for infected wounds. ACTICOAT Flex 3 may be used on infected wounds which are being managed per local clinical protocol. For detailed product information, including indications for use, contraindications, effects, precautions and warnings, please consult the product’s Instructions for Use (IFU) prior to use.

Wound fillers

<table>
<thead>
<tr>
<th>Considerations</th>
<th>PICO</th>
<th>tNPWT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated wound drainage</td>
<td>Low – moderate &lt; 300cc</td>
<td>&gt; 300cc</td>
</tr>
<tr>
<td>Contour of wound bed</td>
<td>Minimal undermining or tunneling</td>
<td>Complex wound contour, significant undermining/tunneling</td>
</tr>
<tr>
<td>Wound filler</td>
<td>May be used with or without filler depending on surface area and contour</td>
<td>Requires wound filler</td>
</tr>
</tbody>
</table>

The use of negative pressure presents a risk of tissue ingrowth into foam when this is used as a wound filler. When using foam filler with PICO, tissue ingrowth may be reduced by using a wound contact layer or by increasing the frequency of dressing changes.
General use

Showering and bathing

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

Cleaning

Adherence to clinical directives concerning hygiene is of prime importance. The pump may be wiped clean with a damp cloth using soapy water or a weak disinfectant solution.
Is the wound PICO° appropriate?

Step 1 **Exudate levels**

Does the wound have low to moderate levels of exudate?

- **Low**
- **Moderate (<300ml)**
- **High (>300ml)**

- **Yes** Continue to Step 2
- **No** Not PICO appropriate

Step 2 **Wound size**

Does the wound fit under 1 of the 10 PICO Dressings?

- **Yes** Continue to Step 3
- **No** Not PICO appropriate

**Recommendation:** Choosing a dressing size that is slightly larger than the wound allows the benefits of negative pressure to extend to the periwound area.
Step 3 Wound depth

**Note:** NPWT requires direct contact with the wound bed. Prior to application, assess the wound to determine depth and if a filler would be required.

**Does the PICO° system conform to the wound bed?**

- **Yes** Begin application
- **No** Continue to Step 4, prior to application

**Wound depth <0.5 cm**

Wounds >0.5 cm in depth are likely to require a foam or gauze NPWT filler. Wounds >2 cm in depth should generally not be treated with PICO dressings.

---

Step 4 Fillers

- **Antimicrobial gauze** 15 cm x 17 cm

**Note:** Gauze should loosely fill to the surface of the wound. Avoid over packing

- **Foam wound dressing** 10 cm x 12.5 cm

**Note:** Please refer to the IFU for information regarding possible tissue ingrowth when using foam filler

**Wear instructions:**
- At the healthcare professional’s discretion, a PICO dressing may be left in place for up to 7 days, depending on level of exudate.
- When a filler is used, the filler and the PICO Dressing should be changed 2 to 3 times a week, according to the local clinical protocol and manufacturer’s instructions.
  - Foam should be changed at least 3 times per week and gauze at least 2 times per week.

---
Wound selection guidance: closed incisions

**Consideration 1: Is the patient high-risk for complications?**

Patient with closed surgical incision

**Major patient-related factors**
Does the patient have any of the following major patient-related factors for surgical site complications:
- BMI ≥ 40 kg/m² or < 18 kg/m²?
- Uncontrolled insulin-dependent diabetes mellitus?
- Renal dialysis?

YES

NO

**High incidence/high consequence procedure**
Has the patient undergone surgery that has a higher incidence and/or higher consequence of surgical site complications?

YES

NO

**Other risk factors**
Does the patient have 2 or more other patient-related or procedure-specific major or moderate risk factors for surgical site complications?

YES

NO

Standard post-operative dressing

Apply NPWT to the closed surgical incision under aseptic conditions and before the patient leaves the operating room

---

**Hernia**

1st application

Day 6

Individual Results May Vary
**Consideration 2: Which PICO® Dressing size best fits the incision?**

<table>
<thead>
<tr>
<th>Dressing</th>
<th>Dressing size</th>
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<tbody>
<tr>
<td>Multisite small</td>
<td>15cm x 20cm</td>
</tr>
<tr>
<td>Multisite large</td>
<td>20cm x 25cm</td>
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<tr>
<td>20cm x 20cm</td>
<td></td>
</tr>
<tr>
<td>25cm x 25cm</td>
<td></td>
</tr>
</tbody>
</table>

**Consumables**

- Foam dressing filler
- Gauze dressing filler
- ACTICOAT® Flex 7
Frequently asked questions and answers

What is the suction pressure of your machine or the range of pressure that the machine achieves?

PICO™ 7, operates at continuous negative pressure of -80mmHg.

Is the pressure pre-set?

The pressure is pre-set on the PICO 7 System and it operates at continuous negative pressure of -80mmHg.

Can it be changed?

The pressure cannot be changed on the PICO 7 System.

Is there an Intermittent feature and when should I use it?

The PICO 7 System does not have an Intermittent feature. If intermittent therapy is clinically necessary consider using tNPWT.

Should I change the canister only when the canister full alarm is initiated?

The PICO 7 System is canister-free. Traditional NPWT may be the best option to manage wound fluid that is expected to exceed greater than 300cc in a week.

Is there a one-way valve to prevent fluid from coming back through the tubing towards the patient?

The PICO 7 System has a filter that prevents fluid from coming back through the tubing toward the patient.

How long does the battery last?

The PICO 7 System runs on two AA batteries that can be changed out if required, but should not be necessary. It is indicated for use up to 7 days, at which time the system is disposable.

How much does the machine weigh? (How portable is it?)

PICO 7 is less than 4.2oz, and is small enough to easily fit in a pocket, like a smart phone.

What is the interface with the wound?

The PICO 7 System employs a proprietary dressing technology that manages exudate, through a process of absorption and evaporation, eliminating the need for canisters.

How often do you recommend changing the dressing?

The PICO 7 System may be left in place for up to 7 days, depending on level of exudate and clinical judgment. If a wound filler is used with PICO, refer to filler guidelines. ACTICOAT FLEX 3 and ACTICOAT FLEX 7 are only approved for use with NPWT for up to 3 days.
Can you “Y” wounds together and if so how many?
PICO® 7 dressings cannot currently be Y-connected.

How do you handle exposed tendon or bone?
Exposed tendons and bone should be covered with natural tissue or a non-adherent dressing layer prior to applying the NPWT dressing.

Do you have any special recommendations for high bioburden or infection?
If available, we recommend the use of Smith & Nephew ACTICOAT™ Flex as a wound contact layer for wounds with a high bioburden or infection. ACTICOAT Flex is compatible for use with gauze or foam NPWT interface materials. ACTICOAT Flex is also indicated for use with PICO 7. Wounds that are infected may require more frequent dressing changes. Wound bed preparation and debridement should be practiced prior to the application of NPWT. ACTICOAT FLEX 3 and ACTICOAT FLEX 7 are only approved for use with NPWT for up to 3 days.
### Dressing Information

<table>
<thead>
<tr>
<th>Dressing</th>
<th>Dressing size</th>
<th>2x dressing kit*</th>
<th>1x dressing kit**</th>
<th>Fluid Management Packs***</th>
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#### Consumables

| Foam dressing filler  | 10cm x 12.5cm | 66801692         |
| Gauze dressing filler | 15cm x 17cm   | 66801691         |
| ACTICOAT® Flex 7      | 1in x 24in    | 66800544         |

References:

9. Lumb H. Bacterial barrier testing (wet-wet) of PICO dressing with a 7 day test duration against S. marcescens.  
19. Supporting healthcare professionals for over 150 years

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