

 **smith&nephew**
PICO[◇]
Single Use
Negative Pressure
Wound Therapy System



PICO clinical guidelines

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PICO[◇] Single Use Negative Pressure Wound Therapy System



Description

The PICO® Single Use Negative Pressure Wound Therapy System consists of a sterile pump and two sterile dressing kits. The PICO pump maintains negative pressure wound therapy (NPWT) at 80mmHg (nominal) +/- 20mmHg to the wound surface. Exudate is managed by the dressing through a combination of absorption and evaporation of moisture through the outer film.

PICO is intended for use in wound sizes (surface area x depth) up to 400 cm³ which are considered to be low to moderately exuding.

The kit is intended to be used for a maximum of 7 days on low exuding wounds and 6 days on moderately exuding wounds. Therapy duration of the kit may be less than indicated if clinical practice or other factors such as wound type, wound size, rate or volume of exudate, orientation of the dressing or environmental conditions, result in more frequent dressing changes.

Indications for use

PICO 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 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.
- Nonenteric and unexplored fistulas.
- Necrotic tissue with eschar present.
- Exposed arteries, veins, nerves or organs.
- Anastomotic sites.
- Emergency airway aspiration.
- Pleural, mediastinal or chest tube drainage.
- Surgical suction.

Warnings

1. 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.

2. The use of anticoagulants does not deem a patient inappropriate for treatment with PICO® however hemostasis must be achieved before applying the dressing. 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 and considered throughout the therapy.
3. 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.
4. Sharp edges or bone fragments in a wound must be covered or removed prior to using PICO due to risk of puncturing organs or blood vessels while under negative pressure.
5. 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.
6. **MR Unsafe.** PICO is not MRI compatible. Do not take PICO into the MRI suite.
7. PICO has not been studied on pediatric patients. Patient size and weight should be considered when prescribing this therapy.
8. PICO is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).

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. PICO dressings should only be applied by a healthcare professional. Dressings are not to be removed or changed by the patient.
3. Where PICO is 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.
4. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing does not compromise circulation.
5. PICO 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.
6. Although PICO 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 device performance.
7. Where PICO is used on patients with fragile skin, a skin protectant such as 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.

8. If reddening or sensitization occurs discontinue use and contact the treating healthcare professional.
9. Do not use PICO® with oil-based products such as petrolatum as it may compromise establishing an effective seal.
10. 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.
11. PICO 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 Single Use Negative Pressure Wound Therapy System.
12. When showering the PICO pump should be disconnected from the dressing. Ensure the end of the tubing attached to the dressing is facing down so that water does not enter the top of the tube.
13. Do not take the pump apart.
14. The dressing should not be used with any other suction pump.
15. Do not alter or cut tubing configuration or pull on the tubing.
16. Do not cut the dressing as this may lead to loss of NPWT application.
17. Always ensure that the dressing is positioned centrally over the wound. The port should be positioned uppermost on intact skin and not extend over the wound so that the risk of fluid collecting around the port and potentially blocking the negative pressure is minimized.
18. CT scans and x-ray have the potential to interfere with some electronic medical devices. Where possible, move the device out of the x-ray or scanner range. If the device has been taken into the CT scan or x-ray range, check that it is functioning correctly following the procedure.
19. This device 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.
20. High temperatures and humidity may reduce wear times of dressings.
21. During transport, there is a potential for radio frequency interference that could affect PICO performance. If the device malfunctions, replace batteries. If not corrected, contact your caregiver to replace the device. PICO is not intended for use aboard aircraft, the batteries should be removed during air travel.
22. 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..

General guidance

The PICO System should be used on wounds which fit comfortably within the area of the pad, observing precautions on port positioning.

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.

- Dressing capacity and wear time are dependent on a number of factors including; wound type, wound size, rate/volume of exudate, orientation of the dressing, environmental conditions.
- When utilizing the larger dressings wounds should generally be no larger than 2cm (4/5in.).
- Wounds greater than 0.5-2.0cm (1/4-4/5in.) in depth are likely to require a foam or gauze NPWT filler to ensure adequate treatment of all the wound surfaces. (see use with fillers section (p. 14) for more information). As with all NPWT devices it is important that there is intimate contact with all areas of the wound bed to ensure that NPWT will be delivered; therefore wound fillers may be necessary.
- Lower extremity wounds are sometimes accompanied by edema. PICO[®] may be used in conjunction with compression.

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.

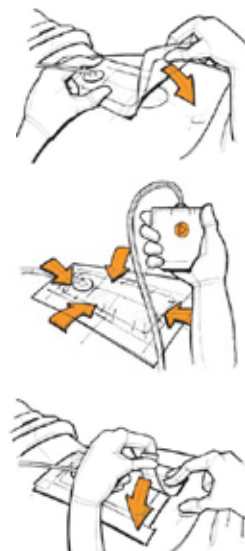
- Choose dressing size slightly larger than incision or wound length to allow the port to be positioned above incision to minimize exposure of port to wound drainage.
- If excessive exudate is present and/or large volume incisional drainage is anticipated, consider the use of traditional NPWT until fluid noted is low to moderate and then transition the patient to PICO.
- May use SKIN-PREP[®] on intact skin surrounding the incision. It is important to allow the SKIN-PREP to dry completely before dressing application.

Split thickness skin graft (STSG)/Skin substitutes

- Generally a non-adherent layer is applied over the graft prior to PICO.
- Depending on the contour of the graft site additional filler may be utilized to stabilize the graft.
- PICO has a set pressure of -80mmHg.
- Monitor dressing and pump functionality frequently.

Product application

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 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 two handles 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 three lights should flash once. (Refer to Table 1.)
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 (indicates system working OK, see Table 1).



Depending on the size of the wound, the pump should take up to 30 seconds to establish negative pressure wound therapy.

If after 30 seconds the system has not established negative pressure wound therapy, the amber air leak light will illuminate. To troubleshoot refer to section (ii) of Table 1.

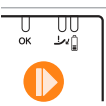
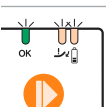
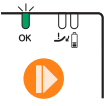
5. If using SKIN-PREP[®] prior to application of the fixation strips (see Precautions), wipe the area surrounding the dressing and allow skin to dry.
6. Apply the fixation strips to each of the four sides of the dressing. Remove top carrier on the strip after each one has been applied. These strips maintain 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 (2/5in.). 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


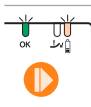
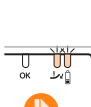
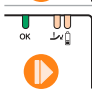

Table 1: Pump status indication, alarms and faults

PICO[®] has visual alarms to let the user know when there is an issue. PICO 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.

Section (i) – Normal function

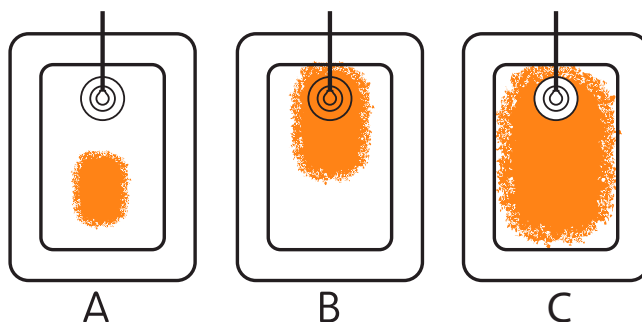
Display status	Indicator status	Possible cause	Comments/trouble shooting
	All lights off.	The pump is OFF. The pump has reached the end of its life. The batteries are no longer functional.	The therapy has been paused. Pressing the orange button will restart the therapy and the green light will flash. After 7 days of therapy the pump will automatically cease functioning, in this case all the lights will turn off. Pressing the orange button will not provide a green flashing light. If the pump has had less than 7 days usage, the batteries may not be functional and should be replaced as below.
	All lights flash once.	This reflects the pump self test once batteries have been inserted and the cover has been replaced.	This is expected.
	Green 'OK' light flashes.	Dressing applied, and full system is functioning properly. No issues.	The pump may be heard running occasionally as it maintains the negative pressure. This is normal. If this occurs frequently (several times an hour) smooth down the dressing to remove any creases that may be allowing air into the system. NPWT is still being applied in this situation.

Section (ii) – Alarms and faults

Display status	Indicator status	Possible cause	Comments/trouble shooting
	Amber 'leak' light flashes.	Air leak detected possibly due to a creased dressing/ border/strip. Pump is in auto pause. NPWT is not being applied to the wound. The pump will auto pause for 1 hour and then will automatically try to re-establish therapy if no remedial action is taken.	Smooth down the dressing and the strips to remove any creases that are allowing air into the system. Press the orange button to restart the therapy. The green "OK" light will flash as the pump tries to establish therapy. If the air leak remains, the amber leak light will start to flash after approximately 30 seconds. If this happens, repeat smoothing actions and press the orange button. If the leak is resolved the green light will continue to flash.
	Green 'OK' light flashes.	System on and functioning properly.	Change of batteries required in <24 hours. Pause the therapy by pressing the orange button.
	Amber 'battery low' light flashes.	Battery power low.	Push open the battery cover at the top of the pump and remove the old batteries. Insert 2 new lithium (LR9) batteries. Replace the cover. Press the orange button, the therapy will re-start and the green light will flash.
	Amber 'leak' light flashes. Amber 'battery low' light flashes.	Creased dressing/ border/strip. Battery power low.	Address air leak as above. Change of batteries or device required in <24 hours as above.
	All lights solidly illuminated.	Pump failed. System is not usable.	Contact S&N representative. Apply new pump and dressing.

Dressing change

1. Dressings should be changed in line with standard wound management guidelines, typically every 3–4 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 PICO[®] is used on infected wounds. At the healthcare professional's discretion a PICO dressing may be left in place for up to 7 days.



- A) Dressing properly positioned and is acceptable to be left in place
B) Dressing requires change
C) Dressing requires change

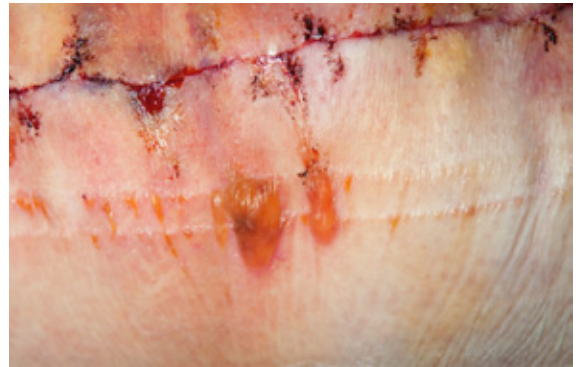
2. Inspect the dressing regularly. If the dressing appears ready for changing (see diagrams AC), press the orange button and disconnect the dressing from the pump. The fixation strips should be stretched away from the skin and the dressing lifted at one corner and peeled back until it has been fully removed. Apply another dressing as per section 7.2, connect to the pump and press the orange button to reinitiate the therapy.
3. Based on dressing change frequency, a new PICO Single Use Negative Pressure Wound Therapy System kit will be required dependent on whichever of the following occurs first either when both dressings have been used, or after 7 days when the pump automatically stops functioning (all the lights will turn off at this point).
4. The dressing should be disposed of as clinical waste. The batteries should be removed from the pump, and both batteries and pump disposed of according to local regulations.
5. For additional information on disposal requirements see: www.possiblewithpico.com.

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.
- After application, assess for wrinkling and smooth down wrinkles in the silicone border prior to the application adhesive anchoring strips.
- If placing PICO® 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 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 incision 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 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, SKIN-PREP® may be used under adhesive strips. Always allow SKIN-PREP to dry completely prior to dressing application.

Closed surgical incision management

- When applying over a cured 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 border 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® 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 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 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.



Gauze filler



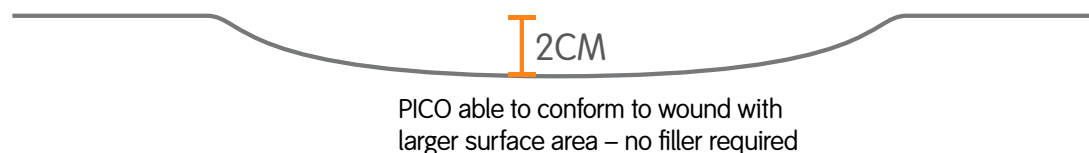
Foam filler



ACTICOAT Flex Silver-Coated Antimicrobial Dressing

Wound fillers

Considerations	PICO	tNPWT
Anticipated wound drainage	Low – moderate < 300cc	> 300cc
Contour of wound bed	Minimal undermining or tunneling	Complex wound contour, significant undermining/ tunneling
Wound filler	May be used with or without filler depending on surface area and contour	Requires wound filler



PICO not able to conform to wound with small surface area – filler required

General use

Showering and bathing

The PICO^o Dressing is water resistant. 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.

Hyperbaric oxygen treatments

The National Fire Protection Agency (NFPA) Code 99, chapter 20 addresses HBO compatibility and materials considered to be potentially hazardous. Materials/compounds such as petrolatum, mineral oil, silk, wool, some synthetic materials, titanium and magnesium are felt to undergo rapid oxidation and therefore are potential risks in an HBO environment. Materials/compounds such as cotton and polyester are not felt to undergo rapid oxidation and therefore are not potential risks in an HBO environment.

Per the Undersea and Hyperbaric Medicine Society the discretion for use of products in the HBO environment is under the oversight of the program Medical Director.

Additional recommendations:

There are two potential options to consider when patients treated with NPWT, including traditional NPWT therapy and the use of PICO, undergo hyperbaric oxygen therapy treatments (dives).

Option one:

Remove the dressing before the dive and cover the wound with moist (saline) gauze or other dressing described in the facility's hyperbaric protocol. After dive is completed, clean surface of wound and surrounding tissue. Replace PICO dressing and initiate NPWT.

Option two:

Since hyperbaric treatments are usually daily, Monday–Friday, and some are twice a day, the removal of the dressing prior to each dive may become too irritating to the surrounding tissue or uncomfortable for the patient and cause added cost. In these cases, the Medical Director of the hyperbaric chamber can authorize the following procedure: Prior to entering the chamber, disconnect the PICO pump from the PICO dressings by disconnecting the Quick Click Connector. The PICO unit does not enter the chamber. Leave the end caps open during the dive to allow pressure changes in the PICO tube and dressing.

For patients being treated with PICO, disconnect the pump unit from the dressing tubing and do not allow the pump to enter the HBO chamber. Once the patient is in the chamber, the end of the connector should be covered by a 4in. x 4in. gauze dressing. After the dive, reconnect the PICO unit to the dressing and turn the therapy ON. Check the dressing for air leaks and seal, if necessary.

Appendix

Algorithm: when to use NPWT*

Patient with wound eligible for NPWT?



Consider if patient requires less disruptive NPWT to mitigate issues with

Is wound small, moderate exudating?
80mmHg suitable pressure for wound?
Wound smaller than 100cm squared?



Traditional NPWT

Yes



Yes



Acute/dehisced wound

Less than 2cm deep with no undermining



Assess for signs of infection – apply ACTICOAT® Flex if



More than 300cc per week

No



Continue with PICO



More than 2cm deep with/without undermining or tunnels



Use filler to fill dead space with silver/and gauze/foam



Yes



Consider changing to traditional NPWT



High risk closed surgical wound/skin graft

Place PICO® over closed incision line or skin graft and leave in place for 3-7 days or until dressing is full with fluid



Is system (both dressings) filled with fluid prior to 3 days?

Yes



No



Continue with PICO



Assess for healing every 2 weeks to ensure goals of therapy are met

Yes

Chronic wounds

Pressure ulcers, DFU



Use filler to fill dead space with silver/and gauze/foam



Difficult to attain seal



Consider ostomy paste/putty to fill cleft (use for all difficult to seal wounds)[†]



Venous leg ulcers



Documented ABI prior to compression



Assess for compression. PICO may be worn under compression. ACTICOAT Flex may be used under the PICO Dressing if signs of infection are present.

* Used by permission from: Hurd T, Trueman P, Rossington A. Clinical performance of PICO Single-Use, Disposable Negative Pressure Wound Therapy in wounds of mixed aetiology: A case series. Wounds UK, Harrogate. 2012.

[†]PICO to be placed over wound with port placed uppermost at opposite end of wound

Wound selection guidance: open wounds

Is PICO[®] Single Use Negative Pressure Wound Therapy (NPWT) the appropriate option?

Consideration 1: Exudate level

Is the wound producing **LESS than 300mL of fluid per week?**



YES



No



Due to the high amount of exudate PICO is not currently suitable for this wound. Traditional NPWT may be a more appropriate NPWT option.

Consideration 2: Wound area

Will the area of the wound fit under one of the 8 PICO dressing options?



YES











No



PICO is not currently suitable for this wound. Traditional NPWT may be a more appropriate NPWT option.

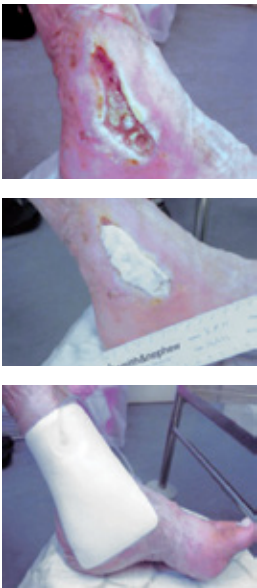
PICO NPWT is appropriate for this wound

PICO pad sizes

	2" x 6" (5 x 15cm) Product code: 66800951		2" x 14" (5 x 35cm) Product code: 66800953
	2" x 10" (5 x 25cm) Product code: 66800952		4" x 4" (10 x 10cm) Product code: 66800954
	4" x 6" (10 x 15cm) Product code: 66800955		6" x 6" (15 x 15cm) Product code: 66800957
	4" x 10" (10 x 25cm) Product code: 66800956		8" x 8" (20 x 20cm) Product code: 66800958

Consideration 3: Is a wound filler required?

Is the depth of the wound greater than 2cm?



YES



WOUND must be filled with a filler before the PICO® Dressing is applied.

No



Is the wound bed uneven?
Is there any undermining?
Is the wound a sinus?

No



A wound filler is not required and the PICO Dressing can be applied directly to the wound bed

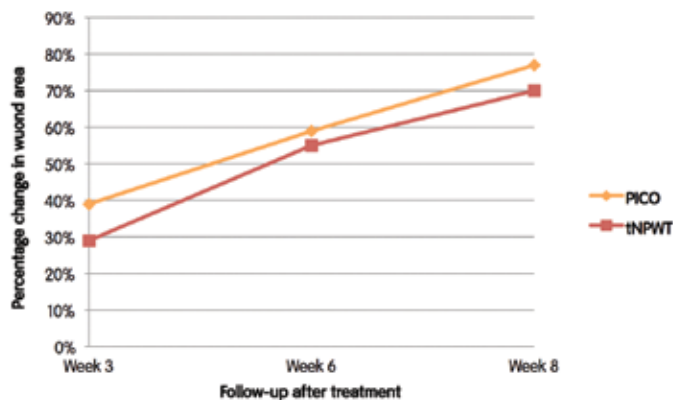
Yes



Consider the use of a filler to ensure that negative pressure therapy reaches all surfaces of the wound cavity

The PICO System's proven effectiveness

The PICO Single Use NPWT System offers all the effectiveness of traditional NPWT for wounds with low to moderate exudate.¹



Comparisons between PICO and tNPWT¹

PICO offers the same medical outcome in a more portable and simple system to traditional NPWT.¹ Clinical tests have shown that PICO operates with the same scientific mechanism as traditional full sized NPWT pumps. The evaluation of a total of 368 patients across a range of wound types in 3 separate studies demonstrates that PICO performs as expected of traditional full-sized NPWT pumps.¹⁻³

The PICO System is contraindicated for:

- Patients with malignancy in the wound bed or margins of the wound (except for palliative care to enhance quality of life)
- Previously confirmed or untreated osteomyelitis
- Non-enteric and unexplored fistula
- Use on necrotic tissue with eschar present
- Use over exposed blood vessels, nerves or organs
- Exposed anastomotic sites

References

1. OC DOF/012 A prospective, open, non-comparative, multi-centre study to evaluate the functionality and dressing performance of a new negative pressure enhanced dressing in acute wounds.
2. Ahmad Z, Davis M, Das-Gupta R. PICO: a revelation in topical negative pressure therapy? *The international journal of lower extremity wounds*. 2013 Mar 26;12(1):16-7.
3. Dowsett C, Grothier L, Henderson V, Leak K, Davis L, Bielby A, et al. Venous leg ulcer management : single use negative pressure wound therapy. *British Journal of Community Nursing*. 2013;(March).

Incision management: closed incision risk assessment

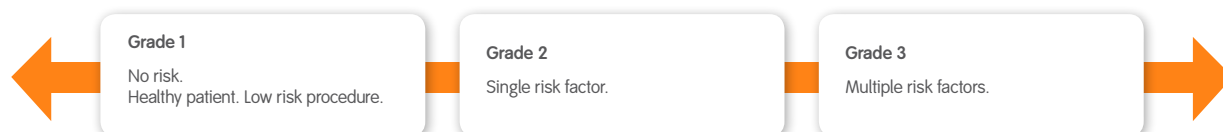


Incision management: risk assessment

Step 1: Risk factor identifier

	No evidence of increased risk of post-operative wound healing complications	Significantly increases the risk of post-operative wound healing complications
Procedural risk		
1. Is the procedure...?	<input type="checkbox"/> Elective	<input type="checkbox"/> Emergency ^{1,2}
2. Is the procedure...?	<input type="checkbox"/> Clean	<input type="checkbox"/> Clean contaminated ² <input type="checkbox"/> Contaminated ^{2,3} <input type="checkbox"/> Dirty ^{2,3}
Patient related risk		
1. Patient aged 70 or older?	<input type="checkbox"/> No	<input type="checkbox"/> Yes ^{2,4,5,6}
2. Underlying medical condition?	<input type="checkbox"/> No	<input type="checkbox"/> COPD ^{1,4,5} <input type="checkbox"/> Jaundice ⁵ <input type="checkbox"/> Anaemia ^{1,4,5} <input type="checkbox"/> Cancer ⁴ <input type="checkbox"/> Hyperglycemia ⁴ <input type="checkbox"/> Alcoholism ² <input type="checkbox"/> Diabetes ^{2,4,6} <input type="checkbox"/> Low serum albumen ^{1,7}
3. Sepsis?	<input type="checkbox"/> No	<input type="checkbox"/> Yes ^{4,5}
4. Smoking?	<input type="checkbox"/> No	<input type="checkbox"/> Yes ^{2,4,8}
5. Malnutrition?	<input type="checkbox"/> No	<input type="checkbox"/> Yes ^{1,4}
6. Adjunctive therapies?	<input type="checkbox"/> No	<input type="checkbox"/> Previous chemotherapy ¹ <input type="checkbox"/> Corticosteroids ^{2,4,6} <input type="checkbox"/> Previous radiotherapy ^{2,4}
7. Obesity?	<input type="checkbox"/> BMI <35	<input type="checkbox"/> BMI >35 ^{4,6}
Surgical considerations		
1. Procedure involves prosthesis?	<input type="checkbox"/> No	<input type="checkbox"/> Yes ⁶
2. Procedure involves limb amputation?	<input type="checkbox"/> No	<input type="checkbox"/> Yes ¹⁰
3. Prophylactic antibiotics?	<input type="checkbox"/> Yes	<input type="checkbox"/> No ^{9,10}
4. Location/type of the surgery	<input type="checkbox"/> Other	<input type="checkbox"/> Bile duct ¹¹ <input type="checkbox"/> Gastric ^{2,11} <input type="checkbox"/> Liver ¹¹ <input type="checkbox"/> Vascular ¹¹ <input type="checkbox"/> Pancreas ¹¹ <input type="checkbox"/> Bowel ¹¹
Peri-operative risk		
1. Hypothermia?	<input type="checkbox"/> No	<input type="checkbox"/> Yes ²
2. Hypoxia?	<input type="checkbox"/> No	<input type="checkbox"/> Yes ⁴

Step 2: Risk grading scheme¹³ – Based on the number of risk factors identified allocate a risk status to the patient



Step 3: Incision management guide

Estimate the patient's risk level for post-operative wound healing complications on the basis of patient risk status, then decide upon an incision management approach:

Grade 1 – Conventional dressing regimen

Grade 2/Grade 3 – Consider PICO® pathway

Conventional dressing regimen

Apply appropriate dressing (OPSITE® Post-Op, OPSITE Post-Op Visible) in line with local incision management protocol/guidelines

Initial review – 48 hours

Wound closed/progressing to closure?



Continue to manage in line with local protocol



Consider use of PICO
If infection is suspected, consult local protocol for guidance, and consider use of ACTICOAT® Flex 3 in conjunction with PICO

PICO pathway

Check the following to ensure PICO is suitable prior to initiating therapy:

- PICO contraindications (A)
- PICO considerations for use (B)

Is PICO suitable?

No

Yes

Initiate PICO

Initial review – 72 hours

Examine dressing for exudate strike-through to determine whether dressing change is required:

1. Dressing can be left in situ if appropriate
2. Blocking port = change
3. Dressing needs to be changed

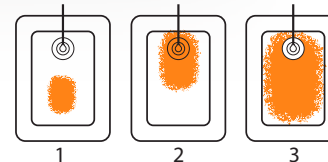
Assess wound progress

- Ensure PICO continues to be suitable for the patient
- Ensure PICO continues to be appropriate for the achievement of wound closure

If infection is suspected...

- Consult local protocol for guidance
- Consider use of ACTICOAT Flex 3 in conjunction with PICO

If depth >2cm, consider use of a filler



Discontinue PICO if

- Wound closure is achieved
- There is excessive bleeding from the wound
- PICO has proven to be unsuitable
- Patient has had an adverse reaction
- Any of the contraindications for PICO are now applicable

Review – 7 days

Assess wound's progression towards closure:

Closure not achieved

- Re-assess wound
- Re-assess patient
- Consult local protocol for guidance

Wound closure achieved

- Exudate levels are minimal
- Wound edges are apposed
- Discontinue PICO

A. PICO contraindications

Do not use PICO if any of the contraindications for PICO use are applicable. PICO is contraindicated for:

- Patients with malignancy in the wound bed or margins of the wound (except for palliative care to enhance quality of life)
- Previously confirmed or untreated osteomyelitis
- Non-enteric and unexplored fistulae
- Use on necrotic tissue with eschar
- Use over exposed blood vessels, nerves or organs
- Exposed anastomotic sites
- The patient has a known sensitivity to adhesive dressings

B. Considerations for PICO use

Patient suitability

Is PICO a suitable treatment for the patient being considered?

- Will the patient be concordant with the therapy?
- Will the patient remove and/or interfere with the dressing and/or device?
- Will PICO be acceptable to the patient?

Wound site

Is the wound location suitable for treatment with PICO?

- Avoid sites with pins and/or external fixation.
- Will it be possible to achieve and maintain a seal?
- Can the port be located in an area which will minimize the risk of pressure damage?
- Consider routing of tubing to avoid risks of pressure damage and entanglement
- Consider proximity of stoma sites
- Consider application technique over joints

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Wound selection guidance: closed incisions

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

Does patient have BMI 35 or over?

Yes

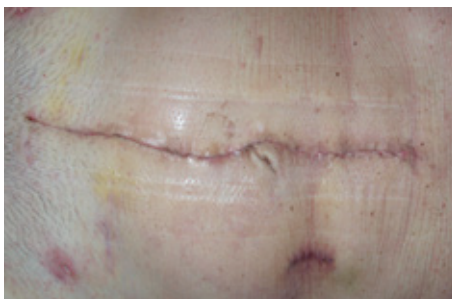


The PICO® System

Hernia



1st application



Day 6

No



Does patient have two or more high-risk factors?

- High BMI
- Hypertension
- Diabetes
- Blood or hematological disorder
- Autoimmune disease
- Multiple Caesarean births
- Pre-existing skin problems that will impact healing
- History of wound or healing problems
- Emergent/urgent Caesarean births

No





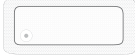





Standard dressing

Yes



The PICO System

Consideration 2: Which PICO^o Dressing size best fits the incision?

PICO pad sizes	
 2" x 6" (5 x 15cm) Product code: 66800951	 2" x 14" (5 x 35cm) Product code: 66800953
 2" x 10" (5 x 25cm) Product code: 66800952	 4" x 4" (10 x 10cm) Product code: 66800954
 4" x 6" (10 x 15cm) Product code: 66800955	 6" x 6" (15 x 15cm) Product code: 66800957
 4" x 10" (10 x 25cm) Product code: 66800956	 8" x 8" (20 x 20cm) Product code: 66800958

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Troubleshooting

How do I know if the PICO® System is working?

While the PICO pump is working correctly a green light located at the top of the device will flash continuously.

The dressing should have a slightly wrinkled appearance and feel firm to the touch.



What happens if the PICO visual alarm display starts flashing?

The PICO pump has a visual alarm for “Low Battery” and “Leak Alarm”. These issues are easily solved, for example:

“Low Battery” – The pump will begin to alert you with a flashing orange light (above the battery symbol) when there are 24 hours and less of battery life. The batteries should be changed at this point. Press the orange button to pause the therapy. Replace batteries, put the cover back on and press the orange button again to restart your therapy.

The green light and the orange light above the battery will flash together when the batteries need changing.



“Leak Alarm” – Air leak detected possibly due to a creased dressing/border/strip.

Pump has gone into Auto Pause. NPWT is not being applied to the wound.

The pump will Auto Pause for one hour and then will automatically try to re-establish therapy if no remedial action is taken.

Smooth down the dressing and the strips to remove any creases that are allowing air into the system. Press the orange button to restart the therapy. The green “OK” light will flash as the pump tries to establish therapy. If the air leak remains, the amber leak light will start to flash after approximately 30 seconds. If this happens, repeat smoothing actions and press the orange button. If the leak is resolved the green light will continue to flash.



Contact your nurse or doctor if you have continuous issues with the flashing low vacuum light.

When will I need a new pump?

The pump is designed to stop working after seven days after initially started. After this time, it will stop and will not restart even with new batteries. Negative pressure therapy is not being applied at this point so your nurse or doctor will need to apply a new PICO therapy system if needed.

The pump will look like this when it has come to the end of its life.



Frequently asked questions and answers

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

PICO^o, operates at continuous negative pressure of nominally 80mmHg.

Is the pressure pre-set?

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

Can it be changed?

The pressure cannot be changed on the PICO System.

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

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

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

The PICO System is canister-free. The larger the PICO dressing, the more fluid can be managed. Traditional NPWT may be the best option to manage wound fluid that is expected to exceed greater than 300cc in 24 hours.

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

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

How long does the battery last?

The PICO 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 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 System employs a proprietary dressing technology that manages exudate, eliminating the need for canisters.

How often do you recommend changing the dressing?

The PICO 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.

Can you “Y” wounds together and if so how many?

PICO® dressing cannot 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. Wounds that are infected may require more frequent dressing changes. Wound bed preparation and debridement should be practiced prior to the application of NPWT.

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Ordering information

To order the PICO[◇] System, call your Smith & Nephew sales representative.

Product code	Product description	Units per kit/case	Order unit
66800951	4" x 8" (10 x 20cm)	3	Case
66800952	4" x 12" (10 x 30cm)	3	Case
66800953	4" x 16" (10 x 40cm)	3	Case
66800954	6" x 6" (15 x 15cm)	3	Case
66800955	6" x 8" (15 x 20cm)	3	Case
66800956	6" x 12" (15 x 30cm)	3	Case
66800957	8" x 8" (20 x 20cm)	3	Case
66800958	10" x 10" (25 x 25cm)	3	Case
66800918	Carrying case	1	Each
66801691	PHMB gauze filler, 6" x 6.75" (15 x 17cm)	50	Case
66801692	Foam filler, 4" x 5" x 0.5" (10 x 12.5 x 1.5cm)	5	Case

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