

PICO[◇] Single Use NPWT System

clinical competency for long-term care providers

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PDQWC mission

PDQWC elevates the importance of critical thinking and educates to improve the practice of skin and wound care.

The PICO Single Use NPWT System clinical competency for long-term care providers was developed with input from the Professionals Dedicated to Quality Wound Care.

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Introduction

This clinical competency booklet has been developed for long-term care providers who use or order PICO®. The target audience for this PICO competency includes:

- Licensed Nurses (RNs, LPNs)
- Physical Therapists
- Physician Assistants
- Nurse Practitioners
- Physicians

Objectives

- Discuss the role of negative pressure wound therapy in the long term care environment
- Distinguish when to use PICO vs. traditional NPWT systems
- Understand the importance of correct patient and wound selection
- Demonstrate proper application techniques
- Demonstrate proper clinical practice when applying PICO

Notes to trainer

- This booklet contains master versions of the following training tools:
 - Skills checklist 1 (PICO standard practice application)
 - Skills checklist 2: (PICO Dressing application/change)
 - Knowledge assessment
 - Certificate of completion
- Please feel free to make copies for trainees as required.
- Please note that there are two versions of the skills checklist. One is designed to observe just the PICO Dressing application/change. The other is designed to observe all steps in the standard practice application. Please choose the checklist that best reflects your institutional protocols, or create your own skills checklist to support your facility's institutional protocols.
- Guidelines and checklists provided in this clinical competency are not intended to supersede independent clinical judgment or institutional protocols.
- Additional Information available at www.possiblewithpico.com.

24/7 PICO Clinical Hotline: 1-800-876-1261



Not intended to supersede independent clinical judgment or institutional protocols.

Negative pressure wound therapy (NPWT)

Negative pressure wound therapy (NPWT) is a topical therapy that provides controlled sub-atmospheric pressure in a sealed system on the surface of a wound. The use of negative pressure began centuries ago in Chinese and Egyptian medicine. From these ancient roots, modern negative pressure wound therapies began to be explored in the mid-twentieth century with the first forms available commercially by the late 1990s.

Over the past decade there has been a significant increase in the use of this therapy and today NPWT provides clinicians with an important option for the advanced management of a variety of chronic and acute wounds. A traditional NPWT system consists of a vacuum pump, drainage tubing and canister, a foam or gauze wound filler, and an adhesive film dressing that covers and seals the site of the wound. During traditional therapy, the vacuum pump creates a continuous or intermittent negative pressure inside the wound to remove fluid, exudate, and potentially infectious materials to prepare the wound for healing.

One of the challenges with traditional NPWT is that mobility may be limited due to bulky equipment. PICO[®] is different. PICO is a disposable NPWT System that offers all the effectiveness of traditional NPWT for wounds with low to moderate exudate. PICO offers the same clinical outcomes with the convenience of a more portable and simple system.¹ Exudate is managed by the dressing, so there is no requirement for bulky canisters, offering the patient more freedom to move around.



PICO Single Use NPWT 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 entire surface of the dressing. 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 may be used for a maximum of 7 days on low exuding wounds and 6 days on moderately exuding wounds.

Patient & Wound Selection

How do you determine when to use PICO vs. traditional NPWT? The two key considerations are exudate level and wound area. If the exudate level is low to moderate (less than 300ml per week), and the area of the wound fits under one of the PICO Dressing options, then PICO may be an appropriate option. If the wound has a high level of exudate (more than 300ml per week), or if the wound area is larger than the available dressing options, then traditional NPWT may be more appropriate. Please refer to the Algorithm in Appendix I for suggestions on when to use PICO vs. traditional NPWT, the flowcharts in Appendix II for open wounds and Appendix III for closed incisions.



Engaging the patient's caregivers

Everyone benefits when the patient's caregivers are involved in the care and monitoring of the patient. When caregivers and loved ones understand the physician's orders, they are more likely to assist the patient in complying with requirements. They are also in a better position to alert the clinical staff if they notice anything out of the ordinary, or to ask questions if they have any concerns about the therapy. In the event of a complication, early intervention is always preferable and helps to ensure positive clinical outcomes. Appendix IV contains information that you can provide to the patient's loved ones to help address their questions or concerns about the PICO® Single Use Negative Pressure Wound Therapy System.

General use & guidance

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, diabetic or pressure ulcers, flaps and grafts and closed surgical incisions

PICO is **contraindicated** in the presence of 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 and surgical suction.



- The PICO System should be used on wounds which fit comfortably within the area of the pad.
- PICO is intended for use on wounds with low to moderate levels of exudate. If excessive drainage is present or anticipated, consider the use of traditional NPWT.
- PICO is not intended for use on wounds with extensive undermining or tunneling.
- 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 and environmental conditions.
- The wound should be monitored regularly to check for signs of infection.
- Patients with a high risk of bleeding should be monitored closely.
- PICO may be used in conjunction with compression therapy in lower extremity wounds with edema.
- 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.
- At all times care should be taken to ensure that the pump and tubing does not:
 - Lie in a position where it could cause damage from pressure to the skin or tissue of 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.
- The PICO System is compatible with gauze and foam fillers where clinically appropriate. When a filler is used, the filler and the PICO Dressing should be changed 2 to 3 times a week, according to your clinical protocol or provider's order. 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.
- When using foam filler with PICO, the risk of tissue ingrowth may be reduced by using a wound contact layer or by increasing the frequency of dressing changes.
- For detailed information related to PICO and the use of defibrillators, CT scans, X-ray, MRI or Hyperbaric Chambers, please refer to the "PICO clinical guidelines" at www.possiblewithpico.com

PICO[◇] Dressing application and change technique

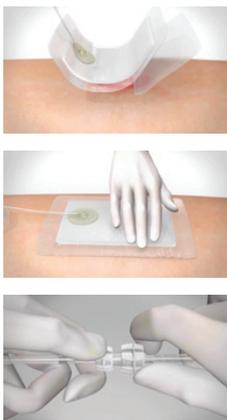
PICO Dressing application

1. Remove any excess hair to ensure that dressing will adhere to periwound skin.
2. Irrigate the wound with sterile saline and pat the wound dry.
3. Using a clean technique, remove central backing from the dressing and position the dressing centrally over the wound or incision. The dressing tubing port should be above the wound towards patient's head.
4. Remove the remaining backing and smooth the rest of the dressing around the wound. Avoid applying any tension to the border during application.
5. Assess the silicone border for wrinkling or creasing, smooth or reposition the dressing if required.
6. Firmly run your fingers around the perimeter of the dressing pad and silicone border.
7. Once the dressing is in place, remove the pump and the batteries from the tray. Open the battery cover, insert the batteries and replace the cover. All three lights should flash once.
8. Join the pump to the dressing by twisting together the tubing connectors. Ensure that the connector between the pump and dressing tubing are securely and tightly attached.
9. Press the orange button to start the application of negative pressure. The green light will start to flash, which indicates that the system is working correctly.
10. 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.
11. Locate and correct the source of the air leak by repeating steps 5, 6 and 8 and re-activate the pump.
12. Apply the fixation strips to each of the four sides of the dressing, so that each strip overlaps the dressing border by approximately 2/5" or 1cm. Remove the top carrier on the strip after each one has been applied. These strips maintain the seal over the wear time of the dressing.
13. Ensure tubing is not twisted or trapped between clothing.

PICO Dressing change

1. Inspect the dressing regularly to determine if a dressing change is required. (See the diagrams to the right)
2. Press the orange button to stop the pump.
3. Disconnect the dressing from the pump.
4. Remove the dressing by stretching the adhesive fixation strips away from the skin, lifting the dressing at one corner and peeling it back until it has been fully removed.
5. Follow your facility protocol for wound cleansing.
6. Apply another dressing and connect to the pump following steps 1-13 in the previous section.
7. Press the orange button to reinitiate the therapy.
8. The dressing should be disposed of as clinical waste.
9. At completion of the therapy the batteries should be removed from the pump, and both batteries and pump disposed of according to local regulations.

Dress

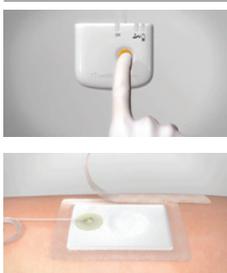


Partially remove backing from dressing and position dressing over wound bed. The port should be uppermost from the wound (if possible) and not over the incision or wound.

Remove remaining backing and smooth dressing edges to secure to periwound skin.

Connect dressing port tubing to pump tubing and twist to secure the connection.

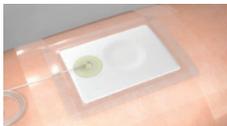
Press



Push the orange button to start delivery of NPWT.

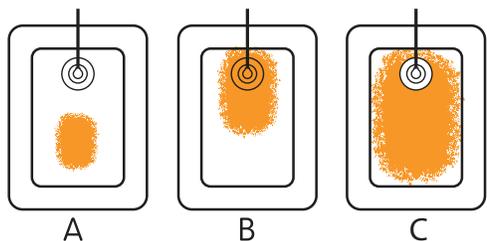
Seal dressing with the supplied adhesive retention strips around all edges.

Go



Change dressing as needed within the 7-day period (pump life) using the additional dressing provided.

Clean and prepare the wound for dressing application according to your facility's guidelines.



A) Dressing properly positioned and is acceptable to be left in place

B) Dressing requires change

C) Dressing requires change

Frequently asked questions

Q. What is the suction pressure, or range of pressure that the machine achieves?

A. PICO° operates at a pre-set, continuous negative pressure of nominal 80mmHg.

Q. Can the pressure be changed?

A. No, the pressure cannot be changed on the PICO System.

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

A. The PICO System does not have an intermittent feature.

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

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

Q. How long does the pump last?

A. The PICO System runs on two AA batteries that can be changed out if required, but this should not be necessary. The pump is indicated for use for up to 7 days, at which time the system is disposable. The pump is designed to stop working, even with new batteries, seven days after activation.

Q. How do I know if the PICO System is working?

A. When 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.

Q. What happens if the PICO visual alarm display starts flashing?

A. The PICO pump has visual alarms for “Low Battery” and “Leak Alarm”.

“Low Battery” – The pump will alert you with a flashing orange light (above the battery symbol) when there are 24 hours or less of battery life. To change the batteries, press the orange button to pause the therapy, open the cover, replace the batteries, put the cover back on and press the orange button again to restart your therapy.

“Leak Alarm” – Air leak detected possibly due to a creased dressing, border or strip. Pump has gone into Auto Pause and NPWT is not being delivered 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. Refer to the Package Insert for further information.

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

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

Q. Can my patient shower or bathe with the PICO system in place?

A. The dressing is water resistant, so light showering is permissible; however, the pump should be disconnected 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 tube.

Q. Can I clean the pump?

A. The pump may be wiped clean with a damp cloth using soapy water or a weak disinfectant solution.

Q. What is the interface with the wound?

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

Frequently asked questions (continued)

Q. How often do you recommend changing the dressing?

A. 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.

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

A. PICO Dressing cannot be Y-connected.

Q. I’m applying PICO over a skin fold and I’m finding it difficult to maintain the seal.

A. If placing PICO in areas of complexity (i.e., skin folds, digits, contours), other wound care product may be used to create a tight seal. Examples include the use of a gel strip or ostomy paste.

Q. How do you handle exposed tendon or bone

A. Exposed tendons and bone should be covered with natural tissue or a non-adherent dressing layer prior to applying the NPWT dressing.

Q. I’m having difficulty getting the dressing to adhere to my patient’s skin. Any suggestions?

A. A skin preparation product such as SKIN-PREP[®] may be used on intact skin prior to dressing application. Ensure that treated area is completely dry prior to application of the dressing.

Q. Do you have any special recommendations for high bioburden or infection?

A. If available, Smith & Nephew ACTICOAT[®] Flex may be utilized 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.

Standard practice application*

Therapy: PICO® Single Use NPWT System

Site of care: Long term care facilities

1. Verify physician order.
2. Assemble supplies.
3. Knock on resident/patient door for permission to enter.
4. Provide privacy for patient.
5. Identify resident/patient per policy.
6. Ask resident/patient if they are experiencing any pain. Report per policy.
7. Explain procedure to the resident/patient.
8. If this is a PICO Dressing change, turn pump off.
9. Cleanse hands.
10. Don/apply gloves.
11. Remove soiled dressing. Dispose of in appropriate container.
12. Measure wound and assess wound for appropriate documentation.
13. Remove gloves.
14. Wash hands and don/apply gloves.
15. Remove as much loose debris from the wound as possible.
16. If necessary, remove any excess hair to ensure that dressing will adhere to periwound skin.
17. Gently cleanse the wound bed with an appropriate wound cleanser.
18. Irrigate the wound with sterile saline and pat the wound dry.
19. Using a clean technique, remove central backing from the dressing and position the dressing centrally over the wound or incision, with the tubing port above the wound towards patient's head.
20. Remove the remaining backing and smooth the rest of the dressing around the wound. Avoid applying any tension to the border during application.
21. Assess the silicone border for wrinkling, smooth any wrinkles or reposition the dressing if required to ensure border is not creased.
22. Firmly run your fingers around the perimeter of the dressing pad and silicone border.
23. Once the dressing is in place, remove the pump and the batteries from the tray. Open the battery cover, insert the batteries and replace the cover. All three lights should flash once (This step applies for new PICO Dressing application only.)
24. Join the pump to the dressing by twisting together the tubing connectors, ensuring that they are secure and tightly attached.
25. Press the orange button to start the application of negative pressure. The green light will start to flash, which indicates that the system is working correctly.
26. If after 30 seconds the system has not established negative pressure wound therapy, the amber air leak light will illuminate. In this case, locate and correct the source of the air leak by repeating steps 20 and 21 and re-activate the pump by pressing the orange button.
27. Once you have verified that the green light is flashing, continue to secure the dressing by applying the fixation strips to each of the four sides of the dressing, overlapping the dressing border by approximately 2/5" or 1cm. Remove the top carrier on the strip after each one has been applied.
28. Check the tubing to ensure that it is not twisted or trapped between clothing.
29. Gather dirty supplies and bag. Dispose of soiled bag in designated area.
30. Remove gloves.
31. Cleanse hands.
32. Ensure resident/patient is safe and comfortable.
33. Discuss treatment/progress with patient's caregiver if appropriate.
34. Document wound measurements, assess the wound, assess patient tolerance and pain level at the completion of the treatment.
35. Document according to facility protocol.

* Steps 1-35 represent the PICO standard practice application. Steps 15-28 relate to PICO Dressing application change only.

The above recommendations are based on standards and practices commonly utilized by PDQWC members related to negative pressure wound therapy dressing changes: such recommendations are not intended to supersede independent clinical judgement or institutional protocols. Where laws, regulations, or other protocols/guidelines require or suggest an alternative approach to be taken, a clinician should follow such measures.

Skills checklist 1: PICO[◇] standard practice application

Employee: _____ Date: _____

Evaluator: _____ Ref #: _____

PICO standard practice application (page 1 of 2)		
Performance criteria	Met	Not met
1. Verify physician order.		
2. Assemble supplies.		
3. Knock on resident/patient door for permission to enter.		
4. Provide privacy for patient.		
5. Identify resident/patient per policy.		
6. Ask resident/patient if they are experiencing any pain. Report per policy.		
7. Explain procedure to the resident/patient.		
8. If this is a PICO Dressing change, turn pump off.		
9. Cleanse hands.		
10. Don/apply gloves.		
11. Remove soiled dressing. Dispose of in appropriate container.		
12. Measure wound and assess wound for appropriate documentation.		
13. Remove gloves.		
14. Wash hands and don/apply gloves.		
15. Remove as much loose debris from the wound as possible.		
16. If necessary, remove any excess hair to ensure that dressing will adhere to periwound skin.		
17. Gently cleanse the wound bed with an appropriate wound cleanser.		
18. Irrigate the wound with sterile saline and pat the wound dry.		
19. Using a clean technique, remove central backing from the dressing and position the dressing centrally over the wound or incision, with the tubing port above the wound towards patient's head.		
20. Remove the remaining backing and smooth the rest of the dressing around the wound. Avoid applying any tension to the border during application.		
21. Assess the silicone border for wrinkling, smooth any wrinkles or reposition the dressing if required to ensure border is not creased.		
22. Firmly run your fingers around the perimeter of the dressing pad and silicone border.		
23. Once the dressing is in place, remove the pump and the batteries from the tray. Open the battery cover, insert the batteries and replace the cover. All three lights should flash once (This step applies for new PICO Dressing application only.)		
24. Join the pump to the dressing by twisting together the tubing connectors, ensuring that they are secure and tightly attached.		
25. Press the orange button to start the application of negative pressure. The green light will start to flash, which indicates that the system is working correctly.		

Not intended to supersede independent clinical judgment or institutional protocols.

PICO° standard practice application (page 2 of 2)

Performance criteria	Met	Not met
26. If after 30 seconds the system has not established negative pressure wound therapy, the amber air leak light will illuminate. In this case, locate and correct the source of the air leak by repeating steps 20 and 21 and re-activate the pump by pressing the orange button.		
27. Once you have verified that the green light is flashing, continue to secure the dressing by applying the fixation strips to each of the four sides of the dressing, overlapping the dressing border by approximately 2/5" or 1cm. Remove the top carrier on the strip after each one has been applied.		
28. Check the tubing to ensure that it is not twisted or trapped between clothing.		
29. Gather dirty supplies and bag. Dispose of soiled bag in designated area.		
30. Remove gloves.		
31. Cleanse hands.		
32. Ensure resident/patient is safe and comfortable.		
33. Discuss treatment/progress with patient's caregiver if appropriate.		
34. Document wound measurements, assess the wound, assess patient tolerance and pain level at the completion of the treatment.		
35. Document according to facility protocol.		

Comments (Re: Not met): _____

Employee signature: _____ Date: _____

Evaluator signature: _____ Date: _____

* Steps 1-35 represent the PICO standard practice application. Steps 15-28 relate to PICO Dressing application change only.

The above recommendations are based on standards and practices commonly utilized by PDQWC members related to negative pressure wound therapy dressing changes: such recommendations are not intended to supersede independent clinical judgement or institutional protocols. Where laws, regulations, or other protocols/guidelines require or suggest an alternative approach to be taken, a clinician should follow such measures.

Not intended to supersede independent clinical judgment or institutional protocols.

Skills checklist 2: PICO[◇] Dressing application/change

Employee: _____ Date: _____

Evaluator: _____ Ref #: _____

Performance criteria	Met	Not met
1. If this is a new dressing application, remove the pump and the batteries from the tray. Open the battery cover, insert the batteries and replace the cover. All three lights should flash once.		
2. If this is a dressing change, turn the pump off.		
3. Don gloves, remove dressing and discard dressing and gloves.		
4. Wash hands and don gloves.		
5. Remove as much loose debris from the wound as possible.		
6. If necessary, remove any excess hair to ensure that dressing will adhere to periwound skin.		
7. Gently cleanse the wound bed with an appropriate wound cleanser.		
8. Irrigate the wound with sterile saline and pat the wound dry.		
9. Using a clean technique, remove central backing from the dressing and position the dressing centrally over the wound or incision, with the tubing port above the wound towards patient's head.		
10. Remove the remaining backing and smooth the rest of the dressing around the wound. Avoid applying any tension to the border during application.		
11. Assess the silicone border for wrinkling, smooth any wrinkles or reposition the dressing if required to ensure border is not creased.		
12. Firmly run your fingers around the perimeter of the dressing pad and silicone border.		
13. Once the dressing is in place, join the pump to the dressing by twisting together the tubing connectors, ensuring that they are secure and tightly attached.		
14. Press the orange button to start the application of negative pressure. The green light will start to flash, which indicates that the system is working correctly.		
15. If after 30 seconds the system has not established negative pressure wound therapy, the amber air leak light will illuminate. In this case, locate and correct the source of the air leak by repeating steps 11 and 12 and re-activate the pump by pressing the orange button.		
16. Once you have verified that the green light is flashing, continue to secure the dressing by applying the fixation strips to each of the four sides of the dressing, overlapping the dressing border by approximately 2/5" or 1cm. Remove the top carrier on the strip after each one has been applied.		
17. Check the tubing to ensure that it is not twisted or trapped between clothing.		

Comments (Re: Not met): _____

Employee signature: _____ Date: _____

Evaluator signature: _____ Date: _____

Not intended to supersede independent clinical judgment or institutional protocols.

PICO^o knowledge assessment

Circle the correct answer to the questions listed below:

- PICO is **indicated** for many types of wounds, including the following:
 - Chronic, acute, traumatic or closed surgical incisions
 - Subacute and dehisced wounds
 - Diabetic or pressure ulcers
 - All of the above
- The use of PICO is **contraindicated** in the presence of several factors including:
 - Previously confirmed and untreated osteomyelitis
 - Nonenteric and unexplored fistulas
 - Necrotic tissue with eschar present
 - Exposed arteries, veins, nerves or organs
 - All of the above
- PICO is intended for use in wound sizes (surface area x depth):
 - Less than 200cm³
 - Up to 400cm³
 - More than 400cm³ but less than 600cm³
- PICO is intended for use in wounds that are considered to be:
 - Non-exuding
 - Low to moderately exuding
 - Moderately to heavily exuding
- PICO manages exudate by:
 - Draining exudate through the tubing
 - Absorbing exudate into the dressing pad
 - Evaporating moisture through the outer film
 - A combination of absorption and evaporation of moisture through the outer film
- The PICO kit is intended to be used for a **maximum** of:
 - 4 days, regardless of wound type
 - 3 days on moderately exuding wounds and 2 days on low exuding wounds
 - 7 days on low exuding wounds and 6 days on moderately exuding wounds
- Lower extremity wounds are sometimes accompanied by edema. PICO may be used in conjunction with compression.
 - True
 - False
- How do you determine when to use PICO vs. traditional NPWT?
 - If the wound area fits under one of the PICO Dressings, then it is appropriate to use the PICO NPWT System, regardless of drainage.
 - If the patient is mobile, then PICO NPWT System is always the correct clinical option.
 - If the exudate level is less than 300ml of fluid per week, and the wound fits under one of the PICO Dressings, then PICO may be an appropriate option.
 - You should always use traditional NPWT first, and then transition to PICO
- How do you handle exposed tendon or bone?
 - Do not use PICO with 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.
 - There is no special accommodation required for bone or tendon
- Can your patient shower or bathe with the PICO Dressing in place if the pump has been disconnected?
 - No, do not allow the patient to shower or bathe with the PICO Dressing in place.
 - Yes, the patient may take a bath with the dressing in place provided the pump has been disconnected.
 - The dressing is water resistant, so light showering is permissible, but the dressing should not be exposed to a direct spray or submerged in water
- Are there any additional resources that I can refer to for clinical questions or clarification?
 - If you have any questions, you should ask your clinical supervisor for direction.
 - Additionally, you can visit the PICO website located at www.possiblewithpico.com
 - If you still need an answer, you can call the PICO Hotline
 - All of the above
- If the PICO System detects an air leak during a dressing application, the silicone border may be lifted and repositioned if necessary.
 - True
 - False

Not intended to supersede independent clinical judgment or institutional/agency protocol.

PICO^o knowledge assessment with answer key

Circle the correct answer to the questions listed below:

1. PICO is **indicated** for many types of wounds, including the following:
 - A. Chronic, acute, traumatic or closed surgical incisions
 - B. Subacute and dehisced wounds
 - C. Diabetic or pressure ulcers
 - D. All of the above
2. The use of PICO is **contraindicated** in the presence of several factors including:
 - A. Previously confirmed and untreated osteomyelitis
 - B. Nonenteric and unexplored fistulas
 - C. Necrotic tissue with eschar present
 - D. Exposed arteries, veins, nerves or organs
 - E. All of the above
3. PICO is intended for use in wound sizes (surface area x depth):
 - A. Less than 200cm³
 - B. Up to 400cm³
 - C. More than 400cm³ but less than 600cm³
4. PICO is intended for use in wounds that are considered to be:
 - A. Non-exuding
 - B. Low to moderately exuding
 - C. Moderately to heavily exuding
5. PICO manages exudate by:
 - A. Draining exudate through the tubing
 - B. Absorbing exudate into the dressing pad
 - C. Evaporating moisture through the outer film
 - D. A combination of absorption and evaporation of moisture through the outer film
6. The PICO kit is intended to be used for a **maximum** of:
 - A. 4 days, regardless of wound type
 - B. 3 days on moderately exuding wounds and 2 days on low exuding wounds
 - C. 7 days on low exuding wounds and 6 days on moderately exuding wounds
7. Lower extremity wounds are sometimes accompanied by edema. PICO may be used in conjunction with compression.
 - A. True
 - B. False
8. How do you determine when to use PICO vs. traditional NPWT?
 - A. If the wound area fits under one of the PICO Dressings, then it is appropriate to use the PICO NPWT system, regardless of drainage.
 - B. If the patient is mobile, then PICO NPWT system is always the correct clinical option.
 - C. If the exudate level is less than 300ml of fluid per week, and the wound fits under one of the PICO Dressings, then PICO may be an appropriate option.
 - D. You should always use traditional NPWT first, and then transition to PICO
9. How do you handle exposed tendon or bone?
 - A. Do not use PICO with exposed tendon or bone
 - B. Exposed tendons and bone should be covered with natural tissue or a non-adherent dressing layer prior to applying the NPWT dressing.
 - C. There is no special accommodation required for bone or tendon
10. Can your patient shower or bathe with the PICO Dressing in place if the pump has been disconnected?
 - A. No, do not allow the patient to shower or bathe with the PICO Dressing in place.
 - B. Yes, the patient may take a bath with the dressing in place provided the pump has been disconnected.
 - C. The dressing is water resistant, so light showering is permissible, but the dressing should not be exposed to a direct spray or submerged in water
11. Are there any additional resources that I can refer to for clinical questions or clarification?
 - A. If you have any questions, you should ask your clinical supervisor for direction.
 - B. Additionally, you can visit the PICO website located at www.possiblewithpico.com
 - C. If you still need an answer, you can call the PICO Hotline
 - D. All of the above
12. If the PICO System detects an air leak during a dressing application, the silicone border may be lifted and repositioned if necessary.
 - A. True
 - B. False

Answer key: 1. D, 2. E, 3. B, 4. B, 5. D, 6. C, 7. A, 8. C, 9. B, 10. C, 11. D, 12. A

Not intended to supersede independent clinical judgment or institutional/agency protocol.

Certificate of completion

This is to certify that

Name

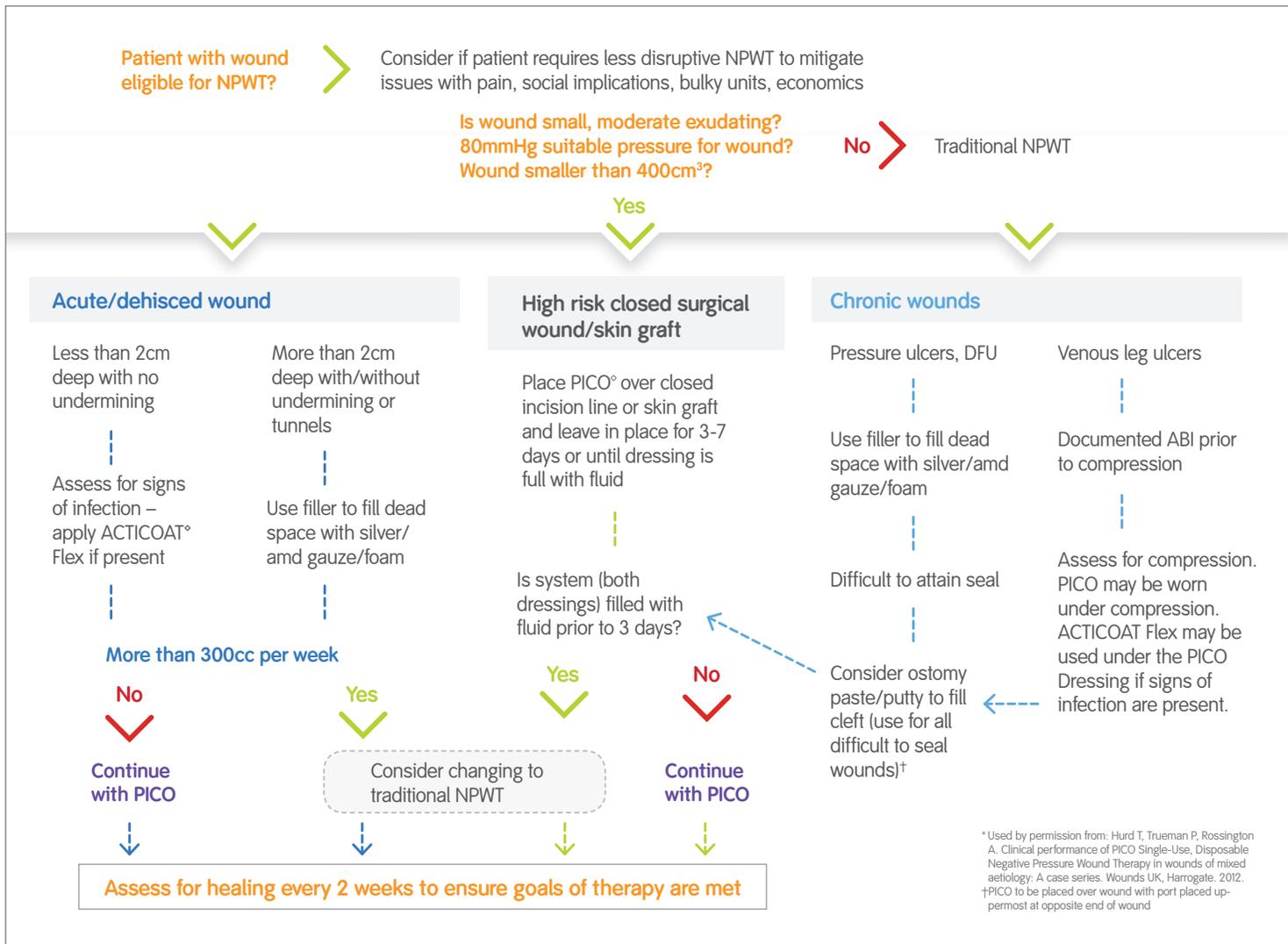
has successfully completed the PICO[®] Single Use Negative Pressure
Wound Therapy System clinical competency for long-term care program

Presented in this the of

Date

Appendix I

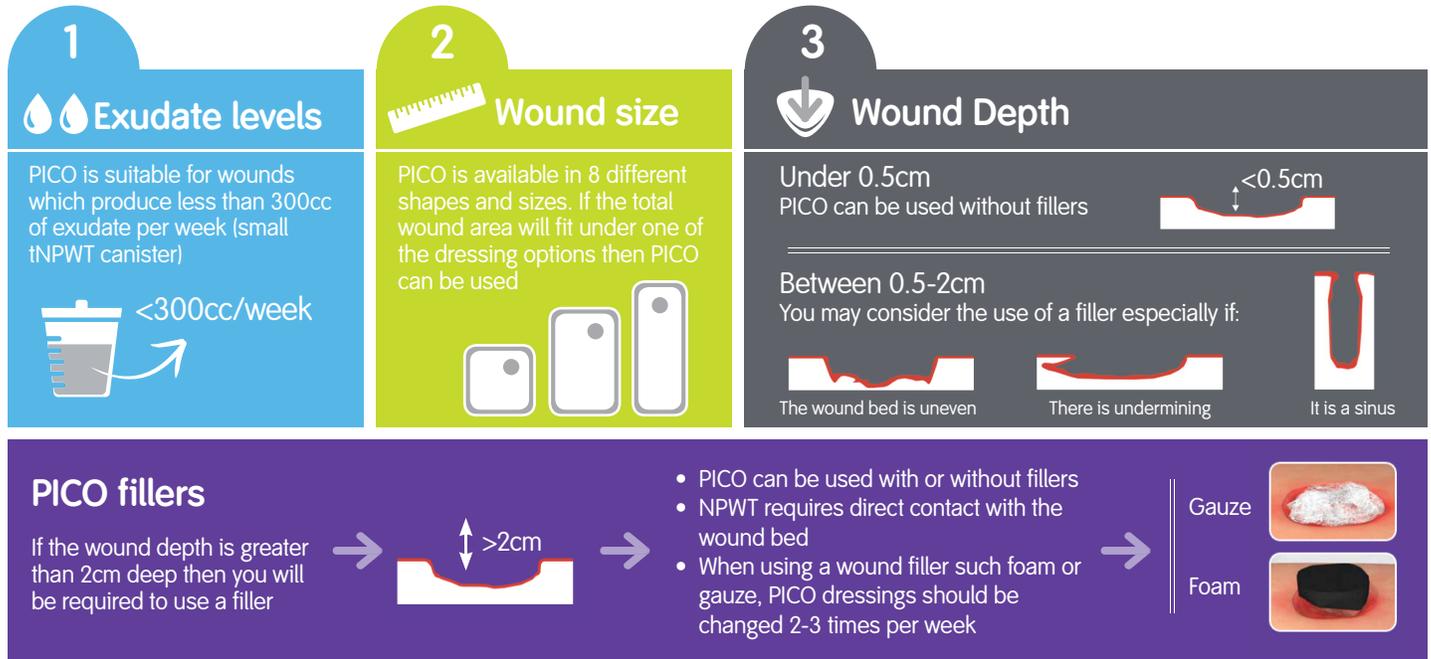
Algorithm: When to use NPWT*



Appendix II

Wound selection flowchart: open wounds

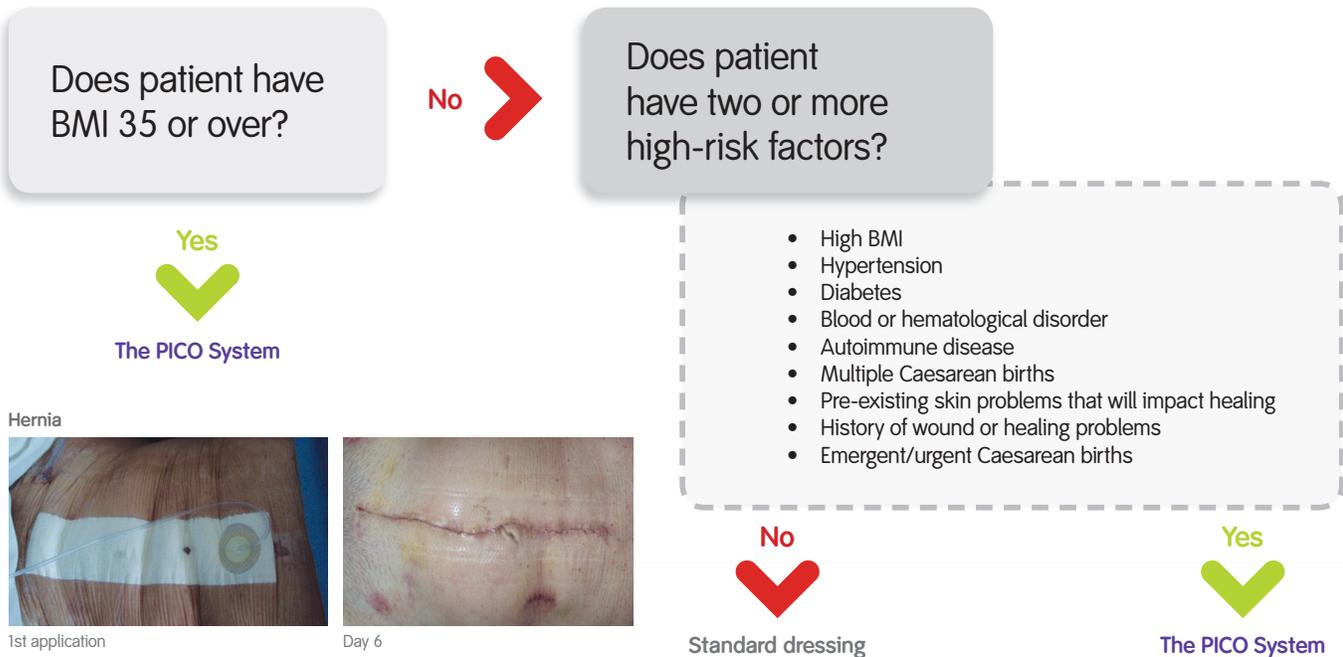
The decision to use PICO or a traditional NPWT System takes just 3 steps:



Appendix III

Wound selection flowchart: closed incisions

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



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

The PICO System may **help reduce the risk of surgical site complications** as part of a comprehensive clinical protocol. The PICO System has been utilized on many incisions, including, but not limited to:

- C-section, Hysterectomy, Total Hip Replacement, Total Knee Replacement, Sternotomy, Colorectal Surgery, Calcaneus Fracture, Mastectomy/Breast Reconstruction

Appendix IV

PICO[◇] Information for patients and caregivers

How does PICO work?

PICO provides suction known as negative pressure wound therapy (NPWT) which draws out excess fluid from the wound. PICO consists of a NPWT pump connected to an innovative dressing which is applied to the wound bed and held in place with adhesive strips. When the pump is turned on, air is pulled out of the dressing and excess fluid from the wound will start to enter the dressing. The dressing helps to protect the wound and helps to prevent bacteria from entering the wound. It may also improve blood flow to the wound which will help it to heal.

How long will it take to improve the wound?

In many cases, an improvement in the wound can be seen when the first dressing is changed, but in some cases, it may take several weeks.

Will it hurt?

Some people may experience slight discomfort during dressing changes, specifically during cleaning of the wound. The first time the PICO Pump is turned on, you may feel a slight pulling or drawing sensation. If you experience any pain or discomfort, please tell your nurse.

How often will the dressing have to be changed?

The dressing may be left in place for up to seven days depending on the type of wound and amount of fluid from the wound. Your nurse or doctor will determine how often your dressings should be changed.

Can the patient move about?

Patients using PICO are free to move around, but this will depend on recommendations provided by your nurse or doctor.

When you are asleep:

Make sure that the PICO Pump is placed somewhere safe and cannot be pulled off a table or cabinet onto the floor during sleep.

Showering and washing:

The PICO Pump is splash proof but should not be submerged in water. The dressing is water resistant, so you can shower with the dressing in place, as long as you do not expose it to direct jets of water as this may cause the dressing to fall off.

Pump light indicators:

When the PICO Pump is working correctly, the 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. A flashing orange light above the battery symbol indicates “low battery”. A flashing orange light above the dressing symbol indicates that an air leak has been detected and the pump has gone into Auto Pause. If there are no lights, then the pump has come to the end of its life. Please notify your nurse if you notice anything other than the flashing green light.

Call the nurse or doctor immediately if you notice:

- A change in the color or amount of the fluid in the dressing, for example: If it changes from clear to cloudy or bright red, or you see the dressing fill rapidly with blood.
- The skin around your wound looks reddened or irritated, or the wound has a foul smell.
- The dressing feels or appears loose.
- You experience pain.
- The alarm display will not stop flashing.

Appendix V

PICO[◇] Single Use Negative Pressure Wound Therapy System product availability

Ordering information

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

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.



PICO[◇] Single Use Negative Pressure Wound Therapy System package insert: instructions for use

PICO[◇] is supplied sterile, single use. Do not use if package is open or damaged.

1. Description

The PICO Single Use Negative Pressure Wound Therapy System consists of a pump and two sterile dressing kits. The PICO pump maintains negative pressure wound therapy (NPWT) at 80 mmHg (nominal) +/- 20 mmHg 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 c.c. 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.

2. 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.

3. 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.
- Non-enteric 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.

1

4. 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).
 9. PICO is not suitable for use in the presence of flammable anesthetic mixture with oxygen or nitrous oxide.

5. 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

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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 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 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.
10. If reddening or sensitisation occurs discontinue use and contact the treating healthcare professional.
11. Do not use PICO with oil-based products such as petrolatum as it may compromise establishing an effective seal.
12. 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.
13. 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.
14. Pump must be protected from sources

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of fluid e.g. from incontinence or spillages. Discontinue device use if fluid ingress is observed.

15. 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.
16. Do not take the pump apart.
17. The dressing should not be used with any other suction pump.
18. Do not alter or cut tubing configuration or pull on the tubing.
19. Do not cut the dressing as this may lead to loss of NPWT application.
20. 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 minimised.
21. 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.
22. 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.
23. High temperatures and humidity may reduce wear times of dressings.
24. 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.

25. 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.

6. 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.

7. Instructions for use

7.1. Guidance on wound suitability for management with PICO

PICO should be used on wounds which fit comfortably within the area of the pad, observing precautions on port positioning (on intact skin and not extending over the wound).

4

As a guide:

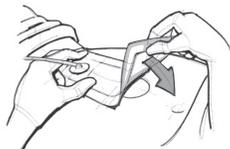
Depth – Wounds greater than 0.5cm (1/4 in.) in depth are likely to require a foam or gauze NPWT filler to ensure adequate treatment of all the wound surfaces. Wounds treated with the larger dressing sizes of the PICO system should generally be no more than 2cm (3/4 in.) in depth.

Exudate – PICO is intended for use on wounds where the level of exudate is low (nominally 0.6g of liquid exudate/cm² of wound area/24 hours) to moderate (nominally 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.

7.2. Application

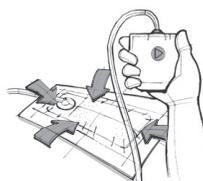
1. Remove any excess hair to ensure close approximation of the dressing to the wound. If necessary, irrigate the wound with sterile saline and pat the wound dry.
2. Using a clean technique, peel off the central release handle and place the dressing centrally over the wound to reduce the chance of wound 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.

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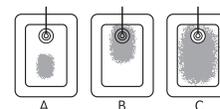
5. If using SKIN PREP prior to application of the fixation strips (see Precautions), wipe the area surrounding the dressing and allow skin to dry.
6. Apply the fixation strips to each of the four sides of the dressing. Remove top carrier on the strip after each one has been applied. These strips maintain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

7.3. 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.
2. Inspect the 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 7.2, 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

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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

7.4. Use with fillers and wound contact layers

PICO 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.

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.

8. General use

8.1. 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 so that water does not enter the top of the tube.

8.2. 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.

9. Faults and technical assistance

If your device develops a fault or there are signs of damage, refer to Table 1.

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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.

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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. Amber 'battery low' light flashes.	System on and functioning properly. Battery power low.	Change of batteries required in <24 hours. Pause the therapy by pressing the orange button. Push open the battery cover at the top of the pump and remove the old batteries. Insert 2 new lithium (L91) 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.

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. (PICO Clinical Guidelines, pg 21)

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