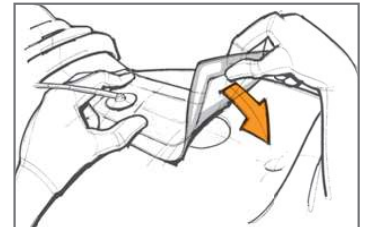
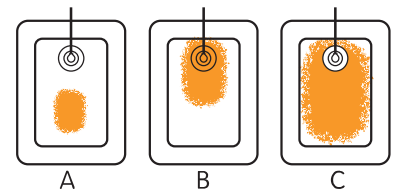


5. PICO[®] does not contain audible alarms. The pump should be carried so that it is accessible and the patient/healthcare professional can check the status routinely.
6. Although PICO can be used under clothing/ bedding, it is important that occlusive materials e.g. film dressings, are not applied over 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.
23. 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.



Dressing change frequency

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, 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

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).

As a guide:

Depth – Wounds greater than 0.5cm (1/4in.) 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 (4/5in.) 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.

Instructions for use

Application

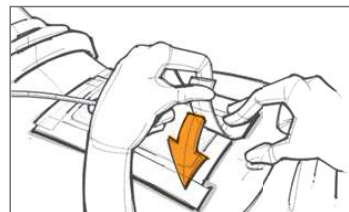
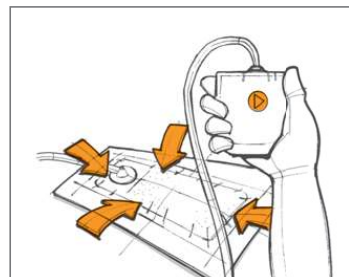
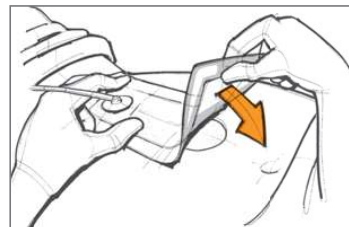
1. Remove any excess hair to ensure close approximation of the dressing to the wound. If necessary, irrigate the wound with sterile saline and pat the wound dry.
2. Using a clean technique, peel off the central release handle and place the dressing centrally over the wound to reduce the chance of wound 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 extend 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 Appendix VI – PICO^o IFU, table 1 on page 72).
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 indicating the system is working properly.

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 Appendix VI – PICO IFU, table 1 on page 72.

5. If using SKIN-PREP^o 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.



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.

General use

Showering and bathing

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

10. Clinical Hotline

For clinical support regarding Smith & Nephew NPWT devices call 1-800-876-1261.

A Clinical Hotline is available to assist patients and healthcare providers with any questions related to Smith & Nephew's NPWT System. This includes generalized questions from the dressing techniques to troubleshooting an alarm situation.

The Hotline is available 24 hours a day, 7 days a week.

Or visit www.myrenasys.com or www.possiblewithpico.com.

11. Appendix

Appendix I

Negative Pressure Wound Therapy product portfolio

Smith & Nephew prides itself in delivering an innovative and comprehensive NPWT product portfolio that offers flexibility and clinical excellence. Our extensive selection of pumps, canisters, kits and accessories are each conformably designed to meet the unique complexities of your patients' wounds. The RENASYS[®] NPWT System helps improve the overall patient experience by promoting wound healing throughout the entire continuum of care.

RENASYS EZ Plus NPWT System	
RENASYS EZ Plus device	
Product description	Product code
RENASYS EZ Plus Component list <ul style="list-style-type: none"> • Pump • Canister holder kit • Power cord • Quick reference guide 	Smith & Nephew 66800697 Acute Care (UHS) ZNP Home Care (Apria) M046689
RENASYS EZ Plus canisters	
800mL S-Canister Component list; 10 kits per case <ul style="list-style-type: none"> • Sealed canister • With or without solidifier • Overflow guard with silicone tubing • Canister tubing 	800mL with solidifier: Smith & Nephew 66800912 Acute Care (UHS) 2012025 Home Care (Apria) M047411 800mL without solidifier: Smith & Nephew 66801066 Acute Care (UHS) TBD
250mL S-Canister Component list; 10 kits per case <ul style="list-style-type: none"> • Sealed canister • Solidifier • Overflow guard with silicone tubing • Canister tubing 	250mL with solidifier: Smith & Nephew 66800913 Acute Care (UHS) 2012225
RENASYS EZ Plus accessories	
RENASYS EZ Plus Canister Holder Kit (accommodates all canister sizes) 1 per case 	Smith & Nephew 66800060 Acute Care (UHS) 2009475
RENASYS EZ Power Cord Hospital Grade 1 per case 	Smith & Nephew 66800193 Acute Care (UHS) 2008025

RENASYS GO NPWT System	
RENASYS GO device	
Product description	Product code
RENASYS GO Component list <ul style="list-style-type: none"> • Pump • Power cord • Quick reference guide • Strap 	Smith & Nephew 66800164 Acute Care (UHS) ZNG Home Care (Apria) M040511
RENASYS GO canisters	
RENASYS GO Large Canister (750mL) Component list; 5 per case <ul style="list-style-type: none"> • Sealed canister • Solidifier • Canister tubing 	750mL with solidifier: Smith & Nephew 66800916 Acute Care (UHS) 2012250
RENASYS GO Canister (300mL) Component list; 5 per case <ul style="list-style-type: none"> • Sealed canister • Solidifier • Overflow guard with silicone tubing • Canister tubing 	300mL with solidifier: Smith & Nephew 66800914 Acute Care (UHS) 2012000 Home Care (Apria) M047406
RENASYS GO accessories	
RENASYS GO Power Supply External Cord 1 per case 	Smith & Nephew 66800161 Acute Care (UHS) 1901102 Home Care (Apria) R037398
RENASYS GO Carrying Case 1 per case 	Smith & Nephew 66800162 Acute Care (UHS) 2009525 Home Care (Apria) R037471
RENASYS GO Carrying Straps Component list; 1 per case <ul style="list-style-type: none"> • Straps include fix-lock buckles, shoulder pad and strap extender 	Smith & Nephew 66800163 Acute Care (UHS) 2009550 Home Care (Apria) R037472
PICO [®] Single Use NPWT System	
PICO device	
Product description	Product code
Dressing size 4in x 8in (10cm x 20cm) 3 kits/case 	Smith & Nephew 66800862
Dressing size 4in x 12in (10cm x 30cm) 3 kits/case 	Smith & Nephew 66800863