

January 2012 PICO™ System Q&A

1) What is the PICO™ system?

The PICO system is a single use, Negative Pressure Wound Therapy (NPWT) system indicated for chronic, acute and traumatic wounds, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The canister-free, pocket-sized system is also indicated for closed surgical incisions, which expands the use of NPWT to a wider range of patients undergoing orthopaedic, plastic and general surgical procedures.

The single use, one-button pump works with a revolutionary dressing technology that effectively manages fluids and eliminates the need for bulky canisters. The pocket-sized design is portable and discreet and allows patients to comfortably go about their daily lives. The system can be used for up to a week, depending on wound exudate levels, and its gentle silicone wound contact layer helps minimize pain at dressing removal.

2) What type of wounds can be treated using the PICO system?

Wound types for which the PICO system is indicated include chronic, acute and traumatic wounds, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. It is also indicated for closed surgical incisions, a relatively new application for NPWT and one that possesses exceptional promise for patients recovering from orthopaedic, plastic and general surgery procedures.

3) What type of patient would benefit most from the PICO system?

The PICO system expands the use of NPWT to a wider range of patients undergoing orthopaedic, plastic and general surgical procedures to help reduce surgical site complications in high-risk patients or those undergoing high-risk surgical procedures. Examples of appropriate high-risk procedures are hip and knee replacement surgery and breast reconstruction and reduction procedures.

4) What type of clinical data supports the efficacy and safety of the PICO system?

A 20-patient non-comparative clinical trial was conducted, in which clinical outcomes and functional performance of the PICO system were tested. Sixteen patients (80%) had surgical wounds, two (10%) patients had traumatic wounds and two (10%) patients received meshed split-thickness skin grafts.

Overall, 11/16 of the surgical incisions were closed at the end of the 14-day study; four were progressing to closure and one was static. There were no incidences of dehiscence. Of the two trauma patients, both were progressing to closure and the take was greater than 80% for the two skin graft patients.

The PICO system was shown to operate successfully in a clinical environment and investigators found the system easy to apply, manage and remove.

Since then, the PICO system has cleared for sale in Canada, Australia and Europe where it is being successfully used by patients and clinicians. The PICO system was also recently cleared for sale in the U.S. by the FDA.

5) How does a patient benefit from using the PICO system?

PICO is very discreet and allows patients to comfortably go about their daily lives. The pocket-sized pump fits in the palm of the hand and is easy to use. The revolutionary dressing technology effectively manages fluids and eliminates the need for bulky canisters. The PICO system can be used for up to seven days, depending on wound exudate levels, reducing dressing changes. Its gentle silicone wound contact layer helps minimize pain at dressing removal.

6) Why would a clinician use the PICO system versus traditional NPWT?

The PICO system is simple, easy to use and on a weekly use basis, PICO costs about 2/3 less than traditional NPWT. It provides effective NPWT for a wider range of wounds and care settings. It is easy to learn and operate, thus reducing the need for staff time or intensive training. The PICO system is also available 'off-the-shelf', which reduces the need for administrative paperwork associated with traditional NPWT. The canister-free, pocket-sized system is patient friendly, portable and discreet and allows patients to comfortably go about their daily lives.

7) How does the PICO system differ from other portable or disposable NPWT products already on the market?

The PICO system is unique because it is a single use disposable and delivers NPWT without a bulky canister. The revolutionary dressing technology effectively manages fluids and eliminates the need for the canister. The pocket-sized pump is portable and discreet and allows patients to comfortably go about their daily lives. The gentle silicone wound contact layer helps minimize pain at a dressing change.

Wound types for which the PICO system is indicated include chronic, acute and traumatic wounds, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. It is also indicated for closed surgical incisions, a relatively new application for NPWT and one that possesses exceptional promise for patients recovering from orthopaedic, plastic, and general surgery procedures.

Additionally, on a weekly use basis, PICO costs about 2/3 less than traditional NPWT.

8) Most NPWT products utilize a canister to hold exudate. Where does the PICO system store the exudate between dressing changes?

The PICO system uses a revolutionary, four-layer dressing technology to effectively manage fluid, eliminating the need for bulky canisters:

- Silicone contact allows fluid to pass and minimize pain of removal
- Airlock layer maintains open airflow and allows even distribution of negative pressure across the dressing
- Proprietary absorbent layer moves exudate away from the wound and initiates evaporation
- The high moisture vapor transmission rate (MVTR) top film allows one-way transpiration of exudate vapor

9) How much fluid can the PICO dressing hold before it needs to be changed?

A 10x20cm PICO system dressing, which is the smallest size, has an absorbent capacity of 40g of exudate. The larger dressings can manage higher levels of fluid.

10) Is there an infection risk because the dressing can stay on for up to seven days?

There is always a risk of infection during wound treatment, even under the most conservative treatment regimens. However, PICO does not present any increased risk of developing infection during use of the system. If the wound is not infected prior to application, the PICO system will protect the wound from contamination from the environment during use.

If infection is a concern, PICO is compatible for use in combination with ACTICOAT FLEX.

11) What type of training will clinicians need in order to use the PICO system in their practice?

The PICO system is simple to learn, apply and operate. Because the system is applied as an advanced wound dressing, minimal training is required for most healthcare professionals. Clinicians will also be able to access the mobile-compatible website, www.possiblewithpico.com to download training videos and other information about the PICO system. All packaging for the PICO system will include an MS Tag that links to an instructional video.

12) What type of clinicians will be likely to utilize the PICO™ system?

Any doctor, nurse or healthcare provider already using NPWT can now easily treat patients using the PICO system. The PICO system is simple to learn, apply and operate. It's a clinically proven NPWT that can be applied like a dressing and is suitable for a range of patients in all care settings. Also, because the PICO system is applied like a dressing, it is now easier for non-wound specialists to use NPWT. Orthopaedic, Plastic, Burn and General Surgeons may begin to utilize the PICO system in hip and knee procedures, breast reconstruction and reduction procedures, or for general incision site management in high-risk patients or high-risk procedures.

13) How does Smith & Nephew plan to promote and launch the PICO system in the U.S.?

Smith & Nephew will promote and support the U.S. launch of the PICO system through a fully integrated marketing campaign and its sales/distribution network. Additionally, healthcare providers and patients can access the www.possiblewithpico.com website for information about the PICO system, or contact customer care at 800-876-1261. Packaging and advertising for the PICO system will include an MS Tag that will link to an application/mechanism of action video, eliminating the need for complex training modules.

14) How does the PICO system contribute to Smith & Nephew's commitment to reduce the human and economic cost of wounds?

The PICO system represents an entirely new way to deliver NPWT and a significant advancement for the patient, clinician and payer. It brings NPWT to a wider range of patients who would benefit from this therapy. Its simplicity and ease of use enables more clinicians to use NPWT in a cost-effective manner. For the payer, the PICO system is more affordable and can significantly reduce therapy costs associated with traditional NPWT. Unlike traditional NPWT, costs are more predictable because the PICO system is available off-the-shelf, helping to conserve and manage healthcare resources.

Additionally, the PICO system may reduce the occurrence of delayed discharges from healthcare institutions, and the administrative burden associated with traditional NPWT. The PICO™ system may also reduce the occurrence of surgical site complications and associated costs, time needed to care for a wound and the risk of re-admission.

15) Is the PICO NPWT System less expensive than traditional NPWT systems?

Yes, on a weekly use basis, PICO costs about 2/3 less than traditional NPWT. The PICO system may also reduce the occurrence of delayed discharges from hospitals and other care settings associated with traditional NPWT, thus reducing the overall administrative burden and costs associated with treatment. Unlike traditional NPWT, costs are more predictable because the PICO system is available off-the-shelf, helping to conserve and manage healthcare resources.

16) How does the PICO system compare to an advanced wound dressing?

The PICO system combines the proven effectiveness of NPWT with the benefits of an advanced wound dressing. The PICO dressing application is the same as it would be for an advanced wound dressing. The revolutionary dressing technology of the PICO system eliminates the need for bulky canisters. The pocket-sized design is portable and discreet and allows patients to comfortably go about their daily lives.

17) What is the cost of the PICO system and what is the reimbursement status?

The PICO system is being launched with an initial emphasis in the acute care setting where it offers a significant savings for CMS and managed care payers over traditional NPWT systems. (On a weekly use basis, PICO costs about 2/3 less than traditional

NPWT.) Smith & Nephew is aggressively working with both Public and Commercial payers to secure favorable coverage and payment for the device within the homecare setting.

Smith & Nephew is committed to developing innovative product solutions that help improve the lives of people with serious wounds. The PICO system demonstrates Smith & Nephew's leadership in wound care and commitment to innovation and underscores its pledge to help reduce the human and economic cost of wounds. For patients, the PICO system is effective, patient friendly and easy to use. For clinicians, the PICO system offers simple and effective NPWT and requires less training time. For payers, the PICO system makes it easier to plan the costs associated with treatment in advance, while simultaneously offering a significant reduction in cost over traditional NPWT.

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