

PICO 7 Warnings and Precautions

Warnings:

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.

The use of anticoagulants does not deem a patient inappropriate for treatment with PICO* sNPWT, 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.

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.

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.

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.

MR unsafe. PICO* is not MRI compatible. Do not take PICO* into the MRI suite.

PICO* has not been studied on pediatric patients. Patient size and weight should be considered when prescribing this therapy.

PICO* is unsuitable for use in areas where there is danger of explosion (eg, hyperbaric oxygen unit).

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

Precautions:

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.
- Non-compliant or combative.
- Suffering from wounds in close proximity to blood vessels or delicate fascia.

If pain, reddening, odor, sensitization, or a sudden change in the volume or color of wound fluid

occurs during use, contact your health care professional.

Where PICO* is used to bolster skin grafts, it is important to visually inspect the system regularly, especially in the first week of treatment to ensure that negative pressure wound therapy is continually applied and a seal is maintained.

Where PICO dressings are used on infected wounds, more frequent dressing changes may be required. Regular monitoring of the wound should be maintained to check for signs of infection. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing or the use of negative pressure wound therapy on ischemic limbs does not compromise circulation.

PICO* does not contain audible alerts. The pump should be carried so that it is accessible and the patient/health care professional can check the status routinely.

Although PICO dressings can be used under clothing/bedding, it is important that occlusive materials (eg, 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.

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.

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.

Where PICO dressings are used on patients with fragile skin, a skin protectant such as NO-STING SKIN-PREP™ should be used on areas of skin where fixation strips are to be applied.

Inappropriate use or repeated application of fixation strips may otherwise result in skin stripping.

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

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

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* System.

The pump must be protected from sources of fluid (eg, from incontinence or spillages).

Discontinue PICO* use if fluid ingress is observed.

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

Do not take the pump apart.

The PICO dressing should only be used with PICO* pumps.

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

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

Always ensure that the PICO dressing is positioned centrally over the wound. The soft port

should be positioned uppermost on intact skin and not extend over the wound so that the risk of fluid collecting around the soft port and potentially blocking the therapy is minimized.

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.

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

The PICO* system is single use only. Use of any part of this system on more than 1 patient may result in cross contamination that may lead to infection.

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

The PICO* system is intended for use in both a hospital and home care setting. The system can also be used in aircraft, train, and boat transportation. Special care must be taken regarding pump positioning when in close proximity to other people (see magnet warning).

During transport, there is a potential for radio frequency interference that could affect PICO* performance. If the PICO* pump malfunctions, replace batteries. If not corrected, contact your health care professional to replace the system.

When applying dressings next to one another, ensure the dressing borders do not overlap.

Adverse Effects/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 health care professional of any sudden or abrupt changes in the volume or the color of exudate.