# NPseal Medium (10) - Instructions For Use

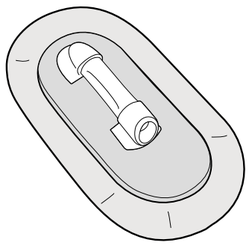
## A. Description

The NPseal Negative Pressure Advanced System is a single-use device that includes an integrated, mechanical pump system. The NPseal maintains Negative Pressure Wound Therapy (NPWT) in the -75 mmHg to -125 mmHg nominal range.

The NPseal is intended for 6 days of use. Therapy duration of the system may be less than indicated if clinical practice or other factors such as wound size, rate or volume of exudate, or orientation of the dressing results in earlier removal or need for system change.
The NPseal can be replaced only one time for a total maximum wear time of 6 days.

The NPseal MEDIUM is intended for surgically closed incisions up to 10 cm x 0.5 cm.

## B. NPseal Features



## C. Indications For Use

The NPseal is indicated for patients who would benefit from wound management via application of negative pressure, particularly as the device may promote wound healing through the removal of small amounts of exudates from closed surgical incisions.

## D. Contraindications

**DO NOT** place the NPseal over:

- Inadequately drained wounds
- Necrotic tissue such as eschar or adherent slough
- Exposed blood vessels, anastomotic sites, organs, tendons or nerves
- Wounds containing malignancy
- Fistulas
- Untreated Osteomyelitis
- Actively bleeding wounds
- Infected wounds

## E. Warnings

- It is a condition of use that the device will be applied by a qualified health care professional who has the necessary training and knowledge of the specific medical application for which the NPseal is being used. Failure to follow these conditions and/or to carefully read and follow all of the NPseal application instructions and the safety information prior to each use may lead to improper device performance and the potential for serious injury.
- The NPseal has not been studied on pediatric patients.
- Complete hemostasis should be achieved prior to use of the system as bleeding may interfere with the normal function of the NPseal. If excessive bleeding is observed, seek immediate medical assistance and take appropriate measures to stop bleeding.
- Extra care and monitoring is required for patients who are on anticoagulants or any hemostatic products that may increase the risk of bleeding because bleeding may interfere with the normal function of the NPseal.
- The NPseal should be removed prior to defibrillation if near the area of pad/paddle placement.
- Discard if packaging is open or damaged.
- Health care professionals, caregivers and patients should frequently monitor the patient's wound, surrounding tissue and secreted exudate (wound drainage) for signs of infection or other secondary conditions such as maceration or tissue necrosis. Infection can be severe and result in septic or toxic shock and/or fatal injury.
- **DO NOT** use NPseal in magnetic resonance imaging (MRI) environments.
- **DO NOT** use NPseal in hyperbaric environments.
- **DO NOT** use NPseal on patients with allergies to polyurethane.
- **DO NOT** reuse, reprocess or resterilize. Reuse, reprocessing or resterilization will compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury or illness.

## F. Precautions

- The NPseal may not be appropriate for treatment of noncompliant or combative patients.
- Patients may shower with the NPseal.
- The NPseal should be stored at room temperature only and should not be exposed to excessive cold or heat.
- **DO NOT** cover the pad area of the dressing as this may impair user ability to assess level of pad saturation, prevent regular ability and assessment of the wound, or disrupt scheduled or required pump maintenance.
- If reddening or sensitisation occurs, discontinue use of the NPseal.
- **DO NOT** cut or resize the dressing as this may lead to loss of therapy.

## G. Disclaimer of Warranty and Limitation of Remedy

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## H. Physician Instructions

The NPseal is capable of creating a maximum negative pressure level of -125 mmHg. Prior to placement of the NPseal, the clinician must assess how to optimally use the system for an individual surgically closed incision.

It is important to carefully evaluate the surgically closed incision and patient, to ensure that the Indications For Use are met. These general guidelines should be adhered to:

- The negative pressure level should never be painful to the patient.
- If a patient reports discomfort related to the negative pressure of the NPseal, then therapy should be discontinued.

Review the label instructions with the patient and/or caregiver and ensure that the patient and/or caregiver understands them adequately.

Ensure the patient and/or caregiver understands the following before release:

- Maintenance of the NPseal every eight hours (see section J).
- When to replace the NPseal (see section K).
- How to identify a leak and what actions to take to address it (see section M).
- Treatment duration (see Section K).
- Discard NPseal after removal (see Section L).

# NPseal Application Instructions

All wounds are unique. The clinician treating the wound needs to make an individual assessment of the optimal dressing and application method.

WARNING: Inspect all packaging before use and do not use products from packages that are open or damaged.

## I. Application and Activation Instructions

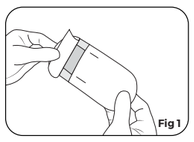
Fig 1

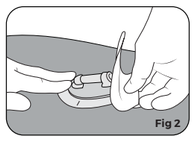
Fig 2

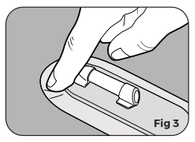
Fig 3

1. Prior to surgery, clip the area where the system will be applied to improve dressing adhesion and seal integrity.
2. After surgery, cleanse the application site with sterile gauze and sterile wound cleaning solution using a circular motion beginning at the center of the surgical area and extending outward to ensure the site is free of foreign material.
3. Ensure that the periwound skin is dry before applying the NPseal for optimal adhesion.
4. Remove the NPseal from the pouch.
5. Hold the NPseal by the pinch pump and remove liner. **TIP:** it is suggested that just one liner be removed first as shown in **Figure 1**. This allows for better control such that one side of the dressing can be applied to the patient without any wrinkles.
6. Place the NPseal dressing pad over the insicional wound and seal. The dressing pad should cover the entire wound. Do not place adhesive over the incision (**Fig 2**). Carefully remove the second liner while smoothing out any wrinkles until the dressing is fully attached to the skin (**Fig 3**).

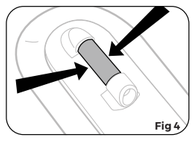
Fig 4

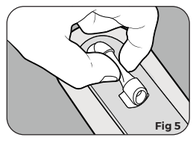
Fig 5

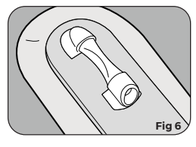
Fig 6

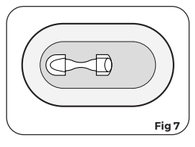
Fig 7

7. To activate the NPseal, pinch the middle of the pump (**Fig 4**) with your thumb and one finger (**Fig 5**). **DO NOT** pinch the ends of the pump.
8. Pinch about 12–15 times until the pump walls remain touching at the middle **(see Figs 6 & 7)**. **DO NOT** flatten the entire pinch area.
9. Check negative pressure operation: the NPseal is working properly if the pump walls remain touching at the middle **(see Figs 6 & 7)**.

   **TIP:** The pump walls can be assessed by visual inspection and/or touch.

## J. Maintaining the NPseal

The NPseal must be maintained every 8 hours according to these instructions:

1. Every eight hours, pinch the middle of the pump **(Fig 4)** with your thumb and one finger (**Fig 5**).
   **DO NOT** pinch the ends of the pump.
2. Pinch as needed, about 1-5 times, until the pump walls remain touching at the middle **(see Figs 6 & 7)**.
   **DO NOT** flatten the entire pinch area.
   **DO NOT** pinch the pump if there is any exudate (wound drainage) in the pump.
3. Check the negative pressure operation. The NPseal is working properly if the pump walls remain touching at the middle **(see Figs 6 & 7)**.
   **TIP:** The pump walls can be assessed by visual inspection and/or touch.

If the NPseal becomes soiled, clean and dry with a soft cloth. Avoid using chemicals or detergents.

**CAUTION: Do not immerse device in fluid. Showering is permissible, but avoid direct spray.**

## K. When to Replace the NPseal

The NPseal is intended for 6 days of use. A dressing change may be required sooner depending on the level of exudate or other patient considerations. The NPseal may be replaced only one time, by a healthcare professional, and therapy should be discontinued after a maximum of 6 days.

The NPseal should be inspected regularly.

1. If exudate (wound drainage) exceeds 50% saturation anywhere on the pad area, the system needs to be replaced.
2. If exudate (wound drainage) is inside of the pump, the system needs to be replaced.

The patient should contact a healthcare professional if the NPseal appears ready to be replaced per the figures below **(Figures 10 and 11)**.

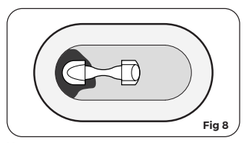
Fig 8
**Keep**

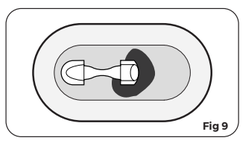
Fig 9
**Keep**

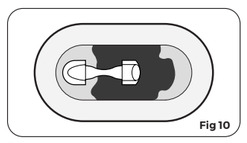
Fig 10
**Replace**

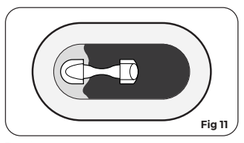
Fig 11
**Replace**

## L. Removal and Disposal

Gently remove the dressing and discard per institutional procedures for dressings and biowaste, if applicable. Patients should be instructed to discard as a normal bandage.

## M. Troubleshooting

| Problem | Possible Cause | Possible Solution |
|---|---|---|
| Pump does not remain in the collapsed state (**Fig. 6**). | Leak may be present at the seal. | - Smooth dressing with fingers to flatten wrinkles.<br>- Activate the system per the instructions above.<br>- If issue persists, consider replacing. |

## N. Symbol Legend

| | | | |
|---|---|---|---|
| 23°C | Store at ≤ 23 degrees Celsius | | Keep dry |
| | Single use | 2 STERILIZE | Do Not Resterilize |
| | Consult instructions for use | **Rx Only** | Prescription only |
| | Do not use if package is damaged | STERILE R | Sterilized using irradiation |
| | Keep away from sunlight | | |