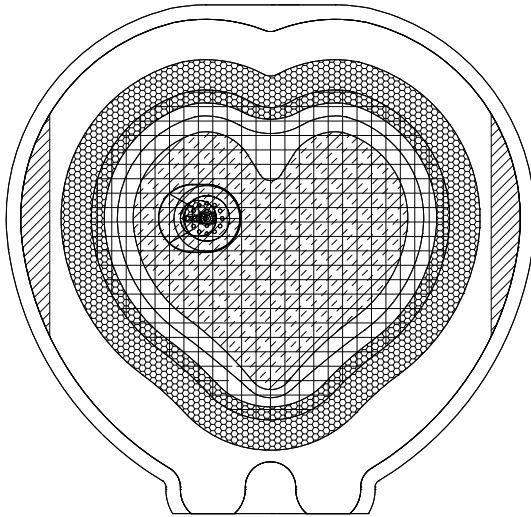
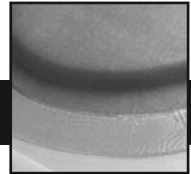
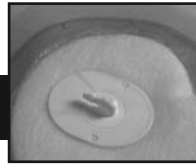
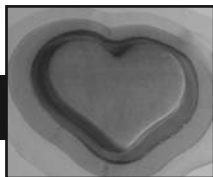


K a l y p t o M e d i c a l

NPD 1000™ Negative Pressure Wound Therapy



70cc Sacral Dressing APPLICATION GUIDE



70cc Sacral Dressing Size: 22.4 cm x 22 cm (8.6" x 8.7")

Wound Contact Area: 11 cm x 12 cm (4.5" x 4.6")

Kalypto
Medical

Dressing and System Components

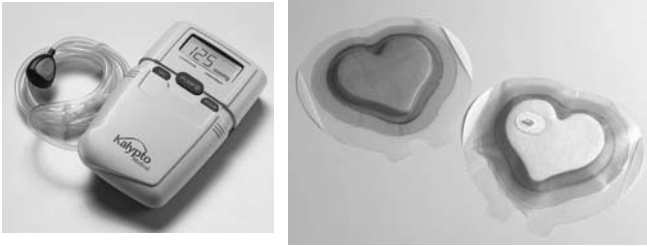


Fig. 1: Pump & Sacral Dressing

- 1- 70cc Sacral Dressing Size: 22.4 cm x 22 cm (8.6" x 8.7")
Wound Contact Area: 11 cm x 12 cm (4.5" x 4.6")
- 1- 18" pigtail dressing tubing
- 1- NPD 1000 Pump

The sacral dressing is a heart-shaped 22.4 cm x 22 cm dressing. It has an 11 cm x 12 cm Silverlon® minimally adherent wound contact layer, a non-woven absorbent pad, an integrated hydrogel gasket, and a transparent laminate adhesive cover.

The dressing's drainage capacity is 70cc. The 18" pigtail dressing tubing is supplied separately.

NOTE: For a list of indications for use and contraindications of the NPD 1000 NPWT system, please refer to instructions for use, shipped with every NPD 1000 device pump, P/N #50000. If a copy cannot be found, a pdf copy can be downloaded at www.kalyptomedical.com/technical.php, or contact Kalypto Medical by email: info@kalyptomedical.com or by phone 877.286.3740.

Introduction

This guide is intended to give a clinician/caregiver instruction on how to apply the Kalypto Medical 70cc Sacral dressing. This dressing is designed for ease of application and to accommodate a wide variety of wound sizes and shapes with no customization or alterations necessary.

Recommended Frequency of Dressing Change

The first 1-2 dressing changes should be made every 24-48 hours. After that time, the frequency can be adjusted depending on amount of drainage. It is recommended that the dressing be changed 2-3 times per week or when the dressing visibility is nearing saturation.

Wound Site Preparation for Dressing Application

Carefully inspect the wound and make sure no contraindications for NPWT are present (see the NPD 1000 System IFU for a complete list of contraindications). Proper handwashing and gloving practices should be followed to prevent infection and cross-contamination.

Careful preparation of the wound bed and the periwound skin is important to insure successful use of the Kalypto dressing system.

- 1) Prepare the wound bed for the application of the dressing per institutional protocol and standards of practice.
- 2) Clip any hair that will be under the dressing.
- 3) Cleanse the periwound skin & dry completely.
- 4) It is recommended to prep the periwound skin with alcohol and allow it to dry completely.
- 5) A skin prep may be applied to the periwound area per the clinicians discretion to protect the skin from drainage and the adhesive border.

Applying the Dressing

After removing the dressing from the sterile package, application of the dressing to the wound is as follows:

1. Fold the dressing in half and grasp firmly. Attach the pigtail tubing to the dressing.
2. Remove the inner release liners from the back of the dressing, exposing the adhesive & gel gasket. (Fig. 2)



Fig. 2: Removing the release liner

3. Carefully place the dressing over the wound, making sure the wound is within the edges of the absorbent pad. (Fig. 3). If there is depth to the wound, tuck the pad down into the wound so it interfaces with the wound bed.



Fig. 3: Placing the dressing

4. Make sure that the dressing is well seated over the wound and is well seated in the natal cleft/buttock crack without stretching the adhesive border. Stretched adhesives can lead to shear resulting in blistering and dermatitis of the periwound skin

6. Run your fingers along the gel gasket to establish the airtight seal with the skin (Fig. 4). If any wrinkles are present, pinch and push them down to help obtain a good seal.



Fig. 4: Creating gasket seal

7. Remove the outer release liners and without tension press the adhesive down to seal it to the skin (Fig. 5).



Fig. 5: Finish applying adhesive border

8. Attach pump tubing to the pigtail dressing tubing and turn on the pump. (Fig. 6)



Fig. 6: Vacuum Seal Established

Cleaning the Dressing During Wear

Due to the location of the sacral dressing and patient issues, such as fecal and urinary incontinence, the Kalypto Sacral dressing is designed to be cleaned. To clean the dressing, wipe it with a wash cloth moistened with warm water and mild soap, or use a pre-moistened incontinence wipe.

NOTE: Cleaning should not be done with excessive amounts of water, which may affect the adhesives holding the dressing in place. Using gentle pressure, wipe down the surface of the dressing, until clean. Be careful to avoid disrupting the gel gasket seal. After cleaning the dressing, wipe down a final time with a clean moist cloth to remove any soap or detergent. If during the cleaning process, the dressing develops an air leak, re-establish the vacuum by pressing down and working the gel gasket as done during initial application. If you are unable to re-establish a seal, apply a new dressing.


The Kalypto Sacral Dressing and the Ambulatory Patient



Some patients utilizing the sacral dressing will be ambulatory. These patients should be aware of the following:

- 1) If a leak develops during wear, re-establish the seal by running a finger along the gasket pressing it to the skin to re-establish the airtight seal. The dressing is designed to retain its "seal" during ambulation, but the patient does have to take precautions to help maintain the seal.
- 2) When changing undergarments, pajamas, etc. make sure to remove the garments carefully so as not to drag across the edges of the dressing & disrupt the seal.
- 3) Although the dressing is waterproof, it is recommended to avoid showering or bathing during wear to minimize the change of disrupting the seal. In the hour or two before the dressing change, turn off the pump, disconnect the pump from the dressing and bathe.

As with any negative pressure dressing, care should be taken to secure the pressure tubing between the dressing and the pump, such that it does not become a tripping hazard.

Troubleshooting

The dressing, once at pressure, should need relatively little attention. If the pump is signaling the presence of a pressure leak with the presence of an audible beeping and visual presence of a burst balloon () on the pump display (see NPD 1000 system IFU for further details on the leak alarm), the following steps should be followed:

1. Kink the tubing near the pump and wait two minutes. If the leak icon () does not disappear, the problem is in the pump and a new pump will be required.
2. Next kink the pigtail tubing near the dressing and wait two minutes. If the leak icon () does not disappear, the problem is in the pigtail connector and it should be replaced.
3. If the pump and the pigtail are fine, the problem is in the dressing seal. If the dressing is accessible, run your fingers along the gasket around the perimeter of the dressing, paying particular attention to any point where the dressing (gasket) is folded due to the anatomical location, i.e. the gluteal cleft. Additionally, make sure that the perimeter adhesives are adhering to the skin in mechanical support of the gel gasket. This reaffirming the seal and adhesives should eliminate the leak within a couple of minutes. If leak persists, it may be best to consider replacing the dressing.

Disposal of the Dressing

The NPD 1000 Negative Pressure Wound Dressing is not constructed with any hazardous materials. Thus, it may be disposed of in the normal medical waste stream for wound care dressing.

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CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

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