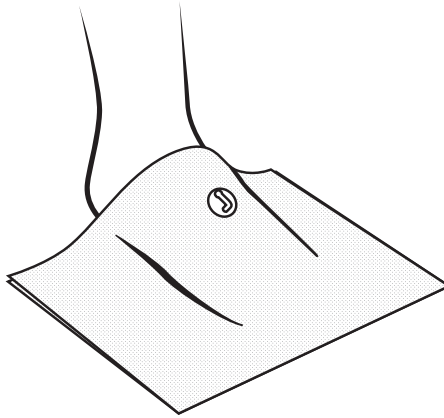


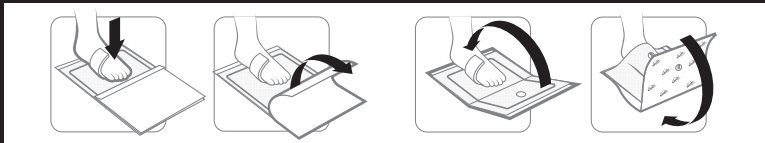
K a l y p t o M e d i c a l

NPD 1000™ Negative Pressure Wound Therapy



DRESSING APPLICATION GUIDE

Forefoot Dressing



Kalypto
Medical

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/50000, 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 Forefoot Dressing for use with the NPD 1000 NPWT System. Unlike other negative pressure wound therapy dressings used on the forefoot, this dressing is designed to accommodate a wide variety of wound sizes and shapes with no customization or alteration of the components. The caregiver applies the supplied wound contact materials to the wound, bridges to the pressure supply port on the top of the foot and encloses the foot in the envelope-like cover material. At this point, the pump is attached, air is removed from the dressing and the patient is ready to go.

Dressing and System Components



Fig. 1: Dressing Components & Pump

- 1- Large (12"x16") occlusive wound cover with pressure port and sealing gel gasket
- 1- Square 50 cc capacity absorbent pad with Silverlon cover
- 1- Long rectangular 50 cc capacity absorbent pad with Silverlon cover
- 1- pack of SteriStrips adhesive tapes
- 1- 6" pigtail pressure supply tubing
- 1- NPD 1000 NPWT Pump

Wound Site Preparation of the Foot for Dressing Application

Carefully inspect the wound and make sure no contraindications for NPWT are present (see the NPD 1000 System IFU P/N #50000 for a complete list of contraindications. If you do not have a copy, please see page 2 of this document for instructions to get one). In preparation for applying the dressing, make sure proper hand washing and gloving practices are followed to prevent infection and cross-contamination. Clean the wound bed according to the institution's protocol and standards of practice prior to application of the negative pressure dressing. To protect the peri-wound area (all skin that will be covered by the negative pressure dressing), care needs to be taken to adequately clean and dry this area. It is recommended that an alcohol-based cleaning product be used to prepare the peri-wound area, as this will effectively remove any remaining moisture. Make sure that any hair is clipped prior to the application of the dressing. A protective barrier wipe, such as Skin Prep[®], can be used to preserve the wound margins and prevent epithelial stripping. This will also insure that the proper adherence of the dressing to the site for the duration of wear.



Fig. 2

REMOVE THE DRESSING FROM THE PACKAGE

Remove the dressing occlusive cover and absorbent pads from the sterile packaging. The cover is folded in half and can be opened to serve as a sterile surface for the absorbent pads until they are needed. (Fig. 2)

MARK THE TOP OF THE FOOT



Fig. 3

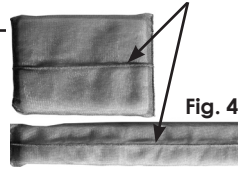
Using the occlusive cover, sandwich the foot between the two halves and mark the top of the foot at the approximate point at which the pressure port will land. (Fig. 3)



Applying the Dressing: Bottom of the Foot

Absorbent Pads First.

NOTE: Keep the absorbent pad's seam facing away from the wound/skin area. (Fig. 4)



1. Place the square absorbent pad over the wound (**seam away from wound**) and secure in place with sufficient (2 or 3) SteriStrips. Make sure the wound is completely covered by the pad. (Fig 5.)



2. Use the long rectangular pad to bridge from the wound to the top of the foot where the pressure port will be located. Again using SteriStrips, lay the long pad over the square pad and secure. Bring the other end of long strip over the side of the foot and secure on the top of the foot. (Fig. 6)

----- Skip to the Application of Occlusive Wound Cover -----

Applying the Dressing: Top of the Foot

Absorbent Pad First.

NOTE: Keep the absorbent pad's seam facing away from the wound/skin area. (See Fig. 4 at the top of the page for seams).



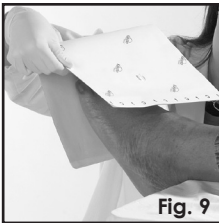
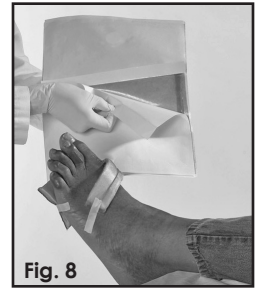
1. Place the square absorbent pad over the wound (**seam away from wound**) and secure in place with sufficient (2 or 3) SteriStrips. Make sure the wound is completely covered by the pad. Additionally, when the occlusive cover is folded over the foot, the pressure port needs to land on top of the absorbent pad. (Fig. 7)

----- Skip to the Application of Occlusive Wound Cover -----

Application of Occlusive Wound Cover

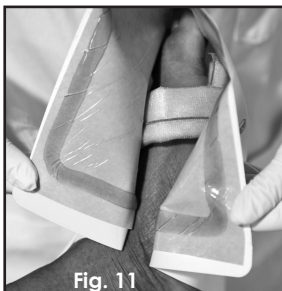
The occlusive wound cover is designed to encase the forefoot like an envelope, folding onto itself with the sealing gasket lining up on each adhesive face. If there is concern with moisture accumulation under the occlusive cover, particularly between the toes, precautions can be taken such as placing gauze between the toes to absorb moisture not absorbed by the pads.

1. Remove the release liner marked A exposing the adhesive layer and gel sealing gasket on half of the dressing. (Fig. 8)



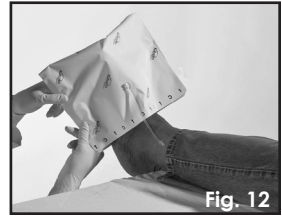
2. Line up the foot so that it is centered in the dressing and the great toe is $\frac{1}{2}$ " to 1" away from the center fold line of the sheet. **NOTE:** The bottom of the foot should contact the half of the sheet that does NOT have the plastic pressure port. (Fig. 9)

3. Carefully apply the dressing to the bottom of the foot so as to not disturb the absorbent pads. (Fig. 10)



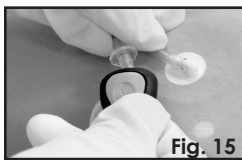
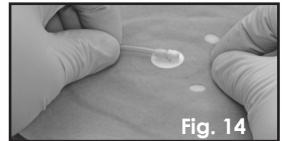
4. Remove the release liner (marked B) exposing the adhesive layer and gel sealing gasket on the other half of the dressing. Fold over the top half to the dressing making sure the plastic pressure port contacts the bridging absorbent pad and make sure that the gel gasket on the side of the dressing is meeting as the two halves come into contact. (Fig. 11)

6. Take care to apply the gel gasket to the top and bottom of the foot and match the gaskets together at the sides of the foot. (Fig. 12)



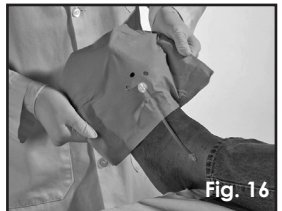
7. Carefully remove the backside release liner from the occlusive cover so as to not disturb the adhesive seals you have established. (Fig. 13)

8. Attach the pressure tubing pigtail to the plastic port. (Fig. 14)



9. Attach the pump to the pigtail and turn on the pump. It will take about 1 minute for the dressing to evacuate. (Fig. 15)

10. As the dressing crinkles up as the air is removed, the pump will stop briefly and may start again for a short time. Work your fingers along the gasket to create a better seal on the foot and gasket to gasket seal. The pump should stop when pressure is achieved. It should not turn on again for a few minutes. (Fig. 16)



What the dressing will look like if applied correctly. Notice the crinkled dressing. (Fig. 17)



Kalypto's NPD 1000 Forefoot Dressing with Adjunctive Therapies

Now that the dressing is pressurized, it must accommodate the footwear (shoe, off-loader boot, total contact cast) being used by the patient. The extra material to the sides of the foot can be wrapped under the foot using a sock or any medical wrap being used on the patient, such as compressive wraps. The dressing is designed to retain its "seal" during ambulation, so the patient does not have to use crutches or similar aides during use of the dressing.

As with any negative pressure dressing on the foot, care should be taken to secure the pressure tubing between the dressing and the pump, such that it does not become a tripping hazard. Running the tubing inside the patient's pants may take it out of the way.

Troubleshooting

The dressing, once at pressure, is designed to need relatively little attention. If the pump is signaling the presence of a pressure leak, 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 the clinician should be notified of the system situation/issue.
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 the clinician should be notified of the system situation/issue.
3. If the pump and the pigtail are fine, the problem is in the dressing seal. If the dressing is accessible (not wrapped in a total contact cast or other hard to remove wrap), run your fingers along the gasket on the sides of the dressing, paying particular attention to the point where the top and bottom of the cover meet at the sides of the feet. This reaffirming the seal should eliminate the leak within a couple of minutes. If this fails, the dressing is likely punctured and needs to be changed. Call your clinician and notify them of the situation/issue.

NOTE: if the dressing cannot be reached, detach the pump and call clinician for instructions

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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