

OxyBand™ Transdermal Oxygen Wound Care Device

OxyBand™ 4.5" x 5.5" Dressing

By the Box: #2804001-10 (Box of 10) - E1 # 1145140
By the Case: #2804001-40 (4 Boxes of 10) - E1 #1170742

SIZE: Outside dimensions: 4.5" x 5.5" (11.43 cm x 13.97 cm)
Reservoir dimensions: 3" x 4" (7.62 cm x 10.16 cm)

OxyBand™ is advanced wound* care that provides high levels of medical grade oxygen to wounds for up to 5 days**.

Two randomized controlled and one double blind clinical study have shown OxyBand™ significantly decreases the time to complete healing; significantly reduces pain without infections. OxyBand™ has been shown to elevate levels of dissolved oxygen (PO₂) for an extended period of time in full thickness porcine wounds. Case studies have shown use of OxyBand™ for 7 days depending upon size and metabolic characteristics of the ulcer***.

OxyBand™ is a multilayer wound dressing that keeps out water, dirt and germs, and supplies oxygen to the wound. It is designed to be applied directly over clean skin or wounds/ulcers for up to five days.

*For simplification wound will be used to describe both wounds and ulcers for this document.

**OxyBand™ provides sustained oxygen delivery to wounds over days. A study has shown that upon attaching OxyBand over a test plate, oxygen levels rise steadily over the device area for the first few hours and then maintain at elevated levels through 5 days as long as the OxyBand™ remains intact and secure around the perimeter. At 5 days OxyBand™ was shown to still have 65% oxygen. Air is 21% oxygen.

***OxyBand™ has been shown in case studies by independent, physicians to be used over 7



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Indications for Use

- OxyBand™ is intended to provide a moist wound environment.
- OxyBand™ can be used to cover and protect wounds and catheter sites or used as a secondary dressing for other wound products such as gauze, alginates, hydrogels, debridement facilitators, or a protective cover over at risk skin.
- Do not use ointment or petroleum products with OxyBand™.

The OxyBand™ Wound Dressings are indicated for:

- Clean closed surgical incisions, skin graft donor sites, pressure ulcers, pressure sores, abrasions, skin tears, and blisters, lacerations, burns, chafed skin, skin continuously exposed to moisture.
- OxyBand™ has been used successfully in Pressure Ulcers, Venous Insufficiency Ulcers, Arterial Ulcers, Mixed Vascular Ulcers, Diabetic Ulcers, compromised acute surgical wounds such as dehisced surgical wounds, compromised skin flaps and grafts, traumatic wounds, burns and chronic ulcers with compromised or delayed healing that are thought to be hypoxic
- Application of transdermal oxygen as a postoperative dressing can also be beneficial by mitigating potential post-operative complications.



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Precautions/Contradictions

- OxyBand™ Wound dressings are not to be used on dirty, contaminated, bleeding or infected wounds, or on puncture wounds.
- Consult your medical provider if you notice any itching, rash or burning, or signs of infection: fever, pain, redness, or swelling.
- The dressing should not be used in place of stitches or to hold wound edges together.
- Do not cut the dressing.
- Inappropriate use or too frequent dressing changes, particularly on patients with fragile skin, can result in skin stripping. As is common with all adhesive products, irritation and/or maceration of the skin surrounding the wound is possible.
- Do not use on children under two years of age.
- Do not use if scab is covering entire wound as scabs do not allow oxygen to reach the wound.
- Do not use ointments or salves under the dressing unless directed by your health care provider as it reduces the amount of oxygen reaching the wound.



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Directions for Use

1. Cleanse and dry wound and surrounding skin.
2. Remove the dressing from the sealed pouch.
3. Dressing must be used immediately upon removal from package.
4. Grasp one of the side tabs (along narrow edge of dressing) and use other hand to remove paper liner from backside of dressing, exposing the sticky surface.
5. Grasp the second tab (on the opposing narrow edge) so that the dressing is being held without touching the sticky surface.
NOTE: Do not remove the paper window frame that is attached to the top side of the dressing yet.
6. Using the tabs, position the dressing over the wound site, allowing for 1/2 inch of healthy skin on all sides of the wound. Gently apply pressure to the dressing perimeter which is still covered with the paper frame.
7. Once dressing is adhered to skin, grasp the slit edge of the paper frame and pull it away from the underlying film surface gently while pressing the edges down toward the skin.
8. Inspect the dressing daily for up to five days.
9. Refrain from frequent bandage changes.
10. Discard after one use.

Change Dressing if

- it begins to leak or is no longer sticking to skin anywhere around perimeter
- there are visible holes in dressing
- there are signs of infection such as fever, pain, redness, swelling, itching, rash or burning.

To Remove

- Grasp one edge of the dressing and slowly pull away from skin, pulling in the same direction of the hair growth.
- While removing the dressing, support the underlying skin with your finger to prevent stretching the skin.



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OxyBand™ Transdermal Oxygen Wound Dressing



PRODUCT INFORMATION

OxyBand Item # 2801001-10
 Size: 4.5" x 5.5"
 Pack of 10

OxyBand™ is the only 100% medical grade oxygen reservoir, wound dressing. No need for a generator, tank or pump. Oxygen is essential for wound healing and tissue repair.

FEATURES

Each package includes: 100% Medical Grade Oxygen Reservoir that target delivers high levels of oxygen to wounds for up to 5 days.

A perforated hydrocolloid wound contact layer and a foam wound contact layer are included for optimal customization.

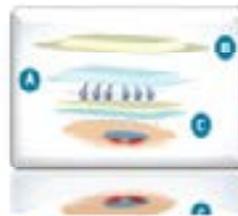


CONTACT

Oxyband Technologies Inc

Sales: 520.595.0551
orders@oxyband.com
 Fax: 914.219.0820
information@oxyband.com
www.oxyband.com

OxyBand has been shown in 2 RCT & 1 Double Blind clinical trial to significantly accelerate wound healing & significantly reduce pain without infection. OxyBand has been shown to raise & maintain pO₂ above 250 mm/hg. *Study references upon request.



- A. OxyBand™ provides medical grade oxygen directly from the patented reservoir system inside of the dressing for up to 5 days
- B. Occlusive outer layer provides barrier to oxygen escaping into the atmosphere and to outside contaminants
- C. Permeable membrane provides targeted diffusion of oxygen to the wound while hydrocolloid and/or Foam wound interface absorbs wound exudate

BENEFITS

- Provides oxygen to wounds directly from the patented reservoir system inside of the dressing
- Impermeable to outside contaminants
- Transparent for wound management
- Easy to apply
- Self-adherent & forms well around wound
- Gentle removal & low trauma to wound
- Sterile | No Latex | Wearable 24/7

APPLICATIONS

OxyBand™ wound dressings are intended to provide a moist, oxygen-rich environment to facilitate the normal wound healing process. OxyBand has been used by clinicians for:

- First & second degree burns
- Abrasions & skin tears
- Eruptions & insect bites
- Cleaned, closed surgical incisions
- Skin grafts and donor sites
- Stage I or II pressure ulcers & pressure sores
- Diabetic & chronic skin ulcers
- Cosmetic procedures

OxyBand FDA

OxyBand Wound Dressing™, FDA 510(k), K043053 is a multilayer wound dressing that keeps out water, dirt and germs, and supplies oxygen to the wound. It is designed to be applied directly over clean skin or wounds for up to 5 days. A study has shown that upon attaching the dressing over a test plate, oxygen levels rise steadily over the device area for the first few hours and then maintain at elevated levels through 5 days as long as the dressing remains intact and secure around the perimeter.



Manufactured by Lighthouse for the Blind, St. Louis, MO