

# OxyBand Overview

## Novel Healing Technology

### Introduction

Oxygen essential for life is also powerful for healing and required for every physiological process to grow and regenerate living tissue. OxyBand Technologies, Inc. has harnessed the power of oxygen and other therapeutic gases to develop powerful, effective healing and regenerative medical devices. 10 years of research and development has led to an extensive patent portfolio, 68 patents, 12 granted and 8 more issued to date, and for platforms and devices; FDA clearance. OxyBand has completed all of the research and development, patents, published peer reviewed randomized controlled clinical trials, FDA Clearance, GMP manufacturing and commercialization of OxyBand proprietary products with partners like, 3M and Lighthouse for the Blind. The Company's first line of products OxyBand Wound Dressing, the only Transdermal Oxygen Delivery System, is available for distribution to both military/government and civilian customers.

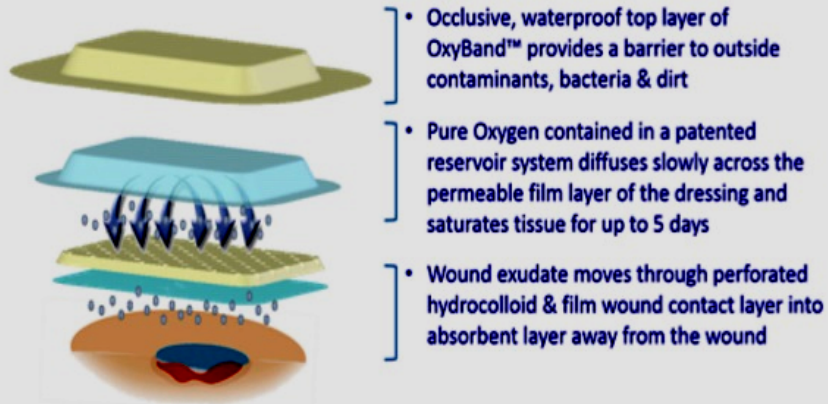
### The Technology

OxyBand wound dressing, provides sustained delivery of 100% oxygen for 5 days while the moisture management system absorbs exudate and the dressing is sterile and acts as a barrier to outside contaminants. OxyBand looks and feels like a transdermal patch or traditional wound dressing yet provides vital oxygen to wounds and tissue for faster healing and tissue regeneration.



## HOW DOES IT WORK

OxyBand is a multilayer wound dressing that keeps out water, dirt & germs, & supplies oxygen to the wound for up to 5 days while absorbing exudate. Oxygen has been shown to improve wound healing & OxyBand has been shown in clinical trials to significantly accelerated wound healing, decrease pain without infection. Acts similar to a transdermal patch with oxygen.



"Oxygen is itself regenerative. Cells in the presence of higher sustained oxygen regenerate. Wound healing is a regenerative process. The USAISR OxyBand Donor Site Study published results demonstrate the benefits of OxyBand in healing of autogenous donor sites which is regenerative healing. 100% healing in significantly less time than standard of care. The results demonstrate OxyBand is a regenerative device."

**Dr. Anthony Atala**, Director of the Wake Forest Institute of Regenerative Medicine & Director of the Armed Force Institute of Regenerative Medicine, Chairman of Urology Baptist Wake Forest Medical Center



## The Clinical Evidence

OxyBand is the only wound dressing proven to deliver therapeutic oxygen continuously from the dressing in a sterile environment for up to five days. Two RCTs and one Double Blind clinical trial, by preeminent military and civilian institutions and published in a peer reviewed journal, demonstrated OxyBand Wound Dressing heals wounds significantly faster (25% to 40%, with a range of 3-8 days) and reduces pain (3x less pain and inflammation with OxyBand) without any infection.

OxyBand has published, two randomized controlled (RCT) and one double blind clinical trial (RCDB). OxyBand has received government and Department of Defense support including two contracts and a prospective, randomized, controlled (RCT), clinical trial conducted by the preeminent, US Army Institute of Surgical Research (USAISR). The USAISR study is published and the results demonstrate significantly superior healing effect of OxyBand (25, 30 and 40% faster healing) in regenerating skin and tissue and reducing pain associated with large (7in x 9in) donor sites of wounded warriors without any infection. Speed of donor site healing for burn victims can be the difference between life and death. OxyBand Wound Dressing has received DAPA and FSS for the DOD and VA. In addition to RCT and RCDB trials, OxyBand has evidence from in vitro, in vivo and case studies of: reduction of dangerous pathogens such as *Acinetobacter baumannii*, *Pseudomonas*, and MRSA; significantly increased wound oxygen level over time (pO<sub>2</sub>), reduced scarring and complete closure of venous, diabetic and chronic chemical burn ulcers.

### Chronic Right Ankle Wound 2 Years Duration Following a Concrete Chemical Burn-Injury



Day 0 / Prior to OxyBand

Day 30 / OxyBand Therapy

Day 90 / Healed

Courtesy George Ellis, MD

## **The Role of OxyBand in Wound Healing**

- Chronic wounds are thought to fail to progress through the phases of healing in an orderly and timely fashion due to one or more defects in the healing cascade, including excessive bioburden, uncontrolled inflammation, the presence of stagnant or senescent cells, the lack of essential cytokines or metabolic factors, and inadequate tissue perfusion resulting in tissue hypoxia and deficient oxygen substrate.
- There is a scientific consensus oxygen improves wound healing, infection control and the rate of amputations from diabetic ulcers. Oxygen is necessary for regenerative medicine. Hyperbaric oxygen therapy is a widely accepted and reimbursed treatment for wounds. Nasal cannula oxygen is now utilized perioperatively to reduce infection.
- Oxygen is essential for maintaining cellular integrity, function, and repair when tissues are injured. Oxygen not only plays an important role in energy metabolism, but also is very important in polymorphonuclear cell function, neovascularization, fibroblast proliferation, and collagen deposition. Research in animals and humans has demonstrated the basic physiology of wound healing is oxygen dependent, and that several aspects of the healing process can be accelerated with oxygen. Additionally, research indicates the importance of oxygen to prevent infection and that low oxygen levels in wounds not only results in increased rates of infection, but impaired collagen deposition and reduced tensile strength.
- Meticulous wound bed preparation including aggressive debridement is paramount to achieving good clinical outcomes. Sharp debridement has been shown to stimulate the stagnant or stalled wound via the delivery of matrix substrate, cytokines, growth factors and mesenchymal stem cell pathways. Debridement will also remove necrotic tissue and decrease bacterial bioburden, encourage wound growth factor release and stimulate tissue perfusion and angiogenic pathways ultimately resulting in enhanced wound oxygenation. This illustrates that all basic wound care efforts are aimed at improving tissue perfusion and the delivery of oxygen.
- While improvement of the wound microenvironment immediately follows wound débridement, this effect may not be sustained long term, resulting in the need for repeated wound stimulation and débridement on a weekly/serial basis.

- Modalities that can extend or continue to provide improvement in the wound microenvironment are readily utilized by clinicians whenever possible (e.g. hyperbaric oxygen therapy, slow release antimicrobial dressings, enzymatic debriding agents).
- **OxyBand is a transdermal oxygen delivery device with the capability of enhancing the wound microenvironment via the sustained delivering of oxygen substrate** for an extended period of time (up to 5 days). This benefit is achieved with a single dressing application.
- The ability to improve tissue oxygenation in chronic wounds hastens healing. Oxygen enhances white cell bacterial killing and bioburden reduction, stimulates cellular metabolic activity, enhances angiogenesis and promotes fibroblast and epithelia cell proliferation.
- The utilization of **OxyBand has the potential to improve clinical outcomes in the management of all types of chronic wounds based on improvement in the wound microenvironment by providing sustained delivery of oxygen substrate.** OxyBand provides clinicians with an intuitively appropriate dressing that is synergistic with all basic wound care efforts via its ability to continue to maintain and enhance the wound base via oxygenation.

“OxyBand technology will revolutionize oxygen therapy in the management of chronic wounds. Using a novel delivery approach OxyBand provides transdermal oxygen, the key cellular metabolic substrate required for wound healing. The clinical studies validate the marked enhancement in healing observed patients with difficult to heal wounds.”

**Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS**  
President American College of Hyperbaric Medicine  
President & CMO of Web CME

