

# Masterclass GUIDES

## Topical Wound Oxygen (TWO<sub>2</sub>) Therapy: Advanced Oxygen Therapy Inc.

### Introduction

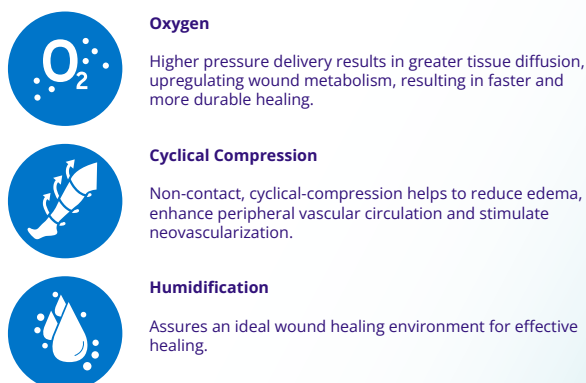
This Masterclass Guide is a concise overview aimed at exploring the use of Topical Wound Oxygen Therapy (TWO<sub>2</sub>) and incorporating this into your practice.

### What Is TWO<sub>2</sub> Therapy?

- TWO<sub>2</sub> is a unique multi-modality topical oxygen therapy that combines **Oxygen**, **Compression** and **Humidification** (Figure 1).
  - Most difficult to heal wounds have complicated etiologies resulting in an oxygen deficit in the wounded tissue. Furthermore, superior wound healing can only occur at oxygen levels greater than those delivered by a healthy blood supply (Figure 2).
  - The **TWO<sub>2</sub> therapy extremity system** (Figure 3) is comprised of three major components: A single use Extremity Chamber (Figure 3b), Controller (Figure 3a) and oxygen source.
- An oxygen flow rate of 10 LPM is used to cycle the therapy pressure between 10 and 50 mb directly at the wound site, within a sealed environment, providing an oxygen partial pressure diffusion gradient of close to 800 mmHg. The therapy offers the option of humidification with the goal of maintaining an ideal moisture balance for healing.
- This allows for the maximum penetration of oxygen into the wounded tissue. Simple on-screen step-by-step instructions provide easy direction for patients and caregivers to apply the therapy at home.<sup>12</sup>
- The **TWO<sub>2</sub> therapy Multi-Patch system** is comprised of two major components: A single use Multi-Patch chamber (Figure 3c) and an oxygen source.
- An oxygen flow rate of  $\approx 4$  LPM applied into the chamber delivers 30 mb of non-contact pressure directly to the wound site, within a sealed and humidified environment.

The resultant oxygen partial pressure diffusion gradient of about 800 mmHg provides for maximum penetration of oxygen into the wounded tissue, penetrating into tunneling wounds, thereby stimulating healing at the deepest point of injury.<sup>1,8</sup>

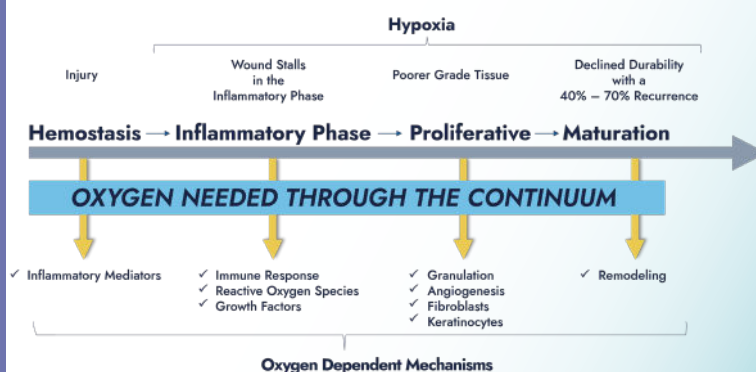
Figure 1: TWO<sub>2</sub> therapy has three component mechanisms:<sup>1,8</sup>



### Keywords

- Advanced Oxygen Therapy Inc.
- Regenerative healing
- Topical Oxygen Therapy
- Diabetic Foot Ulcers
- Wound repair
- Complex wounds
- Peripheral Artery Disease
- Edema

Figure 2: Role of Oxygen in Wound Healing



### How TWO<sub>2</sub> Therapy Works:

#### Click for mechanism of action

#### ■ Benefits of Supplemental Oxygen

TWO<sub>2</sub> provides the highest penetration of oxygen into the wounded tissue. The immediate availability of oxygen at a partial pressure of approximately 800 mmHg provides the greatest diffusion gradient into the tissue and supercharges cellular activity.

TWO<sub>2</sub> propels stalled, non-healing wounds into a robust healing pathway by addressing hypoxia. Increased oxygen levels upregulate enzyme production responsible for the immune response to fight infection, increase angiogenesis, stimulate better organized collagen deposition, and epithelialization. Collectively, this allows for a faster, more organized wound closure resulting in durable sustained healing.<sup>1</sup>

#### ■ Benefits of Cyclical Compression

The non-contact cyclical compression provided is between 10 mb and 50 mb pressure that is equivalent to a level 3 conventional compression dressing (CCD). This helps to reduce both edema and the hydrostatic pressure in the lower leg that is a frequent component of lower extremity peripheral vascular disease. The cyclical nature of the pressure delivery eliminates concerns when treating ischemic wounds.<sup>1</sup>

#### ■ Benefits of Humidification

A medical nebulizer delivers particulate humidity to the chamber to create an ideal moist wound healing environment.<sup>1</sup>

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### Acute and Chronic Wound Indications <sup>8</sup>

- Diabetic ulcers
- Pressure Ulcers
- Venous Leg Ulcers
- Infected Stumps
- Frostbite
- Skin grafts
- Post-Surgical Wounds
- Burn wounds
- Treatment of Acute and Chronic Wounds

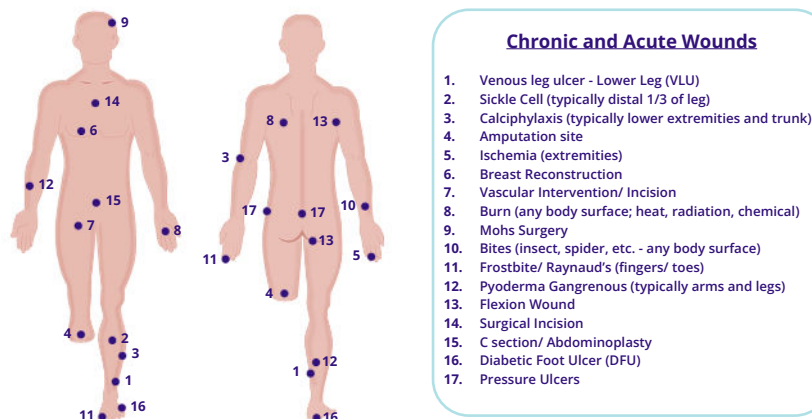
### Contraindications <sup>13</sup>

- Acute thrombophlebitis
- Deep vein thrombosis

Figure 3: 3a: Controller. 3b: Extremity Chamber. 3c: Multi-patch. <sup>8</sup>



Figure 4: Wound Sites and Types. TWO<sub>2</sub> therapy is indicated for any type of acute or chronic wound. <sup>8</sup>



#### What Is the Evidence?

Multimodality cyclical-pressure Topical Wound Oxygen (TWO<sub>2</sub>) therapy has been proven in multiple clinical studies to deliver faster, better quality, and more sustainable wound healing. TWO<sub>2</sub> is an especially effective adjunctive treatment modality for chronic non-healing and acute complex wounds. <sup>4</sup>

Recent high-quality double-blinded, randomized controlled trial (RCT) and real-world evidence (RWE) studies have demonstrated that TWO<sub>2</sub> therapy results in more durable healing and provides significant clinical, quality of life and cost saving benefits. <sup>2,4,9,10,11</sup>

#### Efficacy

- A study conducted in DFU patients found that TWO<sub>2</sub> was associated with "...significant reductions in hospitalizations and amputations in the real-world setting" over 12 months. <sup>2</sup>

The authors conclude: "...6.6% and 12.1% of TWO<sub>2</sub> patients had hospitalizations and amputations, respectively, compared with 54.1% and 41.4% of NO TWO<sub>2</sub> patients... representing 88% and 71% reductions. In matched cohorts 82% fewer TWO<sub>2</sub> patients were hospitalized... and 73% fewer TWO<sub>2</sub> patients had amputations... Logistic regression among matched cohorts demonstrated nearly ninefold and fivefold higher risk of hospitalization and amputation, respectively, for NO TWO<sub>2</sub> versus TWO<sub>2</sub>." <sup>2</sup>

- A robust double-blind placebo controlled RCT in DFU concluded that "...at both 12 weeks and 12 months, adjunctive cyclical pressurized TWO<sub>2</sub> therapy was superior in healing chronic DFUs compared with optimal SOC alone."

- "TWO<sub>2</sub> is prudent, effective, and valuable in managing VLU without the risks of full body hyperbaric chambers. The TWO<sub>2</sub> slashes the time needed for VLU healing and is successful in pain alleviation, MRSA elimination, and management." <sup>3</sup>

"TWO<sub>2</sub> radically degrades recurrence rates, thus providing an improved quality of life." <sup>3</sup>

#### Patient Comfort

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- In VLUs, TWO<sub>2</sub> is associated with significant reduction in pain. <sup>3</sup>
- Patients administer TWO<sub>2</sub> therapy at home while enjoying activities such as reading, watching television, or the like. <sup>5,8</sup>
- At-home therapy improves compliance and access to care helping to address health inequalities.

#### Costs

- In the healthcare system, patients with chronic diseases account for the vast majority of healthcare spending. By more durably healing those ulcers and lessening the reoccurrence, TWO<sub>2</sub> has a direct impact on health economics and cost savings. <sup>2,9,10,11,14</sup>
- As an at-home therapy, TWO<sub>2</sub> can help reduce costly hospital stays. <sup>2,9,10,11</sup>
- TWO<sub>2</sub> provides an easy to use and more cost-effective means of delivering oxygen to the wound. <sup>2,9,10,11</sup>
- Multiple studies state that it would be cost-effective compared to hyperbaric oxygen therapy. <sup>2,9,10,11</sup>
- In the United States, TWO<sub>2</sub> is reimbursed throughout the Veterans Administration and other government sectors under an awarded Worldwide Federal Supply Schedule Contract. Additionally, TWO<sub>2</sub> is also reimbursed by New York State Medicaid. <sup>5</sup>

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### Key Points <sup>4</sup>

- Unique multi-modality topical oxygen therapy that combines pressurized oxygen, non-contact cyclical compression and humidification
- 88% reduction in hospitalization over 12 months
- 71% reduction in amputations over 12 months
- 6x more effective in complete healing in 12 weeks
- 6x lower recurrence rates at 12 months
- Well tolerated by patients, not associated with discomfort or pain
- Supported by the highest level scientific studies

*"We believe that in this rather robust double-blinded RCT we have clearly demonstrated the positive effects of cyclical, pressurized topical oxygen therapy in the healing of chronic diabetic foot ulcers. Accordingly, we now have the evidence required to recommend the use of this therapy as an adjunct to good standard care for the management of difficult-to-heal diabetic foot ulcers."*<sup>7</sup>

*"Mainstay of my practice...most superior system." Dr. Guberman, Podiatric Surgeon <sup>6</sup>*

*"Remarkable results" Dr. Hingorani, Vascular Surgeon <sup>6</sup>*

*"It's a Win/Win... All the way around" Cathy Smith, CWON, FNP-BC, FPA-APRN <sup>6</sup>*

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