Overview - TransCu O_2™ Device & Continuous Diffusion of Oxygen Therapy

The TransCu O_2™ device is a unique, non-invasive, tissue oxygenation system intended for use with lower-cost moist wound therapy dressings for the treatment of diabetic foot ulcers, venous leg ulcers, pressure ulcers and other skin wounds through Continuous Diffusion of Oxygen therapy. The goal of this therapy is to continuously supply pure oxygen at a low flow rate to an oxygen-compromised wound to aid in wound healing while maintaining a moist wound healing environment, maintaining patient mobility and significantly reducing costs.

Current moist wound therapies use a moisture absorbent dressing below an occlusive dressing to keep the wound moist and manage wound drainage while controlling bioburden. These dressings are frequently used on patients who have impaired blood flow, and thus impaired oxygen supply, to the wound. Dressings significantly reduce the amount of available oxygen to the damaged tissue from air at 21% to as little as 4% or less, which can further hinder the oxygen-compromised wound's ability to heal. Oxygen is essential to wound healing and is considered a critical rate-limiting factor in wound repair. Damaged tissue triggers an increase in the body's demand for oxygen; chronic wounds have an inability to heal if the increase in the body's demand for oxygen is not met.

The TransCu O_2™ device uses fuel-cell technology as an electrochemical oxygen concentrator to create pure oxygen at low flow rates of 3-10 ml/hr. The oxygen is delivered to the wound through tubing under the dressings. This creates an oxygen-rich environment for enhanced healing while maintaining a moist wound environment. Preclinical and clinical results have exceeded expectations. The TransCu O_2™ device is silent, lightweight (nine ounces), handheld, rechargeable and provides continuous treatment. The TransCu O_2™ device also incorporates continuous monitoring of oxygen flow rates and pressures to ensure efficacious delivery of the oxygen.

Pure oxygen has the ability to affect multiple molecular targets and cell types, resulting in an overall improvement of cellular functions, which together result in stimulating tissue repair. Oxygen has been reported to increase fibroblast migration and replication[1], increase the rate of collagen production and tensile strength of collagen fibers[2], stimulate angiogenesis[1], promote macrophage chemotaxis[3], and enhance the antibacterial activities of leukocytes, including phagocytic function[4], thereby increasing the removal of cell debris and promoting physiological wound debrisment. Continuous Diffusion of Oxygen therapy using the TransCu O_2™ device can result in approximately a five-fold higher steady-state level of oxygen over that in normal air, resulting in tissue oxygen concentrations in the range for optimal cell function for wound repair. A separate paper on the role of oxygen in wound repair is available[5].

The TransCu O_2™ device received 510(k) clearance from the FDA in August of 2009 (K090681). In support of the 510(k), a preclinical study was conducted to show that Continuous Diffusion of Oxygen "accelerated" both wound closure and re-epithelialization of full-thickness wounds in diabetic mice[6] compared to advanced moist wound therapy alone. Continuous Diffusion of Oxygen was shown to have the following statistically significant advantages compared to moist wound

therapy dressings alone: 130% increase in complete reepithelialization, 64% decrease in the mean epithelial gaps, and a 33% increase in wound-closure rates. Histological evaluation revealed denser collagen in oxygen treated wounds, which furthermore had a more organized appearance, indicating that wound remodeling was significantly more advanced in oxygen-treated wounds. Our findings are in line with a significant body of experimental data suggesting that increasing oxygen supply to diabetic wounds improves wound healing, both in animal models and for patients.

Other approaches to increase wound oxygen levels use short exposures to hyperbaric systemic oxygen or topical high oxygen flow rates applied to entire extremities. Our data suggest that neither high-pressure nor high flow-rates are required for oxygen to improve wound healing. Rather, improving local oxygen supply through Continuous Diffusion of Oxygen into a moist wound bed, and thus increasing the oxygen concentration directly over the site of injury, significantly improves tissue healing while simultaneously allowing for full patient mobility.

Hundreds of patients have been successfully treated with the TransCu O_2™ device. The vast majority of these patients were non-responsive to competitive advanced wound care technologies such as hyperbaric oxygen therapy, advanced wound dressings or negative pressure wound therapy. For the most recent information on current clinical success rates and ongoing clinical trials, please contact customer service at:

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