

## **Curative™ Wound Dressing: Frequently Asked Questions**

### **Q: What is Curative?**

**A:** Curative™ is an oxygen foamed wound dressing emulsion, delivered using a disposable dental tray, and specifically designed to support the natural exchange of gases (oxygen and carbon dioxide) between the healing tissues and the environment. This gas exchange is essential to proper wound healing as well as reducing patient pain as demonstrated in peer reviewed literature.<sup>i,ii,iii,iv,v</sup>

### **Q: What is Curative indicated for?**

**A:** Curative is intended to act as a temporary physical barrier, provide moisture and lubrication, and assist the natural process of wound healing for wounds and/or inflamed mucosal tissues of the maxillary (upper) and mandibular (lower) dental arches.

### **Q: How is Curative used?**

**A:** Curative helps clinicians manage intraoral wounds by assisting in the process of acute and chronic wound healing. A small amount of emulsion is dispensed into a disposable tray aligned with the injured area and the tray is inserted for 30 minutes to 2 hours. The oxygen dissolved in the emulsion expands the emulsion ensuring good contact with the injured tissues.

### **Q: What types of procedures has Curative been used in support of?**

**A:** Clinicians have reported excellent healing results using Curative as a barrier following both non-surgical procedures that produce periodontal tissue injury such as; scale and root planing (SRP), and laser based pocket decontamination and tissue augmentations, as well as surgical procedures such as; bone grafts, implant placement, tooth extractions, gingival grafts (flaps and gingivectomy), crown lengthening, and palatal fistula repair. Detailed case reports on Curative use can be found at [www.oro-science.com](http://www.oro-science.com).

### **Q: What are the clinical results?**

**A:** At one week post-op clinicians are generally reporting well vascularized tissues in an advanced state of healing, and that their patients are complaining less than normal about pain. In a third party controlled double blind animal study, that evaluated wound healing for both surgical and burn injuries, the Curative treated animals healed in roughly 60% the time of non-treated animals with a  $p < .001$ .<sup>vi</sup> They also saw up regulation of vascular endothelial growth factor (VEGF), collagens I and III, and matrix metalloproteinase levels.<sup>vii</sup>

### **Q: How does Curative work as a barrier to protect injured periodontal tissues?**

**A:** The emulsion coats the injured area forming a physical barrier while allowing for the natural exchange of gases between the tissues, the emulsion and the environment. The tray provides an additional physical barrier over the injury that patients have indicated helps them keep their tongue from “playing” with or “sucking on” the injury.

**Q: Why is the natural exchange of gases important for proper wound healing?**

**A:** Peer reviewed literature associates the lack of sufficient oxygen (hypoxia) with pain in the wound area, with the prevalence of hypoxia being more pronounced in patients who are smokers and diabetics. These populations demonstrate slower wound healing and increased risk of wound healing complications compared to healthy patients.<sup>ii, iii, iv</sup>

**Q: What are the roles of O2 in wound healing?**

**A:** Published literature demonstrates that oxygen at the wound site promotes wound healing by stimulating several critical wound healing processes, including:

- Neovascularization<sup>viii, ix</sup>
- Collagen production<sup>x, xi, xii</sup>
- Epithelialization<sup>xiii</sup>
- Phagocytosis (engulfing of microorganisms, cells, or debris by macrophages or neutrophils)<sup>xiv</sup>
- Neutrophil-mediated oxidative microbial killing<sup>xv</sup>
- Degradation of necrotic wound tissue<sup>xvi</sup>

**Q: What is Curative made of?**

**A:** The emulsion is made of perfluorodecalin, water, plant derived emulsifiers and a preservative. Perfluorodecalin is a biologically inert liquid capable of dissolving and exchanging oxygen with the environment.<sup>xvii</sup> The emulsifiers surround small droplets of the perfluorodecalin creating a uniform and stable product that has the consistency of thick whipped cream. The preservative is Nipaguard MPA, a highly effective and commonly used preservative.

**Q: How do you know Curative is safe?**

**A:** Biocompatibility, sensitization and oral toxicity testing as well as animal and human clinical evaluations have all been performed and the product found to be safe for its intended use.

**Q: Does use of Curative cause or effect patient pain?**

**A:** Intermittent and slight tingling or stinging may occur at the injury site during the first 24 hours of Curative use, however, in the majority of cases patients say they find the product soothing and experience little pain from the injury. Patients should be instructed to discontinue treatment and contact their dentist or health care professional if inflammation of the dental arch / gum persists or the wound does not heal after 10 days of Curative use.

**Q: Are there any contraindications or important warnings for Curative?**

**A:** The product should not be used in patients with known allergies to any of the ingredients. The product hasn't been evaluated in pregnant women, so do not use the product if the patient is pregnant or trying to become pregnant. A full list of ingredients, contraindications, warnings, and precautions is included in the Directions for Use, and are available on the product kit packaging and at [www.oro-science.com](http://www.oro-science.com).

**Q: Does Curative cause any discoloration of the patient's teeth or tissues? Is there any kind of colored residue left behind after product use?**

**A:** The product is white and does not cause any discoloration to the teeth or gums. There is no colored residue that might "stick to the tissues" and result in discoloration or appear as a residue. Once the tray is removed, the patient should spit out any material that remains and may gently rinse with water unless otherwise instructed by their clinician.

**Q: Are there "sizes" to the trays? or will the tray "mechanically" injure the sutures or tissues?**

**A:** The disposable trays universally fit both the upper and lower dental arches. The trays are made from a very soft, flexible and compressible foam, and the emulsion also acts as a lubricant between the tray and sutures and/or injured tissues further reducing risk of irritation or injury to either the sutures or tissues.

**Q: How many patients can be treated with a Curative kit?**

**A:** Each kit is designed to fully treat one patient. Each kit contains 30 disposable dental trays, a 1oz can of emulsion, and multi-language Directions for Use. The recommended use is 3x daily for 30 minutes up to 2 hours, for 10 days.

<sup>i</sup> M. Stucker et. al. The cutaneous uptake of atmospheric oxygen contributes significantly to the oxygen supply of human dermis and epidermis. *Journal of Physiology* (2002), 538.3, pp. 985-994.

<sup>ii</sup> Silverstein, P. "Smoking and wound healing. *Am. J. Med.*, 1992;93 (Suppl 1A):22S-24S.

<sup>iii</sup> Carrico TJ, Mehrhof AI, Cohen IK. "Biology of wound healing." *Surg Clinics of North America*. 1984;64(94):721-733.

<sup>iv</sup> Cruse PJE, Foord R. "A five-year prospective study of 23,649 surgical wounds." *Arch Surg*. 1973;107:206-210.

<sup>v</sup> World Union of Wound Healing Societies. Principles of best practice: Minimising pain at wound dressing-related procedures. A consensus document. London: MEP Ltd, 2004. Available from URL: <http://www.wuwhs.org>.

<sup>vi</sup> Partial thickness wounds evaluated starting day 3 (P < 0.001, days 4-7). 2nd degree burns evaluated starting day 7 (P < 0.001, days 7-11, P < .01 day 12).

<sup>vii</sup> Accelerated Wound Healing in Animals; Davis SC, Cazzaniga AL, et al. Topical oxygen emulsion. *Arch Dermatol*. Oct 2007; 143(10):1252-1256.

<sup>viii</sup> Meltzer T, Myers B. The effect of hyperbaric oxygen on the bursting strength and the rate of vascularization of skin wounds in the rat. *Am Surg*. 1986;52(12): 659-662.

<sup>ix</sup> Knighton DR, Silver IA, Hunt TK. Regulation of wound-healing angiogenesis. *Surgery*. 1981;90(2):262-270.

<sup>x</sup> Niinikoski J. Effect of oxygen supply on wound healing and formation of experimental granulation tissue. *Acta Physiol Scand Suppl*. 1969;334:1-72.

<sup>xi</sup> Hunt TK, Pai MP. The effect of varying ambient oxygen tensions on wound metabolism and collagen synthesis. *Surg Gynecol Obstet*. 1972;135(4):561-567.

<sup>xii</sup> Hsu RW, Hsu WH, Tai CL, Lee KF. Effect of hyperbaric oxygen therapy on patellar tendinopathy in a rabbit model. *J Trauma*. 2004;57(5):1060-1064.

<sup>xiii</sup> Kindwall, Eric P; Whelan, Harry T (2004). *Hyperbaric Medicine Practice*, 2nd Edition Revised (Flagstaff, AZ: Best Publishing Company), 184-185.

<sup>xiv</sup> Hohn DC, MacKay RD, Halliday B, Hunt TK. The effect of O<sub>2</sub> *Surg Forum*. 1976; 27(62):18-20.

<sup>xv</sup> Mader JT, Brown GL, Guckian JC, Reinartz JA. A mechanism for the amelioration by hyperbaric oxygen of experimental staphylococcal osteomyelitis in rabbits. *J Infect Dis*. 1980;142(6):915-922.

<sup>xvi</sup> Dalton SJ, Whiting CV, Bailey JR, Mitchell DC, Tarlton JF. Mechanism of chronic skin ulceration linking lactate, transforming growth factor-beta, vascular endothelial growth factor, collagen remodeling, collagen stability, and defective angiogenesis. *J Invest Dermatol*. 2007;127(4):958-968.

<sup>xvii</sup> Perfluorodecalin phase of Periogenix dissolves approx. 16x more O<sub>2</sub> and 3x more CO<sub>2</sub> than water (49 ml O<sub>2</sub>/100 ml and roughly 140 ml CO<sub>2</sub>/100 ml). *Chemtech* Volume 29, No. 10, 7-12. (Table 1: Physical properties of water and some fluorocarbon liquids).