

## Clinical Data

### blue<sup>®</sup>m oxygen technology

Protection for natural teeth and implants. Accelerating wound healing, implant integration and bone regeneration in a safe, effective and non-invasive approach.

- Works instantaneously
- Anti-bacterial activities<sup>40</sup>
- No resistance developed
- No side effects
- Easy applicable in practice (various directions, see annex<sup>abc</sup>)

### Wound healing

Wound healing requires a variety of cells to increase their metabolic activity, resulting in a high oxygen demand<sup>1</sup>. Oxygen at the wound site has been shown to promote wound healing by stimulating several processes, including;

- Neovascularization<sup>2</sup>
- Collagen production<sup>3,4,5</sup>
- Epithelialisation<sup>1</sup>
- Phagocytosis (engulfing of microorganisms, cells, or debris by macrophages or neutrophils)<sup>6,7</sup>
- Neutrophil-mediated oxidative microbial killing<sup>7</sup>
- Degradation of necrotic wound tissue<sup>8</sup>

Lack of sufficient oxygen (hypoxia) has been associated 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>9,10,11</sup>

### blue<sup>®</sup>m mechanism of action

blue<sup>®</sup>m is using a mechanism to deliver active oxygen (H<sub>2</sub>O<sub>2</sub>) in a controlled manner directly to the treatment site. In contact with saline Sodium perborate is converted into sodium borate and H<sub>2</sub>O<sub>2</sub>. In low concentrations of 0.003%- 0.015%, hydrogen peroxide has a desinfectant<sup>8</sup> action, and occurs, together with the antibacterial ROS (reactive oxygen species) during the respiratory burst of neutrophils in normal wound fluid<sup>12,13</sup> and has a chemotactic effect on leucocytes<sup>14</sup>. The concentrations of hydrogen peroxide in the blue<sup>®</sup>m products used are not comparable to the high concentrations (1.5 – 3%) of hydrogen peroxide used in medicine as a disinfectant. It is known that the production of free radicals then causes damage to the wound<sup>7,12</sup>. Research has shown that the continuous presence of a low concentration of hydrogen peroxide kills pathogenic bacteria much more effectively than a one-off high concentration<sup>15</sup> and that fibroblasts are not damaged by this<sup>16</sup>.

### Active ingredients

- Accelerated tissue remodeling: Sodium Perborate<sup>19</sup>

Application of blue<sup>®</sup>m (oral gel) to injured tissues accelerates wound healing. Tissue oxygenation at peri-implantitis sites was significantly decreased ( $p < 0.05$ ) when compared with that at healthy sites<sup>18</sup>.

- Plaque control: Sodium Perborate<sup>21,22</sup> Honey<sup>20,23</sup> and Xylitol<sup>25,26</sup>  
Oxygen molecules (O<sub>2</sub>) can penetrate much deeper into the biofilm to kill the anaerobic bacteria than the Chlorhexidine (C<sub>22</sub>H<sub>30</sub>Cl<sub>2</sub>N<sub>10</sub>) molecule.  
Oxygen molecule (O<sub>2</sub>) can penetrate much deeper into the perimucosal seal around the implant.
- Antiseptic: Methyl Salicylate<sup>38,39</sup>  
Methyl Salicylate has an antiseptic effect and there is some thought that methyl salicylate may have an anti-inflammatory effect as well.
- Bone growth accelerator: Lactoferrin<sup>27,28</sup>  
Lactoferrin potently stimulates the proliferation and differentiation of primary osteoblasts.

### Relative Dentin Abrasion (RDA ~45)<sup>33</sup>

blue<sup>®</sup>m toothpaste has a neutral pH value and contains no scouring ingredients. Therefore no damage can be caused to the surfaces of teeth or implants.

### Fluoride

blue<sup>®</sup>m products are fluoride-free\*. Fluoride impairs the corrosion<sup>29,30,31,32</sup> resistance of the titanium implants. Due to the corrosion microscopic particles of titanium can be found in the surrounding tissue, which may have a negative impact on the devices, as this can potentially be pro-inflammatory.

\* blue<sup>®</sup>m introduced on request of various dentists a toothpaste containing calcium fluoride for patients without implants.

### Treatment indications

- Acute wound healing after implant placement or extraction
- Gingivitis<sup>35</sup>
- Periodontitis<sup>34</sup>
- Peri-implant mucositis
- Peri-implantitis<sup>34</sup>

For all indications see annex<sup>d</sup> 'Indications and blue<sup>®</sup>m solutions overview'.

### Different concentrations of slow oxygen release (O<sub>2</sub>/L)

- toothpaste: +/- 20 mg
- mouthwash: +/- 20 mg
- oral gel: +/- 100 mg
- oral foam: +/- 20 mg
- oxygen fluid: +/- 40 mg
- mouth spray: +/- 20 mg

## Literature

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## Annex

- a. Tooth Directive
- b. Directive Implantology
- c. Directive Endodontology
- d. Indications and blue<sup>®</sup>m solutions overview