Targeted Remineralization Treatment Using Mineral Loaded Starch Nanoparticles



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Clinical Need

Dental caries is the most prevalent chronic disease worldwide. The unmet clinical need is noninvasive treatment through subsurface remineralization of enamel, as current fluoride toothpastes & varnishes incompletely repair caries lesions. Our professional–use products treat both dental hypersensitivity and early–stage caries, to reduce discomfort, preserve precious enamel and improve oral health.

Solution

We produce tiny positively charged, mineral-loaded starch particles, to target and release inside negatively charged tooth subsurfaces. In-situ degradation forms hydroxyapatite crystals, occluding dentinal tubules and enamel porosities. Our products, CrystLCare™ Biorestorative, Fluoride-Free and Fluoride-Plus, are easy-to-use dissolvable dental strips, 14 single-use doses in a Fliptop Pack which release the targeted particles when placed in contact with teeth.

Competitive Advantage

Current fluoride products merely seal the extreme upper surface layer of enamel lesions, but targeting the subsurface enables effective non-surgical treatment of early-stage caries as well as sensitivity relief. Localized delivery of minerals and fluoride facilitates tooth structure regeneration through formation of apatite crystals, yielding superior treatment outcomes compared to currently available products.

Foundational Publications & Patents

- Jones et al. Targeted Enamel Remineralization with Mineral-Loaded Starch Particles. JADA Foundational Science, 2024 (accepted)
- Jones et al. Nanoparticle-based targeting and detection of microcavities. Adv Healthc Mater 2017
- Amaechi et al. Evaluation of a Novel Caries Detecting Oral Rinse. <u>BDJ Open 2023</u>
- <u>US10,987,434</u> Detection and Treatment of Caries and Microcavities with Nanoparticles

Achievements

- CrystLCare™ Biorestorative, Fluoride-Free product, a Class I Medical Device now being sold
- Established partnerships for co-branded product launches with 100,000-dose order from each partner
- CrystLCare[™] Biorestorative, Fluoride-PLUS product submitted as a 510(k) Class II Medical Device for dental hypersensitivity indication in April 2024

Regulatory Pathway

- class I registration (Fluoride-free product)
- 510(k) class II (dentinal hypersensitivity)
- OTC Fluoride anti-caries drug monograph
- de novo application (remineralization/ regeneration)

Opportunities for Partnerships

- Seeking strategic partnership with global dental supply company and/or distributors
- Raising \$4+ million Series A equity investment round