

Vital-Dent, A Revitalizing Root Canal Implant

Clinical Need

Dentist in the USA perform approximately five million procedures per year to treat pulpitis in the pediatric population (5-19 years old). Children are subject to multiple procedures attempting to conserve their permanent immature teeth because most therapies are not regenerative, suffering tooth discoloration, loss of tooth structure, and limited (if any) tooth growth. Definitive treatment is often postponed until the child's growth stops. Therefore, dentists, parents, and insurers desire a commercial product to treat irreversible pulpitis and improve the outcomes of current pulp therapies in children.

Solution

Vital-Dent is an acellular, drug-free, off-the-shelf implantable device to regenerate tooth pulp and maintain vitality of immature permanent teeth treated with endodontic therapies (a.k.a. root canal treatment, RCT). It is a colorless hydrogel supplied as powder in a syringe kit. The dentist rehydrates Vital-Dent with saline in the kit. They then apply the hydrogel into the instrumented canal space as they would conventional canal obturation. The hydrogel set in three minutes with a dental curing lamp and the tooth is sealed with a bioceramic. Restoration follows conventional methods.

Competitive Advantage

Unlike commercially available materials, Vital-Dent is resorbable and promotes continued tooth development, pulp and dentin regeneration, root strengthening, and long-term survival of the tooth. The only regenerative therapy (revascularization) fills the instrumented tooth with a blood clot or other autologous blood product, but is more difficult to implement and has variable outcomes with no definitive implant material. Vital-Dent better fits conventional clinic workflows and yields better outcomes with less canal calcification.

ITP Support

We have planned a product portfolio in regenerative endodontics, a marketplace estimated at \$3B with no leader. With help from the Market Assessment Core, we defined the indication for market entry as pulpectomy of irreversible pulpitis in 10-15 year olds. We filed patent applications with IP analysis with the IP/ Commercialization Core. We froze the device composition and completed a large-scale demonstration of safety and efficacy in a dog model of pulpectomies with the Regulatory Core. We identified a regulatory path with and are working on an FDA request for designation. We established relationships with VC firms and dental suppliers, all advancing commercialization.

Clinical Translation Pathway

Publications: Zaky et al. Effect of the Periapical "Inflammatory Plug" on Dental Pulp Regeneration: A Histologic In Vivo Study. [J Endod 2020](#)

Vieira et al. Pediatric Endodontic Treatment of Adolescent Patients. [Dent Clin North Am 2021](#)

IP: PCT/US2019/023132 Regeneration of Vital Tooth Pulp

Anticipated regulatory pathway: Class II device

Anticipated commercialization strategy: Plan formation of a start-up company

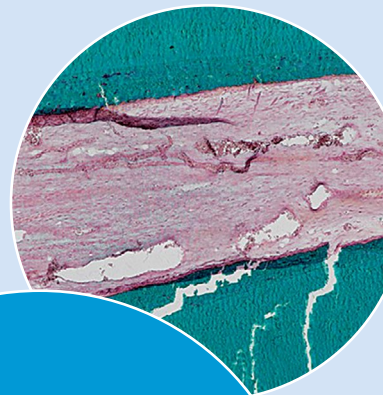
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“...so we are trying to do whatever is possible to save the tooth first”

– Parent of a patient seeking Vital-Dent



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