

# VITAL-DENT, A REVITALIZING ROOT CANAL IMPLANT



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**Clinical Need** – Approximately 5 million procedures are performed in the USA each year to treat pulpitis of permanent teeth in the pediatric population. Children are often subject to multiple procedures, because the standard of care is to stabilize the tooth until more definitive treatment can be performed when the child’s growth stops. The outcomes are unideal, because the whole tooth is not revitalized after pulp removal, resulting in tooth discoloration, loss of tooth structure, and limited (if any) tooth growth.

**Solution** – Vital-Dent is an acellular, resorbable hydrogel scaffold intended for revitalization of pulp and maintenance of tooth vitality in immature permanent teeth treated with endodontic therapies. It is supplied as a powder in a single-use kit with sterile saline. The powder is rehydrated at the chairside using kit tools to make a clear liquid. The liquid is inserted into the instrumented canal space as would conventional sealers, and set in three minutes with a dental curing lamp to form the colorless Vital-Dent hydrogel. The tooth is then sealed with a bioceramic and restored with conventional techniques.

**Competitive Advantage** – Unlike current obturating materials, Vital-Dent is resorbable and promotes continued development of immature teeth, pulp revitalization and regenerative dentin, root strengthening, and long-term survival of the tooth. Vital-Dent eliminates difficulties of the only available revitalization procedure, revascularization therapy, with more consistent outcomes including root development, and a better fit with conventional clinic workflows.

**ITP Support** – With help from the Market Assessment Core, user needs and the indication for market entry were defined. With ITP funding, the device composition was frozen and efficacy in a dog model of pulpectomies demonstrated. In collaboration with the Regulatory Core, our regulatory strategy was defined and the design control processes implemented. Commercialization plans are in development with support from the Innovation Institute at the University of Pittsburgh and the Commercialization Core.

## FOUNDATIONAL PUBLICATION

Zaky et al. Effect of the Periapical “Inflammatory Plug” on Dental Pulp Regeneration: A Histologic In Vivo Study. J Endod 2020

## INTELLECTUAL PROPERTY

PCT/US2019/023132 Regeneration of Vital Tooth Pulp

## ANTICIPATED REGULATORY PATHWAY

510(k)

## ANTICIPATED COMMERCIALIZATION STRATEGY

Plan formation of a start-up company

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