

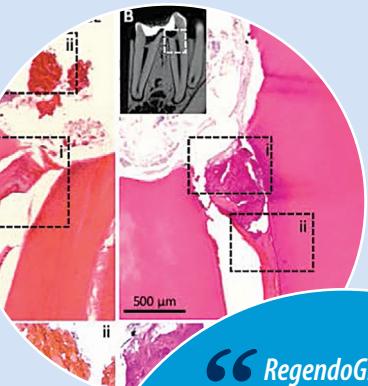
# RegendoGEL: A Bioinspired Hydrogel System for Endodontic Therapy



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**“ RegendoGEL is a first-in-kind regenerative biomaterial for vital pulp therapy, which contains natural tooth derived bioactive molecules that promote vital pulp and dentin regeneration. RegendoGEL is biocompatible, biodegradable and non-inflammatory, and repairs teeth up to 5X faster and better than currently used synthetic pulp therapy materials. ”**



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[www.bertassonilab.com](http://www.bertassonilab.com)

## Clinical Need

Tooth damage, decay and eventual tooth loss is the clinical problem addressed by our product, RegendoGEL. Specifically, RegendoGEL will be used for vital pulp therapy. In contrast to currently used dental materials for tooth repair, RegendoGEL is a first-in-kind regenerative dental product for vital dental pulp and dentin regeneration. RegendoGEL will harness the regenerative properties of natural dental pulp to heal the tooth, by promoting natural dental pulp and dentin formation.

## Solution

RegendoGEL is a hydrogel based material that contains bioactive molecules that promote natural tooth dental pulp and dentin formation. RegendoGEL is a first-in-kind regenerative dental product for vital dental pulp and dentin regeneration, intended to treat damaged teeth in a similar manner currently being used for synthetic, non-regenerative dental materials such as calcium and silicate cements and MTA.

## Competitive Advantage

As compared to conventional rigid silicate or calcium hydroxide-based products, RegendoGEL will stimulate natural dental pulp and dental regeneration, repairing the tooth defect with natural, vital, dental tissues. RegendoGEL has been shown to accomplish this as much as 5 times faster than existing products in the market. Its biocompatibility, non-inflammatory, and degradable properties reverse the degenerative cycle of tooth repair, which normally progresses from a small cavity and filling, to larger fillings, eventually leading to endodontic treatments and replacement therapy such as dental implant or bridge.

## ITP Support

ITP support has been extensive. Business advice has been provided from the Regulatory Core, including the anticipated classification of RegendoGEL as Class II 510(k) product. Pre-clinical Animal Model Core conducted animal studies, and the micro-CT and histology Cores performed analyses of the harvested teeth, under guidance from the Statistical Core. Ongoing guidance on how to bring our product to the market has been provided by the Prototype & Manufacturing Core, and IP/ Commercialization Cores.

## Clinical Translation Pathway

**Publications:** Khayat et al. GelMA-Encapsulated hDPSCs and HUVECs for Dental Pulp Regeneration. [J Dent Res 2017](#)

Parthiban et al. Engineering pericyte-supported microvascular capillaries in cell-laden hydrogels using stem cells from the bone marrow, dental pulp and dental apical papilla. [Sci Rep 2020](#)

**IP:** US16/618,329 Dental Pulp Constructs

US15/777,304 Pulp Regeneration Compositions and Methods of Forming and Using the Same

**Anticipated regulatory pathway:** IDE to enable 510(k)

**Anticipated commercialization strategy:** New company formation, partnership for distribution

Michigan-Pittsburgh-Wyss Regenerative Medicine Resource Center is supported in part by the National Institute of Dental & Craniofacial Research of the National Institutes of Health under Award Number U24DE026915 and U24DE029462. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

