

AMPLIMAG MESH AND MESH FIXATION SYSTEM



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Clinical Need – Over 1M dental bone grafting procedures are performed annually in the US, most frequently before dental implant placement. In the most challenging procedures, revision rates may reach ~25% due to the difficulty of reliably regenerating sufficient bone for implant placement. Currently used barrier membranes, meshes, and fixation systems are unable to offer the form-stability needed to protect healing grafting sites from mechanical insults, while also offering resorbability and gingival tissue friendliness. The inability of regenerative products to offer these three features result in dental bone grafting procedures that are highly technique-sensitive, prone to adverse events, and require invasive removal procedures.

Solution – The AmpliMag Bone Grafting System provides the form-stability and gingival-tissue friendliness needed to minimize adverse events and maximize bone regeneration. The system is fully resorbable which eliminates the need to retrieve hardware following healing. The AmpliMag system is based on a patented magnesium alloy developed by nanoMAG and device designs developed at the University of Pittsburgh.

Competitive Advantage – No other barrier membranes or meshes offer both form-stability and resorbability which, taken together, enable maximization of alveolar ridge augmentation while obviating the need for device removal.

ITP Support – The ITP program has provided financial support for design, manufacturing, and benchtop and pre-clinical testing activities for the AmpliMag barrier membrane. Additionally, the Resource Center has provided expert clinical, market, regulatory, and quality advice.

FOUNDATIONAL PUBLICATION

Brown et al. Porous magnesium/PLGA composite scaffolds for enhanced bone regeneration following tooth extraction. Acta Biomater 2015

INTELLECTUAL PROPERTY

US11,317,955 Magnesium enhanced/induced bone formation

ANTICIPATED REGULATORY PATHWAY

Device, initial de novo classification as one product system (mesh and fixation system) with a follow-on 510(k) to permit marketing of the fixation system separately

ANTICIPATED COMMERCIALIZATION STRATEGY

Emergence Dental, Inc. will partner with an existing dental regenerative or implant company on clinical adoption studies and distribution activities.

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