AmpliMag Barrier Membrane and Membrane Fixation System

CLINICAL NEED
Over one million dental bone grafting procedures are performed annually in the US, most frequently before dental implant placement. In the most challenging grafting procedures, where there is a significant vertical deficit, even expert clinicians face revision rates reaching 25% due to the difficulty of reliably regenerating sufficient bone for implant placement. Currently used barrier membranes 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 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 system developed by nanoMAG and patent-pending magnesium/polymer composites developed at the University of Pittsburgh.

COMPETITIVE ADVANTAGE
No other barrier membranes 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.

CLINICAL TRANSLATION PATHWAY

**Publications:**
Porous magnesium/PLGA composite scaffolds for enhanced bone regeneration following tooth extraction. Acta Biomater 2015.

**Intellectual Property:**
US 10,022,470 High Strength and bio-absorbable magnesium alloys
PCT/US2019/018545 Improved Magnesium Alloy and Process for Making the Same

**Regulatory Pathway:**
Anticipated: Device, 510(k) as 2 separate products (membrane/fixation system)

**Commercialization Strategy:**
Emergence Dental, Inc. was formed to focus on the commercialization of dental regenerative devices based on intellectual property developed at nanoMAG and University of Pittsburgh.

**Product Launch Strategy:**
In partnership with a large implant or dental regenerative company, performing a clinical adoption study and distributing through existing sales channels.

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