

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.



ANDREW BROWN, PHD STEPHEN LEBEAU, PHD

Emergence Dental, Inc.

nanoMAG, LLC

"Emergence Dental was founded to combine biomaterial intellectual property from nanoMAG and University of Pittsburgh to address unmet needs in dental bone regeneration. The Resource Center has enabled us to accelerate the development of the AmpliMag barrier membrane and membrane fixation not just with funding, but with expertise that we have not been able to access elsewhere."

www.nanomag.us

www.emergencedental.com

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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Resorbable Metallic Barrier Membranes for Guided Bone Regeneration

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UNMET CLINICAL NEED

Patients requiring major bone grafting in advance of implant placement face unpredictable outcomes

- Up to 40% of cases require revision grafting procedures or grafting at time of implant placement
- Challenging soft-tissue management as augmentation goals increase
- Reinforced barrier membranes and titanium meshes associated with higher rates of adverse events



Simion, 1998



Simion, 1998

Currently available barrier membrane systems cannot offer:

- Form stability
- Resorbability
- Soft-tissue friendliness
- Robust, resorbable fixation system

MARKET ANALYSIS

Major dental bone grafting represents a small, but expensive, regenerative market segment

- 150,000 major dental bone grafting procedures performed in the US annually
- \$120MM in associated regenerative product spending (grafting material, barrier membranes/meshes, fixation products)
- Reinforced barrier membranes and titanium meshes associated with higher rates of adverse events

Customer discovery interviews with 120 clinicians and market experts aids current product positioning:

- Resorbable metallic barrier membrane can provide the benefits of current reinforced barrier membranes and meshes while improving soft tissue reaction and eliminating removal procedure
- Development of resorbable metallic fixation system will also support development of clinical data and earlier partnering opportunities

INTELLECTUAL PROPERTY

Emergence Dental combines intellectual property from nanoMAG and University of Pittsburgh

- nanoMAG – patented BioMg250 magnesium alloy
- University of Pittsburgh – patent-pending magnesium/polymer barrier membrane composition and manufacturing methods

MANUFACTURING

The Resource Center has supported a transition to go-to-market manufacturing methods under design controls



nanoMAG's BioMg 250 magnesium frame laser-cut to provide polymer membrane reinforcement



Membrane fixation screws machined from nanoMAG's BioMg250 and tooling compatible with standard dental handpiece

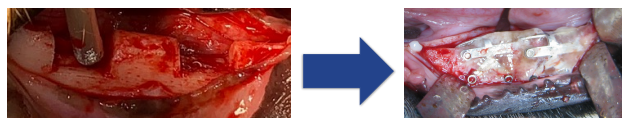


Early emphasis on design for manufacturing and usability testing

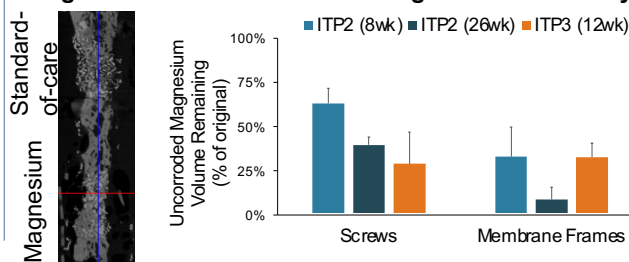
- Prototype feedback by 8 clinicians
- Using standard dental drills and handpieces in pre-clinical study enables near-real world feedback on design

RESULTS

Pitt Pre-Clinical Animal Model Core conducted study comparing resorbable magnesium barrier membrane to gold-standard collagen membrane in vertical ridge augmentation model



Pitt microCT and Histology Cores confirmed that key success criteria for device resorption and bone regeneration were achieved during most recent study



REGULATORY PATHWAY

Emergence Dental is taking a staged approach to seeking 510(k) clearance of barrier membrane system:

- Many resorbable barrier membranes and membrane fixation systems with 510(k) clearance
- Zero magnesium-containing devices cleared/approved for dental/CMF applications
- Seeking 510(k) clearance on membrane fixation system first due to more straightforward substantial equivalence
- Then, seeking 510(k) clearance of barrier membrane using fixation system clinical data to support safety claims

Pre-clinical testing plan well defined based on predicate devices:

- 10993 biocompatibility testing completed on base magnesium material by nanoMAG
- Pivotal pre-clinical study uses recently completed animal and surgical model with same control materials, but longer timepoints through full device resorption

TIMELINE & FUTURE DIRECTIONS

Upcoming Resource Center-Supported Milestones

- Clinician Interviews and Usability Testing – The Avenues will be supporting interviews with clinicians, as well as usability testing using current device designs
- Design history files will be initiated for both the barrier membrane and membrane fixation system with the support of MDRS and the Regulatory and QA/QC cores
- Design freezes on both devices are planned in summer 2021

Longer-term product development goals:

- Micromesh – customer discovery efforts suggest that a magnesium-only mesh design may have value to clinicians
- Tenting screws – build upon pre-clinical data generated at University of Pittsburgh to develop tenting screws or expand indication of membrane fixation screws
- Grafting material – intellectual property developed at the University of Pittsburgh and pre-clinical data demonstrated effectiveness of a porous magnesium/polymer composite for grafting materials

REFERENCES

- Simion et al. Int J Periodont Rest Dent 1998.
- Brown, A., Sfeir, C., US Patent Application 62/411,288, Degradable bulk metallic magnesium polymer composite
- Decker et al. US Patent No.9,017,602, Method and apparatus of forming a wrought material having a refined grain structure
- Decker et al. US Patent No.10,022,470, High strength bioabsorbable magnesium alloys