AmpliMag Mesh and Mesh Fixation System

Clinical Need

Over 1M dental bone grafting procedures are performed annually in the US. In the most challenging procedures, revision rates may reach ~25%. Currently used regenerative devices are unable to offer form-stability, resorbability and gingival tissue friendliness. Thus, these procedures are highly technique-sensitive, prone to adverse events, and require invasive removal procedures.

Solution

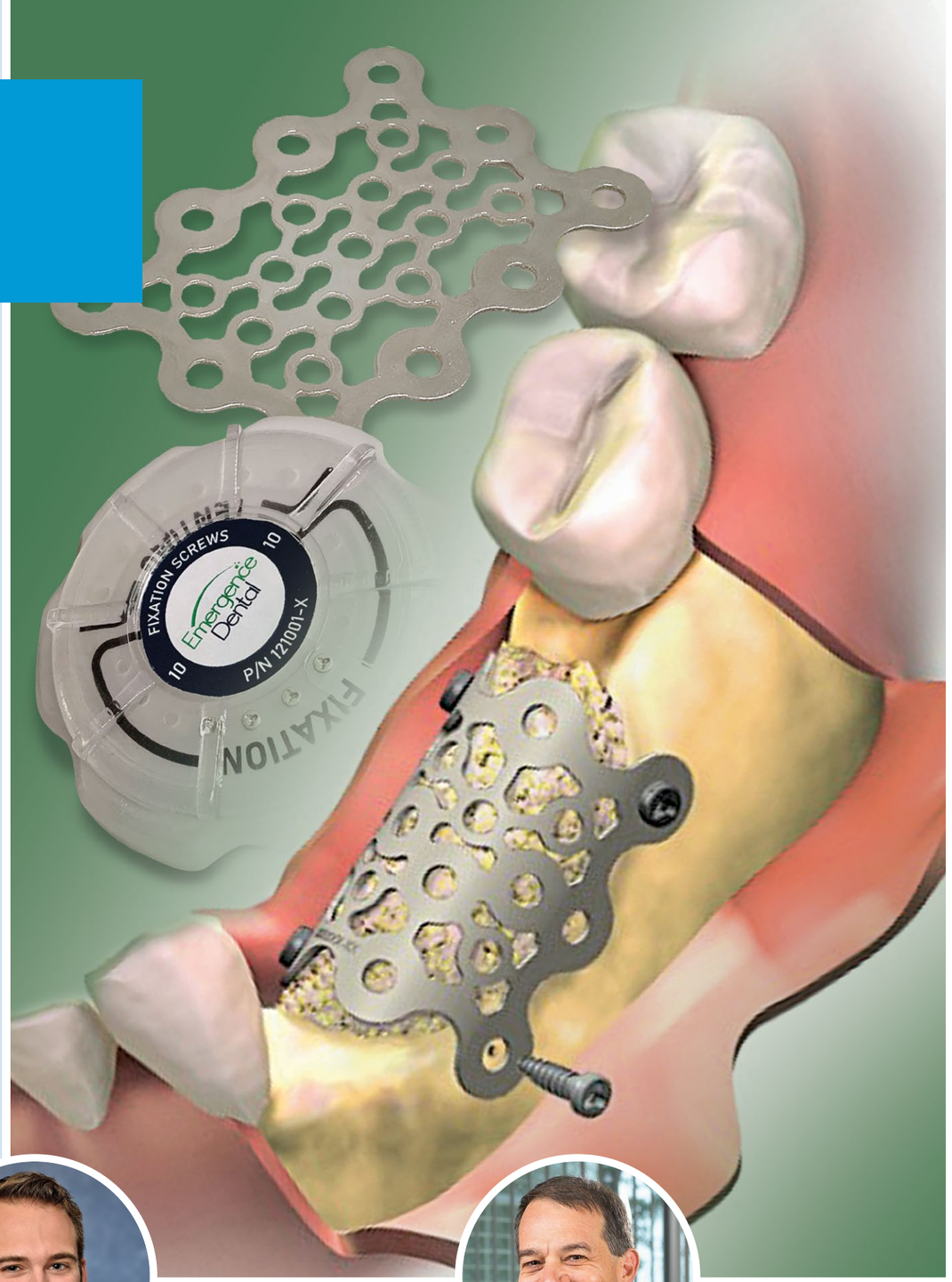
The AmpliMag Bone Grafting System provides the form-stability and gingival tissue friendliness needed to minimize adverse events and maximize bone regeneration. The system is fully absorbable which eliminates the need to retrieve hardware following healing. The AmpliMag system is based on a patented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

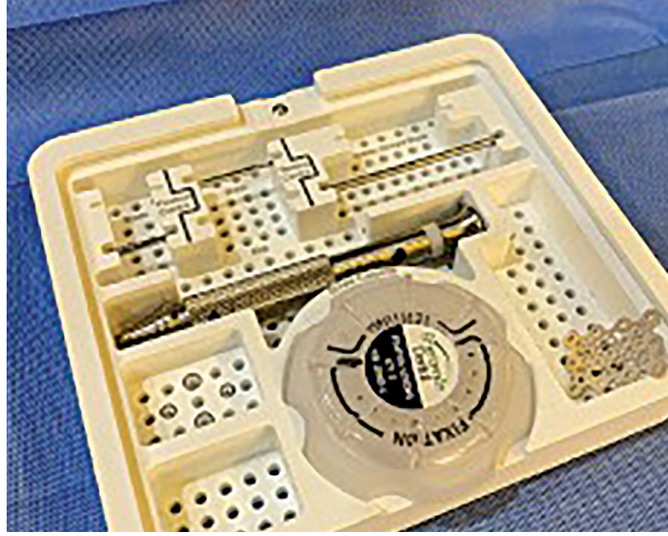
Competitive Advantage

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. Additionally, the magnesium alloy composition (BioMg250®) used in the AmpliMag devices contains only elements found in native bone, providing a safe environment for bone regeneration.

Foundational Publications & Patents

- Brown et al. Porous magnesium/PLGA composite scaffolds for enhanced bone regeneration following tooth extraction. Acta Biomater 2015
- Decker et al. Development of BioMg 250 bioabsorbable implant alloy. In: Magnesium Technology 2018. TMS 2018
- US10,022,470 High Strength and Bio-Absorbable Alloy
- US11,317,955 Magnesium Enhanced/Induced Bone Formation





ITP Support

Since entry into the ITP program in 2018, and the project has completed the design, manufacturing, and benchtop and pre-clinical testing activities for the AmpliMag barrier membrane, including a small pilot in vivo study, with financial and other support from the Resource Center. Additionally, the Resource Center has provided expert clinical, market, regulatory, and quality advice. In 2022, the AmpliMag Bone Grafting System reached a design freeze and begun GMP manufacturing following three FDA pre-submissions.

Key Inflection Points/ Regulatory Pathway

- Closing bridge round and completing benchtop validation studies in 2023
- Closing seed round, completing GLP large animal study in 2024
- IDE clinical study anticipated to begin in 2025
- Completing clinical study and obtaining De Novo Classification as one product system (mesh and fixation system) in 2026

Opportunities for Partnerships

- Emergence Dental is currently seeking dental regenerative partners to help inform clinical study and adoption strategies

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