Customizable CMFlex™ Bone Grafts for Craniomaxillofacial Bone Defect Applications

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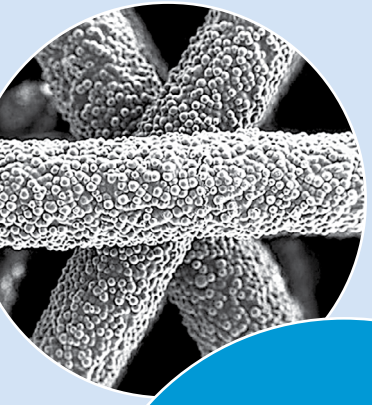
Dimension Inx



"ITP's support will help us develop transformative biomaterials that address critical needs in treating CMF deficiencies."

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Clinical Need

Craniomaxillofacial (CMF) bony defects are challenging to reconstruct. Autologous bone grafting remains the gold standard, but donor site morbidity, surgical complications at the donor site, scarcity of donor tissue, and the time and skill set needed to shape into irregular defects can be limiting. Alternatives such as synthetic or allograft bone chips, granules, or putties are used but can migrate from the defect, inhibit tissue integration due to limited porosity, and increase infection risk. These drawbacks emphasize the significant need for better biomaterial solutions.

Solution

Our intended product is a 3D-printed bone graft, CMFlex™, that possesses a hierarchically porous structure made up of a majority calcium phosphate (CaP) and minority poly(lactide-co-glycolide) (PLG) with the following measurable benefits: osteoregenerative, safe, shape and volume maintaining, surgically-friendly (i.e., pliable enough to be press fit into defects and easily cut/shaped while maintaining structural integrity), manufacturable and scalable, and commercially viable (i.e., acceptable price point).

Competitive Advantage

Unlike other synthetic bone grafts used for these indications, the use of 3D-printing to manufacture CMFlex™ imparts several advantages: 1) a distinct, inherent nano/microstructure that is responsible for much of the product's unique properties (e.g., pliable yet made of mostly osteoconductive ceramic), 2) enables a 3D interconnected porous structure ideal for protein adhesion, cell migration, and tissue integration, and 3) permits future form factors (including patient-specific) to be rapidly designed and implemented. .

ITP Support

ITP program will support continued market development efforts for CMFlex™.

Clinical Translation Pathway

Publications: Jakus et al. Hyperelastic "Bone": A Highly Versatile, Growth Factor-Free, Osteoregenerative, Scalable, and Surgically Friendly Biomaterial. Sci Transl Med 2016

Huang et al. 3D-Printed "Hyperelastic Bone" Scaffolds Accelerate Bone Regeneration in Critical-Sized Calvarial Bone Defects. Plast Reconstr Surg 2019

IP: US10,584,254 Ink Compositions for Three-Dimensional Printing and Methods of Forming Objects Using the Ink Compositions

US15/963,348 Ceramic-Containing Bioactive Inks and Printing Methods for Tissue Engineering Applications

Anticipated regulatory pathway: 510(k)

Anticipated commercialization strategy: Develop products until ready for commercialization and then partner with strategics for marketing, sales, and distribution.

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