Ostiio: A Smart, Fully-Implantable CMF Distractor

Clinical Need

Each year >200K newborns suffer from conditions that restrict growth of the skull or jawbone. Left untreated, these can have life threatening outcomes in an otherwise healthy child. However, treatments are complex and traumatic. Distraction is a gentler therapy that uses a device to slowly expand abnormal bone, but distractors are semi-buried, increasing complication risk; manual expansion is performed by parents, leading to noncompliance; and surgeons are blinded to treatment, forcing weekly X-rays and exams.

Solution

Ostiio's therapy uniquely solves pain points of distraction to improve patient outcomes and experience. The fully buried implant is expanded magnetically, removing the complication risk of semi-buried devices. The automated driver simplifies expansion, reducing parental noncompliance. The remote monitoring platform allows surgeons to track treatment progress, reducing post-op follow-up.

Competitive Advantage

Distraction is the segment within the CMF device market that offers opportunity to differentiate, but technology advancement has been iterative with competitors focused on providing greater flexibility to the surgeon in the OR. Since treatment is home-based, Ostiio instead will transform how distraction is provided by parents and monitored by surgeons to improve patient outcomes and experience.

Foundational Publications & Patents

- Kalmar et al. Forces exerted in craniofacial distraction osteogenesis. J Craniofac Surg 2022
- PCT/US2020/017918 Systems and Methods for a Smart, Implantable Cranio-maxillo-facial Distractor
- PCT/US2023/060119 Systems and Processes for Distraction Control via Torque Sensing

Ari M Wes, MD
Ostiio LLC

ITP Support

At entry to the ITP program, the project had early proof-of-concept prototypes. The ITP program has enabled us to advance our integrated therapy from product conceptual-ization to late-stage, system-level prototypes. Working within an ISO 13485 certified quality management system, Ostiio has developed functional prototypes that exceed the most critical product specifications by >2x. In parallel, we have progressed key regulatory activities and completed important market validation work.

Key Inflection Points/ Regulatory Pathway

- Pilot animal study in Q1 2024
- Design Freeze in Q3 2024
- Fundraising – A round of $1.5M closed by Q4 2023
- 510(k) to be filed Q1 2025

Opportunities for Partnerships

- Investment opportunity: The company is currently seeking a Series Seed financing of $1.5M to complete our product design and validate its performance in animals

Michigan-Pittsburgh-Wyss Regenerative Medicine Resource Center is supported in part by the National Institute of Dental & Craniofacial Research of the National Institutes of Health under Award Number U24DE029462. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.