

OSTIIO: A SMART, FULLY-IMPLANTABLE CMF DISTRACTOR



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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 – Ostio’s integrated therapy uniquely solves pain points of distraction to improve patient outcomes and experience while reducing cost. The fully buried implant is magnetically expanded without contact, removing the complication risk of semi-buried devices. The automated driver simplifies expansion to a button push, reducing parental noncompliance. The remote monitoring platform allows surgeons to track treatment progress and address complications early on, reducing post-op follow-up.

Competitive Advantage – Although distraction is the segment within the cranio-maxillofacial device market that offers differentiation opportunity, major competitors have been iterating upon technology that was first introduced to market >20 years ago with a focus on providing greater flexibility to the surgeon in the OR. However, treatment takes place at home. Ostio instead will transform how distraction is provided by parents and monitored by surgeons to improve patient outcomes and experience while reducing cost.

ITP Support – The ITP program has enabled Ostio to advance its integrated therapy from product conceptualization to late-stage prototypes. Working within an ISO 13485 certified quality management system, Ostio has developed functional prototypes that exceed the most critical product specification by more than 2x. In parallel, Ostio has progressed key regulatory activities and completed important market validation work.

FOUNDATIONAL PUBLICATION

Kalmar et al. Forces Exerted in Craniofacial Distraction Osteogenesis.
J Craniofac Surg 2022

INTELLECTUAL PROPERTY

PCT/US2020/017918 Systems and Methods for a Smart, Implantable
Cranio-maxillo-facial Distractor

ANTICIPATED REGULATORY PATHWAY

Class II medical device via 510(k)

ANTICIPATED COMMERCIALIZATION STRATEGY

Pilot launch in centers of excellence to demonstrate value proposition then
scale according to tiered targeting strategy

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