Spirair

Mission
To improve the quality of life in patients with Nasal Septal Deviation (NSD) using a safe, efficacious, and minimally invasive office-based treatment.

Technology
Spirair is a needle-based delivery device that corrects NSD by anchoring a bioabsorbable tensioning-graft implant to the nasal septal cartilage. When tension is applied to the implant, the cartilage is immediately straightened. As the implant is absorbed over the following 8 weeks, the cartilage is permanently remodeled.

R&D Status
Spirair has early human data demonstrating efficacy using off-the-shelf bioabsorbable implant material. Spirair has also developed a works-like delivery device prototype with benchtop data. Spirair is completing ongoing delivery device development under consultation of a senior medical device engineer. This device will be ready for pre-FDA pilot testing by Q2 2021.

Current US NSD surgical volume
520k cases/year

Projected US/Europe TAM
$2.3B

Regulatory
510(k) with clinicals (predicate K132920). 510(k) clearance can be achieved by 2023 with a 30-patient, 6-month follow-up pivotal trial. Time from enrollment to clearance will be 18 months.

Reimbursement
Spirair is reimbursable under the existing CPT code 30520.

Current Fundraising
$550k seed round to complete a) Gen 1 device and b) 5 patient pre-FDA pilot study demonstrating safety, tolerability, and efficacy in the office setting

Overview
Spirair is a medical device company spun out of Stanford Biodesign that has developed an office-based treatment for NSD. Spirair's 15-minute procedure allows patients to return to work the same day.

Clinical Background
NSD occurs when the nasal septal cartilage (i.e. the midline cartilage dividing both nostrils) is deviated to one side; thereby blocking the nasal airway and resulting in obstruction symptoms. These symptoms can be severe and can result in significant patient discomfort. Surgical correction typically requires a 1-3 week recovery.

ENT Office-Based Treatments
The ENT field has seen a fundamental shift in its practice paradigm with substantial surgeon demand to move procedures out of the operating room (OR) and into the clinic. While many other pathologies treated by ENTs have been moved to the office, NSD has not benefited from an office-based innovation; thereby leaving a clear unmet need.

Team
Spirair was founded by James Kintzing, PhD and Brandon McCutcheon, MD who are both alumni of the Stanford Biodesign Fellowship. James and Brandon both have experience as early stage entrepreneurs.

Benchtop and Clinical Testing
Spirair's technology has been de-risked with benchtop data demonstrating the ability to straighten supraphysiologic 90° deviations in a porcine cartilage model. Spirair also has acute human data demonstrating that a prototype bioabsorbable implant is efficacious.

Market Access and Business Model
Spirair's proposed business model will allow rapid commercialization after FDA 510(k) clearance with an existing CPT code (30520). The in-office payment of this code reimburses at an average range of $900-1300, allowing a comfortable margin to cover Spirair's target $600 ASP. At this price-point, the $300+ physician fee provides an attractive incentive for ENTs by providing a higher return than other common office-based procedures (e.g. new patients ~$100; turbinate reduction ~$200) and an increase in revenue per time compared to septal surgery.

Acquisition Comps

ARRINEX, INC. — ENT office-based treatment for vasomotor rhinitis. $200M acquisition by Stryker 3 years after Series A

Acclarent — ENT office-based treatment for chronic rhinosinusitis. $785M acquisition by J&J 6 years after Series A.