

OHNS HOPKINS WHITING SCHOOL of ENGINEERING

The Problem: Two Surgery Treatment

- **Traumatic Brain Injury** (TBI) is a leading cause of death and disability
- **1.7M cases & 70K deaths** annually in the US
- For severe TBIs, brain begins swelling, leading to further damage and complications
- Only **life-saving treatment** is following pathway:



Injury Patients

elderly falls & vehicle





accidents These surgeries are highly invasive, resulting in high costs (among the top 20 most expensive procedures in the US), significant complications, lengthy hospital stays, and delayed patient rehabilitation.

Our Solution: One Implant, One Surgery

- Transforms the standard care pathway for severe TBI patients by eliminating the secondary surgery
- Reduces the associated invasiveness, costs, complications, and rehabilitation time
- Enables a safer, faster, and more affordable treatment and recovery for patients



implant is soft & elastic to allow unrestricted brain swelling

Clinical Value for Patients

- Reduces invasive procedures
- Reduces short & long term complications
- Avoids delay in reconstruction
- Enables earlier rehabilitation

Economic Value for Payer

- Eliminates the cost of second surgery (\$50,000+)
- Reduces indirect costs of hospital stay, complication management, and reoperation

Neuro Prima Only Competes with the Standard of Care

Neuro Prima

 \checkmark

Single surgery **Optimizes reconstruction timing Reduces complications from unprotected brain Enables deswelling & reconstruction**

Neuro Prima

A novel cranial implant that elimimates a highly invasive, costly, and complication-heavy surgery for severe traumatic brain injury patients.

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Deswelling Period 30-90 Days without brain protection

Secondary Surgery

37% complications

30% reoperation

External Stimuli

Dr

30 Days

Outpatient Visit

implant is hardened non-invasvely for life-long protection

Economic Value for Provider

• Upgraded payment (over 50% higher) for neurosurgeon with alternative surgery, instead of splitting payment with plastic surgeon

Bone Flap	Artificial Implant
X	×
X	X
X	X
\checkmark	\checkmark





Ava Taylor: Research Lead

Kenneth Nova: Business Lead Tufts University, B.A. May 1986 Northwestern University, Kellogg School of Management, MBA June 1993

Sofia Garcia del Barrio Cervera: Technical Lead University Carlos III of Madrid (Spain), B.S. Biomedical Engineering May 2023 | La Caixa Fellowship 2023

Large Market Opportunity



Serviceable Obtainable Market

20,000

Patients annually in US

\$25,000

Neuro Prima's implant cost (82% margin)

Annual Healthcare Cost Savings

\$40K

Second surgery cost

Traction, Go to Market Strategy, & Pathway to Commercialization

2028 2033 **Preclinical Studies Clinical Studies** MVP, benchtop testing, animal Feasibility, pivotal studies, PMA application, testing, manufacturing breakthrough device exemption (BDE) • Identified viable biomaterials, solidified 5 viable transition mechanisms, developed proof of • Collaborating with R&D labs for design and manufacturing of MVP • Filing a provisional patent • Engaged a law firm, regulatory, reimbursement and investment experts to help define our regulatory strategy, prepare for FDA pre-submission, and understand required funding for commericialization pathway • Established partnerships with key opinion leaders and product champion neurosurgeons at Johns Hopkins Hospital Business Model



- significant changes to reimbursement

• Direct sales • 216 high-volume Level I Trauma Centers • Key opinion leaders • Centers of excellence

Our Team

Arjun K. Menta: Clinical Lead

- The University of Texas at Austin, B.S.A Biochemistry, B.B.A May 2020
- Johns Hopkins School of Medicine M.D. Candidate, May 2025 | Paul & Daisy Soros Fellow 202
- High Point University, B.S. Biology May 2024

Shreya Jindal: Technical Lead Rice University, B.S. Bioengineering May 2024

Mentors & Advisors

We are grateful to be **advised by serial MedTech entrepreneurs, world-renowned** neurosurgeons with significant experience in innovation development, and strategic **experts.** Our team is continuously supported by the Center for Bioengineering and Design and an extensive network of industry, FDA and patent advisors who guide our key strategic and business decisions.

- Dr. William Anderson (M.D, Ph.D.): Clinical PI
- Dr. Risheng Xu (M.D, Ph.D.): Clinical PI
- Dr. Youseph Yazdi (M.B.A., Ph.D.): CBID Program Executive Director
- Former Corporate Director at Johnson & Johnson
- Dr. April Zambelli-Weiner (Ph.D.): Strategic Mentor Regulatory Expert | CEO of TTi Health Economics







\$14-24K Current implant cost

30% Reoperation rate from second surgery complications

Commercialization

Post approval study

Revenue Projections

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Yr 2 | 2034 7 centers 1K units

\$50M

Yr 3 | 2035 13 centers 2K units

• Initial focus on centers with high procedure volume and payor concentration • Device cost embedded within existing DRG code to streamline adoption without

Professor of Neurological Surgery | Johns Hopkins University School of Medicine

Assistant Professor of Neurological Surgery | Johns Hopkins University School of Medicine

• Dr. Ashish Nimgaonkar (M.B.B.S., M.S.): CBID Associate Medical Director

Assistant Professor of Gastroenterology | Johns Hopkins University School of Medicine