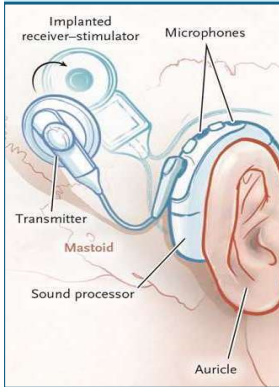


Background



- Cochlear implantation surgery restores severe-to-profound hearing loss in patients with damaged cochleae.
- Cochlear implants are permanent, subcutaneous devices delivering electrical signal directly through the cochlea to the auditory nerve.
- Conventional surgery requires invasive drilling, but the TECII uses the natural ear canal instead of performing a mastoidectomy.

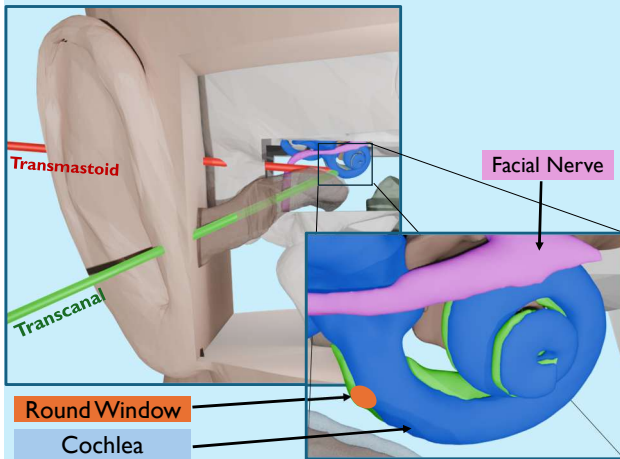
"Cochlear Implant Surgery: Treatment For Hearing Loss." November 18, 2021. <https://www.medicospeaks.com/en/cochlear-implant/>.

Transmastoid Surgery

- Invasive mastoidectomy.
- Risk of facial nerve damage.
- Longer surgery & recovery.

Transcanal Surgery

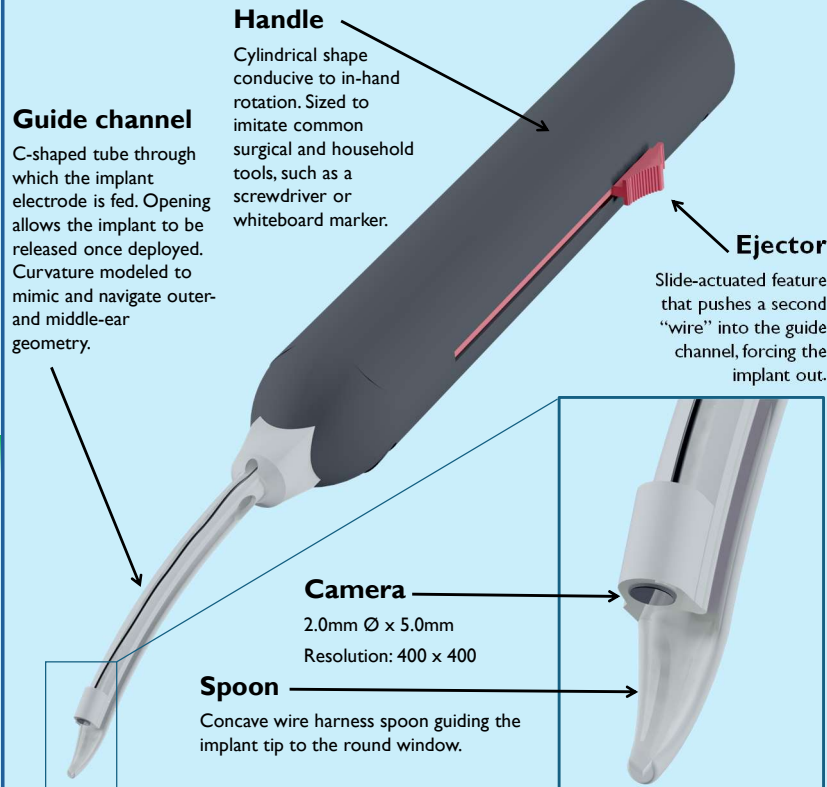
- Minimally invasive.
- Uses existing ear canal.
- Faster surgery & recovery.



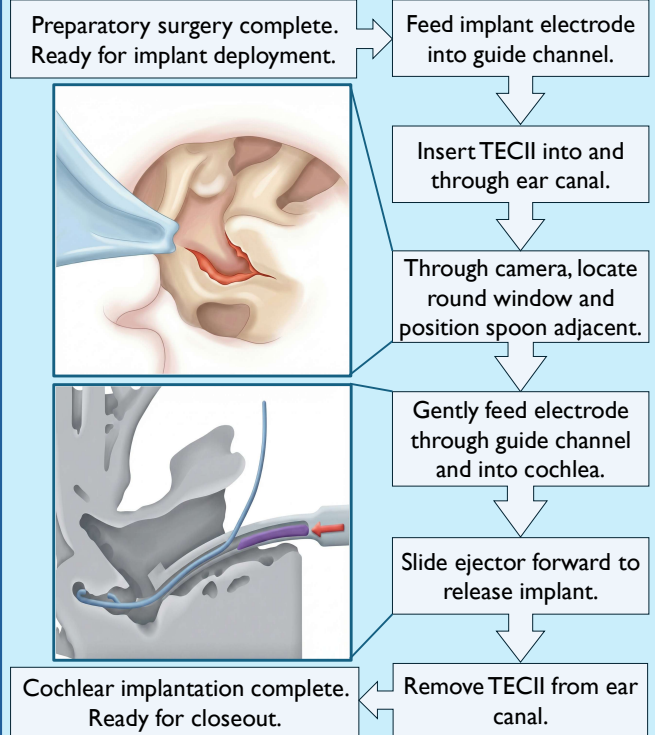
Requirements & Specifications

- ✓ Prototype at $\leq 2x$ scale.
- ✓ Access middle ear via natural ear canal.
- ✓ Deliver implant electrode through the ear canal.
- ✓ Assist **electrode insertion**.
- ✓ Provide user with **visual** of the round window niche.
- ✓ Operated from outside the ear canal.
- ✓ Continuous two-handed operation not required.
- ✓ Fully or partially **single-use disposable**.

Full Assembly



User Operation Sequence



Testing

Expert User Testing

- "Mock surgeries" performed inside 2x scale model of middle ear anatomy. Tests both validated implant deployment functions and device useability.
- Three distinct iterations of handle & control ergonomics evaluated by practicing surgeon and CU surgical residents. Team incorporated progressive feedback in each testing round.



Anatomical Testing

- Dimensionally evaluated in seven distinct, anatomically accurate, 2x-scale inner ear models. Key analyses related to guide channel curvature & width, spoon angle, and camera housing width.
- Guide channel dimensions evaluated at 1x scale via cadaveric testing. Proof of concept at 2x scale and size at 1x validates feasibility for future development.



Results & Impact

- **Massive design simplification...**
 - ...reduces costs, making single-use disposability feasible.
 - ...makes the prototype scalable to 1x.
 - ...includes no powered insertion components.
- Cost reduction and single-use disposability improve **accessibility to more medical facilities and patients.**

Cost Estimation

Unit Count	Material Cost	Overhead	Price per Unit
60,000	\$433.33	50-80%	\$866.66 - \$2,166.65

Continuing Efforts

- Combine implant insertion and ejection functions into a single, easy-to-use feature.
- Scale down patient-interacting components to 1x.
- Continue validation testing on cadaveric ear samples via 1x scale prototypes.