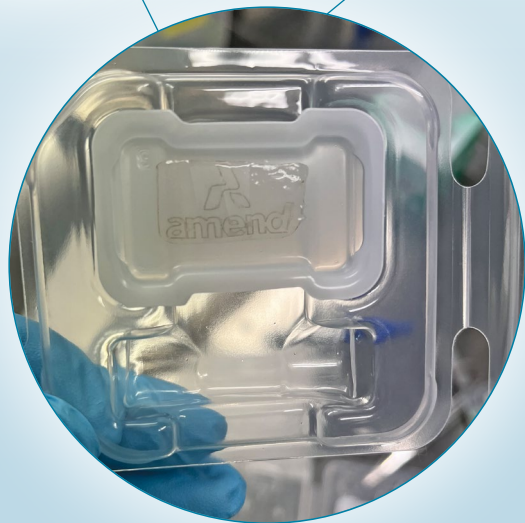
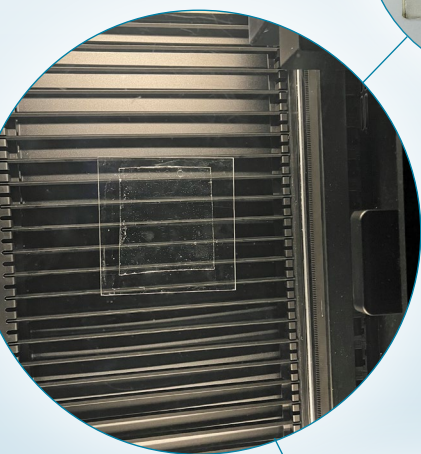
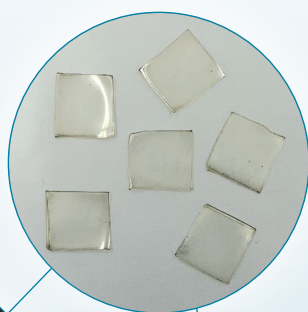


Suture-less Trigeminal Nerve Repair Device



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Clinical Need

Micro-suturing is the current standard of care for the repair of trigeminal nerve injuries. Micro-sutured repairs are technically challenging and often inconsistent, with flaws in both fascicular alignment and spacing between severed nerve ends. Scar tissue associated with suture placement can impede axonal regeneration. Clinical need for oral surgeons: a suture-less repair solution.

Solution

Tissue™ is a degradable, hydrogel and chitosan-based nerve connector that has the adhesion and mechanical strength required to eliminate the need for suture to reconnect peripheral nerves. The product adheres to wet nerve tissue and provides over five times the adhesion energy of cyanoacrylate while also providing flexibility to stretch through range of motion without damaging nerve healing.

Competitive Advantage

Current competitors in peripheral nerve repair offer largely undifferentiated collagen and polymer materials for connectors, conduits, and wraps. None of the competitors offer a suture-less alternative for a direct (non-connector) nerve repair and all of their product lines require suture to prevent migration of their product.

Foundational Publications & Patents

- Wu DT et al. Tough adhesive hydrogel for intraoral adhesion and drug delivery. [J Dent Res 2023](#)
- Freedman, B et al. Degradable and removable tough adhesive hydrogels. [Adv Mater 2021](#)
- [US9,387,276](#), [US10,383,980](#) Interpenetrating networks with covalent and ionic crosslinks

Achievements

- Designed suitable packaging and achieved sterile product through moist heat sterilization while maintaining product integrity
- Modified hydrogel composition to reach desired in vitro degradation timepoints to achieve design freeze by Q4 2024
- Ability to create a fully dried product that rehydrates in 15 seconds prior to application
- Developed study design for non-GLP rat sciatic nerve study to be performed

Regulatory Pathway

- 510(k) anticipated

Opportunities for Partnerships

- Ongoing discussions with strategic