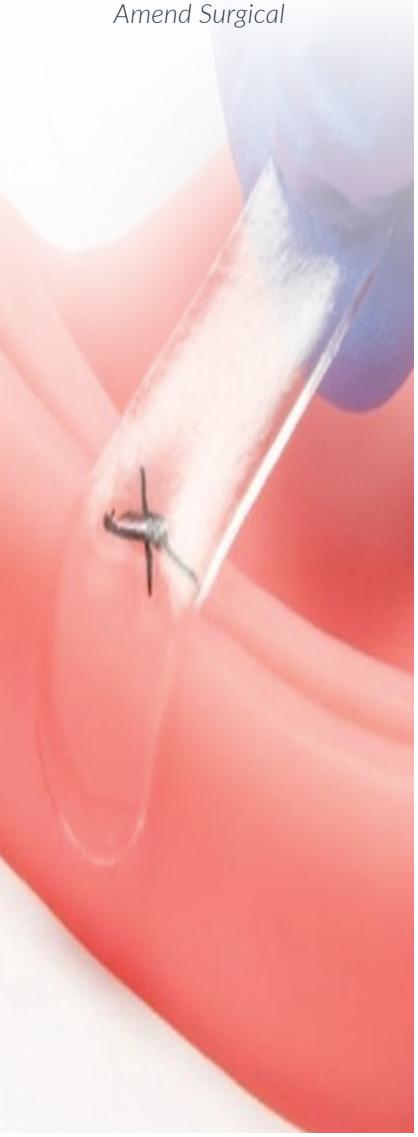
AMEND TISSUE TAPE™ FOR ORAL WOUND CARE

Jamie Shaikoski, PhD
Amend Surgical



Clinical Need – An intraoral wound overlay for soft tissue that is easy to apply, remains in place for the duration of wound healing, and can be removed without causing damage to underlying tissue. Current options for oral wound care are limited to difficult to use, uncomfortable, and largely ineffective glues and resins.

Solution – Amend Tissue Tape™ is a hydrogel-based adhesive comprised of two primary elements. The hydrogel consists of an interpenetrating network of alginate and polyacrylamide. The adhesive is composed of chitosan, which forms covalent bonds across the interface. When used together, the hydrogel and adhesive adhere to wet tissue and provide over five times the adhesion energy of cyanoacrylate while also providing a long duration mechanical barrier for the wound and flexibility to stretch with the wound without damaging the underlying tissue.

Competitive Advantage – There are limited products available that will safely adhere to sutured or non-sutured oral wounds. Periacryl, a cyanoacrylate-based product indicated as a dental cement, is often used off-label for wound closure. It requires a dry environment to fully set and is rigid, not stretching to accommodate movement or swelling. Amend Tissue Tape™ adheres to tissue in a wet environment, stretches with the wound, and stays in place for weeks, allowing wound healing to occur.

ITP Support – Market Assessment Core has facilitated handling demos and introductions with KOLs further validating the clinical need for Amend Tissue Tape™. The ITP program will support design and development activities and execution of a GLP animal study to evaluate wound healing and removal of test articles. This program will provide our project the clinical expertise and market and regulatory guidance leading up to FDA pre-submission.

FOUNDATIONAL PUBLICATION

Li et al. Tough adhesives for diverse wet surfaces. Science 2017

INTELLECTUAL PROPERTY

PCT/US2019/055779 Bio-Inspired Degradable Tough Adhesives for Diverse Wet Environments

ANTICIPATED REGULATORY PATHWAY

510(k)

ANTICIPATED COMMERCIALIZATION STRATEGY

Upon FDA clearance, a post-market multisite clinical study will be initiated. Marketing and sales communications will focus on patient comfort.

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