Tough Adhesive for Oral Wound Care

Clinical Need

Bandages are commonly used for epidermal wounds, but an effective and easy to apply wound care product that stays in place to protect an oral wound does not exist. Unprotected wounds in the mouth can be a source of discomfort, pain, and infection. Application of Tough Adhesive over these wounds will greatly enhance patient comfort and oral wound care.

Solution

Tough Adhesive 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. Tough Adhesive adheres to tissue in a wet environment, stretches with the wound, and stays in place for weeks, allowing wound healing to occur.

ITP Support

The ITP program will support design and development activities including evaluation of sterilization modalities, modifications of the Tough Adhesive technology to the challenges of the oral environment, evaluation of toxicological risks, and execution of a canine animal study to evaluate wound healing and removal of test articles. This program will provide our business with financial assistance, clinical expertise, and market and regulatory guidance leading up to FDA pre-submission.

Clinical Translation Pathway

Publications: Li et al. Tough Adhesives for Diverse Wet Surfaces. Science 2017

Yang et al. Topological adhesion of wet materials. Adv Mater 2018

IP: US11,033,658 Interpenetrating Networks with Covalent and Ionic Crosslinks

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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"Tough Adhesive protects oral wounds and improves wound healing and patient comfort."

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