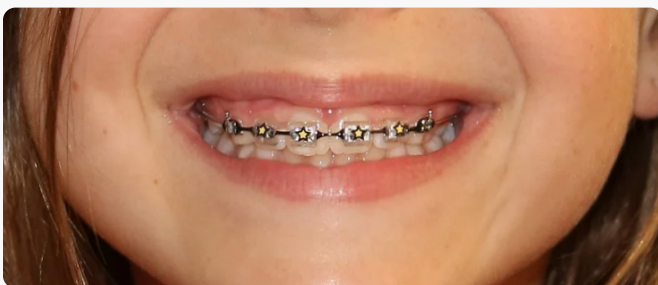




Case Study

Customization for Dental Devices with Fusion Labeling

How Snap Caps™ and Dentagrafix® gave dental patients the ability to customize braces and retainers using FDA compliant polymer fusion labels from Polyfuze.



Executive Summary

Dentagrafix® revolutionized dental device customization by offering unique, personalized solutions that comply with ISO 10993 standards. Meanwhile, Snap Caps™ achieved a breakthrough in custom mini bumpers for braces by meeting stringent FDA requirements. Both utilized Polyfuzer® Graphics Corporation's innovative Polymer Fusion Technology, which provided durable, compliant, and customizable markings crucial for device identification and safety. This case study examines the transformative impact of this technology, demonstrating its crucial role in enabling product differentiation and regulatory compliance.

Background

In the pursuit of innovation, Dentagrafix®, specializing in custom dental retainers and mouthguards, and Snap Caps™, known for their custom mini bumpers for braces, aimed to distinguish their offerings through personalization. Their goal was not only to meet aesthetic desires but also to comply with the highest safety and quality standards, challenging the limitations of traditional labeling methods.

Problem Statement

The ambition to customize posed a significant challenge for Dentagrafix® and Snap Caps™: finding a technology capable of enduring the oral environment without degradation, chemical leaching, or microbial growth. This search highlighted the need for new, robust marking technology that could meet these stringent requirements while being suitable for polyolefin thermoplastics.

Solution

Polyfuzer® Graphics Corporation provided an innovative solution with its Polymer Fusion Technology, specifically designed for polyolefin thermoplastics. This technology underwent extensive biocompatibility testing, affirming its safety and efficacy. For Dentagrafix®, the evaluations confirmed compliance with ISO 10993 standards, showcasing non-cytotoxicity, no irritation, and no sensitization reactions, thus meeting international safety requirements. In parallel, Snap Caps™ leveraged the same technology to satisfy FDA requirements, ensuring their products were safe and effective for market release. This dual achievement underscores the versatility and reliability of Polymer Fusion Technology, making it an indispensable tool for both Dentagrafix® and Snap Caps™ in achieving their customization and compliance objectives.

Results

The integration of Polyfuzer's Polymer Fusion Technology by Dentagrafix® and Snap Caps™ has set new industry standards for customization in dental devices, enabling both brands to offer unique customization options without compromising safety or durability. This advancement has redefined product differentiation in the dental device market and increased confidence among consumers regarding the quality and safety of customized dental devices.

Broad Application

The application of Polyfuzer® Graphics Corporation's Polymer Fusion Technology by Dentagrafix® and Snap Caps™ has not only transformed these brands but also opened a vast landscape of possibilities for the entire dental device industry. This innovative technology enables a leap forward in customization and design across a diverse array of dental products, including snoring aids, retainers, night guards, dentures, aligners, sleep apnea devices, and more. By facilitating durable, safe, and personalized markings, Polyfuzer® technology enhances user experience and product differentiation, offering new avenues for patient-specific solutions in dental care. This advancement signifies a pivotal shift towards more personalized, effective dental devices, promising better outcomes and experiences for patients globally.