

510(k) SUMMARY

As Required By the Safe Medical Devices Act of 1990

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IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE

Bisco DENTIN CONDITIONER™

DENTIN CONDITIONER is an aqueous solution of hydroxyethyl methacrylate (HEMA), and succinic acid-hydroxyethyl methacrylate (SA-HEMA). The product was used at a time when acid etching dentin was unheard of. The product was intended to diffuse into the dentin smear layer and enhance the mechanical bond of subsequently applied bonding resins. The supporting hypothesis was sound in that aqueous solutions ought to easily penetrate the hydrophilic smear layer. After evaporation of the water solvent the acrylic monomers could then wet and bond to the relatively hydrophobic bonding resins (bis-GMA). Both the conditioners and bonding resins could polymerize together effecting a seal of the cut dentin.

PREDICATE DEVICE (cont).

HEMA-BENZ™

HEMA-BENZ is functionally and chemically similar to DENTIN CONDITIONER noted above. The product is intended to perform identical service but HEMA-BENZ is also referred to as a desensitizer. Desensitization, if it occurs at all, is due to the indirect effect of enhanced wetting of subsequent applications of primer resins. That is, reduction of sensitivity is due to the enhanced seal provided by the primers, the enhancement of the seal occurs through improved wetting provided by the products in question.

DESCRIPTION OF APPLICANT DEVICE

WET-PREP™

WET-PREP is an aqueous solution of hydroxyethyl methacrylate. Hence, it is an aqueous re-wetting agent (dentin conditioner) that is applied to acid etching tooth structure, by the dentist following prior to application of a hydrophilic dentin adhesive such as ALL-BOND 2. The purpose of WET-PREP is to keep the dental cavity preparation adequately moist before the dentist restores the lost tooth structure.

It is well known that ALL-BOND 2 and similar hydrophilic primer resin systems are most effective when applied to moist dentin as in the so-called wet technique¹. Some dentists have had difficulty determining exactly how wet to leave the dentin prior to application of hydrophilic primers. Brief drying with an air syringe prior to primer application often leads to desiccation of dentin with resultant collapse of collagen fibers. Collapsed collagen presents an effective barrier to penetration of primers.

Using the WET-PREP technique, the dentist can dry the cavity preparation following acid etching to assess the degree of enamel etching without fear of affecting the primer bond. The dentist simply re-wets with WET-PREP prior to application of the hydrophilic primer. WET-PREP precludes asking the familiar question, "How wet is wet?"

INTENDED USES OF APPLICANT DEVICE

WET-PREP is used to re-wet dried dentin following acid etching and drying of the prepared cavity. Following etching the dentist typically air dries the etched enamel to check that a chalky-white appearance is present indicating that etching has occurred. At this point the dentin and enamel are too dry for effective penetration of subsequently applied primers. Hydrophilic primers will not effectively penetrate the dried collapsed collagen layer. If the primer is unable to penetrate through collapsed collagen an effective seal will not occur and post-operative sensitivity is likely to result.

If WET-PREP is applied prior to application of the primers, it will effectively re-wet the collapsed collagen and allow for penetration of the hydrophilic primers through the moist collagen network. Enhancement of penetration of primers will improve the seal the restorative material makes with the prepared tooth. Since it is well known that microleakage is the predominant reason for post-operative sensitivity it is reasonable to assume an increase in sensitivity ought to result from the use of these products.

SCIENTIFIC CONCEPTS and SIGNIFICANT PERFORMANCE CHARACTERISTICS

WET-PREP is an aqueous solution of hydroxyethyl methacrylate (approx. 35%) with a small amount (<0.5%) of sodium fluoride and benzalkonium chloride. This solution has the ability to easily penetrate etched dentin and enamel and will help to prevent desiccation of the etched surface prior to application of primer resins. That is, after the etched enamel/dentin is dried to determine the quality of the etch, the dentist can re-wet the cut tissue with WET-PREP without concern for desiccation. The HEMA solution will keep the cut surface moist until application of hydrophilic primers.

It was found that WET-PREP significantly improved (greater than four fold increase) the shear bond strength of air dried dentin. This is a good indication of the product's efficacy. Desiccated dentin could be reconstituted so no significant difference could be found between treated teeth and those that were handled in a clinically acceptable fashion.

It was found that there was no statistically significant difference ($p=0.05$, $t=1.29$) between the shear bond strength of WET-PREP treated teeth and those left untreated. This was taken as an indication that WET-PREP did not significantly interfere with the bonding mechanism of the primer resins and the prepared tooth. However, WET-PREP treated teeth were found to have significantly greater shear bond strength when compared to HEMA-BENZ treated teeth ($p=0.5$, $t=3.39$).



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