

Protocols for Use July 30, 2022

Summary

DentaKote S[™] is indicated for use in providing for the relief of primary root recession sensitivity. It is applied using the included, pre-loaded applicator. The tooth root surface must be clean and debrided to be effective.

Indications and Protocols for Use:

- 1. Proper diagnosis needed to ascertain that no underlying pathological condition exists.
- 2. Differential diagnosis must assess for:
 - a. No pulpal pathology
 - b. No infection
 - c. No fractures
 - d. No caries
- 3. Upon satisfactory assessment, the sensitive tooth or teeth are identified. The following steps are prescribed:
 - a. Lightly blow some air on surface to enable a numerical value as to the intensity of the sensitivity using 1-10 with 10 being the most pronounced level.
 - b. Debride the area properly using instruments and flour of pumice only. Do not use fluoride-based cleaning products. These products will occlude the tubules and prevent the DentaKote S from performing as intended.
- 4. Using the pre-loaded applicator, swab (massage into) the affected root surface until the entire identified area is completely covered.
- 5. Promptly, after thorough application, use a two-inch square gauze to wipe off the excess DentaKote S from the applied surface. When wiped away thoroughly the remaining layer of DentaKote will be an ideal thickness. The desired layer is one micron thick, which is not visible without extreme magnification. *Wiping thoroughly will not remove the product, as such there is no concern regarding "over wiping."*
- 6. Wait approximately three minutes and use a gentle air blast from the three-way syringe to obtain the numerical sensitivity value.
- 7. Use a cold water "swish" to verify any other areas of sensitivity and or missed areas on the same sites. Go back in and retouch as needed.
- 8. The process can be repeated more than once during the same visit using the exact same protocol if necessary. Usually, an additional application is indicated because there were areas of the surface that did not receive coverage. It is not because of the thickness of the first application. It is due to voids in the application of the DentaKote S.



9. Some situations may require a secondary brush (composite bonding micro brush) to reach very close and or tight areas between the teeth where roots might be exposed.

Clinical Data

The results as of March 1, 2022.

After evaluating patients and eliminating those with a "differential diagnosis," 102 were selected to participate in the study. The above protocol was strictly adhered to.

The DentaKote S was reported to be 100 percent effective for all 102 patients. As of the publication of this protocol, the earliest (oldest) application was administered six-months prior. This patient and all subsequent patients (ranging from six months and every month thereafter to the present) are reporting 100 percent relief from sensitivity.

It is believed that using the proper screening and eligibility requirements "the protocol," each patient will experience the same results.