

## PerioDT Biofilm Debridement by YOUNG®

**INTRODUCTION:** PerioDT Biofilm Debridement is a topical liquid or gel intended for use as an adjunctive decontamination rinse of tooth surfaces during the performance of certain dental procedures to help remove the smear layer and tooth debris.

**INDICATIONS FOR USE:** PerioDT Biofilm Debridement is indicated for the following uses:

- 1) Chronic Periodontitis Treatment Procedures** - PerioDT Biofilm Debridement is indicated for use as an adjunctive debridement agent of tooth root surfaces during periodontal maintenance procedures to help with the removal of contaminated debris from the sulcus.
- 2) Root Canal Cleanser Procedures** - PerioDT Biofilm Debridement is indicated for use as an adjunctive rinse of tooth root canal systems and adjacent tooth surfaces during standard professional dental procedures to enhance the removal of post-instrumentation dental debris and smear-layer within the root canal systems.
- 3) Caries Restoration Procedures** - PerioDT Biofilm Debridement is indicated for use as an adjunctive rinse of exposed dentin surfaces in cavity preparations to assist in the removal of contaminated debris and smear-layer.

**DESCRIPTION:** PerioDT Biofilm Debridement is an opaque purple, semi-viscous, liquid or gel. It contains sulfonated phenolics and sulfuric acid, which act as desiccants when applied to the surface of tissues as a concentrated solution. Incidental contact with any oral tissue will cause it to temporarily turn "white" until the tissue rehydrates itself.

### 1) GENERAL DIRECTIONS:

Prior to any treatment with PerioDT, dry the surface to be treated with air or gauze. Read the Precautions below. PerioDT Biofilm Debridement is to be delivered topically with an irrigation syringe or other means chosen by the dental practitioner to aid in the cleaning of tooth surfaces post-instrumentation. Depending on the clinician's preference, a blunt-locking tip needle or a closed-end side-port needle may be used for product application. The product is typically either irrigated back-and-forth or delivered as a continuous stream for less than one minute (usually 10-30 seconds) depending upon the clinical situation, and then it is removed with a high-speed evacuator followed by a water rinse. As with any dental irrigation, it should generally start with the deepest portion of tooth surfaces and be irrigated thoroughly to the more superficial areas. Utilize dental barriers (rubber dam/cotton rolls) during application to assist with product location and control. **Excess oral cavity fluids in the irrigated area may reduce the effectiveness of PerioDT Advanced Dental Debridement.** Use cotton, compressed air, or similar methods to dry tooth surfaces as much as possible prior to application. For sites with bleeding, a generous amount of PerioDT Biofilm Debridement may be delivered directly at the source of the bleeding to displace the blood and facilitate cleansing. Remove PerioDT Biofilm Debridement by thoroughly irrigating the area with water and evacuate with suction. Removal of the product is required to stop the cleansing process. NOTE: If the patient has not been given a local anesthetic the product may elicit a stinging sensation during application until it is rinsed off. Prior to any treatment with PerioDT, dry the surface to be treated with air or gauze. Read the Precautions below.

### 2) DIRECTIONS FOR INDICATED CLINICAL PROCEDURES

**(A) Periodontal Debridement Procedures** (Scaling and Root Planing): PerioDT Biofilm Debridement is applied to the periodontal sulcus using an irrigation syringe with a blunt-tipped cannula following tooth root debridement to remove residual debris and calculus. The tip of the cannula is placed at the bottom of the sulcus and the product is delivered for 10-30 seconds until it rises to the gingival margin. The product overflow and tissue debris are captured and removed at the gingival margin by high-speed evacuation. The sulcus is then rinsed with water and the periodontal debridement procedure is then completed according to established protocols.

**(B) Root Canal Cleanser Procedures:** PerioDT Biofilm Debridement is to be used topically only with an irrigation syringe or vial chosen by the dental professional, to the pulp canal for endodontic treatment. As with any irrigation, it should start with the deepest portion of the canal and be irrigated thoroughly to the more superficial areas. Product is applied for up to one minute. Residual product is then immediately flushed from the cavity with a water rinse according to established protocols.

**(C) Caries Restoration Procedures:** PerioDT Biofilm Debridement is applied into the cavity space with an irrigation syringe following excavation of contaminated tissue. The product is delivered to the base of the cavity for 10-30 seconds, or, until all surfaces of the cavity have been rinsed while product overflow and debris are captured by continuous suction evacuation. Residual product is then immediately flushed from the cavity with a water rinse. The cavity restoration is then completed according to established protocol.

**WARNINGS:** Keep out of sight and reach of children. Do not use if the patient is allergic to any material containing sulfur in any form. Prolonged application time should be avoided. It is important to use high speed evacuation/suction to limit overflow of any excess material to areas that do not need to be treated. Avoid eye contact. If eye exposure occurs, immediately remove any lens, and irrigate eyes for at least 15 minutes with lukewarm water. After treatment, a "white patch" is seen in and around the treated mucosal tissue and any other areas that may have been touched by PerioDT. This white patch may flake off during the healing process, which is normal.

**PRECAUTIONS:** PerioDT Biofilm Debridement is for use in the oral cavity only. Safety and effectiveness in pregnant women and children under the age of 18 has not been established. PerioDT Biofilm Debridement may damage clothes or fabric if misapplied. When treating a patient with PerioDT, be sure to thoroughly evacuate and rinse all of the PerioDT from the treatment area. When utilizing PerioDT for periodontal treatment and/or heavy debridement, it is recommended to evacuate and rinse all of the PerioDT before beginning your scaling procedure. Then, if needed, reapply to periodontally diseased pockets and follow the instructions for use. If you choose to use any additional adjunctive treatments post treatment with PerioDT, it is recommended to wait at least 48 hours before placement or beginning treatment. PerioDT Biofilm Debridement is contraindicated for use where it may contact calcium hydroxide. PerioDT Biofilm Debridement is intended to be used in its original viscous state. Diluting with water and/or combining PerioDT Biofilm Debridement with another product will render the product ineffective and potentially harmful. If using PerioDT Biofilm Debridement prior to dental etching procedures, it should be applied and removed completely prior to application of the etching solutions.

**ADVERSE REACTIONS:** PerioDT Biofilm Debridement may cause local irritation upon administration. If excess irritation occurs, discontinue use. Continue to irrigate with water and evacuate until it is removed.

**HOW SUPPLIED:** 1-ml prefilled gel or liquid in an irrigation syringe. Store at room temperature, 15°-30°C or 59°-86°F.

**CONTAINS:** Hydroxybenzenesulphonic Acid, Hydroxymethoxybenzenesulphonic Acid, Sulfuric Acid, Water and FD&C Red #40. Gel contains Colloidal Silica.

For Professional Use Only, Single Use/Single Treatment.

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