

## DIRECTIONS FOR USE

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**DENTSPLY**  
TULSA DENTAL  
SPECIALTIES

# BioPURE<sup>®</sup> MTAD<sup>®</sup>

## ANTIBACTERIAL ROOT CANAL CLEANSER

Manufactured For:  
DENTSPLY Tulsa Dental Specialties  
DENTSPLY International, Inc.  
608 Rolling Hills Dr.  
Johnson City, TN 37604  
Phone: 1-800-662-1202  
Fax: 1-800-597-2779  
Website: www.tulsadentalspecialties.com



See Directions For Use



Non-Returnable If Opened



For Dental Use Only

Rx Only

### DESCRIPTION:

BioPURE MTAD ANTIBACTERIAL ROOT CANAL CLEANSER is a two-part liquid and powder product. Part A is the liquid, and Part B is the powder. The mixed solution cleanses the root canal, removes the smear layer, and kills the bacteria in an instrumented root canal without harming the tooth structure or soft tissue. The smear layer is removed by breaking down the layer into component particles that can be lifted away easily by the action of the fluid surrounding them. It is dispensed easily using a disposable syringe. The mixed solution contains 3% doxycycline.

### INDICATIONS FOR USE:

BioPure MTAD cleanser is used to chemically clean and disinfect root canal system after endodontic instrumentation. BioPure MTAD cleanser is recommended for use with patients over the age of eight (8) years.

### CONTRAINDICATIONS:

- BioPure MTAD cleanser is contraindicated for persons who have shown hypersensitivity to doxycycline or any other tetracyclines.
- BioPure MTAD solution is not a general disinfectant and should not be used as such.
- BioPure MTAD cleanser is not recommended for use in patients who are pregnant, nursing or in children under the age of eight (8) years.
- BioPure MTAD cleanser is not recommended for use in patients who have a known allergy to doxycycline or any other tetracyclines.

### WARNINGS:

- While the amount of doxycycline present in BioPure MTAD cleanser is low, it is not recommended for use in patients who are pregnant, nursing or in children under the age of eight (8) years.
- BioPure MTAD cleanser is not recommended for use in patients who have a known allergy to doxycycline or any other tetracyclines. Use of this product in these patients may cause: difficulty breathing, swollen face or eyes, hives or rash. The patient should be advised to contact his/her dental professional immediately should any of these symptoms occur.
- Skin contact may cause skin irritation. Symptoms include redness, itching, and pain. Immediately flush skin with plenty of cool soapy water for at least 15 minutes. Get medical attention.
- Eye contact may cause severe eye irritation and abrasion. Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.
- Inhalation may cause irritation to respiratory tract and mucous membranes. Symptoms may include coughing, shortness of breath. Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek attention of a physician immediately.
- Ingestion may cause nausea, vomiting, diarrhea and difficulty in swallowing. If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.
- BioPure MTAD cleanser is a single use product.
- Do not reuse irrigation needles.
- BioPure MTAD cleanser must be used as indicated. Reducing the dosage will not achieve an effective kill rate.

## PRECAUTIONS:

- Store both the powder and liquid at room temperature. Keep out of direct sunlight. Keep both the powder and liquid in sealed containers until needed.
- For best results, the use of 1.3% NaOCl for irrigation while instrumenting is recommended.
- BioPure MTAD solution must be used as indicated. Lower dosage (fewer milliliters) of BioPure MTAD cleanser will not kill bacteria as effectively.
- Use BioPure MTAD cleanser as the final irrigant before obturation.  
Do not use other solutions after BioPure MTAD solution.
- Store mixed solution under refrigeration (32-38°F or 0- 3°C).
- Mixed solution should be used within 48 hours.
- Use in a well ventilated area.
- When handling this product, the use of eye/face protection, latex or nitrile gloves and impervious protective clothing as appropriate to prevent skin contact is recommended.
- Wash your hands following use. No eating, drinking or smoking while handling this product.

## ADVERSE REACTIONS:

- While the amount of doxycycline present in BioPure MTAD cleanser is low, it is not recommended for use in patients who are pregnant, nursing or in children under the age of eight (8) years.
- BioPure MTAD cleanser is not recommended for use in patients who have a known allergy to doxycycline or any other tetracyclines. Use of this product in these patients may cause: difficulty breathing, swollen face or eyes, hives or rash. The patient should be advised to contact his/her dental professional immediately should any of these symptoms occur.
- Skin contact may cause skin irritation. Symptoms include redness, itching, and pain. Immediately flush skin with plenty of cool soapy water for at least 15 minutes. Get medical attention.
- Eye contact may cause severe eye irritation and abrasion. Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.
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## STEP-BY-STEP DIRECTIONS:

1. Remove parts A & B from the shipping boxes. Parts A & B will be in one of two dose sizes:
  - a. For a single canal, use a pre-filled 5 ml syringe (liquid) paired with the pre-filled bottle containing 150 mg of doxycycline (powder); both are color-coded blue.
  - b. For multiple canals (up to 4 canals), use a pre-filled 20 ml syringe (liquid) paired with the bottle containing 600 mg of doxycycline hyclate (powder); both are color-coded gray.
2. Select either the single or multidose liquid or powder to be used and remove their protective packaging.
3. Remove the protective cap from the syringe, and insert the syringe without the needle into bottle containing the powder.
4. Push the syringe tip fully into the bottle port. Twist syringe 1/4 turn clockwise to insure snug fit. Depress the plunger, dispensing all the solution from the syringe into the bottle.
5. Holding the bottle and syringe combination, gently rock them for 60 seconds, to dissolve the doxycycline. Do not shake vigorously or too many bubbles will form and make dispensing difficult.
6. If a 20 ml syringe was used, remove it from the bottle and replace it with a 5 ml syringe. After mixing, slowly draw the mixed solution into a 5 ml syringe. If you notice undissolved particles in the solution being drawn out of the bottle, express the solution back into the bottle and continue mixing as in step #5. A multi-canal dose can fill four of the 5 ml syringe.
7. Remove the syringe from the bottle and attach the needle onto the syringe filled with the mixed liquid.
8. Remove the cap on the needle. Insert the needle into the canal being treated.
9. Place the needle tip 1-2 mm of the working length.
10. Slowly express 1 ml of BioPure MTAD solution into the canal space, working the needle in an up-and- down motion. The needle has a side port.
11. Let the 1 ml of BioPure MTAD cleanser remain in the canal for five (5) minutes.
12. Place a #15 hand file to working length and mechanically agitate the solution.
13. Remove the 1 ml of BioPure MTAD solution with suction.
14. Rinse the canal with the remaining 4 ml of BioPure MTAD solution. DO NOT flush or irrigate with any other irrigant.
15. Dry the canal. Seal and obturate as normal.

## STORAGE:

Store both the unmixed powder and liquid components at room temperature. Keep the powder and components out of direct sunlight. Refrigerate any unused 5 ml syringes, filled with mixed solution. These syringes may be used up to 48 hrs later. Mark the date and time on the syringes.