

DIRECTIONS FOR USE

DENTSPLY
TULSA DENTAL
SPECIALTIES

QMiX[®] 2in1

IRRIGATING SOLUTION

Manufactured for:

DENTSPLY Tulsa Dental Specialties
DENTSPLY International, Inc.

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Johnson City, TN 37604
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Keep Away From Sunlight

Store At Room Temperature



NONRETURNABLE
IF SEAL IS BROKEN

For Dental Use Only
Rx Only

CAUTION:

- U.S. Federal law restricts the sale of this device to a dentist or clinician.

INDICATIONS FOR USE:

- QMix[®] 2in1 Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system after endodontic instrumentation.

CONTRAINDICATIONS:

- Do not use as a general disinfectant.
- Do not use as an oral rinse.

WARNINGS:

- Corrosive to metal.
- Keep out of the reach of children.
- Product contains Chlorhexidine which may cause allergic reactions in some people including difficulty in breathing, swollen lips, tongue or throat, hives or rash. Contact your dental professional immediately should this occur. Contact dermatitis from Chlorhexidine has also been reported in some individuals.

Should redness, itching or irritation occur, flush the skin with cool, soapy water for at least 15 minutes, and get medical attention.

- Avoid contact with eyes. 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.
- Direct inhalation may cause irritation to respiratory tract and mucous membranes. Symptoms may include coughing, shortness of breath. Remove patient to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek attention of a physician immediately.
- Do not swallow. Ingestion may cause nausea, vomiting, diarrhea, or difficulty swallowing. In normal conditions of use ingestion is not expected and if it occurs seek medical attention.
- Use a new packaged syringe and/or irrigation needles for each use to avoid contamination of QMix[®] 2in1 material.
- Do not store QMix[®] 2in1 in an application syringe.
- Use QMix[®] 2in1 as indicated. Reducing the dosage will not achieve effective cleaning.

PRECAUTIONS:

- Store at room temperature. Keep out of direct sunlight. Do not refrigerate. Replace cap securely between uses.
- Use of up to 6.15% NaOCl for irrigation prior to use of QMix[®] 2in1 is recommended.
- Rinse out the NaOCl with sterile water or saline prior to use of QMix[®] 2in1.
- Use QMix[®] 2in1 as indicated. Lower dosage (fewer milliliters) will not cleanse or disinfect the root canal as effectively.
- Use QMix[®] 2in1 as the final irrigant before obturation.
- Do not use QMix[®] 2in1 after expiration date.
- Care should be taken not to cross-contaminate solution in bulk containers.
- Use in a well ventilated area.

- When handling this product, the use of eye/face protection, latex or non-latex gloves is recommended.
- Wash your hands following use. No eating, drinking or smoking while handling this product.
- Do not use this product if the tooth is not properly isolated with a dental dam and protective equipment.
- All root canal procedures should be performed with sufficient visibility.

ADVERSE REACTIONS:

- This product contains Chlorhexidine. It may cause an allergic reaction difficulty in breathing, swollen lips, tongue or throat, hives or rash. Contact dermatitis (redness, itching, and/or irritation) from Chlorhexidine has also been reported in some individuals. Contact a dental or medical professional should these symptoms occur.
- Avoid contact with eyes. 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.
- Direct 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.

STEP-BY-STEP INSTRUCTIONS:

- Gently shake or agitate the QMix® 2in1 container prior to dispensing. Avoid creating excessive bubbles or foam inside container.
- Fill a fresh syringe with QMix® 2in1 from either the 60 ml (w/ Luer lock syringe adapter) or 480 ml bottle (w/o Luer lock syringe adapter). Replace cap on container. Syringe not included.
- For 60 ml container only: Push the syringe tip fully into the bottle port (Luer lock). Twist syringe 1/4 turn clockwise to insure snug fit. Pull back on the plunger, withdrawing solution from the bottle into the syringe.
- For 480 ml container: The solution may be poured into a smaller container prior to withdrawal into a syringe.
- Attach an irrigation needle to syringe (e.g. side vented 30 gauge ProRinse® Irrigation Needle with cap). Irrigation needle not included.
- Use up to 6.15% NaOCl for irrigation prior to use of QMix® 2in1.
- As with any final irrigation solution, rinse out the NaOCl with sterile water or saline.
- Remove cap from irrigation needle. Insert the needle into the canal being treated. Place the needle tip safely in canal (no more than 2 mm from apex). Express QMix® 2in1 into canal.
- Irrigate for 60-90 seconds.
- Remove QMix® 2in1 from canal and dispose.
- Dry the canal. Seal and obturate as normal.

STORAGE:

- Store at room temperature. Keep out of direct sunlight. Do not refrigerate. Replace cap securely between uses.
- Do not use QMix® 2in1 after expiration date.
- Do not store QMix® 2in1 in an application syringe.