DENSPLY TULSA DENTAL SPECIALIES



Manufactured for:

DENTSPLY Tulsa Dental Specialties DENTSPLY International, Inc.

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Rx only For Dental Use 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.
- Do not inject into soft tissue. Use irrigation needles only.
- Product contains chlorhexidine which may cause allergic reactions in some people including difficulty in breathing, swollen lips, tongue or throat, hives or rash. See immediate medical help 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 seek 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. Seek emergency medical attention.
- Direct inhalation may cause irritation to respiratory tract and mucous membranes. Symptoms may include coughing and/or 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.
- 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 sterile packaged syringes and irrigation needles for each use to avoid cross-contamination of QMix[®] 2in1 material.
- Do not store QMix® 2in1 in an application syringe.
- Use QMix® 2in1 as indicated.

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.
- It is desirable to rinse out the NaOCI with sterile water or saline prior to use of QMix[®] 2 in 1.
- 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 package expiration date.

- Care should be taken not to crosscontaminate 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 hands following use. Do not eat, drink or smoke while handling this product.
- Do not use this product if the tooth is not properly isolated with a dental dam and protective equipment.

ADVERSE REACTIONS:

- QMix® 2in1 is corrosive to metal.
- Keep out of the reach of children.
- Do not inject into soft tissue. Use irrigation needles only.
- Product contains chlorhexidine which may cause allergic reactions in some people including difficulty in breathing, swollen lips, tongue or throat, hives or rash. See immediate medical help 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 seek 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. Seek emergency medical attention.
- Direct inhalation may cause irritation to respiratory tract and mucous membranes. Symptoms may include coughing and/or 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.
- 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 sterile new packaged syringe and irrigation needles for each use to avoid cross-contamination of QMix® 2in1 material

- Do not store QMix® 2in1 in an application syringe.
- Use QMix® 2in1 as indicated.

STEP-BY-STEP INSTRUCTIONS: Use up to 6.15% NaOCI for irrigation

- prior to use of QMix® 2in1.

 Prior to irrigation solution, it is desirable to rinse out the NaOCI with
- sterile water or saline and suction.

 Gently shake or agitate the QMix® 2in1 container prior to dispensing. Avoid creating excessive bubbles or foam inside container.
- Remove original cap on 60 ml container and replace with Luer lock syringe adapter cap supplied with QMix® 2in1 60 ml.

60 ML USE

 Push the syringe tip fully into the supplied cap w/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.

480 ML USE

 The solution may be poured into a smaller sterile container prior to withdrawal into a syringe.

GENERAL USE

- Attach an irrigation needle to syringe (e.g. side vented 30 gauge ProRinse® Irrigation Needle with cap). Irrigation needle not included.
- Remove cap from irrigation needle. Insert the needle into the canal being treated. Place the needle tip safely in canal (at least 2 mm from apex). Express QMix® 2in1 into canal.
- Utilization of an EndoActivator is recommended as part of your protocol.
- Continuously irrigate for 60-90 seconds.
- Remove QMix® 2in1 from canal utilizing suction.
- Dry the canal with absorbent paper points. 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 package expiration date.
- Do not store QMix® 2in1 in an application syringe.
- Store Upright