# RRITROL TWO-IN-ONE IRRIGATION SOLUTION

This irrigation solution is intended to cleanse root canal systems by irrigating root canals after endodontic instrumentation.

REF Cat. No.

760-16

16oz. (473mL)

Caution: Federal law restricts this device to sale by or on the order of a licensed dentist. MADE IN USA

Directions for Use:

Lift Insert to see detailed product instructions.

Warning: Not to be used as an oral rinse. Avoid contact with eyes.

Visit www.edsdental.com for Safety Data Sheet (SDS).



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Lift Here See insert for full product information





CONSULT INSTRUCTIONS FOR USE











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## INDICATIONS FOR USE:

• IRRITROL is intended to cleanse root canal systems by irrigating root canals.

## CONTRAINDICATIONS:

- Not for use as a general disinfectant and should not be used as such.
- Not for use as an oral rinse.

# WARNINGS:

- Use of this product, in a small number of patients, may cause difficulty breathing, swollen face or eyes, hives or rash. The patient should be advised
- to contact his/her dental professional immediately in the unlikely event that 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.
- 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 nucous membranes.
   Symptoms may include coughing and/or 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.
- 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.
- Use freshly opened packaged syringes and sterile irrigation needles.

Do not reuse

- · Do not store in an application syringe.
- Use IRRITROL as indicated.

Reducing the dosage will not achieve effective cleaning.

• Clinical testing has not been performed to demonstrate the antimicrobial effectiveness of this device.

# **ADVERSE REACTIONS:**

- Use of this product, in a small number of patients, may cause difficulty breathing, swollen face or eyes, hives or rash. The patient should be advised to contact his/her dental professional immediately in the unlikely event that 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.
- 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 and/or 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.
- 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.

### PRECAUTIONS:

- Use of IRRITROL should be consistent with the standard of care for use of systemic antibiotics for endodontic treatment in the practice of dentistry.
- Store at room temperature. Keep out of direct sunlight. Do not refrigerate.

Replace cap securely between uses.

• Use of up to 6.15% NaOCI for irrigation prior

- to use of IRRITROL is recommended.

   Rinse out the NaOCI with sterile water
- or saline prior to use of IRRITROL.

  Use IRRITROL as indicated.
- Lower dosage (fewer milliliters) will not cleanse the root canal as effectively.

  • Use IRRITROL as the final irrigant before
- obturation.
  - · Do not use IRRITROL 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.
  - 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.

### INSTRUCTIONS:

- Gently shake or agitate the IRRITROL bottle prior to dispensing.
  - Avoid creating excessive bubbles or foam inside container.
- Pour the solution into a smaller container prior to withdrawal into a syringe.
   Attach an irrigation needle to syringe and
- draw solution into syringe.
- Use up to 6.15% NaOCI for irrigation prior to use of IRRITROL.
  - As with any final irrigation solution, rinse out the NaOCI 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 appx). Express solution into canal.
  - · Irrigate for 60-90 seconds.
  - Remove IRRITROL 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 after expiration date.
- Do not store in an application syringe.