

# Oraqix™ Dispenser

## Directions For Use

### Indications for Use:

The Oraqix™ Dispenser is indicated for the administration of Oraqix® (lidocaine and prilocaine periodontal gel) 2.5%/2.5%.

### Contraindications:

This Dispenser is contraindicated for use with all injectable local anesthetic products.

### Warnings:

**DO NOT INJECT Oraqix® (lidocaine and prilocaine periodontal gel) 2.5%/2.5%.**

The Dispenser should never be used to inject local anesthetic. Doing so may result in inadvertent intravascular injections. Aspiration is not possible with the Dispenser.

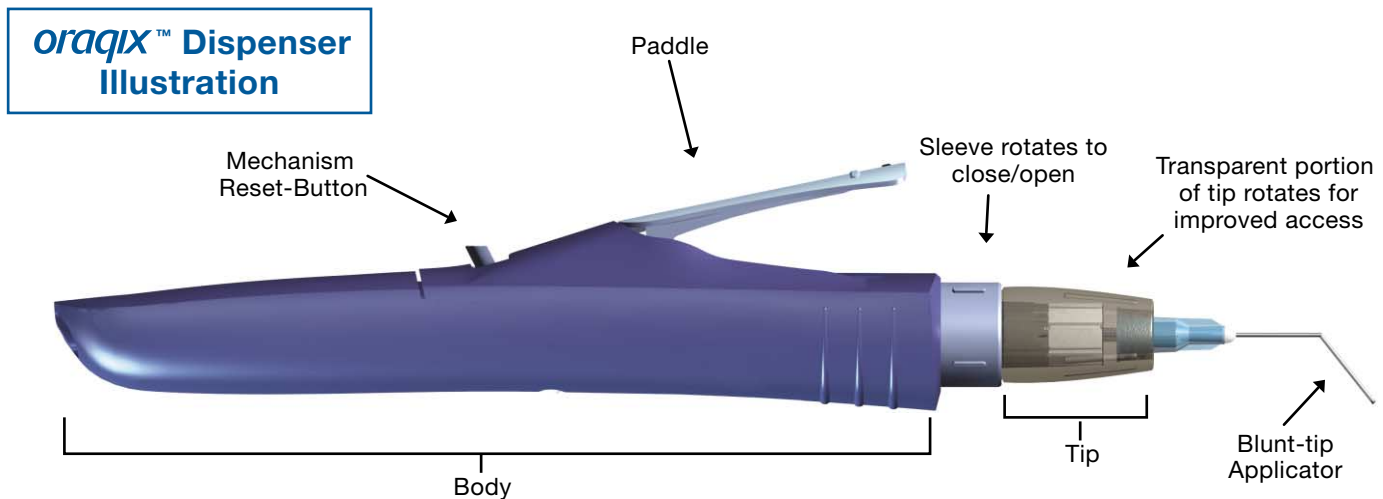
### Precautions:

It is recommended to autoclave the Dispenser before use. Only the steam autoclave cycle recommended in the step-by-step instructions should be used. Other cycles or methods of sterilization have not been validated for effectiveness and may damage the device. It is required to allow the Dispenser to cool to room temperature after autoclaving the device. If the Dispenser is warm, Oraqix® will change to the gel form and dispensing will not be possible. Although the plastic components are "heat-resistant" polymers, some discoloration of these materials will occur after repeated steam autoclave sterilization cycles. This discoloration will not affect the function of the Dispenser. If disinfectants are used, generously spray disinfectant solution on a clean towel or gauze pad and wipe the surface of the Dispenser. Do not spray directly on device surfaces. Do not immerse in disinfectant or any other solution. Prolonged use of some surface disinfectants (such as iodophor-based solutions) may cause discoloration of the plastic Dispenser components.

### Adverse Reactions:

Allergy or sensitivity to the plastic or metal components of the Dispenser is possible but rare.

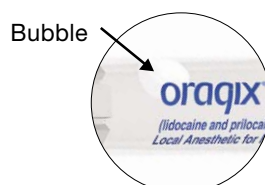
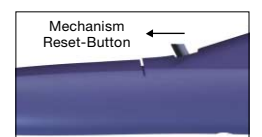
**Note: To clearly illustrate the drawings, the blunt-tip applicator cover is not shown.**



## Step-by-Step Instructions:

### 1. Dispenser Use

- 1.1 Separate an individual Oraqix blister pack at the perforation and remove the lidding paper. Remove the blunt-tip applicator from the plastic blister tray, break the seal and remove plastic cover from the cartridge-penetrating end of the cannula. Keep hands away from the exposed cannula during mounting and removal to prevent accidental injuries.
- 1.2 Attach the blunt-tip applicator to the tip of the Dispenser (Figure 1.2).
- 1.3 Reset the internal ratchet mechanism before loading the first cartridge. This is accomplished by pressing the **mechanism-reset button** towards the back end of the body (Figure 1.3).
- 1.4 The air bubble present in the Oraqix cartridge allows the user to determine if the product is in a liquid or gel form. If the bubble is fixed or moves very slowly, cool the cartridge before use to bring the product back to a liquid form. The cartridge may be loaded into the tip or body of the Dispenser (Figure 1.4).



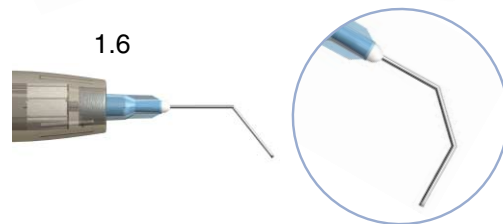
Optional



1.5 Carefully assemble the body and tip of the Dispenser with the cartridge in place (Figure 1.5). Holding the Dispenser in front of you with the tip facing right, rotate the tip sleeve section away from you until locked in place.

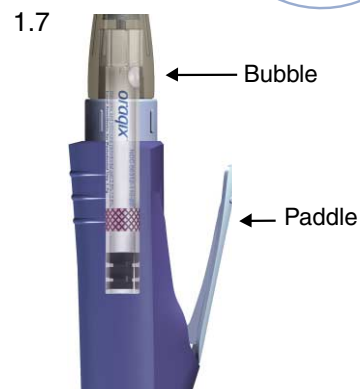


1.6 The applicator tip may be bent to improve access to the periodontal pockets, using the cap. If a greater bend than 45° is desired, a double-bend technique is recommended (Figure 1.6).



**Note: Do not bend the applicator tip more than once in the same location. Breakage may be more likely if bent at the hub.**

1.7 Hold the Dispenser vertically and observe the transparent portion of the tip (Figure 1.7). The air bubble in the cartridge will be visible and can be removed by depressing the paddle. This will provide more consistent flow of Oraqix. A back-light may assist with this step.



1.8 Dispense Oraqix by depressing the paddle. The volume of Oraqix used per tooth is dependent on the periodontal pocket space. Consult the Oraqix® (lidocaine and prilocaine periodontal gel) 2.5%/2.5% package insert for specific dose information.

1.9 Oraqix is a viscous liquid. Dispensing slowly and evenly works best.

1.10 When the cartridge is nearly empty, the rubber plunger will be visible in the transparent section of the Dispenser tip.

1.11 To reload the Dispenser, first depress the reset button (see Figure 1.3). You will hear the ratchet "click" back into the reset position.

1.12 Holding the Dispenser in front of you with the tip facing right, rotate the tip sleeve section toward you to unlock the Dispenser tip.

1.13 Remove the empty cartridge.

1.14 Insert a new Oraqix cartridge. A new blunt tip applicator may be used if needed.

1.15 Reposition the cartridge and tip assembly and lock in place as before.

1.16 When treatment is complete the Dispenser is cleaned and prepared for the next patient.

## 2. Preparing for the Next Use

2.1 Carefully remove the blunt tip applicator. Re-capping makes this easier. Although the tip is blunt, use a one-handed technique to prevent accidental exposure to the contaminated cannula. Dispose of in the same manner as a contaminated dental injection needle.

2.2 Remove the empty cartridge as described above.

2.3 If necessary, wash the surface of the Dispenser to remove any debris, blood or saliva that may be present.

2.4 After cleaning, disinfect and/or sterilize according to your office infection control procedures and the directions below.

### 2.5 Disinfection:

2.5.1 Disinfect the surfaces of the device using a registered hospital-level surface disinfectant. Generously spray disinfectant solution on a clean towel or gauze pad and wipe the surface of the Dispenser. Do not spray directly on device surfaces. Do not disinfect or "sterilize" the Dispenser by immersion.

2.5.2 After disinfection, wrap in a sterile drape and/or store the Dispenser in an area that will prevent contamination.

### 2.6 Sterilization:

2.6.1 Steam autoclave sterilization is recommended between patient uses. "Chemiclave" use has not been tested or validated for efficacy and is not recommended.

2.6.2 After properly cleaning the Dispenser, place the **tip and body (separated)** into an appropriately sized autoclave bag and seal.

2.6.3 Process at 134°C for 12 minutes at a minimum of 210 kPa pressure. Remove the sterile Dispenser from the autoclave when the cycle is complete.

2.6.4 Regularly test the efficacy of steam autoclaves as recommended by the equipment manufacturer or local regulations (e.g., bacterial spore test). Also observe manufacturer recommendations regarding autoclave capacity to prevent sterilization failure.