

Oraqix™ Dispenser

Directions For Use

Consult the ORAQIX Prescribing Information for complete product information. In Canada, prescribing information can be found in the Oraqix Product Monograph. In Australia, prescribing information can be found in the Oraqix Product Information. In New Zealand, prescribing information can be found in the Oraqix Data Sheet. In the US, prescribing information can be found in the Oraqix Package Insert.

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.

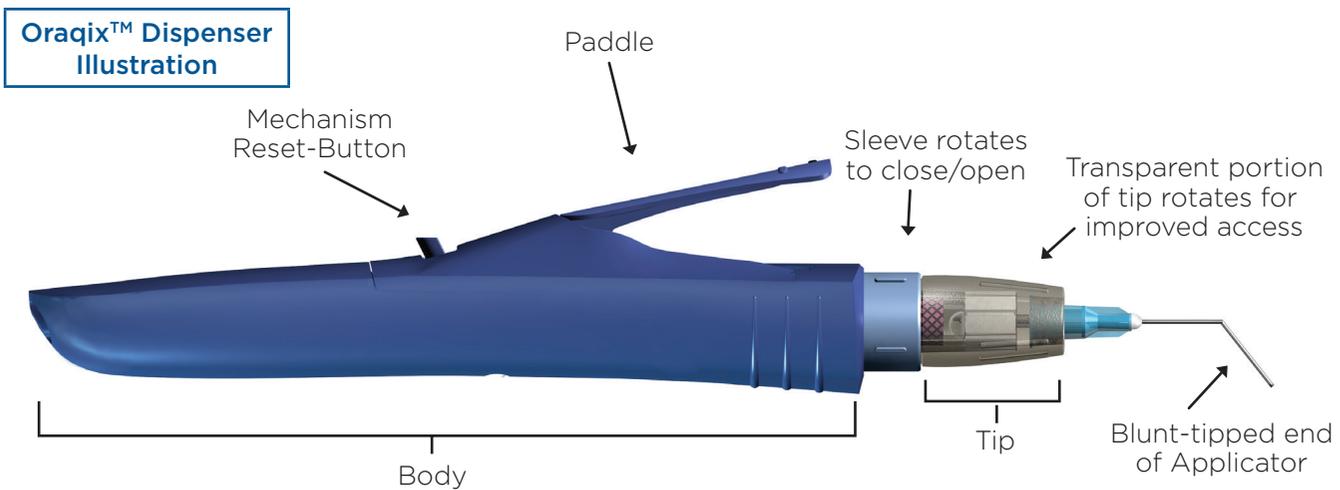
Precautions related to Sterilization of the Dispenser:

It is recommended to autoclave the Dispenser before first use. Only the steam autoclave cycle recommended in the step-by-step Sterilization 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.

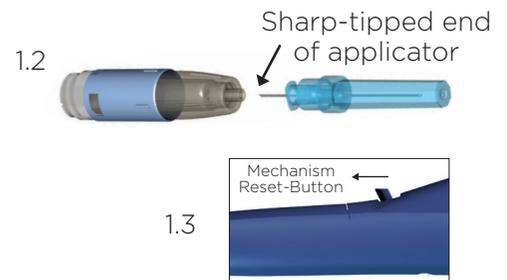
Note: To clearly illustrate the drawings, the blunt-tipped end of applicator cap is not shown.



Step-by-Step Instructions:

1. Dispenser Use

- Separate an individual ORAQIX blister pack at the perforation and remove the lidding paper. Remove the applicator from the 1.2 plastic blister tray. The applicator has a blunt-tipped end for ORAQIX application and a sharp-tipped end for piercing the rubber top of the ORAQIX cartridge. Break the seal and remove the plastic cover from the sharp-tipped end of the applicator. Keep hands away from the exposed sharp-tipped end of the applicator during mounting and removal to prevent accidental injuries.
- Attach the sharp-tipped end of the applicator to the tip of the Dispenser (Figure 1.2).
- 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).
- 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). Do not remove the collar from the cartridge.



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 blunt-tipped end of the applicator 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.

Save the cap from the blunt-tipped end of the applicator as it will facilitate removal of the applicator from the Dispenser when treatment is complete.

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, Data Sheet or Product Monograph/Information 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.

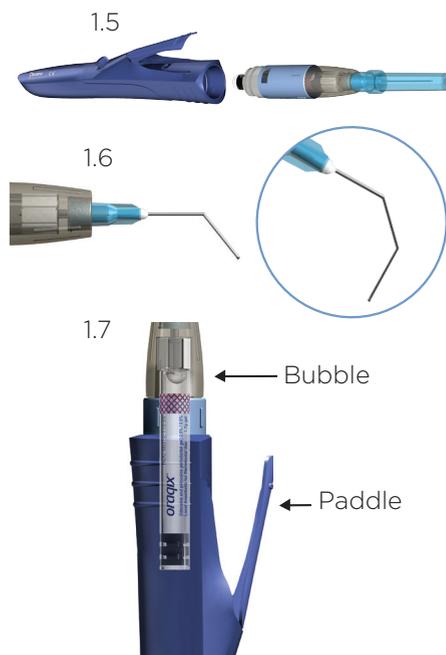
1.12 Holding the Dispenser in front of you with the tip facing right, rotate the tip sleeve section toward you to unlock the Dispenser tip.

1.13 Remove the empty cartridge.

1.14 Insert a new ORAQIX cartridge. A new 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 Remove the empty cartridge as described above.

2.2 Carefully remove the applicator from the Dispenser (avoid the sharp-tipped end of the applicator). Re-capping the blunt-tipped end makes this easier. Although this applicator tip is blunt, use a one-handed technique to prevent accidental exposure to the contaminated tip. Dispose of in the same manner as a contaminated dental injection needle.

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 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, enclose the **tip and body (separated)** into an appropriately sized sterilization pouch intended for steam sterilization.

2.6.3 Gravity Displacement Sterilization:

Full cycle: 134°C (273°F) for 12 minutes

2.6.4 Keep the Dispenser in the sterilization pouch until ready to use in the operatory.

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