

INSTRUCTIONS FOR USE

DentalJect® DJ04000 Applicator Set

Thoroughly Read this “Instructions For Use” before using the DentalJect for the first time.

CAUTION:

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

DENTALJECT DESCRIPTION:

The DentalJect Applicator Set is a prescription device that may be attached to a standard dental syringe and dispenses a non-medicated, non-flammable vapocoolant blend as a topical anesthetic for intact oral mucosa.

INDICATION FOR USE:

The DentalJect is intended for topical application to intact mucous membranes in the oral cavity. The DentalJect is used to target a minimally sized cooling area for lessening pain associated with injections.

PRECAUTIONS:

- Apply only to intact oral mucosa. Do not spray onto open mucosa, ulcerated tissue, puncture wounds, or large areas of damaged mucosa.
- To maintain patient comfort, avoid spraying directly on sensitive (unanesthetized) teeth or teeth with exposed root surfaces.
- Do not spray directly onto dental plaque, as this may contribute to the spread of infection.
- Do not apply to skin or non-oral mucosal surfaces, including genital mucosa.
- Thin mucosa may require shorter or lighter application than thicker mucosa.
- Do not spray into a closed mucosal space.
- Do not spray into or near the eyes; use gauze or protective eyewear to prevent accidental exposure.
- The freezing-thawing cycle may cause transient discomfort and temporarily reduce local resistance to infection; use with appropriate clinical judgment.
- Use caution in patients with systemic or local conditions that may cause reduced saliva flow, impair mucosal integrity, healing, or immune response, which could cause frostbite or tissue sloughing (such as uncontrolled diabetes, dehydration or malnutrition, adrenal insufficiency, vitamin C deficiency, cancer, or autoimmune disease)
- Use caution when oral conditions are present that may complicate effective application or spread infection (such as macroglossia, sexually transmitted infections in the oral cavity, or unbiopsied lesions).
- Avoid repeated or prolonged application beyond the recommended spray duration.
- Discontinue use if irritation or unexpected tissue response develops.

ADVERSE REACTIONS:

Over-application to the same area may cause frostbite and/or alter pigmentation.

CONTRAINDICATIONS:

- Hypersensitivity to HFO-1234ze: (trans-1,3,3,3-tetrafluoroprop-1-ene) or Non-denatured Ethanol.
If irritation develops, discontinue use.
- No salivary flow.

WARNINGS:

- For oral use only.
- Contents under pressure. Do not expose the canister to temperatures above 120°F (50°C).
- **DO NOT AUTOCLAVE** the canister.
- Use only as directed.
Intentional misuse by deliberately concentrating and inhaling the contents can be harmful and potentially fatal.

CONTENTS:

HFO-1234ze: (trans-1,3,3,3-tetrafluoroprop-1-ene), non-denatured ethanol (200prf) and peppermint oil flavor

STORAGE:

Do not expose the canister to heat or store in temperatures above 120°F (50°C).

DISPOSAL:

Do not puncture or incinerate the canister. Dispose of the canister in accordance with local regulations.


PEDIATRIC NOTE:

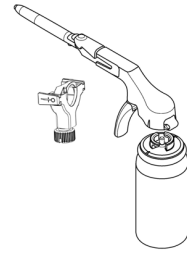
Safety for the use of this device in pediatric patients has not been established; it is therefore recommended that the device should not be used in patients under the age of four years without the consultation of a pediatric dentist.

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS FOR USE: DJ04000 DENTALJECT APPLICATOR SET

DEVICE SYMBOL GLOSSARY:

Syringe Symbol	Purpose:
	The syringe symbol located on the Syringe Connector is used to ensure proper orientation when placing it on the dental syringe. The direction should match that of the syringe when viewed from the side with thumbscrew facing down.

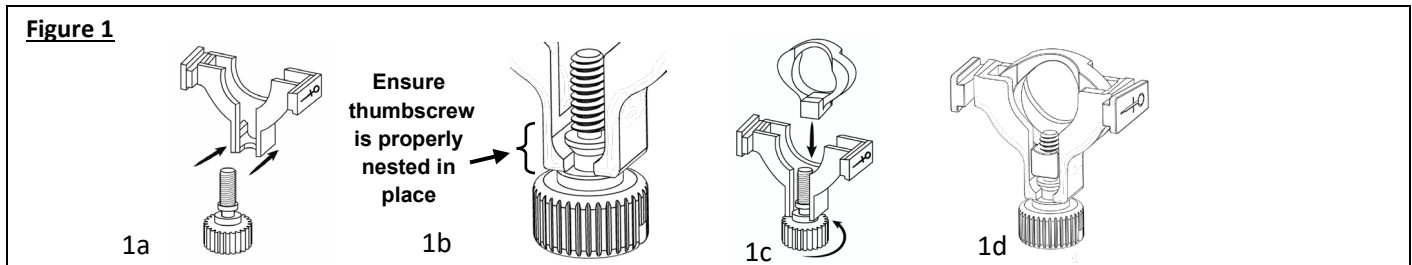


COMPATIBILITY:

DentalJect is compatible with most dental syringes with barrel lengths in standard ranges of 60 to 80 mm and diameters ranging from 11 mm to 13 mm.

NOTE: the DentalJect Applicator may be used without the syringe connector attached. This is referred to as the Assisted Method where an assistant performs the spray, with the dentist following up with the injection. For the Assisted Method proceed to step 6.

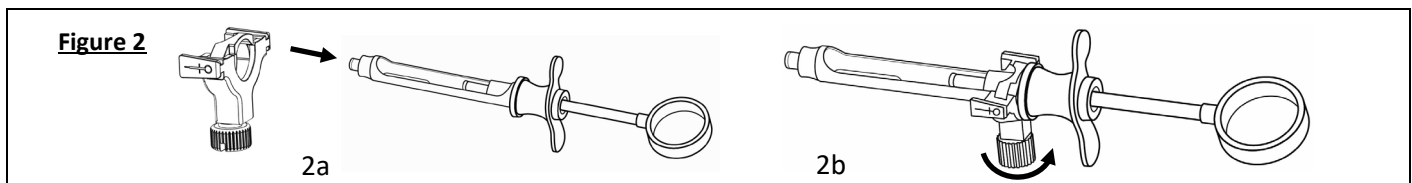
1. Clean and sterilize DentalJect components according to the reprocessing instructions (*Cleaning Procedure and Sterilization Procedure sections, pages 6 & 7*).
2. Assemble the syringe connector per Figure 1, if required. Insert the thumb screw into the connector (Figures 1a & 1b). Per Figure 1c, carefully insert the clamp on the thumb screw, then turn the thumbscrew into the clamp as shown in Figure 1d.



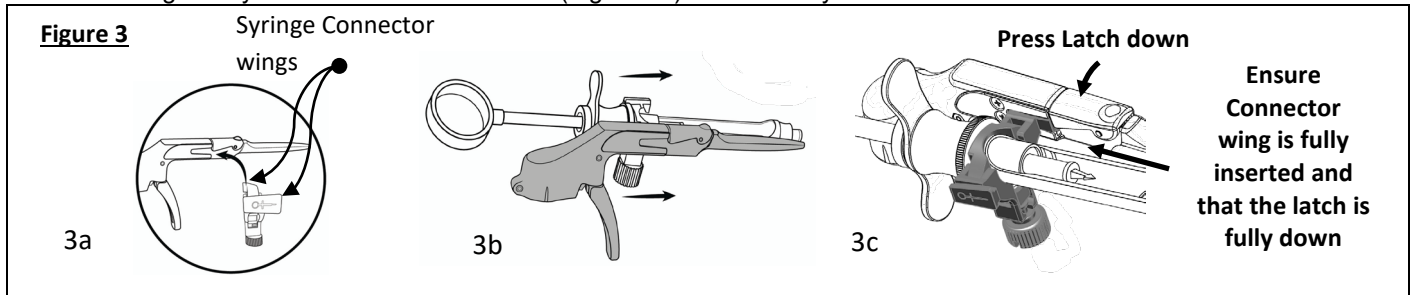
3. Slide the DentalJect Syringe Connector onto the barrel of your dental syringe, ensuring that the engraved syringe marking on the connector is oriented in the same manner as the syringe when viewed from the side (Fig. 4a). Snug the connector up against the finger grip (Fig. 4b) and **ensure the thumb screw is facing down**. The Carpule window should not be obscured.

CAUTION: Do NOT place the Connector onto the syringe or remove the Connector while an exposed (uncapped) needle is attached.

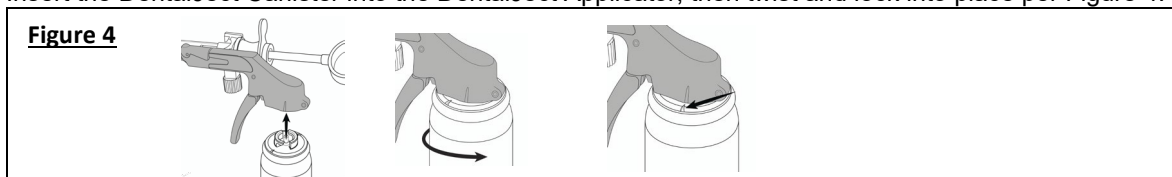
4. Ensure that the DentalJect Syringe Connector is tightly secured to your dental syringe by firmly turning the thumb screw (Figure 2b). Check that it does not move when pushed or pulled. Tighten further if needed. Then attach your needle and local anesthetic carpule, per standard procedures. Ensure that the carpule markings are visible for aspiration and that the needle is securely in place.



5. Per Figure 3, after attaching the DentalJect Syringe Connector to the syringe, slide the wing of the Syringe Connector into the metal slot on the DentalJect Applicator; the latch will automatically lift as you insert the wing (Figures 3a, 3b). Ensure that the connector wing is fully inserted and that the latch (Figure 3c) is all the way down after insertion.



6. Insert the DentalJect Canister into the DentalJect Applicator, then twist and lock into place per Figure 4.



7. Perform a quick ½-second test spray into the air to confirm the device is operating as intended, and tug on the syringe to ensure it is securely connected.
8. Explain to the patient that you are spraying the area to be injected with local anesthetic, which will create a cold sensation.
9. If cleaning of the injection site is required, wipe the area with clean, dry 2x2 gauze per your standard procedures. Ensure the area is NOT dry before spraying, as salivary coating is necessary to develop the blanch.
10. A saliva ejector, or preferred High-Volume Extractor (HVE), should be used during the spray application to reduce the level of “fog” that may occur in the oral cavity.
11. Instruct the patient to gently and slowly exhale during the spray procedure.
12. While positioning the nozzle, use caution and maintain awareness of the needle position. Keep the needle tip ½ inch or more from the mucosal tissue to avoid accidental contact.
13. Avoid spraying vital teeth or teeth with exposed root surfaces.
14. Position the canister vertically/upright. Position the DentalJect nozzle end from 1 inch to 3 inches from the intended injection site. When mounted on a syringe, this distance will vary depending on your needle length. Aim at the intended injection site. Pull the trigger for 1 to 2 seconds. This will dispense the vapocoolant blend at an average rate of 1 gram per second.
15. Do not overspray the target area beyond the state of frost (ice crystals). A residual sensation of cold is considered normal. In most cases the saliva coating will turn white (blanch), this is normal.

Note: The blanch indicates the most effective zone of numbing. Once this appears fully on the targeted area, do not spray for more than 1 second longer.

The total spray time should not exceed 2 seconds

Note: Even if blanching does not occur, a short numbing effect will still be present. However, the most effective numbing lasts for 3 to 8 seconds after blanching occurs, and some decreased sensation may persist for up to a minute.

- 16. Immediately perform the injection after the 1 to 2 second spray.**

17. Cap and remove the needle according to your local safety and disposal practices.

REMOVAL OF DENTAL SYRINGE CONNECTOR FROM THE APPLICATOR

1. Cap the needle before attempting to remove the Syringe Connector from the DentalJect applicator to avoid accidental needlestick injury.

NOTE: Do NOT attempt to remove the Dental Syringe from the Syringe Connector while still attached to the DentalJect Applicator to avoid accidental needle stick injury.
2. Lift the latch on the DentalJect Applicator and carefully slide the wing of the Syringe Connector off the Applicator.

DISASSEMBLY:

1. **Ensure the needle is capped and removed from the syringe BEFORE removing the Syringe Connector.**
2. Per Figure 5, remove the Syringe Connector by rotating the thumb screw as viewed in Figure 5a, and slide off the syringe barrel (Figure 5b).
3. Follow the reprocessing cleaning and sterilization instructions.



NOTE - NEEDLES AND CARPULES:

User-provided needles and local anesthetic carpules **are single-use only** and must be disposed of per state and local laws. Exposure to bloodborne pathogens through needlestick injuries is a serious and potentially deadly occupational risk. Please follow all manufacturers' instructions as well as your established protocol per OSHA Bloodborne Pathogens Standard and the Needlestick Safety and Prevention Act.

REPROCESSING:

NOTE: The DentalJect Device is provided **non-sterile** and must be cleaned and sterilized prior to first use and every use thereafter. If possible, an automatic cleaning and sterilization method should be used. Manual cleaning is only recommended in the event that an automatic method is unavailable.

DENTALJECT CANISTER – CLEANING AND DISINFECTION

Point of Use: Wipe down the canister between uses, as soon as practicable, using disinfection wipes (e.g., CaviWipes™). Follow local and state government requirements for disposal of aerosol containers.

NOTE: DO NOT AUTOCLAVE THE CANISTER.

CLEANING PROCEDURE

1. Disconnect the Canister from the DentalJect Applicator.
2. Use a dry soft-bristle brush to remove any gross debris.
3. Perform a visual inspection to ensure that any visible debris has been removed.

DISINFECTION PROCEDURE:

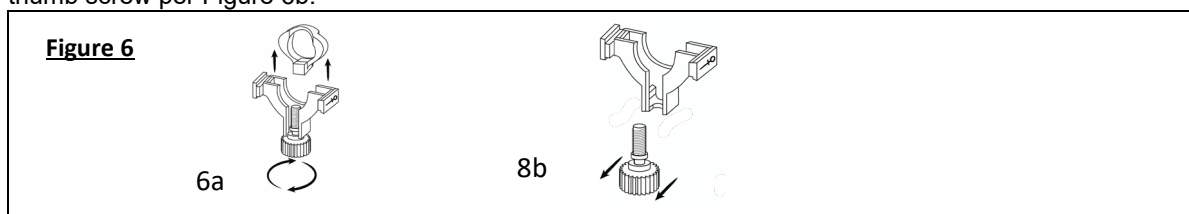
4. Thoroughly wipe down the canister using disinfection wipes (e.g., CaviWipes), ensuring that all surfaces are clean and free from visible debris.
5. Ensure that the surfaces of the canister stay wet for at least 3 minutes or as instructed by the wipe manufacturer's instructions. Use additional wipes as needed to ensure that the surfaces stay wet.
6. Allow the surface of the canister to air-dry. Do not rinse.

DENTALJECT APPLICATOR AND SYRINGE CONNECTOR – CLEANING AND DISINFECTION

Point of Use: Wipe the DentalJect down between uses for the same patient, as soon as practicable, using disinfection wipes (e.g., CaviWipes™). Follow the steps below for reprocessing after use and between patients.

PRE-TREATMENT:

1. Follow Disassembly instructions (pg. 3). The capped needle and carpule should be removed from the syringe before removing the Connector from the syringe.
2. Pre-soak the components in cold tap water for 5 minutes.
3. Disassemble the syringe connector (Figure 6) by turning the thumbscrew as shown in Figure 6a, and remove the thumb screw per Figure 6b.



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CLEANING PROCEDURE:

4. Brush the components using a soft-bristle brush until all coarse residue is removed. Pay close attention to any difficult-to-reach crevices or mating surfaces.
5. Rinse the components under cold running tap water for 1 minute, ensuring all surfaces are exposed to remove any gross debris.
6. Place the components in an ultrasonic bath containing Prolystica 2x Concentrate Enzymatic Presoak and Cleaner, or equivalent, prepared at the minimum concentration according to the manufacturer's instructions, at 45°C for 15 minutes.
7. After being submerged in the ultrasonic bath for 5 minutes, move the trigger 5 times to loosen the remaining debris and to allow for the cleaning solution to penetrate non-rigid surfaces.
8. Return to the ultrasonic bath for an additional 10 minutes for a total exposure of at least 15 minutes
9. Remove the components from the cleaning solution and rinse under running tap water for at least 1 minute.
10. Perform a visual inspection to ensure that any visible debris has been removed. Repeat the steps above if necessary.

STERILIZATION PROCEDURE:

11. Place the components in an FDA 510(k) cleared sterilization pouch or wrap.
12. Use the parameters below to sterilize the DentalJect Device and Syringe Connector:

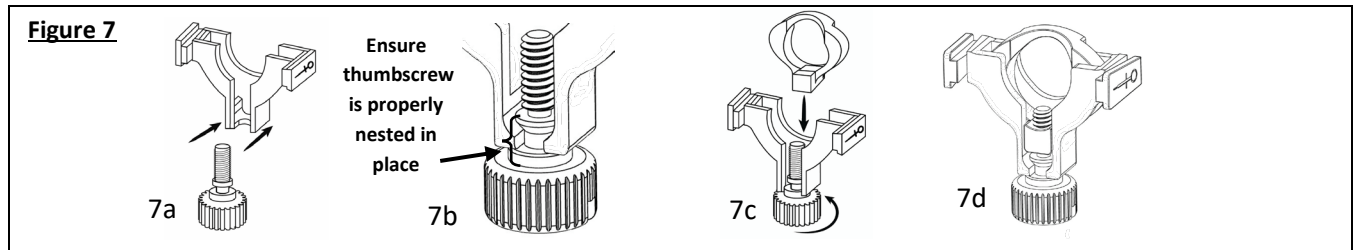
GRAVITY-DISPLACEMENT STEAM STERILIZATION PARAMETERS

EXPOSURE TEMPERATURE	EXPOSURE TIME	DRYING TIME
121°C (250°F)	30 MINUTES	30 MINUTES MINIMUM

DYNAMIC AIR REMOVAL STEAM STERILIZATION PARAMETERS

EXPOSURE TEMPERATURE	EXPOSURE TIME	DRYING TIME
132°C (270°F)	4 MINUTES	30 MINUTES MINIMUM

13. Carefully inspect the device and all its components after sterilization for any signs of cracking, abnormal discoloration, or material degradation.
14. **Connector re-assembly:** Per Figure 7, insert the thumb screw into the connector (figs. 7a & 7b). Then, carefully insert the clamp onto the thumb screw (fig. 7c), and turn the thumbscrew (fig. 7c) into the clamp as shown in fig. 7d.



NOTE: The DentalJect Applicator and Syringe Connector have been validated for reprocessing up to 15 times.

HOW SUPPLIED:

- | | |
|---|-------------------|
| DentalJect Canister
(net weight 40 grams) | DJ03000-01 |
| DentalJect Canister pack of 5
(net weight 40 grams ea.) | DJ03000-05 |
| DentalJect Applicator Set | DJ04000-00 |
| Contains: | |
| DentalJect Applicator with | |
| DentalJect Syringe Connector | |



DISCLAIMER: Use of the DentalJect® device is intended to improve patient comfort during injections and does not guarantee to always eliminate pain.

Note: The **DJ01000 DentalJect Applicator with an integrated spray guide** is also available. The DJ01000 model does NOT allow attachment to a syringe. Refer to the DentalJect DJ01000 IFU.