

CAUTION:

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

DENTALJECT DESCRIPTION:

The DentalJect is a prescription device which 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:

- Thin mucosa will require less misting than thicker mucosa (thickness depends on fat storage, blood vessels, and keratin).
- Do not spray into the eyes. Cover eyes with gauze or protective eyewear to avoid unintentional misting close to the eyes.
- Do not spray on skin; apply only to Intact mucous membrane.
- Do not spray onto open mucosa, or large areas of damaged mucosa, puncture wounds, or serious wounds.
- Do not use on patients with poor circulation (i.e., diabetic) or spray on insensitive tissue.
- Do not use on genital mucous membrane.
- Do not spray plaque to avoid spreading infection.
- Do not spray onto sensitive (unanesthetized) teeth, or teeth with exposed root surfaces due to gingival recession.
- Do not spray into a closed membrane space or chamber.
- The freezing and thawing process may be painful, and freezing may lower local resistance to infection and delay healing.
- Avoid additional spraying in the same location after completing a procedure to avoid adverse reactions.
- Discontinue use if irritation develops.

ADVERSE REACTIONS:

Over-application of 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.
- Uncontrolled diabetic patient or a feeble, malnourished (special diet) and dehydrated patient.
- A patient with any mucosal ulcers or any lesions that were not biopsied to determine the cause.
- Sexually transmitted diseases in the oral cavity.
- Macroglossia (large tongue).
- Adrenal insufficiency.
- Vitamin C deficiency.
- Cancer patients or those with an autoimmune disease.

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

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

APPLICATION METHODS:

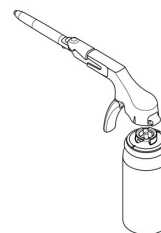
STANDALONE USE (4-handed method, Dentist + Assistant):

When using the DentalJect Applicator not attached to a dental syringe, it is recommended that an assistant perform the spray following Section A. Directions for use: DJ01000, Standalone Method, to allow the practitioner to immediately perform the procedure once the spray is finished.

ACCESSORY USE (2-handed method, Dentist only):

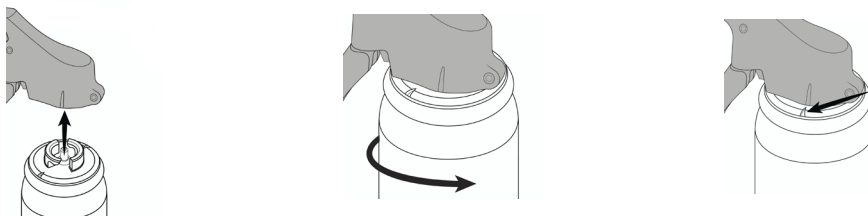
To use the DentalJect Applicator attached to the syringe, follow the instructions on page 4, Section B. Directions for Use DJ04000 DentalJect Applicator Set.

A. DIRECTIONS FOR USE: DJ01000, STANDALONE METHOD



1. Clean and sterilize DentalJect components according to the reprocessing instructions (*Cleaning Procedure and Sterilization Procedure sections, page 3*).
2. Insert the DentalJect Canister into the DentalJect Applicator then twist and lock into place per Figure 1.

Figure 1



3. Perform a quick ½-second test spray in the air to confirm the device is operating as intended.
4. Explain to the patient that you are spraying the area which will create a cold sensation.
5. If cleaning is required at the injection site, wipe the area with clean, dry 2x2 gauze according to your standard procedures. Ensure the area is NOT dry before spraying, as salivary coating is necessary to develop the blanch.
6. A saliva ejector, or High-Volume Extractor (HVE), should be used during the spray application to reduce the level of “fog” that may occur in the oral cavity.
7. Perform a quick ½-second test spray in the air to confirm the device is operating as intended.
8. Instruct the patient to gently and slowly exhale during the spray procedure.
9. While positioning the nozzle, use caution and maintain awareness of the clinician performing the injection and the needle position.
10. Avoid spraying sensitive teeth or teeth with exposed root surfaces due to gingival recession.
11. Position the canister vertically/upright. Position the DentalJect nozzle end from 1 inch to 3 inches from the intended injection site. 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.
12. Do not overspray the target area beyond the state of frost (ice crystals). A residual sensation of cold is considered 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 the blanch does not occur, there will still be a short numbing effect. 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.

13. Immediately perform the injection after the 1 to 2 second spray.

REPROCESSING INSTRUCTIONS FOR DENTALJECT APPLICATOR

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.

Point of Use: Wipe the DentalJect Applicator 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. Pre-soak the DentalJect Applicator in cold tap water for 5 minutes.

CLEANING PROCEDURE FOR DENTALJECT APPLICATOR

2. Brush the DentalJect Applicator using a soft-bristle brush until all coarse residue is removed. Pay close attention to any difficult-to-reach crevices or mating surfaces.
3. Rinse under cold running tap water for 1 minute, ensuring all surfaces have been exposed in order to remove any gross debris.
4. Place 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.
5. 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.
6. Return the Applicator to the ultrasonic bath for an additional 10 minutes for a total exposure of at least 15 minutes.
7. Remove the Applicator from the cleaning solution and rinse under running tap water for at least 1 minute.
8. Perform a visual inspection to ensure that any visible debris has been removed. Repeat the steps above if necessary.

STERILIZATION PROCEDURE FOR DENTALJECT APPLICATOR

9. Place the applicator in a 510(k)-cleared sterilization pouch or wrap.
10. Use the parameters below to perform the sterilization

GRAVITY-DISPLACEMENT STEAM STERILIZATION PARAMETERS

<u>EXPOSURE TEMPERATURE</u>	<u>EXPOSURE TIME</u>	<u>DRYING TIME</u>
121°C (250°F)	30 MINUTES	30 MINUTES MINIMUM

DYNAMIC AIR REMOVAL STEAM STERILIZATION PARAMETERS

<u>EXPOSURE TEMPERATURE</u>	<u>EXPOSURE TIME</u>	<u>DRYING TIME</u>
132°C (270°F)	4 MINUTES	30 MINUTES MINIMUM

11. Carefully inspect the applicator after sterilization for any signs of cracking, abnormal discoloration or material degradation.

REPROCESSING INSTRUCTIONS FOR DENTALJECT CANISTER:

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 FOR DENTALJECT CANISTER

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.

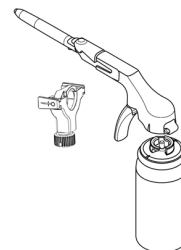
DISINFECTION PROCEDURE FOR DENTALJECT CANISTER

4. Thoroughly wipe down the canister using disinfection wipes (e.g., CaviWipes™), ensuring that all surfaces have been wiped and that no visible debris is present.
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.

B. 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.

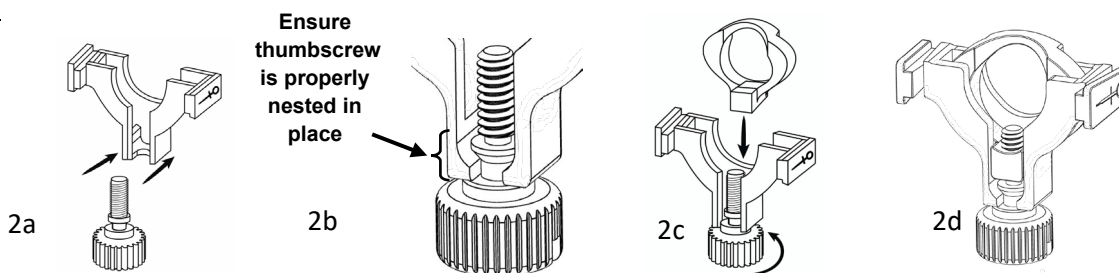


COMPATIBILITY:

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.

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

Figure 2

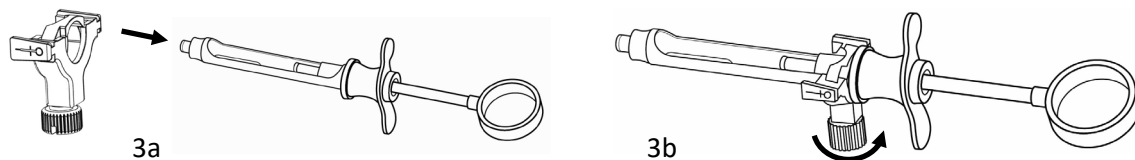


3. Slide the DentalJect Syringe Connector onto the barrel of your dental syringe, ensuring that the engraved syringe marking on the connector is oriented in the same manner as the syringe when viewed from the side (Fig. 3a). Snug the connector up against the finger grip (Fig. 3b) and **ensure the thumb 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 a needle is attached.

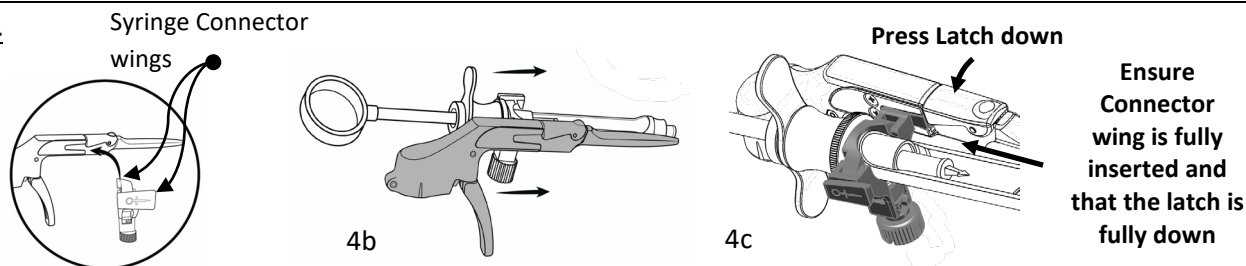
4. Ensure that the DentalJect Syringe Connector is tightly secured to your dental syringe by firmly turning the thumb screw (Figure 3b). Check that it does not move when pushed or pulled. Tighten further if needed. Then attach your needle and drug carpule, per standard procedures. Ensure that the carpule markings are visible for aspiration and that the needle is secure.

Figure 3



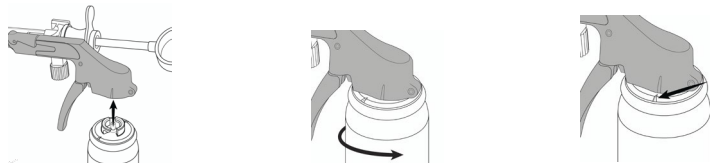
5. Per Figure 4, after attaching the DentalJect Syringe Connector to the syringe, slide the wing of the Syringe Connector into the metal slot on the DentalJect Applicator, the latch will automatically lift as you insert the wing (Figures 4a, 4b). Ensure that the connector wing is fully inserted and that the latch (Figure 4c) is all the way down after insertion.

Figure 4



6. Insert the DentalJect Canister into the DentalJect Applicator then twist and lock into place per Figure 5.

Figure 5



7. Perform a quick ½-second test spray in the air to confirm the device is operating as intended and tug on the syringe to ensure that it is connected securely.
8. Explain to the patient that you are spraying the area which will create a cold sensation.
9. If cleaning is required of the injection site, 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 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 sensitive teeth or teeth with exposed root surfaces due to gingival recession.
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.

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 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 6, remove the Syringe Connector by rotating the thumb screw as viewed in Figure 6a, and slide off the syringe barrel (Figure 6b).
3. Follow the reprocessing cleaning and sterilization instructions.

Figure 6



NOTE - NEEDLES AND CARPULES:

User-provided needles and drug 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., CaviWipesTM). 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:

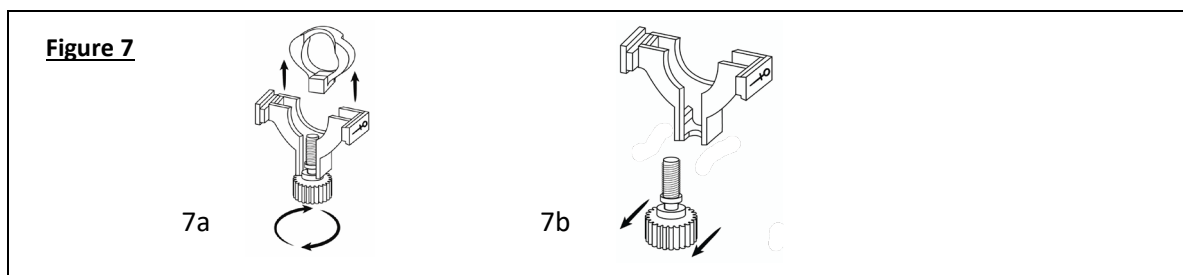
4. Thoroughly wipe down the canister using disinfection wipes (e.g., CaviWipes), ensuring that all surfaces are clean and free from visible debris.
5. Ensure that the surfaces of the canister stay wet for at least 3 minutes or as instructed by the wipe manufacturer's instructions. Use additional wipes 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., CaviWipesTM). Follow the steps below for reprocessing after use and between patients.

PRE-TREATMENT:

1. Follow Disassembly instructions (pg. 5). 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 7) by turning the thumbscrew as shown in Figure 7a, and remove the thumb screw per Figure 7b.



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

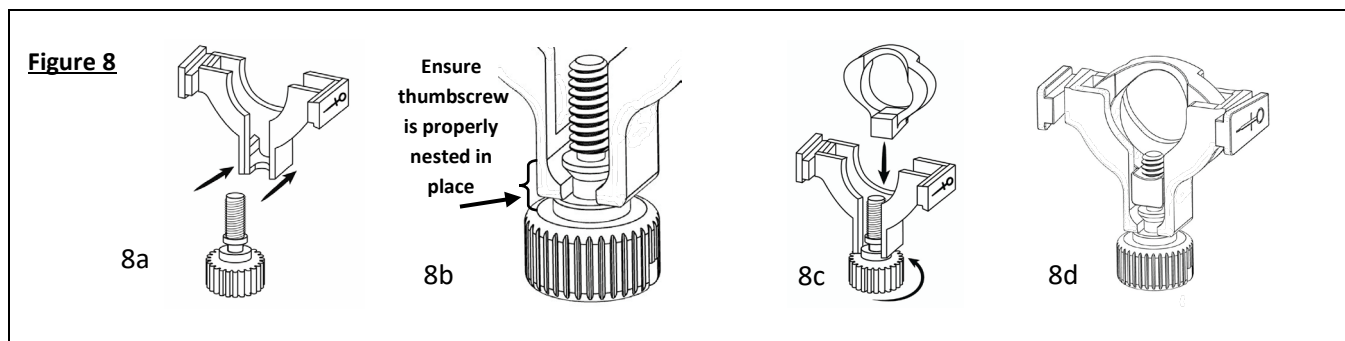
GRAVITY-DISPLACEMENT STEAM STERILIZATION PARAMETERS

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 8, insert thumb screw into the connector (figs. 8a & 8b), carefully insert clamp onto thumb screw (fig. 8c) then turn thumbscrew (fig. 8c) into the clamp as shown in fig. 8d.



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

HOW SUPPLIED:

DentalJect Applicator Set DJ04000-00

Contains:

- DentalJect Applicator DJ01000-00
- DentalJect Syringe Connector DJ02000-00

DentalJect Canister DJ03000-01

(net weight 40 grams)

DentalJect Canister pack of 5 DJ03000-05

(net weight 40 grams ea.)



VAPOCOOLSHOT INC.
Boca Raton, FL 33487
1-844-827-3685
www.vcsmedical.com

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