



INSTRUCTIONS FOR USE

COOLJECT® TARGETED-MIST™

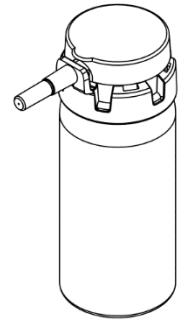
CJ02050-00

TOPICAL ANESTHETIC

CAUTION: **Rx only** Federal (USA) law restricts this device to sale by or on the order of a licensed physician or properly licensed practitioner.

DEVICE DESCRIPTION: CoolJect Targeted-Mist Topical Anesthetic is a vapocoolant (skin refrigerants) intended for instant topical anesthetic.

INDICATIONS FOR USE: The CoolJect Topical Anesthetic is intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The anesthetic is used to target and minimize cooling area for lessening pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incision, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts, and abrasions).



PRECAUTIONS:

- Do not spray into the eyes. Cover eyes with a gauze to avoid unintentional misting close to the eyes when used within 4 inches of eyes, nostrils, or mouth and to close eyes and mouth when within 4 inches.
- Do not spray onto poor circulation (i.e. Diabetic) or insensitive skin.
- Do not spray on large areas of damaged skin, puncture wounds or animal bites or serious wounds.
- Do not use on genital mucous membrane. Apply only to intact mucous membrane.
- The freezing and thawing process may be painful and freezing may lower local resistance to infection and delay healing.
- Over application of the same area may cause frostbite and/or alter skin or mucosa pigmentation. Cover areas that are not intended to be affected with the application of petroleum jelly.
- Discontinue use if rash develops.
- Thin skin will require less misting than thicker skin or mucosa (thickness depends on fat storage and blood vessel and keratin).

ADVERSE REACTIONS: Freezing can occasionally alter skin pigmentation.

CONTRAINDICATION: Hypersensitivity to 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane. If skin irritation develops, discontinue use.

WARNINGS: For external use only. Contents under pressure. For use on minor open wounds only. For use on intact mucous membranes only.

CONTENTS: 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane

STORAGE: Do not puncture or incinerate canister. Do not expose to heat or store in temperatures above 120°F (50°C).

CLEANING and DISINFECTION: Follow your facilities infection control protocol for medical devices.

SPECIAL INSTRUCTIONS: DO NOT AUTOCLAVE

DISPOSAL: Dispose of canister in accordance with local and national regulations.

KEEP OUT OF REACH OF CHILDREN: As the safety for the use of the subject device in pediatric patients has not been established, it is recommended that the device should not be used on patients under the age of four years without consultation of a pediatrician.



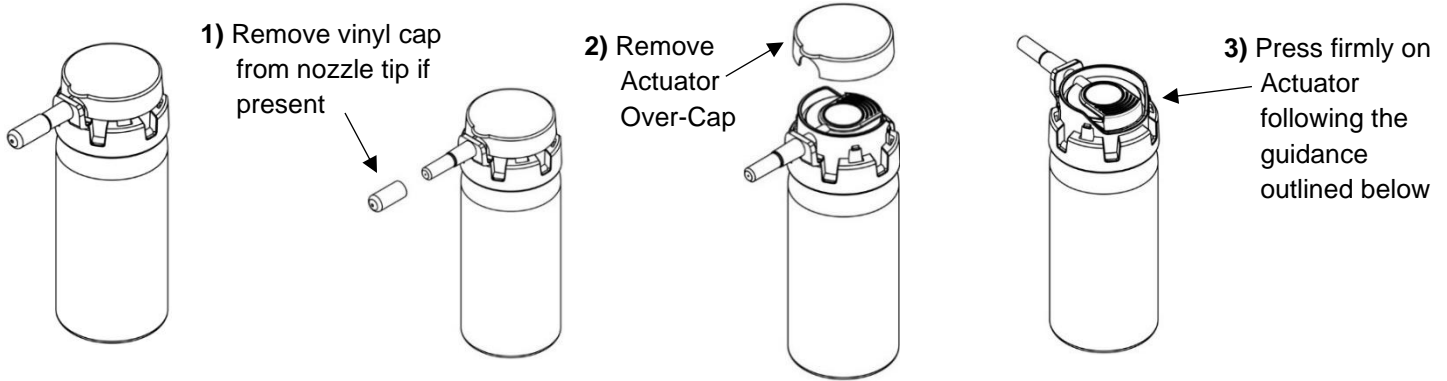
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INSTRUCTIONS:



PRE-INJECTION ANESTHESIA & TOPICAL ANESTHESIA IN MINOR SURGERY: Prepare the procedure site per facility's protocol and have the user provided syringe ready along with all other necessary equipment. Hold the can upright, clean the injection site with an antiseptic. Spray the injection site steadily for 4 to 10 seconds from a distance of 8 to 18 cm (3 to 7 inches) or until the skin begins turning white. Do not frost the skin/area. Avoid spraying the injection site beyond this state. Do not use circular or back and forth motion. After spraying the site, immediately perform the procedure. Reapply if necessary. Do not spray longer than 10 seconds. If desired, apply petroleum jelly to protect adjacent area.

TEMPORARY RELIEF OF MINOR SPORTS INJURIES: The pain of bruises, contusions, swelling, minor sprains, cuts and abrasions may be controlled with CoolJect. The amount of cooling depends on the dosage. Dosage varies with duration of application. The smallest dose needed to produce the desired effect should be used. Spray CoolJect on the target area continuously for 4 to 10 seconds from a distance of 8 to 18 cm (3 to 7 inches) or until the skin just turns white. Do not frost the skin. Avoid spraying of skin beyond this state. Do not spray longer than 10 seconds. Reapply if necessary.

DISCARD AFTER USE: Follow local, state and government requirements for disposal of aerosol containers.

HOW SUPPLIED:

CJ02050-00 CoolJect® Targeted-Mist™ Topical Anesthetic, one canister

Note: each canister holds 2 wt. oz. (60gm) P/N CJ02050-00

CJ02050-12 CoolJect® Targeted-Mist™ Topical Anesthetic, Case of 12 each of CJ02050-00

CoolJect- Topical Anesthetic can be used with CoolJect Accessories which are sold separately.

DISCLAIMER:

The CoolJect does not alone guarantee a complete elimination of painful injection / procedure, but we strive to attain patient comfort.



Manufactured for:

Vapocoolshot Inc.

Boca Raton, FL 33487

833-COOLJCT (833-266-5528)

www.vapocoolshot.com

MADE IN USA