



INSTRUCTIONS FOR USE

COOLJECT™ SYRINGE HOLDING NOZZLE 1-3cc ACCESSORY

CAUTION: ^{Rx only} Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

DEVICE DESCRIPTION: The CoolJect™ Syringe Holding Nozzle is a reusable accessory that will attach to the actuator spout of CoolJect™ Topical Anesthetic Canister that can hold a user provided syringe 1cc (4.5mm) to 3cc (10.8mm) diameters.

INDICATIONS FOR USE: The CoolJect™ Topical Anesthetic Canister is intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The CoolJect™ Topical 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).

The CoolJect™ Syringe Holding Nozzle 1-3cc Accessory is intended to be attached to the actuator spout of the CoolJect™ Topical Anesthetic Canister and allows for the attachment of a user supplied syringe 1cc (4.5mm) to 3 cc (10.8mm) in diameter to facilitate the injection procedure following CoolJect™ Topical Anesthetic application.

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.
- For discretion, cover areas that are not intended to be affected with the application of petroleum jelly if desired.
- 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).
- Syringe and needle are **SINGLE USE ONLY** and must be disposed of per state and local laws.

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 and 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).

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.

INSTRUCTIONS: To apply CoolJect™ Topical Anesthetic from the aerosol canister, remove over-cap, attach the Syringe Holding Nozzle onto canister actuator spout and turn to secure locking tab. Hold the can upright, spray on the target area continuously for 4-10 seconds, approximately 8 to 18 cm (3 to 7 inches) away from the treatment site. Press the actuator button firmly, spraying CoolJect™ directly on the treatment site. After spraying the site, immediately perform the procedure.

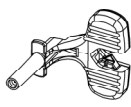
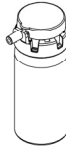
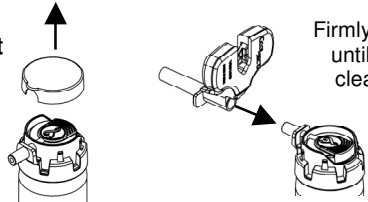
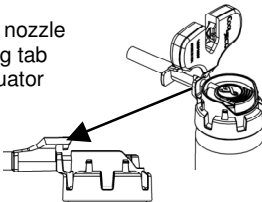
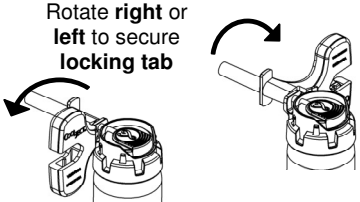
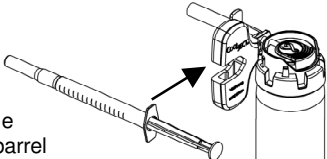
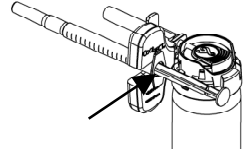
PRE-INJECTION ANESTHESIA & TOPICAL ANESTHESIA IN MINOR SURGERY: Prepare the procedure site per facility's protocol and have the user provided syringe ready along with all other necessary equipment. Hold the can upright, clean the injection site with an antiseptic. Spray the injection site steadily for 4 to 10 seconds from a distance of 8 to 18 cm (3 to 7 inches) 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) 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.

DIRECTIONS FOR USE:

Syringe and needle are not supplied with the CoolJect™ device.

1. Syringe must be already filled (**secured safety cap on**) with drug intended for injection.
2. Remove over-cap from canister.
3. Attach CoolJect™ Syringe Holding Nozzle 1-3cc Accessory to the CoolJect™ Topical Anesthetic Canister actuator spout with the secure locking tab.
4. Attach the syringe 1cc (4.5mm) to 3cc (10.8mm) diameter to the Syringe Holder accessory.
5. Check:
 - a. **Syringe Markings** are visible.
 - b. That syringe is secure
 - c. The barrel flange (finger grip) is flush.
6. During operation the canister **must stand upright**.
7. Perform test spray to confirm device is operating as intended. Explain that you are spraying the area to create a cold sensation.
8. Swab the treatment area with an antiseptic.
9. Press the thumb actuator firmly to spray CoolJect™ on the treatment area continuously from a distance of 8 to 18 cm (3 to 7 inches) until the skin just turns white (usually for 4 to 10 seconds). Do not frost the skin/area. **Immediately perform the injection procedure.** The controlled pain comfort effect is transient.
10. A residual sensation of cold is considered normal. Do not spray longer than 10 seconds.

<p>VM01000-00 CoolJect™ Syringe Holding Nozzle 1-3cc Accessory</p> <p style="background-color: black; color: white; padding: 5px;">REUSABLE DO NOT THROW AWAY</p> 	<p>VM02000-00 CoolJect™ Topical Anesthetic Canister</p> <p>2.0 wt. oz. (60ml)</p> <p style="background-color: black; color: white; padding: 5px;">MUST BE USED WITH NOZZLE</p> 
<p>Syringe Holding Nozzle attachment to canister</p>  <p>Firmly press nozzle until locking tab clears actuator</p>  <p>Rotate right or left to secure locking tab</p> 	
<p>Syringe assembly</p>  <p>Snap Syringe Holding Nozzle onto syringe barrel</p> <ul style="list-style-type: none"> Check that Syringe Markings are visible. Check that syringe is secure. Push syringe finger grip flush to Syringe Holding Nozzle Barrel Clamp before using. 	

RECAPPING NEEDLE GUIDELINE:

1. Have a Sharps Container at the point of use!
2. Place a syringe and needle in an appropriate sharps container immediately after use without recapping when it is reasonable to do so. This should always be the first choice.
3. If recapping is necessary, a one-handed technique should be used.
4. Make sure the Needle devices which have built in safety control devices works as intended with CoolJect™ Syringe Holding Nozzle.
5. Please follow your established protocol per OSHA Bloodborne Pathogens Standard and the Needlestick Safety and Prevention Act.
6. The exposure to bloodborne pathogens through needlestick injuries is a serious and potentially deadly occupational risk.

MANUAL CLEANING:	CoolJect™ Syringe Holding Nozzle 1-3cc Accessory	CoolJect™ Topical Anesthetic Canister
Point of Use:	Clean medical devices as soon as practical after use.	
Containment and Transportation:	No particular requirements.	
Instrument Preparation:	None.	
Cleaning and Disinfection:	Use hospital grade sanitizing wipes per manufacture's instructions. Follow your facilities infection control protocol for reusable medical devices.	
Drying:	Drying should be performed at room temperatures.	
Maintenance and Inspection:	Verify the Syringe Holding Nozzle is free from obvious defects or damage and that the nozzle is clear.	
AUTOMATIC CLEANING:	None (DO NOT AUTOCLAVE)	
SPECIAL INSTRUCTIONS:	None	Discard after use. Follow local, state and government requirements for disposal of aerosol containers.



DISCLAIMER: The CoolJect™ does not alone guarantee a complete elimination of painful injection / procedure, but we strive for attaining patient comfort.

Manufactured for:
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MADE IN USA