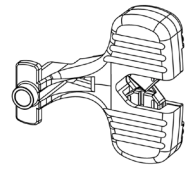




INSTRUCTIONS FOR USE

CJ01050-00

COOLJECT® SYRINGE HOLDER 1-3cc ACCESSORY



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

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

INDICATIONS FOR USE: The CoolJect Syringe Holder 1-3cc Accessory is intended to be attached to the actuator nozzle 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:

- Syringe and needle are **SINGLE USE ONLY** and must be disposed of per state and local laws.
- Make sure Needles which have built in safety control devices work as intended with CoolJect Syringe Holder.

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: Exposure to bloodborne pathogens through needlestick injuries is a serious and potentially deadly occupational risk.

CONTENTS: Quantity 1 device.

STORAGE: No particular requirements.

DISPOSAL: Dispose 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.

DIRECTIONS FOR USE:

Syringe and needle are not supplied with the CoolJect device.

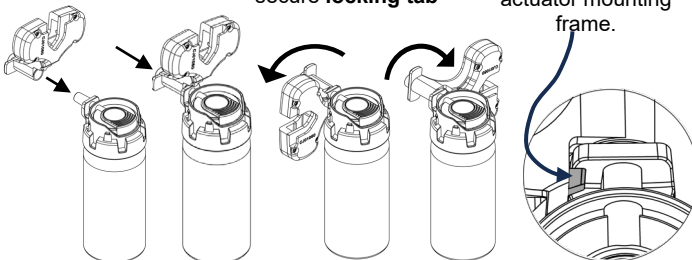
1. Syringe must be already filled (**secured safety cap on**) with drug intended for injection.
2. Remove actuator nozzle cap and over-cap from canister.
3. Attach Syringe Holder Accessory to the CoolJect Topical Anesthetic Canister actuator spout, and rotate left or right with the secure locking tab.
4. Attach the syringe 1cc (4.5mm) to 3cc (10.8mm) diameter to the Syringe Holder accessory, ensuring that the barrel finger flange is placed into the nook (flange-slot).
5. Check that:
 - a. The **Syringe Markings** are visible.
 - b. The syringe is secure in the clamp.
 - c. The barrel finger flange (finger grip) is inserted into the Nook (Flange-Slot).
6. During operation the canister **must be held 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.

SYRINGE HOLDER ATTACHMENT TO CANISTER

Firmly press syringe holder onto actuator until seated.

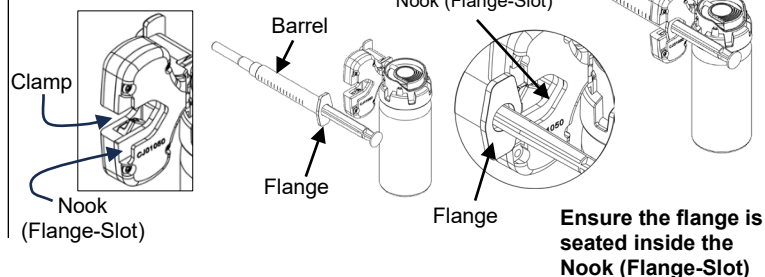
Rotate **right or left** to secure **locking tab**

Syringe Holder Locking Tab must be seated behind the actuator mounting frame.



SYRINGE ATTACHMENT

Align the Barrel Finger Flange with the Nook (Flange-Slot) and press syringe barrel into Syringe Holder clamp.



CAUTION: MISUSE OR MISHANDLING MAY CAUSE SYRINGE TO SNAP OUT OF SYRINGE HOLDER.

Maintain a firm grip on the barrel of the syringe when placing onto, using, or removing from, the Syringe Holder to avoid loss of control of the syringe as it is released from the spring-loaded clamp.

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 Holder.
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:

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 device is free from obvious defects or damage.

AUTOMATIC CLEANING: None (**DO NOT AUTOCLAVE**)

SPECIAL INSTRUCTIONS: None



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

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