

User Manual

skinCooler

Pain Numbing Applicator

Introduction:

The Skin Cooler Pen is a medical product that can be used multiple times. It consists of a plastic handle with a flat metallic tip. After placing the product in the freezer, the liquid inside the metallic reservoir freezes, allowing localized skin cooling for a few minutes. This provides temporary analgesia to the area it touches.

Commercial Presentation of the Product:

The Skin Cooler Pen is packaged in a plastic box containing 1 (one) unit. The Skin Cooler Pen consists of a plastic base that encases the cooling metallic part (stainless steel 304) and a plastic cap.

Indication of Use / Purpose:

The Skin Cooler Pen is an epidermis cooling device (for the skin's surface layer), designed to assist in aesthetic treatments that can benefit from gentle cooling immediately after their completion. Its purpose is to cool the skin to reduce pain during procedures involving punctures or injections, where the needle penetration into the patient's skin may cause discomfort or pain.

Principle of Operation / Mechanism of Action:

The Skin Cooler Pen replaces traditional ice in a more hygienic and ergonomic way to minimize discomfort (pain) for patients during the following procedures, among others: botulinum toxin and filler applications, sclerotherapy, and laser treatments for removing spots or small blood vessels.

Product Usage Instructions:

01. Place the Skin Cooler Pen in the freezer or a cooling unit at -1°C (30°F) for approximately 1 hour.
02. For normal use, gently press the stainless steel part of the Skin Cooler Pen against the skin and massage for a few seconds.
03. After the procedure, clean the pen and return it to the freezer to keep it cool.



Composition:

- The Skin Cooler Pen is a manual device made of ABS plastic and a cooling stainless steel 304 metallic component.

Storage Conditions:

- Store the Skin Cooler Pen at room temperature when not in use for procedures.

Transport Conditions:

- The Skin Cooler Pen is sold in plastic packaging. Avoid dropping it on the floor.

Cleaning and Disinfection:

- As a semi-critical item for dental, medical, and hospital use, the Skin Cooler Pen requires high-level disinfection after cleaning for appropriate use.
- After use, wash the device thoroughly in a sink with plenty of water and soap. Rinse well under running water, allowing excess water to drain off. Drying is not necessary before the next steps.
- After washing, disinfect the pen using a 0.2% Peracetic Acid solution, ready for use, with a contact time of 10 to 30 minutes for complete disinfection. Always follow the manufacturers' instructions for solubility and disinfection procedures of these solutions.
- Place the pen back into the freezer for at least 1 hour to prepare it for reuse.
- After disinfection, attach the cap to the pen, ensuring that the opening for cold entry remains unobstructed.
- Use appropriate protective equipment, such as gloves, masks, protective goggles, and aprons, during the cleaning and disinfection process.

Warnings and Precautions:

- Do not sterilize the product using dry or moist heat (oven/autoclave).
- Keep away from open flames.
- Store the product out of reach of children.

Contraindications:

- The Skin Cooler Pen is contraindicated for patients with a history of cold-induced urticaria.



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