

Pain Ease is Safe for Aseptic Procedures

Gebauer's Pain Ease® topical anesthetic skin refrigerant has passed microbial examinations of non-sterile products and is safe to be used prior to aseptic procedures.

Pain Ease will not introduce or add microorganisms to a site that has already been cleansed with an antiseptic.

"The vapocoolant (Pain Ease) 1,1,1,3,3-pentafluoropropane and 1,1,1,2-tetrafluoroethane is sprayed on skin prepared with povidone-iodine; there is no statistically significant increase in bacterial colonization."

Schleicher WF, Richards BG, Huettner F, Ozturk C, Zuccaro P, Zins JE. Skin sterility after application of a vapocoolant spray. *Dermatol Surg.* 2014 Oct;40(10):1103-7. doi: 10.1097/01.DSS.0000452654.29636.56.

- The proprietary blend of hydrofluorocarbons (HFC's) used in Pain Ease are FDA cleared skin refrigerants and filtered to screen out particulates larger than 0.2 microns.
- Pain Ease is filled in a controlled environment which undergoes microbial monitoring during each manufacturing run.
- The air in the manufacturing environment has HEPA filtration which maintains air particulates to levels established for a Class 100,000 clean room.
- Assessment of the air, surfaces and personnel are based on the recommendations specified in the United States Pharmacopeia (USP) General Chapter <1116>, *Microbial Evaluations of Clean Rooms and Other Controlled Environments*.
- Lots of Pain Ease are tested to USP <61> and USP <62> by an outside, independent laboratory. These tests determine the total aerobic microbial count (TAMC) and total yeast and mold counts (TYMC) present. They also demonstrate that a substance is free from *Staphylococcus aureus* (staph) and *Pseudomonas aeruginosa*.
- Lots of Pain Ease are not released until testing is completed and all microbiological results meet acceptance criteria.



Over 10 years +
50 million applications =
A lot of happy patients

Important Risk and Safety Information for Gebauer's Pain Ease:

Consult your pediatrician when using on children 4 years old and younger. Do not use on large areas of damaged skin, puncture wounds, animal bites or serious wounds. Do not spray in eyes. Over spraying may cause frostbite. Freezing may alter skin pigmentation. Use caution when using product on persons with poor circulation. Apply only to intact oral mucous membranes. Do not use on genital mucous membranes. The thawing process may be painful and freezing may lower resistance to infection and delay healing. If skin irritation develops, discontinue use. CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Pain doesn't wait. Ease it in an instant. Prepare your patient for needle and minor surgical procedures with Pain Ease, the **INSTANT topical anesthetic.**

Skin Sterility After Application of a Vapocoolant Spray

Schleicher, William F. MD*; Richards, Bryson G. MD*; Huettner, Franziska MD, PhD*; Ozturk, Cemile MD†; Zuccaro, Patricia BS‡; Zins, James E. MD, FACS*
Dermatologic Surgery, October 2014- Volume 40, Issue 10, 1103 – 1107.

Background:

Refrigerant sprays have been widely used to reduce pain in the office setting. However, more recently, their use has been limited by both concern regarding flammability and questions of bacterial contamination.

Objective:

We investigated the microbiological effect of 1,1,1,3,3-pentafluoropropane and 1,1,1,2-tetrafluoroethane when sprayed after povidone–iodine application in 50 volunteers.

Materials and Methods:

In 50 volunteers, 3 cultures were taken (1) at time 0 before antiseptic application, (2) after povidone–iodine topical antiseptic, and (3) after spraying with vapocoolant. Cultures at 3 time intervals were analyzed in a blinded fashion, and Gram stains obtained when cultures were positive.

Results:

Bacterial growth was found in 98% of cultures taken before antiseptic was applied (Group 1), in 28 cultures (56%) after povidone–iodine was applied, and in 24 cultures (48%) after spraying with vapocoolant. There was a statistically significant difference found between Group 1 (no antiseptic) and both Group 2 (after antiseptic but before vapocoolant) and Group 3 (after vapocoolant) ($p < .001$).

Conclusion:

The topical antiseptic povidone–iodine significantly reduces skin colonization when compared with unprepared skin ($p < .001$). The vapocoolant 1,1,1,3,3-pentafluoropropane and 1,1,1,2-tetrafluoroethane is sprayed on skin prepared with povidone–iodine; there is no statistically significant increase in bacterial colonization.

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- 3.9 fl. oz. Medium Stream Spray
0386-0008-03
- 1.0 fl. oz. Medium Stream Spray
0386-0008-04
- 3.9 fl. oz. Mist Spray
0386-0008-02
- 1.0 fl. oz. Mist Spray
0386-0008-01

