



TREATMENT PROCEDURE

- 1 Refer to dose timing chart for individual lesion types and dosage times.
- 2 Insert appropriate bud (arrow or round) into canister's trigger nozzle.
- 3 Remove safety cap from actuator
- 4 Push dispensing valve for approximately 3-6 seconds to saturate bud until drips are visible. *Do not press valve while CryDose H applicator is in contact with patient's skin.*
- 5 Remove bud from canister, and point downward (for approximately 15-20 seconds) for bud to reach optimal -55°C freezing temperature.
- 6 Precisely place dosage bud onto patient's treatment area and hold for recommended time (see chart).
- 7 Allow 45-60 seconds for thawing process to be completed before touching lesion.

If desired, after thaw is completed, a second freeze may be administered.

TREATMENT OVERVIEW

Keratin is highly insulating, so when treating a thick lesion, achieving subzero temperatures at the base may be challenging. For increased efficacy, before freezing, consider debriding keratin with curette, scalpel, or pumice stone. Preparatory steps can impact treatment efficacy and reduce number of applications required.

- Functional and cosmetic end results have priority over cure rates. If in doubt, under treat. To ensure successful cure rate, retreatment at a later date is preferable to overtreatment.
- Saturated 2mm applicator retains cold for approximately 90 seconds; 5mm applicator retains cold for approximately 120 seconds – sufficient time to perform 1 to 2 applications on a patient.
- A small ring of healthy tissue around lesion should also be frozen during treatment.
- Freezing starts in seconds. A white discoloration of treated skin may be observed. Patient may experience tingling or pruritus, and possibly a brief smarting sensation.
- After removing applicator, white 'frost' dermal coloration will recede within minutes and erythema will appear, the same size



as frozen region. Any discomfort experienced during freezing typically ends shortly following treatment.

- Blistering (potentially blood-filled) may be anticipated in subsequent days, possibly not visible macroscopically on treatment areas exhibiting a thick stratum corneum.

PAIN MANAGEMENT

Cryotherapy patients experience a subjective degree of discomfort – a moderately painful, burning sensation on the skin. Treatment acceptance can be significantly improved by articulating treatment implications to patients: any required preparatory treatment, anticipated level of pain, possible undesirable effects, potential need for follow-up treatment(s), and how resolution rates are impacted by location and size of warts.

POST-PROCEDURAL CARE

- Keep treated area of skin clean.
- Swimming and showering are permitted.
- Do not scratch or pick treated area.
- If blisters form, do not lance; if blisters open, cover with adhesive bandage.

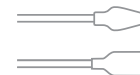
CryoDose H portable cryosurgical system is a highly effective treatment for a wide range of benign skin problems and is intended for use only by medically trained healthcare professionals. Improper use can lead to unintended damage to the skin and underlying tissues.

The aerosol canister is intended for use only with CryoDose H portable cryosurgical system applicator buds.

Recommended Freezing Times

Type of Lesion	Appx length (in seconds)
Acrochordon (skin tags).....	40
Actinic keratosis (facial).....	15
Actinic keratosis (non-facial).....	40
Condyloma acuminata (genital warts)....	40
Lentigo (facial).....	15
Lentigo (non-facial).....	40
Molluscum contagiosum.....	20
Seborrheic keratosis.....	40
Verruca plana (flat warts).....	20
Verruca plantaris (plantar warts).....	40
Verruca vulgaris (common warts).....	40

1 to 4 treatments at an interval of 2 weeks



arrow and bud shape buds

ADDITIONAL INFO & REFERENCES

Info contained in Instruction Manual & Directions for Use and other CryoDose materials: Andrews M. Cryosurgery for Common Skin Conditions. Am Fam Physician. 2004;69(10):2365-2372. Dawber R, et al. Cutaneous Cryosurgery, Principles and Clinical Practice. London: Dunitz Ltd; 1997. Torre D, et al. Practical Cutaneous Cryosurgery. Norwalk, CT: Appleton & Lange; 1988. Wheeland RG. Cutaneous Surgery. Philadelphia: Saunders; 1994. Zimmerman EE, Crawford P. Cutaneous Cryosurgery. Am Fam Physician. 2012;86(12):1118-24. Contact Nuance Medical for additional references.

INSTRUCTION MANUAL & DIRECTIONS FOR USE

Keep for future reference



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IMPORTANT NOTES

CryoDose H should be used only on benign, superficial skin lesions.

If in doubt of lesion's benignity, lesion should first be biopsied.

Do not treat lesions if cancer is suspected.

If lesions persist post-treatment, lesions should be reinspected and confirmed that lesions are not cancerous.

Safety standards for pregnant or pediatric patients are not established.

Not recommended for the use on children under the age of five (5) years without the consultation of a pediatrician or other clinically trained physician.

Sale or other distribution of CryoDose H portable cryosurgical system kit to patients is prohibited.

SYSTEM OPERATION

CryoDose H treats epidermal lesions by freezing, which facilitates a separation between epidermis and basal membranes. A small spray of cryogen is expelled into a CryoDose H applicator bud, holding the coolant until evaporation when applicator reaches approximately -55°C.

After treatment, frozen epidermis peels away (typically within 2 to 3 days) and is replaced new epidermis. Blistering of treated area may occur. 1 to 4 treatments with intervals of 2 weeks may be necessary.

PRECAUTIONS

- Deep pigmentation of dark skin may occur. In light-colored skin, depigmentation is minimal, but is noticeable following sun exposure. Hyperpigmentation is rare, but facial areas should be treated with caution.
- Freezing terminal arteries (fingers and toes) to excessive depth could lead to necrosis, although necrosis has not been observed with the use of CryoDose H. Treat only one side of fingers and toes at a time to avoid freezing arteries or veins.
- Warts located in a medically infected area should first be treated to resolve the infection prior to cryosurgical treatment.

CONTRAINDICATIONS & WARNINGS

Read all instructions and practice technique prior to use on patient.

Inspect all product components prior to use. Damage could occur during shipping and/or prior to use; if any part is damaged in any way, do not use.

Nozzle assembly should be intact and spray tested before use on patient.

Aerosol canister is intended for use only with CryoDose H portable cryosurgical system applicator buds.

Avoid spraying on or near eyes or other sensitive body areas. Shield eyes when treating head or neck area.

Use only in well-ventilated areas.

Absolute contraindication: cryotherapy is contraindicated in patients with cryoglobulinemia.

POTENTIAL COMPLICATIONS

Preparatory treatment

As with any procedure, acute, delayed, prolonged-temporary, and/or permanent complications can occur.

Acute: headache, pain, and/or blister formation.

Delayed: hemorrhage, infection, and/or excessive granulation tissue formation.

Prolonged-temporary: milia, hyperpigmentation, and/or change in sensation.

Permanent: alopecia, atrophy, keloids, scarring, hypopigmentation, and/or ectropion formation.

UNDESIRABLE OUTCOMES

- Stinging or painful sensation during and after freezing (any discomfort rapidly lessens after thawing).
- Changes in pigmentation intensity may occur, generally hypopigmentation. Post-inflammatory hyperpigmentation, due to melanin or hemosiderin, can also occur.
- Improper use can lead to excessively deep-freezing, producing damage to dermis, consequent scar formation and nerve damage.

DANGER:

EXTREMELY FLAMMABLE AEROSOL

Container should be stored in a cool area and not near direct heat sources or in conditions over 120°F.

Contents Flammable:

Dimethyl ether, propane, isobutane

Containers comply with DOT-SP 20217

REUSABLE TREATMENT KIT

- 1 or 2 CryoDose H 88mL spray canister(s)
- Dosing buds
- Directions for use; SDS (MSDS)

CRYODOSE H SYSTEM

PRODUCT# SIZE DESCRIPTION

170375 2 x 88mL Kit
2 canisters, 30 2mm arrows, 40 5mm round buds

170293 88mL Kit
1 canister, 40 2mm arrow buds

170294 88mL Kit
1 canister, 40 5mm round buds

170295 88mL Kit
1 canister, 20 2mm arrow, 30 5mm round buds

170100 88mL
1 canister only

2001 buds - mixed
20 2mm arrow + 20 5mm round buds

2002 buds - arrow
30 2mm arrow buds

2003 buds - round
30 5mm round buds

*cryotherapy,
precisely*

*With CryoDose H,
treating lesions
effectively and precisely
has never been easier.*

For additional information, please contact:

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