



REUSABLE TREATMENT KIT

- One CryoDose spray canister

162mL or 236mL

- Six dosing cones

- Dosing buds

- Instruction manual



CANISTER SIZES

- 162mL

- 236mL



PRODUCT NUMBER & DESCRIPTION

1100 162mL (175g) canister

1101 162mL Kit – canister, cones, buds

1102 162mL 2 canisters

1103 162mL Kit – canister, buds

1500 236mL (255g) canister

1501 236mL Kit – canister, cones, buds

1502 236mL 2 canisters

2001 buds 20 arrow, 20 round

2002 buds 30 arrow

2003 buds 30 round

3001 cones 3, 5, 7, 9, 12, 16mm

FOR PRESCRIPTION ONLY

FOR USE BY MEDICAL PERSONNEL ONLY

See Information on proper use and handling.

Containers comply with DOT-SP 12187 and DOT-SP 15852.

Contents Non-Flammable;
1,1,1-Trifluoroethane, Pentafluoroethane,
1,1,1,2-Tetrafluoroethane

For additional information, please contact:

Nuance Medical, LLC.
300 Carlsbad Village Drive
Carlsbad, CA 92008
760 585-4849
info@CryoDose.com

CONTRAINDICATIONS & WARNINGS

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. Visually inspect and test the product prior to use with patients including:

Nozzle assembly: should be intact and spray properly. If damaged in any way, do not use.

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

Premature discharge of cryogen: if over-pressurized by heat or other factors, a safety mechanism on canister bottom releases. If this occurs, be sure to move canister away from user and patients.

Read all instructions and practice use prior to use on patients.

Do not overfill dosing cones: do not fill past *fill guides* on side of dosing cones.

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.

For additional information or questions contact Nuance Medical prior to use.

POTENTIAL COMPLICATIONS

As with any procedure, complications can occur. Complications can be divided into (1) acute, (2) delayed, (3) prolonged-temporary, and (4) permanent.

Acute complications include headache, pain, and blister formation.

Delayed complications include hemorrhage, infection, and excessive granulation tissue formation.

Prolonged-temporary complications include milia, hyperpigmentation, and change in sensation.

Permanent complications include alopecia, atrophy, keloids, scarring, hypopigmentation, and ectropion formation.

INSTRUCTION MANUAL & DIRECTIONS FOR USE

Keep this manual
for future reference



by Nuance Medical

Nuance Medical, LLC
300 Carlsbad Village Drive
Carlsbad, CA 92008
760 585-4849
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TO BEGIN TREATMENT

Inspect canister prior to use. **Remove safety tab** covering from actuator.

Insert plastic extender straw into nozzle. **Test spray** to be certain system is in working order.

If system is not working properly or you have any questions, contact Nuance Medical.

DOSING CONES

- Choose a dosing cone approximately 1mm larger than the lesion.
- Place cone over lesion. Hold canister at 45° angle and pull trigger gently to spray approximately 1/8"-1/4" of cryogen against inside of cone. *Do not spray straight down.* 1/8" fill lines on dosing cone will assist you in precise treatment.
- Cryogen evaporates in 20-40 seconds; maintain position of cone until evaporation is complete.
- If desired, a second freeze may be administered after a 45-60 second thaw is completed.

Dosing cones are reusable after being disinfected by an EPA-registered disinfectant.

INDICATIONS FOR USE

To treat benign lesions, including:

- verruca (warts) flat, finger, vulgaris, plantar, other superficial warts
- lentigo (age spots)
- actinic keratoses (solar keratoses)
- seborrheic keratoses
- achrochordon (skin tags)
- molluscum contagiosum
- small keloids
- dermatofibromas
- keratoacanthoma
- granuloma annulare
- angiomas
- chondrodermatitis
- epithelial nevus
- porokeratosis plantaris discreta
- leukoplakia
- granuloma pyogenicum
- pyogenic granuloma

TREATMENT BUDS: INSERTED

- Refer to dose timing chart for individual lesion types and dosage times.
- Insert appropriate bud (arrow or round) into canister's trigger nozzle.
- Gently pull trigger for approximately 3-6 seconds to saturate bud until drips are visible.
- Remove bud and point downward for approximately 15-20 seconds for bud to reach optimal freezing temperature (-70°C).
- Carefully place dosage bud onto treatment area and hold for recommended time.
- Allow 45-60 seconds for thawing process to be completed before touching lesion.
- If desired, a second freeze may be administered after thaw is completed.
- Buds are not be used on more than one patient. Dispose of properly.

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

If there is doubt that a lesion is benign, 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 in pregnancy has not been established.

TREATMENT BUDS: HAND-HELD

- Refer to dose timing chart for individual lesion types and dosage times.
- Insert extender straw into canister's trigger nozzle.
- Select appropriate bud (arrow or round).
- Hold non-foam end of bud and slowly rotate while gently spraying cryogen onto bud.
- After approximately 3-6 seconds, when drips are visible, stop spraying. Point bud downward for 15-20 seconds allowing bud to reach optimal -70°C freezing temperature.
- Carefully place dosage bud onto treatment area and hold for recommended time.
- Allow 45-60 seconds for thawing process to be completed before touching the lesion.
- If desired, a second freeze may be administered after the thaw is completed.
- Buds are not be used on more than one patient. Dispose of properly.

ADDITIONAL INFO & REFERENCES

For info contained in Instruction Manual & Directions for Use and other materials:

Dawber R, et.al. *Cutaneous Cryosurgery, Principles and Clinical Practice*. London: Dunitz Ltd; 1997

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.