

COOL RENEWAL[®]

Portable Cryosurgery System

Veterinary Instructions for Use

A GUIDELINE FOR VETERINARY CRYOSURGERY



COOL RENEWAL IS RESTRICTED TO SALE AND USE BY LICENSED MEDICAL AND VETERINARY PROFESSIONALS ONLY.

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Cryosurgery Introduction

Cryosurgery is the use of extreme cold to destroy abnormal tissue. Cryosurgical procedures have been used in medical & veterinary practices for over 100 years, and the clinical applications are continuously increasing and improving.

Cryosurgery requires little time and fits easily into the busy Veterinarian's schedule. Even if this is your first time purchasing a cryosurgical unit, most veterinary professionals have had some exposure to cryosurgical techniques during school, residencies, or continuing education seminars. This short review of the science of cryosurgery will provide more insight to the science of the procedure and expectations.

Liquid nitrogen, which boils at -196°C (-320.8°F), is historically the most commonly used cryogen for clinical use, however, generally, destruction of external benign lesions only requires temperatures of -20°C to -30°C (-4°F to -22°F).

Cool Renewal Cryogen freezes down to -70°C , which is ideal for causing tissue destruction with prolonged exposure, but still gentle enough to minimize the chance of scarring and blistering, as compared to liquid nitrogen which can be extremely dangerous if not used properly.

Mechanisms of injury are the direct effects of freezing on the cells and the vascular stasis which develops in the tissue after thawing. The damaging effects of low temperature on cells begin gradually as temperature drops. Cell metabolism and structure are altered along with their constituent proteins and lipids. As the temperature falls to below 0°C , water crystallizes, which results in more damage than from mere prolonged cooling, forming an "ice ball".

During cryosurgery, both extracellular and intracellular ice formation occur, with fast freezing in the center of the lesion, and slow freezing on the outside border. The loss of blood supply eradicates the likelihood of survival of the cells in the frozen tissue. The degree of damage depends on the rate of cooling and the minimum temperature achieved. Inflammation develops during the 24 hours after treatment, further contributing to destruction of the lesion through immunologically mediated mechanisms. If the freeze time or the thaw time is too short, tissue destruction will not occur.

READ ALL INSTRUCTIONS PRIOR TO USE

Intended Use

COOL RENEWAL CRYOSURGERY SYSTEM'S INTENDED USE IS THE DESTRUCTION OF SKIN THROUGH TARGETED APPLICATION OF CRYOGENIC GAS.

Commonly Treated lesions include:

- PAPILLOMAS/ WARTS
 - SKIN TAGS
 - SEBACEOUS ADENOMAS
 - SARCOIDS
 - DISTICHIASIS
 - TRICHIASIS
 - ANAL GROWTHS
 - EYELID TUMORS
 - LICK GRANULOMAS
 - & MORE
-

Treatment Advantages

- LOW COST FOR CLINICS AND PET OWNERS
- NO SUTURES
- NO ANESTHESIA REQUIRED*
- ODORLESS (AS COMPARED TO LASER & CAUTERY TREATMENTS)
- MINIMAL PATIENT DISCOMFORT
- 2-3 MINUTE PROCEDURE
- COOL RENEWAL SYSTEM IS PORTABLE & DISPOSABLE, AND DOES NOT EVAPORATE OR EXPIRE

Visit our website for Instructional Videos, Demonstration Videos, Before & After Pictures, Literature, & More
WWW.COOL-RENEWAL.COM/VETERINARIANS

Instructions for Use

IDEAL FOR USE ON:
FACE & HEAD, BONY SURFACES,
AND HARD TO REACH AREAS

FOAM TIPPED APPLICATORS

1. Remove the Safety Tab on the top of the Canister Nozzle.
2. Insert the clear extender tube into the nozzle.



3. Select a Foam Tipped Applicator that is ~1mm larger than the lesion being treated.
4. Place the end of the clear extender tube very close to the foam tip and VERY GENTLY apply pressure to the trigger to expel cryogen onto the foam, until the FOAM DRIPS at least 1 time. You may also rotate the foam to ensure complete saturation.



5. Wait approximately 10 seconds for the foam to crystalize,
6. Apply frozen foam to skin with gentle pressure, for 20-40 seconds, depending on skin thickness. DO NOT REMOVE OR "DAB" Applicator during 20-40 second application time, or skin will not be adequately frozen.



7. After removing applicator, and Ice Ball should appear. DO NOT TOUCH SKIN FOR 1 MINUTE. Allow skin to return to normal color naturally. touching the skin during the thaw phase will interfere with the tissue destruction.
8. Repeat Freeze/Thaw Cycle up to 3 times as needed.

Instructions for Use

ISOLATION FUNNELS

IDEAL FOR USE ON:

FLESHY TISSUE AREAS WHERE A
TIGHT SEAL CAN BE ACHIEVED.

NEVER USE ON FACE, HEAD, OR EYES

1. Remove the Safety Tab on the top of the Canister Nozzle.
2. Insert the clear extender tube into the nozzle.



3. Select an Isolation Funnel that is ~1mm larger than the lesion being treated. Position patient to allow for accumulation of cryogen inside the funnel. **If patient cannot be positioned for accumulation, a Foam Tipped Applicator should be used for treatment instead of an Isolation Funnel.**



4. **LIGHTLY** spray the cryogen into the side wall of the funnel for 3-6 seconds to achieve 1/8-1/4 of an inch of accumulation on top of the lesion.

Hold funnel firmly in place until all cryogen has evaporated (approximately 20-40 seconds). **Do Not Remove Funnel until ALL cryogen has evaporated.** A white ice ball should appear after a successful treatment, and should take approximately 25-40 seconds to thaw naturally.



5. **DO NOT TOUCH SKIN FOR 1 MINUTE.** Allow skin to return to normal color naturally. Touching the skin during the thaw phase will interfere with the tissue destruction.
6. Repeat Freeze/Thaw Cycle up to 3 times as needed.

Instructions for Use

SKIN TAG TWEEZERS

Patent No. US D749729 S

IDEAL FOR USE ON:
SKIN TAGS AND OTHER
PEDUNCULATED LESIONS.

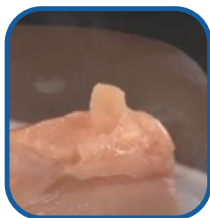
1. Remove the Safety Tab on the top of the Canister Nozzle.
2. Insert the clear extender tube into the nozzle.



3. Lightly spray the foam tips of the tweezers until they drip at least once, and wait 10-15 seconds to allow the foam tip to crystalize.



4. Squeeze the entire skin tag, or squeeze at the base of the stalk for 20-40 seconds. DO NOT REMOVE APPLICATOR during the 20-40 second treatment duration.



5. Remove applicator and DO NOT TOUCH SKIN FOR 1 MINUTE. Allow skin to return to normal color naturally. Touching the skin during the thaw phase will interfere with the tissue destruction.
6. Repeat Freeze/Thaw Cycle up to 3 times as needed.

Tips for Treatments

- To conserve your cryogen and to save costs, always use LIGHT trigger pressure when saturating or filling an applicator.
- Skin should be clean and dry prior to treatment. Debulking is beneficial, but not to the point of bleeding. Blood can interfere with the freezing process.
- NEVER open spray onto skin without using a Cool Renewal® Applicator. Accumulation and concentration of cryogen is essential to successful destruction of tissue.
- Prior to treatment, the area can be “ballooned” with lidocaine to increase the effectiveness of the freeze by raising the lesion, constricting blood vessels, and allowing the cryogen to freeze deeper. Topical Lidocaine is also acceptable.
- When using the Isolation Funnels: Be sure the patient is positioned where the cryogen can accumulate inside the funnel directly on top of the lesion. If the cryogen is spilling back out of the larger end onto the floor, the patient will need to be repositioned or foam tipped applicators should be used.
- Always keep the funnel perpendicular to the ground to allow for accumulation of cryogen inside the funnel. Never remove the funnel until all of the cryogen has completely evaporated.
- When using foam tipped applicators: For maximum coldness, be sure to saturate the foam tip until the tip drips at least 1 time, then wait 10-15 seconds for foam to crystalize. Be sure to hold the applicator in place CONTINUOUSLY for the suggested freeze time. Dabbing or removing the applicator during the freeze time may reduce the effectiveness of the freeze.
- After freezing the skin lesion, you should see a concentric white ice ball. This is the beginning of the thaw stage which lasts about 40 seconds. DO NOT TOUCH THE ICE BALL during the thaw period since the heat withdrawn from your finger will shorten the thaw time and reduce the effectiveness of the freeze. A thaw time significantly less than 40 seconds can be due to inadequate freezing from an under-saturated applicator or inadequate application time.
- Schedule a follow up approximately 14 days after the first treatment, and assess if additional treatments are necessary. Large, thick or calloused lesions may require more than one Freeze/Thaw treatment per visit. If the lesion is greater than 5mm, or is in a thick skin area, up to 3 Freeze/Thaw procedures may be used in the initial visit, with a thaw time of 40 seconds between each freeze. With time and experience you will gain confidence as to which lesions will need multiple treatments.

Information for Pet Owners

CRYOSURGERY is the application of cryogen to the skin to destroy unhealthy tissue. Think of it as controlled frostbite, with little or no discomfort. Once the skin tumor is frozen, the skin may blister or turn red within a few hours or days, and will eventually scab and naturally slough off within 2-3 weeks. New, healthy tissue will regenerate underneath the frozen tissue, and should return to normal color within a few weeks to months after the dead tissue has sloughed.

WHAT TO EXPECT AFTER CRYOSURGERY



- **PAIN:** Most patients experience little or no pain with cryosurgery, but if your pet is showing signs of pain or discomfort, please consult with your veterinarian about medications that could be helpful.
- **BLISTER:** If a large blister becomes present, your veterinarian may drain the blister to relieve pain or discomfort. With a successful treatment, the treated area may blister, turn a dark brown or black, or form a crust/scab within a few hours or days. This is normal and part of the destruction and healing process.
- **SCAB:** Scabbing & crusting is desirable, and it is recommended that you not let your pet scratch or irritate the scab, and let it slough naturally. This should take approximately 7-14 days, depending on the skin lesion size, location and your pet's healing ability.
- **BATHING:** It's ok to bathe your pet, but try to keep the treated area as dry as possible. No bandage is necessary, but may be used to protect the healing lesion from injury or irritation. Try to leave the area open to air as often as possible to promote the crusting/ scabbing process.
- **NEW SKIN:** Once the scab has sloughed, the new skin may be red, sensitive, or even itch as it is healing. Do not bandage, irritate, or apply medications after the scab falls off. Normal skin color should return over a few weeks or months. Contact your veterinarian if you have further questions or concerns.

Cautions & Storage

CAUTIONS & POTENTIAL COMPLICATIONS

Do not use on irritated or infected skin. Do not use on bleeding, open or breached lesions. Do not treat lesions if cancer is suspected. If there is doubt that a lesion is benign, lesion should first be biopsied.

The most common long term effects include nerve damage (usually temporary), pigment issues (usually temporary), changes in hair color (temporary or permanent), tissue defects, and occasional reoccurrence. Many of these problems are due to lack of skill, experience and judgment of the veterinarian performing the cryosurgical treatment

For thin skin or sensitive areas, it is recommend to under-treat the patient and follow up within 14 days for a retreatment if necessary.

No dressing is necessary immediately after freezing, but the animal should not be allowed to scratch or injure the treatment area. Wound wrap or an e-collar may assist in protecting the skin. If the frozen area becomes infected, antibiotics may be required.

STORAGE GUIDELINES

Contents Under Pressure: Do not store in direct sunlight, in hot vehicles, near radiators, stoves or other sources of heat.

Do not store at temperatures over 100 Degrees Fahrenheit (38 Degrees Celsius)- High temperatures may activate the safety release valve.

Contents: NON-FLAMMABLE- See Safety Data Sheet fore more information.

There is a **safety release valve** on the bottom of the canister. Should cryogen ever release from this valve while in use, immediately protect the patient and yourself by promptly removing the canister or people from the area. Allow contents to discharge in a safe area.

Use in a well ventilated area. Do not intentionally inhale the vapors.

Do not puncture or incinerate canister. DO NOT attempt to refill an empty canister. Federal law prohibits transportation if refilled and a penalty of up to \$500,000 and 5 years imprisonment (49 USC 5124).

Frequently Asked Questions

Does Cool Renewal Expire or Evaporate?	Cool Renewal does not expire or evaporate, and has a minimum shelf life of 1 year from the time the canister is first activated.
What happens if the canister is dropped and the nozzle is broken?	If you drop your canister, be sure to inspect the nozzle and canister before use. If the nozzle appears to be broken or is not working properly, contact Cool Renewal Customer Service for a replacement. A broken canister must be returned for a replacement.
Does treatment with Cool Renewal require anesthesia?	The use of anesthesia is not required; however this may depend on the temperament of the patient being treated and the location of the skin lesions being treated.
How long should I freeze each lesion?	<p>Freezing times are based on the size and location of the skin lesion. For thin skin and sensitive areas such as the face, eyes, or ears or extremities, a freeze time of 20-25 seconds with a minimum thaw time of 40 seconds is desirable. For these sensitive areas, it is better to under-freeze versus over freeze. The treatment can always be repeated if necessary. Lesions that are 6mm or larger in size can be frozen for up to 40 seconds, with a minimum thaw time of 40 seconds.</p> <p>For larger, thicker lesions, up to 3 consecutive freeze-thaw cycles may be performed in the same visit, allowing a minimum thaw time of 40 seconds between each freeze.</p>
How many treatments will I get from one Canister of Cool Renewal?	The number of treatments/ freezes per canister will vary depending on the size of the lesions you treat. Based on an average size lesion of 5mm, you should be able to get 65 or more freezes/ applicator saturations per 170mL canister of Cool Renewal. If you are treating lesions that are smaller than 5mm, you may get more than 65 freezes. If you are frequently treating lesions that are larger than 5mm, you may get less than 65 freezes.

Purchasing Options

TO PURCHASE REPLACEMENT COMPONENTS, PLEASE CONTACT YOUR
PREFERRED VETERINARY SUPPLY DISTRIBUTOR,
OR VISIT OUR ONLINE STORE TO VIEW THE FULL CATALOG
WWW.COOL-RENEWAL.COM/PURCHASE-ONLINE

STARTER KITS

-INCLUDE CANISTER(S), APPLICATORS, TRAINING MATERIALS

ITEM # CR-K & CR-K1

REPLACEMENT CANISTERS

-CANISTERS ONLY, APPLICATORS NOT INCLUDED

ITEM # CR-RC & CR-RC1

REPLACEMENT APPLICATORS

-FOAM APPLICATORS- ASSORTED SIZES & INDIVIDUAL SIZES

ITEM # FTA-A, FTA-S, FTA-M, FTA-LXL

-ISOLATION FUNNELS- ASSORTED SIZES & INDIVIDUAL SIZES

ITEM # CR-FA, CR-F5, CR-F8, CR-F12, CR-F14, CR-F16

-SKIN TAG TWEEZERS- ONE SIZE

ITEM # CR-TWZR20