



## DUAL DELIVERY

### ADVANCED PORTABLE CRYOSURGERY

For Veterinary Use Only

ENG-ENGLISH



## INSTRUCTIONS FOR USE

### INTENDED USE

CryOmega® Vet Dual Delivery is intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures. The list below shows some examples of the typical lesions to be treated.

- Warts
- Eyelid Tumors
- Meibomian Gland Tumors
- Skin Tags
- Distichia
- Papillomas
- Adenomas
- Lick Granulomas
- Anal Growths

### BACKGROUND

Cryosurgery is routinely used by Veterinary professionals to treat a variety of lesions (1). Extreme cold works to destroy tissue through lysis of cells and stasis of vessels. This may occur through the formation of ice and rapid changes in osmotic pressure. Both work to increase the overall effectiveness of cryosurgical treatments (1,2).

To successfully destroy topical lesions on companion animals using cryosurgery, the device must apply extreme cold long enough and at a sufficiently low temperature to result in a rapid and deep freeze. The limited capillary network in the dermis and epidermis of companion animals allows for aggressive treatments without pain or blistering (3,4,5). Therefore, following treatment, little aftercare is required, and the animal can be released without any need for sutures or wound care.

CryOmega® Vet Dual Delivery is a self-contained, multi-use, disposable cryosurgical device that dispenses out cryogen— a mixture of pentafluoroethane and difluoromethane. These gases are immediately at effective temperatures ( $-52^{\circ}\text{C}$ ) and require no waiting before use.

CryOmega® Vet Dual Delivery allows users to choose to apply cryogen using Applicators (Buds) or specially designed Focused Treatment Tips (Cones). These two methods of applying cryogen are made easy with CryOmega® Vet Dual Delivery because of its patent pending technology and ergonomic design that allows the cryogen gas to be gently dispensed and applied with one hand. CryOmega® Vet Dual Delivery Buds may also be trimmed before use minimizing any damage to surrounding healthy tissue.

The included Cones also come in a variety of sizes to help Veterinarians treat with precision. Operation is one-handed, with no splashing, and the operator can observe the gas bubbling during Cone use allowing control of the timing.

### PRINCIPLE OF ACTION

Evaporation of liquified cryogenic gas applied to the skin draws heat from the tissue. The CryOmega® Vet Dual Delivery device serves as a reservoir for cryogen gas delivering it onto the lesion to be treated at  $-52^{\circ}\text{C}$  using Cones or  $-67^{\circ}\text{C}$  using Buds. Following treatment, necrosis at the site will occur. Recovery takes about 10 to 28 days, with new tissue growing inwards from the surrounding epidermis and the more deeply situated adnexa. (1,2,3).

The CryOmega® Vet Dual Delivery unit consists of the following items. (Note: Trial Kit contents will differ)

**One canister of cryogen gas. The canister comes complete with the handle and trigger onto which a Bud or Cone Adapter may be mounted.**

- 4–Cone Adapters
- 70–Cones (3mm, 5mm, 7mm, 9mm, 12mm)
- 1–Cone Selection Guide
- 20–Buds
- 1–Neoprene Practice Pad

### STORAGE, TRANSPORT, AND CLEANING

The gas supply is pressurized. Protect the unit from direct sunlight and do not expose to or store at temperatures in excess of  $54^{\circ}\text{C}$  ( $129^{\circ}\text{F}$ ) or near any heat source. CryOmega® Vet Dual Delivery can be operated at ambient room temperature. Use CryOmega® Vet Dual Delivery in a well-ventilated room. (See MSDS for more details). CryOmega® Vet Dual Delivery may be cleaned with 70% isopropyl alcohol or a damp cloth and mild detergent.

### DISPOSAL



Once the CryOmega® Vet Dual Delivery device is empty, attach the green release clip by pulling the trigger and inserting the clip. The device may then be discarded according to local regulations or contact your distributor for additional recommendations.



### GENERAL PRECAUTIONS

Cryosurgery can produce a painful, burning sensation on the skin.

### SUGGESTED INFORMATION FOR THE PET OWNER

Cryosurgery works by destructively freezing target tissue. The uppermost layer of skin, together with the diseased tissue, will disappear. It will be replaced by a new healthy layer of skin in 10–28 days. Freezing commences once cryogen is applied to the skin.

During treatment with Buds or Cones, the affected skin will turn white. From this point on, the animal may experience a momentary stinging or burning sensation until the local nerves are numbed. This sensation will fade rapidly after the Buds or Cones are removed and the treated site is allowed to thaw.

Temporary, visible changes in the intensity of pigmentation may occur following treatment including slight swelling and reddening of the treatment site. These are signs of an adequate treatment. No blister should form, and no wound should appear.



### ADDITIONAL WARNINGS

Once the cryogen dispensing has stopped, the white discoloration of the skin will fade away after a few minutes followed by erythema.

Canine and Feline skin should generally not blister following treatment, and treatment will generally not create an open wound. If the companion animal accidentally scratches the site

and bleeding is evident, treat with topical antibiotic and protect the site until it is healed.

Examples of types of lesions for treatment are listed. Treatment of other types of lesions should only be performed based on the professional's experience.

## FOLLOW-UP TREATMENT SUGGESTIONS

- Keep the treated area clean.
- Swimming and bathing are permitted.
- Do not allow the animal to pick or scratch the treated area.
- Use a bandage to protect any wound that accidentally forms.



## UNDESIRABLE EFFECTS-WARNINGS

- Changes in the intensity of pigmentation or localized hair loss may occur. This will generally take the form of hypopigmentation.

## LIST OF LESIONS AND SUGGESTED FREEZE TIMES

The depth of freezing using CryOmega® Vet Dual Delivery will be dependent upon the time and technique used. The veterinary literature has many reports of varying cryogen treatment times. The thickness, location, and hydration of the target tissue can affect freezing time and therefore outcomes.

In general, the shorter treatment times shown below are for thin skin lesions and locations while the longest treatment times are for more difficult to treat lesions.

Veterinarians should be familiar with cryosurgical techniques when using CryOmega® Vet Dual Delivery. Buds are for sensitive or hard-to-reach locations while Cones are generally more aggressive.

Common Lesions	Freeze Time Ranges
<b>Warts</b>	Debride dry thickened layers. Freeze/thaw 3 times. Thaw between freezes.
<b>Eyelid Tumors</b>	Apply with applicator for 10-20 seconds.
<b>Meibomian Gland Tumors</b>	Apply with applicator for 10-20 seconds.
<b>Skin Tags</b>	Freeze stalk if possible or freeze/thaw 3 times. Thaw between freezes.
<b>Distichia</b>	Treat eye-lash margin for 10 seconds with applicator.
<b>Papillomas</b>	Freeze/thaw 3 times. Thaw between freezes.
<b>Adenomas</b>	Freeze/thaw 3 times. Thaw between freezes.
<b>Lick Granulomas</b>	Freeze/thaw 3 times. Thaw between freezes.
<b>Anal Growths</b>	Freeze/thaw 3 times. Thaw between freezes.

## INSTRUCTIONS FOR ACTIVATION & USE

### BUD USE

1. Remove the CryOmega® Vet Dual Delivery device from the packaging.
2. Place the BUD snugly into the holder at the top of the device.
3. Grip the CryOmega® Vet Dual Delivery handle and invert the device so that the BUD is directed downward.
4. Pull the trigger for **3-5 seconds** to saturate the BUD with cryogen. Release the trigger to stop the dispense of cryogen.
5. With the BUD remaining attached to the device, place the cold BUD directly onto the lesion for desired seconds.
6. **Optional:** Remove the BUD by gripping the BUD base and pulling to remove it from the dispenser. Use BUD to apply from any angle for the desired number of seconds.
7. **Freeze/Thaw:** If performing repeat freezing, thaw the lesion for 40 seconds before beginning the next freeze. Repeat step 4 above to refill the BUD with cryogen before beginning to refreeze.
8. Once the treatment is complete the BUD must be discarded.



### CONE USE

1. Remove the CryOmega® Vet Dual Delivery device from the packaging.
2. Select a CONE that is approximately 1mm larger than the borders of the lesion being treated.
3. Insert the disposable CONE onto the reusable CONE ADAPTER.
4. Place the CONE and CONE ADAPTER snugly onto the canister.
5. Grip the CryOmega® Vet Dual Delivery handle and invert the device so that the CONE is directed downward.
6. Place the assembled dispenser, CONE and CONE ADAPTER over the lesion. Pull the trigger for **3-5 seconds** until bubbling of the gas can be seen within the lower part of the CONE. Release the trigger to stop the dispense of cryogen.
7. Hold the CONE and CONE ADAPTER over the lesion until the bubbling stops.
8. **Freeze/Thaw:** If performing repeat freezing, thaw the lesion for 40 seconds before beginning the next freeze starting with Step 6 above.
9. Once the treatment is complete the CONE must be discarded.

**NOTE: Use enclosed neoprene pad for practice.**







**IMPORTANT: Save and store the reusable CONE ADAPTER in the CryOmega® Vet Dual Delivery kit box. It should NOT be discarded.**

## ADDITIONAL PROCEDURE SUGGESTIONS

- Buds may be most appropriate when treating hard to reach or thin-skin surfaces.
- To help focus the bud onto a lesion and minimize damage to surrounding healthy tissue, trim the tip as shown on right.
- Avoid touching the lesion during the thaw phase following treatment
- Use Freeze-thaw cycles when treating deep or difficult lesions.
- Buds are not interchangeable between animals and should be discarded after use with the primary animal.
- Buds may be used to treat multiple lesions on a single animal. They may also be recharged with additional cryogen between lesions.
- Buds may be used immediately after dispensing cryogen. They are immediately at effective temperature.
- Resolution rates will improve with freeze-thaw cycles.
- Cryosurgical research suggests that a narrow strip of healthy tissue should be frozen along with the target tissue for maximum effectiveness (3).



## TABLE OF SYMBOLS

	INSTRUCTIONS FOR USE
	CAUTION/ATTENTION
	WARNING
	MANUFACTURER

## REFERENCES

1. Seim HB, *Mechanisms of Cold-Induced Cellular Death. Veterinary Clinical of North America, Small Animal Practice*, 10:4, 755-762 (1980)
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4. Gage AA, *What Temperature is Lethal for Cells? J Dermatol Surg Oncol*, 5-6 (1979)
5. Pavletic MM, *Anatomy and circulation of the canine skin. Microsurgery*, 12, 103-112 (1991)



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Patents Pending

