

Cryosurgery using the CryoPen®

FAQ

CRYOSURGERY

What is cryosurgery?

Cryosurgery is a procedure that uses extreme cold to destroy tissue.

How can my practice benefit from using cryosurgery in my practice?

Cryosurgery in the office offers an excellent modality for eliminating referral time while creating an added source of revenue.

How can my patients benefit from having cryosurgery in my practice?

Patients will appreciate the efficient use of their time and decreased cost of services by avoiding secondary visits to specialists. By keeping the procedure in house, patients will put a greater value on your practice.

How is cryosurgery better than other methods of removing skin lesions?

Cryosurgery requires no anesthesia and has less scarring than other techniques of skin lesion removal with minimal post-op care.

What is the mechanism of cell destruction in cryosurgery?

Cell destruction occurs when a cell is rapidly brought down to a very low temperature. When these two criteria are met (varies with cell type), ice crystals form, destroying the cell organelles and protein matrixes. Water then rushes into the surrounding area causing a blister and a disruption of the local blood supply. Cytologic evidence of cell destruction can be seen as soon as two hours after the procedure.

What types of lesions are appropriate to freeze?

Almost any unwanted skin lesions are appropriate such as warts, moles, actinic keratosis, seborrheic keratosis, keloids, lentigos, dermatofibromas, and hemangiomas to just name a few. In most practices, over 90% of unwanted lesions encountered are amenable to using cryosurgery.

What types of lesions are not appropriate to freeze?

All Melanomas and Recurrent Basal Cell Carcinomas are contraindicated for cryosurgery.

Can I freeze anywhere on the body?

Care should be taken for areas of very thin skin and areas in which color may be cosmetically important. These include such areas as the face, ears, scrotum, and lateral surface of fingers. See full prescribing information for specific contraindications and cautions.

Why not freeze recurrent basal cell carcinoma?

Basal Cell Carcinoma is typically spread by local extension. If recurrence is suspected then metastasis is highly likely and the patient needs more extensive surgery.

Why not freeze Melanoma?

Melanoma can spread by any of several means including local, lymphatic, and blood. There is some concern that partially treated Melanoma changes to a much more aggressive form with higher tendency toward metastasis and that part of the lesion will be left behind-undetected.

How does the physician determine if a lesion is suitable for cryosurgery?

Cryosurgery education from AAFP, articles or short courses.

How long does the blister last after treatment?

A blister forms 2-24 hours after freeze. Blisters may take several days to drain or dissolve. Once a blister breaks, a crust will form over the lesion. Healing occurs from 1-6 weeks depending on depth of freeze and size of lesion.

What are the series of events after the cryosurgery procedure?

During the procedure, the area freezes and turns white. After this white area thaws, a flushing occurs that turns the area red. This thawing is associated with a pinching sensation as a wheal is formed. This wheal may develop into a blister or not depending on the area of the body and length of freeze. This blister may last 3-5 days then begin to form a scab. This scab will fall off in 1-2 weeks. Depending on the extent of freeze and tissue area, a new scab may form and repeat the process. The lesion will be completely healed in 2-6 weeks, again depending on the extent of freeze and tissue area. After primary healing occurs, the area will be lighter than the surrounding area due to loss of melanocytes. Melanocytes are very cold sensitive, dying at -5°C and below.

TECHNIQUES**How long does a single freeze take?**

Freeze times vary with the type of lesion and the area on the body. A typical freeze may last from 5 seconds for a small flat wart to 90 seconds for a full thickness malignant lesion. But for general purposes most lesions take about 20 to 30 seconds.

How does the physician determine how long to freeze a lesion?

Education from reading articles, attending workshops, freeze time charts, and experience.

How much pressure should be applied when freezing the lesion?

Just enough pressure should be applied to make good surface contact. Increased surface pressure will compress tissues and accentuate the freeze depth.

When do I know that I am ready to perform cryosurgery in the office?

When you are able to identify which lesions are appropriate for cryosurgery and times of freeze, then you will be ready to perform cryosurgery in the office.

Are there areas of the body that may not be frozen?

Freezing is cautiously not done in areas with very thin delicate skin, limited blood supply or superficial nerves. These areas include but are not limited to the face, ears, scrotum, and lateral surface of fingers. Limited blood supply should be suspected in lower extremities of diabetics, and anyone else with peripheral vascular disease. Also, any area where color is very important cosmetically is best avoided. Melanocytes (pigment cells) are some of the most sensitive cells to extreme cold temperatures which is why a hypo-pigmented area is left after a freeze. If there is doubt, perform a test freeze on a hidden low risk area first.

Is there a list of lesions that may be frozen?

Many articles have lists, but for example: almost any benign lesion due to chronic sun damage, keloids, warts, hemangiomas etc. (see articles or educational programs for a more in-depth explanation of what lesions can be removed using cryosurgery).

What preoperative preparation is needed before freezing?

No preoperative preparation is necessary prior to cryosurgery except when removing plantar warts. Preparing the plantar warts with a denuding agent such as, over the counter salicylic acid preparations, and paring them down prior to freezing can make their removal more effective.

Is there any anesthesia?

No! The extreme cold causes anesthesia soon after applied, which allows the procedure to be tolerable.

When is surface gel useful during freezing?

Water soluble gels are most useful when freezing a raised dry lesion to improve surface contact.

Why is the surface temperature best between -50°C and -80°C?

The temperature required to kill most cells is optimally below -20°C. If for example to freeze a lesion down 3mm in depth the surface would have to be at -50°C because for each 1mm of depth, approximately a 10°C loss of temperature occurs into the epidermis. Therefore if the skin surface temperature is at -50°C then a 2mm depth is still at -30°C and well below the kill temperature.

How many lesions can be frozen at one session?

Usually it is prudent to freeze only 3 lesions per session to limit the degree of systemic inflammatory response.

What type of physician can perform cryosurgery?

Any physician with an interest can quickly be comfortable performing cryosurgery in their office. This is a skill that most primary care physicians should perform.

RISKS

Can anyone have cryosurgery?

Yes, cautions about skin type and location should be considered prior to deciding on freeze times. Also, people with high levels of cryoglobulins should be treated with caution. Please see full prescribing information for more specifics.

Can you freeze anywhere on the body?

Freezing is typically not done (or done with caution) in areas with very thin delicate skin or limited blood supply or superficial nerves. These areas include but are not limited to the face, ears, scrotum, and lateral surface of fingers. Limited blood supply should be suspected in lower extremities of diabetics, and anyone else with peripheral vascular disease.

Also, areas where color is very important cosmetically are best avoided.

What happens if the freeze is too long?

Prolonged freeze times can cause more destruction of the connective tissue (CT) and surrounding vascular and lymphatic infrastructure. Damage to CT can increase scarring. Damage to the surrounding infrastructure can cause prolonged healing time for the cryolesion. A very general rule of thumb is that a freeze using the CryoPen for less than 60 seconds will not damage connective tissue.

What is the risk to freezing Melanoma?

Melanoma can spread by any of several means including local, lymphatic, and blood. There is some concern that partially treated Melanoma changes to a much more aggressive form with higher tendency toward metastasis, and that part of the lesion will be left behind undetected. Melanomas or lesions suspected of being a Melanoma should not be frozen.

How does cryosurgery compare to other methods of skin lesion removal regarding scarring?

Cryosurgery causes the least scarring. It does this by killing tissue cells and leaving the surrounding connective tissue intact. This provides an organized infrastructure for the re-growth of tissue cells during healing.

What are the contraindications to cryosurgery?

There are few contraindications to cryosurgery. Cryosurgery should be avoided in persons with cold intolerance. Other high risk patients would include anyone having a problem with vascular insufficiency. Also, anyone with sensitivity to alcohol should avoid contact with the uncovered CryoPen tip.

How dangerous is the CryoPen tip?

The CryoPen tip is extremely cold. Its purpose is to destroy tissue. If handled improperly it can cause freeze burns.

What if the CryoPen gets stuck on a lesion?

Remove the CryoPen from the disposable tip. The disposable tip will quickly return to room temperature and easily be removed from the lesion. The tip will usually thaw in less than 10 seconds.

What are the risks of cryosurgery in dark pigmented patients?

Melanocytes are the most sensitive to cold injury. Therefore they are the most easily damaged with cryosurgery. Dark pigmented patients must weigh the risk of permanent loss of pigment when considering cryosurgery.

Can the CryoPen be used on children?

Yes- There are very few lesions which are treatable with cryosurgery in the pediatric age group. However, cryosurgery can be very effective with common Nevi and Molluscum contagiosum.

CRYOPEN CRYOSURGICAL SYSTEM**How does the CryoPen system work?**

The CryoPen is a refrigeration system that is capable of attaining extreme cold temperatures. The system reaches a temperature of approx. -95°C. The base unit cools the pens which when removed from the wells are approximately -90°C. The pen when touched to the skin surface then rapidly extracts the heat from the surrounding tissues causing a precipitous drop in the temperature of the affected tissue. When the temperature of a cell drops below -20°C the target cells are killed by several converging mechanisms of action.

How long does the pen (handheld module) stay cold?

The CryoPen handheld modules will stay at therapeutic temperatures for approximately 10 minutes.

How cold does the pen (handheld modules) get?

When the CryoPen handheld module is removed from the CryoPen system it is down to approximately -90°C

How deep does the CryoPen freeze?

The CryoPen can effectively freeze therapeutically to depths of 2-3 mm if desired.

Why do the freeze times vary?

Freeze times vary due to type of lesion and thickness of skin.

How do I know if the CryoPen is at the correct temperature?

Each CryoPen System comes with a temperature indicator which will light green when the CryoPen is at the therapeutic temperature. It lights red when the CryoPen is not ready for use. Note: The temperature Indicator also lights red when not connected to a pen and the button is pushed.

How is it better than currently available techniques for cryosurgery?

The CryoPen is better than currently available techniques in that it requires no exposure to gases, no dealing with canisters or tanks, no OSHA rules. It is simple, safe and cost effective.

What is the length of the warranty?

Manufacturer's warranty is 1 year.

Who will fix the CryoPen if it breaks?

Repairs should only be done by CryoPen, Inc. or authorized repair centers.

What happens if I drop the Pen?

The Pens are sturdy, however, if dropped the pen should be examined for possible damage. Visual damage may include: cracked caps or body or dented/chipped tips. If there is no physical damage but the pen is not operating optimally-call technical support.

What if I spill liquid in the machine?

The system has electrical parts and is extremely cold. Liquids spilled into the machine can cause a possible electrical hazard. Liquid in the CryoPen bays will freeze rapidly both obstructing the placement of the CryoPens and causing a significant deterioration in the ability of the System to cool the CryoPens. Immediately turn off the unit, and allow the system to warm to room temperature. Next, using a dry cloth in the end of a forcep or clamp, dry the bay in which the liquid was spilled. Following the Quick Set-Up Instructions, restart the unit and allow to return to operating temperature.

Is the CryoPen FDA cleared?

Yes- since April 2002

Can the unit be turned off each day?

Yes- however, we recommend leaving the unit on. (leaving unit on reduces the possibility of unit freezing up)

How long after the unit start up until the CryoPens are ready for use?

It will require about 90 min once turned on to regain therapeutic temperature. It takes about 10 min to cool a pen when placed in the cooling cylinder during operation. Readiness of the pens can always be evaluated using CryoPen temperature indicator provided.

PATIENT CONCERNS

Will there be scarring?

Typically, cryosurgery leaves the least amount of scarring of any form of lesion removal because it causes the least damage to the connective tissue infrastructure. A hypopigmented lesion will be noted until this darkens with new tanning.

Is there pain with the procedure?

There may be some tingling with the initial freezing but most patients get an anesthetic effect from the extreme freezing temperatures. More of a pinching sensation occurs when the area thaws out. Some patients have some discomfort for the first day after the procedure. Acetaminophen and Ibuprofen are usually adequate.

How long will the lesion take to heal?

The cryolesion usually develops a blister during the first 24 hours which lasts 2 to 5 days. After it scabs over the lesion, healing depends on how deep the wound is. Typically, healing occurs from 2 to 6 weeks, depending on length of freeze and location.

How permanent is the cure?

For most lesions cryosurgery is a permanent removal. Some lesions are harder to remove than others. In more delicate places a shorter freeze time with repeat procedures may be required to get a final result with the least damage to the surrounding skin. In other instances a deep lesion may take several aggressive treatments to get a final result. In particular, warts that don't have pre-treatment may take multiple freezes.

Will there be permanent discoloration?

Since melanocytes are the most sensitive cell type, persons with dark pigmentation or prolonged freeze times in any individual may cause extremely long color recovery or permanent color loss even after the lesion is healed in other respects.

Will my wart fall off after one treatment?

Most small common warts will respond to a single treatment. However, certain types and very large ones can be very difficult to remove and may take more than one treatment.

Will my activities be limited and for how long after the procedure?

There are no limitations on activity except to protect the cryolesion from damage or abrasion. Activity should be limited as one would for a second degree burn with a blister.

How do I take care of the blister?

Keep it protected best as possible and do not break the blister unless it leaks, then apply antibiotic ointment and keep it covered.

Can I go swimming after cryosurgery?

Sure, as long as the blister hasn't popped.

What if the blister pops?

If the blister pops, the use of an antibiotic cleaning solution and ointment is recommended. Covering the area with a bandage also promotes healing.

What are the most common complications after cryosurgery?

An early blister that pops could potentially become infected if not cleaned properly.

When will I need to return for follow up with the physician?

Only if re-treatment is needed or if the lesion appears infected.

Will I need more than one freeze treatment for each lesion?

Depending on the type of lesion frozen and response of the first freeze.

Will the physician use local anesthesia?

No, the extreme cold from the CryoPen will cause a local anesthesia very soon after the procedure begins.

What will my patient physically experience during the procedure?

During the procedure, the area freezes and turns white. After this white area thaws, a flushing occurs that turns the area red. This thawing is associated with a pinching sensation as a wheal is formed. This wheal may develop into a blister or not depending on the area of the body and length of freeze. This blister may last 3-5 days then begin to form a scab. This scab will fall off in 1-2 weeks. Depending on the extent of freeze and tissue area, a new scab may form and repeat the process. The lesion will be completely healed in 2-6 weeks, again depending on the extent of freeze and tissue area. After primary healing occurs, the area will be lighter than the surrounding area due to loss of melanocytes. Melanocytes are very cold sensitive, dying at -5°C and below.

MEDICAL MANAGEMENT

How long will the cryolesion take to heal?

From 2-6 weeks depending on length of freeze and location.

What are the limitations on activities during the healing phase?

Only if the blister pops should caution be taken to ensure a clean environment to guard against infection.

How is the cryo lesion blister managed?

Cover with a bandage to avoid hitting the lesion- see above if it pops.

What follow up is necessary?

Follow up should be scheduled for cancerous lesions at 3-4 weeks to assure that the entire lesion was removed. Follow up for re-freeze at 2 week intervals should be scheduled for lesions requiring more than one treatment.

What, if anything, is required for pre-op?

Pre-Op treatment of large verucca and all plantar warts should be done for two weeks prior to treatment. This treatment should consist of a chemical denuding agent such as salicylic acid pads or (Keratolytic Agent). Then superficial sharp paring could be performed immediately prior to cryosurgery. This pre-op treatment would allow the freeze zone to get below the wart.