CryoPen GY2 Cryosurgical System
Cervical Attachment

OPERATOR'S MANUAL

cryosurgery at your fingertips®

OM-GY2-01-R6
Updated: 3-31.14

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(Minimally invasive cryosurgical unit and accessories for physician use only)

- **Caution: "Federal law restricts this device to sale by or on the order of a Physician".**

Manufactured in the U.S.A. by IDM Tech, LLC for CryoPen, Inc.
Distributed by: CryoPen, Inc.
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CONTENTS: **Gynecological Configuration**	**ITEM NUMBER:** **GY2**
Non-Sterile GYN Handle (1 ea.)	GY2-0001
GYN Pen Cores - Green (2 ea.)	GY2-0002
Non-Sterile Re-usable CryoPen® GY2 Tips (4) (Green)	(Provided in Customer Selected Assorted Sizes)
Customer Selects from the following sizes:	
Non-Sterile Re-usable CryoPen® GY2 Tip 3mm	GY2-0003
Non-Sterile re-usable CryoPen® GY2 Tip 10mm	GY2-0010
Non-Sterile re-usable CryoPen® GY2 Tip 19mm	GY2-0019
Non-Sterile re-usable CryoPen® GY2 Tip 24mm	GY2-0024
Black Core (Non-functional) (1ea.)	GY2-0005
Temperature Indicator (Green) (1ea.)	GY2-0004
AA Batteries (2)	GY2-4103

Note: GY2 System to be used in conjunction with CT-2000 CryoPen® Cryosurgical System. The CT-2000 System uses Pen cores & Re-usable CryoTips which are blue. The GY2 system employs green Pen cores, Re-usable CryoTips, and Temperature Indicator.

Indications For Use:

- Intended use: Cryosurgical unit used for ablative type surgical technique
- Indications for use: Multiple organ systems, wide range of disease, viral, premalignant and malignant tissue.
- Cryosurgical instrument used to necrose unwanted tissue in the gynecological and dermatological practice

Contraindications:

The CryoPen® is contraindicated in patients with recurrent basal cell cancers; lesions on the lower extremities (i.e. feet, ankles, lower legs) when circulation is in question, especially in patients with diabetes; lesions in the nasolabial fold or preauricular area (basal cells often are more extensive in this area); lesions in the immediate periorbital area; port-wine stains, lesions in areas in which hair loss or pigmentary changes are critical to the patient. Cryosurgery is contraindicated for use in patients with Melanoma. Additionally, gynecologic cryosurgery is not recommended for patients who are pregnant.

Gynecologic cryosurgery is contraindicated for invasive cancer.

Do NOT use the CryoPen® when any of the above listed conditions are present. The use of cryosurgical procedures in the treatment of the above listed conditions may cause serious injury to the patient.

WARNINGS:

WARNING: If re-usable tip gets stuck on skin, remove the Pen Core from tip by gently rotating counter clockwise to unlock it and allow to thaw.

WARNING: This device should be used with caution on patients with diabetes, peripheral vascular disease or cold intolerance problems.

WARNING: Do not perform cryosurgery using GYN attachment when ECC[a] is positive for CIN[b].

WARNING: Gynecologic cryosurgery is not recommended for patients who are pregnant.

WARNING: Do not perform Gynecologic cryosurgery on lesions not fully visible or extending beyond the range of the cryotherapy probe.

WARNING: Do not use the electrical charging unit near or in water. Doing so may cause electrical shock resulting in serious injury or death to the user.

WARNING: Do not use an extension cord. Use of extension cords may present potential fire hazards.

WARNING: Explosion hazard! Do not use in presence of flammable anesthetics. Unit contains 1oz. of an ethanol based proprietary solution.

WARNING: Ethanol is poisonous! May be fatal if swallowed and harmful if inhaled or absorbed through skin. Please refer to Material Safety Data Sheet regarding the ethanol based reservoir solution.

WARNING: Reservoir solution contains alcohol (ethanol). Avoid skin contact with the reservoir solution on persons taking the medication ANTABUSE®.

WARNING: The CryoPen® Pen Cores are extremely cold. Accidental contact with core may result in frostbite. Touch only the green plastic handle when core is at cryogenic temperatures.

WARNING: Do not use the CryoPen® Pen Core without a sterile tip. Doing so will expose your patients to non-sterile conditions and may cause cross patient contamination. Pen Core could also become stuck on patient's skin thereby causing injury to the patient.

WARNING: Do not use E-beam, Gamma radiation, or Ethylene oxide to sterilize tips for Gynecologic or General Cryosurgery use.

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[a] Endocervical curettage (ECC) is a procedure performed during a colposcopy where a curette, a spoon-shaped instrument, is used to scrape the mucous membrane of the endocervical canal (the passageway between the cervix and uterus). This procedure obtains a small tissue sample.

[b] Cervical intraepithelial neoplasia (CIN), also known as cervical dysplasia and cervical interstitial neoplasia, is the potentially premalignant transformation and abnormal growth (dysplasia) of squamous cells on the surface of the cervix. The CIN system differentiates mild (CIN 1), moderate (CIN 2), and severe dysplasia/CIS (CIN 3) based on the proportion of abnormal cells relative to the full epithelial thickness

WARNING: The handle of the Gynecologic attachment when removed from the tip portion, may be wiped down with an alcohol wipe or similar agent. Do not submerge the handle in a liquid disinfectant or sterilant as doing so will render the handle inoperable.

PRECAUTIONS:

CAUTION: Never leave the chilling wells open. Doing so will render your unit inoperable. Always replace a cold pen core with a warm pen core that has been wiped dry and dipped in the CryoPen Reservoir Solution, or use the black non-functional core to replace a cold pen core.

CAUTION: Use of CryoPen® on lesions with hair, may cause patient to lose hair.

CAUTION: Use of CryoPen® on lesions in areas where pigment is critical to patient, patient should be made aware that change in pigment may result.

CAUTION: Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

CAUTION: Handle the pen cores with great care. Dropped pen cores will be damaged and may become trapped in the pen tips.

CAUTION: Cold pen cores should be placed in a tip or defrost wells immediately to avoid damage.

CAUTION: Clean CryoPens® Pen Cores by wiping down with soap and water or with standard solutions such as isopropyl alcohol. Clean only when they have reached room temperature. Do not submerge the Pen Cores. Doing so will render them inoperable.

CAUTION: Should CryoPen® GY2 tips become attached to the patient, remove the GY2 pen core from the GY2 handle and insert a room temperature pen core into the handle, allow to thaw, and then remove the tip from the treatment area.

CAUTION: GYN attachment handle contains two, AA alkaline batteries. Dispose of batteries according to applicable regional and national laws. Upon failure, batteries may be replaced with AA, alkaline batteries. Use of rechargeable cells is NOT recommended.

CAUTION: Discontinue use of Aluminum reusable tip in the presence of discoloration or tarnishing and alert CryoPen Technical Support.

CAUTION: Please refer to current clinical practice guidelines to determine which patients with cervical cancer precursors are candidates for cryotherapy.

POWER OUTAGE

- ***Step one:*** Turn unit off and allow to defrost (Red light will illuminate on front of unit) Note: You will hear the fan running.
- ***Step two:*** After unit has reached room temperature, approximately 8 hours, unplug the power supply from unit and remove Pen Cores from the chilling wells.
- ***Step three:*** Using the 14" swab that is provided, remove all reservoir solution and water from the chilling wells. Wells should be completely dry.
- ***Step four:*** Remove reservoir tube from the unit, discard old solution and refill to the maximum line (3 pipettes).
- ***Step five:*** Dry all Pen Cores with cotton towel. Using the supplied plastic Pipette, fill each chilling well with reservoir solution (one Pipette full per well). Place 1 pen core into each of the wells. Place remaining two pen cores in the holding wells.
- ***Step six:*** Plug the power supply into the unit and turn unit on (Located on left side of unit). Green light will illuminate on front of unit. System will be ready for use in approximately 60 minutes. Test Pen Cores for readiness using the temperature indicator.

The above steps should be followed each time you have a power outage.

POWER SURGE

- ***Step one:*** Turn unit off and unplug from wall outlet/surge protector, wait 3-5 minutes then re-plug electrical cord into wall outlet/line surge protector and turn system back on. This will allow your system to reset.
- ***Step two:*** If unit does not chill properly after this process, turn unit off and follow the steps for a Power Outage and/or call Technical Support at 1.877.246.3955.

Note: We recommend using a line surge protector to protect this system and your investment.

DESCRIPTION

The CryoPen® GY2 system allows for Gynecologic cryosurgery applications and provides a means of freezing tissue without the use of cryogenic gases or liquids. The system consists of a handle, two pen cores, four re-usable tips in various sizes and a temperature indicator. The handle consists of two AA batteries and LEDs to help visualize lesions. When used properly, in conjunction with a CT-2000 unit, the system will deliver effective temperatures for tissue ablation.

The CryoPen® GY2 Pen Cores (Green): Consists of a heat sink that has been shaped at one end to form a treatment surface that is inserted into the reusable tips. A connection for proper temperature indication is on the top of the pen core. Readiness of the Pen Cores should be checked using the temperature indicator for readiness before each use.

The CryoPen® GY2 Re-usable Tips (Green): Tips consist of resilient medical grade plastic that contains an aluminum tip. When surgery is complete, remove the pen core from the tip. Re-sterilize tips in-between patients. Failure to do this will result in non-sterile conditions and may cause cross patient contamination.

GY2 Temperature Indicator (Green)**:** Indicates readiness of CryoPen® Pen Cores.

INSTRUCTIONS FOR MODEL CT-2000 CONFIGURED FOR GYNECOLOGY APPLICATION:

SET UP

WARNING: SET-UP IS SIMPLE BUT YOU WILL WANT TO CAREFULLY REVIEW THE OPERATOR'S MANUAL BEFOREHAND.

1. Read Operator's Manual

2. Unpack contents of GY2 system containing: (2) GYN Pen Cores - Green, (1) Black Core (non-functional), (1) Handle, (2) Batteries, (1) Temperature Indicator for GYN application, and 4 non-sterile tips.

3. Locate CT-2000 base unit by the nearest 110-240 volt outlet. Plug power supply into the unit and electrical cord into outlet (See Note Below). Fan will automatically come on and red light will illuminate on front of unit. If green light on front of unit is illuminated at this time, place the power switch to the off position. **Unit should not be turned on yet**. Unit must be placed at least 1½ inches away from the wall/counter backsplash to prevent overheating.
Note: We recommend the use of a line surge protector to protect the unit and your investment
WARNING: Do not use an extension cord. Use of extension cords may present potential fire hazard.

4. Fill Reservoir Tube to the line using the supplied Reservoir Solution. Do Not Overfill! Store remaining solution in a cool, dry place. **Note:** The use of any other solution other than that obtained from CryoPen, Inc. will render the unit inoperable and will void your warranty. After the Reservoir tube is filled, remove the (2) pen cores from the Chilling Wells located on top of unit. Using the supplied transfer pipette, fill each well with (1) one pipette full of reservoir solution from the reservoir tube or reservoir bottle.

5. Insert 2, Green GY2 Pen Cores fully into the chilling wells. **Pen Cores should always be dipped into Reservoir Solution before inserting into chilling wells after initial set-up.** Chilling wells reach between -105ºC to –110ºC. Make sure pen cores are properly seated in chilling wells. Failure to do this will result in pen cores not reaching optimal temperature. If a Pen Core is not replaced into a chilling well, freezing of the well will occur and unit defrosting will be necessary.
Note: Never leave chilling wells open.

6. Turn on power switch at left side panel of unit. When unit is turned on a green light will illuminate on front of unit. The unit will be operational in approximately 120 minutes. Unit is designed to remain on unless a problem is encountered, service is needed, or for periods of non-use longer than three days. Set up instructions should be followed to re-start the system.

7. After the unit has reached operating temperature in approximately 120 minutes, test the Pen Core temperature readiness using the green temperature indicator.

To initialize, please ensure that the connector on the bottom of the indicator is fully seated on the pen core. If the status LED fails to light, please try again.

When the temperature indicator is plugged into the CryoPen® Pen Core please allow between one/two seconds for the indicator to register one of the following:

- Solid red light indicates the CryoPen® GY2 pen core is not cold enough for a procedure;
- Green light (blinking or solid) indicates that the CryoPen® has reached optimal temperature to perform cryoablation of a lesion on the cervix;
- Blinking red /green lights together, indicates the CryoPen® is too cold and could damage unit. Please contact CryoPen® immediately in such an instance.

The temperature indicator's status LED will stay lit for approximately three to five seconds while connected to a Pen Core. To ensure accurate reading of pen core readiness, leave the temperature indicator seated on the pen core for 5-10 seconds subsequent to initial reading. This allows the male and female connectors to thermally equilibrate. After 5-10 seconds, take another reading of the pen core by removing and then re-seating the temperature indicator onto the pen core. The first and second readings should be the same. Otherwise, please repeat this step.

Note: It is unnecessary to test pen core readiness with the temperature indicator prior to performing the latter portion of a freeze-thaw-refreeze cycle. During refreeze, the GY2 cores will have recovered to temperatures below -90° Celsius if the procedure outlined in Step 8 is followed appropriately.

Note: The temperature indicator also turns solid red when connected to a pen core at ambient conditions. If no light is visible when the indicator is attached to a pen core after several readings, contact CryoPen, Inc. at 1-877-246-3955

8. To perform Gynecologic Cryosurgery

A.) Prepare and drape the patient appropriately for the procedure.

B.) Adequately visualize the intended lesion.

C.) Select appropriate tip. (sizes: 3mm, 10mm 19mm, 24mm)

D.) Check temperature readiness of pen core in chilling wells using the green GY2 Temperature Indicator.

E.) Insert appropriate tip by threading onto the Handle and lock into place by rotating clock wise until it seats fully.

F.) Using the GY2 handle, place the selected Cryopen tip firmly against the intended lesion.

G.) Remove Pen Core from chilling well. Replace with Black, non-functional core in the chilling well.

H.) Holding the GYN attachment in one hand, insert the Pen Core completely into the handle slot and lock into place by gently turning clock wise until it locks.

I.) CryoPen is now engaged and freezing begins upon insertion. Leave tip in contact continuously throughout the freeze period.

J.) At the end of one minute, replace pen core with a fresh core. Unlock the Pen Core by turning it counter clockwise. Remove the Pen Core and insert the second pen core from the unit into the GY2 handle for two minutes.

K.) With the help of an assistant - wipe dry, dip and insert the pen core removed during step ***J*** into the open chilling well.

L.) During the freeze period, the tip will become attached to the Cervix. Once the freeze is ended after three minutes, remove the pen core from the GY2 handle and insert an ambient temperature CT-2000 "blue" pen core. The temperature of the tip will return to above freezing, allowing release of the tip from the cervix. If the tip is slow to detach, room temperature water may be sprayed on the tip to facilitate thawing.

M.) With the help of an assistant, wipe dry, dip and insert the core which was removed from the GY2 handle in step ***L*** into the chilling well by removing the Black, non-functional core.
N.) Allow the ice ball created from the three minute freeze described above to thaw for five minutes.
O.) After sufficient thaw, repeat steps ***C*** thru ***N*** if a freeze-thaw-freeze cycle is desired.
P.) After defrosting, remove tip from handle of Gynecology attachment. Clean and process tips according to Step 12.

Note: After performance of cryosurgery, allow warm CryoPen® Pen Cores to chill in chilling wells until temperature indicator reads "green" again. Always check readiness by using the temperature indicator. **Pen Cores should always be dipped into Reservoir Solution before inserting into chilling wells.**

9. Batteries powering the two LEDs on the handle of the Gynecology attachment (used to aid in visualization during cryosurgery) may be replaced with two, AA, alkaline batteries upon battery failure. To replace batteries, slide down on the battery compartment door and replace batteries by matching polarity to plastic embossment. Should the batteries expire or the lighting system become otherwise non-functional, the operator may continue using the device by employing an external light source as is typically done during examination procedures with a speculum. In the eventual case of battery failure, the Gynecology attachment is still capable of performing cryosurgery.

DIP NOTE: Pen Cores should always be wiped dry before dipping into reservoir tube. Failure to wipe dry can contaminate solution and may cause failure of unit.

NOTE: Holding the selected tip in position, insert the pen core aligning the two small locking pins with the slots in the tip. Gently rotate clock wise to lock in place. **Caution:** Do not use excessive force. **Caution:** Aluminum tip is now at cryogenic temperatures.

10. If CryoPen® Pen Cores become stuck in chilling wells turn unit OFF and allow unit to defrost. (approximately 8 hours) Wells and pen cores should be wiped dry using the supplied cotton towel and swabs. Set Up instructions must be followed to restart the system. (See separate Instructions for Maintenance and Power Outage).

11. System is designed to remain on. Turning the unit on and off will cause the pen cores in the chilling wells to defrost causing water contamination to the reservoir solution. Chilling wells have to be cleaned.

12. System should be turned off for periods of non-use longer than three days (such as vacations, holidays, etc.). Set Up instructions must be followed to restart the system.

Warning: Pen Cores are extremely cold, accidental contact with skin may cause frostbite.

12. Instructions for Cleaning & Reprocessing CryoPen Reusable and Sterilizable tips: (for Gynecology use)

A. Thoroughly clean all surfaces of the CryoPen tip to remove blood and particles.

1.) Wear heavy-duty rubber gloves, a plastic apron, eye protection, and mask during cleaning as needed.

2.) Soak the instruments in normal tap water containing a detergent such as Enzol®, according to manufacturer's instructions.

3.) Scrub instruments as necessary to completely remove all foreign material using a soft brush or old toothbrush, detergent, and water. Hold items under the surface of the water while scrubbing and cleaning to avoid splashing. Do not attempt to disassemble the tip. Be sure to brush where organic material can collect and stick.

4.) Flush through the inside of the tip.

5.) Rinse items thoroughly with clean water to remove all detergent. Any detergent left on the items can reduce the effectiveness of further processing.

6.) Inspect items to confirm that they are clean and free of visible debris.

7.) Allow items to air dry or dry them with a clean towel if chemical disinfection is going to be used. This is to avoid diluting the chemical solutions used after cleaning. Items that will be processed in an autoclave do not need to be dried.

B. Perform one of the following:

1.) Place in cold soak high level disinfectant/sterilant fluid (e.g. glutaraldehyde based solutions) and follow manufacturer's instructions.

2.) Steam sterilize (autoclave) by gravity with a cycle temperature of 270 degrees Fahrenheit @ 20-30psi for 15 minutes. Allow 20 minutes to dry.

C-1. Upon removal from chemical disinfectants or sterilants, all surfaces must be wiped with CryoPen Reservoir Solution (or an alcohol pad) and allowed to air dry completely.

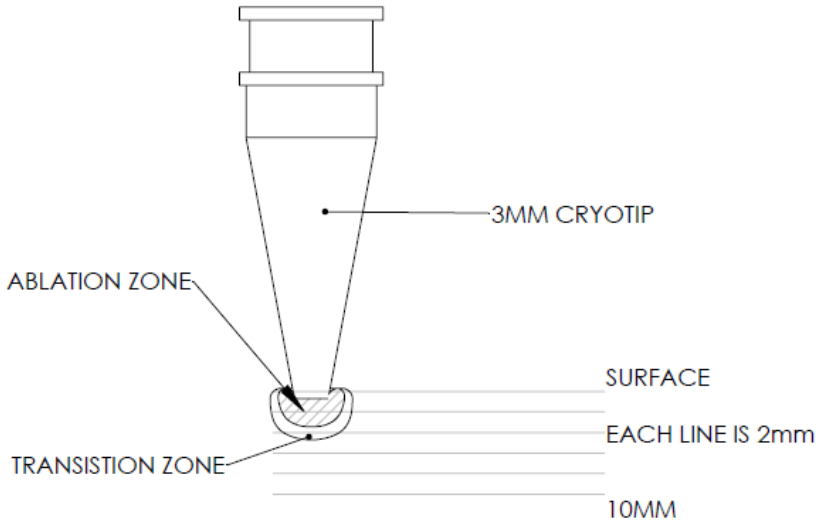
C-2. Upon removal from autoclave, please allow tip to dry completely

D. The CryoPen tip is now ready for reuse.

***Reservoir Solution*:** Should be filled to the maximum line at all times and should be completely changed weekly. Swab and dry out tube completely before refilling. Refill with reservoir solution from 500ml. bottle. **Note:** The use of any other solution other than that obtained from CryoPen, Inc. will render the unit inoperable and will void the warranty.

Expected Ablation and Transition Zone For Gynecology Applications

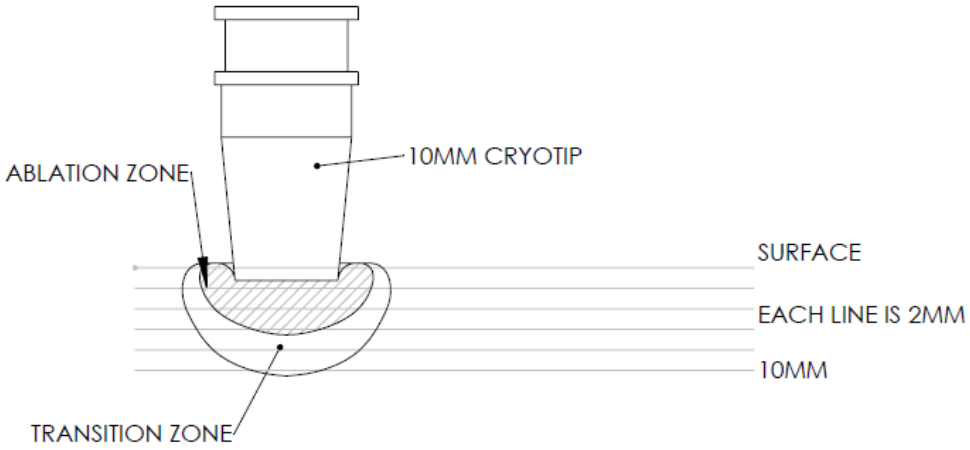
a.) Expected Cryoablation zone for 3mm Tip, 180 seconds of contact (data derived from bench testing on ballistic gelatin)



CROSSHATCHED AREA IS THE ABLATION ZONE
ABLATION ZONE IS COLDER THAN -20*C
TRANSISTION ZONE IS BETWEEN 0*C AND -20*C
BASED ON FREEZING OF BALLISTIC GELATIN

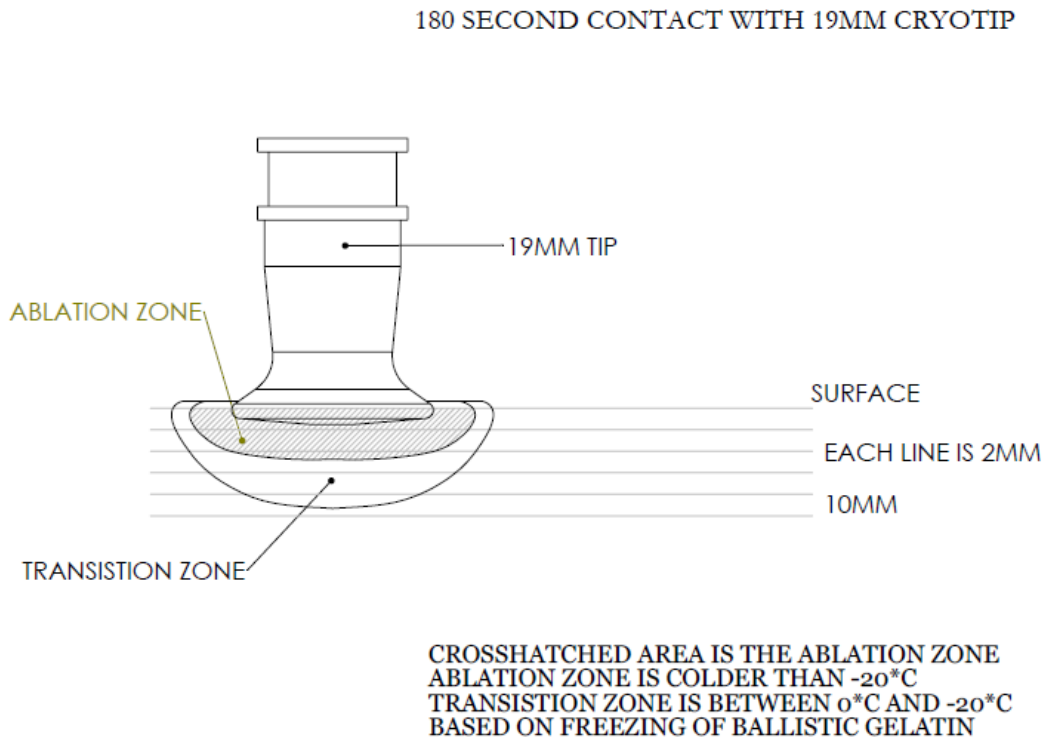
b.) Expected Cryoablation zone for 10mm Tip (data derived from bench testing on ballistic gelatin)

180 SECOND CONTACT WITH 10MM CRYOTIP

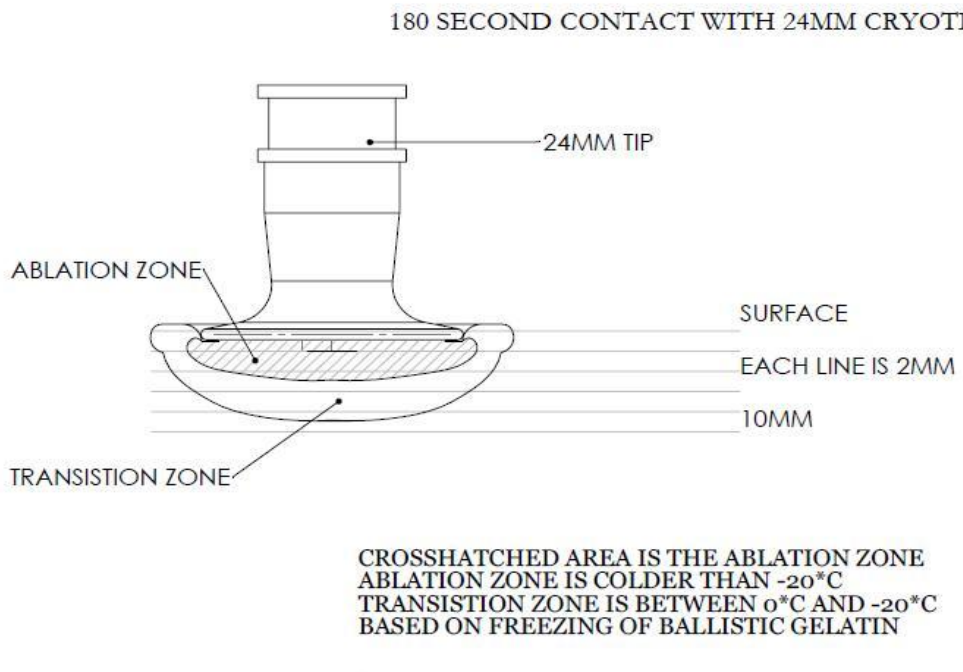


CROSSHATCHED AREA IS THE ABLATION ZONE
ABLATION ZONE IS COLDER THAN -20*C
TRANSISTION ZONE IS BETWEEN 0*C AND -20*C
BASED ON FREEZING OF BALLISTIC GELATIN

c.) Expected Cryoablation zone for 19mm Tip (data derived from bench testing on ballistic gelatin)



d.) Expected Cryoablation zone for 24mm Tip (data derived from bench testing on ballistic gelatin)



CLEANING OF CT-2000 UNIT:

The CryoPen® Cooling System: The main unit, except for the CryoPen® chilling wells, may be cleaned and disinfected as needed. CryoPen® chilling wells may be cleaned periodically as dust and debris may collect in them to the point of making poor contact with the Pen Cores. To clean these chilling wells, use the provided swabs. Use a blotting and circular motion to clean out chilling wells. Never place your fingers into the chilling wells, due to the extreme cold. Do not submerge the unit into water; doing so will present an electrical hazard and destroy the unit. It is important **not to** leave chilling wells open for an extended period of time.

The CryoPen® Pen Cores: may be wiped cleaned with soap and water when the Pen Cores are at room temperature (70-75 degrees Fahrenheit) or cleaned (with such standard solutions as isopropyl alcohol) as needed. Do not submerge pen cores into liquid of any kind. Doing so will render them inoperable. CryoPen® Pen Cores should never be used for a procedure without the appropriate tip in place.

Maintenance

DAILY MAINTENANCE:

Daily maintenance can be done while the unit is on. Rotate pen cores from the holding wells to the chilling wells at the end of each day. (Make sure all pen cores from holding wells are wiped dry and dipped before placing into chilling wells) Reservoir tube should be checked daily and filled as needed to the maximum line.

Note: Reservoir solution level in tube should be kept at the maximum level at all times. (Remove Reservoir Cap if used and discard old solution at the end of each week. Dry tube thoroughly using the supplied swab, replace tube into unit. Refill the tube with supplied Reservoir Solution stored in the 500ml bottle. Open cap and dispense into reservoir tube. NOTE: Reorder 500ml Reservoir Solution as needed. Clean and disinfect system as needed. Make sure unit and surrounding area is kept free from dust.

Periodically remove holding wells from unit and clean with warm soapy water and air dry.

QUARTERLY MAINTENANCE:

The unit must be turned off before quarterly maintenance can be performed. We recommend waiting 8 hours for unit to reach room temperature. Thoroughly dry wells using the supplied swabs and wipe pen cores dry. Then, follow the initial set-up procedure located on the quick set-up instructions, or Operator's Manual.

There are no user-serviceable parts contained in the CryoPen® Cryosurgical System. Only CryoPen, Inc. designated personnel are authorized to perform repairs on the CryoPen® Cryosurgical System or accessories. Use of unauthorized personnel will void any and all manufacturer's warranties.

FOR GENERAL INFORMATION AND TO ORDER ADDITIONAL SUPPLIES CONTACT CRYOPEN, INC.:

Call: 1-877-246-3955

CryoPen, Inc.
Corporate Office: 800 N. Shoreline Blvd. • Suite 900S • Corpus Christi TX 78401

Toll Free: 1-888-246-3928
E-Fax: 1-281-754-4359

TECHNICAL SUPPORT AND/OR SERVICE/REPAIR DEPARTMENT:

Call: 1-877-246-3955

If your CryoPen® Cryosurgical System becomes inoperable or any device related incidents or problems occur, which are suspected to represent a safety issue should be reported immediately to CryoPen, Inc. at 1-877-246-3955

Our staff will be happy to assist you.

WARRANTY

The only warranty granted herein is an expressed, limited warranty as written, as there are no implied warranties.

CryoPen, Inc. warrants, to the extent and subject to the limitations described in this warranty, the **CryoPen® GY2 Cryosurgical System** sold hereunder to be free from defects in material and workmanship if properly installed, serviced, and operated under normal conditions according to the CryoPen® GY2 Cryosurgical System Operators Manual.

This is a limited warranty and CryoPen, Inc. agrees only to correct or replace, at its option, any CryoPen® system that shall be returned to CryoPen, Inc. Transportation of the unit will be prepaid by the original owner, after being placed into service by the original owner, provided that CryoPen, Inc. is satisfied that the equipment was originally defective in either workmanship or materials. This warranty is not transferable without the expressed written consent of CryoPen, Inc. and there shall be no obligation by seller to repair or replace, in whole or in part, either the entire unit, and/or any component part.

Normal "wear and tear" is not warranted. If any unit is rendered unusable because of misuse, negligence, or accident, or if any unit has been altered or serviced by someone other than CryoPen, Inc. then this warranty shall be voided.

This warranty is not applicable to components manufactured by others. If components of the unit have been manufactured by someone other than CryoPen, Inc. then that manufacturer's warranty shall apply to those components manufactured by a third party. If any part of the unit is serviced by persons, firms, or agents not authorized by CryoPen, Inc., then this warranty is void.

This warranty is in lieu of all other warranties, expressed or implied, including warranties of merchantability and fitness for a particular purpose, and no person, agent or dealer is authorized to give any further warranties on behalf of CryoPen, Inc. unless such warranty is in writing and signed by an officer of CryoPen, Inc.

This limited warranty is in effect for one year from the date of the original purchase and is non-transferable and only valid for original purchaser.