SPE/QA/2034/D | PT/QA/860:05 | Date - 06/01/2026 | IFU | CRYOPOP
English Language | CE | Size - 75 x 155 mm

Do not use if package is damaged.	Keep Dry	Keep away from sunlight	Non Sterile Device	Unique device identifiaction
Batch Code	Use-by date	Date of manufacture	Manufactured by.	Country of Manufacturer
Medical Device	Authorized representative in the European community /European Union		Conformity European	Consult instruction for use or consult electronic instruction for use

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PREGNA INTERNATIONAL LTD.

Plot No. 219, Survey No. 168
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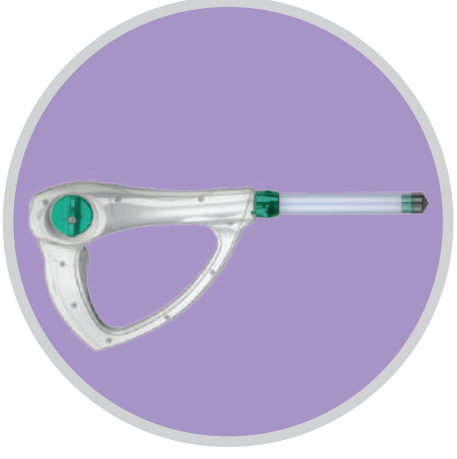
Email: sales@pregna.com
Website: www.pregna.com

PT/QA/860:05
Effective Date - 06/01/2026

For Product detail.

CryoPop

CRYOTHERAPY DEVICE



INSTRUCTIONS FOR USE

SPE/QA/2034/D | PT/QA/860:05 | Date - 06/01/2026 | IFU | CRYOPOP
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INDICATIONS

Cryotherapy Device is indicated for Cryo based treatment in gynecology for all women in reproductive age.

INTENDED USE

Treatment of precancerous cervical lesions.

PRODUCT DESCRIPTION

The CryoPop is a cryotherapy device that uses dry ice as a cold source to ablate unwanted tissue. The CryoPop consists of three assemblies: applicator with tip, snowhorn and the handle assembly. When these assemblies are used correctly, the CryoPop will be able to achieve temperatures necessary to ablate undesired tissue at the desired location. The CryoPop is intended for use by trained healthcare professionals.

HANDLE ASSEMBLY

The handle assembly consists of a handle, an applicator body and a tip. The handle contains a wheel that retracts a spring to prepare the device to fill with dry ice and a thumb button to begin the freeze cycle. The handle connects with the proximal end of the applicator, which contains all the dry ice necessary for the cryotherapy procedure. The distal end of the applicator interfaces with the snowhorn. The tip which connects to the distal end of the applicator, contacts the surface of the cervix and is composed of aluminum to allow heat transfer from the cervix to the dry ice. The dry ice in the applicator body is continually compressed against the tip to ensure the tip temperature remains cold enough for successful cryotherapy as heat is absorbed from the cervix.

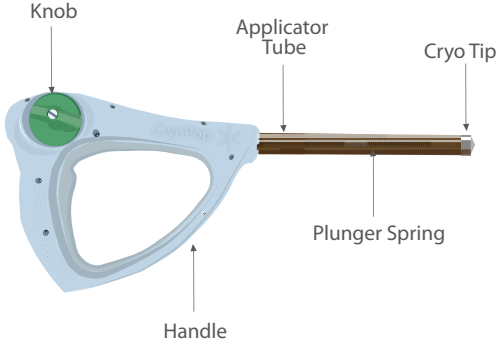


FIG.1 CRYOPOP DEVICE

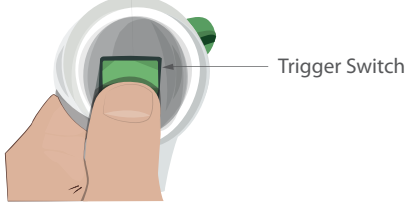


FIG.2 TRIGGER SWITCH

SNOWHORN

The Snowhorn interfaces with the tank adapter and the the distal end of the applicator to allow passage and appropriate expansion of liquid CO_2 form the tank into the applicator to create the dry ice necessary for cryotherapy.

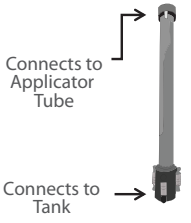


FIG.3 SNOWHORN

CRYOPOP PACKAGE CONTENTS

Cryopop device assembly	1 Nos
Additional Applicator tube with Cryotip	1 Nos
Snowhorn tube	1 Nos
Flow Orifice assembly	1 Nos
Filter	5 Nos
Teflon washer	5 Nos
Tank adapter assembly	1 Nos
Tips	5 Nos
Wire Cutter	1 Nos
Cleaning Pin	1 Nos
Double ended spanner	1 Nos
Teflon Tape	1 Nos
Weighing Scale	1 Nos

MECHANISM OF ACTION

The CryoPop is a cryotherapy device that uses CO_2 (dry ice) as a cold source to ablate unwanted tissue. The temperature can reach upto -65°C. The CryoPop device assembly consists of four parts - Cryotip, Applicator, Snow horn and handle body. Cryotip is a conical shape made of Aluminum attached to applicator. The primary purpose of the Cryo tip is to conduct heat away from the surface of the patient's cervix into the sublimating dry ice on the inside surface of the tip. The tip in turn freezes to the wet surface of the cervix creating good conduction through the metal into the dry ice. The applicator connects to the handle body and then connects to the snowhorn in order to collect the dry ice necessary for a 3-minute freeze procedure. The dry ice in the applicator is then continually compressed against the tip to ensure the tip temperature achieves the necessary cold (-50 to -60^{0}C) for successful cryotherapy. The handle houses the mechanisms and user interfaces which control the start and end of the freeze through the advancement and locking of the plunger which applies compressive force against the dry ice.

CONTRAINDICATIONS (ABSOLUTE)

- Blood dyscrasias of unknown origin.
- Cold intolerance.
- Raynaud's disease.
- Cold urticaria.
- Cryoglobulinemia.
- Lesions in which tissue pathology is required.
- Lesions in areas of compromised circulation.
- Sclerosing basal cell carcinoma (BCC) or recurrent BCC or squamous cell carcinoma (SCC) located in high-risk areas like the temple or nasolabial folds.

CONTRAINDICATIONS (RELATIVE)

- Keloidal tendency.
- Collagen vascular diseases.
- Dark-skinned individuals due to the high risk of developing cosmetically unacceptable protracted hypopigmentation.

- Lesions over the nasolabial fold, eyelid margins, ala nasi and hair-bearing areas (high risk of developing alopecia, especially cicatricial alopecia).
- Patients with sensory loss at lesional sites.
- Pyoderma gangrenosum.

WARNINGS

- The tip of the CryoPop is extremely cold. Contact with unintended tissues may result in frostbite.
- The tip of the CryoPop and applicator must be adequately decontaminated prior to use to eliminate risk of infection.
- The CryoPop is reusable and should be clean by High level disinfectant (0.5% Chlorine) after every use.
- Never use excessive force to remove the tip of the CryoPop from tissue if it is frozen in place. This can severely damage the tissue.

PRECAUTIONS

- The packaging containing the tip, applicator, and snowhorn should be available.
- The CryoPop should only be used with components and accessories provided in the CryoPop package.
- Ensure the CryoPop is used in a room with adequate ventilation·

INSTRUCTIONS

TANK AND CRYOPOP DEVICE SETUP

1. Ensure the tank adapter assembly is done as shown in the Fig.4

Note :- Ensure the weight of the cylinder is minimum 10.5 kg for sufficient ice formation (without tank adapter assembly).

2. Place the cylinder vertically and make sure that the valve of the cylinder is closed to avoid accident. Take plyer from the box and cut the wire which is connected to teflon cap. With the help of spanner remove the teflon cap. Now connect the tank adapter assembly to cylinder with the help of spanner. Take out the tank adapter assembly from the box. Fit the tank adapter assembly to cylinder by connecting the nut onto nozzle. Make sure that the assembly remain straight while tighting the adapter nut. Take out the FLOW ORIFICE from the box. Now apply teflon tape on the thread by rotating 3 times. Remember to leave 1 or 2 threads at beginning. Place the provided filter into the filter slot in FLOW ORIFICE adapter assembly. Ensure that the valve of tank adapter assembly is closed. Now open the knob of cylinder (tank) to check whether the gas is coming out or not, open the half valve if the gas is coming out then close it and check if there is any leakage between tank and tank adapter.

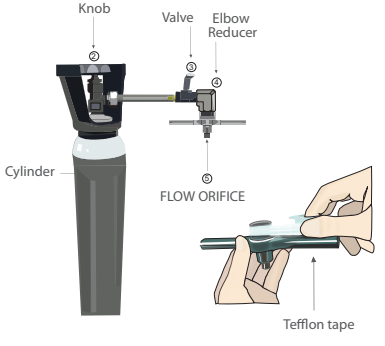


FIG.4 FLOW ORIFICE ADAPTER ASSEMBLLY

CO_2 CYLINDER AND ADAPTOR ATTACHMENT

3. Unpack the contents of the Cryopop: Cryopop device, Applicator tube with tip (2 nos) and Snowhorn.
4. Remove the components from their packaging and place them on a clean, disinfected surface.
5. Attach the snowhorn tube to the tank adapter assembly by rotate it in anticlockwise direction. Do not over-tighten the snowhorn; hand tight is adequate. Over- tightening may cause damage to the snowhorn or the nozzle.

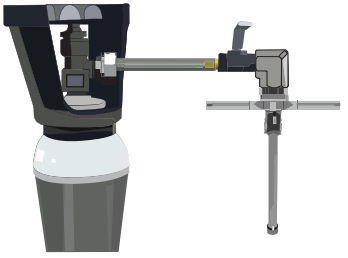


FIG.5 SNOWHORN ATTACHMENT

6. Pick up the Cryopop device for the charging. This done by rotating the wind knob in the clockwise direction which has the effect of retracting the plunger into the handle body by compressing the plunger spring. The trigger must be in the “Off” position for the plunger to remain locked with each progressive rotation of the wind knob. It takes approximately 6-7 turns by the user to retract the plunger. The plunger is in the fully retracted state once the wind knob is physically unable to rotate any further.



A. PLUNGER SPRING IN RELEASE POSITION



B. PLUNGER SPRING IN RETRACT POSITION

FIG.6 PLUNGER SPRING POSITION

7. Replacing of applicator tube - This is done by inserting the non-threaded end of the applicator (1) into the handle, aligning the pins of applicator (2) with the two matching slots in the handle. The two are then pushed together to enable the applicator to rotate until the embossed triangle on the head of the handle (3) lines up with the embossed triangle on the proximal end of the applicator (4). Once in the fully locked position there will be no distance between the head of the handle and the grips of the applicator (fig.7)



FIG.7 APPLICATOR TUBE

8. Remove the tip attached to applicator by rotating anti-clockwise.

9. The handle and applicator assembly is then connected to the snowhorn. The connection uses the threads of the distal end of the applicator to tighten to the bottom of the snowhorn. Once the connection is hand tightened, the fill process can be initiated.

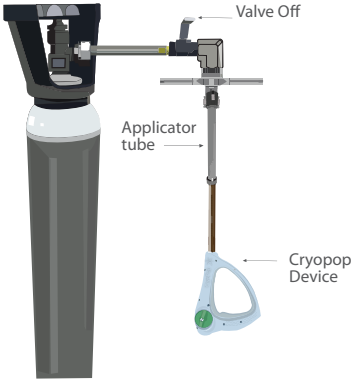


FIG.8 CRYOPOP DEVICE CONNECTED TO SNOWHORN "OFF" POSITION

10. To start the fill, the adapter valve is turned to the "open" position (1). This allows CO_2 to exit through the flow orifice and expand in the snowhorn to form dry ice. During the fill, the adapter valve remains in the open position and dry ice collects in the applicator. The dry ice level builds from the handle end of the applicator until it is visible in the snowhorn above the connection point. (2). At this point the tank adapter valve is turned to the "closed" position. Failing to turn the adapter valve to the "closed" position allows dry ice to continue to build into the snowhorn, gradually

increasing the pressure in the system. Before the pressure reaches a critical level, the extension springs at the snowhorn nut (3) expand to allow blow off, releasing excess pressure and preventing rupture of the system.

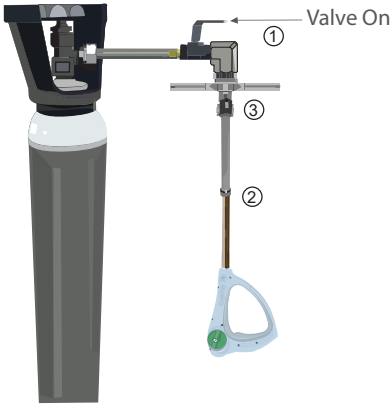


FIG.9 CRYOPOP DEVICE CONNECTED TO SNOWHORN "ON" POSITION

11. Once the applicator is filled and after the adapter valve is turned off, the handle and applicator assembly is removed from the snowhorn. Dry ice that is beyond the length of the applicator can be flicked or brushed off and allowed to fall aside. The aluminum tip is then attached to the distal end of the applicator using the same threads that were used to connect to the snowhorn. This connection is also hand tightened.

12. Store the cylinder in a safe location for use when needed. It is not necessary to detach the tank adapter from the cylinder between uses.

BEFORE THE PROCEDURE

1. Explain the procedure, and why it is important to return for further management as requested. Ensure that the woman has understood and obtain informed consent.
2. Show her the cryotherapy equipment and explain how you will use it to freeze the abnormal areas on the cervix.
3. Prepare the patient for a gynecological examination, and perform a speculum examination.
4. If there is no evidence of infection, proceed with cryotherapy.

FREEZE AND DEFROST

1. Wipe the cervix with a saline-soaked cotton swab and wait a few minutes.
2. Apply acetic acid to outline the abnormality and wait a further few minutes
3. Tell the woman she might feel some discomfort or cramping while you are freezing the cervix.
4. Wipe the cryotip surface with saline to ensure optimum effectiveness.
5. Inserts the tip of the applicator through the patient's vaginal canal (kept open by a speculum) until the tip comes in contact with the surface of the cervix. The provider ensures that the tip is well centered on the surface of the cervix, If the lesion extends more than 2 mm beyond the tip, discontinue procedure.

6. Ensure that the vaginal wall is not in contact with the cryotip or you may cause a freezing injury to the vagina.
7. Set the timer and press the trigger into the "On" position



FIG.10 TRIGGER “ON”

which releases the plunger and allows the plunger spring to apply force to compact, and advance the dry ice. The provider maintains the contact force against the cervix while the tip freezes to the cervix. The cold temperature at the tip is maintained by a dynamic process occurring during the active freeze cycle. Dry ice at the tip is consumed as it sublimates. The force of the spring continues to push on the dry ice, advancing it and ensuring that dry ice is constantly replenished at the tip to achieve a constant cold.

The freeze continues for 3 minutes during which time the provider monitors the formation of the ice ball ensuring that the edges extend approximately 5mm away from the edge of the tip by the end of the freeze.

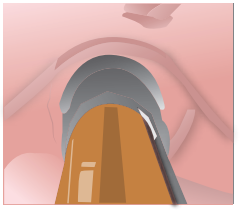


FIG.11 ICE BALL ON
THE SURFACE OF CERVIX

8. After the 3-minute freeze is complete the cervix is subjected to a timed 5-minute thaw cycle. The thaw cycle begins when the provider presses the trigger button to turn the device into the "Off" position. The"Off" position locks the advancement of the plunger which stops any advancement of the ice, and allows the tip to warm or 'defrost'. The tip will defrost for a period of about 3 minutes before it warms up enough (heated by surrounding tissue and the warming of the cervix) to detach from the surface of the cervix and allow the device to be removed from the patient.



FIG.12 TRIGGER “OFF”

Note: If the trigger button doesn't operate or doesn't go back to " off " position then rotate the wind knob clockwise 45° and then operate the trigger button.

9. The provider then winds the knob to retract the spring which shears the remaining dry ice off of the plunger into the applicator, removes the applicator from the handle (without removing the tip) and Clean and disinfect the applicator and tip assembly with high level disinfectant.
10. The provider then repeats the assemble, fill, and freeze steps with a second applicator and second tip to perform the second 3-minute freeze of the cervix.
11. Once the second freezing is complete, allow time for thawing before attempting to remove the probe from the cervix. Removing it before it is fully thawed will pull tissue off the cervix.
12. Gently rotate the probe on the cervix to remove it. The area you have frozen will appear white.
13. Remove the speculum.

AFTER THE PROCEDURE

1. Provide a sanitary pad.
2. Instruct the woman to abstain from intercourse and not to use vaginal tampons for 4 weeks, until the discharge stops completely. This to avoid infection.
3. Invite her to return in 2–6 weeks to be checked for healing, and again in 6 months for a repeat Pap smear and possible colposcopy.

DECONTAMINATION OF THE CRYOPOP COMPONENTS PRIOR TO USE AND AFTER EVERY USE.

There are three basic steps for decontamination, and cleaning of CryoPop components, before they can be reused: (1) Decontamination, (2) Cleaning, and (3) High-level disinfection (HLD).

1. DECONTAMINATION

To decontaminate cryotip and applicator tube immediately after use, immerse them in a large plastic bucket containing 0.5% chlorine solution for 10 minutes (not longer, as the component may become corroded); remove and rinse with clean water. It must be prepared fresh daily and discarded as soon as it appears dirty. 70–90% ethanol or isopropanol can be used as an alternative to chlorine solution.

2. Cleaning

Soon after decontamination, cryotip and applicator tube should be cleaned by a person wearing heavy gloves and glasses or goggles. Use a brush to scrub components with water and detergent, and rinse thoroughly with boiled water.

3. High-level disinfection (HLD)

One of the following processes can be used for HLD:

I. Boil components for at least 20 minutes in plain tapwater, which is changed at least daily. Make sure that components are fully covered by the water, and start timing after the water with the components is fully boiling. Do not add anything to the pot once you have started to time.

II. Soak components in 0.1% chlorine solution for 20 minutes, Rinse thoroughly in boiled water, air-dry and store.

The use of CryoPop device for minimum 500 cycles (Freeze-Thaw-Freeze) has been validated by Pregna International Ltd. Beyond this time, the provider should verify the mechanical and thermal performance of the device before using it.

TYPES OF CRYOTIPS

1. Endo - Exo Deep Convex Cryotip
2. Endo - Exo Flat Cryotip
3. Endo - Exo large Convex Cryotip
4. Endo - Exo Small Convex Cryotip
5. Endo - Exo Convex Cryotip

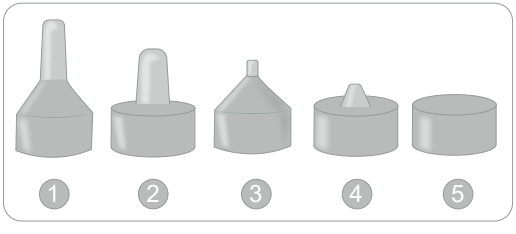


FIG.13 CRYOTIPS

TROUBLE SHOOTING

1. NO ICE FORMATION

STEP 1 : CLEAN THE FLOW ORIFICE

1. Close the main valve of the cylinder (ensure that the valve is closed to avoid accidents).
2. Release the remaining pressure by opening the valve on the tank adapter.
3. Rotate the handle of FLOW ORIFICE in clockwise direction to detached it.

4. After detaching the flow orifice replace the filter with a new one.
5. Insert the cleaning pin and move it up and down to remove dust particles from the flow orifice hole.
6. Remove the old Teflon tape and apply three rounds of new Teflon tape on the flow orifice, leaving 1 or 2 threads exposed.
7. Check if ice is forming or not if not follow 3 step

STEP 2: CHECK THE WEIGHT OF CYLINDER

1. Remove the snowhorn tube.
2. Weight the cylinder on weighing scale.
3. May need to be refilled, if the cylinder weight is 10 kg (with tank adapter assembly).

2. IF THE TRIGGER SWITCH GETS STUCK

While operating the device if trigger switch is not working properly.

1. Rotate the knob 45 in clockwise and press the trigger switch

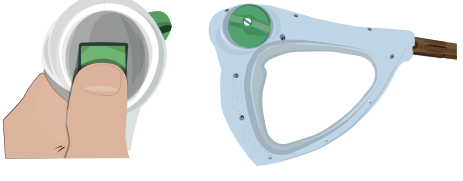


FIG.14 TRIGGER SWITCH

2. Now, the trigger switch start working properly

DO'S

- Ensure decontamination of the cryopop components prior to use and after every use
- Ensure that the tank adapter assembly and snowhorn is at 90° (straight)
- Snowhorn tube should be hand tighten.
- Flow orifice should be hand tighten.
- Rotate the knob in clockwise direction.

DON'T

- Don't touch the cryotip after a freeze cycle is "ON".
- Don't over-tighten the snowhorn tube using tools; it should only be hand-tightened.
- Don't over-tighten the flow orifice beyond what can be done by hand, as this could damage the threads.
- Don't rotate the knob in the anticlockwise direction unless otherwise instructed.

CLINICAL / MEDICAL BENEFITS

Benefit related to Legacy Device:

1.Prevention of cervical cancer: Cryotherapy destroys precancerous cells (cervical intraepithelial neoplasia, CIN) by freezing them with liquid nitrogen or carbon dioxide. This prevents abnormal cells from developing into invasive cervical cancer.

2.High efficacy for low-grade lesions: Particularly effective for CIN 1 and CIN 2 lesions, cryotherapy achieves high cure rates, often exceeding 85–90% in properly selected patients.

3.Lower risks

4.Minimally invasive procedure: The treatment is performed in outpatient settings without

anesthesia. It requires only a cryoprobe applied to the cervix for a few minutes, making it accessible in low-resource environments.
5.It is appropriate for use in low resource settings because it is effective, has limited side-effects, does not require electricity, is inexpensive compared to other treatment options.

Benefits related to equivalent Device from the market:

1.Cryotherapy Device removes abnormal cells from the cervix
2.Lower risks
3.Minimally invasive treatment. Compared to traditional surgery, it usually has less pain and bleeding and a lower risk of damaging healthy tissue near the abnormal cells
4.No Infections
5.Cryotherapy device have benefits, including improved psychological well-being, faster recovery, and improved performance

TARGET PATIENT

The use of cryotherapy is limited to patients (females of any reproductive age) who have developed precancerous cervical lesions.

PERFORMANCE CHARACTERISTICS

- Achieves and maintains cryoablation temperatures of -50°C to -65°C at the applicator tip during a standard 3-minute freeze procedure.
- Designed for use with CO_2 dry ice as the cold source.
- Composed of medical-grade materials
- applicator tube (ULTEM RESIN 1000P, 10% glass fiber filled) and aluminum tip.

TRAINING OR FACILITIES

This device must only be used by trained medical professionals. Use in appropriate medical facilities.

SAFETY DISPOSABLE PRECAUTIONS

On completion of use, dispose the items as per the local regulations governing disposal of nonrecyclable waste/medical waste.

INSTRUCTIONS FOR REPORTING SERIOUS INCIDENTS

The user and/ or patient should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of your Member State. For more information:

https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

DEVICE LIMITATIONS OR INCOMPATIBILITY RISKS

- Not to be used with any gas source other than approved CO_2.
- Do not use in patients with contraindications to cervical procedures (e.g., active pelvic infection).
- Not intended for combination with other medical devices.
- Do not use if packaging is damaged or device components are missing.

SAFETY MEASURES FOR DEVICE MALFUNCTION OR ALTERED PERFORMANCE

If the CryoPop device malfunctions or does not achieve the required freezing temperature,

immediately discontinue use, inspect for visible damage or blockages, and contact Pregna International Limited or your local distributor for troubleshooting or replacement.

POSSIBLE SIDE-EFFECTS AND ADVERSE EFFECTS

Cryotherapy with CryoPop may cause mild pain, discomfort, or local tissue reactions. Rare complications include excessive bleeding, infection, and unintended tissue injury. All residual risks are mitigated through training and labeling.