



# CRYO SURGERY

## USER MANUAL



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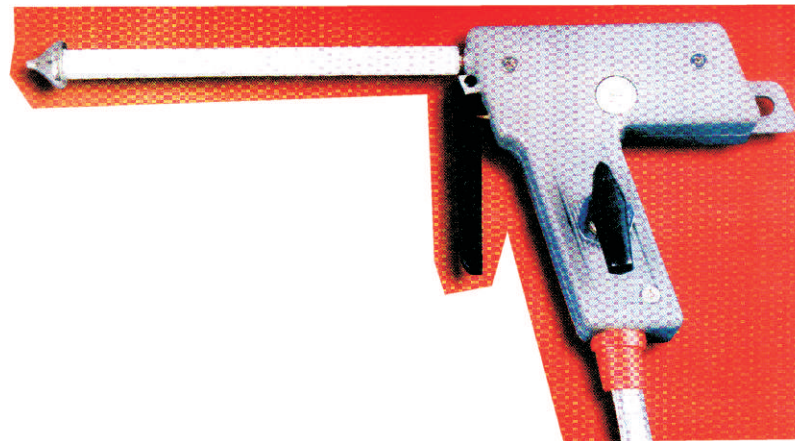
Email : [westernsurgical@gmail.com](mailto:westernsurgical@gmail.com)

Email : [info@westernsurgical.in](mailto:info@westernsurgical.in)

Ph. : +91-281-2232871 / 2243159

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## PROBE DETAILS FOR DIFFERENT APPLICATIONS

### GYNAECOLOGY



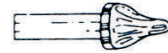
1] ENDO-EXO LARGE CERVICAL (D-25,L-8): This is used for Cervical Erosion, Cervical Lesion, for Chronic cervicitis and for superficial lesions and this is more useful for multiparas (having more than one child) i.e. large cervix to cover more area at a time, more area superficially and slightly inside the Endo Cervical Canal.



2] ENDO-EXO CERVIX (D-22,L-15): This is called common Endo-Exo and this is attached with the Equipment. This is useful for Cervical Erosion, Cervical Lesion, Chronic Cervicitis. This is used superficially and also little deeper i.e. 1/2 cm inside the Endo cervical canal.



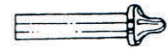
3] EXO-CERVICAL (D-22,L-10): This is useful for Cervical Erosion, Cervical Lesion, Chronic Cervicitis and this is only for superficial lesions.



4] DEEP ENDO-EXO CERVICAL (D-22,L-25) This is equal to common Endo-Exo but the design is having a little difference and it takes the shape of the cervix when freezing takes place and also this enters the canal deeper than common Endo-Exo.



5] SMALL ENDO-EXO CERVICAL (D-19,L-13): This serves the purpose as above probes but specially for nulliparas (small cervix).



6] SPECIAL ENDO-EXO CERVICAL (D-19,L-10): This is also equal to small Endo-Exo but it takes the shape of the probe and the front tip is slightly bigger to enlarge the Endo Cervical Canal.



7] FLAT CERVIX (D-19,L-00): This is useful for superficial lesions, Chronic cervicitis to apply the Epithelium level of the cervix. The contact of the probe surface with the mucosa is faster and penetration of the temperature is equally spread by this probe. So it can be touched in 2-3 places in lesser time i.e. 30 seconds for each successful freezing.



8] SHARP MICRO (D-8,L-10): This probe is very useful for condyloma, vulval warts, vaginal warts and for the lesions in the Endo cervical canal and this is useful for even facial warts, which are very small in size to freeze with pinpoint accuracy.



9] DEEP ENDO CERVICAL(D-5,L-25): This is useful for deeper cervical erosion mainly used in Endo cervical canal without touching the adjacent healthy skin.

10] MICRO TIP (D-2,L-12): Micro tip with ball nose tip (D-2, L-8) is used for condyloma as well as vaginal vulval warts.

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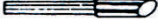
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## PROBE DETAILS FOR DIFFERENT APPLICATIONS

### GENERAL SURGERY

-  1] HEMERRHOID GENERAL PURPOSE PROBE ROUND (D-8,L-25): This is used for internal and external hemerrhoids (Piles).
-  2] HEMERRHOID GENERAL PURPOSE PROBE DOUBLE SIDE FLAT (D-8,L-25): This is also used for internal and external hemerrhoid and it is having double side flat surface which is essential when we touch from the sides to contact more surfaces.
-  3] RUDO HEMERRHOID PROBE (D-8,L-10): This is used mainly for external hemerrhoids and also for internal hemerrhoid and this probe was designed by Dr. Rudd.
-  4] HEMERRHOID CONE PROBE (D-8,L-27): This is used for internal hemerrhoid.
-  5] BEVEL EDGE DERM PROBE (D-8,L-15): This is used for Dermatology, raised skin warts.

### OTORHINOLARYNGOLOGY (E.N.T.)

-  1] STRAIGHT NASAL PROBE (D-4, L-20): This is used for Chronic Rhinitis, Nasal Epistaxis, Nasal Polyps and allergic Rhinitis, turbinates.
-  2] CURVED NASAL PROBE (D-4,L-1 0): This is used for Chronic Rhinitis, Nasal Epistaxis and nasal polyps and mainly useful for Sphenopalatine Foramen.
-  3] INSULATED FLAT NASAL: 20x3.5mm from portion. This is insulated all over and it is only exposed with measurement of 20x3.5mm surface area only. Because of the insulation we can avoid touching the adjacent area.
-  4] SPECIAL MINIATURE TIP (D-2,L-3): This is used for maintaining pinpoint accuracy to touch the exact point by using a miniature sharp point at the tip and also it is useful for skin cags and skin warts.
-  5] MOUTH PROBE: (Oral Probe): This is useful for tonsils, pharynx, mucosa and also for hemangiomas (oral Surgery).
-  6] SPECIAL MICRO LARYNGEAL (D-2.5 mm,L-5 mm): This probe is for laryngeal papilloma virus for deeper applications since it is 12" long.
-  7] EAR POLYPSE (D-2.5 mm,L-5 mm): This is used for doing Cryo surgery through ear.
- 8] Special Straight Nasal Probe 50mm length double side flat for turbinates.

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## INDICATIONS

### GYNAECOLOGY

Cervical Erosion  
Cervical Lesion  
Chronic Lesion  
Chronic Cervicitis  
Dysplasiae on Vaginal Cervix  
Condyloma acuminatum  
Colpopolypus  
Benign Tumours

### OTOLARYNGOLOGY

Tonsil Remnants  
Maniere's Disease  
Hypophysectomy  
Chronic Rhinitis  
Polyps  
Erosive conditions  
Nasal Epistaxis  
Laryngeal Papillomatosis  
Granular Pharyngitis  
Vascular Malformations  
Hyperkeratosis and Leukoplakia  
Granulomatous and Hyperplastic conditions  
Denture Hyperplasia  
Papillary Hyperplasia of the Palate  
Fibrous Epulides

Fibreopithelial Polyps  
Mucous cysts  
Vasomoto Rhinitis  
Nasal Surgery  
Haemangeomas

### PROCTOLOGY (GENERAL SURGERY)

Internal and External  
Hemorrhoids  
Rectal polyps  
Anal & Rectal Cancer 'In situ'  
Skin warts  
Skin lesions

### NEUROLOGY

Treatment of dystonia musculorum deformans  
Parkinson's disease  
Vascular Haemangeomas  
Removal of brain tumors as a forzen mass without appreciate hemorrhaging  
Stereotaxic transsphenodal  
Hypophysectomy

### UROLOGY

Transurethral resection of prostate

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## 1.1 CRYO- THERAPY - INTRODUCTION

CRYO- Therapy is a process of destroying unwanted tissues using extreme cold and inducing 'Thermal Shock' to cells. It is painless & bloodless.

Adiabatic expansion of a compressed gas (Nitrous oxide or Carbon- di-oxide) drops the temperature of a Probe tip to 'freezing levels' and forms ice crystals. The 'ice ball' formed at the Probe tip freezes the cells and kills them. The Probe tip is then 'Thawed' by de-freezing the tip and removed from the surface.

Cryo -therapy's benefit does not stop with its better curative power. It treats patients more kindly, spares them from pain and enables faster recovery.

CRYO- THERAPY is very useful in Gynaecology, Otolaryngology, Dermatology and General Surgery. Specific Indications are given in the back inside cover of this manual.

## 1.2 FEATURES AND BENEFITS OF CRYO- THERAPY

<i>FEATURES</i>	<i>BENEFITS</i>
1. No electricity is used	1. It is safe for use and it is portable.
2. No stenosis and no scar after surgery.	2. Good tissues revive after surgery.
3. Clinical cure rate is more than 90%.	3. Highly successful and dependable therapy.
4. There is no excision.	4. It is haemostatic.
5. The low temperature deadens nerve Sensations	5. Reduces patient Trauma and no anaesthesia required.
6. It is very simple to operate	6. Not much of prior training is required.

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### 1.3 EFFICIENCY OF CRYO- THERAPY

Cryo- Therapy is very efficient in terms of its cure rate, cost & easiness of operation. The following aspects would support this.

- The cure rate of cryo-therapy in treating Chronic cervicitis is more than 95% while the electrical cautery cure rate for the same indication is about 32% only. The table given below elaborates this.
- Cryo-therapy can be done using Nitrous-oxide available in the hospitals/Nursing homes for anaesthesia (BOYLE's Apparatus) or by using commercial carbon-di-oxide (soda gas). Generally, about 12 cases can be done with a 9Kg cylinder of N2O (about 10 cases with Co<sub>2</sub>).
- Considering the precision characteristics of the instrument, its reliable design features and the high quality materials used, it is reasonably priced.
- Cryo-therapy instrument has no moving parts nor does it use electricity. Hence it is 'fail safe', long lasting and extremely simple to maintain.
- Cryo-therapy can be done with minimal practice and the patients can be treated as out-patients.

#### SUMMARY OF CLINICAL TESTS ON TREATMENT OF CERVICITIS USING CRYO - SURGERY AND ELECTRICAL CAUTERY

Place of clinical study: SMS Medical College & Saha Hospital, Jaipur

Group	Total no. of Patients	Clinical cure		Symptourate cure			
		Number	%	Vaginal Number	Discharge %	All symptom Number	%
CRYO-SURGERY							
TREATED	75	73	97.3	74	98.6	64	85.3
ELECTRICAL							
CAUTERY TREATED	25	8	32.0	13	52.0	13	52.0

Courtesy : Journal of Obstetries Gynaecology

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## RECOMMENDED PROCEDURE, RECOVERY AND SIDE EFFECTS

### 2.1 THE INSTRUMENT AND PREPARATION

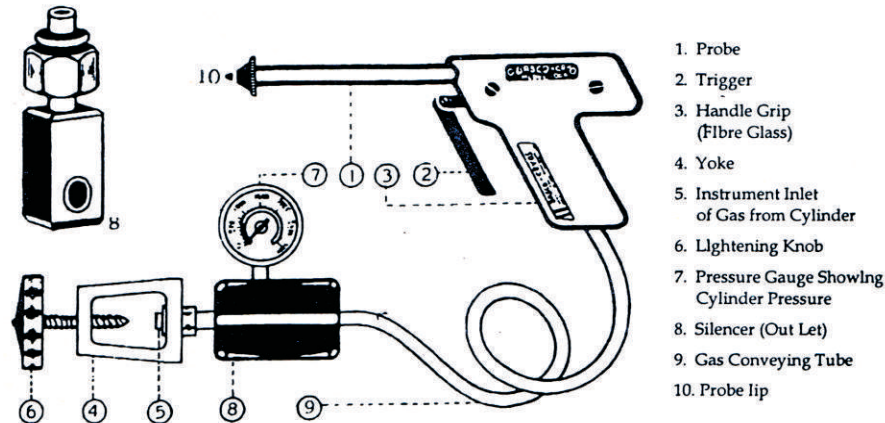
The instrument used and the preparation for CRYO-THERAPY are common for Gynaecology, General Surgery, Otorhinolaryngology and Dermatology.

#### THE INSTRUMENT

The BASCO Cryo-Therapy instrument is hand-operated. Its sleek design and light weight enables easy manoeuvrability. It does not require any electricity. Cryogenic gas ( $N_2O$  or  $CO_2$ ) is the only requirement to use this instrument.

The instrument has following components:

1. Yoke assembly for connecting to  $N_2O$  cylinder.
2. Silencer Unit
3. Pressure gauge.
4. Tube housing for gas tubes.
5. Trigger for trapping and releasing the gas.
6. Hypodermic needle for conveying the gas.
7. Probe(Removable)
8.  $CO_2$  gas cylinder adaptor.



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## 2.2 SETTING THE INSTRUMENT

1. Use newly filled Nitrous Oxide cylinder which is used for Anaesthetics.
2. Place the cylinder in an upright position(vertical) and use proper stand or any holding device.
3. Connect the yoke with the cylinder and tighten the knob properly(hand tightening is enough) spoil the yoke rubber washer due to high pressure gas and inadequate tightening will result in leakage of the instrument near the cylinder.
4. Choose the correct probe and fix on the instrument. Tighten probe connection adequately with hand.
5. Check up the pressure of the gas with pressure gauge. Working pressure should be 600 - 1000 psi or 40 - 70 Kg/ cm<sup>2</sup>. The instrument will not work when the pressure is less than 40 Kgs/ cm<sup>2</sup>. Vent out extra pressure if it is more than 70 Kg/ cm<sup>2</sup>.
6. While the instrument is put in operation by pressing the trigger, the trapped gas leaves the probe tip to minus 98°C and releases through the silencer near the cylinder. This is generally mistaken as leak in the instrument but it is only the outlet of the gas.
7. If there is any noise near the PROBE connection, before pressing the trigger, close the cylinder immediately, release the gas by pressing the trigger and bring the reading to '0' in the dial and remove the probe. Check the probe washer whether it is damaged; if so replace it by a new one from the spares.
8. When the freezing is completed, defrost by releasing the trigger twice and remove the probe with slight traction.
9. When the operation is over, close the cylinder, trigger the instrument to remove the gas inside the tube.

## 2.3 CO<sub>2</sub> GAS TECHNIQUE WITH CRYO

CO<sub>2</sub> Gas (Carbondioxide gas) cylinder is always filled with excess pressure since it is a commercial gas. The cryo instrument is designed to work with working pressure of 600-1000 psi or 40-70 Kg/ cm<sup>2</sup>. If the pressure is more than 1000 psi the instrument will get clogged and the freezing will stop.

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### Method of use

When CO<sub>2</sub> gas is used a CO<sub>2</sub> adaptor is necessary which is available with manufacturers. Fix the adaptor firmly with the cylinder and fix the instrument. Use adopter washer. Now remove the probe from the instrument and then open the cylinder valve and vent out the extra pressure or excess pressure by letting the gas out for atleast 1-2 minutes. Close the cylinder and again fix the probe properly. Now open the cylinder and see the pressure in the dial whether it is showing 100 psi or 70 Kg/cm<sup>2</sup>. This is the correct working pressure. The probe tip temperature that can be achieved using CO<sub>2</sub> gas is about 65°C.

Note: The probe tip temperature has a direct relation to the Diameter of the Ice ball formed, which is as follows:

<i>Gas used</i>	<i>Probe tip temp</i>	<i>Dia. of Ice ball</i>
N <sub>2</sub> O	98°	3.0 x Dia. of Probe tip.
CO <sub>2</sub>	65°C	2.5 x Dia. of Probe tip

Hence using N<sub>2</sub>O gas will always be more effective & efficient.

## 2.4 GYNAECOLOGY

### CRYO THERAPY PROCEDURE

1. Set the instrument as given in the earlier chapter and ensure the correct operating pressure.
2. Moisten the tissues to be removed, using K-Y jelly or saline water to enable good thermal conduction. If the tissues are not wet, the probe will not 'stick' to the tissues.
3. Use Cusco's speculum for easier operation. This also avoids vaginal damage.
4. Place the probe on the tissue to be destroyed and press the trigger of the instrument (part no.5). Freezing will begin now. Please note that the IUD (if it is already there) can be left in place during the entire procedure.
5. The ice crystals forming at the Probe tip and on the tissues will gradually grow larger in size(3 to 5 mm from the edge of probe tip) and will extend 3-5 mm into the normal tissues.
6. The freezing should be for about 2 minutes if Nitrous Oxide gas is used and 3 minutes if CO<sub>2</sub> gas is used.
7. After completion of freezing, release the trigger. The defrosting will not commence and it will be completed in 5 seconds. The probe will automatically detach from the tissue surface. Remove the probe out with slight tracking.

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8. If the tissues have not been completely covered in the first procedure, repeat the freezing from different angle, after moisturing the tissues.
9. After completely covering all the tissues to be destroyed, close the gas cylinder valve and press the trigger of the instrument to release the entrapped gas in the tubes.
10. Wash the probe in warm water, wipe it dry. Sterilise the probe tip with spirit and keep it ready for next therapy. The entire instrument can be sterilised in Ethylene Oxide gas or using Formalin.

#### RECOVERY

1. Counsel patients to expect frequent water discharge for 2 to 6 weeks. The heaviest discharge will be during the first 10 days to 2 weeks period. The discharge will gradually reduce as the healing progresses.
2. Advise patients to use pads liberally during the 'water discharge' period.
3. There could be some 'spotting' in few cases. But, there will be no profuse bleeding.
4. It is suggested to follow-up with the patient on a weekly basis during the healing period. However, with more experience on cryotherapy, this follow-up can be changed to 'after 6 or 8 weeks'.

### 2.5 CRYO HEMORRHOIDECTOMY

#### PROCEDURE

1. Set the instrument and check correct operating pressure.
2. Moisten the tissues to be removed, using K-Y jelly or saline water to enable good thermal conduction. If the tissues are not wet, the probe will not 'stick' to the tissues.
3. Insert the Proctoscope (under diazepam or similar sedation, if necessary) and allow the hemorrhoids to swell and prolapse into the lumen of the proctoscope.
4. Apply the cryoprobe at the inner aspect of each pile so as to wrap the probe completely by the pile mass.
5. Start 'freezing' by pressing the trigger of the instrument.
6. Continue freezing for 1 to 1½ minutes and then release the trigger to 'de-frost'. Shift the probe to another segment (untreated segment) of the pile tissue and repeat the 'freeze - de-freeze' procedure. Complete freezing of the entire pile mass this way.
7. A 'Freeze - Thaw - Freeze' cycle gives better results than continuous 'Freezing De-freezing' cycle, particularly in the case of External-hemorrhoids.
8. After completing the procedure and removing of the probe, close the gas cylinder valve and press the trigger of the instrument to release the entrapped gas in the tubes.
9. Wash the probe in warm water, wipe it dry. Sterilise the probe tip with spirit and keep it ready for next therapy. The entire instrument can be sterilised in Ethylene oxide gas or using formalin.

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### PRECAUTIONS & SIDE EFFECTS

1. If Valium is administered, the patient must be allowed to recover from its effects before being discharged from the office or outpatient facility.
2. The occurrence of vaso-motor reactions has been reported in some patients within the first half hour following cryorectal surgery. This reaction is characterised by light-headedness, headache, flushing, dizziness and unusually fainting. Merely detain patient for a short period following treatment to rule out the possibility.
3. The patient is usually comfortable enough to return to normal activity the day following surgery.

### RECOVERY-HEMORRHOIDS

1. Immediate edema will occur.
2. Within 2-3 hours, a watery discharge will begin. This discharge will continue for 10 days to 2 weeks. In occasional cases, the discharge may continue longer. It can be controlled by peri-pads. Frequent change of pads may be required while the flow is at its highest. With the constant moisture present, the skin of the buttocks can become raw and chafed. This area may be protected by liberal applications of zinc oxide immediately post-op and continued as long as the leukorrhea persists.
3. The necrotic process may be observed at one week, characterised by the enlarged mass and colour variation. Odour will be evident on external hemorrhoids, especially. Some itching may be present.
4. If the scar is disturbed, secondary bleeding can occur.
5. By two weeks, substantial shrinking would have occurred and is usually no longer a problem.
6. Pain, in the few days following cryosurgery, is usually at a low level, if it occurs at all, and can be controlled with non-necrotic analgesics.
7. Defecation is accomplished without discomfort, all through the recovery period.
8. External residual skin tags are sometimes observed after healing is completed. They are asymptomatic. If it is felt necessary to remove them for the sake of hygiene, they can be treated further cryosurgically.
9. Management of open necrotic lesions produced by cryo-surgery of external hemorrhoids is handled much like similar lesion produced by excisional surgery.

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## 2.6 CRYO- THERAPY DERMATOLOGY

1. Set the instrument and check correct operating pressure.
2. Moisten the wart to be removed, using K- Y jelly or saline water to enable good thermal conduction. If the tissues are not wet, the probe will not 'stick' to the tissues.
3. Choose the correct type of probe depending on the size and location of the wart. The pointed probe is for tiny warts while the bevelled edge probe is for larger warts, particularly with a curvature on the surface.
4. Apply the cryo-probe on the wart and start freezing by pressing the trigger of the instrument. Do not start freezing before placing the probe on tissues, because the ice formation will act like an insulation.
5. Continue freezing for 1 to 1 ½ minutes and then release the trigger to 'de-frost'. Again freeze it for another 30 seconds
6. A 'Freeze - Thaw - freeze' cycle gives better results than continuous 'Freezing De-freezing' cycle, particularly in the case of External-hemorrhoids and skin warts.
7. After completing the procedure and removing of the probe, close the gas cylinder valve and press the trigger of the instrument to release the entrapped gas in the tubes.
8. Wash the probe in warm water, wipe it dry. Sterilise the probe tip with spirit and keep it ready for next therapy. The entire instrument can be sterilised in Ethylene oxide gas or using formalin.

### PRECAUTIONS AND SIDE EFFECTS

Generally there is no anaesthesia required for cryo-therapy - Dermatology procedures, since this is a 'non-invasive' technique. Some patients may report Vaso-motor reactions within the first half-hour following cryotherapy. Merely detain patient in such a case, for a short while and allow some rest. The patient is usually comfortable enough to return to normal activity immediately after cryo-therapy.

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## 2.7 OTORHINOLARYNGOLOGY

1. Set the instrument and check correct operating pressure.
2. Tilt the patient's head and apply local anaesthesia to the turbinates.
3. Apply the probe to each turbinate and freeze for 60 seconds.
4. Release the trigger and allow the probe to thaw.
5. Again freeze the probe for 60 seconds.
6. Release the trigger and thaw the probe. Track and remove the probe from the turbinate.
7. Close the gas cylinder valve and press the trigger of the instrument to release the entrapped gas in the tubes.
8. Wash the probe in warm water, wipe it dry. Sterilise the probe tip with spirit and keep it ready for next therapy. The entire instrument can be sterilised in Ethylene oxide gas or using formalin.
9. Use appropriate probe for each case.
10. For Laryngeal papilloma virus use microlaryngeal unit foot operated 11 inches long and 2.5 mm tip dia.

**APPLICATION:** These probes were designed by E.N.T. surgeons at Royal Infirmary for the treatment of nasal obstruction as an outpatient procedure.

**INDICATIONS:** Cryo-therapy of the inferior turbinates, and where accessible the middle turbinates, can successfully relieve nasal obstruction caused by chronic or episodic vasomotor and allergic rhinitis.

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**ADVANTAGES :** Cryo-therapy offers a single treatment for vasomotor and allergic rhinitis, which avoids the complications of submucous diathermy and trimming, and the side effects and inconvenience of long term drug therapy. A local anaesthetic is used making it an excellent outpatient procedure.

**SUMMARY OF TECHNIQUE :** The patient's head is tilted back and a local anaesthetic such as 20% cocaine paste applied to the turbinates. The probe is applied to each turbinate with slight pressure and a double freeze thaw cycle instigated, using a 90 second freeze.

#### **PRECAUTIONS & SIDE EFFECTS**

Rhinorrhoea may be noticed for a few days after the procedure, but other side effects are minimal. Relief is apparent after 3-4 days.

#### **OPERATING HINTS**

1. Do not attempt to remove yoke assembly without first turning off the supply cylinder.
2. Do not unscrew the probe or remove the probe line quickly disconnect without turning on-off valve to OFF and releasing the trigger on the probe handle.
3. When the trigger valve is depressed and then released during operation, an audible surge of gas will be heard. This is normal.
4. Prior to beginning a procedure, the probe should be at room temperature. Depress the trigger to warm the tip before applying to tissue.
5. In the unlikely event of an uncontrolled freeze, simply turn the on-off valve to OFF and irrigate the probe tip until it defrosts.
6. In case of inadequate freeze or premature defrost, check the following:
  - a. Low cylinder pressure - replace cylinder.
  - b. On-off valve of cylinder partially open - open valve fully.
  - c. Obstruction in line or delivery tube or return to factory for repair. Use cleaning Instrument.
  - d. Contamination (water) in supply cylinder - clean lines and replace supply cylinder.
  - e. Leaks in fittings - check washer and O-ring tighten fittings.

\* Carrying Warranty at Rajkot only on site warranty not provided free of cost.

\* Due to constant upgradation design, price and features are subject to change any time without prior notice.



*Western Surgical*

[www.westernsurgical.in](http://www.westernsurgical.in)

Email : [westernsurgical@gmail.com](mailto:westernsurgical@gmail.com)

Ph. : +91-281-2232871 / 2243159



## FAULT DIAGNOSIS & TROUBLE SHOOTING

1. Noise through Silencer (Black Cylinder) is only an exhaust not a leak. If heard some surge of sound it is only outlet of the gas escaping through Silencer and it is normal.
2. Leak near the probe joint - change the probe washer (Rubber 'O' ring) and check up, the plastic spacer (white colour) because there may be invisible crack.
3. Clogging of the Inner needle (Nozzle). When you remove the probe use cleaning kit, to make a reverse flow so that the dust and other foreign matters entered in the inner nozzle will be removed by making a reverse flow technique with use of the service kit.
4. Flat type of washer is used for yoke cylinder fitting. If there is a leak close the cylinder and replace the flat washer by new one.
5. Using CO<sub>2</sub> gas (Carbon-di-oxide gas) follow the CO<sub>2</sub> technique. Always check up the cylinder pressure for the correct operating pressure whether it is in the green zone. If it is more, remove excess pressure. This is only for CO<sub>2</sub> gas.
6. Before fixing with any cylinder first open the cylinder for 2 seconds and close it, this ensures any foreign body is not entered inside the nozzle,
7. Use full cylinder of N<sub>2</sub>O gas to get the maximum temperature.
8. Escaping of gas near the Hand trigger pin is only little back pressure from the valve and that will be stopped automatically within seconds.
9. In the failure case of cryo i.e. not getting defrosting while using. Close the cylinder immediately and irrigate the probe and allow the probe without removing from the tissue for at least 2 minutes to get the tissue temperature to the probe and then the probe is removed slowly with slight traction from the tissue.
10. Still there is a problem in operating this Instrument, inform to the manufacturers and explain clearly the reasons or send the equipment to the manufacturers for repair.

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Date of Installation	Installed By
Model No.	Serial No.
Warranty Period	
Name of Doctor & Address :	

\_\_\_\_\_  
Customer Sign. With Stamps

\_\_\_\_\_  
Marketed By: Western Surgical  
Sign. With Stamps

**No Claim Warranty :**

- 1) Any Defect Throughtout Power Supply
- 2) Any Physical Damage

3) Under Warranty Standby Unit Not Provide

4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

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www.westernsurgical.in

Email : westernsurgical@gmail.com

Ph. : +91-281-2232871 / 2243159

# OUR OTHER PRODUCTS RANGE



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## Western Surgical®

“Happy Home”, 2nd Floor, 23, Karanpara,  
 B/h. S.T. Bus Stand, Kanak Road,  
 Rajkot-360 001. Ph. : 0281-2232871/2243159  
 Mo. : 98250 69069 - 98250 45997  
 Email : westersurgical@gmail.com  
 Email : info@westersurgical.in

\* [www.westersurgical.in](http://www.westersurgical.in) \*

