INTEGRA™
Miltex

CryoSolutions™

A simple yet high performance Cryosurgical therapy product.

Product Manual

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TABLE OF SYMBOLS

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Consult Instructions for Use

Part Number

Protect from direct sunlight

Rx ONLY

Rx Only: Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner.

Steam sterilization only

Serial Number

Upper temperature limit 122° F (50°C)

Keep dry

Handle with care

INTRODUCTION

Please review the information contained within this Product Manual to fully understand this unique Cryosurgical product. Questions may be directed to Miltex Customer Service at 800-654-8000 or email at customerservice@miltex.com

GENERAL WARNINGS:

- *The user of this equipment should review the Product Manual and be familiar with the set-up, use and care of the unit prior to use. The instructions should be followed with special attention to warnings and control features. This manual should be readily available to users and other appropriate personnel.*
- *Before each use, ensure that the CryoSolutions™ unit is not damaged and is operating properly.*
- *Patients must be informed of possible risks prior to treatment.*
- *In general, the degree of cold delivered to the treatment site will be decisive in determining outcome. However, a prolonged low temperature treatment will risk irreversible tissue damage as well as unsatisfactory treatment. Other factors, such as, application times, the type of lesion as well as its depth are also relevant.*
- *It is important to recognize that prolonged cold exposure could lead to unwanted tissue destruction.*
- *Do not use for longer than recommended.*

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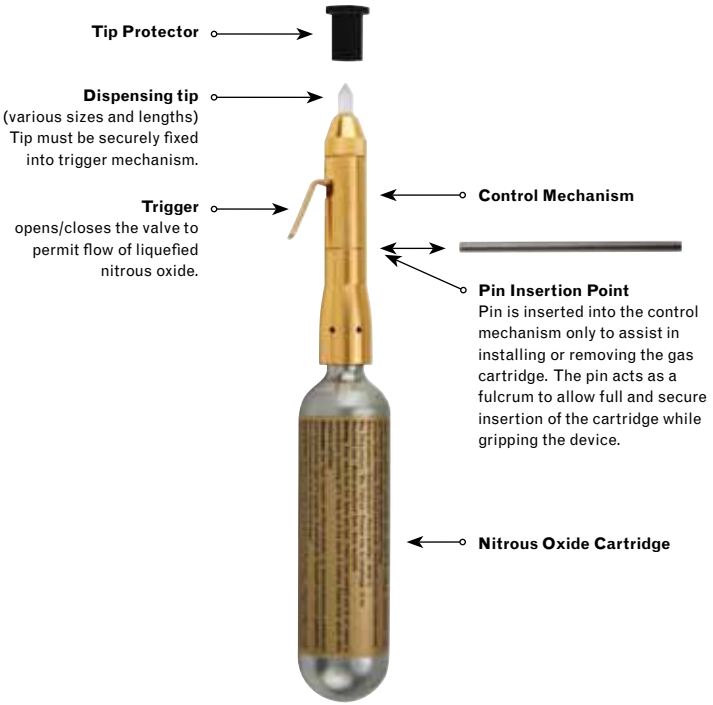
Intended use of CryoSolutions™ is the destruction of unwanted tissue during a cryosurgical procedure by application of extreme cold.

PRODUCT LISTING AND REPLACEMENT PARTS

Miltex REF	Description
33510	CryoSolutions™ complete set, includes unit with standard 1mm wide tip, one cartridge (23.5 g N2O), metal pin, user manual and plastic case
33511	CryoSolutions™ Standard 1mm wide glass tip
33512	CryoSolutions™ Dermatology 2mm wide glass tip
33513	CryoSolutions™ Dermatology 3mm wide glass tip
33514	CryoSolutions™ Dermatology 4mm wide glass tip
33515	CryoSolutions™ Gynecology tip, non-flexible, 13cm long
33516	CryoSolutions™ 10 Pack of Cartridges (23.5 g N2O) medical grade, with threaded safety valve
33517	CryoSolutions™ 4 Pack of Cartridges (23.5 g N2O) medical grade, with threaded safety valve
33519	CryoSolutions™ Plastic carrying case with protective foam
33520	CryoSolutions™ Replacement Metal Pin



TECHNICAL DATA

Refrigerating Method – Open system Cold Performance (-89°C / -128°F)

Control Mechanism is gold plated brass and stainless steel which has a trigger for opening and closing the valve to permit dosing (gas flow). There is a safety filter within the cartridge holder, PTFE and acrylonitrile - butadiene silicone rubber seals.

Dispensing tips are also gold plated metal which encase the borosilicate glass top.

Metal cartridges with thread and valve contain 23.5 grams of nitrous oxide (N_2O).
Cartridge content pressure of 50 bars.

GENERAL INFORMATION

Cryosurgery has been used to treat dermal lesions for many years. A variety of modalities are available and the Clinician will elect a specific therapy based upon a number of factors.

The recognized advantages of cryosurgery include: the ease and speed of treatment, the low or virtually non-existent patient discomfort, high rate of successful outcomes as well as infrequent adverse results, such as, tissue damage and scarring.

CryoSolutions™ employs liquid nitrous oxide in a pressurized cartridge which creates the desired cold performance for the efficacious treatment of an extensive array of lesions.

In addition to Dermatology, Cryosurgery has been adopted by a number of Specialties in order to effectively treat the particular needs of their patients.

CARTRIDGE INSTALLATION/ REPLACEMENT

Always use protective gloves when installing or removing cartridges.

Attaching /replacing the cartridge into the control mechanism is aided by a pin which is easily inserted into the control mechanism

- *Insert the metal pin in the hole on the control mechanism.*
- *Hold the control mechanism at the pin position and not at the on|off trigger. This helps grip the body without damaging the trigger.*
- *Screw the cartridge into the control mechanism in a clockwise direction both quickly and completely to ensure proper functionality.*
- *Care should be taken to align the cartridge and control mechanism so that gas does not inadvertently escape.*
- *Small amounts of gas escaping from the cartridge while being attached indicates poor alignment of the cartridge to the control mechanism.*
- *Remove the pin.*

Once the cartridge is empty it is easily replaced.

- *Insert the metal pin in the hole on the unit body*
- *Hold the control mechanism at the pin position and not at the on|off trigger. This helps grip the body without damaging the trigger.*
- *Unscrew the cartridge from the control mechanism in counter clockwise direction*
- *Remove the pin.*

Always attach replacement cartridges only after currently installed cartridge is completely empty. Any remaining gas will cause it to be more difficult to remove the cartridge.
In addition, gas escaping from the cartridge may be evident though this is not considered significant.

Always use protective gloves when installing or removing cartridges.

Cartridges are thermo sensitive.

Do not expose to temperatures above 50° C / 122° F.

CRYOSOLUTIONS™ TREATMENT
CONTACT APPLICATIONS*

- *Remove the plastic protective cap.*
- *Place the Dispensing tip perpendicular to and directly on the skin surface and area to be treated.*
- *Depress the trigger to open the valve and immediately liquefied gas will be delivered to the dispensing tip and on to the skin.*
- *Application times are normally very brief as Miltex CryoSolutions™ provides high performance cold temperature to the treatment area (exceptions may include plantar warts).*

* See Miltex Product Literature for recommended application times as well as indications for use on a variety of lesions.

Rx ONLY **Physicians only product - Patients should be informed of potential risk. As an example, prolonged contact application time could damage the skin and result in scarring.**

Device use should be restricted to intended clinical applications.

Ultimately, the Clinician will determine the most effective duration of treatment based upon experiences with a variety of lesions as well as their size.

Most lesions are removed with a single treatment. However, others may require a second treatment or even further applications, such as plantar warts.

Unsuccessful outcomes are not necessarily linked to the performance of the CryoSolutions™ device but may be influenced by poor contact or ineffective application times.

Successful outcomes, therefore, are very dependent upon the optimal cold performance delivered by CryoSolutions™ and application times guided by clinical experience.

TREATMENT

Reaction to Cryosurgery may differ depending upon the patient as well as size, type and location of area being treated. These could range from a barely evident reaction to an immediate blistering.

In most instances, there will be a graduated darkening of the treatment site followed by the natural loss of necrotic tissue.

The time expected to return to a full repigmentation will differ and is often very dependent on skin color.

Anesthesia is rarely employed in Cryosurgical treatments and this is due, in part, to the anesthetic effect of the cold. Typically, patients will experience little or no discomfort during treatment. Subsequently, there could be a very light feeling of irritation at the site. Longer contact application times could produce some patient reaction.

FOLLOW-UP

Depending on the patient and the treatment, qualitative results may be only a few days (e.g., age pigmentation) or several months, (e.g., plantar warts). It is recommended that patient follow-up be considered if adequate time has elapsed. Unsatisfactory outcomes may require additional treatment which could include longer application time.

Formation of a blister, if that should occur, must be addressed as would any other wound in order to preclude infection. Additionally, this area should be protected until a full pigmentation is evidenced.

MAINTENANCE

Storage:

Always protect the Dispensing Tip with the cap provided with the CryoSolutions™ product when not in use.

Use caution in returning the device to the custom container so that the trigger on the control mechanism is not inadvertently depressed and gas is expelled.

Protect the unit against heat when in storage; temperatures should be 10° C/14° F to 45° C/113° F to ensure protection of the device.

Cartridges are thermo sensitive.

Do not expose to temperatures above 50° C / 122° F.

CLEANING / STERILIZING OF DISPENSING TIPS

The glass dispensing tips should be steam sterilized* if in contact with blood, mucous or infected tissue. Do not subject the control mechanism to steam sterilization.

Normally the tips may be cleaned and disinfected with alcohol or a disinfecting agent.

Remove tip from unit and sterilize following EN norms 13060 and 285 for steam sterilization. All other sterilization methods are not recommended

Hot air sterilization may damage tip and is not recommended

*sterilized at 273° F/134° C over 9 minutes (half cycle)

Steam sterilization only.

PRODUCT WARRANTY

Miltex Inc. warrants that the CryoSolutions™ products (except the cartridge) shall be free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of shipment from Miltex. Miltex's sole and exclusive liability under the warranty shall be, at the manufacturer's option, either to repair or to replace any component which fails during the warranty period due to any defect in workmanship or material F.O.B. factory if:

1. Customer promptly reports such defect to Miltex in writing.
2. If requested by Miltex, customer returns equipment to Miltex with shipping charges prepaid,
3. Upon inspection, the manufacturer finds the equipment to be defective.

This warranty is contingent upon normal and proper use of the equipment. It does not cover equipment modified without the written approval of Miltex, subjected to unusual physical or electrical stress, altered with non-Miltex parts or damaged during shipment back to Miltex. This warranty is non-transferable unless authorized in writing by Miltex.

Miltex reserves the right to make design changes on its products without liability to incorporate said change in Miltex products previously designed or sold. Upon receipt of the product, it should be carefully inspected. If any defect is discovered, Miltex must be notified immediately.

REPAIR AND RETURN

This device must be clean of all blood or other organic material prior to returning to Miltex. Miltex reserves the right to return un-repaired any equipment that is contaminated with blood or other organic material.

Warranty Service and Repair:
To obtain service under warranty or return product for repair, the customer should contact your local Miltex distributor or call Miltex Customer Service at 866.854.8300 (US only) or 717.840.9335.

RETURNED GOODS POLICY

Products must be returned with proof of purchase and in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint or product defect. Determination of a product defect will be by Miltex. Products will not be accepted for replacement if they have been in the possession of the customer for more than 120 days.

PRODUCT INFORMATION DISCLOSURE

Miltex, Integra and manufacturer exclude all warranties, whether expressed or implied, including but not limited to any implied warranties of merchantability or fitness for a particular purpose. Neither Miltex, Integra nor manufacturer shall be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Neither Miltex, Integra nor Manufacturer assume nor authorize any person to assume for them any other or additional liability of responsibility in connection with these products.

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www.miltex.com

SAFETY

- Use the device for intended clinical purposes.
- Do not attempt to alter or, in any way, modify the device or its performance. Such action would render the warranty invalid.
- Please note storage instructions, particularly for the heat sensitive cartridge.
- Never use a damaged unit regardless of evident functionality.
- Do not use cartridge other than those provided by Miltex as these would prove incompatible to the control mechanism.
- Do not employ excess force when connecting the cartridge to the control mechanism; these must be compatible and are equipped with a safety valve.
- Keep away from children.
- Do not attempt to use the cartridges for any other purpose.

CryoSolutions™ devices are to be used only with the compatible nitrous oxide cartridges provided by Miltex. Attempted use of substitute cartridges is a safety hazard and will void the warranty and any liability. Never use the cartridges for any other purpose.

Distributed by:

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