# Integra® Miltex®

## CryoSolutions®

## Cryosurgical Unit

Directions for Use


*+H834CRYOSOLIFU05*

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3018 Bern
Switzerland

Manufactured for
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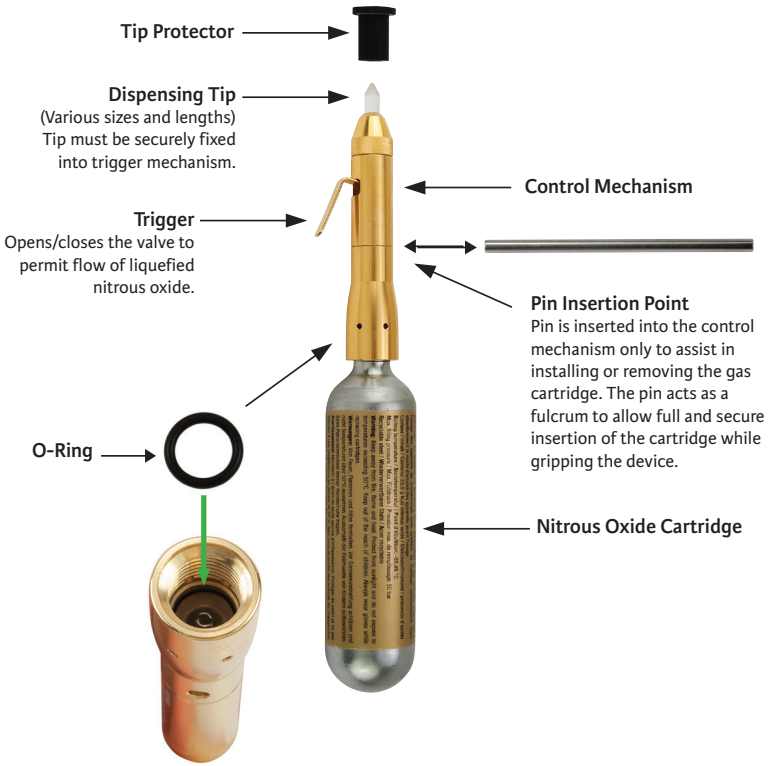
## Description

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. 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.



## 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.

## Indications

The CryoSolutions® device is indicated for destruction of tissue during surgical procedures by applying extreme cold.

## Contraindications

The well-known contraindication of cold are in particular all kinds of cryoproteinemia and cold urticarial.

## Warnings

- Always wear gloves when using CryoSolutions® device.
- 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.
- The 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.
- 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.

## Precautions

- Inspect cartridge for o-ring. If the o-ring is missing do not attach the cartridge.
- Do not attempt to alter or, in any way, modify the device or its performance. Such action would render the warranty invalid.
- Never use a damaged unit regardless of evident functionality.
- The CryoSolutions® device is to be used only with compatible nitrous oxide cartridges provided by Integra LifeSciences Production Corporation ("Miltex"). Attempted use of substitute cartridges is a safety hazard and will void the warranty and any liability.
- Do not attempt to use the cartridges for any other purpose.
- Cartridges are thermo sensitive. Do not expose to temperatures above +50° C / 122° F or below -5° C / 23° F.
- Always use protective gloves when using CryoSolutions® device, including when installing or removing cartridges.
- Pin must be fully inserted into the pin insertion point before attaching the cartridge.
- Cartridge must be aligned properly prior to assembly.
- Do not employ excessive force when connecting the cartridge to the control mechanism.
- Do not remove cartridge until empty.
- Center tip prior to screwing into place. Do not over-tighten.
- 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 dependent upon the optimal cold performance delivered by CryoSolutions® and application times guided by clinical experience.
- Only use lint-free cloth.
- Sterilize tips at recommended parameters. See "Cleaning/Sterilizing of Dispensing Tips."

## Adverse Reactions

- 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.

## Instructions

### Cartridge Installation

- Always use protective gloves when installing cartridges.
- Inspect cartridge for o-ring. If o-ring is missing, do not attach the cartridge. Contact Integra Miltex for o-ring replacement.
- The pin must be fully inserted into the pin insertion point before attaching the cartridge.
- Do not use the trigger or any other mechanism to attach cartridges.
- Contact Integra Miltex for replacement pins.
- Insert the metal pin in the pin insertion point 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.
- Care should be taken to align the cartridge and control mechanism so that gas does not inadvertently escape.
- Screw the cartridge into the control mechanism in a clockwise direction both quickly and completely to ensure proper functionality.
- Small amounts of gas escaping from the cartridge while being attached indicates poor alignment of the cartridge to the control mechanism.
- Remove the pin.

## Cartridge Replacement

- Always use protective gloves when removing the cartridges.
- Insert the metal pin in the pin insertion point 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.
- Unscrew the cartridge from the control mechanism in a counter clockwise direction.
- Remove the pin.
- Inspect the control mechanism for o-ring. If o-ring is missing, do not attach the cartridge. Contact Integra Miltex for o-ring replacement.
- Do not remove cartridge until empty.
- Any remaining gas will cause it to be more difficult to remove the cartridge.

## CryoSolutions® Treatment

## Contact Applications

- Always use protective gloves when using CryoSolutions®.
- Remove the plastic protective cap.
- Place the Dispensing tip perpendicular to and directly on the skin surface and area to be treated.
- Do not apply additional pressure 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 CryoSolutions® provides high performance cold temperature to the treatment area (exceptions may include plantar warts).
- Most lesions are removed with a single treatment. However, others may require a second treatment or even further applications, such as plantar warts.

* See Integra's Product Literature for additional information on application.

## Treatment

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.

## Cleaning/Sterilizing of Dispensing Tips

- Tips should be cleaned with an alcohol swab or disinfectant.
- Only use a lint-free cloth to clean, disinfect and wipe off tips in order to avoid particles sticking to the inlet of the tip, which may result in a blocked tip.
- Rinse tips with deionized, sterile, or demineralized water immediately following disinfection in order to avoid particles from drying and sticking to the inlet of tip, which may result in a blocked tip.
- 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.

- Remove tip from unit and sterilize following EN norms 13060 and 285 for steam sterilization.
- Other sterilization methods are not recommended.
- Dry heat sterilization may damage tips and is not recommended.
- Steam sterilize glass tips only. Sterilize at 273° F/134° C for 9 minutes.

## 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 between -5° C/23° F to +50° C/122° F to ensure protection of the device. Cartridges are thermo sensitive. Do not expose to temperatures above +50° C / 122° F or below -5° C / 23° F.

## Product Warranty

Integra LifeSciences Production Corporation 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 Integra. Integra'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.

1. Customer promptly reports such defect to Integra in writing.

2. If requested by Integra, customer returns equipment to Integra 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 Integra, subjected to unusual physical or electrical stress, altered with non-Integra parts or damaged during shipment back to Integra. This warranty is non-transferable unless authorized in writing by Integra. Integra reserves the right to make design changes on its products without liability and to incorporate said changes in Integra products previously designed or sold. Upon receipt of the product, it should be carefully inspected. If any defect is discovered, Integra must be notified immediately.

### Repair and Return

This device must be clean of all blood or other organic material prior to returning to Integra. Integra 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 Integra distributor or call Integra 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 Integra. 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

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 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 Integra nor manufacturer assume nor authorize any person to assume for them any other or additional liability or responsibility in connection with these products.

## Symbols

Symbols may be used on some package labeling for easy identification.

Manufacturer [1]


Caution: See warning or precautions


Consult instructions for use and website address

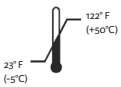

Catalog number


Lot number

Keep away from sunlight


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


Serial Number




Temperature Limitation
Upper temperature limit 122° F (+50°C)
Lower temperature limit 23° F (-5°C)

Keep dry

Handle with care

[1] Company responsible for a device marketed under its own name regardless of whether "manufactured for" or "manufactured by" the company.

For translated versions of this DFU refer to www.integralife.com/integra-miltex