UNITED ORTHOPEDIC®

Cryo-Gel™

Orthopedic Surgical Device for Tumor

Surgical Technique Guide

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Device Description

Cryo-Gel –

The Cryo-Gel system is designed for intraoperative preparation and delivery of an ethanol-based cryogenic medium for localized low-temperature application in orthopedic procedures. Using liquid nitrogen and 95% ethanol, the system forms a solidified Cryo-Gel that can be applied to target sites. Upon placement, the material transitions to a semi-solid state, conforming to the local anatomy while maintaining a cryosurgical environment.

INDICATIONS

This product is intended for intraoperative preparation and application of a cryogenic ethanol-based medium for localized low-temperature use in orthopedic surgical procedures. It is indicated for use as a temporary cryogenic medium delivery system to support controlled application of cryosurgical conditions at the surgical site during treatment.

PRECAUTIONS

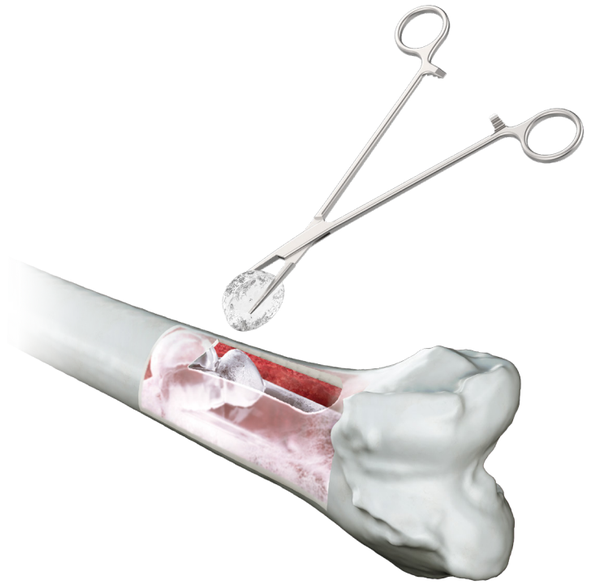
1. This product does not contain any cryogenic medium or pre-formed cryogenic material. It is designed solely as a storage and preparation system for the fabrication of Cryo-Gel. The probe is non-measuring in function and is intended only as a handheld accessory to facilitate handling during the preparation and retrieval process.
2. This product is intended for single use only. Do not reuse.
3. This product should only be used by physicians who are trained in cryogenic techniques and who fully understand the principles of cryotherapy.
4. Store the product in a dry indoor environment at room temperature and avoid direct sunlight exposure.
5. The shelf life of this product is 3 years.

WARNINGS

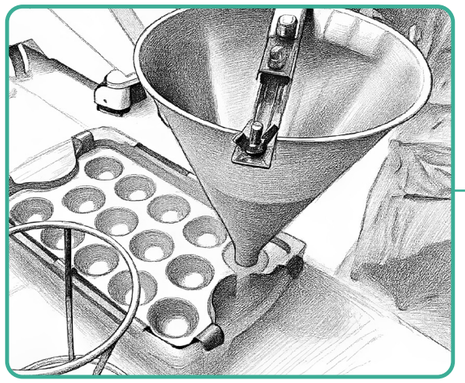
1. Disconnect all electrocautery device during Cryo-Gel treatment to avoid potential flaming.
2. Take extra caution while managing liquid nitrogen and Cryo-Gel which may cause cryogenic injury to both patient and operating personnel.

MATERIALS

Stainless steel, medical-grade silicone.

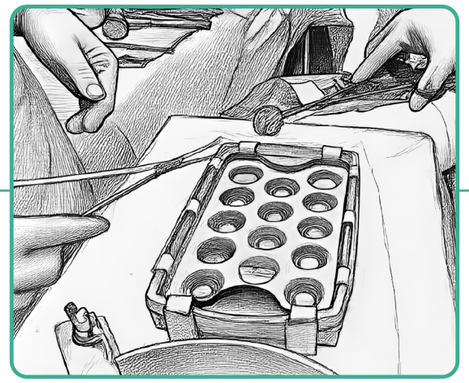


Surgical Overview

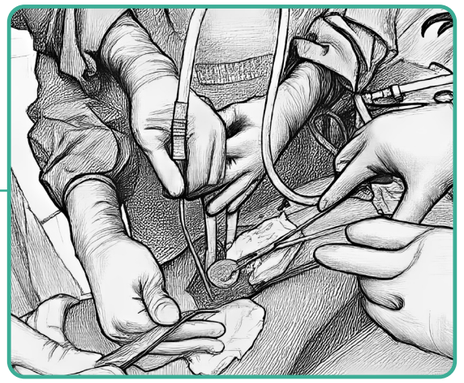


A. Mold Assembly Verification and Pre-cooling

B. Cryo-Gel Preparation



C. Cryo-Gel Retrieval



D. Cryo-Gel Placement

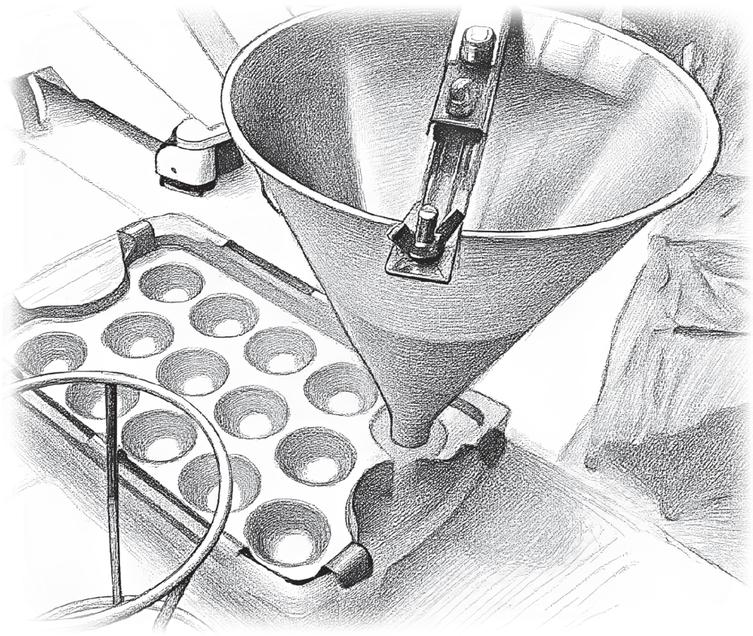
A. Mold Assembly Verification and Pre-cooling

Verify that the metal tray and outer silicone shell are properly assembled with full contact and without deformation or misalignment.

Fill the silicone shell with liquid nitrogen up to the indicated level.

Note:

1. Proper interface contact between the metal tray and silicone shell is recommended to support uniform cooling performance.
2. A distributor may be used to facilitate controlled delivery of liquid nitrogen.



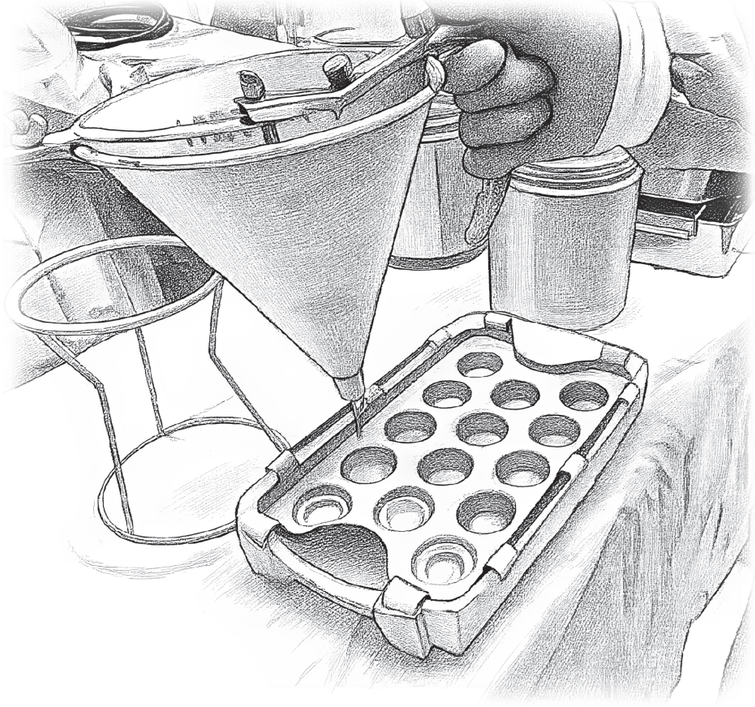
B. Cryo-Gel Preparation

Load 95% ethanol into the distributor and dispense into the wells of the metal tray. Allow the ethanol to solidify within the pre-cooled tray.

A probe may be partially inserted into the ethanol prior to complete solidification to assist with retrieval.

Note:

Maintain sufficient liquid nitrogen level within the silicone shell during preparation to support continuous cooling.



(Optional) Acceleration of Solidification

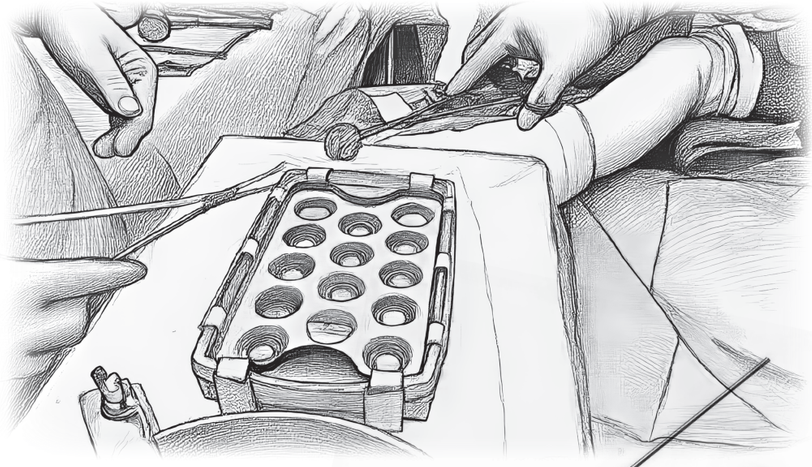
Liquid nitrogen may be introduced into the distributor containing ethanol to facilitate faster cooling and modify the consistency of the material.

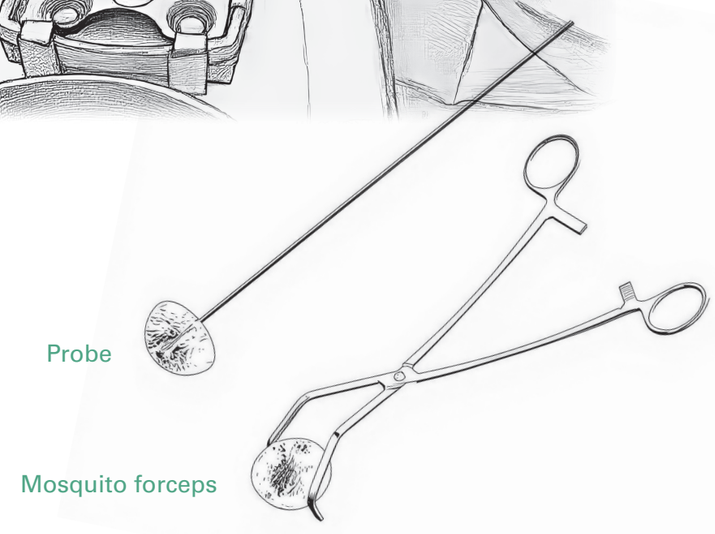
Note:

1. A semi-solid consistency may improve handling and dispensing characteristics.
2. Excessive liquid nitrogen may lead to rapid solidification and reduced workability, limiting the ability to dispense the material into the mold.

C. Cryo-Gel Retrieval

Remove the solidified Cryo-Gel from the mold using the probe or appropriate surgical instruments.





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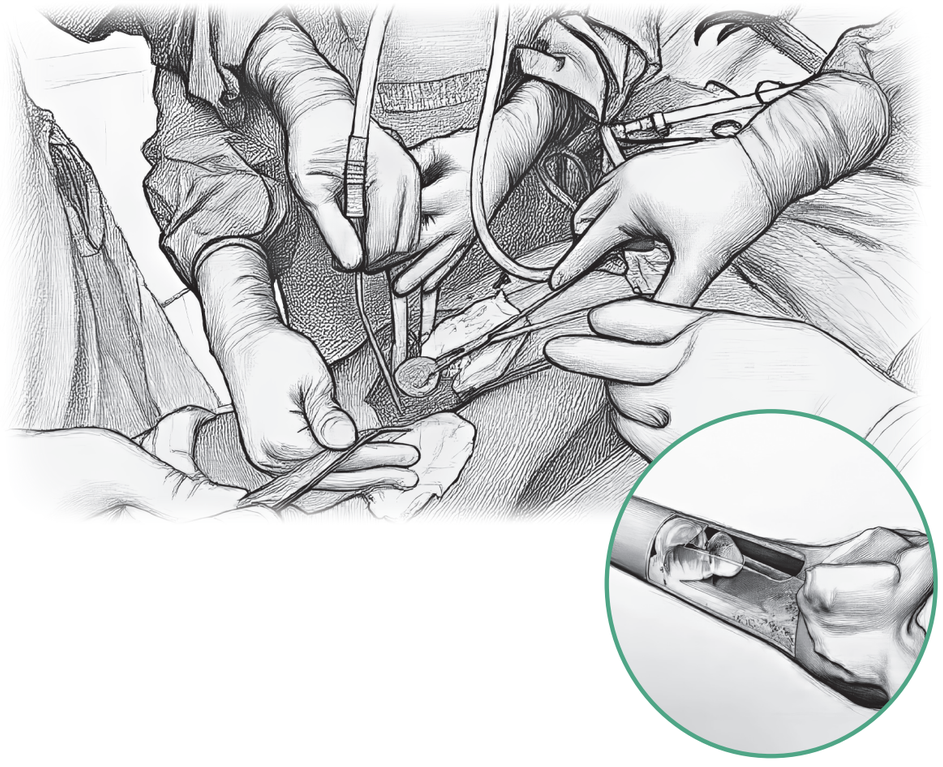
D. Cryo-Gel Placement

Place the prepared Cryo-Gel onto the target area using appropriate instruments. Additional Cryo-Gel may be applied as needed to achieve coverage of the intended region.

Following completion of the procedure, remove residual material from the surgical site using appropriate suction.

Note:

1. The material may transition from solid to semi-solid or liquid state during application, allowing conformity to the target surface.
2. Continuous application of Cryo-Gel may help maintain a cryosurgical environment at the treatment site.



Each Step
We Care

Order Information

	Catalog Number	Description
	SPH-14	Cryo-Gel Preparation Set – Round, 14-well, Sterile
	CRO	Cryo-Gel Preparation Set – Round, 14-well, Non-sterile
	REC-12	Cryo-Gel Preparation Set – Rectangular, 12-well, Sterile
	CRO REC-12	Cryo-Gel Preparation Set – Rectangular, 12-well, Non-sterile
	DIS	Cryo-Gel Distributor with Ladle
	DL2000	Double-layer Insulation Cylinder

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