IrvineScientific

cryo-GO Vitrification Device

Catalog No. 70307-R, 70308-Y, 70309-B, 70310-G, 70311-P	**10 Devices**
70312-R, 70313-Y, 70314-B, 70315-G, 70316-P	**50 Devices**

Glossary of Symbols*:

REF	Catalog Number
LOT	Lot Number
MD	Medical Device
QTY	Quantitiy
UDI	Unique Device Identification
30°C 15°C	Storage Temperature 15-30°C
STERILE R	Sterilized using Irradiation
irvinesci.com	Consult instructions for use
	Do not use if package is damaged
	Do not re-use
2 STERILIZE	Do not resterilize
	Expiration: Year - Month - Day
	Manufacturer
	Date of Manufacture: Year - Month
Rx Only	U.S. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

*Symbol Reference - **EN ISO 15223-1,** Medical devices – Symbols to be used with medical device labels, labeling and 21 CFR 801.109.

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P/N 41300, Rev.07
Effective Date: 24-FEB-2025

U.S. CAUTION:

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INTENDED PURPOSE/ USE

cryo-GO Vitrification Device is a cryopreservation device intended for use in vitrification procedures to contain and maintain human oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

INDICATION FOR USE

cryo-GO Vitrification Device is a cryopreservation device intended for use in vitrification procedures to contain and maintain human oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

DEVICE DESCRIPTION

A device composed of a body and a cap for use in ART procedures which includes oocytes and embryos cryopreservation by vitrification. The device is to be used with a vitrification and warming protocol.

COOLING RATE

-1,650°C/min

WARMING RATE

+16,500°C/min

QUALITY ASSURANCE

cryo-GO Vitrification Device is sterilized by gamma irradiation and is processed according to manufacturing procedures that have been validated.

Each lot of cryo-GO Vitrification Device is tested for:

Endotoxin USP<85>, USP<161> by LAL methodology ≤ 2 EU/device

One-cell MEA tested and passed with ≥ 80% expanded blastocyst within 96 hours

Sterility assurance level (SAL) of 10-6 according to ISO 11137-1

All results are reported on a lot of specific Certificate of Analysis which is available upon request.

PRECAUTIONS

This device is intended to be used by staff trained in assisted reproductive procedures. These procedures include the intended application for which this device is intended.

The user has the primary responsibility for adhering to the information outlined in this document.

The user facility of this device is responsible for maintaining traceability of the product and must comply with national regulations regarding traceability, where applicable.

To avoid problems with contamination, handle using aseptic techniques.

To avoid injuries with liquid nitrogen, wear protective gloves and glasses.

Use fresh liquid nitrogen per patient or device.

Do not use any device(s) in which the sterile packaging or the device has been compromised (open or damage). Do not clean device tips with alcohol or equivalents as material properties may be altered.

Refer to manufacturer's instructions when using micropipettes to load specimens onto the device.

When using tools to handle the device, do not apply excessive force from the tools onto the device as it may cause the device to break.

When using the device, carefully insert or remove the body of the device to and from the cap, making sure not to misalign the device to prevent accidental breakage. Always use the device with its corresponding cap that was packaged together. Discard the device if the cap is not present.

Load a maximum of 2 specimens per device.

Research literature indicates the long-term effects of vitrification on oocytes and embryos currently remains unknown.

WARNINGS

Do not use if packaging is damaged or if the tamper seal is missing or if functionality may be compromised.

Do not re-use or re-sterilize the devices or packages.

After opening the packages, all unused devices must be discarded.

Improper use of the device can result in loss of specimens.

For use as a closed system vitrification device. Not for use as an open system vitrification device.

The media used for vitrification and warming should be cleared for use by the FDA for vitrification procedures.

DIRECTIONS FOR USE

COOLING

1. Prepare a liquid nitrogen bath for vitrification procedures.
2. Open the cryo-GO Vitrification Device box, remove and open the sterile pouch.

3. Verify the correct patient information. Print and affix labels to, or write patient information on the device using a liquid nitrogen-resistant pen.
4. Follow the vitrification solution protocol provided by the manufacturer.
5. Prior to loading the samples, remove the cap from the device.

Note: Users are not intended to pre-cool the device.

6. Using the black mark as guidance, load the sample(s) in a volume of media not exceeding 0.5 µl onto the concave surface of the loading area and remove excess media, if applicable.

Note: Load no more than 2 specimens per device.

7. Quickly and carefully, insert the loading tip into the opening of the cap and twist gently to ensure a tight seal.

Note: The black marks on the device body and cap do not have to be aligned.

8. Immediately plunge the device cap first into the prepared liquid nitrogen bath.
9. Store the device according to laboratory procedures with the cap facing down in liquid nitrogen until warming.

WARMING

1. Prepare a liquid nitrogen bath for vitrification warming procedures.
2. Follow the vitrification warming protocol for preparation of media according to manufacturer instructions.
3. Retrieve the identified sample from liquid nitrogen storage.
4. Verify the correct patient sample according to laboratory procedures.
5. Remove the device from liquid nitrogen. Immediately remove the cap by gently twisting and pulling the cap without bending the device and, within 2 seconds, plunge the loading tip area, with the sample(s) facing up, directly into the warming solution.
6. Visualize the sample(s) detaching from the loading area. If sample(s) remain on the device, gently shake the device in the warming solution to release the sample(s).
7. Once the sample(s) have been detached from the device, carefully remove the device from the warming solution without disturbing the sample(s).
8. Continue with the vitrification warming protocol according to manufacturer instructions.
9. Discard device according to local state/provincial and national regulations/requirements after use.

DEVICE STORAGE AND DISPOSAL INSTRUCTIONS

Store unopened cryo-GO Vitrification Devices at 15-30°C in a clean storage area and away from direct sunlight and heat source.

When stored as directed, the device is stable until the expiration date shown on the packages.

Contain and dispose of in accordance with local state/provincial and national regulations/requirements.