

Available in 5 different colors:
Orange, Clear, Blue, Yellow, and Green



Glossary of Symbols:

- REF** Catalog Number:
CL-R-CT for Cryolock and
S-CL for S-Cryolock
- LOT** Lot Number
- Expiration date:
Year-Month-Day
- STERILE R** Sterilized using radiation
- Single sterile barrier
- Do Not use if package is damaged
- Do Not- Re-Sterilize
- Do not Re-use
- Rx only** US Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
- MD** Medical Device
- Consult instructions for use
- UDI** Unique Device Identifier
- Country of Manufacturer
- Manufacture By
- CE** 2797 CE Mark
- UK CA** 0086 UKCA Mark
- EC REP** EU Authorized Representative
Atlantico Systems Ltd
34 Oldfield, Kingston
Galway, Ireland
+35391443609
- UK Responsible Person:**
Compliant Medical Devices Ltd
58 London Street, Whitchurch,
Hampshire, RG28 7LN England
+44(0)7581 317 331

PRODUCT SPECIFICATIONS

Product information is identical unless otherwise noted.

Description:

- The body is a square shape stick made of medical grade resin, has a fine concave tip where the embryos are placed.
- The cap is made of the same resin, provides an airtight seal by the coupling of two tapered surfaces in a 0.250" of sealing surface.

Dimensions:

- Cryolock®
Body 4.56"L x 0.118"W x 0.118"H
Tip width 0.050"
Tip thickness 0.01"
Cap 1.78"L x 0.118"W x 0.118"H
- S-Cryolock®
Body 4.56"L x 0.094"W x 0.094"H
Tip width 0.037"
Tip thickness 0.01"
Cap 1.78"L x 0.094"W x 0.094"H

Performance:

- Cryolock®
Cooling rate \cong -1,490°C/min
Warming rate \cong 21,000°C/min
- S-Cryolock®
Cooling rate \cong -3,320°C/min
Warming rate \cong 29,710°C/min

Certificate of Analysis:

- Available upon request
- 1 cell MEA \geq 80% expand blastocysts within 96 h.
- Endotoxin LAL \leq 2 EU/device.
- Sterility: 25-40 kGy (SAL10⁻⁶).

Long-term storage:

- Biotech supported up to 3.5 years under liquid nitrogen, beyond that time is unknown.

Notice to the user:

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

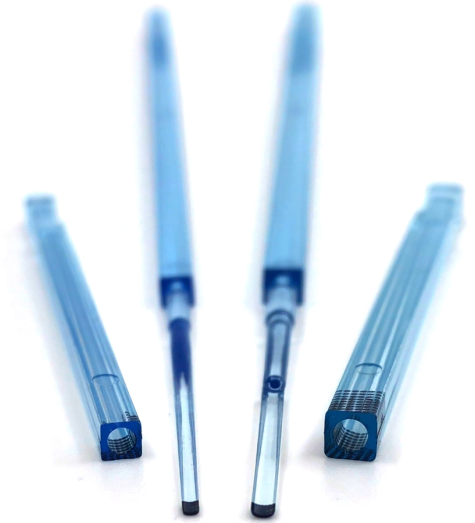
For more information go to:

www.cryolock.info

Manufacturer by



CRYOLOCK®
S-CRYOLOCK®
CRYOLOCK FAMILY DEVICES



Closed System
Vitrification of
1-Cell Stage
Embryos

Intended For Use:

Cryolock® Family Devices are cryopreservation storage devices that are intended for use in vitrification procedures to contain and maintain human 1-Cell stage embryos.

For non US-countries: For Oocytes and/or Embryos.

EN ISO 15223-1:2021 – Symbols to be used on the medical device labels.
(FDA only symbol: Rx only).

INSTRUCTIONS FOR USE

Warnings

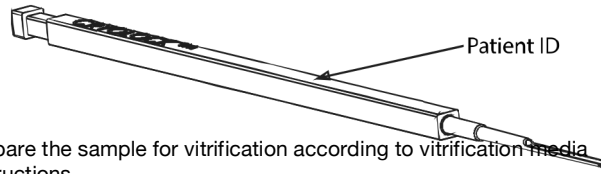
- All procedures must be performed under aseptic laboratory conditions.
- To avoid injuries with LN₂, wear protective gloves and glasses.
- Do not use device if:** (a) Pouch or package is open or damaged, (b) Gamma indicator is yellow or missing, or (c) Expiration Date has expired.
- Before loading 1-cell embryos, verify integrity of device under microscope view, discarding any devices with cracked tips, scratched, brittle, with flash, bubbles, presence of foreign material or abnormal shape.
- For better survival rates, use 1-cell stage embryos within 18-24 hours post fertilization while 2 pronucleus are still visible. Use only with licensed media for the embryo stage being vitrified.
- Avoid direct contact of the tip of device at any time; with any surface or material different to vitrification/warming media or pipettes holding the specimens.
- Always use the device with its corresponding cap as it was originally packaged.
- To prevent accidental loss of embryos, perform loading and unloading of 1-cell embryos under microscope view, avoiding contact of the tip against other surfaces. (i.e. edge of petri dishes, or liquid nitrogen containers)
- Load specimens with a maximum of 1 µL of vitrification media, excessive media may cause low survival rates as well as attachment of the tip to the inner cavity of the device cap and possible breakage of tip or cap during warming.
- To avoid accidental rushing, or inappropriate time of exposure of specimens to vitrification solutions during loading and plunging into LN₂, perform ONLY 1 or 2 specimens at a time.
- When plunging device into LN₂ always use a separate fresh aliquot LN₂ per patient. Be careful when releasing the device under LN₂, don't throw devices into LN₂, place them gently into the corresponding goblets previously equilibrated under LN₂.
- It is important that the container holding LN₂ be filled no less than 20cm (8"). Not doing so could cause the user to add unnecessary stress to the device and potentially causing the device to break.
- Do not re-sterilize or re-use Cryolock® or S-Cryolock® devices. Device properties may change decreasing device performance. Possible contamination, low survival rates, lysis and/or Embryo degeneration may occur.
- If device is dirty, discard it, DO NOT clean or wipe device tips with alcohol or equivalents, material properties may change.
- The long-term safety of 1-cell stage embryo vitrification on children born following this procedure is unknown.

Precautions

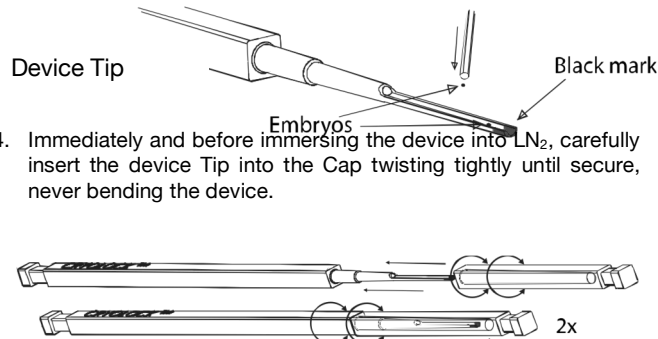
- Caution:** Federal Law restricts this device to be sold only to a physician or practitioner trained in its use.
- The correct use of the device is responsibility of the user. For exclusive use of embryologists, biologists or laboratory technicians duly trained on cryopreservation techniques and vitrification protocols.
- For vitrification and warming purposes, have all necessary materials, tools and equipment ready and handy before starting procedures.
- For Laboratory use only. Not for diagnostic use.
- Storage Instructions:** Store at room temperature
- Disposable:** After each package containing 5 devices is opened, all devices need to be used or discarded. Cryolock® and S-Cryolock® is for single use only.
- For infectious patients: a) Never reuse liquid nitrogen when plunging specimens from infectious patients. b) Always keep infectious specimens on a separate "dewar" exclusively assigned for "infectious patients", follow laboratory procedures for infectious patients.

LOADING AND CLOSING

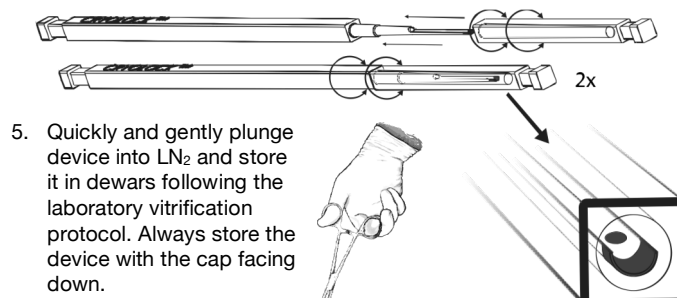
- With a liquid nitrogen-resistant label or a cryomarker pen, identify patient information, using the label on the same surface where Cryolock® or S-Cryolock® logo is engraved.



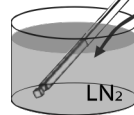
- Prepare the sample for vitrification according to vitrification media instructions.
- Using a micropipette, carefully load a maximum of 2 embryos on the concave surface of the tip (same side of Cryolock® or S-Cryolock® logo) and about 3mm (1/8") from the inner edge of black mark (use black mark as a reference) removing any excess of cryo-protectant solution leaving as minimum volume of vitrification media as possible. (≤ 1 µL). Excessive media may cause low survival rates as well as attachment of the tip to the inner cavity of the device cap.



- Immediately and before immersing the device into LN₂, carefully insert the device Tip into the Cap twisting tightly until secure, never bending the device.



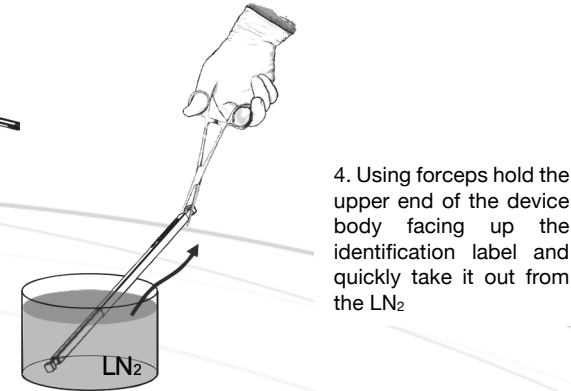
- Quickly and gently plunge device into LN₂ and store it in dewars following the laboratory vitrification protocol. Always store the device with the cap facing down.



Note:
Due to the concave shape of the tip, embryos are securely loaded and isolated against displacement of the sample during closing if loaded with less than 1 µL of vitrification media.

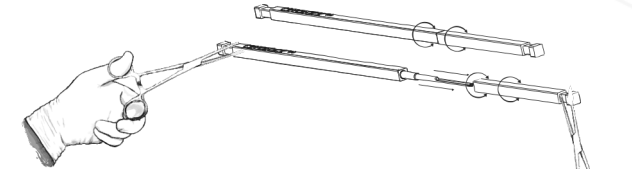
WARMING

- Prepare the warming solutions according to media instructions.
- Identify the sample to be warmed.
- Place the warming solution under microscopic view.

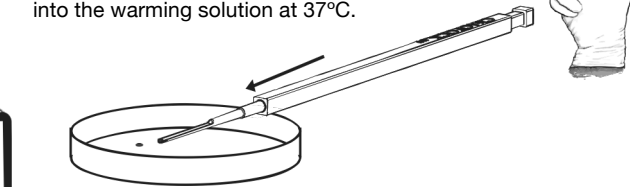


4. Using forceps hold the upper end of the device body facing up the identification label and quickly take it out from the LN₂

- Using forceps, remove the capped device from LN₂, and then quickly remove the cap with a gentle twist pulling the cap straight and away from the device body.



- Immediately plunge the concave tip of the device with specimens facing up into the warming solution at 37°C.



- Under microscopic observation, gently shake the Cryolock® or S-Cryolock® until specimens are released from the tip.
- Continue the warming according to media instructions.
- Discard device after completion of procedure, in accordance with the applicable medical/hazardous waste regulations.

Note: Transition between steps 4 to 6 should be no longer than 5 seconds.