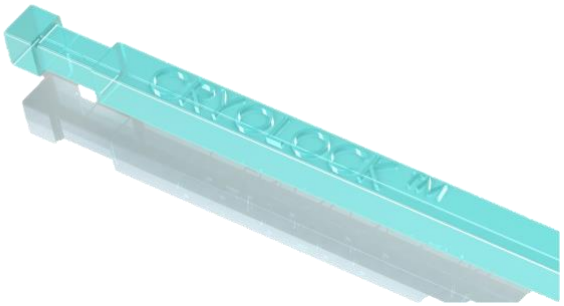
CRYOLOCK®

The simplest and most efficient system for vitrification



Available on 5 different colors:

Orange, Blue, Green,

Yellow, and Clear

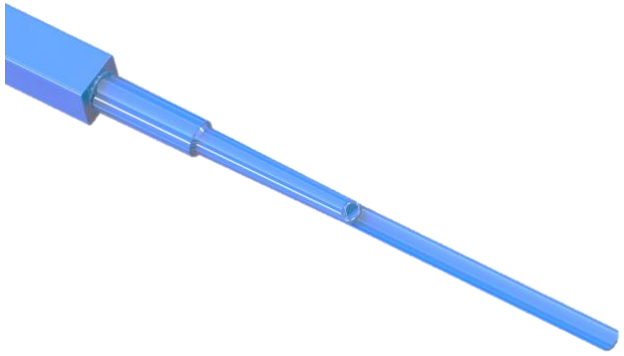
For more information go to:

www.Cryolock.info

Certificates of Analysis
Available upon request

- 1 cell MEA ≥ 80% expand blast.
- Endotoxin LAL ≤ 2 EU/device
- Sterility: SAL10^{-6}

Distributed by



CRYOLOCK

Intended for Use:
Cryolock® is an assisted reproduction labware intended to be used for holding, cryopreservation and storage of oocytes or embryos under liquid nitrogen (LN_2)

Bio Tech

CE 2797

DO NOT RE-USE

EC REP
Atlantico Systems Ltd
34 Oldfield, Kingston
Galway, Ireland
+35391443609

REF
CL-R-CT

STERILE R
SAL 10^{-6}

Biotech Inc.
5975 Shiloh Rd, Suite 101, Alpharetta GA 30005
1-800-313-7793

System For Oocyte and/or Embryo Vitrification

INSTRUCTIONS FOR USE

Warnings

- All procedures must be performed under aseptic laboratory conditions.
- To avoid injuries with LN_2, wear protective gloves and glasses.
- Do not use Cryolock® if: (a) vial or package is damaged, (b) tamper evident seal is broken or missing, (c) gamma indicator is yellow or missing, or (d) Expiration Date has expired.
- Before loading MII oocytes or embryos, verify integrity of Cryolock® under microscope view, discarding any Cryolocks with tips cracked, scratched brittle, with flash, bubbles, presence of foreign material or abnormal shape.
- For better survival rates, use MII Oocytes or good quality emrbyos. Use only with licensed vitrification media for the embryo stage being vitrified.
- Avoid direct contact of the tip of Cryolock® at any time; with any surface or material different to vitrification/warming media or pipettes holding the specimens.
- Always use the Cryolock® 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 o 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 Cryolock cap and possible breakage of tip or cap when warming.
- Immediately and before immersing the Cryolock® into LN_2, carefully insert the Cryolock® Tip into the Cap twisting tightly until secure
- To avoid accidental rushing, or inappropriate time of exposure of specimens to vitrification solutions during loading and plunging into LN, perform ONLY 1 or 2 sets of embryos at a time.
- When plunging Cryolock® into LN_2 always use a separate fresh aliquot LN_2 per patient. Be careful when releasing the Cryolock under LN_2, don't throw Cryolocks into LN_2, place them gently into the corresponding goblets previously equilibrated under LN_2.
- It is important that the container holding LN_2 be filled no less than 20cm. Not doing so could cause the user to add unnecessary stress to the Cryolock® device and potentially causing the device to break.
- Never leave several Cryolocks with oocytes or embryos loaded uncapped under LN.
- Do not re-sterilize or re-use Cryolock®. Device properties may change decreasing Cryolock® performance. Possible contamination, low survival rates, lysis and/or Embryo degeneration may occur.
- If Cryolock is dirty, discard it, DO NOT clean or wipe Cryolock tips with alcohol or equivalents, material properties may change.
- The long-term vitrification safety of oocytes and embryos on children born following this procedure is unknown.

Precautions

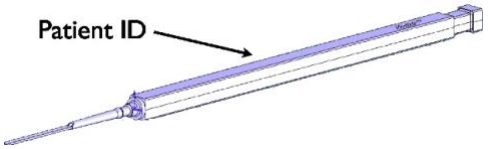
- The correct use of the device is responsibility of the user. For exclusive use of embryologists, biologists or laboratory technicians duly trained on cryopreservation techniques and vitrification protocols.
- For vitrification and warming purposes, have all necessary materials, tools and equipment ready and handy before starting procedures.
- For Laboratory use only. Not for diagnostic use.

Storage Instructions: Store at room temperature

Disposable: After each vial containing 5 devices is opened, all Cryolocks need to be used or discarded. Cryolock® is for single use only.

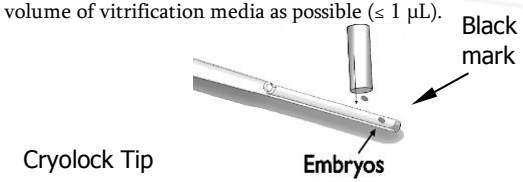
LOADING AND CLOSING

1. Use a liquid nitrogen-resistant label to identify oocytes and embryos of the patients, using the label on the same surface where Cryolock® is engraved.

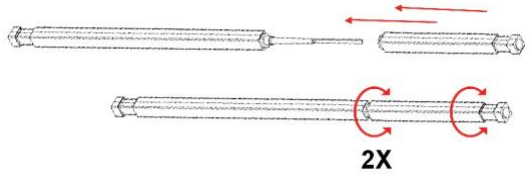


2. Prepare the sample for vitrification according to laboratory vitrification protocol.

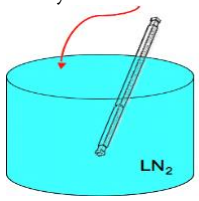
3. Using a micropipette, carefully load a maximum of 2 specimens on the concave surface of the tip (same side of Cryolock® logo) and about 3mm (1/8") from the edge of tip (use black mark as a reference) removing any excess of cryo-protectant solution leaving as minimum volume of vitrification media as possible (≤ 1 µL).



4. Immediately immerse Tip and use the black mark of the Cap as a guidance for capping under LN_2. Allow equilibration until stop bubbling. Carefully insert the tip into the cap twisting tightly enough until secure. Never throw uncapped Cryolocks containing specimens and leave unattended



5. Storage specimens on dewars following the laboratory vitrification protocol. Always store the Cryolock® with the cap facing down.



Note: Perform steps 3 to 5 in less than 1 minute.
After vitrification, Cryolock® must be kept under liquid nitrogen at all times.

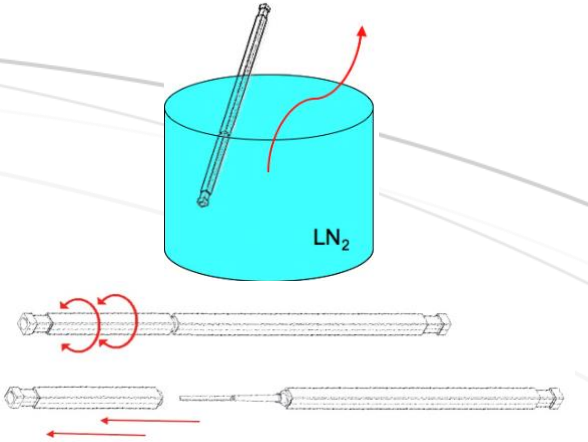
WARMING

1. Prepare the warming solutions according to laboratory vitrification protocol.

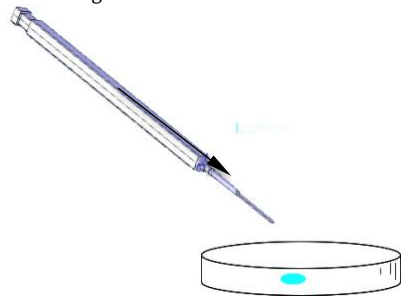
2. Identify the sample to be thawed.

3. Place the warming solution under microscopic view.

4. Using forceps hold the upper extreme of the Cryolock® body and then quickly remove the cap with a gentle twist pulling the cap straight and away from the Cryolock body until reléase, never bend Cryolcok body or cap.



5. Immediately plunge the tip of Cryolock® with specimens facing up into the warming solution at 37°C.



6. Under microscopic observation, gently move the Cryolock® until embryos are released from the tip.

7. Continue the warming according to laboratory vitrification / warming protocol.

8. Discard Cryolock after completion of procedure.

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