CRYOLOCK™

Cryolock® consists of the following two parts:

1). The body is a square shape stick (4.56”L x 0.118”W x 0.118”H) made of Polystyrene medical grade, has a fine concave tip where the embryos are placed.

2) The cap (1.78”L x 0.118”W x 0.118”L) made of the same material, provides an airtight seal by coupling of two tapered surfaces in a 0.250” of sealing surface.

PRODUCT SPECIFICATIONS:

1cell MEA ≥ 80% expand blastocysts within 96h

Endotoxin LAL ≤ 2 EU/Device

Sterility: SAL 10-6

Cooling rate of -1,494°C/min@-60°C

Warming rate +21,000°C/min

Available on different colors:

Clear, Blue, Green, Orange & Yellow

CRYOLOCK™

The Simplest and Most Efficient System for Vitrification

Read Instructions for use before use

Do not use if package is damage

Do not re-use, Do not re-sterilize Discard after procedure.

Sterile R — Sterilized by Radiation

REF — Catalog Number: CL-R-CT

LOT — Lot Number

Expiration Date

Rx Only
FDA Cleared
510(k): K122982

CE 2797

EC REP
Atlantico Systems Ltd
34 Oldfield, Kingston
Galway, Ireland
+353914443609
Authorized Representative in European Community

Bio Tech
Manufacturer by

Biotech, Inc.
5975 Shiloh Road, Suite 101
Alpharetta GA 30005 USA
Customer Service
1-800-313-7793

CRYOLOCK™

Closed System

Vitrification of 1-Cell Stage Embryos

Intended For Use:
Cryolock® is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 1-Cell stage embryos.

INSTRUCTIONS FOR USE

Warnings

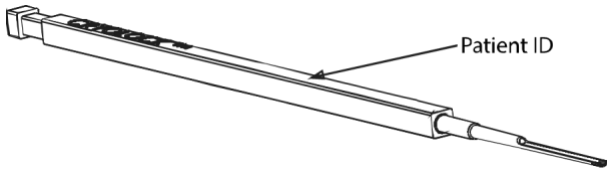
- All procedures must be performed under aseptic laboratory conditions. To avoid injuries with LN_2, wear protective gloves and glasses.
- Do not use Cryolock® if: (a) vial or package is damaged, (b) tamper evident seal is broken or missing, (c) gamma indicator is yellow or missing, or (d) Expiration Date has expired.
- Before loading 1-cell 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 1-cell stage embryos within 18-24 hours post fertilization while 2 pronucleus are still visible. Use only with US licensed 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_2, 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 (8"). Not doing so could cause the user to add unnecessary stress to the Cryolock® device and potentially causing the device to break.
- 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 safety of 1-cell stage embryo vitrification on children born following this procedure is unknown.

Precautions

- Caution: Federal Law restricts this device to sale by or on the order of 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 vial containing 5 devices is opened, all Cryolocks need to be used or discarded. Cryolock® is for single use only.

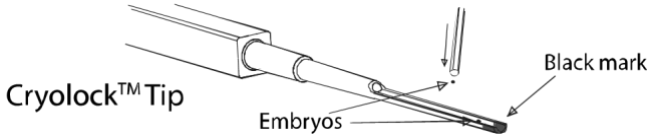
LOADING AND CLOSING

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

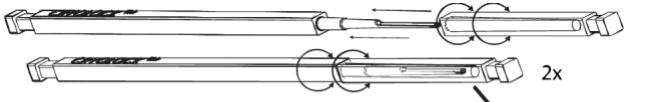


2. Prepare the sample for vitrification according to vitrification media instructions.

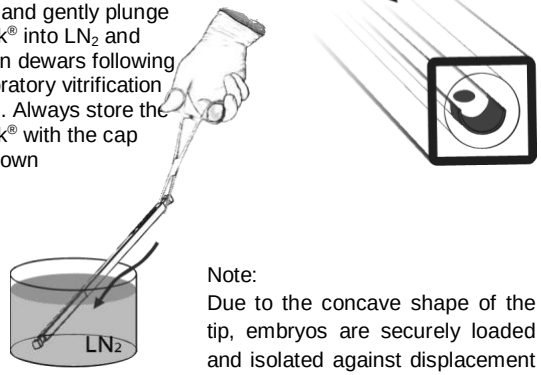
3. Using a micropipette, carefully load a maximum of 2 embryos on the concave surface of the tip (same side of Cryolock® logo) and about 3mm (1/8") from the inner edge of black mark (use black mark as a reference) removing any excess of cryo-protectant solution leaving as minimum volume of vitrification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



4. Immediately and before immersing the Cryolock® into LN_2, carefully insert the Cryolock® Tip into the Cap twisting tightly until secure, never bending the Cryolock



5. Quickly and gently plunge Cryolock® into LN_2 and store it in dewars following the laboratory vitrification protocol. Always store the Cryolock® with the cap facing down



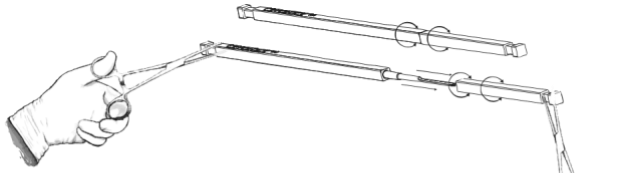
Note:
Due to the concave shape of the tip, embryos are securely loaded and isolated against displacement of the sample during closing if loaded with less than 1 µL of vitrification media.

WARMING

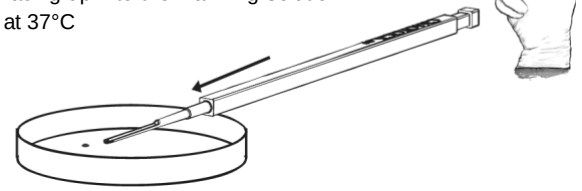
1. Prepare the warming solutions according with media instructions.
2. Identify the sample to be warmed.
3. Place the warming solution under microscopic view.

4. Using forceps hold the upper end of the Cryolock® body facing up the identification label and quickly take it out from the LN_2

5. Using forceps, remove the capped Cryolock® from LN_2, and then quickly remove the cap with a gentle twist pulling the cap straight and away from the Cryolock body..



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



7. Under microscopic observation, gently shake the Cryolock® until specimens are released from the tip.
8. Continue the warming according to media instructions.
9. Discard Cryolock® after completion of procedure.

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

LL-5006 Rev. J 5/31/2019 DOC#19-06