Available in 8 different colors:
Yellow, Lime Green, Blue, Orange, Clear, Green, Pink, and Purple.



**Glossary of Symbols:**

| | |
|---|---|
| REF | Catalog Number:<br>CL-R-CT for Cryolock and<br>S-CL for S-Cryolock |
| LOT | Lot Number |
| | Expiration date:<br>Year-Month-Day |
| STERILE R | Sterilized using radiation |
| | Single sterile barrier |
| | Do Not use of package is damaged |
| 2 STERILIZE | 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 |
| USA | Country of Manufacturer |
| | Manufacture By |
| CE 2797 | CE Mark |
| UK CA 0086 | UKCA Mark |
| EU 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

EN ISO 15223-1:2021/A1:2025 – Symbols to be used on the medical device labels.
(FDA only symbol: Rx only).

## 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 ≅ -19,800°C/min
  Warming rate ≅ 27,000°C/min
- S-Cryolock®
  Cooling rate ≅ -29,500°C/min
  Warming rate ≅ 40,500°C/min

**Certificate of Analysis:**
Available upon request

- 1 cell MEA ≥ 80% expand blastocysts within 96 h.
- Endotoxin LAL ≤ 2 EU/device.
- Sterility: 25-40 kGy (SAL$10^{-6}$).

**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

BIOTECH

5975 Shiloh Rd, Suite 101
Alpharetta, GA 30005 USA
1-800-313-7793

# CRYOLOCK®
# S-CRYOLOCK®

## CRYOLOCK FAMILY DEVICES



# Open System

# Vitrification of Oocyte and/or Embryo

**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.

## INSTRUCTIONS FOR USE

### Warnings

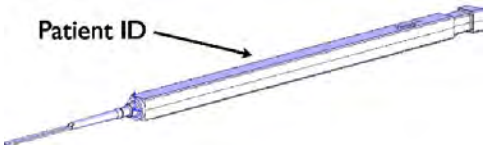
- All procedures must be performed under aseptic laboratory conditions.
- To avoid injuries with $LN_2$, wear protective gloves and glasses.
- Do not use device if: (a) Pouch or package is open or damaged, (b) Gamma indicator is yellow or missing, or (c) Expiration Date has expired.
- Before loading MII oocytes or embryos, verify integrity of device under microscope view, discarding any device with cracked tips, scratched brittle, with flash, bubbles, presence of foreign material or abnormal shape.
- For better survival rates, use MII Oocytes or good quality embryos. Use only with licensed vitrification 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 when warming.
- Immediately and after immersing the device into $LN_2$, carefully insert the device 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 specimens at a time.
- When plunging device into $LN_2$ always use a separate fresh aliquot $LN_2$ per patient. Be careful when releasing the device under $LN_2$, don't throw devices 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 device and potentially causing the device to break.
- Never leave several devices with oocytes or embryos loaded uncapped under $LN_2$.
- 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 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 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.

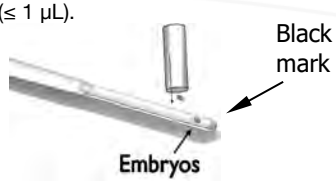
## LOADING AND CLOSING

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

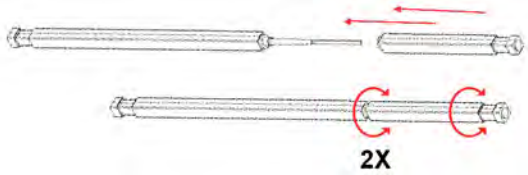



2. Prepare the sample for vitrification according to laboratory vitrification protocol.

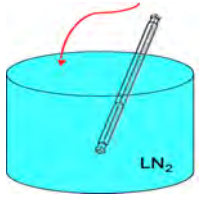
3. Using a micropipette, carefully load a maximum of 2 specimens on the concave surface of the tip (same side of Cryolock® or S-Cryolock® logo) and about 3mm (1/8") from the edge of tip (use black mark as a reference) removing any excess of cryo-protectant solution leaving as minimum volume of vitrification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




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




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

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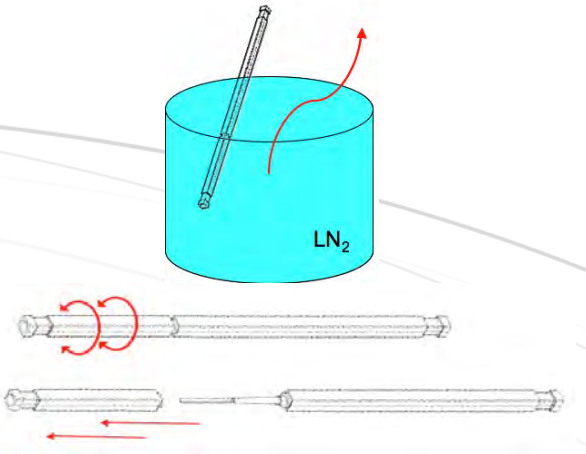
## WARMING

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

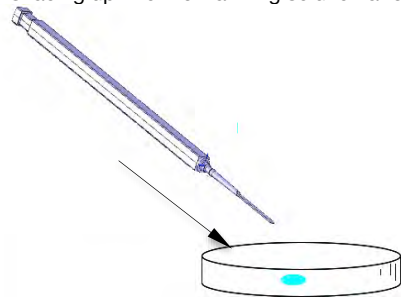
2. Identify the sample to be thawed.

3. Place the warming solution under microscopic view.

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




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



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

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

8. Discard device after completion of procedure, in accordance with the applicable medical/hazardous waste regulations.

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