

# 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.

LL-5006-WW Rev. C – 5/22/2023 DCO#: 23-04

### 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<sup>-6</sup>).

#### 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](http://www.cryolock.info)

Manufacturer by



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

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



### Glossary of Symbols:



Catalog Number  
CL-R-CT for Cryolock  
and S-CL for S-Cryolock



Lot Number



Expiration date:  
Year-Month-Day



Sterilized using radiation



Single sterile barrier



Do Not use of package is damaged



Do Not- Re-Sterilize



Do not Re-use



US Caution: Federal law restricts this  
device to sale by or on the order of a  
licensed healthcare practitioner



Medical Device



Consult instructions for use



Unique Device Identifier



Country of Manufacturer



Manufacture By



CE Mark



Atlantic Systems Ltd  
34 Oldfield, Kingston  
Galway, Ireland  
+35391443609

EU  
Authorized  
Representative



UK Responsible Person:  
Compliant Medical Devices Ltd  
58 London Street, Whitechurch,  
Hampshire, RG28 7LN England  
+44(0)7581 317 331

UKCA  
Mark

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

## ENGLISH

**NOTE: English is the official and updatable language for the instruction of use.**

### INSTRUCTIONS FOR USE

#### Warnings

- All procedures must be performed under aseptic laboratory conditions. To avoid injuries with LN<sub>2</sub>, 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 LN<sub>2</sub>, perform ONLY 1 or 2 specimens at a time.
- When plunging device into LN<sub>2</sub> always use a separate fresh aliquot LN<sub>2</sub> per patient. Be careful when releasing the device under LN<sub>2</sub>, don't throw devices into LN<sub>2</sub>, place them gently into the corresponding goblets previously equilibrated under LN<sub>2</sub>.
- It is important that the container holding LN<sub>2</sub> 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. *See drawing A.*
- 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. ( $\leq 1 \mu\text{L}$ ). Excessive media may cause low survival rates as well as attachment of the tip to the inner cavity of the device cap. *See drawing B.*
- Immediately and before immersing the device into LN<sub>2</sub>, carefully insert the device Tip into the Cap twisting tightly until secure, never bending the device. *See drawing C.*
- Quickly and gently plunge device into LN<sub>2</sub> and store it in dewars following the laboratory vitrification protocol. Always store the device with the cap facing down. *See drawing D.*

**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.
- Using forceps hold the upper end of the device body facing up the identification label and quickly take it out from the LN<sub>2</sub>. *See drawing E.*
- Using forceps, remove the capped device from LN<sub>2</sub>, and then quickly remove the cap with a gentle twist pulling the cap straight and away from the device body. *See drawing F.*
- 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.

#### DRAWING REFERENCE

