allwin® Medical Devices

SureLock Vitrification System

For US only

Description:

SureLock Vitrification Straw

REF	Colour
SUL-P	Pink
SUL-Y	Yellow
SUL-G	Green
SUL-B	Blue
SUL-V	Violet

Device Description:
SureLock vitrification straw consists of a straw (male part) and a cap (female part). The tip of the straw is concave and marked. A maximum of 2 specimens should be loaded per device, on the concave tip. The concave shape of the tip protects the specimen and prevents its damage or loss. The upper part of the straw is flat, providing a surface for writing patient information. The cap of the device has a marking to identify the correct orientation. The cap hermetically seals the straw after the sample is loaded and is designed to enable easy handling with forceps.

Indications for Use:
The SureLock Vitrification Straw is a cryopreservation storage device. It is intended for use in vitrification procedures to contain and maintain human oocytes (MII) or 1-cell stage embryos.

Specifications:
One-cell MEA: ≥ 80% embryos expanded to blastocyst at 96 hours
Bacterial Endotoxins (LAL) ≤ 2 EU/device.
Cooling Rate: -1700°C/minute
Thawing Rate: 13300°C/minute

Equipment:
- Liquid nitrogen container
- Liquid nitrogen
- Cryocane with goblet and appropriate storage vessel or equivalent equipment
- Micropipettes for manipulating oocytes or embryos
- Stereo microscope with a heated stage
- Cryomarker pen or labels intended for storage in liquid nitrogen
- Forceps or tweezers for handling device components

Contraindications:
None

Complications:
None

Caution:
Federal (USA) law restricts this device to sale by or on the order of a physician.
The media used for vitrification and warming should be cleared for use by the FDA for vitrification procedures.

It is essential to ensure that liquid nitrogen does not enter the cap and come in contact with the specimen or straw at any time during the procedure.

Warning:
- Do not use if package is opened or damaged.
- Liquid nitrogen may cause serious harm if in contact with skin or eyes
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- This device is supplied sterile and intended for single use only.
- Do not resterilize.
- Only experienced practitioners should use this device.

Precaution:
- For vitrification and warming purposes, have all necessary materials, tools and equipment ready and handy before starting procedures.
- Before loading 1-cell embryos, verify the integrity of SureLock under a microscope, discarding any SureLock with tips cracked, flush on well or abnormal shapes.
- Use appropriate precautions and safety devices when work with liquid nitrogen.
- Always use a separate fresh aliquot of liquid nitrogen per patient.
- Storage temperature between 5ºC to 30ºC.

Instructions for Use:

Vitrification

1. Open the sterile pack of SureLock and place patient identification information on the flat surface of the handle using a cryomarker pen or liquid nitrogen compatible label.
2. Fill a container 90% full of fresh liquid nitrogen. Place the container near the working area to allow easier handling during the vitrification procedure.
3. Before vitrification, pre-cool the SureLock cap for a minimum of 5 seconds by holding the cap vertically with forceps with the closed end of the cap submerged in liquid nitrogen and the open end at least 3 cm above the liquid nitrogen level to prevent exposure of the cap interior to liquid nitrogen.
4. Prepare the oocytes or embryos in accordance with the Instructions for Use for the vitrification media.

Note:
Steps 5-6 should be performed in <1 minute.

5. Using a micropipette, load a maximum of 2 oocytes or embryos on the concave surface of the tip on the SureLock straw (same side as arrow) and about 3 mm from the edge of the tip. Remove excess media, leaving a minimum volume (≤1 µl).
6. Immediately after loading, insert the SureLock straw vertically into the open end of the pre-cooled SureLock cap that has been maintained in the position stated in Step 3 above to prevent contact of the sample with liquid nitrogen

REF Catalogue Number | LOT Batch Code | Date of Manufacture | Use By | Do not re-use | Do not Re-Sterilize | Rx only | Caution : Federal (USA) law restricts device to sale by or on the order of a physician.

Consult Instruction for use | Do not use if Packing is damaged | Caution | Keep out of sunlight | Keep Dry | STERILE R Sterilized Using Gamma Radiation | Temperature Limit | CE 0123

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(i.e., closed end of cap in liquid nitrogen with open end above the liquid nitrogen level). Using the forceps holding the cap and hand holding the straw, fit the cap to the straw by pressing together and ensuring a tight fit. Then immerse SureLock in liquid nitrogen.

Note:
When capping the SureLock device, ensure that the closed end of the cap is always maintained below the liquid nitrogen level. Following capping, the SureLock should be maintained submerged in liquid nitrogen. Inappropriate handling may cause warming which can lead to de-vitrification of the oocytes or embryos.

7. Place the storage vessel (e.g., cryocane with attached goblet) into the liquid nitrogen container. Move the SureLock devices into the storage vessel with the cap portion facing down. Store SureLock devices in dewars following laboratory protocols.

Thawing/ Warming:

1. Prepare the warming media in accordance with the Instructions for Use for the warming media.
2. Fill a container 90% full of fresh liquid nitrogen. Collect the specific SureLock for thawing from the storage dewar and place it in the liquid nitrogen container. Ensure that the SureLock remains completely submerged in liquid nitrogen until ready to thaw.
3. Before thawing verify the patient information on the handle of the SureLock.
4. Place the dish containing the warming media on the stage of the microscope used during the warming procedure.
5. Using forceps, hold the neck region of the SureLock Straw and position it vertically with the closed end of the SureLock cap where the oocytes and embryos are located below the liquid nitrogen level and the cap/straw connection 3 cm above liquid nitrogen level to prevent contact of the sample with liquid nitrogen during or after cap removal. Use a second set of forceps to grasp the square SureLock cap. Carefully separate the cap from the straw.
6. Quickly (preferably less than 2 seconds) plunge the tip of the SureLock straw into the first warming solution with the oocytes or embryos on the tip facing up.
7. Under microscopic observation, gently move the tip of the SureLock straw in the media until the oocytes or embryos are released from the tip.
8. Proceed with warming according to the Instructions for Use provided with the warming media.
9. Discard SureLock after completion of the procedure.

Limited Express Warranty:
The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

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