

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:

SureLock Vitrification straw is a cryopreservation storage device. It is used in vitrification procedure to contain and maintain oocytes and 1-cell stage embryos

Specifications:

One-cell MEA: ≥ 80% embryos expanded to blastocyst at 96 hours Bacterial Endotoxins (LAL) ≤ 2 EU/device.

Contraindications:

None

Complications:

None

Caution:

Federal (USA) law restricts this device to sale by or on the order of a physician.

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.

- When plunging SureLock in LN2 always use a separate fresh aliquot LN2 per patient.
- Storage temperature between 5°C to 30°C.

Instructions for Use:

Vitrification

- With a cryomarker pen or a label register the name of patient on the top surface or surface having an arrow.
- Prepare the sample for vitrification according to laboratory protocol.
- Using a micropipette, load a maximum of 2 specimens on the concave surface of the tip (same side of arrow) and about 3mm from edge of tip eliminating any extra volume of solution present and leaving as minimum vitrification solution as possible. (≤1µL).
- Now carefully insert tip into cap ensuring the tightness and immediately immerse SureLock in LN2.
- Store the specimens in dewars following the laboratory protocol. Always store with cap facing down.

Note:

Perform steps 3 to 5 in less than a minute. After vitrification, SureLock must be kept in liquid nitrogen at all times

Thawing/ Warming:

- Prepare the warming solutions according to media instructions.
- Collect the specific SureLock from the dewar in the liquid nitrogen. Verify with the information about the patient on the handle of the SureLock.
- Place the warming solution under microscopic view.
- Using forceps hold at the neck region provided on SureLock body keeping the neck region upwards and tip downwards and quickly take it out from the LN2.
- Using forceps carefully separate the square cap from the SureLock body.
- Quickly immerse the SureLock tip into the thawing solution with specimens facing up.
- Under microscopic observation, gently move the SureLock until specimens are released from the tip.
- Continue the warming according to media instructions.
- Discard SureLock after completion of procedure. (NOTE: Transition between steps 4 to 6 should not take more than 5 seconds)

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.

 Catalogue Number
  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
 Sterilized Using Gamma Radiation
  Temperature Limit
 CE 0123

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