

Description:
SureStrip Vitrification Straw

REF	Colour
SUS-W	White
SUS-R	Red
SUS-I	Ivory
SUS-B	Blue
SUS-Y	Yellow

Device Description:

SureStrip vitrification straw consists of a straw (male part) and a cap (female part). The tip of the straw is marked and has a flexible and transparent strip. The specimen is loaded on the marking on the strip. A maximum of 4 specimens should be loaded per SureStrip straw. The straw handle is flat, providing a surface for writing patient information. The cap of the device is transparent, with marking on one end and a 3 mm seal on the other. It allows the straw to be hermetically sealed after the sample is loaded.

Indications for Use:

The SureStrip Vitrification Straw is a cryopreservation storage device. It is intended for use in vitrification procedures to contain and maintain human oocytes (MII), 4-8 cell-stage embryos, or blastocyst stage embryos."

Specifications:

One-cell MEA: $\geq 80\%$ embryos expanded to blastocyst at 96 hours.

Bacterial Endotoxins (LAL) ≤ 2 EU/device.

Cooling Rate: $-1700^{\circ}\text{C}/\text{minute}$

Thawing Rate: $13200^{\circ}\text{C}/\text{minute}$

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 the 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.

Precautions:

- Use appropriate precautions and safety devices when working with liquid nitrogen.
- Always use a separate fresh aliquot of liquid nitrogen per patient.
- Storage temperature between 5°C to 30°C .

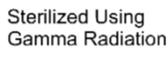
Instructions for Use:
Vitrification

1. Open the sterile pack of SureStrip 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 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. Position the SureStrip under the microscope with the flat side of the handle facing up. Using a micropipette, load a maximum of 4 oocytes or embryos on the tip on the straw beside the black mark. Remove excess media, leaving a minimum volume ($\leq 1 \mu\text{l}$).
6. Immediately after loading, insert the straw vertically into the open end of the pre-cooled cap that has been maintained in the position stated in Step 3 above to prevent contact of the sample with liquid nitrogen (i.e., closed end of cap in liquid nitrogen with open end of cap above the liquid nitrogen level). Using the forceps holding the SureStrip cap and hand holding the SureStrip straw, fit the cap to the straw using a twisting motion and then fully immerse SureStrip in liquid nitrogen.

 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 R	 Sterilized Using Gamma Radiation	 Temperature Limit 3°C	 CE 0123



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Note:

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

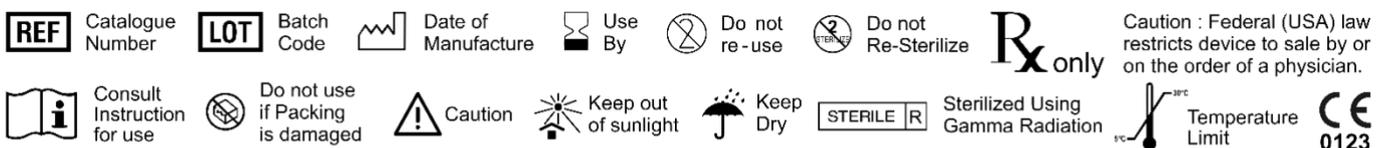
- Place the storage vessel (e.g., cryocane with attached goblet) into the liquid nitrogen container. Move the SureStrip into the storage vessel with the cap portion facing down. Store SureStrip in dewars following laboratory protocols.

Thawing/ Warming:

- Prepare the warming media in accordance with the Instructions for Use for the warming media.
- Fill a container 90% full of fresh liquid nitrogen. Collect the specific SureStrip for thawing from the storage Dewar and place it in the liquid nitrogen container. Ensure that the SureStrip remains completely submerged in liquid nitrogen until ready to thaw.
- Before thawing verify the patient information on the handle of the SureStrip.
- Place the dish containing the warming media on the stage of the microscope used during the warming procedure.
- Using forceps, hold the SureStrip straw and position it vertically with the closed end of the SureStrip cap 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 SureStrip cap. Carefully separate the cap from the straw using a twisting motion.
- Quickly (preferably less than 2 seconds) plunge the tip of the SureStrip straw into the first warming solution with the oocytes or embryos on the tip facing up.
- Under microscopic observation, gently move the tip of the SureStrip straw in the media until the oocytes or embryos are released from the tip.
- Proceed with warming according to the Instructions for Use provided with the warming media.
- Discard SureStrip 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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