

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 3 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:

SureStrip Vitrification straw is a cryopreservation storage device. It is used in vitrification procedure to contain and maintain oocytes, 4-8 cell- stage, or blastocyst 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 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.
- When plunging SureStrip in LN₂ always use a separate fresh aliquot LN₂ per patient.
- Storage temperature between 5°C to 30°C.

Instructions for Use:

Vitrification

- Open the sterile pack of SureStrip and write necessary information about a patient on the flat surface of the handle of SureStrip.
- Fill 90% of a container with fresh liquid nitrogen.
- Prepare embryos or oocytes for vitrification according to laboratory protocol.
- Take the straw cap of SureStrip and plunge it into the fresh liquid nitrogen.
- Place the SureStrip tip under the microscope and adjust the focus on the black mark of the SureStrip. Flat side on the handle should be facing up.
- Gently and precisely place the oocytes or embryos besides the black part of SureStrip with minimal volume of vitrification solution using a suitable pipette.
(Notes: The recommended load of the SureStrip is up to 4 oocytes or embryos.)
- Quickly plunge the SureStrip into fresh liquid nitrogen.
- Hold the straw cap with tweezers and insert the SureStrip.
- Fit the SureStrip with the cap by hands with screwing tightly.
- Put the SureStrip in a cane and store it in a tank for long term storage.
(Caution: Take care that the SureStrip remains immersed in liquid nitrogen at all times until thawing.)

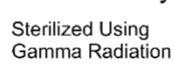
Thawing/ Warming:

- Prepare the thawing media according to laboratory protocol.
- Retrieve the cane which has the specific SureStrip and quickly immerse the cane in a container filled with fresh liquid nitrogen. Collect the specific SureStrip from the cane in the liquid nitrogen. Verify with the information about the patient on the handle of the SureStrip.
(Caution: The SureStrip except the handle remains immersed in liquid nitrogen at all times. Place a container for liquid nitrogen besides the stereo microscope)
- Carefully untwist and separate the straw cap from the SureStrip body in liquid nitrogen.
- Quickly immerse the SureStrip film tip into the thawing solution. It should not take more than 5 seconds.
- One minute after immersing into the thawing solution, gently aspirate the oocyte/embryo using a suitable pipette.

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 R	 Sterilized Using Gamma Radiation	 Temperature Limit	 CE 0123

EC REP
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