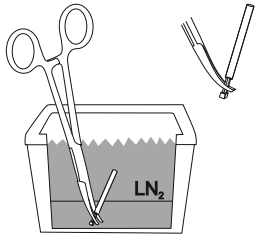
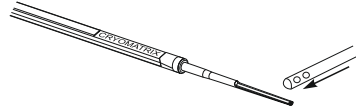


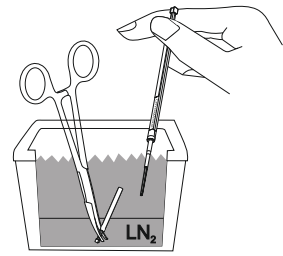
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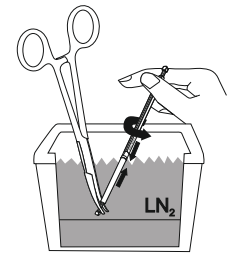
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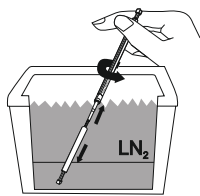
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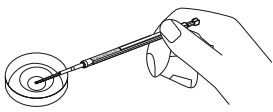
4



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Cryomatrix™

Device Description:

The Cryomatrix™ device is a cryopreservation storage device.

Indications for Use:

The Cryomatrix™ is a cryopreservation storage device intended to store vitrified human oocytes, cleavage stage embryos and blastocysts under Liquid Nitrogen (LN₂) temperature. The product should only be used by professionals trained in ART treatment.

Pack Size

STR01010 - CryoMatrix Clear

(1 x 10 units)

STR01040 - CryoMatrix Yellow

(1 x 10 units)

STR01020 - CryoMatrix Blue

(1 x 10 units)

STR01050 - CryoMatrix Orange

(1 x 10 units)

STR01030 - CryoMatrix Green

(1 x 10 units)

STR01060 - CryoMatrix Pink

(1 x 10 units)

Quality Control Testing

Mouse Embryo Assay (MEA) tested and Endotoxin tested.

Note: The Certificate of analysis can be obtained by sending a mail to info@cryobiomatrix.com

Storage instruction and Stability

Store in original container at 20 – 25°C.

The product is stable till the expiry date. Avoid prolonged exposure to elevated temperature.

Precautions and Warnings

Cryomatrix is used for storage of oocytes cleavage stage embryos and blastocysts under Liquid Nitrogen (LN₂) Temperature.

1. The procedure needs to be performed under aseptic laboratory conditions.

2. Protective hardware needs to be used to avoid injuries with LN₂.

3. Only trained professionals for the procedure, should be handling the product.

DO NOT use the product if:

A. It is damaged or the seal is broken.

B. Its expiry date has been exceeded.

C. The loading surface of Cryomatrix has been touched manually and compromised.

Note : The Cryomatrix is an open system which means that the oocytes and embryos are in direct contact with Liquid Nitrogen.(LN₂).

Note : Specimen must be loaded on concave surface. (Figure: 1) name Cryomatrix on the device indicates concave side up, also notch at the back top indicates the concave surface up.

Note : Device to be disposed as per the local regulation for disposal of medical devices of the respective countries.

Instruction for use

Cooling

1. Use a suitable label (resistance to LN₂) to identify specimen of patient.

2. Prepare the specimen for vitrification as per the media kit instruction.

3. Using forceps gently TWIST and open the cap of the straw. Keep the cap submerged in LN₂ (Figure: 2).

4. Using a micropipette, carefully load a maximum of 3 specimens in minimal volume on to the concave surface near the end of the tip (Figure: 3). Use the black mark as reference for loading.

5. If necessary, remove excess media just prior to plunging in LN₂ in accordance with the recommendation of the media kit.

6. Quickly plunge the tip into LN₂ and allow temperature stabilization. (Figure: 4)

7. Carefully insert the tip into the cap and TWIST gently to ensure a tight seal. (Figure: 5) Make sure that tip as well as cap are kept immersed during this procedure.

8. Ensure that the Cryomatrix remains immersed in LN₂ during transfer to the storage container.

Note : Cryomatrix should be store with a Cap down and notch up which indicates that the concave tip is on the same side of the notch.

Note : After vitrification Cryomatrix must be immersed under LN₂ at all times.

Warming

1. Prepare the warming media as per the protocol mentioned in the media Kit.

2. The sample to be thawed is to be transported in LN₂.

3. Using forceps TWIST & pull the Cryomatrix cap & body apart, ensuring always tip region is fully immerse in LN₂ during this step. (Figure: 6)

4. Immediately within 2 sec. with the Cryomatrix tip (vitrified specimen), facing up need to be dipped in the warming solutions. (Figure: 7)

5. Under microscopic observation, gently move the Cryomatrix until the specimen are released from the tip.

6. Continue the protocol of warming as mentioned in the media kit.

7. Do not Re-use/Re-sterilized Cryomatrix under any circumstances.

Note : Discard Cryomatrix after completion of procedure as per the local regulation for disposal of medical devices of the respective countries.