## WARMING

1. Prepare the warming media according to the preferred media kit's recommendations.
2. Collect the VitriGuard™ from cryostorage and keep in transportable vessel while maintaining the tip region fully immersed under $LN_2$.
3. Uncap the VitriGuard™ by simultaneously pulling and twisting the cap apart from the stick (Figure 5).

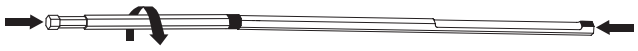

**Figure 5**

4. Quickly, within 2 seconds, plunge the VitriGuard™ tip with the vitrified specimen(s) facing up into the warming solution (Figure 6).

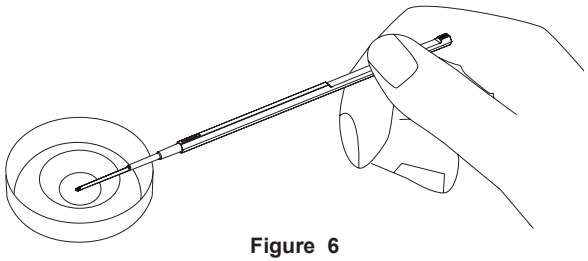

**Figure 6**

5. Under microscopic observation, gently move the VitriGuard™ until the specimen(s) are released from the tip.
6. Perform the warming procedure according to the preferred media kit's recommendations.

## Storage Instructions

STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

## Explanation of Symbols

| | |
|---|---|
| REF | Reorder Number |
| LOT | Batch code |
| | Use-by date |
| | Consult instructions for use |
| | Caution |
| | Do not re-use |
| | Do not use if package is damaged or opened |
| STERILE R | Sterilized using gamma irradiation |
| | Manufacturer |
| **$R_x$Only** | **Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician |



38434-IFU Rev. A 01/17

# VitriGuard™

Cryopreservation Storage Device

## $R_x$Only

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a CooperSurgical Company

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

## Important Statement

This Instruction for Use is designed to assist in using this product. It is not a reference to surgical techniques. This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device. The long term safety of vitrification procedures is unknown. The preferred media kit used for vitrification and warming should be cleared for use by the FDA for vitrification procedures.

## Description

The VitriGuard™ device is a cryopreservation storage device composed of a stick and cap.

Cooling Rate: ≈-2,271°C/min
Warming Rate: ≈36,377°C/min

## Indication for Use

The VitriGuard™ cryopreservation storage device is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.

## Quality Control Testing

1. 1 cell Mouse Embryo Assay (MEA) ≥ 80% Blastocysts within 96h
2. Endotoxin LAL ≤ 2 EU/device
3. Sterility SAL 10-6

***Note:*** The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

## Warnings and Precautions

### WARNINGS

1. Cryopreservation procedures should be performed only by qualified personnel familiar with these techniques
2. Do not use the product if:
   - Product packaging appears damaged or if the seal is broken
   - Expiration date has been exceeded
3. Do not reuse.

### PRECAUTIONS

***Note:*** Before loading specimens, verify integrity of the VitriGuard™ tip.

***Note:*** To avoid injuries with Liquid Nitrogen ($LN_2$), wear appropriate personal protective equipment.

***Note:*** Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

***Note:*** Specimen to be loaded on concave surface of tip.

## Instructions for Use

### COOLING

1. The flat surface provided on the VitriGuard™ is for recording patient information (Figure 1) and indicates orientation of concave surface for specimen loading.

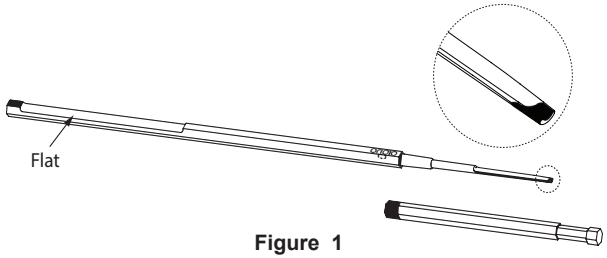


**Figure 1**

2. A region on the Cap is provided for stronger grasping as illustrated in Figure 2.

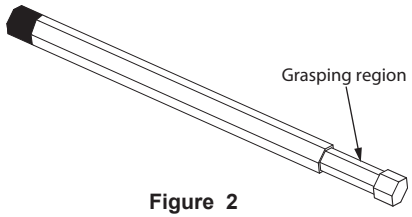


**Figure 2**

3. Prepare a suitable container with $LN_2$ and the preferred vessel to hold the VitriGuard™ during cryostorage.
4. Prepare the specimens for vitrification according to the preferred media kit's recommendations.
5. Using a micropipette, carefully load a maximum of 3 specimens in a minimal volume (<0.5µl) on to the concave surface near the end of the tip (Figure 3). If necessary, remove excess media. Use the black mark as reference.

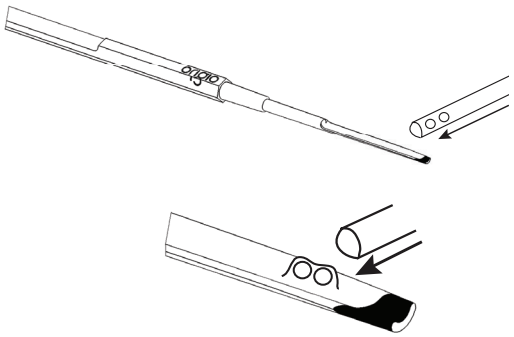

**Figure 3**

6. Prior to assembling the VitriGuard™, cool the Cap for a minimum of 2 seconds in the cryogenic nitrogen vapor or by partially submerging the cap in the liquid nitrogen. The opening of the cap must be kept above the liquid level. Note: Cooling of the cap is required for proper closure of the device.
7. Immediately after loading the specimen, assemble the VitriGuard™ by carefully inserting the tip into the pre-cooled cap pressing them together gently while twisting gently to ensure tight seal (Figure 4).

**Figure 4**

8. Once assembled, plunge the device into the liquid nitrogen. Note, ensure the VitriGuard™ remains immersed in $LN_2$ during transfer to the storage container.