COOK®
MEDICAL

Nest VT ™ Vitrification Storage Device

Instructions for Use

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NEST VT™ VITRIFICATION STORAGE DEVICE

Read all instructions carefully. Failure to properly follow the information provided may lead to the device not performing as intended or injury to the patient.

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner). Please read all instructions before using this device.

DEVICE DESCRIPTION

The Nest VT™ Vitrification Storage Device is a 12.5 cm long styrene co-polymer stick that has a triangular cross-section 3.6 mm wide (**Fig. 1**). It has a specimen-holding section **(a)** near the distal end and a flat section for labeling (**b**) near the proximal end. The 3.9 cm long cap is designed to protect the specimen from liquid nitrogen contact. The device has laser-etched marks to indicate the location of the tip **(c)**, the upright orientation of the device (**d**) and the opening of the cap **(e)**. The Vitrification Storage Device allows for the cryo-storage and warming of oocytes and embryos intended for in vitro fertilization.

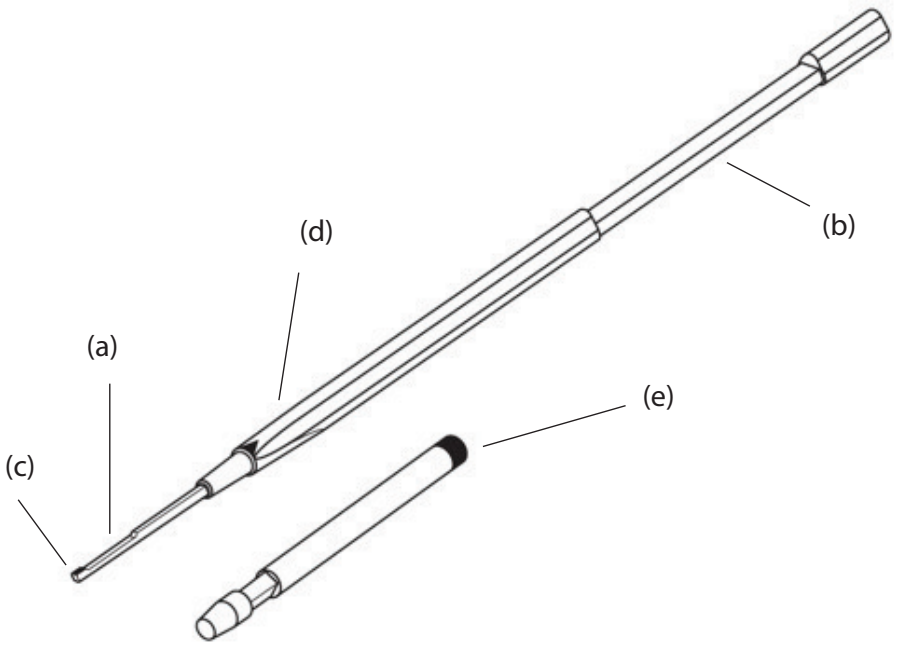

Fig. 1

Performance Characteristics

- Profile of the Vitrification Storage Device allows storage of up to 5 Devices in a standard 10mm goblet.
- Recessed specimen-holding section allows for ease of use.

- One-cell System: ≥ 80% embryos developed to expanded blastocyst at 96 hours.
- Endotoxin (LAL): <2 EU/device
- The results of each lot are stated on a Certificate of Analysis, which is available upon request.
- Sterility: SAL 10^{-6}
- Closed vitrification cooling rate: -1,744 °C/min*
- Closed vitrification warming rate: 48,818 °C/min*

**Cooling and warming rates are calculated as the average between -20 and -120 °C when a 0.5 µL drop of media is used.*

Patient Population

The Vitrification Storage Device is indicated for patients undergoing fertility preservation and/or IVF treatment.

Intended User

The Vitrification Storage Device is intended for exclusive use by embryologists, biologists, and laboratory technicians experienced with cryopreservation and vitrification techniques.

Contact With Body Tissue

The Vitrification Storage Device has no direct patient contact. It is intended for use with human embryos and oocytes during IVF procedure.

INTENDED USE

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

INDICATIONS FOR USE

The Vitrification Storage Device is indicated for fertility preservation and/or IVF treatment.

CONTRAINDICATIONS

No known contraindications.

WARNINGS

- Federal law restricts this device to sale by or on the order of a practitioner trained in its use.
- Visually inspect the integrity of the sterile packaging. Do not use the device if the sterile packaging is damaged or unintentionally opened before use.
- This single-use device is not designed for re-use. Attempts to

reprocess, resterilize, and/or reuse may lead to contamination with biological or chemical agents and/or mechanical integrity failure of device.

PRECAUTIONS

- Before loading specimens, verify integrity of the device tip.
- To avoid injuries with liquid nitrogen, wear appropriate personal protective equipment.
- Perform all procedures under aseptic laboratory technique.
- When using forceps, grasp the device only at the intended location at the proximal labeling end to avoid the risk of damage to the device (**Fig. 2**).

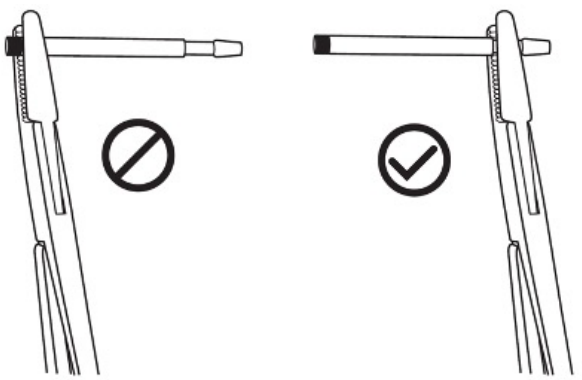

Fig. 2

- Do not place a device into the goblet if resistance is met during insertion.
- Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practice.

POTENTIAL ADVERSE EVENTS

- Lower survival rate for cryopreserved oocytes and embryos
- Lower live birth rate for cryopreserved oocytes and embryos

HOW SUPPLIED

Supplied sterilized by ionizing radiation in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store at room temperature and avoid prolonged exposure to elevated temperatures and UV light. Upon removal from the package, inspect the product to ensure no damage has occurred.

INSPECTION OF DEVICE

Visually inspect the device thoroughly including all levels of the packaging to verify that there is no damage prior to use. Visually

inspect and confirm that the sterile barrier has not been compromised in any way.

DEVICE PREPARATION

For vitrification and warming purposes, prepare all necessary materials, tools, and equipment before starting the procedure.

INSTRUCTIONS FOR USE

Vitrification

1. Prepare the liquid nitrogen bath, ensuring that the level of liquid nitrogen is deep enough to accommodate the Vitrification Storage Device. **NOTE:** Maintain this level due to the rapid evaporation of liquid nitrogen.
2. Use a liquid nitrogen-resistant label or a cryomarker pen to label the device on the flat, recessed portion of the stick with the identifying information for the patient and sample.

   NOTE: To prevent accidental contact of the device with a non-sterile surface, the device can be labeled while in the packaging tray (**Fig. 3).**

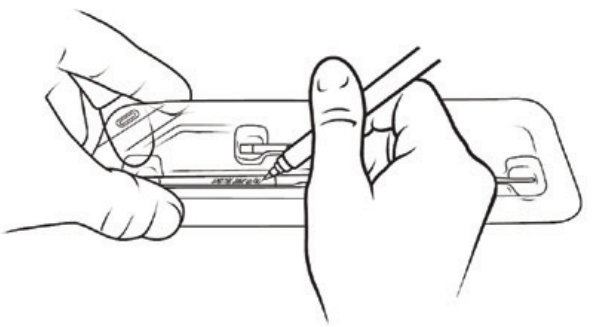

Fig. 3

3. Prepare the sample(s) for vitrification according to media and laboratory vitrification protocols.
4. Load up to 3 specimens in a maximum of 1 µL of media in the specimen-holding area of the Vitrification Storage Device (**Fig. 4**).

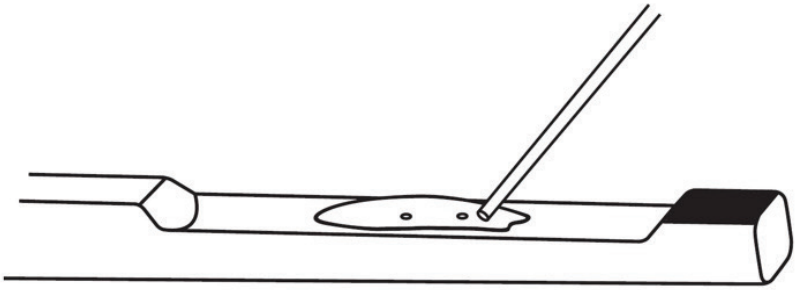

Fig. 4

5. Aspirate any excess vitrification media opposite the specimens to leave a minimal volume of media in the specimen-holding area of the Vitrification Storage Device (**Fig. 5**).

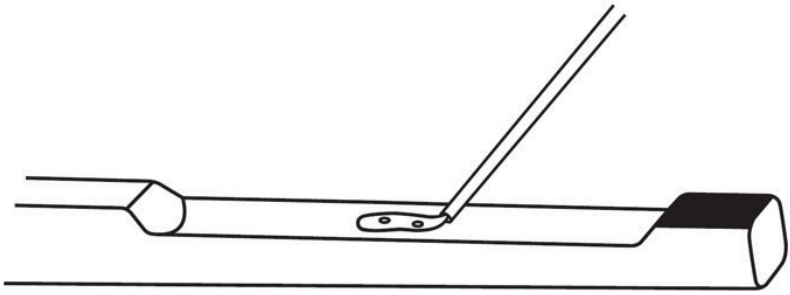

Fig. 5

6. As quickly as possible, push and twist the cap over the distal tip containing the specimens(s) pressing firmly until the cap is securely closed (**Fig. 6**).

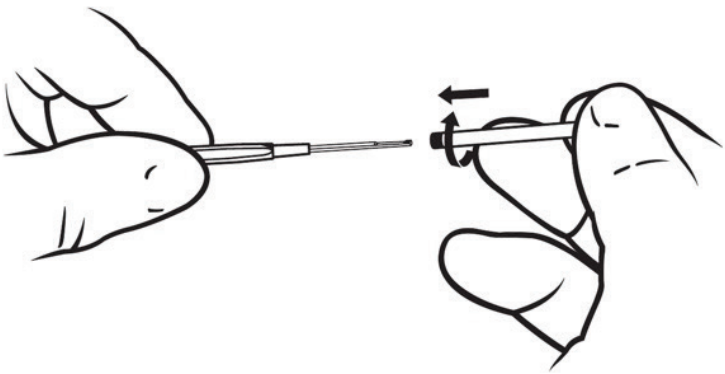

Fig. 6

7. Immediately immerse the closed distal tip and cap of the device in liquid nitrogen until equilibrium is reached (when boiling ceases) (**Fig. 7**).

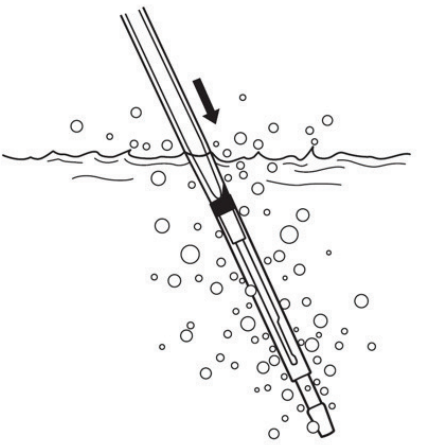

Fig. 7

8. Keep the distal tip pointed downward and immersed in liquid nitrogen during transport and storage.
9. Store the specimen(s) according to laboratory protocol.

Warming

10. Prepare the warming solutions according to laboratory warming protocol.
11. Identify the sample(s) to be warmed and keep the device in a transportable vessel with the distal tip region fully immersed in liquid nitrogen (**Fig. 8**).

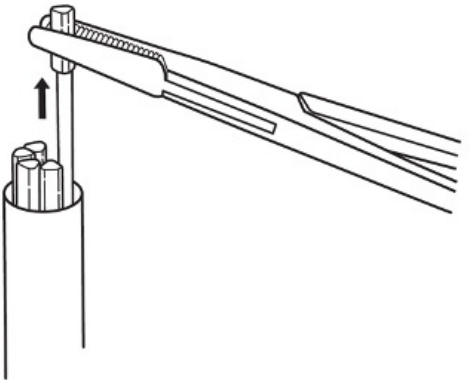

Fig. 8

12. Place the warming solution in the microscope's field of view.
13. Perform the following actions as quickly as possible:
    - Use forceps to hold the proximal end and remove the whole device from liquid nitrogen.
    - Grasp the recessed portion at the distal end of the cap and twist gently to remove the cap from the device (**Fig. 9**).

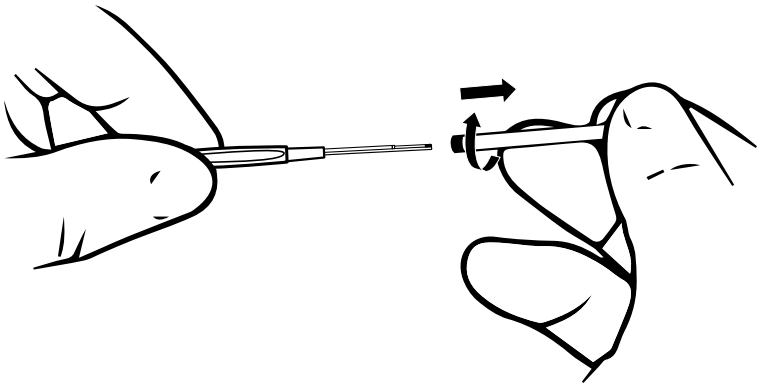

Fig. 9

- Place the distal tip of the device into warming solution with the specimen-holding portion facing up, as indicated by the laser etch mark (**Fig. 10**).

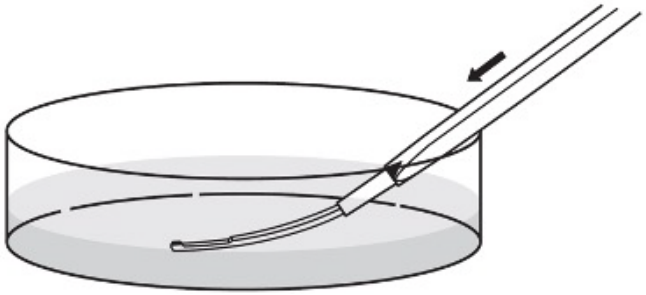

Fig. 10

14. Find the specimen(s) under direct microscopic visualization. If the specimen does not dislodge immediately, gently swirl the device under the warming solution to release the specimen(s) (**Fig. 11**).

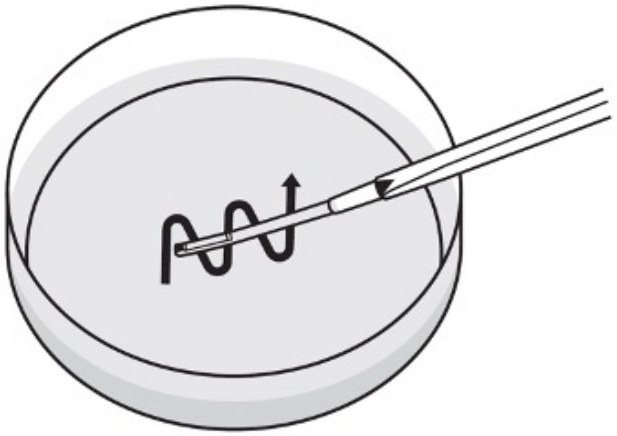

Fig. 11

15. Continue to perform the warming procedure according to media instructions.

DISPOSAL OF DEVICES

After the procedure, this device may be contaminated with potentially infectious substances of human origin and should be disposed of in accordance with all applicable Federal, State, and local Medical/ Hazardous waste practice.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.

PATIENT COUNSELING INFORMATION

Please inform the patient as necessary of the relevant warnings, precautions, contraindications, measures to be taken, and limitations of use that the patient should be aware of.

SERIOUS INCIDENT REPORTING

If any serious incident has occurred in relation to the device this should be reported to Cook Medical.

This shall also be reported to the competent authority the device was used in.

Do not use if package is damaged and consult instructions for use

Medical Device

Packaging Unit

cookmedical.com/symbol-glossary

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