



VitaVitro® Straw Set User Manual

VitaVitro® Straw Set in sterilized packet



CAUTION

For Professional
Use Only.

INDICATION FOR USE

VitaVitro® Straw Set is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human MII-phase oocytes, cleavage stage embryos and blastocysts.

PRODUCT DESCRIPTION

One straw set contains a straw and a container (Please refer to Figure 1). The Straw Set is a closed vitrification storage device that is used for holding human oocytes or embryos in the appropriate medium during the cooling, storage, and warming phases of vitrification. The straw is hermetically sealed within the container to avoid direct contact with liquid nitrogen and cross-contamination during the loading process.



Figure1. Container and straw

MATERIAL

Copolyester

PERFORMANCE

EO sterilization	SAL 10 ⁻⁶
Mouse Embryo Assay (1-cell)	≥80% development to blastocyst at 96 h
Bacterial endotoxins (LAL assay)	<0.5 EU/device

WARNING

- 1) The long-term safety of embryo cryopreservation is unknown.
- 2) Do not use the product if packaging is open, damaged, or tampered.
- 3) To avoid contamination, only use aseptic technique.
- 4) Do not reuse. Reuse may lead to contamination of cells.
- 5) Don't use the device beyond its shelf life.
- 6) The life time of the device is two years. Don't use the device beyond its life time. The risk of the device being used past the specified device lifetime is unknown.

PRECAUTIONS

- 1) The user should be a trained professional (e.g. a doctor or embryologist).
- 2) The user should read and understand the user manual and be properly trained to perform procedures using VitaVitro Straw Set.
- 3) Each Straw Set can store 1-3 oocytes or embryos. A new Straw Set will need to be used if more than this number of oocytes or embryos is to be stored.

- 4) The process of disposing of the device must follow the local infectious disposal law or laboratory rule.
- 5) In order to avoid cracking of the closed container after leaving liquid nitrogen caused by the internal gas expansion when temperature increases, the user should cut sealed end of the container before taking it out from the liquid nitrogen.
- 6) The user should wear gloves while using the straw set.
- 7) The user shall validate following sealing parameters of the heat sealer before clinical use: temperature 120-130 °C, time 2-3 seconds, width 3-10 mm.
- 8) The expected lifetime of the device is 2 years. The risk of using the device past the lifetime is unknown.

STERILIZATION METHOD

Ethylene oxide

SHELF LIFE

24 months

STORAGE CONDITIONS

Store at 10°C to 30°C. Keep away from sunlight.

EXPLANATION OF SYMBOLS

The symbol glossary is in line with the SDO-developed standard ANSI/AAMI/ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General requirements.

Reference number	Symbol	Title of symbol
5.1.1		Manufacturer
5.1.2		Authorized representative in the European Community
5.1.3		Date of manufacture
5.1.4		Use-by date
5.1.5		Batch code
5.1.10		Model number
5.1.11		Country of manufacture
5.2.3		Sterilized using ethylene oxide
5.2.8		Do not use if package is damaged and consult instructions for use
5.2.11		Single sterile barrier system
5.2.14		Single sterile barrier system with protective packaging outside
5.3.2		Keep away from sunlight
5.3.7		Temperature limit
5.4.2		Do not re-use
5.4.3		Consult instructions for use or consult electronic instructions for use
5.7.7		Medical device

REFERENCES

Survival, re-expansion and cell survival of human blastocysts following vitrification and warming using two vitrification systems

Ana S. Lopes

J Assist Reprod Genet. 2015, 32:83-90

Current progress in oocyte and embryo cryopreservation by slow freezing and vitrification

J Saragusty, A Arav

Reproduction. 2011, 141(1):1

Current trends, biological foundations and future prospects of oocyte and embryo cryopreservation.

AC Varghese, ZP Nagy, A Agarwal.

Reproductive Biomedicine Online, 2009, 19 (1):126-140

OTHER MATERIALS THAT ARE REQUIRED BUT NOT INCLUDED

- It is supposed to be used with Vitrification and Warming Kits manufactured by Shenzhen Vitavetro Biotech Co., Ltd. and Kitazato BioPharma Co., Ltd. as part of human ART procedures.
- Liquid nitrogen and Liquid nitrogen (LN₂) reservoir
- A rack to hold the straw set when in liquid nitrogen
- Temperature-controllable heat sealer
- Scissors
- Tweezers
- 10 µL automatic pipettes with the appropriate sterile tips

OPERATION PROCEDURES

The following procedures take the blastocysts for example. The procedures of cleavage embryos and oocytes are the same.

PREPARATION

Prepare blastocysts in media by referring to the Instructions for Use of the Vitrification Kit. A maximum of three blastocysts can be loaded into each storage straw in a maximum of one microliter of vitrification media.

LOADING AND COOLING

- 1) Open the sterile pack of Straw Set under aseptic conditions. Label the VitaVitro Straw Set with the patient's identification information or according to local regulations.
- 2) To prepare for vitrification, the container straw needs to be pre-cooled in liquid nitrogen for at least three minutes before loading the open-pulled straw (OPS). The closed end of the container straw should be placed in a rack in liquid nitrogen that keeps the container straw an upright position. The open end of the container straw must remain 3-4 cm above the liquid nitrogen to prevent contamination. (See Figure 2)

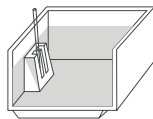


Figure 2. Rack in liquid nitrogen

- 3) When the blastocysts are ready, pipette a small vitrification medium droplet (~1 µL) containing blastocysts into the lid of a Petri Dish. Each droplet should contain no more than three blastocyst stage embryos.
- 4) Touch the droplet with the narrow end of the OPS. The media with the blastocysts will be automatically drawn into the tip of the straw (See Figure 3).

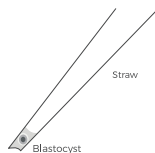


Figure 3. The blastocyst in the tip of the OPS

- 5) Without direct contact with liquid nitrogen, transfer the OPS into the pre-cooled container straw. Insert the narrow end of the OPS first. The blastocysts are now vitrified and should be kept in liquid nitrogen until you perform the warming procedure (See Figure 4).

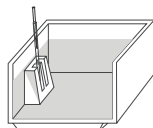


Figure 4. Transfer the OPS into the pre-cooled container straw

- 6) Manually seal the open end of the container straw using the temperature-controllable heat sealer. Inspect the seal and ensure that there are no holes, tears or other openings. (See Figure 5). Recommended sealer parameters: Temperature 120±5 °C, setup time 2-3 s.

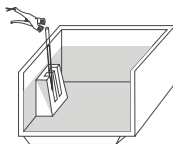


Figure 5. Sealing the container straw

- 7) Transfer the sealed container straw to the Dewar filled with liquid nitrogen (LN₂) (See Figure 6).

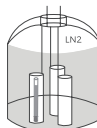


Figure 6. Dewar Filled with liquid nitrogen

WARMING

- 1) Collect the VitaVitro® Container Straw from Dewar and keep in liquid nitrogen (LN₂) box while ensuring the narrow end is fully immersed under liquid nitrogen.

- 2) Lift the sealed end of the container slightly about 5 ~ 6 cm above the liquid nitrogen (LN₂) level and cut it with scissors. The narrow end of the OPS in the container straw must remain well below the liquid nitrogen.
- 3) Use small tweezers to remove the wide end of the OPS from the container and hold it between your thumb and middle finger.
- 4) Remove the OPS, and within 3 seconds immerse the vitrified liquid column into the first warming medium. Observe the immersion process under the stereomicroscope until the vitrified column melts and warming medium enters the straw.
- 5) Immediately cover the open end of the OPS with your index finger (refer to Figure 7). The medium will flow out from the OPS as a result of the increased pressure of the warming air inside the OPS. If the medium remains in the straw, use a 10 µL micropipette to expel air into the wide end of the OPS to eject the liquid.
- 6) Subsequent processing of the blastocysts should follow the Instructions for Use provided with the warming kit used.



Figure 7. Cover the open end of the OPS with index finger

The clinical benefits of this device are significant and can have a positive impact on assisted reproductive technologies. Here are some potential clinical benefits:

- 1) Enhanced Fertility Preservation: IVF cryopreservation tools allow for the freezing and preservation of eggs, sperm, or embryos. This is particularly beneficial for individuals or couples facing fertility challenges due to medical treatments (such as cancer therapies) or age-related fertility decline. These preserved reproductive materials can be used in the future, increasing the chances of a successful pregnancy.
- 2) Reduced Treatment Cycles: Cryopreservation can reduce the need for repeated IVF cycles, which can be emotionally and financially taxing for patients. With frozen embryos or gametes readily available, patients may undergo fewer stimulation and retrieval procedures.
- 3) Minimized Ovarian Stimulation: IVF cryopreservation tools can help minimize the need for extensive ovarian stimulation, reducing the risk of ovarian hyperstimulation syndrome (OHSS) and other potential complications associated with fertility treatments.
- 4) Fertility Preservation for Medical Reasons: For individuals facing medical conditions or treatments (such as chemotherapy or radiation) that may affect their fertility, cryopreservation provides the option to preserve their reproductive potential for the future.



Shenzhen VitaVitro Biotech Co., Ltd.
R601, Building B, Hai Ke Xing Tech Park,
Baoshan Road No.16, Pingshan District,
Shenzhen, Guangdong, China 518118
Phone: +86 755 84511813
Service hotline: +86 755 84511813
(MON-FRI 9:00 to 17:00 CDT)
www.vitavitro.com

EC REP MedNetEC-REP C III GmbH
Borkstrasse 10, 48163 Münster, Germany

The electronic IFU (e-IFU) of the device is identical to the hardcopy and can be found via the link: www.vitavitro.com
Any serious incident that has occurred in relation to the device could be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

Doc. No.: IU01201709002

Rev. No.: 02

Initial Issue Date: March 19, 2020

Last Revision Date: May 28, 2024