



VitaVtro

VitaVtro® Straw Set User Manual

VitaVtro® Straw Set in sterilized packet



CAUTION

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

INDICATION FOR USE

VitaVtro® Straw Set is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human blastocyst stage embryos.

PRODUCT DESCRIPTION

One straw set contains a straw and a container. The Straw Set is a closed vitrification storage device that is used for holding human blastocysts in the appropriate medium during the cooling, storage, and warming phases of vitrification. The straw component is hermetically sealed within the container during the loading process to avoid direct contact of samples with liquid nitrogen (LN₂) to avoid contamination.

MATERIAL

Copolyester

WARNING

- 1) The long-term safety of embryo cryopreservation is unknown.
- 2) Do not use any product which shows evidence of packaging damage or tampering, or is broken.
- 3) To avoid contamination, only use aseptic technique.
- 4) Do not reuse.

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
Cooling rate	5.127°C/min
Warming rate	17.899°C/min

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 trained in the correct procedures before using VitaVtro® Straw Set.
- 3) Each Straw Set can store 1-3 blastocysts. A new Straw Set will need to be used if more than this number of blastocysts is to be stored.
- 4) In order to avoid cracking of the closed container after leaving liquid nitrogen caused by the internal gas expansion when temperature increasing, the user should cut sealed end of the container before taking it out from the liquid nitrogen and should not let the liquid nitrogen into the container straw before sealing.

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

- Cleared vitrification and warming medium indicated for use in vitrifying/warming human blastocyst stage embryos are needed to complete vitrification and warming procedures. The VitaVtro® Vitrification Kit and the VitaVtro® Warming Kit that are sold separately from the Straw Set are cleared medium indicated for vitrification and warming of human blastocyst stage embryos
- LN₂ and box
- A rack to be used for holding straw set when in liquid nitrogen
- Heat sealer
- Scissors
- Tweezers
- 10 µL automatic pipettes with the appropriate sterile tips

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	Description of symbol
5.3.2		Keep away from sunlight	Indicates a medical device that needs protection from light sources.
5.4.2		Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.1.1		Manufacturer	Indicates the medical device manufacturer.
5.1.3		Date of manufacture	Indicates the date when the medical was manufactured.
5.3.7		Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
5.1.4		Use-by date	Indicates the date after which the medical device is not to be used.
5.1.5		Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.2.3		Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.

STERILIZATION METHOD

Ethylene oxide

SHELF LIFE

24 months

STORAGE CONDITIONS

Store at 10°C to 30°C, keep away from sunlight.

PREPARATION

Follow the preparation of blastocysts in the Instructions for Use of the vitrification medium used. A maximum of three blastocysts can be loaded into each storage device in a maximum of one microliter of vitrification medium.

LOADING AND COOLING

- 1) Open the sterile pack of Straw Set under aseptic conditions. Label the VitaVibro® Straw Set with the patient's identification information or according to local regulations.
- 2) To preparation for vitrification, the container component needs to be pre-cooled in liquid nitrogen for at least 3 min before loading the straw component. The closed end of the container component should be placed in a rack in the liquid nitrogen container that is able to maintain the container in an upright position. The open end of the container must remain 3-4 cm above the surface of the LN₂ to prevent contamination of the interior of the container.

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

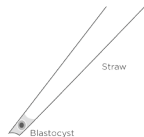


Figure 1. The blastocyst in the tip of the straw

- 5) Without direct contact with LN₂, insert the narrow end of the straw containing the blastocysts into the pre-cooled container. The blastocysts are now vitrified and should be kept in LN₂ until the warming procedure is performed.
- 6) Seal the open end of the container using the hand-type heat sealer. Inspect the seal to ensure that sealing was correctly performed. Make sure that the seal is complete and that no holes or defects are present.
- 7) Transfer the sealed straw to the Dewar filled with LN₂. (See Figure 2).

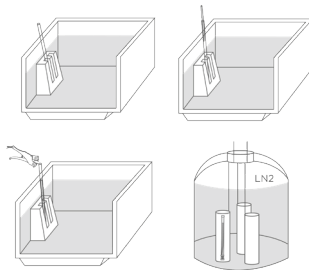


Figure 2. Cooling and sealing

WARMING

- 1) Collect the VitaVibro® Straw from Dewar and keep in LN₂ box while maintaining the tip region fully immersed under LN₂.
- 2) Lift the sealed end of the container slightly about 5 ~ 6 cm above the surface of LN₂ and cut the sealed end with scissors. The narrow end of the straw in the container must remain well below the LN₂.
- 3) Use small tweezers to remove the wide end of the straw from the container and hold it between your thumb and middle finger.
- 4) Remove the straw, and immerse the vitrified liquid column into the first warming medium within 3s. 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 straw with your index finger (refer to Figure 3). The medium will flow out from the straw as a result of the increased pressure of the warming air inside the straw. If the medium remains in the straw, use a 10 µL micropipette to expel air into the wide end of the straw to eject the liquid.
- 6) Subsequent processing of the blastocysts should follow the Instructions for Use provided with the warming medium used.



Figure 3. Cover the open end of the straw with index finger

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