IFU SafeSpeed Warming Media kit

Intended use

SafeSpeed Warming Media is designed for ultra-rapid warming of human oocytes and embryos previously cooled by vitrification.

Products for warming included in the kit:

1 x Vial 1 (2ml): Thawing Solution (TS)
1 x Vial 2 (2ml): Diluent Solution (DS)
1 x Vial 3 (2ml): Washing Solution (WS)

Other materials needed for warming not included in the kit:

- Vitrification straws (with the samples)
- Metal clamps
- Sterile Petri dish, suitable for embryology use
- Liquid Nitrogen container (15 cm depth)
- Container for sterile water
- Water bath (capable to maintain 37 °C)
- Aspiration system (Stripper Pipette) *
- Sterile absorbent paper
- Connector: SafePreservation provides a compatible specific connector for all aspiration systems
- Microscope
- Stopwatch or timer
- Micropipette (100-1000 µL)
- Straw cutter: sharp scissors

***Note**: *Use a pipette with an internal diameter suitable for the oocytes or embryos. Capillaries of 170 µm are recommended for vitrification of oocytes and embryos, capillaries of 200 µm for early blastocysts (up to type 3 according to Gardner or ASEBIR classification) and capillaries of 290 µm for expanded blastocysts. This makes possible to optimize the volume of the solutions to achieve the best dilution condition and obtain a high survival rate*.

Chemical composition

Base components (Vial 1: Washing Solution – WS)

Phenol Red	Na-Pyr	NaOH	Sucrose
PBS	HPC	HCl	

Vial 1: Thawing Solution (TS)
Sucrose 1 M

Vial 2: Diluent Solution (DS)
Sucrose 0.5 M

Quality Control testing

Each solution of the SafeSpeed Warming Media kit is sterilized by filtration and confirm a sterility assurance level (SAL) 10-6.

Each lot of SafeSpeed Warming Media is tested for:
Endotoxins by LAL methodology ≤ 0.5 EU/ml
Mouse Embryo Assay (one-cell) ≥ 80 % expanded blastocyst after 96 h
Sterility test according to UNE EN ISO 11737-2
pH test: 7.2-7.6

All results are reported on a lot specific Certificate of Analysis which is available upon request.

Storage Instructions and Stability

The products are aseptically processed and supplied sterile.

The solutions should be stored in their original, unopened vial and refrigerated at a temperature between 2-8 °C protected from (sun) light. Do not use media that have not been store under these conditions. When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

The product is supplied in single-use vials.

Do not freeze before use.

Warnings and precautions

- Read the instructions for use before using the product.
- Do not re-sterilize.
- Do not re-use. This product is for single use and not to be reused due to the risk of contamination and infection.
- Not injectable.
- Do not use any vial if shows evidence of damage, leaking, suspended particles, turbidity, or has changed colour. Discard the product in accordance with the applicable standards.
- The product should not be used if the sterile package is found to be incomplete or open.
- Do not use and discard the product if it has passed its expiry date.
- Dispose of excess (not used) after warm-up.
- Each media is for same patient use.
- This product is intended to be used by professional trained personal in assisted reproductive techniques that includes the intended application for this product.
- To avoid contamination problems, aseptic handling techniques should be used.
- Additional precaution, it is recommended to carefully examine the vitrification straw when removing it from its package and check it does not show cracks or ruptures.
- Dispose the product as residual and non-reusable solutions.
- Dispose the containers and packaging as indicated to containers with solutions inside.
- It is recommended to use sealed vitrification instruments.

- Currently, clinical research literature indicates that the long-term effects of vitrification on oocytes and embryos, and on new-born infants born after cryopreservation remain unknown.
- The User facility of this device is responsible for maintaining product traceability and must comply with national regulations regarding traceability, where applicable.
- It is strongly recommended that the patient's name and the batch number of the SafeSpeed Media product being administered be recorded to ensure the patient-product relationship. Vecmedical Spain S.L. will keep the information regarding the product batch for 20 years.

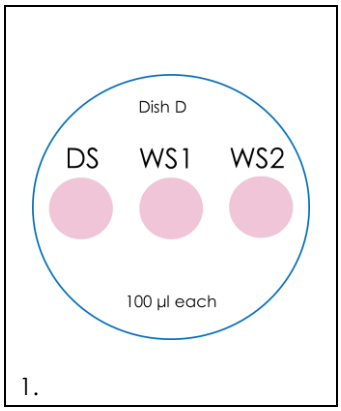
Contraindications

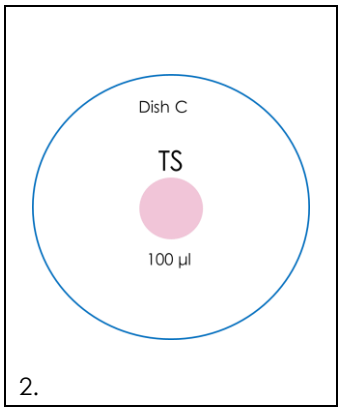
This product contains Ethylene glycol (EG) and dimethyl sulfoxide (DMSO), the user must take the necessary precautions to ensure that the patient is not sensitive to any of these components.

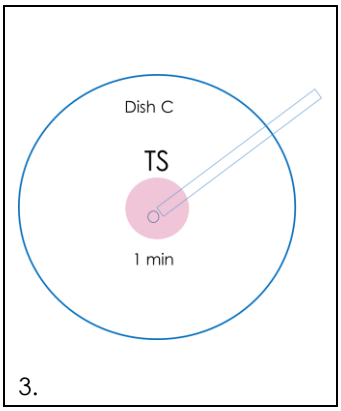
Instructions for use

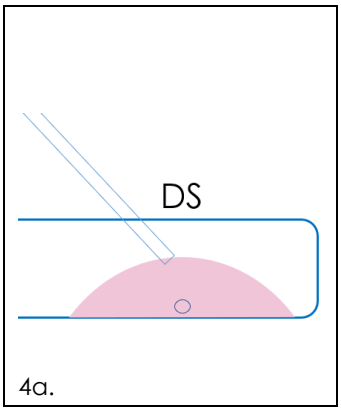
Make sure that all media have their content homogenized before using them by gently inverting them twice. It is recommended to read all the steps of the vitrification procedure before starting the process.
The process should be performed at room temperature (~22-24 °C).

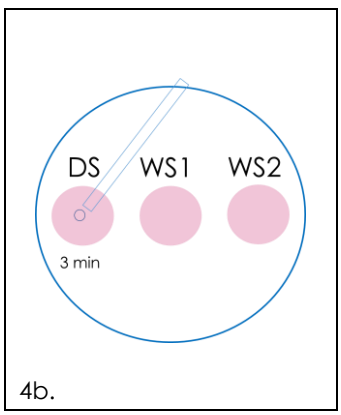
Illustrations

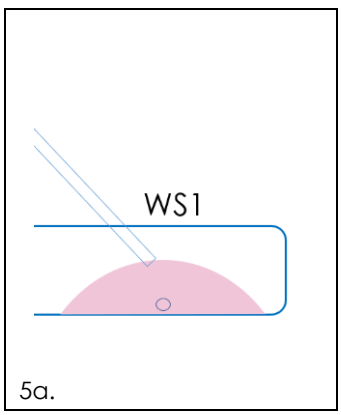


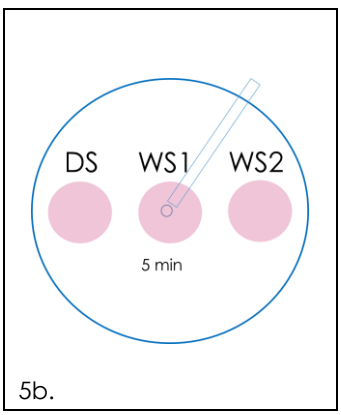


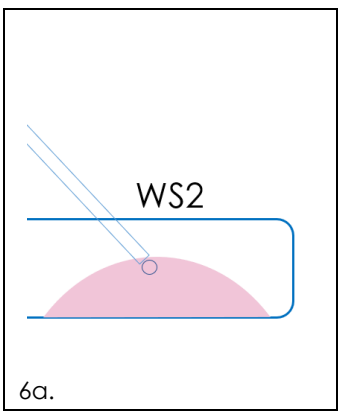


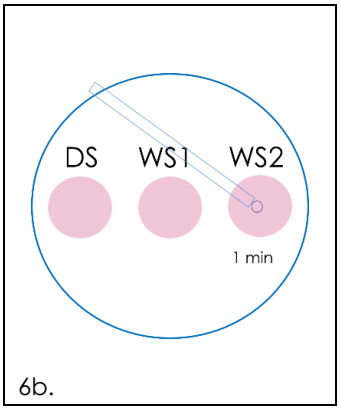




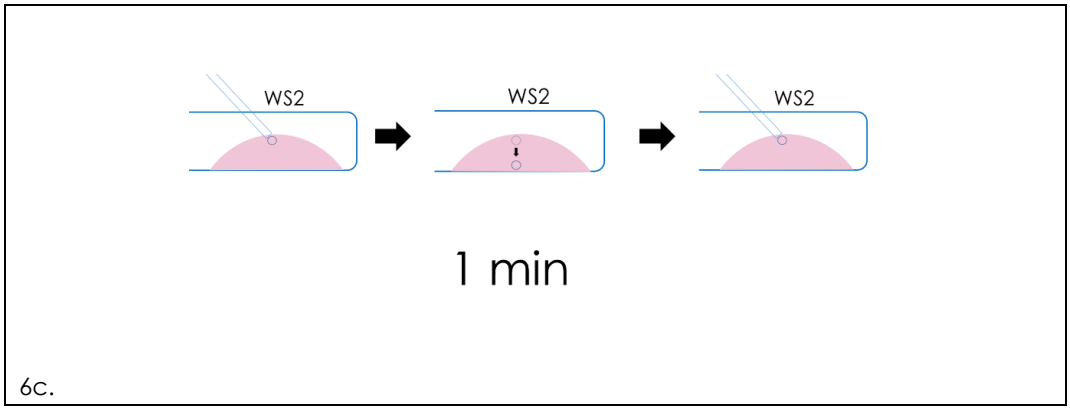








6b.



6c.

Preparation for warming

1. Heat the TS vial (sealed) and a Petri dish (dish C) in an incubator at 37 °C (> 1.5 hours) or in a CO2-free oven (do not heat on a hot plate).
2. Expose vials with DS and WS solutions to room temperature at least one hour before use.
3. Label DS, WS1 and WS2 on the petri dish cover (dish D).
4. Gently invert each vial of DS and WS twice to help homogenize their contents.
5. Using a micropipette, form the following three drops on the dish D: one drop of 100 µL from DS on the DS mark, one drop of 100 µl from WS on the WS1 mark and one last drop of 100 µl from WS on the WS2 mark (See illustration 1). Place the dish D on the microscope and cover it.
6. Prepare the sterilized water bath (at least 15cm deep) at 37 °C as close as possible to the liquid nitrogen container that will contain the vitrification device with the samples.
   Note: It is recommended to use the SafeBox (SafePreservation S.L., Spain) to facilitate the warming process.
7. Take the TS vial and the Petri dish C from the incubator. Place the Petri dish C in the microscope, and gently invert the TS vial twice to help homogenize its contents and form a drop of 100 µL TS on the Petri dish C (See illustration 2).
8. Adjust the focus of the microscope to the Petri dish C with the TS. Fill 90 % of the container with liquid nitrogen.

Warming

CAUTION: Use metal clamps to avoid direct user contact with the liquid nitrogen.

9. Remove the vitrification device with the samples to be warmed from the storage tank and transfer it to the container with liquid nitrogen.
   CAUTION: In this process it is essential that the samples are always covered by liquid nitrogen.
10. Set the timer. Use the timer to control the next steps that require it.
11. Aseptically, select the vitrification straw with the samples and prepare it according to the instructions for use of the device.
    CAUTION: Make sure that the capillary with the samples is constantly immersed in liquid nitrogen during handling.

12. Rapidly (< 1 second), remove the vitrification straw with the samples as vertically as possible and in the same position transfer it to the water bath, immersing it and shaking it for 2 seconds to improve heat transfer.
    CAUTION: Avoid hitting the walls and bottom of the container with the device, it could break.
13. Immediately and carefully clean off any remaining water at the tip of the capillary with sterile absorbent paper.
14. Gently eject the oocyte/embryo from the vitrification straw using the aspiration system within 100 µL of TS, avoiding the creation of air bubbles, as it would be easy to lose the oocyte/embryo or even compromise its viability. The maximum duration of exposure of the oocyte/embryo in the TS is 1 minute. If possible, carry out several washings to remove any residue of VS with a micropipette of appropriate diameter, without touching or introducing it into.

Note: it is important that the connection to the aspiration system does not introduce air pressure into the vitrification device that could displace the oocyte/embryo downwards.

Dilution

15. Aspirate with the pipette tip the oocyte/embryo with a small volume of TS and gently place it at the bottom of the drop of 100 µL from DS of the dish D. Leave it for 3 minutes (See illustration 4a-b).

Washing

16. Aspirate the oocyte/embryo from the DS with a small volume of DS, and gently place it at the bottom of the 100 µL drop of WS1. Leave it for 5 minutes (See illustration 5a-b).
17. Aspirate the oocyte/embryo with the minimum volume of WS1 with the pipette tip and transfer it onto the drop surface of 100 µL of WS2 (See illustration 6a-b).
18. When the oocyte/embryo falls to the bottom of the WS2 drop, repeat the work on the WS2 drop. For one minute (See illustration 6c).
19. Transfer the oocyte/embryo to a culture plate with the appropriate culture medium. Incubate the oocyte/embryo in a CO2 incubator at 37 °C for complete recovery before microinjection/transfer.

Note: *a two-hour recovery of the oocyte/embryo is recommended*.

Symbols explanation

Symbol	Description
CE 0318	(European Conformity)
	Symbol "DO NOT REUSE"
	Symbol "DO NOT RESTERILIZE"
	Symbol "DO NOT USE IF PACKAGE IS DAMAGE"
	Symbol "USE-BY DATE"
LOT	Symbol "BATCH CODE"
STERILE A	Symbol "STERILE USING ASEPTIC PROCESSING TECHNIQUES" (BY FILTRATION)
REF	Symbol "CATALOG CODE"
	Symbol "CAUTION".
	Symbol "CONSULT INSTRUCTIONS FOR USE"
	Symbol "TEMPERATURE LIMIT"
	Symbol "MANUFACTURER"

The Safety Data Sheet is available to the user.
Please contact the manufacturer for the MSDS.

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DISTRIBUTED BY: SafePreservation S.L.

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