Réf. 025322

Cryo Bio System
Groupe I.M.V. Technologies

CBS™ HIGH SECURITY VITRIFICATION STRAW

Cryopreservation device for vitrification of embryos at all stages.

Precautions

- The user should read the entire Instructions for Use before using the High Security Vitrification straws. The vitrification and thawing techniques involve multiple stages that must be mastered in order for them to be performed rapidly. People using this device should be qualified, especially for AMP laboratory Best Practices. Training in all these steps without viable biological material is essential to perfect techniques and prevent damage to the biological sample, spillage of liquid nitrogen or any accidental thawing/freezing that could be harmful to the sample.

- *For the USA:* Federal Legislation restricts the sale of this equipment to a prescription from a doctor or a practitioner trained in its use.

- The safety of embryo vitrification and the long-term consequences for children born as a result of this technique are as yet unknown.

Warnings

- For the USA: HSV straws must only be used in association with United States approved vitrification media.

- The volume of the drop containing the biological sample must be as small as possible and must never exceed 0.5µl in order to prevent any contact with the surrounding straw.

- The HSV straw is a single-use device for the vitrification of a single and unique biological sample per straw.

- Do not use the product if the packaging is damaged or open as the sterility and integrity of the product can no longer be guaranteed.

- Use under strict observance of aseptic techniques.

- Store in a clean, dry place, away from light and heat sources.

- HSV straws are designed to avoid all contact between the biological sample to be vitrified and liquid nitrogen, under normal conditions of use. Nevertheless, all procedures relating to the handling of liquid nitrogen and the prevention of liquid nitrogen contamination should be followed. People should be qualified to LN2 handling according to local regulations.

Avoid any spillage of liquid nitrogen or contamination through spray of droplets containing the biological samples or surfaces of the device or solutions in which the biological samples will later be placed.

Description

The physical properties and method of sealing HSV straws guarantees that they remain sealed when immersed and stored in liquid nitrogen, with no direct contact between the biological sample and the liquid nitrogen. After storage, the HSV is opened and the droplet containing the biological sample is immersed in the warming solution.
HSV straws are for single usage and are packed in 4 individual peel-off blisters placed in an outer peel-off bag, then sterilized by irradiation. The packaging, designed to provide a "double sterile barrier", facilitates transfers into aseptic working areas.

The HSV high security vitrification straw is made up of three distinct parts:

- A colored handling rod/gutter assembly with the following specifications: Gutter with clear groove combined with a colored handling rod. The groove is concave, with an internal diameter of around 0.7mm. The colored handling rod is designed to facilitate identification (available in white, blue, red, green, yellow and pink) and can be connected to a blue plastic introduction device.

- Blue plastic introduction device. It enables the colored handling rod/gutter assembly to be inserted into the straw to optimum depth, which is around 1mm from the clear resin plug separating the ballast compartment from the "biological sample" compartment of the straw.
It is not in any way a gripper system for the handling rod/gutter.

- The HSV transparent straw featuring one open, flared end and one sealed end. The flared end ensures a clean introduction of the colored handling rod/gutter assembly.
The distal end (opposite to the flared end) is pre-sealed and weighted with a small tab of stainless steel, separated from the biological compartment by a clear resin plug. After the introduction of the colored handling rod/gutter assembly, the HSV straw is sealed using a special sealing device from the SYMS® range.

Essential equipment not included:
- Sealing device (Only heat sealing device from the SYMS® range have been approved as compatible)
- Tweezers
- Liquid nitrogen container (minimum depth: 130mm)
- Liquid nitrogen
- Opening tool

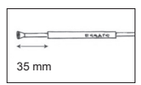
Quality Assurance

Every batch of HSV straws undergoes the following tests:

- Endotoxin level using LAL method (<1 EU/unit)

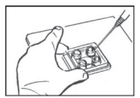
- MEA test. (> 80% expansion rate to blastocysts in 96 hours).

Instructions for filling and sealing the HSV straw



1. Prepare a liquid-nitrogen resistant identification label for the HSV straw no longer than 40mm, and place it around 35mm from the flared end. Placed in this way, the label will not fully cover the colored rod or the biological sample compartment.

2. If you wish to connect the end of the blue introduction device to the colored rod end of the colored handling rod/gutter assembly, ensure the fingertips are very close to the tab opening on one side and the tip of the blue introduction device on the other.
The introduction device must not be used as a gripping device for the gutter: it must be held at the rod's tip.

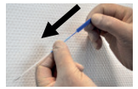


3. Prepare the sample to be vitrified according to current laboratory protocol and the recommendations of the supplier of the vitrification medium.

Caution: The time between the final vitrification bath and immersion in liquid nitrogen must not exceed that indicated by the supplier of the vitrification medium. This should be taken into account for the execution of steps 4 to 8.

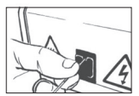
4.Using a micropipette and binocular microscope, carefully place the biological sample to be vitrified into the groove, at least 1mm from the distal end. The volume of the drop containing the biological sample must be as small as possible and can never exceed 0.5 µl, in order to prevent any contact with the surrounding straw.

The HSV straw is designed to receive a single biological sample.



5. If it is not pre-connected, use the blue introduction device to push, if it is pre-connected, immediately insert the colored handling rod/gutter assembly into the HSV straw through the flared end and continue inserting it smoothly until the edge of the introduction device touches the flared end of the straw.

6. Gently pinch the straw between thumb and index finger at the level of the colored rod and remove the introduction device.



7. Then seal the open end of the straw using a sealing device from the SYMS® range.

Check the aspect of sealing.

Vitrification

8. Gently hold the straw with tweezers at the level of the colored rod and insert it immediately, vertically and fully into the liquid nitrogen. Keep the straw immersed, rotating it for several seconds to prevent the formation of an insulating layer of air.

Cryopreservation in liquid nitrogen

The transfer of vitrified straws from the vitrification bath to the storage containers must always be carried out in liquid nitrogen in order to avoid any accidental warming.

Warming

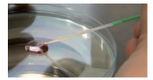
Sample warming procedures must be carried out in the controlled environment of a laminar airflow hood.

1. Prepare the warming and dilution media according to current laboratory protocol and the recommendations of the media supplier.

2. Using tweezers, transfer the selected straw from the storage container to a transportation container filled with liquid nitrogen in order to avoid any accidental warming.

3. Using the tweezers, lift the straw sufficiently to expose the colored rod, ensuring that the distal end of the straw, containing the biological sample always remains immersed in the liquid nitrogen, including during step 4.

4. Hold the straw in two or three fingers and cut it open using an opening tool at the level of the colored rod, in a place not covered by the label. Holding the opened section of the straw, grasp the colored handling tab and remove the colored handling rod/gutter assembly by sliding it out backwards.



5. Next, insert horizontally the end of the groove without excessive pressure in the first drop of warming solution (in compliance with the volume and temperature recommended by the vitrification media supplier). Move it around gently to ensure the sample is properly transferred to the solution.

Disposal after use

After retrieving the sample, dispose of this device in compliance with local directives on disposal of contaminated medical waste.

Date of first CE marking: 2006

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REF Reference
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Manufacturer
Use by
STERILE R Sterilized by irradiation
Single use
See Instructions for use
Do not use if package is damaged

Edition: 11/2018
IFU-000012-D