



Instructions for use

CBS™ HIGH SECURITY SPERM STRAW
for cryopreservation of sperm

Caution

- The user should read the entire Instructions for Use and understand the Cautions and Warnings and be trained in the correct procedure before using the CBS™ High Security sperm straw. People using this device should be qualified, especially for ART Laboratory Best Practices.
 - Cryopreservation and thawing procedures involve multiple steps that must be done quickly and smoothly. Repeated practice of all steps without viable samples is highly recommended to perfect techniques and prevent inadvertent thawing/freezing or loss of biological samples.
 - Guarantee of the cryogenic resistance of the CBS™ High Security sperm straws in liquid nitrogen depends on strict compliance with the instructions for use of the CBS™ filling nozzle and the equipment and sealers referred to in these instructions.
- For the USA only: Federal legislation restricts the sale of this device to a prescription from a doctor or a practitioner trained in its use.

Introduction

The physical properties and the method of filling and sealing CBS™ High Security sperm straws ensure a leak-proof environment after sealing for cryopreservation through freezing of human sperm, especially in liquid nitrogen. Manufactured with biocompatible materials, the CBS™ High Security sperm straw is designed for use in Assisted Reproduction Technologies, particularly for cryopreservation of sperm.

Warning

The CBS™ High Security sperm straw is a sterile single-use device.

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

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

Cryo Bio System recommends using the CBS™ High Security sperm straws in a controlled environment, such as a laminar flow hood.

Description

The CBS™ High Security sperm straw is a flexible, transparent tube made of non-toxic ionomeric resin, 133 mm long and 2.50 mm in internal diameter. The CBS™ High Security sperm straw can be autogenically sealed using the SYMS type sealer, PACE, MAPI or DIVA equipment, specifically designed for this purpose by Cryo Bio System.

CBS™ 0.3 mL straw

This straw is composed of two distinct sections separated by a white safety plug. The first section is designed to hold the sperm sample and has a useful volume of 0.3 mL. The second section, on the opposite side of the useful volume, allows for manipulation and identification of the straw. For use with PACE or MAPI, CBS™ High Security 0.3 mL straws are provided with fixed colored identification rods and white external jacket.

CBS™ 0.5 mL straw

The section designed to hold the sperm sample has a useful volume of 0.5 mL. The external part of the sliding security plug is colored.

A. Identification (traceability)

The biological sample must be identified according to laboratory protocols. Depending on the straw reference used, it is possible to:

- Identify by printing (with MAPI machine) or manually identificate (with a nitrogen-resistant ink pen) on the white jacket.
- Identify by sticking a nitrogen-resistant label on an identification rod which will be introduced in the straw on the unused side. After sealing the straw, the identification is then inviolable (step B.5).
- Identify by sticking a nitrogen-resistant label on the outside of the straw (without jacket).

B. Manual filling and sealing

For sperm storage with a view to specific applications such as intrauterine insemination or in-vitro fertilization (IVF), CBS™ High Security sperm straws are filled individually using a specific sterile filling nozzle and a micro-aspirator or a syringe equipped with a special connector.

The SYMS sealer assures an impermeable seal.



1. Attach a sterile filling nozzle to the straw at the opposite end from the plug. A characteristic «click» can be felt and/or heard when the nozzle is correctly fitted.

2. Attach micro-aspirator or a syringe equipped with a special connector on the plug end. Load the prepared semen. The biological sample should rise through the first cotton and up to half of the powder.



3. Gently withdraw the filling nozzle by twisting it, avoiding any shaking movements in order to keep the end of the straw free of semen.

4. Seal the released extremity with a SYMS type sealer, holding the straw near the sealing jaws.

5. Seal the other extremity as indicated above with a SYMS type sealer.

B'. Automatic filling and sealing

For large-scale application (for example, sperm banks), the CBS™ High Security sperm straws are filled with PACE, MAPI or DIVA automated filling and sealing machines using a purpose-designed injection and aspiration nozzle. Consult the relevant user's guides.

C. Freezing

Once the straw is filled and sealed on both sides, freeze according to laboratory regulations and refer to the user manual of the equipment used. Staff should be qualified to handle LN2 according to local regulations.

D. Storage in liquid nitrogen

A full line of storage containers provides versatility for the inventory management of CBS™ High Security straws in liquid nitrogen: visotubes, goblets and canisters in different colors and/or dimensions are currently available. It is essential not to break the cold chain in order to guarantee the integrity of the biological sample.

E. Thawing

In order to prevent samples from thawing, CBS™ High Security straws should be kept in liquid nitrogen.

1. Prior to removing it from its stored location, check the identity of the straw by the color of its plug or its identification rod and/or by the alphanumeric code, and/or by the barcode.
2. Carefully remove the straw from the storage visotube using a pair of tweezers.
3. Thaw the straw by immersion in warm water (+37°C maximum) for about 30 seconds.
4. Make sure to proceed with the thawing one straw at a time in order to preserve traceability.

Usage in Intra-uterine insemination / In-vitro fertilization

1. Prepare the working area and the receptacle (Tube, Petri Dish) previously identified according to the straw, based on the destination of the biological sample and the protocol used in the laboratory.
2. After having wiped and decontaminated the straw, empty the straw by capillarity, cutting the sealed ends first on the rod side and then on the biological sample side under the plug using a dry disposable scalpel or disinfected scissors and remove the biological sample.

Quality assurance

Cryo Bio System products are manufactured from biocompatible materials and designed for Assisted Reproduction Technologies. Sterilization is done by irradiation.

Each lot of CBS™ High Security sperm straws receives the following tests: endotoxin and MEA.

Shelf-life

Three years of shelf-life (see date mentioned on the label).

Disposal after use

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

First CE marking: 1998



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Do not reuse

Notice must be read

Do not use if package is damaged