

Instructions for use Sterile CBS™ High Security Tube

Intended use

The sterile CBS™ High Security tube is designed for the long-term cryogenic storage of biological samples. Made from virgin-grade ionomeric resin, the tube is designed to be thermally sealed airtight after filling. Once sealed, sterile CBS™ High Security tubes can be cooled down to cryogenic temperatures in compressor controlled freezers or nitrogen vapor freezers, or by complete immersion in liquid nitrogen.

Cautions

The user must read the entire Instructions for Use before using the sterile CBS™ High Security tube. Personnel using this device must be qualified, especially in Laboratory Best Practices. Cryopreservation and thawing procedures involve multiple steps that must be done quickly and smoothly. Repeated practice of all steps without viable biological samples is highly recommended to perfect the techniques and avoid harming the biological sample to be frozen.

Guaranteeing the cryogenic resistance of sterile CBS™ High Security tubes depends on strict compliance with the instructions for using them and the CBS accessories and sealing machine named in these IFU.

Warnings

This device is a single use device.

- Sterile CBS™ High Security tubes contain a maximum volume of 1.2 ml of liquid (biological fluid and/or medium) in order to leave sufficient space for volume expansion in the freezing process.
- Do not use if the packaging is open or damaged, as the sterility and/or integrity of the product can no longer be guaranteed.
- To avoid all risks of contamination,

handle this product using aseptic techniques.

- Store and transport at ambient temperatures not exceeding 40°C. Protect from sources of light and heat.
- CBS™ High Security Tubes are designed to prevent the biological sample from coming into direct contact with the liquid nitrogen provided that they are used correctly. Nevertheless, follow all established procedures for liquid nitrogen handling and prevent risks of contamination. Pathogen viruses have been shown to survive in liquid nitrogen. Prevent any splashing of liquid nitrogen or aerosolized liquid nitrogen on equipment or surfaces with which biological samples are likely to come into contact.
- Personnel must be qualified in nitrogen handling according to local regulations. Wear protective equipment, particularly for the face and hands, in all manipulations involving liquid nitrogen and when opening tubes withdrawn from liquid nitrogen storage.

Description

Sterile CBS™ High Security tubes are available in strips of 20 peel-off blister packs or in bags of 50 tubes, and are radiation sterilized. This packaging method provides a double barrier to facilitate transfer into aseptic work areas.

The physical properties of the sterile CBS™ High Security tube, combined with the filling and sealing method used, provide a completely airtight environment allowing the immersion and storage of biological samples in liquid nitrogen without any direct contact between the sample and the liquid nitrogen.

Instructions

Filling: The sterile CBS™ High Security Tube has a slightly flared opening that facilitates filling without contaminating the thermal seal area. If this area becomes contaminated, the quality of the seal and its ability to withstand cryogenic storage conditions cannot be guaranteed. Should there be any droplets on the inner surface of the sealing area, wipe and dry it with absorbent paper. Make sure the area is clean and dry before sealing.

Sealing: Thermal sealing must be performed

with a SYMS III thermal sealer (Ref 025547 Cryo Bio System, France) with its touch screen in automatic or manual mode and settings selected for sterile High Security tubes. Sealing with any device other than a SYMS III is strongly discouraged, as the integrity and resistance of the sealing area cannot be guaranteed.

Freezing: When freezing the tube in liquid nitrogen, take care to plunge the tube directly and completely into the liquid nitrogen bath by holding it with forceps or simply by clipping it to a cane. Do not let the tube float on the surface of the liquid nitrogen in the freezing process.

Storage: sterile CBS™ High Security tubes can be stored on aluminum canes or in cryogenic storage boxes, in ultra-low temperature freezers (-70°C and lower), or in vapor or liquid nitrogen vessels (-196°C).

Identification: sterile CBS™ High Security tubes can be identified with adhesive labels designed specifically for use in cryogenic conditions. For good adherence the label should wrap over itself around the tube. Colored or white inserts with a 2D code can be clipped to the base of CBS™ High Security tubes to aid identification. RFID tags can also be inserted (on request).

Warning: For warming, withdraw the selected tube from its storage rack and reheat / thaw according to the laboratory protocol.

Opening: Open the tube by cutting with special curved scissors, positioning the blades in the area between the thermal seal and the body of the tube. To avoid any risk of contamination, place a fingertip over the top of the tube before opening. Wear protective equipment, e.g. face mask and gloves, to avoid risks of contamination through splashing of biological sample droplets. Sterile CBS™ High Security tubes can also be emptied using a hypodermic needle (19G or 21G) and syringe, by piercing through the circular areas indicated for this purpose.

Quality Assurance

Sterile CBS™ High Security Tubes are sterilized by irradiation. Each batch undergoes MEA and endotoxin testing.

Shelf life

Three years from date of manufacture (see date stated 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: 2012

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