

AN ASEPTIC CLOSED VIAL SYSTEM FOR CRYOPRESERVATION AND STORAGE OF BIOMATERIALS

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Current good manufacturing practices recommend the cryopreservation storage of cell therapy products in a closed system to prevent any possible contamination or infection during freezing, storage, thawing and shipping. We recently developed and tested a new kind of closed sterile cell cryopreservation device (CCD) for the robust prevention of microorganism and a secure control over sterility during routine cryopreservation and storage of clinically relevant cellular products at cryopreservation temperatures.

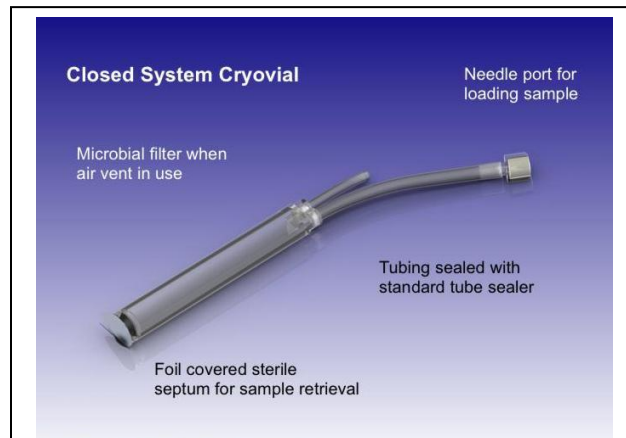


Figure 1: Closed System Cryopreservation Device (CCD)

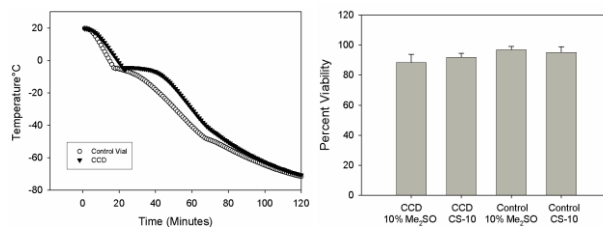


Figure 2: A: Temperature-Time history experienced by the cells in CCD and Corning™ cryo-vials when 10%DMSO was used as CPA. B: The post-thaw viability of DPSCs in CCD and control vials (Corning™ vials) when cryopreserved with 10%DMSO and Cryostor™ (CS-10) as CPAs

The design of the CCD has two ports: One port consists of a needle septum at the end of a length of tubing integrally attached to the vial body. This needle septum port is sealed after introduction of the sample into the CCD by standard blood bag tubing sealer. The second port is a foil covered sterile septum at the bottom of the device that can be used to extract the stored products using a sterile syringe. The drawing in Figure 1 shows a concept of the CCD.

Mesenchymal stem cells from dental pulp (DPSCs) and endometrium (ERCs) were used as a test to validate of the CCD. The temperature-time history experienced by the cells in CCD during dump freezing in a -85°C freezer were compared with that of cells in routinely used Corning cryo-vials (Figure 2A). The thawing rates experienced by the cells in a 37 °C water bath were also compared. The data suggested that although the cells were subjected to different cooling/thawing rates at different time points in both CCD and Corning cryo-vials, the average cooling/thawing rates experienced by them were statistically similar. Furthermore, the preliminary analysis showed no significant variation in immediate post-thaw

viability of DPSCs and ERCs cryopreserved in CCD when compared to Corning cryo-vials (Figure 2B). For all the cryopreservation experiments, both 10%DMSO and 10%Cryostor (CS-10) (Biolife solutions, USA) were used as CPAs. Ongoing studies on the CCD include mechanical evaluation through drop tests, sterility maintenance tests, dye ingress and microbial challenge tests to further validate the suitability of CCD for clinical banking of cell therapy products.