

Transport CBU – Regulatory issues

1. Introduction

This document gives an overview on the requirements for dry shippers and the transportation of cord blood units (CBU) from the Cord Blood Banks (CBB) Basel and Geneva and the hybrid Cord blood bank (SSCB) to a transplant centre.

2. Specification of dry shippers for transport of CH CBU

According to FACT/NetCord Standards, cryopreserved CB units must be transported or shipped in a liquid nitrogen cooled dry shipper that contains adequate absorbed liquid nitrogen and has been validated to maintain a temperature of – 150°C or colder for at least 48 hours beyond the expected time of arrival at the receiving facility.

The dry shipper must be equipped with a temperature logger that measures the temperature continuously during transportation/cooling time. The temperature history for every transport must be recorded by means of a printable temperature curve or similar form of documentation.

3. Transportation with dry shipper

The dry shippers are provided and prepared by the courier company assigned by SBSC.

The CBB supplies the documentation and information required for the organization of the transport according to FACT/NetCord Standards and is responsible for loading the CBU into the dry shipper. Loading of the dry shipper with specimens / a CBU must be executed according to the manufacturer's instructions.

Loaded dryshippers are transported unaccompanied as a standard. Whenever possible SBSC will have the courier company assign a designated driver for the transport. These couriers must be trained especially for the transport of CBUs by the courier company prior to transport.

The temperature in the dry shipper must be measured continuously during the entire time of the transport. The courier company supplying the dry shipper must send documentation of the temperature readings to SBSC after completion of the transport.

At the end of the stem cell product transport a final inspection must be performed and documented according to the "Transport of Stem Cell Product Audit" form, to be completed by courier and transplant centre.

4. Service and Maintenance

The courier company provides full service of the dry shippers and is responsible for their maintenance.

The courier company does not have to submit complete documentation on the maintenance measures, but must ensure at all times that the dry shippers and courier's methods of transportation meet FACT/NetCord Standards as required.