

Central Venous Catheter – Regulatory issues

1. Introduction

The WMDA Standards and Recommendations are the basis for Swiss Blood Stem cells (SBSC) Policies regarding Swiss patients and Swiss donors and corresponding WorkUps.

2. Insertion and Removal of a Central Venous Catheter (CVC)

Following recommendations regarding the insertion of a CVC for PBSC collection from unrelated donors must be taken into account.

- Requirement for central venous catheter must be assessed and documented in the donor dossier as follows:
 - The peripheral venous access must be carefully examined at the time of donor medical evaluation.
 - If peripheral access is not possible, alternative methods of donation must be discussed.
 - The donor must be counseled about the advantages and the risks of a central venous catheter. A written justification for placement of a CVC must be provided.
 - The donor must sign an informed consent which must be kept in the donor dossier.
- The collection center must have a SOP that guarantees the correct insertion of a CVC for PBSC collection for an unrelated donor and that specifies the qualifications and required expertise of the person(s) permitted to insert the CVC.
- All sites for CVC insertion are permitted.
- A radiological control after insertion is mandatory except for femoral access.
- All donors with CVCs must be kept in hospital care and cared for by appropriately trained personnel.
- The donor must stay in the hospital for one hour after removal of CVC.

3. Adverse events

It is required to report all SAE/AEs to SBSC.