

**Implementation of 5 Buffy Coat Pooled Platelet Components Treated
with the INTERCEPT Blood System™ (IBS):
Experience in German Red Cross Blood Donation Service North**

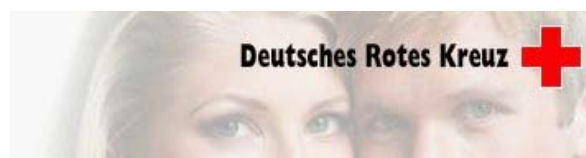
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Implementation of 5 Buffy Coat Pooled Platelet Components Treated with the INTERCEPT Blood System (IBS): Experience in German Red Cross Blood Donation Service North

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Background

Inactivation of pathogens and leukocytes in platelet components (PCs) using a combination of amotosalen and UVA treatment (INTERCEPT™) (Figure 1) is CE marked and in routine use in many European countries. The German Red Cross Blood Donation Service Nord, Institute Lütjensee, produces approximately 3800 PCs each year (Figure 2), all of which are prepared by the buffy coat (BC) pooling method. To ensure effectiveness of the INTERCEPT process, the input parameters specific for a processing set must be met. The input parameters for the INTERCEPT Large Volume (LV) set are: 2.5-7.0x10¹¹ platelets in 300-420mL of 32-47% plasma, and <4x10⁶/mL RBC (Table 1).

Figure 1: The INTERCEPT Blood System for Platelets

Using a sterile connecting device (SCD), the platelet container is connected to the INTERCEPT kit. Amotosalen (1) is added by gravity flow and the platelet mixture is illuminated with UVA light (2). Residual amotosalen and its photoproducts in the platelet mixture are reduced to low levels using a compound adsorption device (CAD) (3) before the platelets are transferred to the storage container.

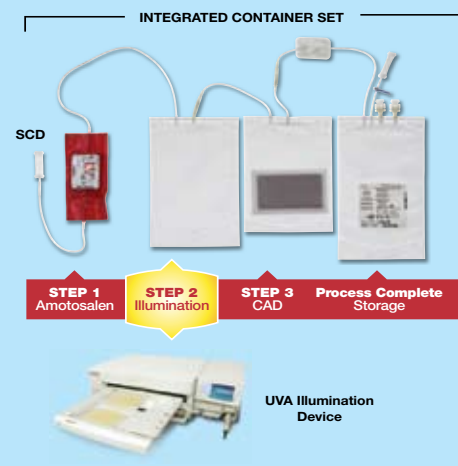


Table 1: INTERCEPT Large Volume (LV) Set PC Input Parameters

Parameters	Input requirement (LV)
Plt dose (x10 ¹¹)	2.5 - 7.0
Volume (mL)	300 - 420
Plasma content (%)	32 - 47
Platelet additive solution content (%)	53 - 68
RBC (x10 ⁶ /mL)	<4
WBC (x10 ⁶ /unit)	<1

Figure 2: INTERCEPT Processing at Institute Lütjensee



Aims

The objective of this study was to validate the INTERCEPT process using 5 buffy coat pooled platelet components including:

- 1) Production of buffy coat PCs meeting the input requirements of INTERCEPT,
- 2) Verification of in vitro parameters after INTERCEPT treatment and 5 days of storage.

Methods

BCs from whole blood donations (500 mL) were prepared using Compomat® G4. For each PC, five ABO-matched BCs were manually pooled with 280 mL InterSol™. After low speed centrifugation, the PC was collected by expressing the supernatant fraction through a leuko-reduction filter and stored under continuous agitation at 22 ±2°C before treatment. Within 24 hours of whole blood donation, each PC was treated with the INTERCEPT LV set according to the manufacturer's instructions. Eighteen BC PCs were treated and sampled immediately after treatment (day 1) and after 5 days of storage. In vitro platelet function was assessed by platelet dose, pH, swirling, and CD62 expression.

Results

Prior to INTERCEPT treatment the mean platelet dose was 3.6 ±0.6x10¹¹ platelets in 351 ±6.5 mL of 34.1 ±0.9 % plasma with the balance in InterSol™ (n=18). The RBC content was 1.0 ±0.9x10⁶/mL and WBC was 0.2 ±0.2x10³/mL. All BC PCs met the input requirements for processing using the INTERCEPT LV set. After INTERCEPT treatment, which included a mean of 10.8 hours (range 6-16 hr) of incubation in a compound adsorption device (CAD), the mean platelet content was 3.1±0.5x10¹¹/unit, indicating an average platelet processing loss of 13.7 ±2.0% (Table 2).

After INTERCEPT treatment and 5 days of storage, the platelet dose was 2.9 ±0.5 x10¹¹/unit. The pH remained stable during 5 days of storage (6.9 ±0.1 on day 6 vs. 7.0 ±0.0 on day 1). All units had pH values >6.6 on day 6. Treated platelets maintained positive swirling throughout storage. CD62 expression increased significantly during storage (41.4 ±5.8% on day 6 vs. 20.5 ±4.3% on day 1), while maximum CD62 expression after activation decreased slightly (83.8 ±5.9% on day 6 vs. 90.0 ±4.1% on day 1) (Table 3).

Table 3: In vitro platelet functions after INTERCEPT treatment*

Parameter	Day 1 (immediately after treatment) (n=18)	Day 6 (5 days storage after treatment) (n=18)
Platelet dose (x10 ¹¹ /unit)	3.1 ± 0.5	2.9 ± 0.5
pH	7.0 ± 0.0	6.9 ± 0.1
swirling	+	+
CD 62 w/o aggregation (%)	20.5 ± 4.3	41.4 ± 5.8
CD 62 w aggregation (%)	90.0 ± 4.1	83.8 ± 5.9

*Data are presented as mean ± SD, statistical significant difference between Day 6 and Day 1 (immediate treatment) with p-values <0.05 are indicated in bold

Table 2: Platelet characteristics before and after INTERCEPT treatment

Parameter	Pre-treatment (n=18)
Volume (mL)	351.1 ± 6.5
Plt dose (x10 ¹¹ /unit)	3.6 ± 0.6
Plasma content (%)	34.1 ± 0.9
RBC (x10 ⁶ /mL)	1.0 ± 0.9
WBC (x10 ³ /mL)	0.2 ± 0.2
Parameter	Post-treatment (n=18)
Volume (mL)	319.8 ± 6.1
Plt dose (x10 ¹¹ /unit)	3.1 ± 0.5
Platelet loss (%)	13.7 ± 2.0

Conclusions

- PCs prepared from a pool of 5 BCs and InterSol met the input requirements of the INTERCEPT LV set in our centre.
- After treatment of INTERCEPT, PCs maintained adequate platelet in vitro function up to 5 days of storage, meeting our own quality requirements and those of the German Red Cross Blood Donation Service Baden-Württemberg - Hessen.