

SAFETY OF BLOOD PRODUCTS

# THERAFLEX UV Platelets

PATHOGEN INACTIVATION SYSTEM FOR PLATELET CONCENTRATES

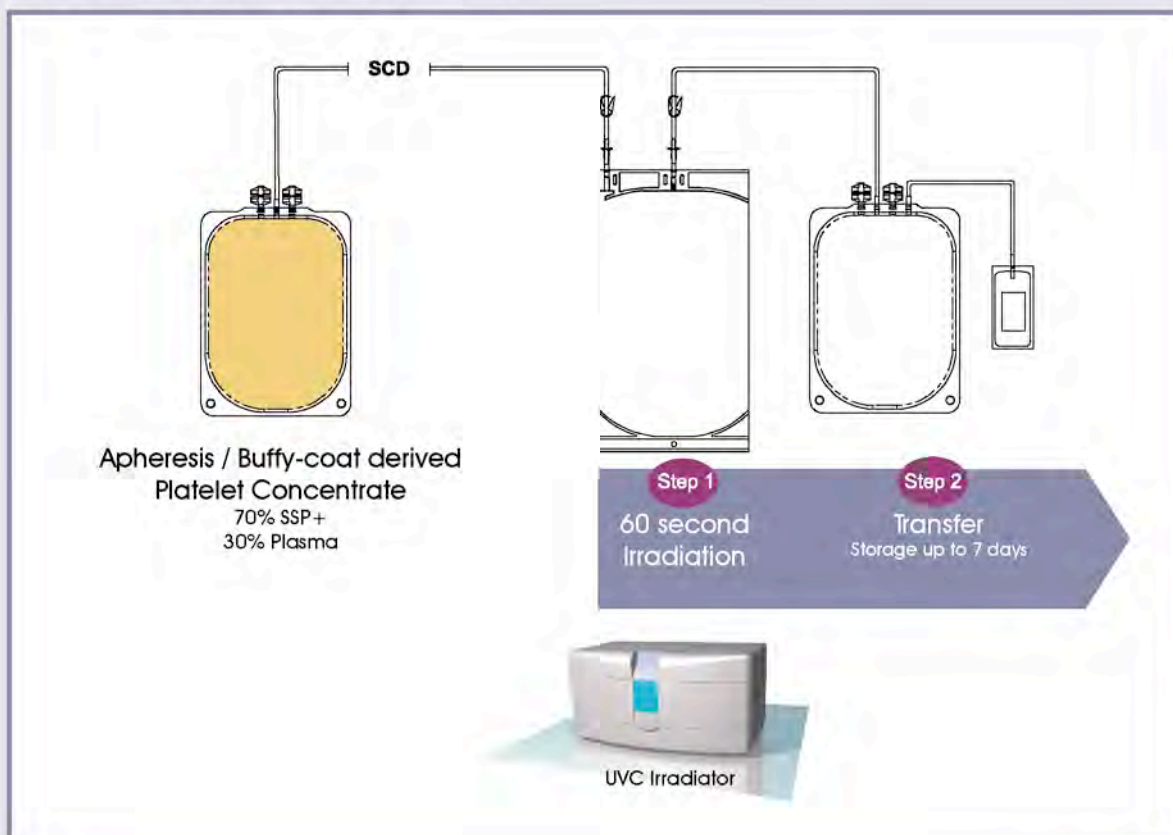
MacoPharma's latest development in the Safety of Blood Product Range:

- No photosensitizer
- Two step process
- 60 second UVC irradiation

Performance Targets:

- Apheresis and Buffy-coat derived platelet concentrates
- Efficacy on Bacteria, Spores, Non-envelopped and Envelopped Viruses, Leucocytes, Parasites
- Storage up to 7 days with SSP+

THERAFLEX UV Platelets: 2 step process



# A NOVEL TECHNIQUE FOR PATHOGEN INACTIVATION AND ITS EFFECT ON THE QUALITY OF PLATELET CONCENTRATES: THERAFLEX UV PLATELETS

Walker W H<sup>1</sup>, Tolksdorf F<sup>1</sup>, Mohr H<sup>2</sup>, Gravemann U<sup>2</sup>, Müller T H<sup>2</sup>,

<sup>1</sup> MacoPharma International GmbH, Langen, Germany

<sup>2</sup> German Red Cross Chapters of NSTOB, Springe, Germany

ISBT Regional Congress Asia, Hanoi, November 2007

## INTRODUCTION

The use of a pathogen inactivation technology is an option to enhance the safety of platelet transfusions. Current procedures need chemicals to be added to the platelet concentrates (PCs). These compounds are of concern if they remain in the final product. Moreover, treatment may cause deterioration of the platelets. A novel procedure has been developed using only short-wave UV light (UVC, 254 nm) that effectively inactivates pathogens in plasma-reduced PCs. The equipment used consists of an irradiation device with a specific mechanism for agitation. Its capacity is one platelet unit (random donor or apheresis) per treatment cycle. Treatment parameters, e.g. UVC intensity, UVC dose, temperature and agitation, are microprocessor-controlled. Platelets are processed in the THERAFLEX twin-bag kit, which comprises a highly UV-transparent polyolefin acetate bag[1] for irradiation and a platelet storage container (Fig.1, 2). It was investigated to what extent platelet integrity and storage stability of the treated products were influenced by this new inactivation procedure.

## MATERIALS & METHODS

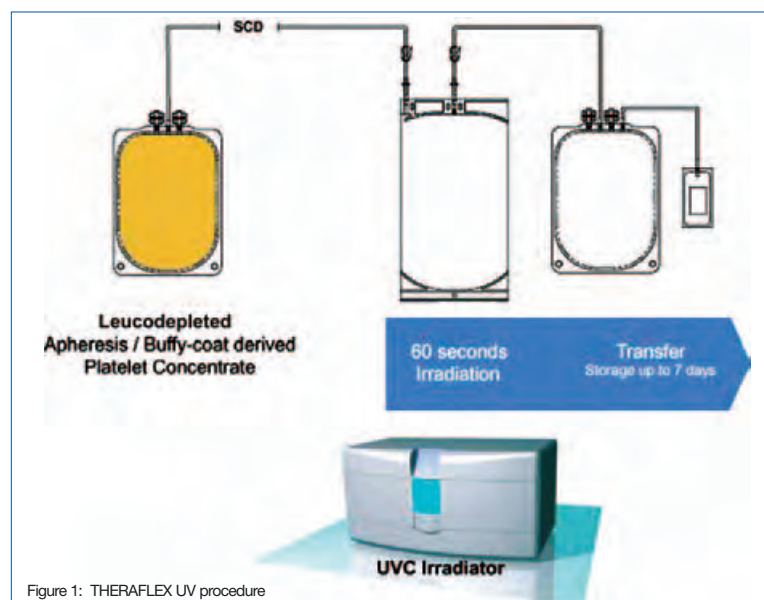


Figure 1: THERAFLEX UV procedure

Plasma-reduced PCs were treated with the THERAFLEX UV procedure (Fig.1) and stored until day 8 after blood donation (day 6 after treatment). The in vitro quality of UVC treated PCs was evaluated in comparison to non-treated control platelets. Control PCs were stored for the same time period. PCs in storage medium SSP+ (MacoPharma) were prepared from pools of 5 buffy coats. The average volume treated was 350 mL. Plasma concentration was approx. 30%. PCs were transferred into irradiation bags (Fig.2) and treated with UVC light at a dose of 0.4 J/cm<sup>2</sup> (approx. 60 sec) (Fig.3). They were strongly agitated during irradiation.



Figure 2: Twin-bag kit

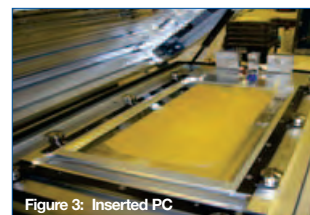


Figure 3: Inserted PC

## RESULTS

In vitro characteristics were hardly influenced by the THERAFLEX treatment. HSR reactivity was only slightly reduced whereas collagen induced aggregation was moderately increased. Glucose consumption and lactate formation were found to be marginally higher in the treated PCs. Thus, pH slightly dropped but remained above 7.0 until day 8 after donation. The mean platelet loss due to UVC treatment was 4% (Tab.1).

Day 3	Plts [x10 <sup>9</sup> /mL]	HSR [%]	pH	Spontaneous aggregation [%]	Collagen-ind. aggregation 100 µg/mL [%]	Glucose [mg/dL]	Lactate [mmol/L]
Control	10.2 ± 1.6	68 ± 4	7.13 ± 0.05	11 ± 3	94 ± 3	122 ± 8	7.5 ± 1.0
Treated	9.6 ± 1.3	64 ± 5	7.07 ± 0.07	14 ± 2	89 ± 5	118 ± 6	7.7 ± 0.8
Day 6							
Control	9.9 ± 1.0	66 ± 2	7.24 ± 0.13	12 ± 2	74 ± 9	86 ± 10	10.8 ± 1.0
Treated	9.5 ± 1.3	64 ± 8	7.09 ± 0.06	14 ± 3	81 ± 9	68 ± 10	12.8 ± 1.5
Day 8							
Control	9.4 ± 1.6	68 ± 1	7.29 ± 0.12	10 ± 1	62 ± 7	63 ± 9	12.5 ± 0.9
Treated	9.1 ± 1.3	61 ± 8	7.09 ± 0.05	16 ± 4	69 ± 7	41 ± 8	15.2 ± 1.0

Table 1: Platelet parameters of untreated and treated PCs on day 3, 6 and 8 after blood donation (mean ± SD; n=4)

## CONCLUSIONS

Plasma-reduced PCs were only slightly affected when treated with the THERAFLEX UV system for pathogen inactivation. In vitro parameters and storage stability were well preserved until day 8 after blood donation.

[1] Polyolefineacetate bags for pathogen inactivation and for storage of platelet concentrates, H Mohr, TH Müller, F Tolksdorf, WH Walker, Vox Sang 2004; 87 (Suppl. 3): 70