PLATELET ADDITIVE SOLUTION

Container
(Polyolefin, non-PVC)

Cliché:
fixed information

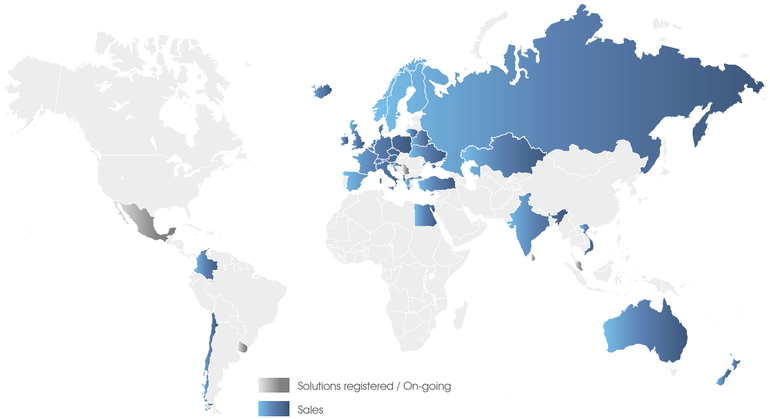
Label: variable
information:
Barcode ISBT 128

Luer-lock for
connection to
aphaeresis kits
(PVC)

Tubing for sterile
connection (PVC)

WORLDWIDE PRESENCE

Since 2002, more than 7 million units of Macopharma Platelet Additive Solution have been distributed in more than 40 countries.



Digitally signed by Şarco Alexandru
Date: 2023.11.17 15:27:06 EET
Reason: MoldSign Signature
Location: Moldova

SSP+ is a CE marked medical device.
It is not available for sale in the United States.
Please refer to the Instructions for Use

CE 0459

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TRANSFUSION macopharma DESIGNED FOR LIFE

XTAA01D 06/2017 - RCS : 391 600 905 Lille Métropole

SSP+ ADDITIVE SOLUTION

LEAD THE WAY IN BLOOD SAFETY

TRANSFUSION macopharma DESIGNED FOR LIFE

PRINCIPLE OF ACTION

Efficient replacement of up to 80% of plasma in platelet concentrates

Platelet Concentrates and Platelet Additive Solution: What are they for?

Platelet concentrates (PC) are notably used for the prevention and treatment of bleeding complications in thrombocytopenic patients. Therefore platelet quality, function, storage stability, morphology and cell integrity needs to be well maintained during processing and storage. Platelet Additive Solution SSP+ (PAS III-M/PAS E* generation) was developed to improve storage stability of buffy-coat and aphaeresis PCs for up to seven days after collection. With SSP+, platelets quality is maintained even under stressful conditions like interruption of agitation or pathogen inactivation[1,2].
The possible ratio is up to 80% SSP+ / 20% plasma.

SSP+ Formulation

Concentration of electrolytes (mmol/L)

SODIUM CHLORIDE	69.3
CITRATE	10.8
ACETATE	32.5
PHOSPHATE	28.2
POTASSIUM	5.0
MAGNESIUM	1.5

Effects on Platelet metabolism[3] and on Platelet membrane function[4-7]

Phosphate: stimulates glycolysis to produce more lactic acid, acts as a buffer to prevent fall in pH, and is of importance in maintaining good *in vitro* characteristics during interruption of agitation.

Acetate: is used as a substrate for platelet metabolism; it reduces production of lactate by platelets and by formation of bicarbonate, and it maintains stable pH levels during storage of platelet concentrates.

Citrate: prevention of coagulation.

Magnesium: prevents aggregates, reduces platelet-derived cytokines, and reduces activation of platelets.

Potassium: prevents aggregates, reduces activation of platelets, reduces glycolysis (reduced glucose consumption & lactate production), better maintenance of pH levels.
The combined action of potassium and magnesium maintains viability of platelets and limits their activation.

*ISBT 128 Terminology for Platelet Additive Solutions.

Patient safety is our priority

Benefits

Patient safety:

Reduced plasma volume to decrease adverse events[8-11] (TRALI, ABO mismatch):** To reduce transfusion risks, the New Zealand Blood Service took the decision to progressively move to provision of platelets suspended in additive solutions, and chose SSP+ for 100% of their needs. From the beginning of the use of SSP+, there was no reporting on transfusion reactions related to the platelet solution[12].

Improved bacterial detection performance[13,14]: Due to the presence of proteins, nutrients (including glucose) in plasma, the contaminating bacteria form a biofilm which attaches on the surface of the bag container evading detection by sampling. PAS reduces biofilm-formation in platelet concentrates (PCs) while improving bacteria distribution in contaminated PCs. This might be associated with increased availability of bacteria for detection.

Equivalent platelet recovery and CCI (Corrected Count Increment)[15]: There is no statistically significant difference of recovery and CCI between PCs stored in SSP+ and PCs stored in plasma.

Blood bank efficiency:

Streamlined blood bank organisation

Compatible with all technologies for preparation of platelet products[16-19] (e.g. automated devices for whole blood and aphaeresis derived platelets).

Compatible with Pathogen Inactivation Treatment[20-24]
SSP+ has been validated with all pathogen inactivation technologies (Mirasol, Intercept, THERAFLEX UV-Platelets).

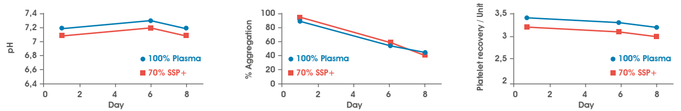
Having a large volume of available plasma as a blood product for transfusion or for fractionation[25-26].

Platelet quality is maintained even under stressful conditions: PCs in SSP+ can sustain at least 4 days without agitation during a 7-day storage period[1].

Reduction of discard-rate due to expiry: compatibility with extended platelet shelf life up to 7 days[27].

Platelet Quality with SSP+

SSP+ is recognized as the most suitable additive solution on the market that helps standardise platelet concentrates and improves storage conditions. *In vitro* quality[2,27,28,29,30] and post-transfusion recovery[15] of SSP+ platelets is well maintained. Both, Buffy-Coat and Aphaeresis derived platelets perform at least as well as platelets stored in 100% plasma[31].



In vitro quality of buffy-coat derived platelets
(data provided by Red Cross Blood Services NSTOB, Springe, Germany)

**Transfusion Related Acute Lung Injury.

Platelet quality and recovery in SSP+ is equivalent to platelets stored in 100% plasma

Specifications

- Class III Medical Device.
- 2 year shelf-life => Available volumes: 250, 280, 300, 500 mL.
- 1 year shelf-life => Available volumes: 200, 220 mL.
- 16 product codes.
- Polyolefin container (Non-PVC).
- Barcode ISBT 128.
- Full connectivity: tubing for sterile connection, luer-lock for easy connection to aphaeresis kits.
- Steam sterilised.

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