cerus

INTERCEPT® Blood System for Plasma Pathogen Reduction System

Proven Safe and Effective

Efficacy

The risk of transfusion-transmitted infections (TTIs) has been greatly reduced due to current donor selection and testing measures, particularly with regard to established TTIs, such as HIV, HBV, and HCV. Yet, residual risks exist such as those due to emerging pathogens.[1,2] Examples include the chikungunya virus, Plasmodium parasites, and Babesia, pathogens for which there are no commercially available tests. The INTERCEPT Blood System for Plasma offers a proactive approach to pathogen reduction by inactivating bacteria, viruses, protozoans, and certain emerging pathogens.[3]

Comprehensive, robust pathogen reduction*

The INTERCEPT Blood System for Plasma provides broad-spectrum, high levels of inactivation for most clinically relevant pathogens, including:

- Established threats such as HIV-1, HBV, and HCV[3]
- Certain emerging pathogens, including those that cause malaria and chikungunya, for which there are no commercially available tests[3]
- T-cells, which have been associated with transfusion-associated graft-versus-host disease (TA-GVHD)[3]

Help **protect your patients** against TTIs with INTERCEPT treated plasma

*There is no pathogen inactivation process that has been shown to eliminate all pathogens. Certain non-enveloped viruses (e.g., HAV, HEV, B19 and poliovirus) and *Bacillus cereus* spores have demonstrated resistance to the INTERCEPT process.

Table 1.
Broad spectrum reduction, with ≥4 logs for most pathogens.

Virus *(enveloped and non-enveloped)*	Log Reduction
HIV-1IIIB, cell-associated	≥6.2
HIV-1IIIB, cell-free	≥6.1
DHBV (HBV model virus)	4.4 to 4.5
BVDV (HCV model virus)	>4.3
HTLV-I	≥4.1
HTLV-II	≥4.7
West Nile virus	>5.5
SARS-Associated Coronavirus	≥4.0
Chikungunya virus (CHIKV)	6.5
Influenza A virus (H_5N_1 Avian Influenza)	≥5.7
Parvovirus B-19	1.8
Bluetongue Virus	4.2
Adenovirus 5	≥5.6
Bacteria	**Log Reduction**
Klebsiella pneumoniae	>6.0
Enterobacter cloacae	≥6.7
Psuedomonas aeruginosa	>6.8
Yersinia enterocolitica	≥6.6
Staphylococcus epidermidis	>6.8
Staphylococcus aureus	>6.2
Treponema pallidum (Syphilis)	≥5.4
Borrelia burgdorferi (Lyme disease)	≥9.9
Anaplasma phagocytophilum	≥3.6
Protozoan Parasite	**Log Reduction**
Plasmodium falciparum	>6.5
Babesia microti	≥4.9
Trypanosoma cruzi	>6.7
Leukocyte	**Log Reduction**
Human T-Cells	4.0

For a full list of pathogens, see package insert.

INTERCEPT® Blood System for Plasma Pathogen Reduction System

Safety & Efficacy

Clinical trials

The safety and efficacy of INTERCEPT Blood System processed plasma ("INTERCEPT Plasma") has been evaluated in a number of prospective clinical studies, with a total of 42 healthy subjects and 203 patients requiring plasma transfusion (Table 2). All studies met primary endpoints. INTERCEPT Plasma has been demonstrated to effectively support patients with acquired coagulation factor deficiencies resulting from liver disease or liver transplant, those undergoing therapeutic plasma exchange (TPE) due to TTP*, and those undergoing liver transplantation.

*See Warnings and Precautions below. Monitor patients for signs and symptoms of cardiac events during TPE for TTP.

Table 2.
INTERCEPT Plasma clinical trials.[4-7]

Population (sample size)*	Phase (Ph) / Study Design	Primary Result(s)
Healthy subjects (N=15)	Ph1; Randomized, single-blind, crossover.	Comparable coagulation factor levels attained between test and control fresh frozen plasma (FFP).[4]
Healthy subjects, warfarin anticoagulated (N=27)	Ph2; Randomized, single-blind, crossover.	Comparable prothrombin time and FVII kinetics between test and control FFP.[4]
Multiple coagulation deficiencies (N=13)	Ph2; Randomized, double-blind, parallel group.	INTERCEPT plasma was safe and well tolerated by patients impaired with hepatic function. Comparable hemostatic activity attained between test and control FFP.[5]
Acquired coagulation deficiencies (N=121)	Ph3B; Randomized, double-blind, parallel group.	Comparable coagulation responses and clinical hemostasis were attained between test and control FFP.[6]
Thrombotic thrombocytopenic purpura (TTP) (N=35)	Ph3C; Randomized, double-blind, parallel group.	Remission rates, time to remission, relapse rates, and time to relapse, as well as number of TPE and volume of FFP required were comparable between INTERCEPT Plasma and conventional FFP.[7]

*Sample size (N) is the total of test and control patient samples.

Shown safe in routine use

National hemovigilance (HV) programs provide a comprehensive view of transfusion and adverse event rates over time. HV programs in France (ANSM) and Switzerland (Swissmedic) have documented consistent safety profiles before and after the introduction of pathogen reduction.[8,9]

A three-year head-to-head comparison of transfusion reaction rates in conventional and INTERCEPT Plasma in France showed no difference in the frequency of adverse events with INTERCEPT Plasma in routine clinical use (Table 3).

Table 3.
Routine use of INTERCEPT Plasma demonstrates low ATR* rates through a French national HV program.[8]

Year	Product	Plasma Units	ATRs per 1,000 Units
2009	Untreated Plasma	348,725	0.55
	INTERCEPT Plasma	22,933	0.52
2010	Untreated Plasma	329,757	0.59
	INTERCEPT Plasma	52,692	0.47
2011	Untreated Plasma	311,482	0.31
	INTERCEPT Plasma	68,440	0.31

*Acute Transfusion Reaction (ATR)

INTERCEPT® Blood System for Plasma Pathogen Reduction System

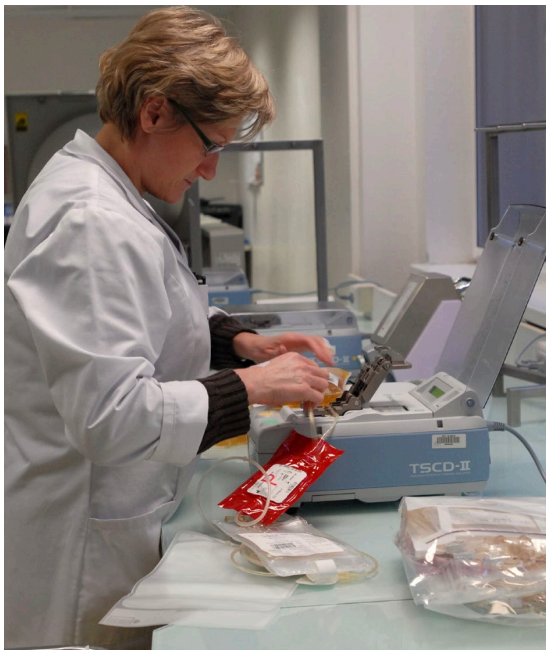
Effective at retaining plasma coagulation function

INTERCEPT Plasma maintains hemostatic efficacy, as shown by the retained activity of key coagulation factors.[3]

Table 4.
Maintained coagulation function of INTERCEPT Plasma versus untreated plasma.*

Factor	Untreated Plasma	INTERCEPT Plasma*
Global Coagulation Parameters		
Prothrombin Time (seconds)	11.9	12.7
Activated Partial Thromboplastin Time (aPTT) (seconds)	28.1	30.9
Coagulation Factors and Proteins of the Hemostatic System		
Fibrinogen (g/L)	2.57	2.04
Factor II (IU/mL)	0.96	0.86
Factor V (IU/mL)	1.01	0.92
Factor VII (IU/mL)	0.80	0.71
Factor VIII (IU/mL)	0.87	0.65
Factor IX (IU/mL)	0.96	0.79
Factor X (IU/mL)	0.90	0.78
Factor XI (IU/mL)	1.01	0.88
vWF Ristocetin Cofactor Activity (IU/mL)	1.12	1.09
ADAMTS-13 (Antigenic) (%)	78	80
ADAMTS-13 (Functional) (%)	113	108
Anticoagulant Proteins		
Antithrombin III (IU/mL)	1.02	0.95
Protein C (IU/mL)	0.98	0.87
Protein S (IU/mL)	0.94	0.86
Proteins of the Fibrinolytic System		
Alpha-2-plasmin inhibitor (IU/mL)	1.06	0.88
Markers of Coagulation Activation		
Thrombin-Antithrombin Complexes (µg/L)	4.6	4.3
Factor VIIa (ng/mL)	<3.12	<3.12

*Data shown is for whole blood derived plasma frozen within 24 hours. For apheresis plasma, please see package insert.



Proven **safe and effective** through routine use and clinical trials

INTERCEPT® Blood System for Plasma Pathogen Reduction System

References

1. Stramer SL, Hollinger FB et al. Transfusion 2009;49(S2):1S-29S.
2. Dodd RY. Practical Transfusion Medicine. 4th ed. Chichester: Wiley; 2013;161-7.
3. The INTERCEPT Blood System for Plasma Package Insert, September 6, 2022.
4. Hambleton J et al. Transfusion 2002;42:1302-1307.
5. de Alarcon P et al. Transfusion 2005;45:1362-1372.
6. Mintz PD et al. Blood 2006;107:3753-3760.
7. Mintz PD et al. Transfusion 2006;46:1693-1704.
8. ANSM Annual Hemovigilance Report. https://ansm.sante.fr/.
9. Swissmedic Annual Hemovigilance Report. https://www.swissmedic.ch/swissmedic/en/home.html.

Contraindications

Contraindicated for preparation of plasma intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens.

Contraindicated for preparation of plasma intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen.

Warnings and Precautions

Only INTERCEPT Processing Sets for plasma are approved for use in the INTERCEPT Blood System for Plasma. Use only the INT100 Illuminator for UVA illumination of amotosalen-treated plasma. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any plasma not exposed to the complete INT100 illumination process.

Tubing components and container ports of the INTERCEPT Blood System for Plasma contain polyvinyl chloride (PVC). Di(2-ethylhexyl)phthalate (DEHP) is known to be released from PVC medical devices, and increased leaching can occur with extended storage or increased surface area contact. Blood components will be in contact with PVC for a brief period of time (approx. 15 minutes) during processing. The risks associated with DEHP released to into the blood components must be weighed against the benefits of therapeutic transfusion.

Amotosalen-treated plasma may cause the following adverse reaction:

Cardiac Events In a randomized controlled trial of therapeutic plasma exchange (TPE) for TTP, five patients treated with INTERCEPT Blood System processed plasma and none with conventional plasma had adverse events in the cardiac system organ class (SOC) reported. These events included angina pectoris (n=3), cardiac arrest (n=1), bradycardia (n=1), tachycardia (n=1) and sinus arrhythmia (n=1). None of these events resulted in documented myocardial infarction or death. Monitor patients for signs and symptoms of cardiac events during TPE for TTP.

RX only.

There is no pathogen inactivation process that has been shown to eliminate all pathogens. Certain non-enveloped viruses (e.g., HAV, HEV, B19 and poliovirus) and *Bacillus cereus* spores have demonstrated resistance to the INTERCEPT process. See package insert for full prescribing information..

cerus

Global Headquarters | 1220 Concord Avenue | Concord, CA US 94520 | 855.835.3523

www.cerus.com | hcp.intercept-usa.com