cerus

INTERCEPT® Blood System for Platelets Pathogen Reduction System

Proven Safe and Effective

ROBUST, BROAD SPECTRUM PATHOGEN INACTIVATION*

Transfusion-transmitted infections (TTIs) persist despite interventions used to reduce risk. Bacterial contamination of platelets presents the most significant infectious risk,[1,2] followed by emerging pathogens.[3,4] The INTERCEPT process provides robust inactivation and can be used as an alternative to gamma irradiation for prevention of transfusion-associated graft-versus-host disease (TA-GVHD).[5]

This includes:

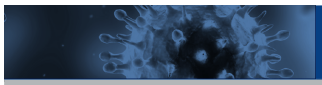
- Bacteria frequently implicated in septic transfusion reactions[5]
- Certain emerging pathogens, including those that cause chikungunya and dengue, for which there are no commercially available tests[5]
- Established threats such as HIV-1, HBV, and HCV[5]
- T-cells which are reduced to a level to lower the risk of TA-GVHD[5]

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

Bacteria (gram-negative, gram-positive, spirochetes)	Log Reduction (cfu/mL)[a] Platelets in 65% PAS-3/ 35% plasma	Log Reduction (cfu/mL)[a] Platelets in 100% plasma
Escherichia coli	≥6.3	>5.9
Yersinia enterocolitica	≥5.9	>6.3
Klebsiella pneumoniae	>6.2	>6.2
Serratia marcescens	≥6.7[b]	>7.1
Staphylococcus epidermidis	≥6.4	>6.5
Staphylococcus aureus	≥6.6	≥6.5
Streptococcus pyogenes	≥6.8[b]	>6.1
Bacillus cereus (vegetative)	≥5.5	≥5.6
Clostridium perfringens (vegetative)	≥6.5	>6.0
Propionibacterium acnes	≥6.5	>6.7
Treponema pallidum (Syphilis)	≥6.4	>6.3
Borrelia burgdorferi (Lyme disease)	≥6.8	>4.1

Protozoan Parasite	Log Reduction (pfu or cfu/mL)[a]	
Plasmodium falciparum	≥6.6	>6.5
Babesia microti	≥4.9	>4.5
Trypanosoma cruzi	≥7.8	>8.4

a. Based on input titer and post-treatment titer in 1 mL.
b. Based on culture of full platelet unit (300 mL).
c. Not tested



Virus (enveloped and non-enveloped)	Log Reduction (pfu/mL)[a] Platelets in 65% PAS-3/ 35% plasma	Log Reduction (pfu/mL)[a] Platelets in 100% plasma
HIV-1 IIIB, cell-associated	≥5.4	≥4.7
DHBV (model virus for HBV)	≥4.8	≥4.3
BVDV (model virus for HCV)	≥4.1	>3.5
HTLV-I	4.7	[c]
HTLV-II	≥5.1	[c]
West Nile virus (WNV)	≥6.3	>6.3
Chikungunya virus (CHIKV)	≥5.7	>6.5
Dengue virus	>5.4	>5.5
Cytomegalovirus (CMV)	≥4.9	[c]
Pseudorabies virus (model for CMV)	[c]	≥4.2
Influenza A virus	≥5.9	[c]
Bluetongue virus (model non-enveloped virus)	5.2	4.4

Leukocyte	Log Reduction	
Human T-cells	4.0	4.0

For a full list of pathogens, see package insert.

*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.

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ROUTINE USE OF THE INTERCEPT PROCESS DEMONSTRATES SAFETY OF INTERCEPT PLATELETS

Hemovigilance (HV) programs provide a comprehensive view of transfusions and potential adverse events via the surveillance of blood donations in routine use settings. Nationally mandated HV programs in France, Switzerland, and Belgium have reported reduced TTIs and no fatalities attributed to INTERCEPT treated platelets (INTERCEPT Platelets).[6-11]

Table 2. *Nationally Mandated HV Programs in France, Switzerland, and Belgium*

		Conventional Platelets		INTERCEPT Platelets	
Country	Year	Units Transfused (n)	TTBI (Fatalities)	Units Transfused (n)	TTBI (Fatalities)
France	2006-2015[6,7]	2,302,388	49 (9)	214,293	0 (0)
	2016[7]	285,305	4 (0)	21,817	0 (0)
	2017[7]	242,906	2 (0)	66,004	0 (0)
	2018[7]	378	0 (0)	320,235	0 (0)
	2019[7]	977	0 (0)	326,605	0 (0)
	2020[7]	43	0 (0)	331,149	0 (0)
	2021[7]	29	0 (0)	342,641	1 (0)***
Switzerland	2005-2015[8,9,10]	156,809	13 (3)	167,200	0 (0)
	2016[8,9]	–	–	38,374	0 (0)
	2017[8,9]	–	–	37,490	0 (0)
	2018[8,9]	–	–	38,947	0 (0)
	2019[8]	–	–	36,317	0 (0)
	2020[8]	–	–	35,715	0 (0)
	2021[8]	–	–	38,898	0 (0)
Belgium	2009-2015[11]	252,809	9 (0)	227,797	0 (0)
	2016[11]	–	–	65,501	0 (0)
	2017[11]	–	–	67,398	0 (0)
	2018[11]	–	–	67,395	1 (0)**
Total		**3,241,644**	**77 (12)**	**2,443,776**	**2 (0)**

** Belgium 2018: *Staphylococcus hominis* was reported in a patient who recovered. This case was not thoroughly investigated for modes of contamination via storage container leaks or other environmental sources.[12] ***France 2021: *Bacillus cereus* transmission was reported in a patient who recovered. *B. cereus* is a spore-forming bacteria resistant to the INTERCEPT process.[13]

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EVALUATED IN NUMEROUS CLINICAL TRIALS

The INTERCEPT Blood System for Platelets has been evaluated in numerous clinical trials involving thousands of subjects. Primary endpoints were met in the controlled, randomized clinical trials, including corrected count increments (CCI) and bleeding criteria, both of which are measures of hemostatic efficacy.

Table 3. *INTERCEPT Platelets clinical trials*

Study Description	Patients	Design	Primary Endpoint	Primary Endpoint Met?
Safety of INTERCEPT Platelets, hem/onc patients[14]	2291	Prospective, open-label, non-randomized, sequential, two-cohort	Incidence of Treatment Emergent Assisted Mechanical Ventilation (TE-AMV)	✓
Viability of INTERCEPT Platelets, clearance of amotosalen, healthy patients[15,16]	65	Randomized, single-blind, cross-over	Recovery/survival, clearance of amotosalen	✓
Safety/efficacy of INTERCEPT Platelets, thrombocytopenic patients[17]	645	Randomized, double-blind, parallel	WHO Grade 2 bleeding	✓
Safety/efficacy of INTERCEPT Platelets, thrombocytopenic patients[18]	43	Randomized, double-blind, parallel	1 hour CCI	✓
Safety/efficacy of INTERCEPT Platelets, thrombocytopenic patients[19]	32	Randomized, double-blind, cross-over	Bleeding time	✓
Safety of INTERCEPT, Routine setting[20]	51	Single-arm, open label	Frequency of acute transfusion reactions was 1.6%	
Safety of INTERCEPT, Routine setting[21]	46	Single-arm, open label	Frequency of acute transfusion reactions was 2%	

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CONTRAINDICATIONS

Contraindicated for preparation of platelet components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of platelet components 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 platelets are approved for use with the INTERCEPT Blood System. Use only the INTERCEPT INT100 Illuminator for UVA illumination of amotosalen-treated platelet components. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any platelet components not exposed to the complete INT100 illumination process. Tubing components and container ports of the INTERCEPT Blood System 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 into the blood components must be weighed against the benefits of therapeutic transfusion.

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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.

Reduce TTIs While Providing Safe and Effective Platelets to Patients.

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