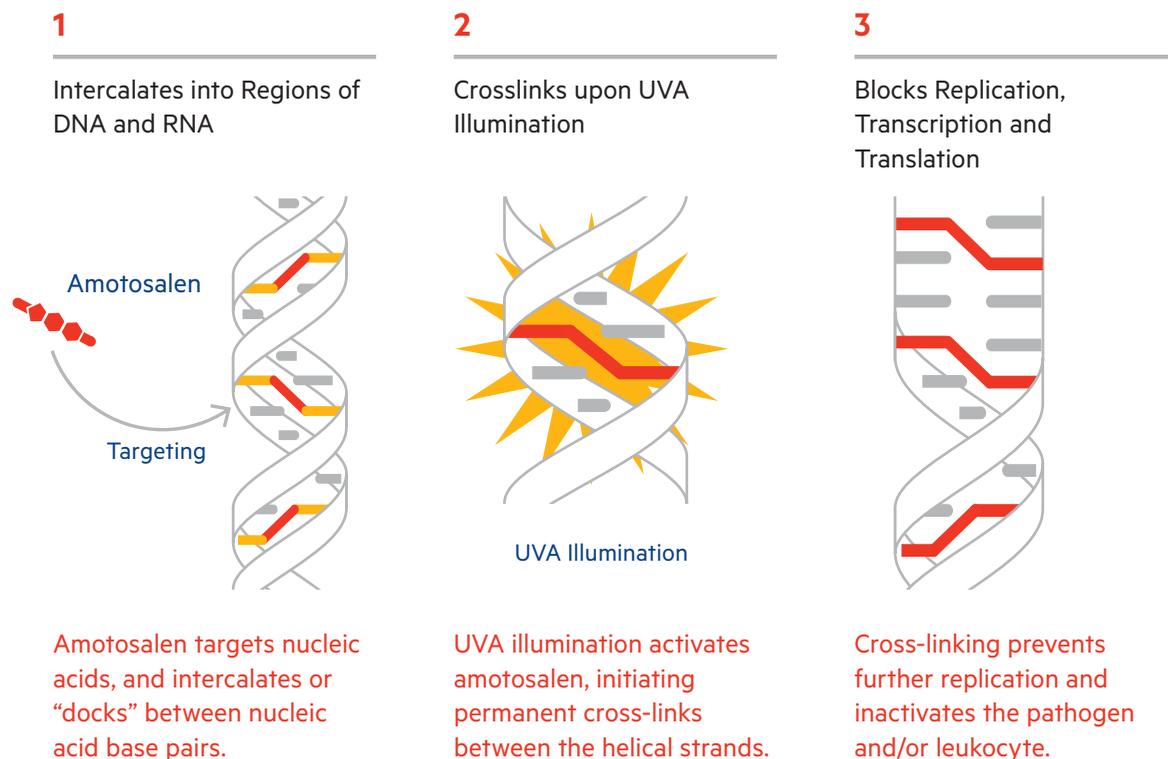


INTERCEPT[®] Blood System for Platelets and Plasma Pathogen Reduction System

Targeting DNA and RNA to Prevent Pathogen Proliferation.

A proactive approach to blood safety through reduction of a broad range of pathogens

The INTERCEPT Blood System uses amotosalen - a well characterized photoactive compound that specifically targets DNA and RNA - and UVA illumination to irreversibly cross-link nucleic acids. In doing so, the INTERCEPT treatment blocks replication of viruses, bacteria, and parasites, rendering them inactive.¹



Broad Spectrum Pathogen Reduction

The INTERCEPT Blood System is a proactive approach to reducing transfusion-transmitted infection (TTI) risk through the broad spectrum inactivation of viruses, bacteria, parasites, and leukocytes that can be found in platelet and plasma components.^{2,3}

† Platelets in PAS-3²
* Platelets in 100% plasma²
◇ Plasma³

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. For a full list of pathogens, please refer to package inserts.

Gram-Negative Bacteria

Klebsiella pneumoniae † * ◇

Yersinia enterocolitica † * ◇

Escherichia coli † *

Pseudomonas aeruginosa † * ◇

Salmonella choleraesuis † *

Enterobacter cloacae † * ◇

Serratia marcescens † *

Anaplasma phagocytophilum ◇

Gram-Positive Bacteria

Staphylococcus epidermidis † * ◇

Staphylococcus aureus † * ◇

Streptococcus pyogenes † *

Listeria monocytogenes † *

Corynebacterium minutissimum † *

Bacillus cereus † *

Lactobacillus species † *

Bifidobacterium adolescentis †

Propionibacterium acnes † *

Clostridium perfringens (vegetative) † *

Spirochetes

Treponema pallidum † * ◇

Borrelia burgdorferi † * ◇

Enveloped and Non-Enveloped Viruses

HIV-1 † * ◇, HIV-2 †

DHBV (model for HBV) † * ◇

BVDV (Model for HCV) † * ◇

HTLV-I † ◇

HTLV-II † ◇

West Nile virus (WNV) † * ◇

Cytomegalovirus (CMV) †

Pseudorabies virus (model for CMV) *

Chikungunya virus (CHIKV) † * ◇

Dengue virus (DENV) † *

Influenza A † ◇

SARS-Associated Coronavirus ◇

Parvovirus B-19 ◇

Bluetongue Virus † * ◇

Calicivirus † *

Adenovirus † * ◇

Protozoa

Trypanosoma cruzi † * ◇

Plasmodium falciparum † * ◇

Babesia microti † * ◇

Leishmania mexicana †

Leukocytes

Human T-Cells † * ◇

References

- 1) Wollowitz, S. Seminars in Hematology, 2001. 38 (Suppl 11): p. 4-11.
- 2) INTERCEPT Blood System for Platelets [Package Insert]. Concord, CA: Cerus Corporation; May 28, 2019.
- 3) INTERCEPT Blood System for Plasma [Package Insert]. Concord, CA: Cerus Corporation; May, 1 2020.

Contraindications

Contraindicated for preparation of platelets or plasma intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of platelet or plasma 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 plasma or platelet components are approved for use in the INTERCEPT Blood System. Use only the INT100 Illuminator for UVA illumination of amotosalen-treated plasma or platelet components. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any plasma or platelet components not exposed to the complete INT100 illumination process. Tubing components and/or 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. PLATELETS: INTERCEPT processed platelets may cause the following adverse reaction: *Acute Respiratory Distress Syndrome* (ARDS). An increased incidence of ARDS was reported in a randomized trial for recipients of INTERCEPT processed platelets, 5/318 (1.6%), compared to recipients of conventional platelet components (0/327). Monitor patients for signs and symptoms of ARDS. PLASMA: 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.



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Rx only. See package insert for full prescribing information.