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

MOA

Targeting DNA and RNA to prevent pathogen proliferation

The INTERCEPT 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

1. Amotosalen targets nucleic acids, and intercalates or “docks” between nucleic acid base pairs.
2. UVA illumination activates amotosalen, initiating permanent cross-links between the helical strands.
3. Cross-linking prevents further replication and inactivates the pathogen and/or leukocyte.

For CONTRAINDICATIONS, WARNINGS, and REFERENCES, see inside pages.
See package insert for full prescribing information.
References

2. INTERCEPT Blood System for Platelets - Dual Storage Set Package Insert; Cerus Corporation; March 15, 2016.
INTERCEPT® Blood System for Platelets and Plasma
pathogen reduction system

CONTRAINDICATIONS

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

Contraindicated for preparation of plasma or 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 plasma or platelets 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 container ports of the INTERCEPT Blood System for Plasma or Platelets 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

Pulmonary events: Acute Respiratory Distress Syndrome (ARDS)

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.
Broad spectrum pathogen reduction

The INTERCEPT Blood System is a proactive approach to reducing transfusion-transmitted infectious (TTI) risk through the comprehensive inactivation of viruses, bacteria, parasites, and leukocytes that can be found in plasma and platelet components. Robust inactivation is achieved, with ≥4 log reduction for most pathogens when using the INTERCEPT system.²,³

**GRAM-NEGATIVE Bacteria**
- Klebsiella pneumoniae ² ³
- Yersinia enterocolitica ² ³
- Escherichia coli ²
- Pseudomonas aeruginosa ²
- Salmonella choleraesuis ²
- Enterobacter cloacae ²
- Serratia marcescens ²
- Anaplasma phagocytophilum

**GRAM-POSITIVE Bacteria**
- Staphylococcus epidermidis ² ³
- Staphylococcus aureus ²
- Streptococcus pyogenes ²
- Listeria monocytogenes ²
- Corynebacterium minutissimum ²
- Bacillus cereus (vegetative) ²
- Lactobacillus species ²
- Bifidobacterium adolescentis ²
- Propionibacterium acnes ²
- Clostridium perfringens (vegetative) ²

**ENVELOPED VIRUSES**
- HIV-1 ² ³
- Chikungunya ² ³
- HTLV-I ²
- Dengue ²
- HTLV-II ²
- Influenza A ²
- CMV ²
- WNV ²
- DHBV (model for HBV) ² ³
- BVDV (model for HCV) ² ³
- Pseudorabies (model for CMV) ²

**NON-ENVELOPED VIRUSES**
- Bluetongue virus ²
- Adenovirus ² ³
- Parvovirus B-19 ²

**PROTOZOA**
- Trypanosoma cruzi ² ³
- Plasmodium falciparum ²
- Babesia microti ²

**LEUKOCYTES**
- T-cells ² ³

† pathogen reduced Amicus apheresis platelets in PAS-3
◊ pathogen reduced Trima apheresis platelets in 100% plasma
# pathogen reduced plasma

Rx only. There is no pathogen reduction 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 CONTRAINDICATIONS, WARNINGS, and REFERENCES, see inside pages. See package insert for full prescribing information.