

# Supplemental Information for Hospitals Participating in the MIPLATE Clinical Trial

## Reference Document

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## Mirasol Pathogen Reduction Technology

The Terumo BCT Mirasol PRT System for Platelets is an extracorporeal blood treatment process which uses ultraviolet light energy and riboflavin (vitamin B2) to damage the nucleic acids necessary for replication of parasites, bacteria, viruses and residual white blood cells. The use of Mirasol-treated platelet apheresis reduces the risk of transfusion-transmitted infection and transfusion-associated graft-versus-host disease.

## The MIPLATE Clinical Trial

The CTS-5030 Clinical Effectiveness of Conventional Versus Mirasol-treated Apheresis Platelets in Patients with Hypoproliferative Thrombocytopenia (MIPLATE Study) clinical trial is designed to demonstrate the clinical hemostatic efficacy of Mirasol-treated apheresis platelets compared to stand of care apheresis platelets in hematology oncology patients with treatment-induced thrombocytopenia.

## Mirasol-Treated Platelet Production

Mirasol-treated platelet apheresis will be produced at LifeSouth Community Blood Center's Civitan Region, located in Gainesville, Florida. Production will occur on an as-needed basis, for hospitals participating in the clinical trial: *CTS-5030 Clinical Effectiveness of Conventional Versus Mirasol-treated Apheresis Platelets in Patients with Hypoproliferative Thrombocytopenia (MIPLATE Study)*.

## ISBT Codes and Product Labeling

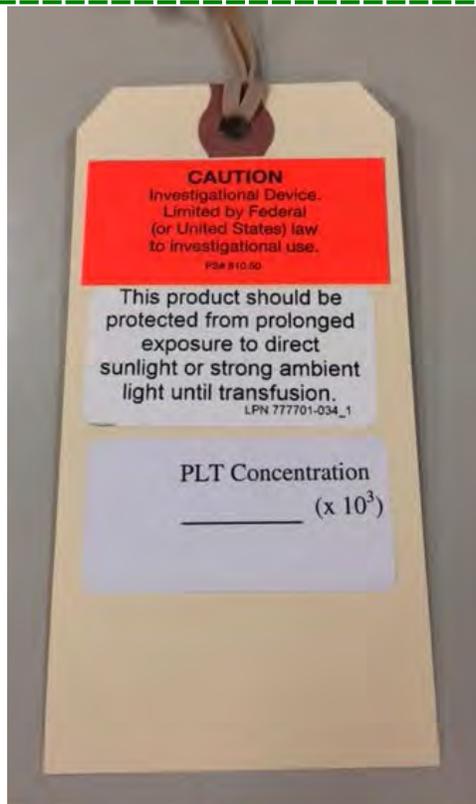
Mirasol-treated apheresis platelet products are leukoreduced and will bear an ISBT 128 compliant label. Please ensure these codes are entered into your hospital computer system before ordering:

ISBT Product Code	Description (Apheresis Platelets in Plasma, Mirasol-Treated)
<b>Leukoreduced to &lt; 5x10e6 – Mirasol treated</b>	
E5748	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5log6 Riboflavin-treated
E5749	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5log6 1st container Riboflavin-treated
E5750	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5log6 2nd container Riboflavin-treated
E5751	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5log6 3rd container Riboflavin-treated
<b>Leukoreduced to &lt; 5x10e6 – Mirasol treated &amp; Irradiated</b>	
E5756	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5log6 Riboflavin-treated
E5757	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5log6 1st container Riboflavin-treated
E5758	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5log6 2nd container Riboflavin-treated
E5759	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5log6 3rd container Riboflavin-treated

Not Under Document Control if Printed



In addition to the label, a tie tag will be attached to every Mirasol-treated apheresis platelet. This tag will bear the unit number (DIN), platelet concentration, investigation statement and instructions for protecting the product from light. The figure below, shows a representation of the tag:



## Storage Requirements for the Mirasol-Treated Platelet

Mirasol-treated platelets are light sensitive, and must be protected from prolonged exposure to direct sunlight or strong ambient light sources. Storing these units on the top shelf of an open tabletop platelet agitator is prohibited. Store until the labeled expiration date at 20-24C with gentle agitation, out of direct ambient light or sunlight.

## Ordering Platelet Products for the MIPLATE Study

Order Mirasol-treated apheresis platelets from the blood center utilizing the *CTS-5030: MIPLATE PLT Order Form*. See **HPM.1.6, Request MIPLATE Apheresis Platelets**, located on [www.lifesouth.org](http://www.lifesouth.org), for details. Production of Mirasol-treated products will require regular communication about upcoming patient enrollment and the expected transfusion dates of enrolled patients. Sharing this information is key to meeting the needs of hospital patients and ensuring timely delivery.

For hospitals local to the Gainesville area, Mirasol-treated platelets can usually be obtained same day. For hospitals outside the local area, Fed Ex or a local ground courier will facilitate next day delivery (in most cases, if the order is received by noon – the platelets will arrive at your hospital the following morning).

Products will be transported in validated shipping containers, along with documents that identify the intended recipient. Empty shipping boxes can be returned your nearest LifeSouth location (if LifeSouth is your blood provider).

Please consider your need for CMV negative or HLA matched products before placing your order. Orders with specific requirements will require more lead time for donor recruitment in order to ensure product availability.

Control arm apheresis platelets (i.e. current standard of care apheresis platelets) can be obtained from your existing inventory, or ordered from LifeSouth or your current blood supplier, according to your established procedure. Absolute platelet counts for control arm products are available on request (via phone, email or fax).

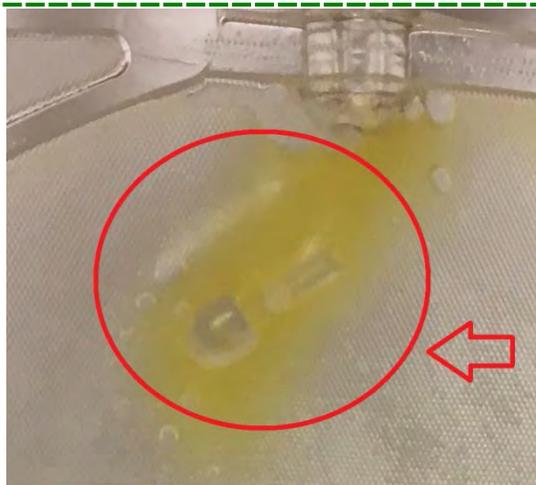
## Administering Mirasol-Treated Platelets & Reporting Adverse Events

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Mirasol-treated apheresis platelet products may only be transfused to patients who have been consented and enrolled in the clinical trial.

The color of the product and the urine of the recipient may have a yellow tint (a known side effect of the riboflavin used in the processing of the platelets).

Additionally, broken parts of frangible connectors (introduced during processing and pictured below) will be present in the Mirasol-treated storage bag. This is normal and should not interfere with transfusion.



Please report ALL adverse transfusion events transpiring within the study to Terumo BCT (including events surrounding test and control arm platelets, as per the MIPLATE protocol).

## Returning Unused Mirasol-treated Platelets

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Unused Mirasol-treated platelets can be returned to LifeSouth (utilizing the same box the product was shipped in) for use in monthly quality control testing. Returned products will be credited as appropriate.