

MIRASOL[®]

PATHOGEN REDUCTION TECHNOLOGY (PRT) SYSTEM

Routine use data and clinical trials support the safety and effectiveness of Mirasol-treated blood products.

INTRODUCTION

- In routine use **since 2009**, Mirasol is now used in **more than 20 countries** in Europe, the Middle East, Latin America and Asia Pacific.
- **No serious adverse events** have been reported after more than 750,000 Mirasol disposable kits sold and about 190,000 recorded transfusions of Mirasol-treated products.
- All the clinical studies evaluating Mirasol and the routine use **data confirmed the safety and effectiveness** of Mirasol-treated blood products.

At Terumo BCT, we remain committed to advancing global blood safety, including continuing to research and track the use of Mirasol.

ROUTINE USE DATA DEMONSTRATES THE SAFETY AND EFFECTIVENESS OF MIRASOL-TREATED PRODUCTS.

Hemovigilance (HV) is an integral part of quality management in a blood system, allowing for continual improvement in the quality and safety of blood components and transfusion processes.

	Active HV Warsaw 2011 to 2013 ¹	Passive HV Multiple Sites 2010 to End of 2015 ²
Number of countries where data was collected	1	6
Total number of transfusions	11,756	> 188,000
Number of platelet units transfused	7,827	> 91,000
Number of fresh frozen plasma units transfused	3,929	> 96,000
Increase in adverse reaction rates?	No	No
Conclusion	Proven safe for patients	Proven safe for patients

MANY CLINICAL STUDIES ALSO DEMONSTRATED THE SAFETY AND EFFICACY OF MIRASOL-TREATED PRODUCTS.

Results from these studies tracking nearly 1,300 patients have been peer-reviewed and published or accepted for publication.

Study Name or Design	Number of Patients	Study Population	Design	Primary Endpoints
PREPAREs³ Efficacy/safety of Mirasol-treated PLTs	567	Thrombocytopenic patients	Randomized controlled clinical trial	No. and % episodes of bleeding \geq WHO grade 2
IPTAS⁴ Efficacy/safety of Mirasol-treated PLTs	138	Thrombocytopenic patients needing \geq 2 PLT transfusions	Single-blind, randomized controlled clinical trial	% patients with bleeding \geq WHO grade 2
Safety/efficacy ⁶	19	Therapy-induced thrombocytopenic patients	Prospective, observational open-label study	CCI _{1hour} CCI _{24hours}
Safety/efficacy ⁷	146	Thrombocytopenic patients	Retrospective/prospective observational open-label study	CCI _{24hours}

Study Name or Design	Number of Patients	Study Population	Design	Primary Endpoints
Safety/efficacy of Mirasol-treated PLTs transfused in children ⁸ Routine setting	137	Therapy-induced thrombocytopenic patients	Retrospective, open-label, single-center study	% patients with bleeding on any day of PLT support No. of ARs
Performance/safety of Mirasol-treated PLTs ⁹ Routine setting	54	Thrombocytopenic patients	Prospective observational study	% CCI _{1 hour} ≥ 7,500 % CCI _{24 hours} ≥ 4,500
AIMS¹⁰ Reduction in TTM with Mirasol-treated WB	214	Adult patients who required up to two WB transfusions within 3 days	Prospective, randomized, parallel-group, double-blind, controlled, single-center study	Efficacy of Mirasol-treated WB in preventing TTM
IMPROVE¹¹ Performance of RBCs derived from Mirasol-treated WB	11	Healthy adult volunteers	Recovery and survival of RBCs resulting from Mirasol-treated WB using three different UV light energies (22, 33 and 44 J/mL RBC)	Recovery and survival
IMPROVE II¹² Performance of RBCs derived from Mirasol-treated WB	24	Healthy adult volunteers	Recovery and survival of RBCs resulting from Mirasol-treated WB at 80 J/mL RBC	Recovery and survival
Total Number of Patients	1,310			

KEY: AR = adverse reaction; CCI = corrected count increment; FFP = fresh frozen plasma; PLT = platelet; RBC = red blood cell; TTM = transfusion-transmitted malaria; WB = whole blood; WHO = World Health Organization

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To learn more about advancing global blood safety with Mirasol, contact your Terumo BCT representative.

TERUMOBCT

As a global leader in blood component, therapeutic apheresis and cellular technologies, we believe in the potential of blood to do even more for patients than it does today. This belief inspires our innovation and strengthens our collaboration with customers.

UNLOCKING THE POTENTIAL OF BLOOD | TERUMOBCT.COM

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