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.

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.

<table>
<thead>
<tr>
<th>Study Name or Design</th>
<th>Number of Patients</th>
<th>Study Population</th>
<th>Design</th>
<th>Primary Endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREPARES³</td>
<td>567</td>
<td>Thrombocytopenic patients</td>
<td>Randomized controlled clinical trial</td>
<td>No. and % episodes of bleeding ≥ WHO grade 2</td>
</tr>
<tr>
<td>IPTAS⁴</td>
<td>138</td>
<td>Thrombocytopenic patients needing ≥ 2 PLT transfusions</td>
<td>Single-blind, randomized controlled clinical trial</td>
<td>% patients with bleeding ≥ WHO grade 2</td>
</tr>
<tr>
<td>Safety/efficacy⁶</td>
<td>19</td>
<td>Therapy-induced thrombocytopenic patients</td>
<td>Prospective, observational open-label study</td>
<td>CCI1 hour, CCI24 hours</td>
</tr>
<tr>
<td>Safety/efficacy⁴</td>
<td>146</td>
<td>Thrombocytopenic patients</td>
<td>Retrospective/prospective observational open-label study</td>
<td>CCI24 hours</td>
</tr>
</tbody>
</table>

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.
### CLINICAL DATA OVERVIEW

#### Safety/efficacy of Mirasol-treated PLTs transfused in children
- **Study Population**: Therapy-induced thrombocytopenic patients
- **Design**: Retrospective, open-label, single-center study
- **Primary Endpoints**: % patients with bleeding on any day of PLT support
- **Number of Patients**: 137

#### Performance/safety of Mirasol-treated PLTs
- **Study Population**: Thrombocytopenic patients
- **Design**: Prospective, observational study
- **Primary Endpoints**: % CCI ≥ 4,500
- **Number of Patients**: 54

#### AIMS
- **Reduction in TTM with Mirasol-treated WB**: 214
- **Study Population**: Adult patients who required up to two WB transfusions within 3 days
- **Design**: Prospective, randomized, parallel-group, double-blind, controlled, single-center study
- **Primary Endpoints**: Efficacy of Mirasol-treated WB in preventing TTM

#### IMPROVE
- **Performance of RBCs derived from Mirasol-treated WB**: 11
- **Study Population**: Healthy adult volunteers
- **Design**: Recovery and survival of RBCs resulting from Mirasol-treated WB at 80 J/mL RBC
- **Primary Endpoints**: Recovery and survival

- **Performance of RBCs derived from Mirasol-treated WB**: 24
- **Study Population**: Healthy adult volunteers
- **Design**: Recovery and survival of RBCs resulting from Mirasol-treated WB at 80 J/mL RBC
- **Primary Endpoints**: Recovery and survival

**Total Number of Patients**: 1,310

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**REFERENCES**


Available in select markets. Not approved for sale in the U.S. Not licensed for sale in Canada.

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

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**TERUMO BCT**

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.

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