Features and Benefits of the Tropocells™ System

Effectiveness
- Enables high platelet concentration by reducing the volume of plasma
- Rapid and single-step process—only one centrifugation and one primary tube is used
- Adjustment to a specific clinical application by controlling the final PRP volume
- Specially designed accessories for OR setting

Safety and Quality
- Closed, biocompatible and virus-free system, minimizing safety concerns
- Approved medical device by the European (CE) and USA (FDA) Regulatory Authorities (FDA clearance for orthopaedic applications only)
- ISO 9001 Quality System International Standards for manufacturing under EN ISO 13485 and ISO 9001, approved medical device by the European (CE) and USA (FDA)
- Compliance with the requirements of the IVDR (EU) 2017/745 and the MDR (EU) 2017/745, safety and quality system, minimal safety risks.

Unique Biological Profile
- Custom designed Separator Gel above optimizing Tropocells™ PRP biological profile by
  - Removal of monocytes that present in PRP to minimize a catabolic effect by secreting catabolic mediators including metalloproteinases [13].
  - Eliminating undesired erythrocytes, which have been shown to significantly decrease platelet proliferation and augment apoptosis in vitro [14].
  - Virtually eliminating granulocytes from PRP, which are considered not beneficial in terms of regenerative processes and may contribute to a catabolic effect by secreting catabolic mediators including metalloproteinases [13].

Effectiveness
- Time-saving, easy-to-use, offering a user-friendly, single-step, closed system
- Virtually eliminating granulocytes and other contaminating elements
- Maximal concentration of platelets rather than creating a gradient, which leads to lower platelet yield
- Rapid and simple one-step process—only one centrifugation and one primary tube is used
- Specially designed Separator Gel allows optimizing of Tropocells™ PRP biological profile by
  - Removal of monocytes that present in PRP to minimize a catabolic effect by secreting catabolic mediators including metalloproteinases [13].
  - Eliminating undesired erythrocytes, which have been shown to significantly decrease platelet proliferation and augment apoptosis in vitro [14].
  - Virtually eliminating granulocytes from PRP, which are considered not beneficial in terms of regenerative processes and may contribute to a catabolic effect by secreting catabolic mediators including metalloproteinases [13].

References:
- 15. Peripheral Blood Mononuclear Cells Enhance the Anabolic Effects of Fibroblasts In Vitro
- 14. Red Blood Cells Inhibit Proliferation and Stimulate Apoptosis in Human Lung Fibroblasts In Vitro

Side effects and contraindications
- The autologous nature of PRP eliminates concerns for disease transmission and minimizes chances for possible side effects, which may be in a form of mild bruising, irritation, swelling, or pain at the injection site
- Blood pathologies and cancer. Furthermore, consistent use of NSAIDs within 48 hours of PRP application should be avoided
- Be aware of the possibility of anaphylaxis, particularly in patients with a history of allergy

Tropocells™ Plus

Simplifying PRP Preparation
Tropocells™ Plus is Estar Medical’s proprietary PRP preparation kit, fulfilling the preparation processes of pure, concentrated and biologically active PRP in a closed environment.

References:
Features and Benefits of the Tropocells™ System

**Effectiveness**
- Enables high platelet concentration by reducing the volume of plasma
- Rapid and simple one step process – only one centrifugation and one primary vial is used
- Adjustment to a specific clinical application by controlling the final PRP volume
- Specially designed accessories for OR setting

**Safety and Quality**
- Closed, biocompatible and xeno-free system, minimizing safety concerns
- Manufactured under EN ISO 13485 and ISO 9001 Quality System International Standards
- Approved medical device by the European (CE) and USA (FDA) Regulatory Authorities (FDA clearance for orthopaedic applications only)
- ISO 9001 Quality System
- Standards.

**Unique Biological Profile**
- Specially designed Separator Gel allows optimization of Tropocells™ PRP biological profile by:
  - Maintaining concentration of platelets rather than creating a gradient, which leads to lower platelet yield.
  - Virtually eliminating granulocytes from PRP, which are considered not beneficial in terms of regenerative processes and may contribute to a catabolic effect by secreting catabolic mediators, including metalloproteinases [13].
  - Removing undesired erythrocytes, which have been shown to significantly decrease fibroblast proliferation and augment apoptosis in vitro [9].
- Remnant of mononuclear cells present in PRP assets in fighting infection and is thought to enhance anabolic effects of PRP [15].

**References**


**Side Effects and Contraindications**
- Blood pathologies and cancer. Furthermore, consistent use of NSAIDS within 48 hours of PRP application should be avoided. [16].
- Pain, swelling or infection. Standard skin disinfection should be used before PRP injection. [16].
- Contraindications include pregnancy, breast feeding, autoimmune or systemic diseases.
- The autologous nature of PRP eliminates concerns for disease transmission and minimizes chances for possible side effects, which may be in a form of mild bruising, pain, swelling or infection. Standard skin disinfection should be used before PRP injection. [16].

**Tropocells™ PLUS**

Simplifying PRP Preparation
- Tropocells™ PLUS is Estar Medical’s proprietary PRP preparation kit, shortening the preparation process of pure, concentrated and biologically active PRP in a closed environment
- PRP Preparation – Simplicity for Success

Manufacturers:
Estar Technologies Ltd.
15, Hamerkava St. Holon, Israel
Obelis s.a. St. Général Walhs 53, B-1130 Brussels, Belgium
www.estar-medical.com

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What is Platelet-Rich Plasma?
Platelet-Rich Plasma (PRP) is an innovative and promising approach in tissue regeneration. PRP is defined as an autologous concentrated preparation of platelets and their associated growth factors in a small volume of plasma [1]. Platelets are a natural source of a myriad of growth factors in their natural and biologically determined ratios [2].

Therapeutic Effect of PRP
PRP is thought to promote physiological wound healing and rapid soft and hard tissue regeneration by delivering growth factors at high concentrations to the treated site.

PRP Growth Factors
Upon activation, platelets release growth factors and other molecules stored in their α granules, which are part of the natural healing process. These growth factors are regeneration-associated signaling molecules, such as Platelet-Derived Growth Factor (PDGF), Transforming Growth Factor-β (TGF), Vascular Endothelial Growth Factor (VEGF), Fibroblast Growth Factor (FGF) and others. These molecules regulate the healing cascade, including inflammation, cell proliferation, reepithelialization, angiogenesis and tissue remodeling processes [1-2].

Platelet Activation
Platelets may be activated via addition of activating substances, such as thrombin and calcium chloride. However, it has been postulated that in situ activation of platelets (caused by injection and exposure to in situ coagulation factors, such as collagen, exposed endothelium) results in a slow release pattern of growth factors secretion, which may be beneficial for stimulating a continuous healing response [3].

PRP Applications
PRP’s safety and effectiveness have been established for accelerating soft and hard tissue healing in treatment of tendinopathies [4-6], osteoarthritis [7] and various joint and muscle pathologies in Orthopaedics and Sports Medicine [8]. PRP may be used as a standalone treatment or as a biological adjunct to other biomaterials, such as bone substitutes, hyaluronic acid, collagen and mesenchymal stem cells [9]. Moreover, PRP has been used extensively for treating Chronic wounds [11*], in Plastic [1, 12*] and Oromaxillofacial surgery [9].

PRP Preparation using Tropocells™ Plus
PRP is prepared by taking a small sample of the patient’s own blood, then separating platelets from Platelet-Poor Plasma (PPP), red blood cells (RBC) and leukocytes via centrifugation. PRP is then collected and can be injected back into the treated site to promote healing response. The whole preparation process is simple and takes up to 20 minutes.*

Proven Performance
The Tropocells™ system was tested to ensure biocompatibility, platelet yield, growth factors availability (PDGF, EGF and VEGF), platelet in vitro-characteristics and viability.

Quality Assurance
Tropocells™ is CE Marked [Class IIb, CE 1023], FDA 510(k) cleared medical device (for orthopaedic applications). Quality System complies with EN ISO 13485:2003, ISO 9001:2008 international standards.

Usage Performance

<table>
<thead>
<tr>
<th>Tropocells™ PRP - 2 ml</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Platelet concentration fold</td>
<td>4-5</td>
</tr>
<tr>
<td>• RBC (10⁶/µl)</td>
<td>0.0</td>
</tr>
<tr>
<td>• WBC (10³/µl)</td>
<td>0.2</td>
</tr>
<tr>
<td>• Granulocytes %</td>
<td>8.5</td>
</tr>
<tr>
<td>• Mononuclear cells %</td>
<td>86.2</td>
</tr>
<tr>
<td>• PDGF (pg/ml)</td>
<td>2048</td>
</tr>
<tr>
<td>• VEGF (pg/ml)</td>
<td>220</td>
</tr>
<tr>
<td>• EGF (pg/ml)</td>
<td>218</td>
</tr>
</tbody>
</table>

* For a detailed protocol please refer to the instructions for use.
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Platelet Activation

Platelets may be activated via addition of activating substances, such as thrombin and calcium chloride. However, it has been postulated that in situ activation of platelets caused by injury and exposure to in situ coagulation factors, such as collagen, exposes endothelial proteins, which result in a slow-release pattern of growth factor secretion, which may be beneficial for stimulating a continuous healing response [3].

PRP Applications

PRP’s safety and effectiveness have been established for accelerating soft and hard tissue healing in treatment of tendinopathies [4-6], osteoarthritis [7] and various joint and muscle pathologies in Orthopaedics and Sports Medicine [8]. PRP may be used as a standalone treatment or in combination with other modalities, such as collagen, exposed endothelial proteins, which result in a slow-release pattern of growth factors secretions, which may be beneficial for stimulating a continuous healing response [3].

TROPOCELLS™ PRP - 2 ml

- Platelets concentration fold: x4 - x5
- PDGF (pg/ml): 2048
- VEGF (pg/ml): 220
- EGF (pg/ml): 269
- WBC (10^3/ul): 0.2
- Granulocytes %: 8.5
- Mononuclear cells %: 86.2
- Bacteria count %: 0
- Intravascular: 0
- Extravascular: 0
- Hematological analyses of PRP vs. Whole Blood. (A-B) Stained whole blood smears containing numerous erythrocytes and leukocytes. Conversely, PRP smears (C, D) contain primarily platelets (arrow), while the erythrocytes and granulocytes are eliminated.

PRP Preparation using Tropocells™ Plus

PRP is prepared by taking a small sample of the patient’s own blood, then separating platelets from Platelet-Poor Plasma (PPP), red blood cells (RBC) and leukocytes via centrifugation. PRP is then collected and can be injected back into the treated site to promote healing response. The whole preparation process is simple and takes up to 20 minutes.*

1. Collect blood directly into Tropocells™ vacuum blood collection gel and anticoagulant.
2. Centrifuge for 10 min at 1500 g. Gel separates Platelets from Platelet-Poor Plasma (PPP), RBC and platelets reside on top of the gel.
3. Centrifuge for 10 min at 1500 g. Gel separates Platelets from Platelet-Poor Plasma (PPP), RBC and platelets reside on top of the gel.
4. Reconstitution of the platelets in the remaining plasma to generate PRP.
5. Collects of PRP using PRP collection syringe.

Quality Assurance

Tropocells™ PRP - 2 ml

- Platelets concentration fold: x4 - x5
- PDGF (pg/ml): 2048
- VEGF (pg/ml): 220
- EGF (pg/ml): 269

* For a detailed protocol please refer to the instructions for use.

* Publications with Tropocells’ device for PRP preparation.

Proven Performance

The Tropocells™ system was tested to ensure biocompatibility, platelet yield, growth factors availability (PDGF, EGF and VEGF), platelet-in vitro-characteristics and viability.

Hematological analyses of PRP vs. Whole Blood. (A-B) Stained whole blood smears containing numerous erythrocytes and leukocytes. Conversely, PRP smears (C, D) contain primarily platelets (arrow), while the erythrocytes and granulocytes are eliminated.

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Platelets may be activated via addition of activating substances, such as thrombin and calcium chloride. However, it has been postulated that in situ activation of platelets (caused by injection and exposure to in situ coagulation factors, such as collagen, exposed endothelium) results in a slow release pattern of growth factors secretion, which may be beneficial for stimulating a continuous healing response [3].

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*Publications with Estar’s device for PRP preparation.

**PRP Preparation using Tropocells™ Plus**

PRP comprising a small sample of the patient’s own blood, then separating platelets from Platelet-Poor Plasma (PPP), red blood cells (RBC) and leukocytes via centrifugation. PRP is then collected and can be injected back into the treated site to promote healing response. The whole preparation process is simple and takes up to 30 minutes.

**Tropocells™ Orthopedics**

The Tropocells™ system was tested to ensure biocompatibility, platelet yield, growth factors availability (PDGF, EGF and VEGF), platelet in vitro-characteristics and viability.

**Usage**

**Quality Assurance**


**Performance**

Hematological analyses of PRP vs. Whole Blood. (A-B) Stained whole blood smears containing numerous erythrocytes and leukocytes. Conversely, PRP smears (C, D) contain primarily platelets (arrow), while the erythrocytes and granulocytes are eliminated.

**Tropocells™ PRP - 2 ml**

- Platelet concentration fold  X 4 - 5
- RBC (10^6/μl)   0.0
- WBC (10^3/μl)  0.2
- Granulocytes %   8.5
- Mononuclear cells %  86.2
- PDGF (pg/ml)  2048
- VEGF (pg/ml)  220
- EGF (pg/ml)  269

**Usage**

- Collect blood directly into Tropocells™ vacuum tube containing gel and anticoagulant.
- Centrifuge for 10 min at 1500 g. Gel separates platelets from platelet-poor plasma (PPP), RBC and granulocytes. Platelets reside on top of the gel.
- Remove gel of PPP using PPP collection syringe for increasing PRP concentration.
- Collect PRP using PRP collection syringe.

**Performance**

- Platelets concentration fold  X 4 - 5
- RBC (10^6/μl)   0.0
- WBC (10^3/μl)  0.2
- Granulocytes %   8.5
- Mononuclear cells %  86.2
- PDGF (pg/ml)  2048
- VEGF (pg/ml)  220
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**Quality Assurance**


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Features and Benefits of the Tropocells™ System

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- Rapid and simple one step process – only one centrifugation and one primary tube is used
- Adjustment to a specific clinical application by controlling the final PRP volume
- Specially designed accessories for OR setting

**Unique Biological Profile**
- Specially designed Separator Gel allows maximal concentration of platelets rather than creating a gradient, which leads to lower platelet yield
- Virtually eliminating granulocytes from PRP which are considered not beneficial in terms of regenerative processes and may contribute to a catabolic effect by secreting catabolic mediators including metalloproteinases [13]
- Eliminating undesired erythrocytes, which have been shown to significantly decrease fibroblast proliferation and augment apoptosis in vitro [4]

**Safety and Quality**
- Closed, biocompatible and xeno-free system, minimizing safety concerns
- Approved medical device by the European (CE) and USA (FDA) Regulatory Authorities (FDA clearance for orthopaedic applications only)
- Manufacturing under EN ISO 13485 and ISO 9001 Quality System International Standards

**Effectiveness and Corroborative Data**


4. The autologous nature of PRP eliminates concerns for disease transmission and minimizes chances for possible side effects, which may be in a form of mild bruising, pain, swelling or infection. Standard skin disinfection should be used before PRP injection [16]. Contraindications include pregnancy, breast feeding, autoimmune or blood pathologies and cancer. Furthermore, consistent use of NSAIDs within 48 hours of PRP application should be avoided [16].

**References:**