PRP Preparation

SIMPLICITY FOR SUCCESS
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.

PLATELET 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-promoting signaling molecules, such as Platelet-Derived Growth Factor (PDGF), Transforming Growth Factor group (TGF), Epidermal Growth Factor (EGF), 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 for accelerating soft and hard tissue healing have been established in various medical fields, including Orthopaedics and Sports medicine [4-9*], Chronic wounds [10*, 11*, 12*], Plastic [1,11*] and Oromaxillofacial surgery [13]. Moreover, its positive effect on skin rejuvenation [14*,15*] and hair restoration [16, 17*] has been repeatedly reported as a standalone treatment or as a biological adjunct to other methods, such as biodegradable fillers, including HA, collagen, autologous fat tissue transplant etc.

*Publications with Estar’s device for PRP preparation.

PRP FOR SKIN REJUVENATION

PRP leads to slow down of the aging process and rejuvenation by stimulating:

• Fibroblast proliferation
• Stem cell proliferation and differentiation
• Neocollagenesis and Extra Cellular Matrix formation
• Angiogenesis
PRP PREPARATION USING CELLENIS™ PRP

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 dermal stimulation, augmentation and matrix remodeling, resulting in skin rejuvenation [14*, 15*]. The whole preparation process takes up to 20 minutes.

1. Collect blood directly into Tropocell™ vacuum tube containing separation gel and anticoagulant.

2. 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.

3. Remove a portion of PPP to achieve higher platelet concentration (optional).

4. Resuspend platelets in the remaining plasma by replacing the lid and inverting the tube gently 10 times.

5. Insert slowly the filter sleeve into the tube until it reaches the gel. PRP passes through the filter.


* For a detailed protocol please refer to the Instructions for use.
ADVANTAGES OF PRP THERAPY IN AESTHETICS

• Improvement of skin texture and tone
• Gradual increase in skin thickness and vitality
• Minimal safety concerns – non-allergenic and free from concerns over transmissible diseases
• May be used for sensitive areas, like fine skin under the eyes
• May be combined with other treatments to stimulate biological effect

PRP is applied using dermal mesotherapy injection techniques/topically/using Dermaroller (micro needling).

SUITABLE AREAS FOR AESTHETIC TREATMENT

Sun-damaged and aged skin
• Around the eyes
Cheeks and mid-face
Nasolabial folds
Jaw Line
Sagging skin of the neck
Area of hair loss
Back of the hands
Décolletage
• Acne scars
• Stretch marks
• Other parts of the body

PROVEN PERFORMANCE

The Tropocells™ system was tested to evaluate biocompatibility, platelet yield, growth factors availability (PDGF, EGF and VEGF), platelet in vitro-characteristics and viability (platelet aggregation, p-selectin and hypotonic stress) immediately vs. four hours after preparation.

QUALITY ASSURANCE

Tropocells System is a CE Marked medical device [CE 1023], FDA 510(k) clearance for orthopaedic applications only. Manufacture in compliance with EN ISO 13485:2003, ISO 9001:2008 international standards.

Cellenis™ PRP

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelets concentration fold</td>
<td>X 4 - 5</td>
</tr>
<tr>
<td>RBC (10^9/ul)</td>
<td>0.0</td>
</tr>
<tr>
<td>WBC (10^9/ul)</td>
<td>0.2</td>
</tr>
<tr>
<td>• Granulocytes</td>
<td>8.5% from WBC</td>
</tr>
<tr>
<td>• Mononuclear cells</td>
<td>86.2% from WBC</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>269</td>
</tr>
</tbody>
</table>

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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**ADVANTAGES OF PRP THERAPY IN AESTHETICS**

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- May be used for sensitive areas, like fine skin under the eyes
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**Cellenis™ PRP**

**Platelets concentration fold**

<table>
<thead>
<tr>
<th>Parameter</th>
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<tbody>
<tr>
<td>RBC (10^6/ul)</td>
<td>0.0</td>
</tr>
<tr>
<td>WBC (10^3/ul)</td>
<td>8.5%</td>
</tr>
<tr>
<td>Granulocytes</td>
<td>86.2%</td>
</tr>
<tr>
<td>Mononuclear cells</td>
<td>2048</td>
</tr>
</tbody>
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**PDGF (pg/ml)**

- Cellenis™ PRP
- 220

**VEGF (pg/ml)**

- Cellenis™ PRP
- 269

**EGF (pg/ml)**

- Cellenis™ PRP
- 1023

**SUITABLE AREAS FOR AESTHETIC TREATMENT**

- Area of hair loss
- Back of the hands
- Décolletage
- Acne scars
- Stretch marks
- Other parts of the body
- Sun-damaged and aged skin around the eyes
- Cheeks and mid-face
- Nasolabial folds
- Jaw Line
- Sagging skin of the neck

**QUALITY ASSURANCE**

- Tropocells System is a CE Marked medical device [CE 1023], FDA 510(k) clearance for orthopaedic applications only.

**FEATURES AND BENEFITS**

**EFFECTIVENESS**

- Enables high platelet concentration by reducing the volume of plasma.
- 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 filter sleeve facilitates PRP harvest.

**SAFETY AND QUALITY**

- 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).
- Manufactured in clean rooms, under EN ISO 13485 and ISO 9001 Quality System International Standards.

**UNIQUE BIOLOGICAL PROFILE**

SPECIALY DESIGNED SEPARATOR GEL ALLOWS OPTIMIZING OF CELLENIS™ PRP BIOLOGICAL PROFILE BY:

- Maximal concentration of platelets (rather then creating a gradient), which leads to higher platelets yields.
- Virtually eliminating granulocytes from PRP, which are considered not beneficial in terms of regeneration process and may contribute to a catabolic effect by secreting catabolic mediators, including metalloproteinases [18].
- Eliminating undesired erythrocytes, which have been shown to significantly decrease fibroblast proliferation and augment apoptosis in vitro [19].
- Remnant of mononuclear cells present in PRP assists in fighting infection and is thought to enhance anabolic effects of PRP [20].

**CELENIS™ PRP**

**SIMPLIFYING PRP PREPARATION**

Cellenis™ PRP is Estar-Medical’s proprietary PRP preparation kit, facilitating the preparation process of pure, concentrated and biologically active PRP.
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, pain, swelling or infection. Standard skin disinfection should be used before PRP injection. 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 [21].

REFERENCES:


7. Platelet-rich plasma vs hyaluronic acid to treat knee degenerative pathology: study design and preliminary results of a randomized controlled trial. Filardo G et al. BMC Musculoskelet Disord. 2012


14. Using objective criteria to evaluate cosmetic effects of platelet rich plasma Amgar et al. Prime 2011


16. A randomized, double-blind, placebo and active-controlled, half-head study to evaluate the effects of platelet rich plasma on alopecia areata. Trink et al. BJD 2013


