

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 filters facilitate PRP harvest.

SAFETY AND QUALITY

- Biocompatible and xeno-free system, minimizing safety concerns.
- Approved medical device by the European (CE) and US (FDA) Regulatory Authorities*
- Manufactured in clean rooms, under EN ISO 13485 and ISO 9001 Quality System International Standards.

*(FDA clearance for orthopaedic applications).

UNIQUE BIOLOGICAL PROFILE

SPECIALLY DESIGNED SEPARATOR GEL ALLOWS FOR THE OPTIMIZATION OF CELLENIS® PRP BIOLOGICAL PROFILE BY:

- Maximizing concentration of platelets (rather than creating a gradient), which leads to higher platelets yield.
- 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].

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).





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:

1. Platelet-rich plasma: a review of biology and applications in plastic surgery.

Eppley BL et al. Plast Reconstr Surg. 2006

2. Platelet-rich plasma: from basic science to clinical applications.

Foster TE et al. Am J Sports Med. 2009

 The effect of thrombin activation of platelet-rich plasma on demineralized bone matrix osteoinductivity.
 Han B et al. J Bone Joint Surg Am. 2009

4. Positive effect of an autologous platelet concentrate in lateral epicondylitis in a double-blind randomized controlled trial: platelet-rich plasma versus corticosteroid injection with a 1-year follow-up.

Peerbooms JC et al. Am J Sports Med. 2010

5. Platelet-rich plasma versus autologous whole blood for the treatment of chronic lateral elbow epicondylitis: a randomized controlled clinical trial.

Thanasas C et al. Am J Sports Med. 2011

- Platelet rich plasma in arthroscopic rotator cuff repair: a prospective RCT study, 2-year follow-up.
 Randelli P et al. J Shoulder Elbow Surg. 2011
- 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

- 8. Patellar tendon healing with platelet-rich plasma: a prospective randomized controlled trial.
- de Almeida AM et al. Am J Sports Med. 2012
- 9. Platelet-Rich Plasma Versus Focused Shock Waves in the Treatment of Jumper's Knee in Athletes.

Vetrano et al. AJSM. 2013

10. Application of platelet-rich plasma accelerates the wound healing process in acute and chronic ulcers through rapid migration and upregulation of cyclin A and CDK4 in HaCaT cells.

Kim SA et al. Mol Med Rep. 2013

11. Efficacy of intradermal radiofrequency combined with autologous platelet-rich plasma in striae distensae: a pilot study. Kim IS et al. Int J Dermatol. 2012

12. Platelet-Rich Plasma induces increased expression of G1 cell cycle regulators, type I collagen, and Matrix

Metalloproteinase-1 in human skin fibroblasts

Cho. Int. J. Mol. Med. 2011

13. Role of platelet-rich plasma in combination with alloplastic bone substitute in regeneration of osseous defects

Singh et al. Journal of Oral Biology and raniofacial Research 2011 14. Using objective criteria to evaluate cosmetic effects of platelet rich plasma.

Amgar et al. Prime 2011

15. Platelet rich plasma (PRP) for facial rejuvenation. Zenker S. J. Méd. Esth. et Chir. Derm. 2010

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

17. Platelet-Rich Plasma: a Therapy For Hair Growth. Amgar et al. Prime 2011

18. Growth factor and catabolic cytokine concentrations are influenced by the cellular composition of Platelet Rich Plasma. Sundman et al. Am J Sports Med. 2011

19. Red blood cells inhibit proliferation and stimulate apoptosis in human lung fibroblasts in vitro.

Fredriksson K et al. Scand J Immunol. 2004

20. Peripheral blood mononuclear cells enhance the anabolic effects of Platelet Rich Plasma on anterior cruciate ligament fibroblasts.

Yoshida R et al. J Orthop Res. 2013

21. ICMS guidelines, section VIII Platelet Rich Plasma (PRP) Guidelines, 2011





Mailing Address: Estar Technologies LTD POB 2150, Holon 5812101, Israel Tel: +972 3 5596414, Fax: +972 3 5596424 Email: sales@estar-medical.com





Cellenis® PRP is Estar-Medical's proprietary PRP preparation kit, facilitating the preparation process of pure, concentrated and biologically active PRP.



Platelet Rich Plasma 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 Oral Maxillofacial 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

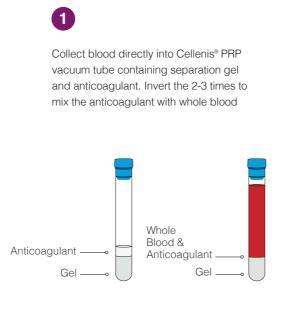
PRP leads to skin rejuvenation and slows down the aging process by stimulating:

- Fibroblast proliferation
- Stem cell proliferation and differentiation
- Neocollagenesis and Extra Cellular Matrix formation
- Angiogenesis

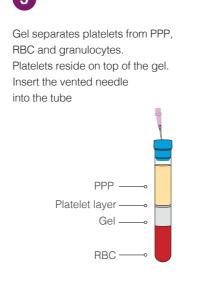


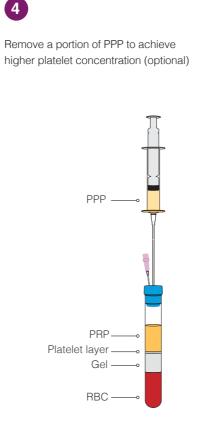
PRP PREPARATION USING CELLENIS® CLOSED SYSTEM

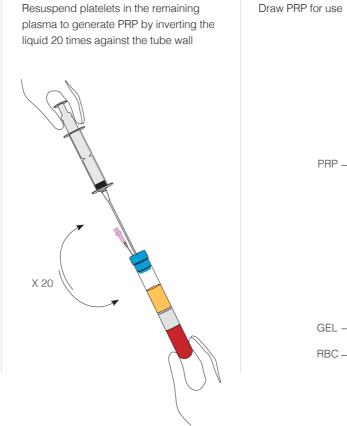
PRP is prepared by taking a small sample of the patient's own blood, then separating platelets from Red Blood Cells (RBC), leukocytes and Platelet Poor Plasma (PPP) via centrifugation. PRP is then collected and can be injected back into the treated site to promote healing response and dermal stimulation, augmentation and matrix remodeling, resulting in skin rejuvenation [14*, 15*]. The whole preparation process is simple and takes up to 15 minutes.

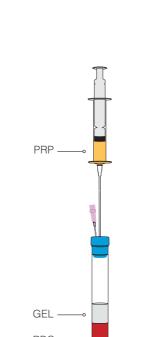






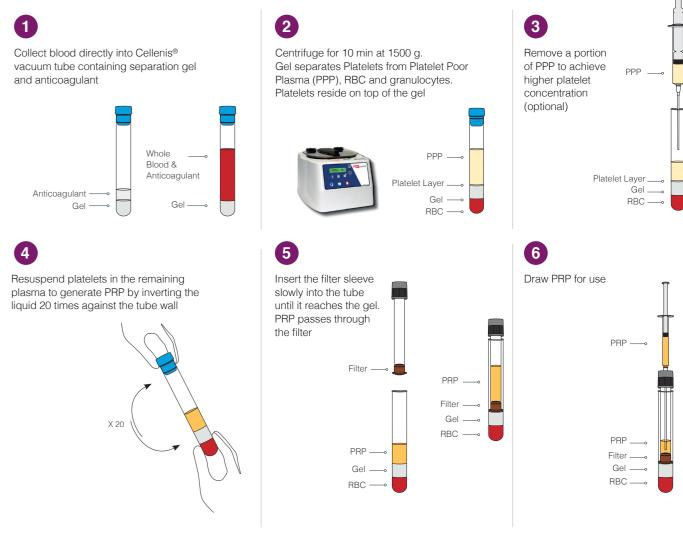








PRP PREPARATION USING CELLENIS® OPEN SYSTEM

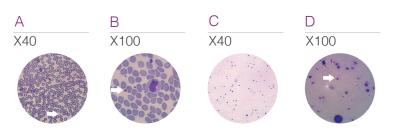


^{*} For a detailed protocol please refer to the Instructions for use

PROVEN PERFORMANCE

The Cellenis® 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) at time 0 and four hours after preparation.

CELLENIS® PRP	
Platelets concentration fold	X 4 - 5
RBC (10 ⁶ /ul)	0.0
WBC (10 ³ /ul)	0.2
 Granulocytes 	8.5% from WBC
 Mononuclear cells 	86.2% from WBC
PDGF (pg/ml)	2048
VEGF (pg/ml)	220
EGF (pg/ml)	269



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.

QUALITY ASSURANCE

Cellenis® is a CE Marked medical device, FDA 510(k) cleared for orthopaedic applications.

Manufactured in compliance with EN ISO 13485:2012, ISO 9001:2015 international standards.