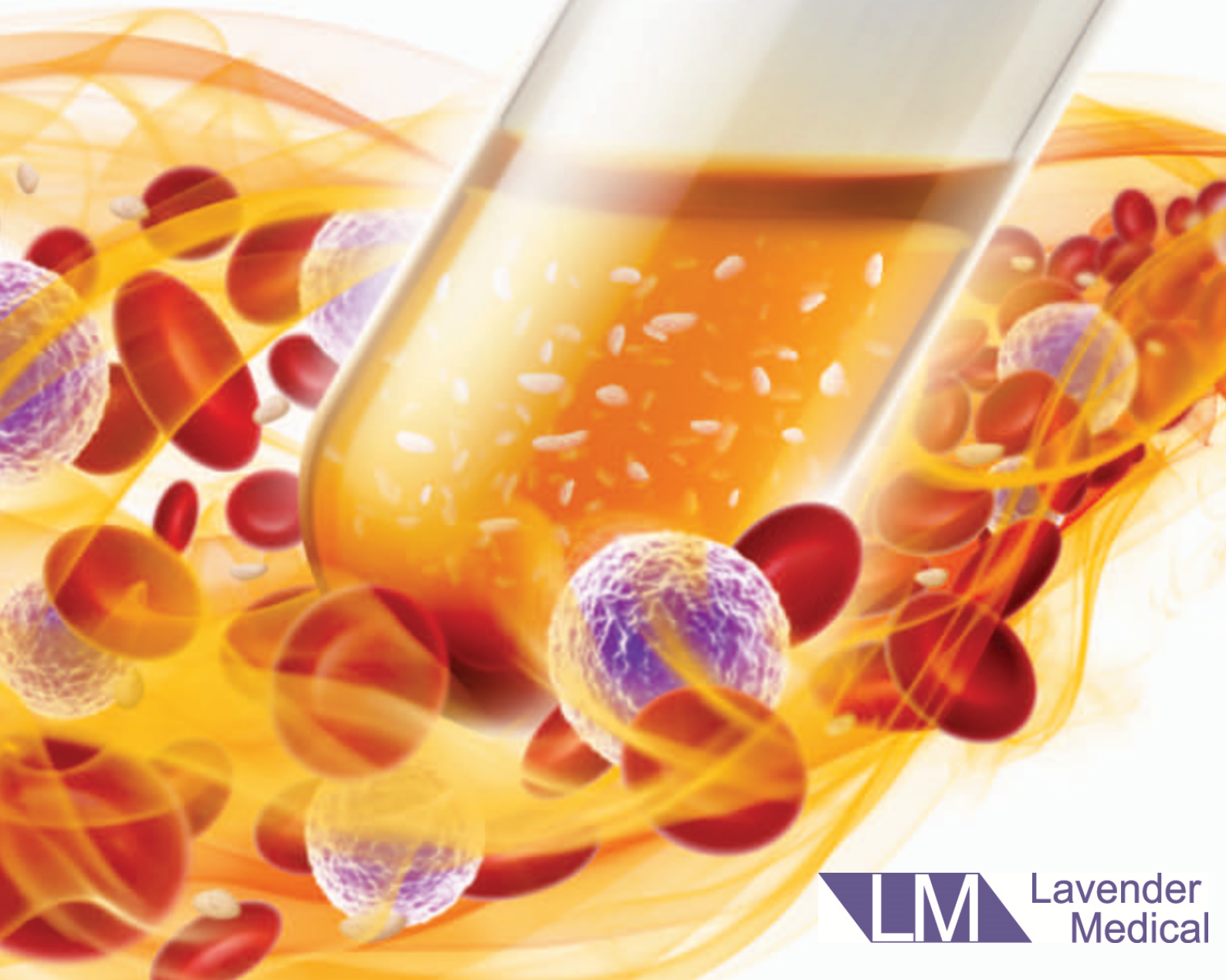


Tropocells[™] *BASIC*



PRP Preparation **Simplicity for Success**



Lavender
Medical

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 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).
- Manufacturing under EN ISO 13485 and ISO 9001 Quality System International Standards.

Unique Biological Profile

Specially designed Separator Gel allows optimizing of Tropocells™ PRP biological profile by:

- Maximal concentration of platelets rather than creating a gradient, which leads to lower platelet 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 [15].
- Eliminating undesired erythrocytes, which have been shown to significantly decrease fibroblast proliferation and augment apoptosis in vitro [16].
- Remnant of mononuclear cells present in PRP assists in fighting infection and is thought to enhance anabolic effects of PRP [17].

Tropocells™ Basic

Simplifying PRP Preparation

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



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 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].

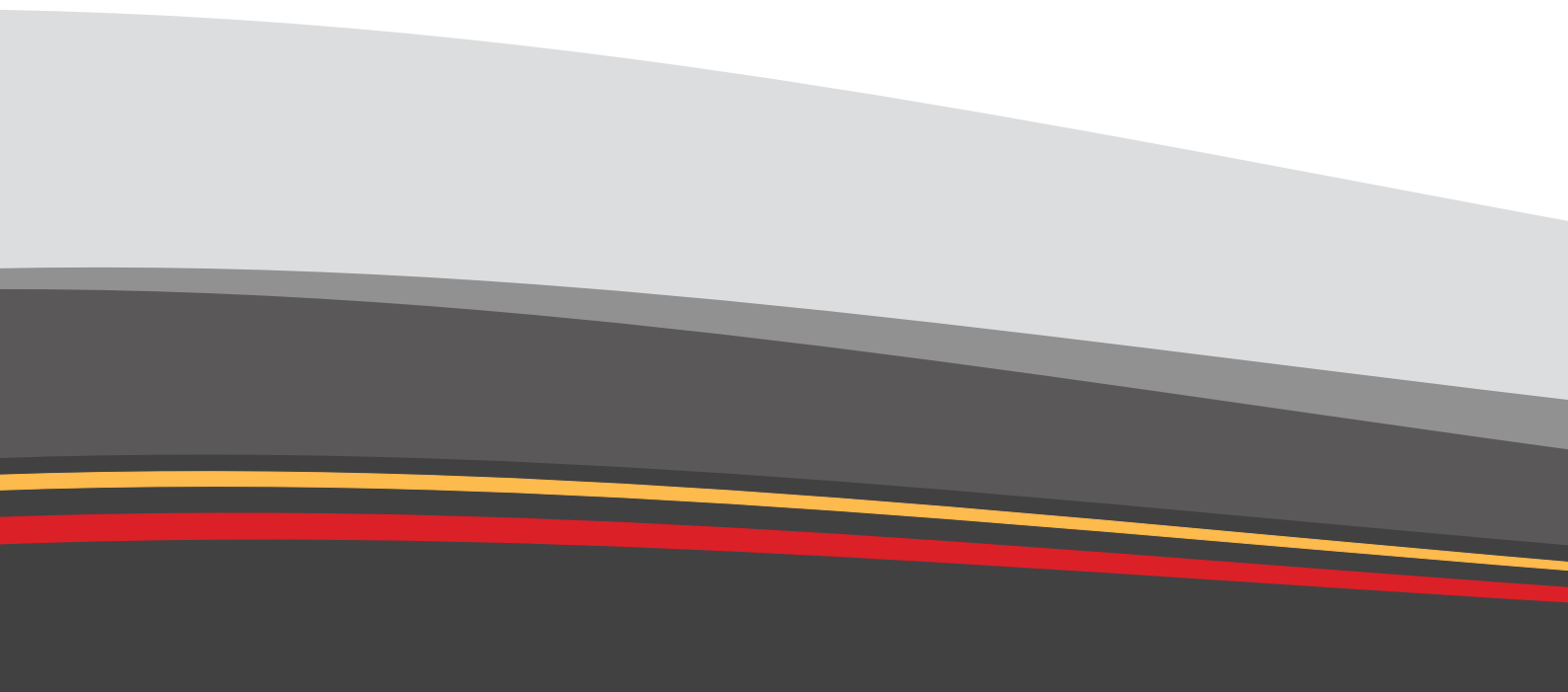
Platelet Activation

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

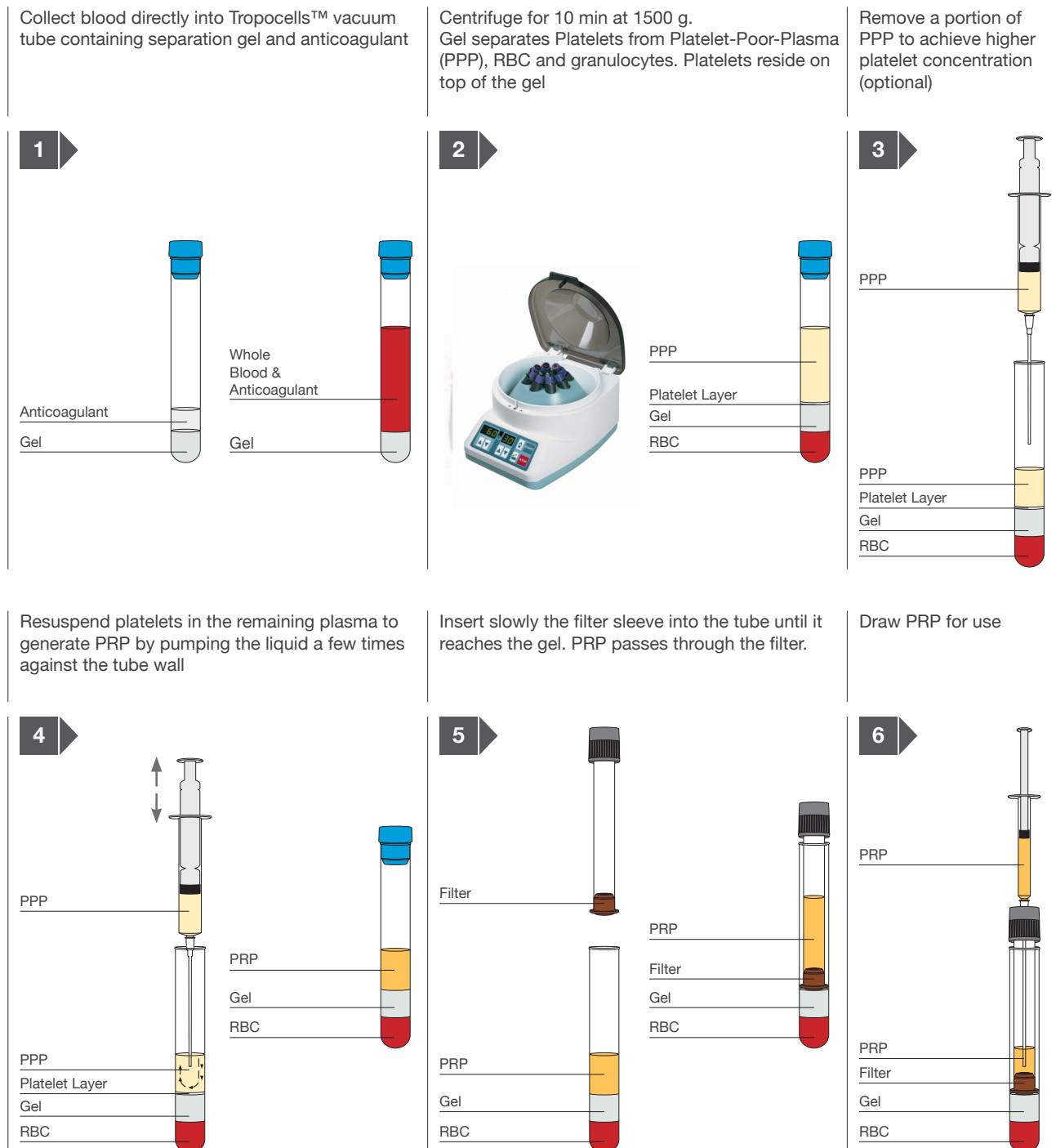
PRP's safety and effectiveness have been established for accelerating soft and hard tissue healing in treatment of tendinopathies [4-6], osteoarthritis [7] and various joint and muscle pathologies in Orthopaedics and Sports Medicine [8]. PRP may be used as a standalone treatment or as a biological adjunct to other biomaterials, such as bone substitutes [9], hyaluronic acid, collagen and mesenchymal stem cells [10]. Moreover, PRP has been used extensively for treating Chronic wounds [11*], in Plastic [1, 12*] and Oromaxillofacial surgery [9].

*Publications with Estar's device for PRP preparation.



PRP Preparation using Tropocells™ Basic

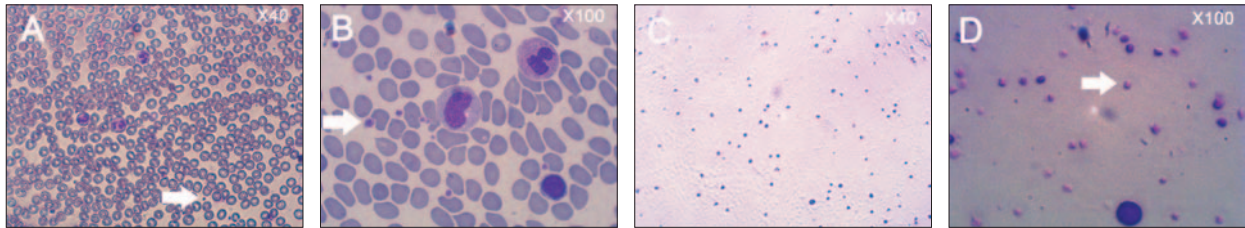
PRP is prepared by taking a small sample of the patient's own blood, then separating platelets from Platelet-Poor Plasma (PPP), red blood cells (RBC) and leukocytes via centrifugation. PRP is then collected and can be injected back into the treated site to promote dermal stimulation, augmentation and matrix remodeling, resulting in skin rejuvenation [12*, 13*]. The whole preparation process takes up to 20 minutes.



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

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.

Tropocells™ PRP – 2ml	
Platelets concentration fold	X 4 - 5
RBC (10^6 /ul)	0.0
WBC (10^3 /ul)	0.2
Granulocytes %	8.5
Mononuclear cells %	86.2
PDGF (pg/ml)	2048
VEGF (pg/ml)	220
EGF (pg/ml)	269

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.



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 [18].

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Tropocells™ BASIC



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