FEATURES AND BENEFITS OF THE TROPOCELLS™ PRP 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 accessories for operation room setting.

SAFETY AND QUALITY

- Closed, biocompatible and xeno-free system, minimizing safety concerns.
- Approved medical device by the European (CE) and USA (FDA) Regulatory Authorities*.
- Manufactured in clean rooms, 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 higher platelets yield.
- Virtually eliminating granulocytes from PRP, which are not considered beneficial in terms of regeneration process and may contribute to a catabolic effect by secreting catabolic mediators, including metalloproteinases [20].
- Eliminating undesired erythrocytes, which have been shown to significantly decrease fibroblast proliferation and augment apoptosis in vitro [21].
- Remnant of mononuclear cells present in PRP assists in fighting infection, increase collagen expression and is thought to enhance anabolic effects of PRP [22].

ADVANTAGES OF PRP THERAPY IN ORTHOPEDIC

- Initiate connective tissue healing, bone and joint surface regeneration and repair, promote development of new blood vessels and stimulate wound healing.
- Significant improving in symptoms.
- Minimal safety concerns – non-allergenic and free from concerns over transmissible diseases.
- May eliminate the need for surgery.
- May be combined with other treatments to stimulate biological effect.

* FDA clearance for orthopedic applications only.

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 [23]. Contraindications include pregnancy, breast feeding, autoimmune or blood pathologies and cancer. Furthermore, use of NSAID drugs within 7 days prior to and 5 weeks after TROPOCELLS™ PRP should be avoided [23].

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Tropocells™ PRP

ORTHOPEDICS SOLUTION

ADVANCE REPAIR RESTORE

YOUR BODY'S ABILITY / POTENTIAL
IN A NATURAL WAY

Platelet-Rich Plasma (PRP) Therapy

www.estar-medical.com

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 in a small volume of plasma [1]. PRP owes its therapeutic interest to the crucial instrumental role of growth factors released by platelets granules which possess multiple regenerative properties. The autologous nature of Tropocells™ PRP guarantees its excellent safety profile [2].

THERAPEUTIC EFFECT OF PRP

PRP is thought to promote physiological healing and rapid soft and hard tissue regeneration by delivering high concentrations of growth factors essential for connective tissue healing; regenerating and repairing bone, tendon, cartilage and ligament; promoting development of new blood vessels and stimulating wound healing.

PRP GROWTH FACTORS

Upon activation, platelets release growth factors, cytokines and other bioactive proteins, 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 growth factors control and regulate the healing cascade, by exerting their effects on inflammatory process, cell proliferation, reepithelialization, angiogenesis, wound healing, collagen production and other 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; upon contact with connective tissue and exposure to in situ coagulation factors, such as collagen), the cell membrane of the platelet is "activated" to release these alpha granules, resulting in a slow release pattern of growth factors secretion, which is 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 Orthopedics and Sports Medicine [8, 9*]. PRP may be used as a standalone treatment or as a biological adjunct to other biomaterials, such as bone substitutes [10], hyaluronic acid, collagen and stem cells [11].
Moreover, PRP has been used extensively for treating chronic wounds [12*, 13*, 14*], in Plastic [1, 13*], Oromaxillofacial surgery [10] and even skin rejuvenation [15*,16*] and hair restoration [17, 18*, 19*]

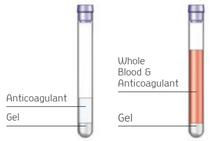
* Publications with Estar Medical's device for PRP preparation.

PRP PREPARATION USING TROPOCELLS™ 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 healing response. The whole preparation process is simple and takes up to 15 minutes.

Collect blood directly into Tropocells™ PRP vacuum tube containing separation gel and anticoagulant

1

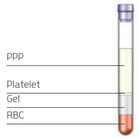


Centrifuge for 10 min at 1500 g.

2

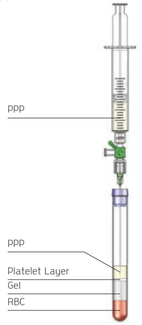
Gel separates platelets from PPP, RBC and granulocytes. Platelets reside on top of the gel

3



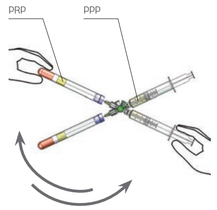
Remove a portion of PPP to achieve higher platelet concentration (optional)

4



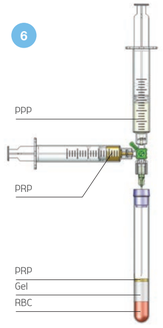
Resuspend platelets in the remaining plasma to generate PRP by inverting the liquid a few times against the tube wall

5



Draw PRP for use

6



Other accessories such as one check valve (I), 2 check valves (Y) and several types of filters are also available.

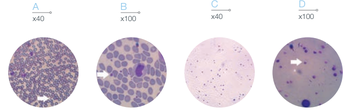
* For a detailed protocol please refer to the Instructions for Use.

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 a CE Marked Class IIb 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.

CE 1023



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.

MAIN PRP APPLICATIONS IN ORTHOPEDICS & SPORTS MEDICINE