



**BLUE KIT**<sup>®</sup>  
PRP  
system

Platelet Rich Plasma System

PLATELET RICH PLASMA  
PLATELET RICH PLASMA KIT

[www.bluekitprp.com](http://www.bluekitprp.com)



## WHAT IS PRP? PRP is a Regenerative Cell Therapy.

Platelet Rich Plasma is plasma rich in thrombocytes. Thrombocyte cell has a structure without a nucleus, containing several growth factors. This cell works in harmony with functional stem cells, and it is very effective in respect to regeneration, repair or nurturing of a damaged area. (A tissue that begins healing process through bleeding well-explains this mechanism). Our blood has three structural elements (erythrocyte, thrombocyte, leukocyte).

Erythrocytes play a significant role in conveying oxygen within our system whereas leukocytes are defense mechanism of our bodies, thrombocytes take part in repair, coagulation and healing process. Knowing PRP means knowing function, duty and miracles of thrombocytes.

Thrombocytes enriched with PRP Kit are activated (platelet activation) and injected to the area containing damaged tissue using an appropriate method without need for surgical intervention to initiate cellular therapy. All of the consumables required to administer this treatment are fully included within Blue Kit PRP System.

PRP (Platelet Rich Plasma) is a thrombocyte rich plasma. It is obtained by centrifuging the blood sample and separating cells into layers by their molecular weights.

We are able to gather 2-2.5 ml platelet rich plasma from 9 ml blood within PRP tube.

In addition to blood coagulation functions, thrombocytes produce secretions named growth factor which remedy tissue damages. Thrombocyte count that is approximately 200 thousand in one micro-liter of a healthy human blood can be concentrated to 2 – 3 folds or more by PRP.

PRP is an autologous method that can only be administered by doctors, where the material obtained from the individual is re-administered to the individual. Material obtained from individual cannot be administered to another.



## POINTS OF CONSIDERATION WHEN SELECTING PRP KIT

PRP Kits must be devices accepted by Republic of Turkey, Ministry of Health, and certified by notified bodies authorized by European Union Committee.

Medical devices that are subjected to the tests and assessments specified in Medical Device Regulation issued by Ministry of Health must meet relevant classification requirements of the medical devices regulation.

PRP is (preparation of a material known as Platelet Rich Plasma Fluid from individual's own blood) renown around the world as a treatment method intended for bone and soft tissue recovery.

### PRP APPLICATION KITS ARE MEDICAL DEVICES

PRP Kits must be in a specific classification in accordance with the Classification Rules requirements under relevant ANNEX (Annex II) of 93/42/EEC directive published by European Union Committee, and must have a certification bearing CE mark and number for medical devices subject to **Class III** accordingly. This is the number assigned to the certification body by European Committee.

Accordingly;

PRP Kits must fall within the following class. Other products cannot be used for PRP.

MEDDEV technical regulations published by European Union Committee for medical devices (12-2017 BORDERLINE) clearly stipulates that PRP Kits must have CE certification in accordance with Class III norms. Since the relevant regulation states that medical devices containing anti-coagulant and gel (for testing purposes) which are used **non-invasively** must have Class 2a CE certificate, this is often abused. Blue Kit PRP System is an **invasive** device, therefore it is granted Class III CE certificate.

### COMPARISON OF BLUEKIT PRP SYSTEM WITH IVD TUBES

MDD – Medical Device Directive	IVD – In Vitro Diagnostic Tubes
Directive 93/42/AT	EU Directive 98/79/EC
<b>Class III</b>	Listed Under A and B Device Lists.
Specifically Requires CE Mark (CE 2292)	Specifically Requires IVD Mark.
Requires Clinic Use Approval.	Clinical Use is NOT Permitted.
Requires Bio-compatibility Test.	Bio-compatibility Test is NOT Required.
Requires Clinical Evaluation.	There is no clinical evaluation.
Must Have ISO 13485 Standards.	

## FIELDS OF USE FOR BLUE KIT PRP SYSTEM



# PRP (Platelet Rich Plasma) THERAPY IN JOINT DISEASES

## USE IN MUSCLE SKELETON SYSTEM DISEASES

- **Physiotherapy and Rehabilitation**
- **Orthopedics and Traumatology**
- **Neurosurgery, Brain and Nerve Surgery**
- **Sports Medicine**

**Chronical Tendinopathies and enthesitis;** Lateral epicondylitis, Patellar-tendinopathy, Achilles tendinopathy, Rotator cuff tendinopathy, Digital tendon pathologies, Plantar fasciitis.

**Acute/chronic ligament injuries;** Medical collateral ligament injury, Anterior cruciate ligament reconstruction. Acute/chronic muscle tears and strains

**Cartilage and bone diseases;** Osteoarthritis, Osteochondritis dissection, Arthroplasty surgeries, Meniscal pathologies, Delayed fracture healing and non-unions, Inter-vertebral disc diseases, Spinal fusion.

The most important element for successful outcomes is preparation of PRP through proper harvesting and resuspension.



## USE IN MUSCLE SKELETON SYSTEM DISEASES



**PRP Method** plays a significant role for ensuring regeneration in bone, muscle, cartilage, tendon, tendinitis and joint diseases.

**PRP Method** can be used in treatment of calcification, damages and cartilage tissue losses in all joints including knee, shoulder, elbow, back, hip, etc.



## FIELDS OF USE FOR BLUE KIT PRP SYSTEM

### Dermatology, Plastic and Reconstructive Surgery, Medical Aesthetic



**BLUE KIT PRP** system stimulates hair follicles, leading to release of growth factor, making your hair bright, vibrant and strong. Growth factors stops hair loss in balding spots.

**BLUE KIT PRP** system increase blood circulation in hairy areas and the perimeter, allowing higher oxygen and vitamin delivery to hair follicles.

**BLUE KIT PRP** system rejuvenates skin. Tissue losses occurring in the skin through time results in increased wrinkles and occurrence of collapses. Post-PRP application growth factor release enables restructuring of collagens, increasing elasticity of skin and firming saggy skin. It corrects skin faults.

**BLUE KIT PRP** application maintains functioning of melanocyte cells at normal levels through release of growth factors to eliminate skin blemishes. This treatment method also helps elimination of acne, pimple scars.



### Acute and Chronic Wounds

**BLUE KIT PRP** system also enables a rapid healing of wound areas that are difficult to heal such as foot ulcers, venous ulcers, decubitus wounds.



## FIELDS OF USE FOR BLUE KIT PRP SYSTEM

### Dentistry, Maxillofacial Surgery

**BLUE KIT PRP** is used for bone grafting in dental implanting, rapid healing of bone deformations after tooth and cysts removal, repairing fistula in sinus cavity and gingival recession in dentistry and maxillofacial surgery.

### Urology

**BLUE KIT PRP** system is used for treatment of erection problems, chronic prostatitis, chronic pelvic pain syndrome, interstitial cystitis and chronic cystitis.



### Ophthalmology

**BLUE KIT PRP** system is used for treatment of corneal ulcers, dry eyes syndrome, etc. problems.



## KIT CONTENT AND PRP PREPARATION

### BLUE KIT PRP MODEL KIT CONTENT

#### **BASELINE PRODUCT (1): OA 5000 MODEL**

- 10 ML PRP TUBE WITH SODIUM CITRATE  
(PREFERRED INJECTOR NEEDLE TIPS INCLUDED AS COMPLIMENTARY)

#### **BASELINE PRODUCT (2): OA 1000 MODEL**

- 2 EACH 10 ML PRP TUBES (WITH SODIUM CITRATE) 16 mm x 10 cm
- 1 EACH RESUSPENSION TUBE 16 mm x 10 cm
- 1 EACH VACUTAINER BUTTERFLY GREEN NEEDLE TIP
- 1 EACH HOLDER
- 2 EACH 21 G GREEN NEEDLE TIP
- 1 EACH 30 G x 13 mm YELLOW NEEDLE TIP
- 1 EACH 5 CC INJECTOR
- 3 EACH 2,5 CC INJECTORS
- 1 EACH 18 G x 9 cm PRP HARVESTING NEEDLE



First, blood is taken into PRP tube through a contained system using vacutainer blood taking needle, and the blood inside the tube is shaken 7-8 times to enable mixing with the fluid inside the tube, then centrifuge process is performed at 3000 rpm for 8-9 minutes. Using PRP harvesting needle, the layer referred as buffy coat which contains the highest rate of grayish thrombocytes is gently collected in an amount of 2-2,5 cc ensuring minimum contact with erythrocytes, then it is re-suspended (homogenous distribution of PRP) by shaking for 30-40 seconds, and injected to the application area.



## HOW TO USE BLUE KIT?

### 01 Harvesting the Whole Blood Into Tube

Using the kit contained in BLUE KIT PRP, blood is directly collected into the tubes. Each tube is 10ml volume including 1ml of anticoagulant. Tubes provide easily harvesting of the whole blood as they are vacuumed tubes. Both tubes stop when vacuum is finished. So, you have totally the 18ml of whole blood. After harvesting the whole blood, gently shake both tubes to permeate the anticoagulant into whole blood in the tubes.

### 02 Centrifugation

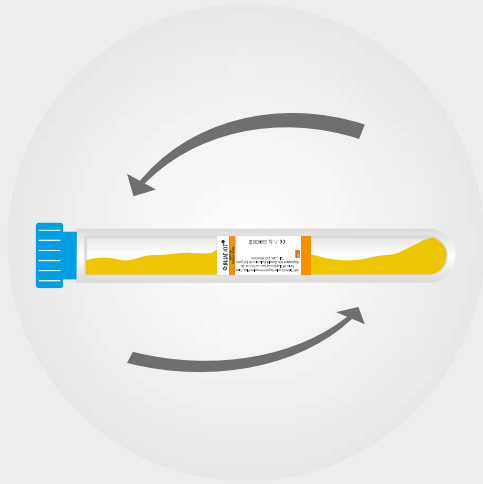
Any centrifuge device can be used to perform this process. Both tubes should be placed in opposite directions to ensure centrifuging balance. No special centrifuging device is provided. The only important subject for centrifuging is to perform centrifuge process at 3000 RPM for 8 minutes.

### 03 Harvesting the PRP

Harvesting the PRP

The long PRP harvest needle is attached on the preferred injector, and inserted vertically into the tube. The edge of needle is placed right on the buffy coat layer, and 2-3 ml PRP is collected with tornado movement of the needle and injector. It is also recommended to collect small amount of RBCs along with Buffy Coat layer with PRP, which is important for the Cell-Cell interaction during re-suspension process.

## HOW TO USE BLUE KIT?



### 04 Re-Suspension Process

The PRP collected into injector is carried to Re-Suspension Tube without removing long needle. Re-suspension Tube is plain and sterile. This tube has 10ml volume and used for total of 5-6 ml PRP to be collected from both tubes. Tube is turned horizontally and gently and manually shaken for about 30 seconds to 1 minute. This process supports the homogenization of the thrombocytes in the PRP. After this process, PRP is collected inside preferred injector and is ready for injection.

### 05 Understanding the PRP Layer

The bottom layer in dark red color is formed of Red Blood Cells, and right above the RBC layer, there is thin buffy coat layer where white blood cells and thrombocytes are accumulated. This fraction is less than 1% of total blood. Upper layer is in light yellow color, composed of two layers that cannot be differentiated by naked eye. PRP is located at the bottom of this light yellow layer, the 2 ml fraction right above buffy coat layer. The top layer over PRP is referred as PPP and is poor in thrombocytes.

This is the most important fraction that requires great care in order to achieve a correct PRP. Pay attention to avoid any vibration on the tube after leaving centrifuge. Tube content must be visibly separated into 3 layers. Visibility of those three layers indicates a correct centrifuge process.