

IFU INDICATION FOR USE  
DPGPRP PRP

## KIT USER GUIDE DESCRIPTION:

Medical device for the preparation of autologous P.R.P. (Platelet Rich Plasma).

It is a medical device for the preparation of Platelets Rich Plasma (PRP) starting from the blood sample collection, which includes:

- Box No. 1: Contains ACD tubes pre-labeled with a colored cap containing ~ 1 ml of anticoagulant (ACD); each tube labeled, for example 9/12 ml of capacity, has a pre-calibrated vacuum for ~ 9/12 ml of blood collection.

In the box there are tubes, in each of which there is a separator gel based on an inert polymer and an anticoagulant (named for better understanding, type 1 tube, necessary for the separation of platelet-enriched serum (injectable liquid enriched with growth factors) and the concentration of red blood cells (clot) of the blood that is obtained after centrifugation.

**PURPOSE OF USE:** Acceleration of the tissues' healing.

DPGPRP PRP is a kit designed for easy & efficient separation and preparation of plasma with a higher platelets concentration in a optimal quantity.

DPGPRP PRP Regenerative Therapy Kit allows for point of care preparation of Platelet Rich Plasma (PRP) through centrifugation of a fraction of autologous blood.

Its use can help for skin rejuvenation, acne/scarring, and alopecia/hair loss conditions. Advantages of using DPGPRP PRP includes induction of cell differentiation, Extra Cellular Matrix formation and recruitment of other cells to injury'site.

The preparation is based on a method called "BUFFY COAT" with a glass tube, which differs from the "EMPTY TUBE" (a simple test tube for vacuum blood collection), which does not obtain a concentrate but a serum; it is not able to separate the blood with high precision and to obtain a high concentration of PRP and does not allow to extract only the intermediate layer (PRP). Furthermore, the plastic of the test tubes contains micronized silicone that can also generate platelet activation. All this results in a serum free of platelets after the centrifugation process which cannot be used for PRP.

In addition to centrifugation, PRP can also be obtained for: CELL VERTICAL PRECIPITATION: if a cell separation is required to obtain the P.R.P. by cellular precipitation of different specific weights (GRAVITATIONAL VERTICAL DECANTATION), place the tube vertically on a tube holder and wait for the cell separation by natural gravitational action from 2 to 3 hours.

The medical device in question is not made of plastic that contains micronized silicone.

The Platelet Rich Plasma (PRP), also called autologous platelet gel (Autologous Platelet Gel), plasma rich in growth factors (PRGF) or platelet concentrate (PC), is essentially an increase in the concentration of autologous platelets contained in a small amount of plasma after the patient's own blood centrifugation.

The medical device must only be used by appropriately trained medical or nursing personnel under the medical responsibility.

## DPGPRP PRP KIT COMPONENTS

PRP Medical Device Kit includes components necessary for the preparation of Platelet Rich Plasma.

All components are single use, sterile, and conforms the regulation of European Union to a high standard of manufacturing control for safety.

PRP Tubes (Sterile, Pyrogenic-Free): 1Tube x 9/12 ml

Each 9/12 ml PRP Tube contains:

- A cell-selector gel.
- An anticoagulant (Sodium Citrate 3-4%).

## Read all instructions prior to using the Kit.

## PRECAUTIONS

- PRP should be provided to the same patient whom the blood was drawn from (AUTOLOGOUS).
- Tubes must be stored between at room temperature.
- Do not use tubes if foreign matter is present.
- Anticoagulant liquid is clear. Do not use tubes after their expiration date.
- Do not re-sterilize and do not attempt to clean this product.
- Do not use tubes if transparent outer tube packing is damaged.
- Use prepared platelet concentrate material **within 4 hours** including drawing blood from patient.
- DPGPRP PRP 9/12 ml tube gives greater draw volume of whole blood which gives more plasma and platelets in a single tube.

## HOW TO USE DPGPRP PRP KIT OBTAIN Platelet-Rich Plasma VEINIPUNCTURE TECHNIQUE AND SPECIMEN COLLECTION PRACTICE UNIVERSAL INSTRUCTIONS

**Wear gloves during venipuncture and when handling blood collection tubes to minimize exposure hazards.**

- Select a DPGPRP PRP kit and a blood collection set with pre-attached holder.
- Place tube into the pre-attached holder of blood collection set without puncturing the rubber stopper
- Select the best site for venipuncture.
- Place patient's arm in a downward position.
- Apply tourniquet and prepare a large venipuncture site with an appropriate antiseptic.
- Do not palpate again venipuncture after cleansing**
- Remove butterfly needle sheath and perform venipuncture by holding wings.
- Have a look to the needle to visualize the blood coming into the sleeve.
- Push the tube onto the needle puncturing holder.
- Blood will automatically fill the tube thanks to the inside vacuum.
- Remove tourniquet as soon as blood appears in the tube.

If no blood flows into the tube or if blood ceases to flow before an adequate specimen is collected, the following steps can be realized to complete satisfactory collection:

- Push the tube forward until tube stopper has been penetrated and hold in place to ensure complete vacuum draw.
- Check and confirm the right position of needle inside the vein.
- If second tube does not draw, remove needle and discard.
- Once the tube has been filled and blood flow automatically ceases, remove the tube from holder
- Repeat this step for all successive and necessary tubes.

- Immediately after removing the tube PERFORM gentle inversions in order to mix well the anticoagulant.**

**If not, inadequate mixing may result in platelet clumping/aggregating, clotting after centrifugation and incorrect the results.**

- After removing the needle from vein, apply a dry sterile swab with pressure on the arm staying horizontal.
- As soon as a good clotting has occurred apply a small bandage.
- Discard all used needle and holder in biohazards containers approved for their disposal.

**DO NOT RESHIELD** Use the Safety-Lok shield activation of the Butterfly needle, because reshielding of the needles increases the risk of needle-stick injury and blood exposure.

- Handle all blood collection injectables (Butterfly needles, luer adapters or blood collection sets) according to the universal policies and procedures.
- Be strongly careful in case of any exposure to biologic samples (through a puncture injury) as there is a potential transmission of hepatitis, HIV (AIDS), or other infectious diseases.
- Discard all blood collection with needles materials in biohazard containers approved for their disposal.
- Be careful during blood transfer from the tube to a syringe in case of vacuum lasting in it.
- Under-filling of tubes will result in an incorrect blood to anticoagulant ratio with a possible inadequate PRP result.

## POSSIBLE ADVERSE EFFECTS

- Potential damage to blood vessels after venipuncture as, hematoma, bruise, infection or irritation may occur.
- As with any injection-based treatment, risk of infection has to be strongly prevent.

## CONTRAINDICATION

According to the guidelines of the International Cellular Medical Society for the use of Platelet Rich Plasma (ICMS Guidelines, Section VIII Platelet Rich Plasma (PRP), 2011), the following contraindications were published:

## ABSOLUTE CONTRAINDICATIONS

- Patient unwilling to accept risks.
- Platelet dysfunction syndrome.
- Critical thrombocytopenia.
- Hemodynamic instability.
- Septicemia.
- Local infection at the site of the procedure.

## RELATIVE CONTRAINDICATIONS

- Consistent use of NSAIDs within 48 hours of procedure.
- Corticosteroid injection at treatment site within 1 month.
- Systemic use of corticosteroids within 2 weeks.
- Tobacco use.
- Recent fever or illness.
- Cancer- especially hematopoietic or of bone.
- HGB < 10 g/dl.
- Platelet count < 105/ul In addition, there is a general recommendation not to treat with PRP during pregnancy or breast-feeding.

## PREGNANCY / BREASTFEEDING

There are no adequate data regarding the use of the product in pregnant or breastfeeding women. Experimental data on the safety and efficacy of PRP in children who have not reached skeletal maturity are not available.

## OTHER INFORMATION

The devices are disposable and cannot be re-sterilized at the risk of infections related to different blood, not autologous.

Any material residues must be eliminated according to local laws. Do not use after the stated expiration date. The product is sterile as long as the package remains closed and undamaged. Do not use the product if the sterile package is damaged.

## DURATION

Check the expiration date on the outer packaging. Do not use the material after the expiration date.

## DISPOSAL

The product must be disposed of as special waste. It must be disposed of in accordance with national and local medical waste disposal regulations.

## CENTRIFUGATION PROCESSING

It is essential to always correctly balance the centrifuge before starting it.

So, place filled (with water) counter balance tube with the same weight directly opposite from the platelet preparation tube in the centrifuge.

When processing even number of PRP tubes (2 for example), insert the filled tubes into the centrifuge facing each other to balance the machine.

Adjust the centrifugation values as follows:

**Time: 5 minutes**

**Centrifugal force (RCF): 1700g**

**RPM: 4000**

**\*NB: Depending on the centrifuge rotor if fixed or adjustable the RCF can vary.**

RCF	= relative centrifugal force.
RPM	= rotational speed (rpm).
r	= centrifugal spin in mm = distance from the center of rotation to the bottom of the centrifuge.

$$RCF = \left( \frac{RPM}{1000} \right)^2 \times r \times 1,118 \Leftrightarrow RPM = \sqrt{\frac{RCF}{r \times 1,118}} \times 1000$$

Where "r" is the radius of the centrifuge.

## PRP COLLECTION

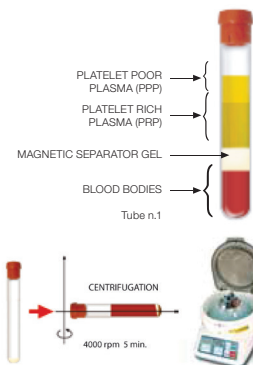
After centrifugation, the tube should contain upper clear yellowish fraction, separation gel barrier, and a lower red colored fraction.

The platelets reside on the top of the separation gel.

For specific application in which whole plasma is needed.

- Once centrifugation step is completed, take the tube and invert it (in half turn movements) 10 times to mix well the plasma with the platelets situated upon the gel.**
- Aseptically clean the cap of the tube by wiping it gently with an alcohol swab.
- Insert the syringe with Spinal Needle 18G/70mm into the tube by piercing the cap to extract the PRP. A sterile specific transfer device can be used to fill the syringe from the tube.

- Now PRP is ready to inject.



## DESCRIPTION OF USE AND RISK CLASS

Medical devices for the preparation of the concentrate platelet liquids are classified in Class IIa medical device according to rule 3 of Annex IX of Directive 2007/47/EC.

## SYMBOLS



SYMBOL	DESCRIPTION
	Read use instructions before application
	Lot number
	Product code
	Sterilized
	Monouse device
	Expiry date
	Manufacturer
	European conformity by notified body 0425



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Organization operating in conformity of principles of  
ISO 9001:2015 and ISO 13485:2016

**MADE IN ITALY**



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