

Instructions for Use (IFU) JOINT-PRP KIT 20 ml

The preparation of autologous PRP using JOINT PRP KIT involves the collection of 20 mL of whole blood, plus anticoagulant (Sodium Citrate) into a separation device and the blood components centrifugation for 5 minutes at 3200 RPM. PPP (low platelet plasma) and PRP (platelet rich plasma) are collected in two different sterile syringes through of a push-out screw mechanism which makes the separation of the two blood components easier and precise. Finally, the extracted PRP is immediately ready for use.

Steps in detail:

1. Aspirate with 20 ml syringe and short needle 19G, 2 ml of anticoagulant (Sodium Citrate) from the vial. The ratio of sodium citrate must be 10% compared the volume of blood required.
 2. Collected 20 ml of venous blood from the patient with the 20G butterfly needle connected to the preloaded syringe with 2 ml of anticoagulant, then replace the butterfly needle with the second short needle 19G and inject the collected blood in the separation device (PRP-KIT) through the green plug located on the top of the device (be careful to sting the middle of the cap)
 3. Open the centrifuge (*MD-416 Centrifuge the Gyrozen – Korea*), insert the separation device with the patient's blood into the bucket and, also, the balance weight to ensure a correct balance (as balance weight use a same separation device filled with 20 ml of water)
 4. Close the centrifuge lid and press the “Soft Start / Stop” program whose parameters settings are:
5 minute x 3,200 rpm
 5. When the centrifuge stops and the lid open automatically, extract the device gently, without shaking it. Check the correct blood components separation in the device, from the top: the poor plasma (PPP), the rich plasma (PRP), the buffy coat and the red blood cells (RBC).
- Now paid attention to perform the following procedures taking care to keep the separation device vertical and avoiding strong shaking!!*
6. Replace the bottom cap of the separation device with a dedicated screw plunger (use the SP-A code screw plunger, supplied separately) that allow the recovery of blood components through a push out system.
 7. For the collection of PPP and PRP use the two 10 ml luer lock syringes. First unscrew the top cap of the separation device and insert the first syringe firmly on the top of the separator cylinder for PPP extraction. Turning gently the screw plunger, already inserted on the bottom, the poor plasma (PPP) will begin to be collected in the 10 ml syringe through the push out system. Continue to rotate until the level of red blood cells reach the cylinder base (total final volume of PPP= 6/7 ml)
 8. Replace the first PPP syringe with the second 10 ml syringe. Slowly rotate the screw plunger to extract now the PRP and the buffy coat. It starts to be visible the buffy coat slowly come up through the cylinder, so continue to rotate up to collect also the buffy coat into the syringe to obtain a leucocyte rich PRP (**L-PRP**) for a final volume of 2/3 ml.

9. Remove the syringe containing 2/3 cc of PRP, shake gently two or three times to promote mixing between PRP and buffy coat. Now the L-PRP it's ready for use.

Be careful to the following steps:

Step 1. The anticoagulant sodium citrate should be pre-loaded into the syringe and NOT injected directly in the separation device.

Step 2. The reason of using a 19G needle is to minimize the platelets damage during blood transfer in the separation device

Step 5. - Don't force to open the MD-416 centrifuge until it stops, the lid opens automatically.

- If, at the end of the centrifugation, the blood components separation didn't occur and the plasma is all red, probably the blood hemolyzed during the collection, so repeat blood collection as instructed.

- Be careful, once separation has occur, to not shake the device to prevent mixing all components. If it happens repeat the centrifugation as instructed.

Step 7/8. During these PPP and PRP extraction steps, it is recommended to insert the syringe firmly on the top of the separator cylinder. Make sure the screw plunger is correctly screwed during these operations.

Warnings:

The use of this kit is strictly limited to medical professionals. All JOINT PRP KIT components are in sterile packs for single use. Do not re-sterilize. Eliminate open or damaged packages. Do not use in case of sterility expiration.

Storage:

Store in a dry place, at a temperature between 5°C and 25°C.

Keep the device away from excessive heat sources and from direct heat sources, including direct sunlight.

Elimination:

After use JOINT PRP KIT components should be treated as medical waste in accordance with local regulations to prevent biological risks.

CE Mark - RDM (Italian Register of Medical Device) and CND (Italian Classification Medical Device)

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|-----------------------------------|---------|---------------|-------------------|
| Separation Device PRP-KIT: | CE 0068 | RDM 1753244/R | CND B0501 |
| Sodium citrate vial 10 ml: | CE 0373 | RDM 45095 / R | CND V9099 |
| Luer- lock Syringes 10 and 20 ml: | CE 0476 | RDM 354853 | CND A020102020102 |
| Short needles 19G: | CE 0476 | RDM 862666 | CND A01010101 |
| Butterfly needle 20G: | CE 0476 | RDM 501513 | CND A010105 |

The Manufacturers Name

Separation device PRP-KIT: Produced by GoodmorningBio Co. Ltd. (South Korea)

Sodium citrate vial 10 ml : Produced by SALF Spa - Cenate Sotto (BG) - Italy

Luer syringes / lock 10 and 20 ml: Produced by Rays Srl - Osimo (AN) - Italy

Short needles and needle Butterfly: Produced by Rays Srl - Osimo (AN) – Italy

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