

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

1. Aspirated with 20 ml syringe and short needle 19G , 2 ml of anticoagulant (Sodium Citrate). The ratio must be 10% compared the volume of blood required.
2. Collected 20 ml of venous blood from the patient, to replace the 20G butterfly needle for taking blood samples, with the second short needle by 19G. Inject 20 ml blood collected in the separation device (PRP-KIT) through the green plug located the top of the separation device. Be careful to sting in the circle in relief of green cap. Discard syringe and needle for the venipuncture.
3. Arrange for the centrifugation a separation device of the same volume filled with water as a balance weight.
4. Open the centrifuge. Insert the separation device with the patient's blood into the bucket.
5. Insert also the balance weight so as to ensure a correct balance. Close the centrifuge lid.
6. Press the Soft Start / Stop dedicated to centrifugation of the separation device.
For these devices is used MD-416 Centrifuge the Gyrozen - Korea
Centrifugation time and RPM for 20cc kit: **5 minute x 3,200 rpm**
To extract gently, without shaking the separation device, when the centrifugation is completed and the lid opens automatically.
7. Check the correct line of separation of blood components in the device, the poor plasma (PPP) from the buffy coat and the red blood cells (RBC). Replace the bottom cap of the separation device with a dedicated screw piston
*. Perform the subsequent operations, taking care to keep the vertical separation device and avoiding strong shaking.
* Use the SP-A code for the 20cc kit
8. Use for the collection of PPP and PRP the two 10 ml syringes with luer lock. Unscrew the top cap of the separation device and insert the first syringe firmly into the fitting top of the funnel for the collection of PPP, platelet poor plasma.
9. Turn gently the plunger screw already inserted, poor plasma (PPP) will begin to collect in the 10 ml syringe. Continue to rotate until the level of red blood cells do not reach the center line of the separation device. Do as reference the beginning of the funnel place about half of the device.
10. Replace the first from the 10 ml syringe with the PPP collected with the second 10 ml syringe. Insert the second 10 ml syringe once again into the fitting top of the funnel of the device. Slowly rotate the screw plunger to collect the PRP and the buffy coat. The total volume of concentrated platelets varies from 2 to 3 ml.
11. Remove the syringe containing 2/3 cc of PRP, shake gently two or three times to promote mixing between PRP and buffy coat. Insert a needle for subsequent use of platelet concentrate on the patient.

Intended use:

JOINT PRP is a disposable kit dedicated to the production of platelet concentrate from autologous peripheral blood for the local supply of biological growth factors in the treatment of inflammatory processes and degenerative tissue. These tips are intended for users of the JOINT PRP to extract, separate and collect the maximum number of platelets from autologous blood in a simple way and secure.

The JOINT PRP kit has been designed and produced to obtain the maximum possible concentration of PRP by single centrifugation. The separation device equipped with a clear view of the blood components and an easy and safe collection of PRP in the syringe, it complies with the requirements of the EC medical devices in Class IIa.

Carefully read the instructions for use described above, put into practice the advice and suggestions to be qualified in all phases of the procedure by the JOINT PRP kit.

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

Step 6. Do not groped to open the MD-416 centrifuge until it stops, the lid opens automatically.

Step 7. If, at the end of the centrifugation, there are no lines of separation of blood components, but the plasma is all red, probably the blood during withdrawal it is hemolyzed. In the case of this eventuality repeat the venipuncture as instructed.

Step 8. Be careful, once separated blood components do not shake the separation device to prevent mixing between the layers of PRP, buffy coat and red blood cells. If it presents this eventuality repeat centrifugation as instructed.

Step 9/10. During these passages describes the separation steps of the PPP and PRP. It is recommended to insert the syringe firmly into the fitting top of the funnel of the separation device. Make sure the screw piston is correctly screwed during these operations.

Step 11: The PRP in the syringe is ready for application on the patient

Remarks:

The anticoagulant sodium citrate is recommended to pre-load in the syringe is not injected in the separation device. Inject the venous blood taken from the patient in the separation device, always with 19G needle.

And 'it recommended for increased safety and sterility, withdraw the plasma fraction PRP and PPP unscrewing the lid of the separation device, and fix the syringe into the connection not through the green cap.

Warnings:

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

Storage:

Keep the device away from excessive heat sources. Keep at room temperature, away from direct heat sources, including direct sunlight.

Elimination:

The components of the JOINT PRP kit after use should be treated as medical waste in accordance with local regulations to prevent biological risks.

JOINT PRP Kit is intended for the production of platelet concentrate from autologous blood.

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

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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