PlateRich Tube

Intended Use of the Device

This device is used for the separation of autologous platelet rich plasma (PRP) and other plasma-derived products.

Indications for Use

All models of PlateRich tubes are designed to be used for the safe and rapid preparation of autologous PRP from a small volume of blood.

Contraindications

It is recommended that a patient should not receive PRP when they have:

- Cancer or metastatic disease
- An active infection
- A low platelet count
- Pregnant or breastfeeding

Warnings and Precautions

- FOR SINGLE USE ONLY
- Use PRP only on the same patient from whom the blood was drawn
- Autologous PRP must be prepared from fresh blood and used within four hours
- Use appropriate safety precautions to protect yourself from needles and blood products. Samples of blood should be regarded as potentially infectious
- Discard the entire kit after single use. Do not reuse. The product should be discarded and treated as a potentially infectious blood product. The product should be discarded into biological hazard container.
- Do not use if the packing is damaged or open. Do not re-sterilize
- Do not use product if foreign matter is present in the tube
- Storage above 40^0C may damage the gel stability
- Storage of tubes with blood at or below 0^0C may result in tube breakage

- Do not underfill tubes with blood as an incorrect blood to additive ratio may result in poor product performance
- Follow the manufacturer's instructions when using the centrifuge
- Do not use excessive centrifugation as it may result in breakage of the tube. centrifuge as recommeded in the instructions.
- Do not use after the expiry date

Possible adverse events

- Temporary or permanent nerve damage that may result in pain or numbness
- Damage to blood vessels/hematomas
- Infection

Storage and stability

- Store at room temperature 15 - 30^0C
- Do not expose to sunlight
- Do not use if the sterile package is damaged.
- Do not use after expiry date

Instructions for Use

Important: Use standard aseptic technique throughout the following procedure.

1. Open the blister pack and remove a PlateRich tube
2. Draw blood from the patient using standard venous puncture procedures and fill the PlateRich vacuum tube with whole blood (approximately 8 ml). The vacuum should automatically collect the correct amount of whole blood. A 19 - 21G butterfly needle is recommended.
3. Invert the tube several times to ensure the anticoagulant is mixed with the blood.
4. Place the tube into the centrifuge. Always ensure the centrifuge is correctly balanced before beginning the centrifuge (counterbalance with a PlateRich tube filled with water)
5. Centrifuge at 1800 g (RFC) for 10 minutes

6. After centrifugation, the red blood cells and most of the white blood cells will be below the plug of gel.

7. Gently invert the PlateRich tube several times to re-suspend the platelets in the plasma . Approximately, 2 - 4 ml of plasma will be available.

8. Withdraw the PRP with a sterile syringe and needle, the PRP is now ready for use.

9. Alternatively, if you wish to concentrate the platelets in a smaller volume of plasma. Prior to inverting and resuspending the platelets gently remove the top half of the plasma (the platelet poor plasma). Then gently invert the PlateRich tube several times to re-suspend the concentrated platelets in the remaining plasma.

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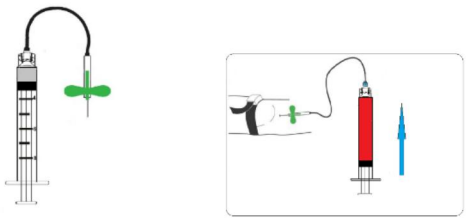

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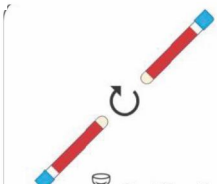

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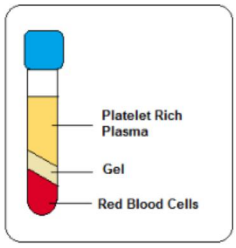

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Symbol Use

Symbol	Meaning
	CE with number – confirmation of meeting EU requirements
	Manufacturer
	Sterile product; sterilized using irradiation
	Batch code – the manufacturer's code
	Use-by-date – indicates the date after which the medical device is not to be used
	Do not re-sterilize
	Do not re-use – product for single use only
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Temperature limits to which the medical device can be safely exposed
	Instructions for use attached to the product
	Part Number/Catalog Number