

## Instruction for use of the procedure pack

# Xerthra™ PRP kit



### Description

Procedure pack designed for isolation and separation of platelet-rich plasma (PRP) from patient's own blood. Isolated autologous PRP is intended for local injections to improve the regenerative properties of cells and tissues by providing a large number of growth factors to specific areas.

### Procedure pack consists of the following medical devices:

- ① Xerthra™, *Biovico* (separation device)
- ② Venofix® A, 21G, *B.Braun* (butterfly needle)
- ③ Microlance™ 3, 21G x 1½" – 3 pcs., *BD* (needle)
- ④ dicoNEX Single use syringe, 3-part 20 ml, *Zarys*
- ⑤ dicoNEX Single use syringe, 3-part 10 ml, *Zarys*
- ⑥ dicoNEX Single use syringe, 3-part 5 ml, *Zarys*
- ⑦ dicoNEX Single use syringe, 3-part 2 ml, *Zarys*
- ⑧ Microlance™ 3, 27G x ¾", *BD* (needle)

### Cautions

For use only by qualified, trained personnel.

Before using the procedure pack, please read the instructions for use.

The procedure pack consists of disposable medical devices. Do not reuse. Do not use any of medical devices in case of damage of its direct package.

Medical devices are sterile only during their indicated shelf life.

Store the procedure pack at room temperature. Protect from direct sunlight, high temperature and high humidity.

Local symptoms such as pain, redness and swelling may occur at the injection site.

Wear personal protective equipment when using the procedure pack.

Ensure that no one is exposed to direct contact with the collected blood. Place all used pack parts in a medical waste container and utilize them.

### Contraindications

Because of the lack of clinical data on the use of PRP therapy in children, pregnant and breastfeeding women, therapy should not be used in those groups of patients.

Use only fresh blood. PRP shall be used immediately after isolation.

### Preparation before use

1. Collect 1.5 ml of anticoagulant with the needle ③ to a 20 ml syringe ④.
2. Using a butterfly needle ②, collect the patient's blood into the syringe with the anticoagulant. Fill the syringe until 15 ml.
3. Mix gently by inversion.
4. Mark the syringe with the collected blood with the patient's code or name.

**NOTE:** To avoid contamination of the isolated PRP, perform the entire isolation procedure with caution to sterility.

### Instructions for use

1. Remove the Xerthra™ ① from the package and position it vertically. Mark Xerthra™ ① with the patient's code or name to avoid confusions.
2. Open the top cap of the Xerthra™ ①.
3. Transfer the collected blood with the anticoagulant using the needle ③ into the Xerthra™ ①. Close the top cap. Check if the bottom cap of the Xerthra™ ① is correctly tightened.
4. Open the centrifuge cover and place the Xerthra™ ① as well as properly prepared counterweights.
5. Centrifuge for **5 minutes at 1700G (RCF)**.
6. Open the cover and carefully take out the Xerthra™ ① with centrifuged plasma. Hold the tube upright, do not shake it to avoid mixing of separated fractions.
7. Unscrew the bottom cap of the Xerthra™ ①.
8. Replace the bottom cap with controller's screw cap and fasten the Xerthra™ ① to controller screw.
9. Turn bottom part of controller screw to the left, counterclockwise, until plasma reaches horizontal line on the top end of the Xerthra™ ①.
10. Open the top cap of the Xerthra™ ①.
11. Connect 10 ml syringe ⑤ in a place of top cap to collect PPP (platelet-poor plasma). Rotate a controller until RBC (red blood cells) fraction reaches line marked as "1.0" on the Xerthra™ ①.  
If extraction of PPP is not necessary, continue rotating without attaching a syringe and let the plasma to get into empty area beyond the Xerthra™ ① neck and then connect syringe to collect PRP.
12. In order to collect PRP connect another 5 ml ⑥ or 2 ml ⑦ syringe. Rotate a controller screw until RBC fraction reaches the end of the top part of the Xerthra™ ①.
13. Disconnect the syringe with PRP ready to injection, attach needle ③ or ⑧ depending on required procedure.
14. Mark PRP syringe with the patient's code or name to avoid confusions.

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