



REGENKIT[®]-THT (20ml) / RegenCell[®]

Model: RK-THT-3-20

Attention to the physician

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable kit after one use, using acceptable disposal method for potentially contaminated blood products.

DESCRIPTION

RegenKit[®]-THT aids separation of the patient's own blood components through the use of the Regen[™]THT20 vacuum tubes and clinical centrifuge.

The RegenKit[®]-THT permits platelet concentrate to be rapidly prepared from a small volume of the patient's blood that is drawn at the time of treatment.

Blood is drawn from the patient and then spun in a centrifuge accordingly to centrifuge operating instructions. The platelet-rich plasma is collected with syringes and can be mixed during application onto the patient site.

MATERIALS

The materials used for platelet separator tubes consist of medical grade polymer glass and bromobutyl rubber suitable for use as medical devices. All kit components supplied with RegenKit[®]-THT (model: RK-THT-3-20) are sterile.

INDICATIONS FOR USE

RegenKit[®]-THT-3 (20ml) model is containing additional Regen[™]THT20 tubes, separately packaged, that should be used along with other RegenKit[®]-THT when larger amounts of platelets are needed by the clinical use requirements.

All models of RegenKit[®]-THT are designed to be used for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to an orthopaedic surgical site as deemed necessary by the clinical use requirements.

RegenKit[®]-THT models are for single use only.

CONTRAINDICATIONS

- Direct connection to patient's vascular system of circulating blood volume.

WARNINGS AND PRECAUTIONS

1. Use proper safety precautions to guard against needles.
2. Use a horizontal head (swinging bucket) centrifuge or a fixed angle head centrifuge. Follow manufacturer instructions when using centrifuge.
3. Excessive centrifugation force (over 2200 RCF) may cause tube breakage, exposure to blood, and possible injury. Regen[™]THT20 tubes should be centrifuged, as recommended in the instructions for use, at 1500 RCF.
4. Centrifuge carriers and inserts should be of the size specific for the Regen[™]THT20 tubes. Use of carriers too large or too short for the tube may result in breakage. Care should be taken to ensure that Regen[™]THT20 tubes are properly seated in the centrifuge cup. Tubes must be balanced in the centrifuge head to minimize the possibility of glass breakage.
5. Do not use sterile component of this kit if package is opened or damaged.
6. Single use device, do not reuse any part of the kit.
7. The practitioner is to be thoroughly familiar with the equipment and the procedure prior to using the kit.
8. The patient is to be made aware of general risks associated with treatment and possible adverse effects.
9. Platelet-rich-plasma concentrate is to be prepared from fresh blood and used extemporaneously.
10. The platelet rich plasma must be used within four (4) hours of blood collection.
11. Store between 5 °C - 30°C. Bring kit to ambient temperature before using Regen[™]THT20 tubes.
12. Do not use components of this kit if they are broken or present a defect.



POSSIBLE ADVERSE EFFECTS

1. Damage to blood vessels, hematoma, delayed wound healing and/or infection.
2. Temporary or permanent nerve damage that may result in pain or numbness.
3. Early or late operative infection.

STERILITY

RegenKit®-THT (model: RK-THT-3-20) are packaged in single blister and are sterilized by exposure steam sterilization. All RegenKit®-THT models are non-pyrogenic. Do not re-sterilize. Do not use after the expiration date.

INSTRUCTIONS FOR USE

NOTE: Deviations from the Regen™ preparation method can introduce complications and does not guarantee the preparation of a Regen™ product as described in product literature. Use standard aseptic technique throughout the following procedures.

Additional materials required:

The practitioner must use additional components with the RK-THT-3-20 kit. Then, to ensure product quality, the manufacturer's recommendation is to use the **Accessory Set** (ref. **BCA-SET3-20**, provided separately) that is adapted to Regen™THT20 tube.

For blood collection: The "Blood Collection Set" is provided in the BCA-SET3-20.

For platelet rich plasma collection and application: one 10 ml Luer-Lok™ syringe is required, and the "Transfer Device Set" is provided in the BCA-SET3-20.

To discard platelet poor plasma: for each Regen™THT20 tube, one 18G x 1 ½" Red transfer needle and one 5 ml Luer-Lok™ syringe are required.

Step 1: Collect whole blood

1a. Open the blister pack with care.

1b. Follow the instruction for use of **BCA-SET3-20** to withdraw blood.

Perform the venous puncture using the "Blood Collection Set" provided in the Accessory set **BCA-SET3-20**. Wait for the presence of blood in the flexible tube, under the plastic section (the blood is visible over 1-2 mm).

Pierce the stopper of the Regen™THT20 tubes to fill it with the whole blood using the internal needle of the "Blood Collection Set". Hold the tube gently but firmly in the "Regen Lab Tube Holder" during blood withdraw. The vacuum within the tube will enable automatic collection of the necessary volume of blood (about 20 ml).

1c. Invert the Regen™THT20 tube for 5 inversions to mix anticoagulant additive with blood.

1d. Activate the safety mechanism, as described in the instruction for use of **BCA-SET3-20**. The safety mechanism is activated by pressing in the light part on both sides of the hub to engage the lock. Slide the safety mechanism backward until an audible click is heard.

Step 2: Centrifugation

2. Verify that your centrifuge is suitable for Regen™THT20 tubes. It is essential to correctly balance the centrifuge before running the machine.

If necessary, fill a counterbalance tube (supplied separately) with water until it reaches the same level as blood in Regen™THT20 tube.

Insert the filled tubes into the centrifuge facing each other to balance the machine.

Adjust the centrifugation values as follows:

- Time: 9 minutes

- Centrifugal force (RCF): 1500 g

Check centrifuge operating instructions to establish the correspondence between the centrifugal force in RCF and centrifugal speed in Round per Minute (RPM). To convert RCF to RMP use the following formula:

$$\text{RPM Speed} = \sqrt{\frac{(\text{RCF}) \times (100,000)}{(1.12) \times (r)}}$$

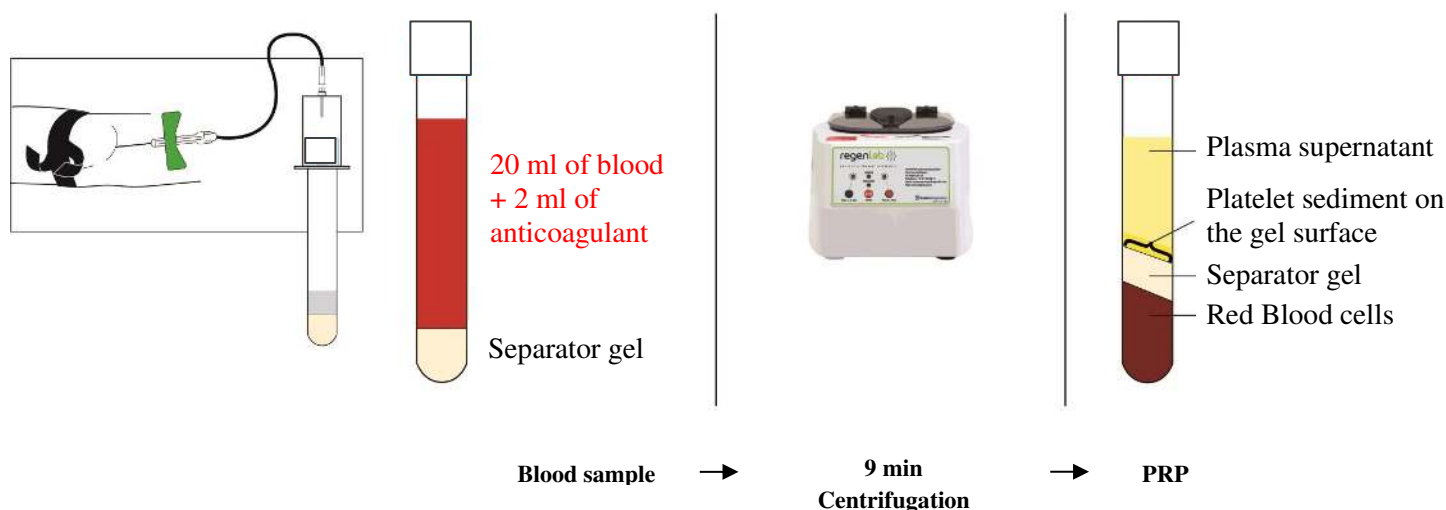
Wherein r (in centimeters) is the radius of fixed angle rotor or the distance from the centrifuge axis to the tube bottom, when the tube is in the horizontal position in swinging bucket rotor, and RCF is the desired centrifugal force (e.g. RCF = 1500g for the Regen[™]THT20 tube).

WARNING: Excessive centrifuge speed over 2200 RCF may cause tube breakage, exposure to blood, and possible injury.

Centrifuge at room temperature (18-25 °C).

Step 3: Centrifugation results

3. After centrifugation blood is fractionated. Red blood cells are trapped under the gel, and the platelet sediment is above the separator gel.



Step 4: Homogenization

4a. Method 1: By gently inverting the Regen[™]THT20 tube 20 times, proceed to the re-suspension of the platelet sediment in the supernatant. About 10 to 11 ml of PRP will be obtained for each tube.

4b. Method 2: (OPTIONAL: to increase platelet rich plasma concentration): Prior to platelet resuspension, delicately remove the desired amount of supernatant (platelet poor plasma) with a 18G red transfer needle connected to a 5ml syringe and discard it. Subsequently re-suspend the platelet sediment into the remaining plasma by gently inverting the Regen[™]THT20 tube.

WARNING: The 18G Red Transfer Needle should be used only to remove platelet poor plasma.

Step 5: Collecting the Platelet-Rich Plasma (PRP) in a syringe

5a. First mount the “Transfer Device Set” following the instruction for use of **BCA-SET3-20** then screw a 10ml syringe.

5b. Introduce the Regen[™]THT20 tube into the “Transfer Device Set”, previously screwed to the syringe. Collect the desired quantity of platelet rich plasma with the syringe.



List of necessary components for the RK-THT-3-20 kit may be purchased directly from Regen Lab or Becton Dickinson:

Accessory Set	Regen Lab Product reference BCA-SET3-20
5 ml Luer-Lok™ Syringe	Becton Dickinson Product number 309646
10 ml Luer-Lok™ Syringe	Becton Dickinson Product number 309604
18G x 1 ½ ” red Blunt Fill transfer needle	Becton Dickinson Product number 305180

To protect the safety of the handling healthcare personnel as well as to the patient, needles must not be re-capped, removed, or re-attached onto a syringe for re-use.

WARNING The platelet rich plasma must be used within four (4) hours of blood collection.

CONTENTS

RK-THT-3-20 Kit: 3 Regen™THT20 tubes (6b)

PRODUCT ORDERING INFORMATION

Codes are RK-THT-3-20 in single packaging containing three (3) Regen™THT20 tubes.

CAUTION

Federal Law of the United States of America limits this device to sale or use by or on the order of a physician.

SYMBOL DEFINITION

Rx only: Caution: Federal (USA) law restricts this device to sale by or on the order to a physician

 : Store Between 5°C – 30°C

 YYYY-MM-DD: Date of Manufacture

 YYYY-MM-DD: Expiration Date

 : See Instructions for Use

 : Do not Reuse

 : Medical device

 Sterilized by Steam

 : Single sterile barrier system

 : Catalog Number

 : Lot Number

 : Number of Units

 : Do Not Use if Package is Damaged

 : Do Not Resterilize

 : Manufacturer

 : Non-pyrogenic

If you have not understood the contents of these directions for use and safety precautions or parts thereof, please contact RegenLab® directly before using RegenKit®-THT (20ml) for the first time.

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