RegenKit®-BCT / RegenPlasma®

Model: RK-BCT-T-U; RK-BCT-3-U

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®-BCT aids separation of the patient's own blood components through the use of the Regen™ BCT vacuum tubes and clinical centrifuge. The RegenKit®-BCT 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 according to centrifuge operating instructions. The platelet–rich plasma is collected with syringes and is mixed during application onto the patient site.
This model is provided to complement the RegenKit®-BCT 2 or 4 models.

MATERIALS

The materials used for syringes, needles, tubing, connectors and platelet separators consist of medical grade polymer, glass, and stainless steel suitable for use as medical devices. All kit components supplied with RegenKit®-BCT (model: RK-BCT-3-U; model: RK-BCT-T-U) are sterile.
All models of RegenKit®-BCT Family Kits must be centrifuged in a clinical centrifuge.

INDICATIONS FOR USE

All models of RegenKit®-BCT 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 a bony defect for improving handling characteristics.

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™ BCT 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™ BCT tubes. Use of carriers too large or too small for the tube may result in breakage. Care should be taken to ensure that Regen™ BCT 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 components 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™ BCT 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

The RegenKit®-BCT-3 model, RegenKit®-BCT-T of RegenKit®-BCT Family kits are packaged in single blister and are sterilized by Steam Sterilization. All RegenKit®-BCT 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.

The practitioner must use additional components with the RegenKit-BCT-3- U,RegenKit-BCT-T-U kits:
For blood withdrawal: one Safety–Lok™ Butterfly needle and one Collection holder (blue top) are required.
For platelet rich plasma collection and application: for each Regen™ BCT tube used, one Vacutainer® blood transfer device (pink top) and one 5 ml Luer-Lok™ syringe are required.
To discard platelet poor plasma: for each Regen™ BCT 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. Perform the venous puncture using the butterfly needle connected to the collection holder (blue top). Wait for the presence of blood in the flexible tube, under the yellow plastic section (the blood is visible over 1-2 mm).
Pierce the stopper of the Regen™ BCT tube to fill it with whole blood using the internal needle of the collection holder. Hold the tube firmly in the collection holder during blood withdraw. The vacuum within the tube will enable automatic collection of the necessary volume of blood (about 10 ml).
1c. Invert the Regen™ BCT for 5 inversions to mix the anticoagulant additive with the blood.
1d. Close the blood collection needle with the Safety-Lok™ system before throwing it away.

Step 2: Centrifugation
2. It is essential to correctly balance the centrifuge before running the machine.
If necessary, fill the counterbalance tube (supplied separately) with water until it reaches the same level as blood in Regen™ BCT tube.
Insert the filled tubes into the centrifuge facing each other to balance the machine.

Adjust the centrifugation values as follows:
- Time: 5 minutes
- Centrifugal force (RCF): 1500 g

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

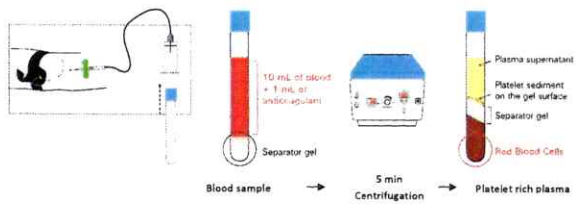
$$\text{RPM Speed} = \sqrt{\frac{(\text{RCF}) \times (100{,}000)}{(1.12) \times (r)}}$$

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™ BCT 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™ BCT tube several times, proceed to the re-suspension of the platelet sediment in the supernatant. About 5 ml of platelet rich plasma 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™ BCT tube.
WARNING: The 18G Red Transfer Needle should be used only to remove platelet poor plasma.

Step 5: Collecting the Platelet Rich Plasma in a syringe
5a. Screw the 5ml syringe to the transfer device (pink top)
5b. Introduce the Regen™ BCT tube into the transfer device (pink top), previously screwed to the 5ml syringe, and collect the desired quantity of platelet rich plasma with the syringe.

WARNING

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

COMPOSITION

RK-BCT-3
3 Regen™ BCT tubes; 1 Regen™ BCT tubes .

Necessary components to use with the RK-BCT-3-U kit and RK-BCT-T-U kit may be purchased directly from Becton Dickinson with the following references:

Safety-Lok™ Blood Collection Set	Becton Dickinson Product number 367296
Collection holder (blue top)	Becton Dickinson Product number 364902
5 ml Luer-Lok™ Syringe	Becton Dickinson Product number 309649
18G x 1 ½ '' red needle	Becton Dickinson Product number 305180
Vacutainer® blood transfer device (pink top)	Becton Dickinson Product number 364880

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

PRODUCT ORDERING INFORMATION

Codes are RK-BCT-3-U in single packaging containing three (3) Regen™ BCT tubes, and RK-BCT-T-U in single packaging containing one (1) Regen™ BCT tube.

CAUTION

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

SYMBOL DEFINITION

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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

MD : Medical device

STERILE Sterillized by Steam

: Single sterile barrier system

REF : Catalog Number

LOT : Lot Number

QTY : Number of Units

: Do Not Use if Package is Damaged

: Do Not Resterilize

: Manufacturer

:Non-pyrogenic

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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®-BCT for the first time.

RegenLab USA LLC
95 Greene Street
Jersey City, NJ, 07302 USA

Telephone: 1-800-220-9082
Email: info@regenlabusa.com
www.regenlabusa.com

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