RegenExtracell® BMC & GLUE

The Flexible & Reproducible Bone Marrow Concentrate System



WHAT ARE RegenExtracell[®] BMC & GLUE PREPARATIONS ?

BONE MARROW CONCENTRATE (BMC) IS AN AUTOLOGOUS CELL CONCENTRATE FROM BONE MARROW ASPIRATE.

The bone marrow is known to be rich in a heterogeneous population of mature and pluripotent stem cells (Bone Marrow Stem Cells). The bone marrow microenvironment, or medullary stroma, harbours, in addition to the well known blood cell progenitors (hematopoietic stem cells, HSCs), various immature cells such as mesenchymal stem cells (MSC's, which are the musculoskeletal cell precursors), pre-adipocytes, endothelial progenitor cells, etc. Many studies have demonstrated the involvement of bone marrow stem cells in tissue regeneration within a variety of clinical domains.

A-PRP : THE PATIENT'S PLATELET CONCENTRATE PREPARED WITH REGENKIT®

Platelets are key factors in hard and soft tissue repair mechanisms ¹. They provide essential growth factors, such as FGF, PDGF, TGF-B, EGF, VEGF, IGF, which are involved in stem cell migration, differentiation and proliferation. Additionally, platelets also stimulate fibroblasts and endothelial cells to induce new extracellular matrix deposition and neo-vascularisation respectively. The platelets are concentrated from the patient's own blood.

Plasma contains many factors essential for cell survival including nutrients, vitamins, hormones, electrolytes, growth factors (such as IGF and HGF), and proteins. Among the plasma proteins, the molecules vital for the coagulation process and for the fibrin polymer formation will serve as a scaffold for cell migration and new tissue generation.

THE GLUE PREPARATION IS THE RESULT OF MIXING BMC & AUTOLOGOUS THROMBIN SERUM (ATS)

Autologous Thrombin Serum (ATS) converts soluble fibrinogen to fibrin monomers which polymerize to form the clot. Addition of Autologous Thrombin Serum (ATS) to the patient's platelet concentrate restarts the coagulation process in a physiological manner. This natural process induces the formation of three-dimensional fibrin matrix in which the platelets are entrapped, allowing a long lasting growth factor delivery at the treatment site where the matrix serves as a scaffold for new tissue reconstruction.







RegenKit[®] Extracell BMC & GLUE

RegenExtracell BMC & GLUE cell separator gel facilitates the easy, rapid and consistent preparation of BMC with optimal cell concentration, from a small volume of bone marrow aspirate.

Kit components are provided in double sterile packaging, which is required for use in an operating theatre setting.



Overall MSC yields are in the range of 1 x 104 cells/ml of bone marrow aspirate. ²

RegenExtracell BMC & GLUE achieve recovery rates from bone marrow aspirate of 74% of MNC's and 87% of MSC's. ⁵

Differentiation potential tests confirmed that the concentrated MSC's were capable of undergoing osteogenesis and chondrogenesis.⁷

Osteotomy

RegenExtracell BMC used in polytherapy with RegenKit RegenExtracell Glue was administered percutaneously A-PRP and a bone graft substitute, was shown to accelerate directly at the site of pseudarthrosis with the same trocar healing to 2 months as compared to 3.5 months with the used for collecting the medullar blood.³ use of bone graft substitute alone.²

Fracture repair

In a comparative clinical study on osteotomies, The MSC preparation from either RegenExtracell BMC or



Of 61 patients treated with MSC, 49 (80%) achieved complete healing of the fracture in an average timeframe of 4.9 months.³



REFERENCES

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4- Capanna R. Growth Factors, mesenchymal staminal cells and scaffold in bone regeneration: personal experience in 300 patients. Proceedings Biobridge Generation Regeneration Congress, 2013. 5-Barry F. A report on the phenotypic characterization of mesenchymal stem cells isolated from human bone marrow using the Regen ZHT, AC-P and Regen BCT blood separation systems. Data on file, Regen Lab, 2015. 6-Scaglione M, Fabbri L, Dell'omo D, Gambini F, Guido G. Long bone nonunions treated with autologous concentrated bone marrow-derived cells combined with dried bone allograft. Musculoskeletal surgery 2013. 7-Barry F. Stem cell therapy in Orthopaedics: strategies for selection and delivery. Proceedings Biobridge Generation Regeneration Congress, 2014.

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These claims and indications of use have been reported in a number of cases during the Biobridge Conferences of 2013, 2014 and 2016. For more information please contact our scientific team.

Bone defect & Pseudoarthrosis

in the range of 79% to 100% with healing times as short surgical technique.^{4,6,8,9} as 2.5 months, even in complex indications such as severe bone defects, AVN, pseudarthrosis, complex patterns, and comorbidities.

> Records of 242 cases, including 4:



MAJOR BONE DEFECTS OR WIDE CAVITY DEFECTS (131 cases):

• Follow up	58 months (6-96)
Healing	94.5 %
Healing time	6 months (3-14)





RegenExtracell BMC

protocol allowed the use of

in different physical states

tailored to patient's need.⁹

autologous MSCs concentrate



OSTEONECROSIS STEINBERG STAGE II A-B (28 cases):

• Follow Up

25months (6-60)

- Healing
- Healing time

80 %

3 months (2-12)



POST-TRAUMATIC PSEUDOARTHROSIS (83 CASES)

Follow-Up

6 months

Healing

- Percutaneous. BMC + PRP
- Open, BMP +/- scaffold
- Open, BMP + scaffold + BMC
- Healing time

60% 89% 100% 6 months



The Biobridge Foundation is Regen Lab's Educational Partner. Register and Login to access Scientific Content, Workshops and Conferences.

RegenExtracell[®] BMC & GLUE



ORDERING INFORMATION

RegenKit[®] Extracell BMC

Trocar,
Transfer devices,
RegenTHT film tubes,
transfer needles,
x 80 mm transfer cannula,
Self-adhesive discs.

ma-derived products from venous blood or medullar blood

INTENDED USE OF THE DEVICE

Preparation of autologous platelet rich plasma and other plas-

Intellectual Property Rights (IPRs) as Core Assets www.regenlab.com/patents

CE0086

One Step

Closed System

RegenKit[®] Extracell BMC 2

1 Trocar,
2 Transfer devices,
2 RegenTHT film tubes,
2 transfer needles,
1 x 80 mm transfer cannula,
Self-adhesive discs.

RegenKit[®] Extracell Glue

Trocar,
Transfer devices,
RegenTHT tubes,
Red transfer needles,
x 80 mm transfer cannula,
Self-adhesive discs.

Safety–Lok[™] Butterfly needle,
Collection holder,
RegenTHT tubes,
RegenATS tube,
x 1 ml Luer-Lok[™] syringe,
x 5 ml Luer-Lok[™] syringe,
Red transfer needle.
x 80 mm transfer cannulas
Self-adhesive discs
Transfer device

Quality

ISO 13485 Certified Patented Innovations +1 Million Patients treated

Patented by Regen Lab SA - Platelet Rich Plasma

U.S. patent US8529957, European patent EP2073862B, Swiss patent CH696752

PATIENT

Safety

GMP Manufacturing Class IIb Medical Devices Non Pyrogenic - Sterile A-PRP® Efficacy

Dedicaded Kits for specific preparations 100 published studies

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