RegenExtracell®
BMC & GLUE

The Flexible & Reproducible Bone Marrow Concentrate System

RegenExtracell BMC & GLUE were shown to result in successful healing rates for bone defects in the range of 79% to 100% with healing times as short as 2.5 months.[3]

regenlab®
PRP & CELL THERAPY SPECIALISTS

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-ß, 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.

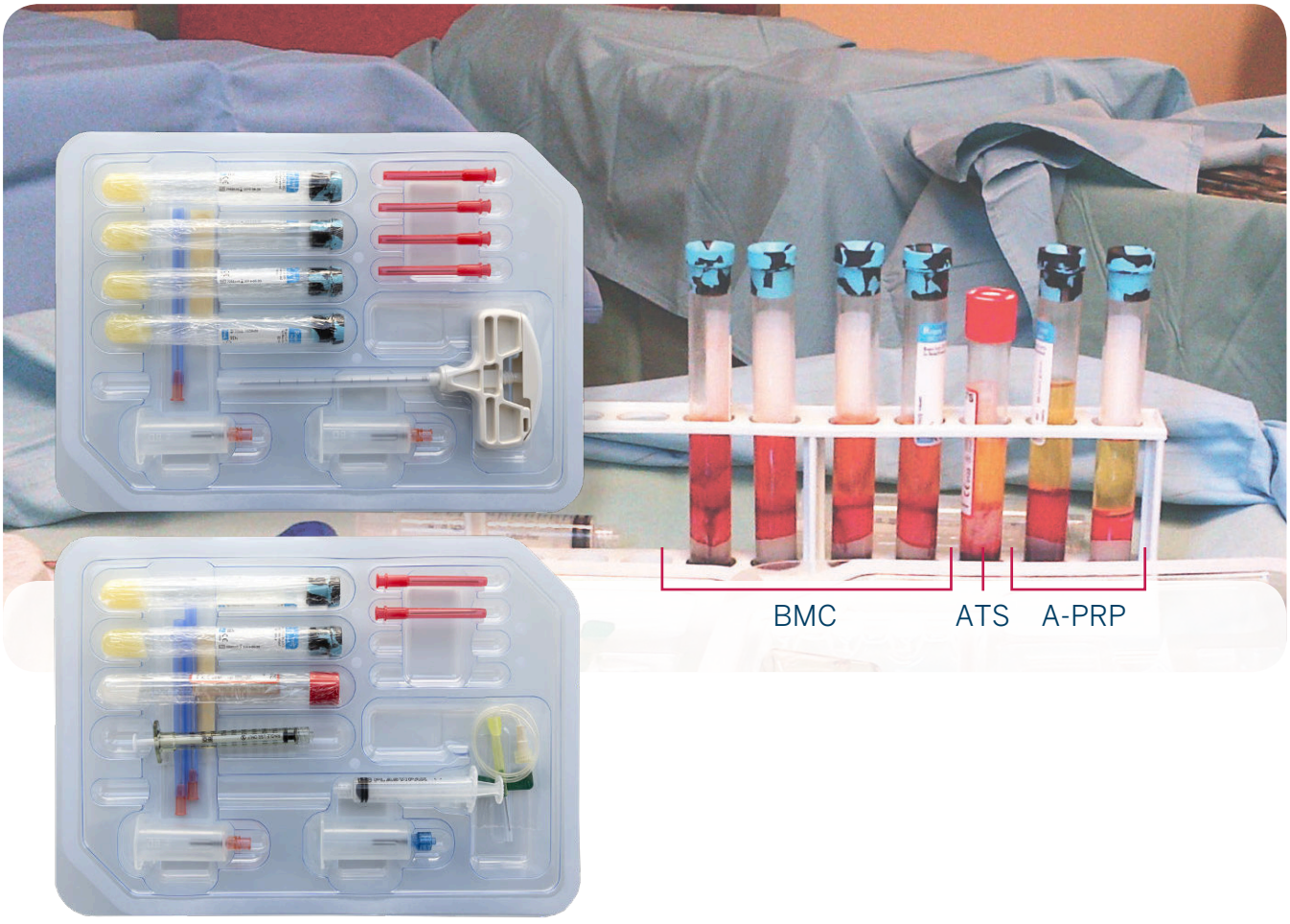
THE GLUE PREPARATION IS THE RESULT OF MIXING BMC & AUTOLOGOUS THROMBIN SERUM (ATS)

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]

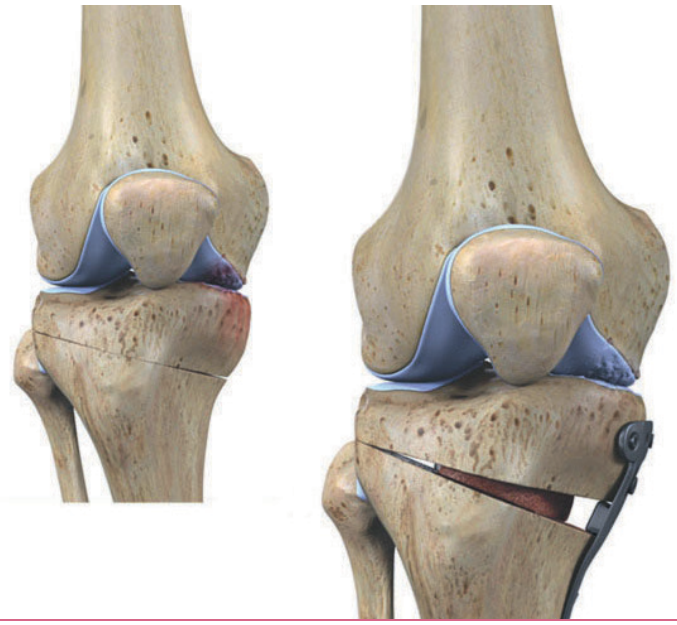
Osteotomy

In a comparative clinical study on osteotomies, RegenExtracell BMC used in polytherapy with RegenKit A-PRP and a bone graft substitute, was shown to accelerate healing to 2 months as compared to 3.5 months with the use of bone graft substitute alone. [2]

Fracture repair

The MSC preparation from either RegenExtracell BMC or RegenExtracell Glue was administered percutaneously directly at the site of pseudarthrosis with the same trocar used for collecting the medullar blood. [3]

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



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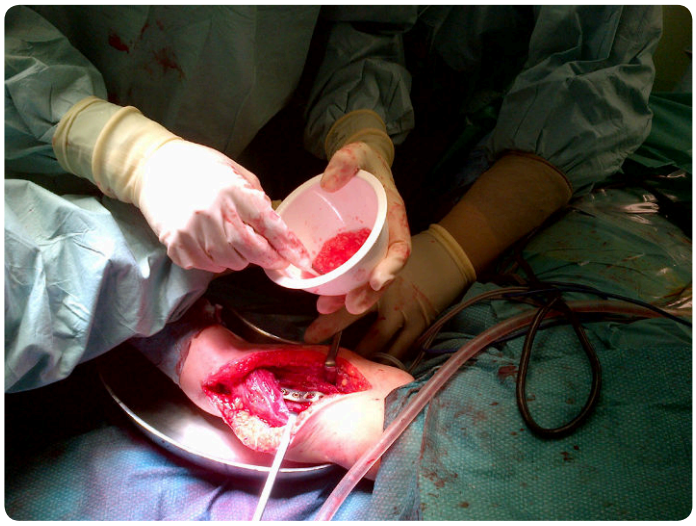
These claims and indications of use have been reported in a number of cases during the Biobridge Conferences of 2013, 2014 and 2016. For more information please contact our scientific team.

Bone defect & Pseudoarthrosis

In clinical studies, RegenExtracell BMC & GLUE were shown to result in successful healing rates for bone defects in the range of 79% to 100% with healing times as short as 2.5 months, even in complex indications such as severe bone defects, AVN, pseudarthrosis, complex patterns, and comorbidities.

There was a very satisfying "biological boost" in critical patterns and patients and good outcome with every surgical technique.[4,6,8,9]

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)

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

• Follow Up	25months (6-60)
• Healing	80 %
• Healing time	3 months (2-12)

POST-TRAUMATIC PSEUDOARTHROSIS (83 CASES)

• Follow-Up	6 months

Healing

• Percutaneous, BMC + PRP	60%
• Open, BMP +/- scaffold	89%
• Open, BMP + scaffold + BMC	100%
• Healing time	6 months

RegenExtracell BMC protocol allowed the use of autologous MSCs concentrate in different physical states tailored to patient's need. [9]

BIOBRIDGE KNOWLEDGE

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

RegenExtracell®
BMC & GLUE

INTENDED USE OF THE DEVICE

Preparation of autologous platelet rich plasma and other plasma-derived products from venous blood or medullar blood

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

ORDERING INFORMATION

CE 0086

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

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

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

One Step Closed System !

PRODUCT
Quality

ISO 13485 Certified
Patented Innovations
+1 Million Patients treated

PATIENT
Safety

GMP Manufacturing
Class IIb Medical Devices
Non Pyrogenic - Sterile

A-PRP®
Efficacy

Dedicaded Kits for specific preparations
100 published studies

Patented by Regen Lab SA - Platelet Rich Plasma
U.S. patent US8529957,
European patent EP2073862B,
Swiss patent CH696752

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