

# Cellular Matrix®

## Natural HA enriched by your Platelets Growth Factors



RegenLab<sup>®</sup> is a leading innovator of medical products for the preparation of platelet-rich plasma.

Regen Lab provides expertly designed & patented Medical Devices for platelet-rich plasma preparations, CE certified, registered by most national agencies worldwide.

Regen Lab remains committed to providing products of the highest quality and safety, as well as protecting customers through enforcement of its intellectual property rights.

A revolutionary innovation in skin care, combining two treatment concepts in one for natural results.

### **Cellular Matrix BCT-HA**

Cellular Matrix tubes allow the preparation of autologous platelet-rich plasma (RegenPRP) combined with a non-crosslinked hyaluronic acid (HA) in a closed-circuit system.

The resulting Cellular Matrix RegenPRP-HA preparation is named CM-PRP-HA.



## TECHNOLOGY PLATFORM FOR STANDARDISED AUTOLOGOUS REGENERATIVE MEDICINE

### The simple, safe and efficient point-of-care preparation of autologous platelet-rich plasma.











Blood Collection

Centrifugation

Resuspension

Resuspended

Ready to Use

### TECHNOLOGY ADVANTAGES

- User-independent standardised preparation
- Minimum volume of blood required
- Safe closed-circuit system
- Mechanical isolation of PRP using a biologically inert separator gel after a 5-minute centrifugation
- Reversible anticoagulation with a pharmaceutical grade solution of sodium citrate at pH 7
- Minimal learning curve and ease of use
- Operationally and clinically efficient process
- Facilitates and streamlines routine practice

### SCIENTIFIC ADVANTAGES OF RegenPRP

- Demonstrated safety and efficacy
- Evidence-based outcomes for numerous therapeutic indications.
- Large number of clinical studies, with over 200 publications.

### **CELLULAR MATRIX PLATFORM**

- Certified technology for the preparation of RegenPRP combined with hyaluronic acid (HA) (CM-PRP-HA)
- Contains 2 ml of non-crosslinked HA at a concentration of 20 mg/ml (40 mg total)
- HA produced by bacterial fermentation, thus free of animal proteins



### **BIOLOGICAL ADVANTAGES**

- RegenPRP is standardised, leucocyte reduced and easily reproducible. Regen Lab specific separating gel technology guarantees minimal variability
- Platelet recovery > 70%
- High platelet quality. Viable & functional platelets
- Full plasma recovery. No loss of plasma growth factors and fibrinogen
- Leucocyte reduced PRP. Depletion ~ 94.3% of pro-inflammatory granulocytes, leaving mainly lymphocytes and monocytes
- Virtually no red blood cells. Depletion of ~ 99.5% of erythrocytes

## What is RegenPRP<sup>®</sup>?

RegenPRP: the patient's platelet-rich plasma prepared with the Cellular Matrix device, provides an autologous reservoir of growth factors from the patient's own blood.

Platelets, in addition to their role in hemostasis, are key factors in tissue repair mechanisms.<sup>3</sup> FGF, PDGF, TGF- $\beta$ , EGF, VEGF, IGF, which are involved in stem cell migration, differentiation and proliferation. Platelet growth factors also stimulate fibroblasts and endothelial cells to induce the deposition of new extracellular matrix and neovascularisation, respectively.

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 formation of the fibrin polymer will serve as a scaffold for cell migration and new tissue generation.<sup>4</sup>

RegenPRP could be considered as an effective procedure for facial rejuvenation as it induces collagen production in the dermis.<sup>5</sup>

### RegenPRP standardised performance

Regen Lab devices use a separating gel technology that separates the plasma and platelets from the blood cells to produce RegenPRP with a standardised composition:

BCT-HA® Tube Properties	BLOOD SAMPLE VOL PER TUBE	PRP VOL PER TUBE	PLATELET RECOVERY	GRANULOCYTE DEPLETION	RED BLOOD CELL DEPLETION
	4 ml	~2 ml of PRP combined with	> 70 %	94.3 %	99.5%
	2 ml of HA			DeconPCT UA Derformance cummary v2 data on fi	

The volume of blood that is drawn using the BCT-HA tube is 4 ml, allowing the preparation of a final combination of 50% PRP – 50% HA in a volume of around 4 ml.

- 1. Hersant B. et al. Efficacy of autologous platelet-rich plasma combined with hyaluronic acid on skin facial rejuvenation: A prospective study. J Am Acad Dermatol 2017;77(3):584--6 2. Micheels P. De l'intérêt de la combinaison « acide hyaluronique + plasma riche en plaquettes » en mésothérapie esthétique. AFME 2017. www.afme.org/corps/autres-corps/ combinaison-acide-hyaluronique-et-prp/ (accessed October 15, 2020).
- Fountain, John H., and Sarah L. Lappin. Physiology, Platelet. StatPearls Publishing, Treasure Island (FL), 2019.
  Mathew, Joscilin, and Matthew Varacallo. Physiology, Blood Plasma. StatPearls Publishing, Treasure Island (FL), 2019.

## CellularMatrix: RegenPRP in combination with HA

**Hyaluronic** acid is a key molecule involved in skin moisture and has a unique property in retaining water <sup>6-7</sup>.

- More than 25 years of clinical experience in skin hydration and volume correction
- Major component of the extracellular matrix
- Binds water and creates volume
- Stimulates migration and proliferation of cells

### Hyaluronic acid seems to improve the activity of several molecules contained in platelet-rich plasma<sup>8</sup>

As demonstrated by Smith et al., fibrin polymerisation in the presence of HA generates a clot with large pores, which facilitates cell migration.<sup>9</sup>

Cellular Matrix is a unique, regulatory approved, patented technology, that allows the safe, closed-circuit preparation of a cell-friendly PRP-HA network in which platelets and plasma components are retained.

### CM-PRP-HA has an excellent safety profile in clinical practice<sup>1-2</sup>



5. Abuaf, O.K. et al. Histologic Evidence of New Collagen Formulation Using Platelet Rich Plasma in Skin Rejuvenation: A Prospective Controlled Clinical Study. Ann Dermatol 2016, 28(6):718-24.

6. Laurent T.C., Frase J.R.E. Hyaluronan. FASEB J 1992;6:2397-404.

7. Stern R. Devising a pathway for hyaluronan catabolism: are we there yet? Glycobiology 2003 Dec;13(12):105R-115R.

### FACIAL APPEARANCE

In a prospective study, 31 patients were treated by mesotherapy with the RegenPRP and HA combination prepared with Cellular Matrix (CM-PRP-HA) at 0, 1, and 2 months. Clinical benefits were evaluated by FACE-Q scores and biophysical measurements of skin elasticity.

Comparison of FACE-Q scores showed significant improvement at 6 months compared with baseline (p=0.03). Similarly, objective biophysical measurements showed significant improvement in skin elasticity (R5) compared to baseline (p=0.036) at 6 months post-treatment.

No serious side effects were reported.

# Significant improvement in skin elasticity. <sup>1-2</sup>



### SKIN QUALITY

A prospective study with 5 patients evaluated the clinical benefits of the combination of RegenPRP and HA prepared with Cellular Matrix (CM-PRP-HA) when used as a mesotherapy on the hand and face. Evaluations of skin quality and tonus were performed by both the treated subjects and evaluators.

A significant improvement was observed on the skin of the hands and face of all subjects, including improvement of skin quality and tonus, as well as wrinkle depth after three treatment sessions.



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No serious side effects have been reported. Discomfort at the injection site and bruising (lower eyelid and back of hands) were reported.

# Cellular Matrix improves skin tonus and quality.<sup>2</sup>

8. Abate M. et al. Efficacy and safety profile of a compound composed of platelet-rich plasma and hyaluronic acid in the treatment for knee osteoarthritis (preliminary results). Eur J Orthop Surg Traumatol 2015 Dec; 25(8):1321-6.

9. Smith J.D. et al. Improved growth factor directed vascularization into fibrin constructs through inclusion of additional extracellular molecules. Microvasc Res. 2007;73(2):84-94.

### **CELLULAR REGENERATION**

CM-PRP-HA can be used either as a stand-alone treatment injected directly into the superficial dermis or together with the deeper injection into the superficial musculoaponeurotic system (SMAS)<sup>10-11</sup>.

HA acts as a bio-scaffold, increasing growth factor residence time in tissue and enhancing cell migration and regeneration. CM-PRP-HA makes the balancing of volume and lift much easier and gives an instant result<sup>9-10-11</sup>.

The combination of RegenPRP and HA provides better contouring and seems to accelerate cellular regeneration, making this combination the right tool for skin hydration.<sup>10-11</sup>



© - Dr. Chok R. Australia



10. Chok R. Combination of Cells and Growth Factors in a supporting matrix for skin age management. Proceedings Biobridge Generation Regeneration Congress, 2014. 11. Chok R 3D Facial Remodelling with Regenlab Cellular Matrix as Bioscaffolding. Proceedings Biobridge Generation Regeneration Congress, 2016.



### ALWAYS READ THE INSTRUCTION BEFORE USE

### INTENDED USE OF THE DEVICE

Device used to prepare intra-articular injections into the knee for symptomatic treatment of articular pain and mobility improvement. Device used to prepare intra-dermal injections for hydration of dehydrated and wrinkled skin tissues.

### CellularMatrix / BCT-HA-3

Ref: BCT-HA-3 **3 BCT-HA tubes** 



### **Class III CE certified Medical Devices** Regen Lab SA is an ISO13485 :2016 and MDSAP certified medical device manufacturer

CONTRA-INDICATIONS Absolute contraindications: Do not administer the PRP/HA preparation to patients with ascertained hypersensitivity to one of the components, including hyaluronic acid. Do not use on patients with hereditary or acquired hematologic /coagulation disorders such as platelet dysfunction syndrome, critical thrombocytopenia, impaired coagulation or patients suffering from uncontrolled severe metabolic or systemic disorders. Do not treat patients who present septicemia or acute infection in the area of the treatment. It is recommended not to use the PRP/HA preparation in patients with partial or total knee prosthesis.

Relative contraindications: It is recommended not to use the PRP/HA preparation in patients with malignancy, particularly with hematologic or bone involvement and metastatic disease, in the previous 5 years, with autoimmune diseases with presence of antibodies and progressive (Hashimoto, rheumatoid arthritis, lupus, etc), with recent fever or illness and with platelet count less than 100'000'000/ml. Taking medication or dietary supplement which alter platelet function, within 3 days, may affect the effectiveness of the treatment. The safety and effectiveness have not been evaluated in children and in pregnant or lactating women.

### Patented by Regen Lab SA – CellularMatrix (PRP+HA)

U.S. patent US9517255 European patent EP2544697B1 Canadian patent CA2789533C, Chinese patent CN103079577B, Australian patent AU2011225828B, Japanese patent JP6076091, Russian patent RU2614722, Israeli patent IL221133

POSSIBLE SIDE EFFECTS Possible side effects of blood collection Blood collection may cause damage of blood vessels, hematomas, superficial phlebitis, delayed wound healing and / or infections, temporary or permanent nerve damage that may result in pain or numbness and early or late infections.

Following injection with HA, there have also been occasional reports of hyper-sensitivity, including, rarely, anaphylaxis. The administration of HA was also reported to provoke pronounced inflammatory reactions. Reversible inflammatory reactions have been observed 1 or 2 weeks after micro-papular injections Injection may lead to infection if general precautions for injection and asepsis are not respected.