CELLULAR MATRIX®

One Step Closed System !

Breaking the vicious cycle of osteoarthritis

CellularMatrix synergistically combines the complementary clinical effects of HA and A-PRP® to provide added benefit for OA patients. [2]

regenlab®

PRP & CELL THERAPY SPECIALISTS

CELLULAR MATRIX®

Synergistically combines the complementary clinical effects of A-PRP and HA to provide added benefit for OA patients. [2]

A-PRP: the patient's platelet concentrate prepared with CellularMatrix, provides an autologous resevoir of growth factors.

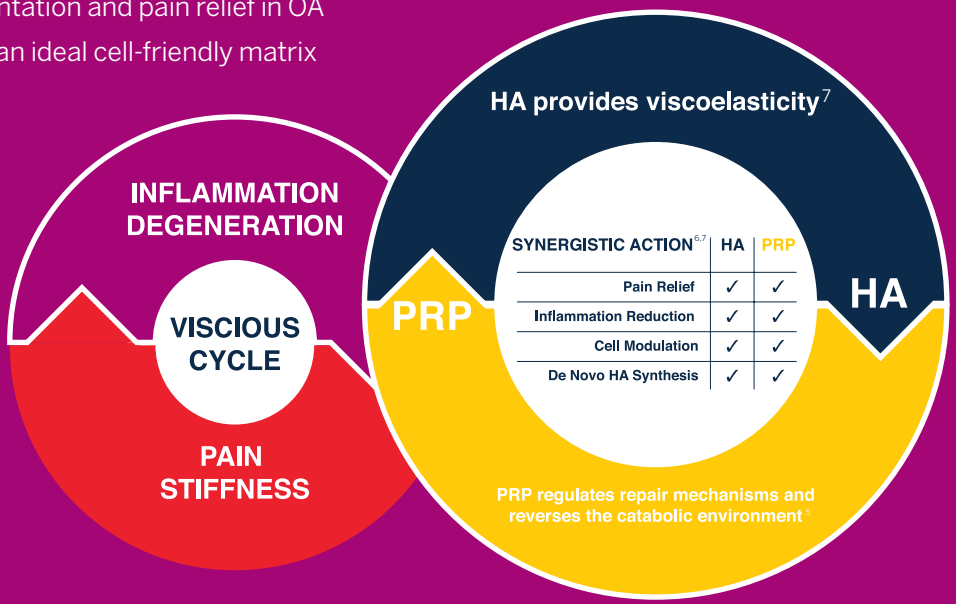
Platelets are key factors in hard and soft tissue repair mechanisms [1]. They provide essential growth factors, such as FGF, PDGF, TGF-ß, EGF, VEGF, IGF, which are involved in stem cell migration, differentiation and proliferation. Additionally, platelets also stimulate fibroblasts and endothelial cells 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.

- Proven role in the healing of soft and hard tissues, with key actions on cell migration, proliferation and differentiation
- Growing body of evidence to support the treatment of OA mechanism of action comprises anti-inflammatory activity and activation of cell-signalling cascades
- Key role in new matrix synthesis for tissue regeneration

Hyaluronic Acid (HA) is a major component of synovial fluid contributing to joint homeostasis.

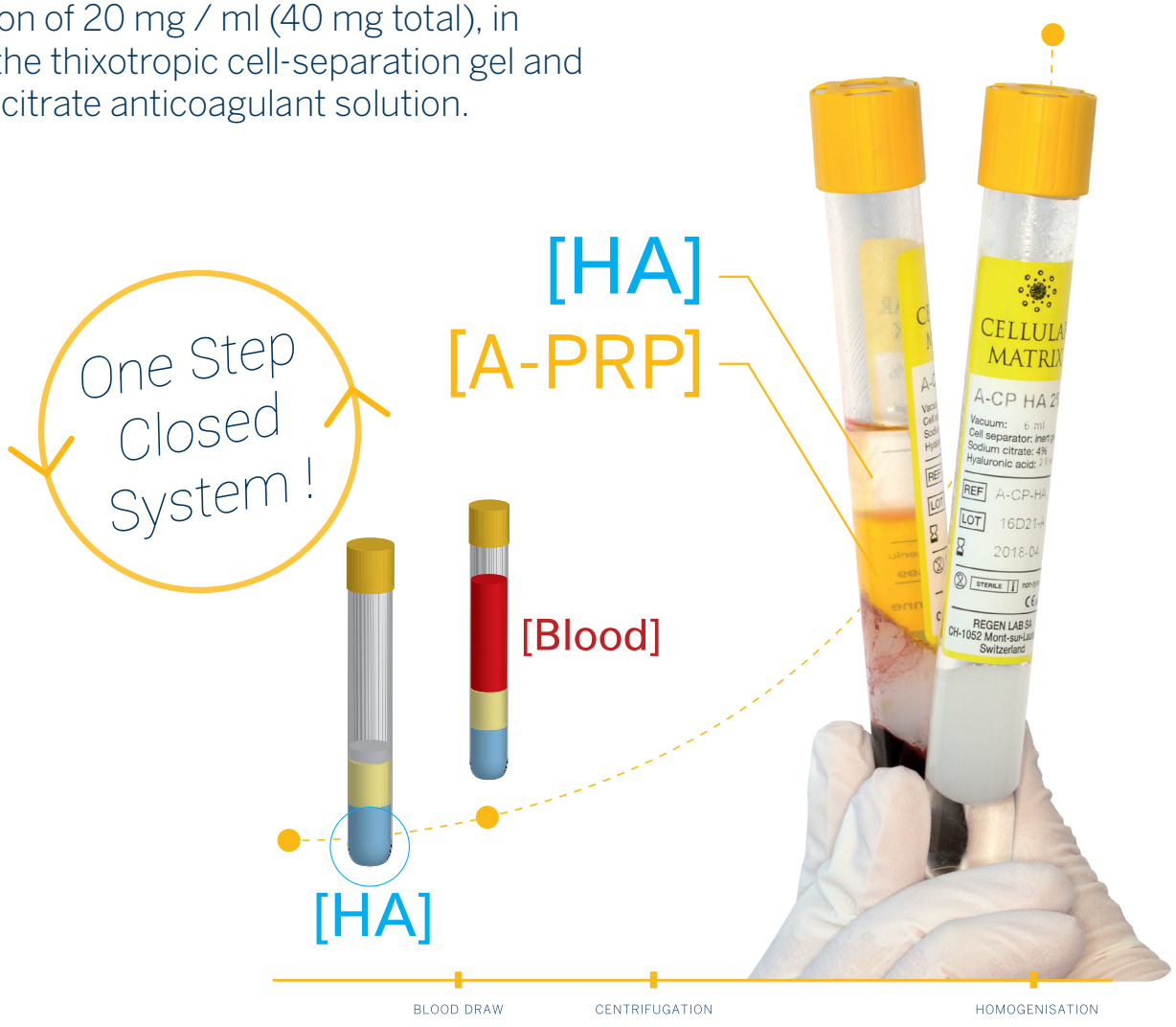
- 25 years of clinical experience show pain relief and functional improvement lasting 6 to 12 months
- Plays a major role in viscosupplementation and pain relief in OA
- A network of HA chains constitutes an ideal cell-friendly matrix



CELLULAR MATRIX®

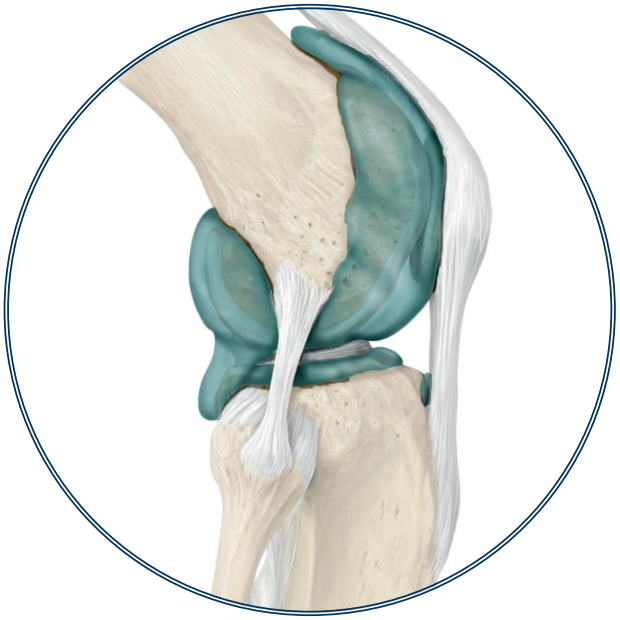
Immediate formation, in one easy step, of a cell-friendly HA network in which platelets are dispersed, using a system which is specifically approved for preparation of the HA / A-PRP association.

CellularMatrix is a Medical Device that contains 2 ml of natural, non-crosslinked, HA at a concentration of 20 mg / ml (40 mg total), in addition to the thixotropic cell-separation gel and the sodium citrate anticoagulant solution.



Both HA and the Patient's A-PRP prepared with CellularMatrix have excellent safety profiles in clinical practice.

The study involved 100 symptomatic patients with knee cartilage degenerative lesions (Kellgren Lawrence scale grade 0 to III). Fifty patients, who had previously unsatisfactory clinical response to HA alone, were treated with IA injections of autologous CM-PRP-HA combination that was repeated 3 times with 3-week interval, while the other 50 patients were treated with IA HA injections. [3]



WOMAC Score (pain) 2 - 6 & 12 months

Pain	HA	CM -PRP -HA	CM -PRP -HA versus HA
Basal	Basal vs 2 mon	Basal vs 2 mon	Basal vs Basal
	t-value: 13.7 P < 0.0001	t-value: 16.8 P < 0.0001	t-value: 0.5 P = 0.6307
2 mon	Basal vs 6 mon	Basal vs 6 mon	2 mon vs 2 mon
	t-value: 10.9 P < 0.0001	t-value: 14.5 P < 0.0001	t-value: 16.5 P < 0.0001
6 mon	Basal vs 12 mon	Basal vs 12 mon	6 mon vs 6 mon
	t-value: 5.4 P < 0.0001	t-value: 12.1 P < 0.0001	t-value: 5.96 P < 0.0001
12 mon	2 mon vs12 mon	2 mon vs 12 mon	12 mon vs 12 mon
	t-value: 9.99 P < 0.0001	t-value: 5.9 P < 0.0001	t-value: 4.4 P < 0.0001

Both A-PRP and HA have been extensively used to improve lubrication, modulate inflammation and modify the joint catabolic micro-environment, aiming not only for reducing clinical symptoms, but also interfere with OA progression. [3]

"CellularMatrix offers several advantages in the treatment of OA: HA creates a bioactive scaffolding through which the platelets progressively release their GFs to the target site. A-PRP does not negatively affect the mechanical, elastic or viscous properties of HA." [2]

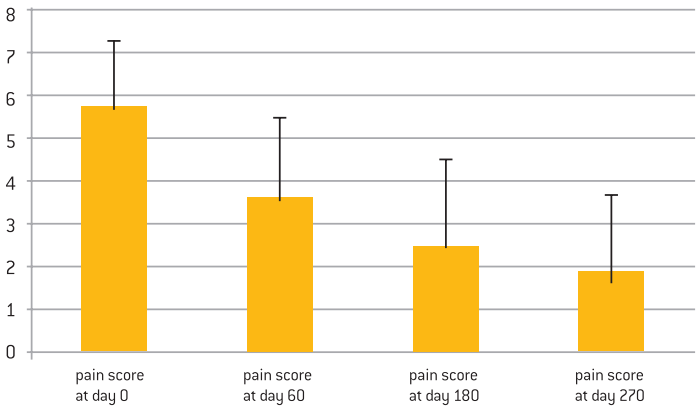
1. Marx RE. Platelet-rich plasma: evidence to support its use. J Oral Maxillofac Surg 2004;62:489-96.
2. Abate M, Verna S, Schiavone C, Di Gregorio P, Salini V. Efficacy and safety profile of a compound composed of platelet-rich plasma and hyaluronic acid in the treatment for knee osteoarthritis (preliminary results). European journal of orthopaedic surgery & traumatology : orthopedie traumatologie 2015;25:1321-6.
3. Seleem, N.A., et al., Intra-Articular Injections of Platelet-Rich Plasma Combined with Hyaluronic Acid Versus Hyaluronic Acid Alone in Treatment of Knee Osteoarthritis. ejpmr, 201. 4(4): p. 608-615.
4. Renevier JL, Marc JF. Etude Pilote d'un dispositif médical intra-articulaire innovant dans la prise en charge de la gonarthrose symptomatique fémoro-tibiale grade II-III radiologique après échec d'un AH. Revue du Rhumatisme 2014;81:A202.
5. Chen CPC et al. The influence of platelet-rich plasma on synovial fluid volumes, protein concentration, and severity of pain in patients with knee osteoarthritis. Exp Gerontol 2017; 93: 68-72.
6. Chen WH et al. Synergistic anabolic of hyaluronic acid and platelet-rich plasma on cartilage regeneration in osteoarthritis therapy. Biomaterials 2014; 35(36): 9599-95607.
7. Balazs EA, Denlinger JL. Viscosupplementation: a new concept in the treatment of osteoarthritis. J Rheum Suppl 1993; 39:3-9.

A French multicentre, prospective study, in patients with knee joint OA, shows that 3 injections of 2ml of A-PRP + 2ml of non-cross-linked HA (CellularMatrix) represent a new medical alternative to knee surgery after failure of HA alone.[4]

Number of patients: 71 [4]

- Average age: 63 (low of 40yrs and high of 84yrs)
- Gender: 37 males (52.1%), 34 females (47.9%)
- Average BMI: 26.83 (low of 20.32 and high of 39.06)
- Kellgren and Lawrence Grading Scale: grade II (46.5%) and grade III (53.5%)

WOMAC A1 Score (pain) at Days 0, 60, 180 and 270



Results [4]:

- 87.3% of patients were responders to treatment with CellularMatrix based on the OMERACT-OARSI criteria.

- Significant decrease of WOMAC A1 score between day 0 and day 270.

- This study demonstrated that 3 injections A-PRP+HA represent a new medical alternative to knee surgery in patients who do not respond to treatment with HA alone.

"CellularMatrix provided significant pain relief and functional improvement in 87.3% of patients who had an unsatisfactory clinical response to previous therapy with HA alone." [4]

CELLULAR MATRIX®

INTENDED USE OF THE DEVICE

Device used to prepare intra-articular injections for symptomatic treatment of articular pain and mobility improvement.

CONTRA-INDICATIONS
Do not administer to patients with ascertained hypersensitivity to one of the components, or suffering from serious disease such as cancer or infection in joint or in the treated area. The administration of the HA/PRP preparation to patients suffering from inflammatory joint diseases and autoimmune diseases such as rheumatoid arthritis or Bechterew disease is not recommended. The administration to children, pregnant or lactating women is not recommended.

POSSIBLE SIDE EFFECTS
Blood puncture and injection may cause damage of the blood vessels and hematomas. When injected intra-articularly, local secondary inflammatory reactions may occur at the site of injection. This may result in temporary pain, feeling of heat, redness and swelling in the joint or area treated with the HA/PRP preparation. Icepacks application in the minutes following the injection, or local analgesic treatment the day following the injection may decrease these inconveniences. There have also been occasional reports of hyper-sensitivity, including, rarely, anaphylaxis. The administration of HA was also reported to provoke pronounced inflammatory reactions. Injection may lead to infection if general precautions for injection and asepsis are not respected.

CE 0086

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

ORDERING INFORMATION

CellularMatrix / A-CP-HA-3
(Double Blister)
Ref: A-CP-HA-3

3 A-CP-HA tubes

One Step Closed System !

PRODUCT
Quality

ISO 13485 Certified
Patented Innovations
+1 Million Patients treated
CE Certified

PATIENT
Safety

GMP Manufacturing
Class III Medical Devices
Non Pyrogenic - sterile

A-PRP®
Efficacy

Dedicaded Kits for specific preparations
+ 100 published studies

Patented by Regen Lab SA - CellularMatrix (PRP+HA)
U.S. patent US8945537,
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

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