The art of regenerative medicine

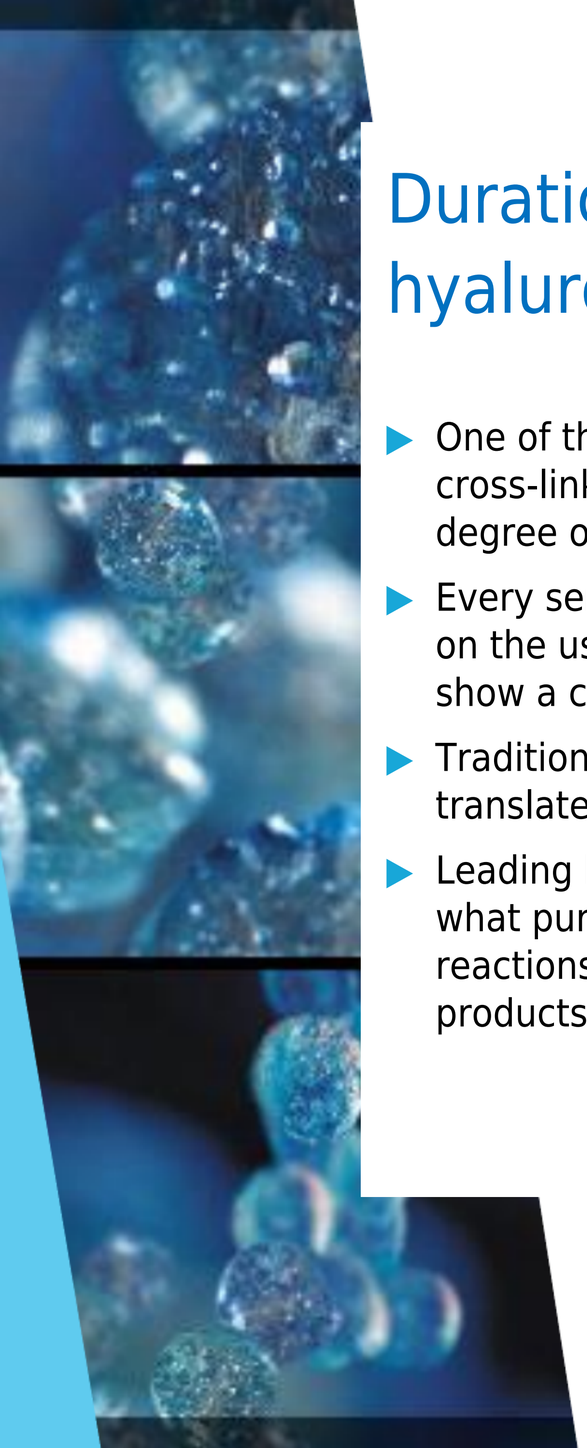
Doubly cross-linked hyaluronic acid for traumatology use

CRESPINE® GEL +

Ruhe im Gelenk

Why hyaluronic acid and why synthesize it?

- HA is one of the components of synovial fluid. It reduces friction between cartilage and other tissues in the joints, helping to lubricate and cushion them during movement.
- The first HA produced industrially was of animal origin: rooster comb (Hylaform).
- The duration of native HA in our tissues is 12 to 24 hours.
- It is inevitable that these HA products contain impurities, lower biocompatibility and hypersensitivity reactions.
- Today, HA from all laboratories is obtained through bacterial fermentation. Streptococcus equi is the microorganism most frequently used. Kablik J, Monheit G, Yu L, Chang G, Gershkovitch G. Comparative physical properties of hyaluronic acid dermal fillers. Dermatol Surg. 2009;35(Suppl 1):302-312
- The duration of synthetic HA, depending on its degree of cross-linking, is several months.



Duration and purity of hyaluronic acid

- One of the necessary “modifications” to obtain durable and pure HA is cross-linking: the higher the degree of cross-linking, the higher the degree of purity and duration.
- Every serious laboratory uses a cross-linking method; however, all agree on the use of cross-linking agents such as BDDE or DVD, both of which show a certain degree of toxicity.
- Traditional cross-linking uses a large number of chemical bonds, which translates into greater toxicity.
- Leading laboratories have developed other forms of cross-linking. For what purpose? To provide greater safety (nullifying potential adverse reactions) and durability (moving from multiple-dose to single-dose products).

BioPolymer GmbH - specialist in hyaluronic acid

Spezialist für

bio polymer
Manufacturer of medical devices

- BioPolymer GmbH is a German company pioneering the medical use of hyaluronic acid, with professionals who have more than 30 years of medical-surgical experience.
- BioPolymer GmbH is committed to innovation and quality, working with and for the most demanding medical professionals in Europe.
- BioPolymer GmbH is committed to the quality of its products and services, as its technological leadership is the starting point of its efforts.

Crespine Gel & Crespine Gel +:
third-generation hyaluronic acid => greater cross-linking & purity

- BioPolymer GmbH developed the Covalent Reticulated Matrix technique (CRM technique) in Germany, the most advanced technique on the market.
- The CRM technique enables the production of a doubly cross-linked hyaluronic acid gel.
- Its main advantages:

  i. It is a purer HA, thereby eliminating hypersensitivity reactions
  ii. By increasing the number of cross-links, its toxicity decreases exponentially
  iii. Because it is a highly cross-linked HA, it is chemically more stable
- The CRM technique provides the most unique characteristic of these products: Advanced Thixotropic Technology.

How is the double cross-linking of *Crespine Gel & Crespine Gel+ performed?*

Covalent Reticulated Matrix (CRM technique) & Advanced Thixotropic Technology (ATT)

1st stage	▶ Obtaining an HA solution from sodium of non-animal origin (bacterial fermentation).
2nd stage	▶ First cross-linking of HA (BDDE is used). Washing, filtering and stabilization of the HA gel. It is ensured that there are no traces of BDDE in the final product.
3rd stage: CRM & ATT	▶ Extension of the reaction surface of the HA gel (the larger the surface, the greater the water uptake). Second “coil-linked” cross-linking (spring- or spiral-shaped) => ATT technology. Terminal purification process.

ATT & CRM double cross-linking: a new standard

- The second “coil-linked” cross-linking provides major benefits =>
  - homogeneous HA molecule size, and
  - an important physical characteristic: THIXOTROPY
- Thixotropy => the property of certain gels or fluids to modify their viscosity according to an external mechanical stimulus.
- As thixotropic products, Crespine Gel & Crespine Gel + have the following unique characteristics:

Crespine Gel &

Crespine Gel +

- **are less viscous (flow more easily) when they are injected into the patient**
- **are more viscous under static conditions (therefore requiring fewer mg of HA per ml to ensure greater durability)**
- **are purer and more chemically stable due to a higher degree of cross-linking**

Crespine Gel & Crespine Gel +

- BioPolymer GmbH manufactures both products in Germany according to the highest European standards of quality and safety.
- Presentation: 1 pre-filled syringe of 2 ml.
- Composition of Crespine Gel (1.0 ml contains):
  - 14 mg cross-linked hyaluronic acid
  - 1.0 mg hyaluronic acid
  - 6.9 mg sodium chloride
  - 1 ml water for injection
- Composition of Crespine Gel + (1.0 ml contains):
  - 14 mg cross-linked hyaluronic acid
  - 1.0 mg hyaluronic acid
  - 3.0 mg prilocaine
  - 1 ml water for injection

Executive Summary

- Crespine Gel & Crespine Gel + are produced in Germany under the most demanding European standards.
- The CRM technique guarantees a 100% synthetic, doubly cross-linked HA.
- The ATT technology gives the HA gel a dual effect: it is extremely fluid at the time of injection and highly viscous once it settles in the patient’s joint.
- Crespine Gel & Crespine Gel + are products:
  - of unprecedented purity and 100% synthetic, eliminating hypersensitivity reactions
  - with great durability for a single-dose product
  - of only 2 ml, thereby reducing joint pressure during infiltration and facilitating application in small joints
- Crespine Gel + is the only product worldwide with included prilocaine that:
  - minimizes pain during injection
  - minimizes tissue reactions
- Crespine Gel & Crespine Gel + establish a new quality standard in the local market.

Company Osteo Device SL

CEO Dr Wolfgang Schmitt

Management and administration of polyclinics
Purchase and sale of medical supplies
Organization & training courses & workshops for doctors
Exclusive importer of various medical products for Spain and Portugal

Distribution: Medical products based on hyaluronic acids
Anti-Aging & Traumatology

Crespine® / Crespine®Gel +

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