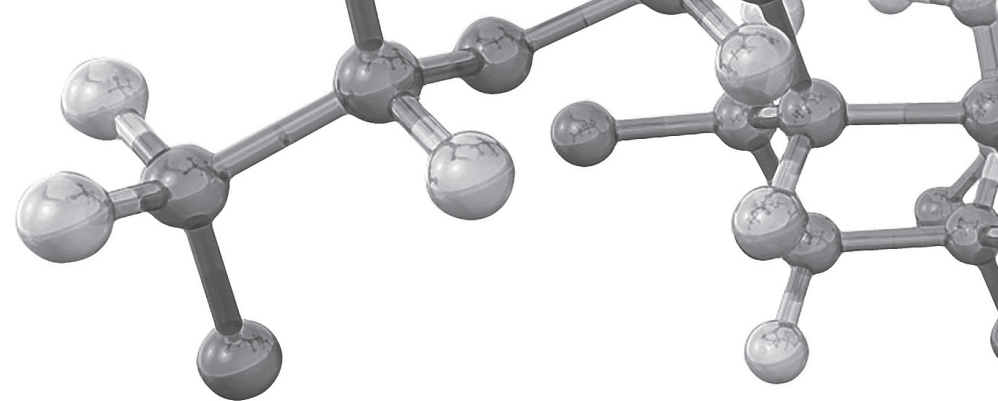


HYAcorp





Introduction

BioSCIENCE GmbH is a family owned manufacturer of medical devices based on hyaluronic acid.

Our activities embrace several medical fields:

- aesthetic medicine (dermal fillers: HYAcorp, Genefill and CRM)
- abdominal surgery/gynaecology/urology (HYAcorp Endo Gel/Urodex/CRM Vurdex)
- dentistry (HYAdent, HYAdent Barrier Gel)

We are located in Ransbach-Baumbach, near Frankfurt/Main, Germany, and cooperate with distributors all over the world. The company, founded in 2006, scopes development, production, final inspection and distribution of sterile medical devices.

The company is divided in 3 departments:

1. Office (Ransbach-Baumbach, Germany)
2. Plant (Dümmen, Germany)
3. Scientific Laboratory (Schossin, Germany)

BioSCIENCE observes successful growth for more than 7 years. We interact with qualified

partners concerning product design, research and manufacturing. BioSCIENCE only uses raw materials from qualified manufacturers. We have implemented a Quality Management System (EN ISO 13485 + AC: 2007) and were given the CE mark 1252 by the notified body QS International, Schaffhausen (CH).

HYAcorp is our product line of dermal fillers for body and face contouring to be utilized in minor surgical rooms. This treatment uses a specially designed hyaluronic acid gel (HA-gel), which is of non-animal source and needs less re-injections.

HYAcorp achieves an excellent volume effect and is well known for its long lasting results.

HYAcorp products can be stored at room temperature and are easy to inject.

The safety of HYAcorp products is ensured by manufacturing according to ISO 13485 and routine testing of every batch by an independent laboratory according to ISO 9001.

- Sensitization test (DIN ISO 10993-10)
- Cytotoxicity assay (DIN EN ISO 10993-5)
- Intracutaneous reactivity (DIN ISO 10993-10)

Furthermore, each batch produced is subject to test for sterility as well as the test for endotoxine by an independent, GLP-certified laboratory.

Quality and Safety of the HYAcorp products

The safety of HYAcorp products is ensured by manufacturing according to ISO 13485 and routine testing of every batch by an independent laboratory according to ISO 9001.

The following tests have been conducted for the HYAcorp product line:

- Test for Endotoxine, Ph. Eur. 2.6.1
- Test for Sterility, Ph. Eur. 2.6.1

Hyaluronic acid and the Advanced Thixotropic Technology (ATT)

Hyaluronic acid (HA) is used in medicine for a long time with a high safety profile.

HA in his natural form has a short duration time in the tissue (~24h) because of enzymatic degradation by hyaluronidases and free radical metabolism. Smaller particles have a greater surface and therefore tend to a faster degradation, while larger particles are more robust against enzymatic degradation, as they present a smaller particle surface.

To prevent the degrading effects, HA can be modified by crosslinking to form a water-insoluble polymer hydrogel, which is more resistant to degradation but with a similar biocompatibility as non-modified HA.

The so-called „Advanced Thixotropic Tech-

nique“ is based on a special manufacturing process for hyaluronic acid gels. Here, covalent bonds are created that ensure greater stability and thus durability of the product. The network formed by this thixotropic HA gel reduces the diffusion rate of degrading enzymes into the matrix.

The covalently crosslinked gels become less viscous under increasing pressure (injection force). This allows them to be injected with thinner needles than conventional gels, which results in less trauma in the area of injection. This effect also allows gels with larger particles to flow easily through small needles. The gel returns to its original viscosity upon ending the pressure (injection force).

HYAcorp in general

HYAcorp is a clear and viscous gel of cross-linked hyaluronic acid for restoring of volume and contouring of body and face surfaces.

The innovative crosslinking technique used by BioSCIENCE creates smooth, homogeneous gels with excellent viscoelastic properties, an easy way of injection and a long duration in the tissue.

The products vary in crosslinking degree, particle size and concentration of HA. The combination of these three factors allows to choose the best suiting product for each area.

The crosslinking degree is responsible for the elasticity and duration of the product. Treatments in deeper skin structures require firmness, thus, high crosslinked HA should be

used. Areas intended to be soft after treatment like e.g. face and lips necessitate a lower level of crosslinking.

The duration of the filling effect can vary and is dependent on the depth and area of injection.

HYAcorp is supplied in special syringes and designed for single use only. The depth of the injection may vary from subcutaneous to supraperiosteal administration depending on the treatment site.

Hyaluronic acid used in HYAcorp products is endotoxin- and BDDE-free. Protein concentrations are not significant and the HA is tested BSE-free and of non-animal origin.

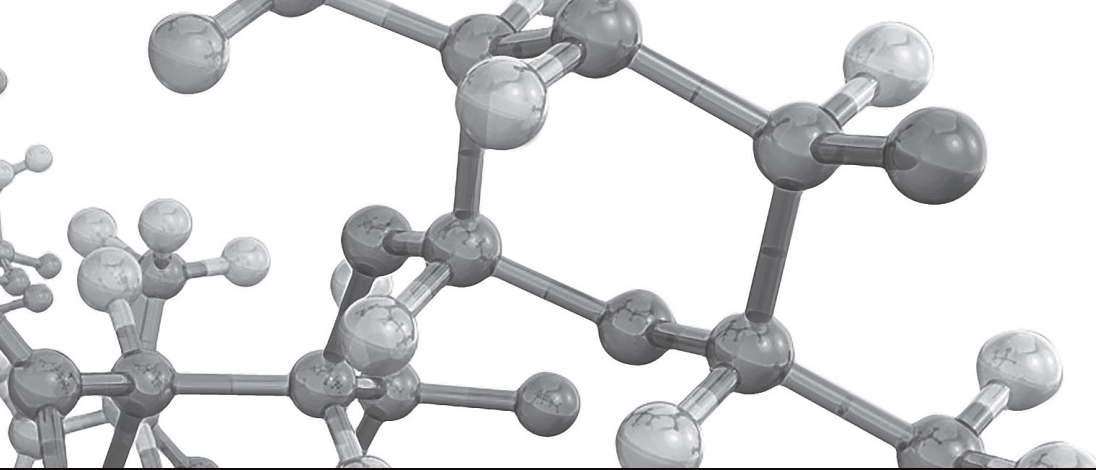


fig. in 10 ml



fig. in 10 ml

Tissue development with HYAcorp – the alternative to surgery

Treatment with HYAcorp is not a surgical procedure. It is carried out as an out-patient under local anesthetic. The result is immediately visible. After treatment the patient can normally start work again straight away or devote themselves to leisure activities.

HYAcorp is implanted in an easy procedure and it causes little if any bruising.

The effect achieved with HYAcorp lasts for several months but is dependent on skin type and external factors like smoking and stress. In most cases follow-up treatment once a year is sufficient after the first treatment.

Market research and surveys have shown that a large number of people would like to make small changes to their body and would like to adjust the shape of their body in a natural, non-permanent way that does not involve the use of implants, body fat or stem-cells in a major surgical procedure. Many of them are also very hesitant about undergoing general anesthesia or being left with a scar.

HYAcorp presents a natural opportunity without the use of implants, autologous fat injections or surgical procedures.

Hyaluronic acid is a natural component of human skin which plays an important part in health. It is not derived from animals, no risk of usual allergic reactions or transfer of illnesses. With HYAcorp, the procedure is short and requires only local anesthetic which avoids the risks of a full anesthetic.

Treatment is not permanent and as opposed to permanent (non-reversible) procedures offers the possibility of adapting the natural shape of skin and body. It binds moisture perfectly and at the same time stimulates the regeneration of collagen. This provides the skin with new elasticity and creates a fresher look. Thus, hyaluronic acid fillers like HYAcorp present superb opportunities for restoring tissue volume.

To minimize adverse events and side effects, the products should only be applied within their indication, e.g. Body Contouring fillers are explicitly not intended for use in facial region.

Our dermal fillers should only be applied if the area to be treated is free of inflammation. An extended anamnesis is as well a solid base for a successful treatment as an experienced professional.

The treated area should neither be exposed to intense heat or extreme cold nor to constant pressure for a few weeks until initial swelling has resolved. The injection should be made by physicians with the knowledge and the experience of fat transplantation and similar treatments.

Only correct to 100% of the desired volume effect. Do not overcorrect.

The HYAcorp Body Contouring products

HYAcorp MLF1

calves, correction of concave deformities

HYAcorp MLF2

calves, correction of concave deformities

Indication

Injection depth

Composition

Particle size

Crosslinking degree

Syringe volume

Needle

subcutaneous / supraperiosteal

Na-hyaluronate, crosslinked 20 mg,
Na-hyaluronate, 2 mg

200 - 350 µm

10 ml

Not provided

subcutaneous / supraperiosteal

Na-hyaluronate, crosslinked 20 mg,
Na-hyaluronate, 2 mg

300 - 500 µm

10 ml

Not provided

* low level crosslinked HA

** mid level crosslinked HA

*** high level crosslinked HA



fig. in 1 ml



fig. in 1 ml



fig. in 1 ml



fig. in 2 x 2 ml

The HYAcrop facial products

	HYAcrop Fine	HYAcrop Lips	HYAcrop Face	HYAcrop Face 2 x 2 ml
Indication	face, neck, décolleté, back of the hand	lips (contour and volume), philtrum, moderate wrinkles, anger folds, nasolabial folds	Indication deep folds, accentuated nasolabial fold, chin, cheek, eyebrows, contour defects in facial region, regio zygomatica	deep folds, accentuated nasolabial fold, chin, cheek, eyebrows, contour defects in facial region, regio zygomatica
Injection depth	upper dermis	mid/deep dermis	Injektion depth deep dermis / subcutis	deep dermis / subcutis
Composition	Na-hyaluronate, noncrosslinked 14 mg	Na-hyaluronate, crosslinked 16 mg, Na-hyaluronate, 2 mg	Composition Na-hyaluronate, crosslinked 20 mg, Na-hyaluronate, 2 mg	Na-hyaluronate, crosslinked, 20 mg, Na-hyaluronate, 2 mg
Particle size	N/A	80 - 150 µm	Particle size 80 - 150 µm	80 - 150 µm
Crosslinking degree	N/A	*	Crosslinking degree **	**
Syringe volume	1 ml	1 ml	Syringe volume 1 ml	2 x 2 ml
Needle	30 G	30 G	Needle 27 G kit (sharp/blunt)	27 G kit (sharp/blunt)

* low level crosslinked HA

** mid level crosslinked HA

*** high level crosslinked HA

Imprint

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