For Restoration of volume and contour of body surfaces.

INSTRUCTION FOR USE (IFU)

Description

HYAcorp MLF1 / MLF2 is an absorbable skin implant with a high level of purity. It is a medical device intended for single use only and is produced from a hyaluronic acid of non-animal origin. **HYAcorp MLF1 / MLF2** is a sterile, apyrogenic, viscoelastic, biologically compatible (non-immunising, non-inflammatory, non-toxic) gel implant that is insoluble in water and produced from a hyaluronic acid obtained by fermentation. Hyaluronic acid is a naturally occurring polysaccharide in the dermal matrix of human skin. The hyaluronic acid in the tissues of all higher organisms is chemically, physically and biologically identical.
HYAcorp MLF1 / MLF2 is a clear viscous gel supplied in a 10 ml syringe with a Luer lock port.

Composition

1 ml of **HYAcorp MLF1 / MLF2** contains:

Hyaluronic acid	2.0 mg
Hyaluronic acid cross-linked	20.0 mg
Sodium chloride	6.9 mg
Water for injection ad	1.0 ml

Mode of action

HYAcorp MLF1 / MLF2 is implanted into the subcutaneous and/or supraperiostal tissue to supplement the intercellular matrix and the intradermal tissue in order to restore lost anatomical structures. Its mechanism of action is based on the latest biotechnological developments in the production of injectable hyaluronic acid. The product is completely degraded over time.

Indication and application

HYAcorp MLF1 / MLF2 is intended to be used as a means of restoring lost volume and contouring body surfaces. The depth of the injection can vary depending on the treatment site, the subcutaneous application and the supraperiostal application.

- Buttocks
- Calves
- Correction of concave deformities

Contouring the body with **HYAcorp MLF1 / MLF2** ensures that the volume of the buttocks and other parts of the body is increased in a natural way. One of the uses of **HYAcorp MLF1 / MLF2** is for contouring the cleavage, but it is also used to supplement cosmetic surgery procedures such as liposuction. The gel is injected deep into the skin and lifts the tissue in a natural way. The duration of the filling effect can vary and depends on the depth and the injection area. A greater augmentation of volume can be achieved with **HYAcorp MLF2**.
The results that can be achieved depend on the type of skin and on the changes requested.
The treatment should be carried out only by doctors with knowledge and experience in the field of fat grafting or similar treatments.

Contraindications

HYAcorp MLF1 / MLF2 must not be used on patients who:

- have a tendency to hypertrophic and keloid scarring
- have an intolerance to gram-positive bacteria
- are prone to active inflammatory or infectious processes
- are suffering from acute or chronic skin diseases
- are undergoing anti-coagulant therapy
- have a known allergy to hyaluronic acid
- are suffering from autoimmune diseases

No clinical data is available on the administration of the product during pregnancy or lactation or on its administration to adolescents under 18 years of age. Patients with multiple allergies should be excluded from treatment.

⚠ The use of **HYAcorp MLF1 / MLF2** in the facial area is contraindicated. **HYAcorp MLF1 / MLF2** is intended for subcutaneous and/or supraperiostal application only. The use of **HYAcorp MLF1 / MLF2** for breast and genital augmentation is contraindicated.

Warnings

HYAcorp MLF1 / MLF2 must not be injected into blood vessels or intramuscularly as this could result in an occlusion of the vessels and an embolism.
HYAcorp MLF1 / MLF2 should not be injected into an area in which a permanent implant has been placed.
HYAcorp MLF1 / MLF2 should not be used on or in the vicinity of anatomical sites affected by an active skin disease, inflammation or associated conditions. The use of the product in areas that have already been treated with another augmentation solution is not recommended.
The normal precautionary measures associated with intradermal injections must be observed.
HYAcorp MLF1 / MLF2 is intended for subcutaneous and/or supraperiostal injection. A technique and injection depth appropriate to the area treated must be chosen. To ensure the success of the treatment it is crucial that doctors using the product have the relevant expert knowledge and have undergone special technical training in injection techniques.
In common with all procedures of this type the implantation of **HYAcorp MLF1 / MLF2** is associated with the inherent risk of an infection. A thorough anatomical knowledge of the treatment site is absolutely vital and special care must be exercised if areas are being treated in the direct vicinity of vulnerable structures such as nerves, vessels and the gut.

The doctor carrying out the treatment should be thoroughly conversant with the patient's anamnesis. Suitable precautionary measures should be taken in the case of patients suffering from pre-existing diseases and guidance and explanations should be provided. Patients taking medication affecting blood clotting, such as aspirins or non-steroidal anti-inflammatory drugs, will experience, as is the case with any injection, increased bruising or increased bleeding at the injection site.
The area treated must not be exposed to excessive heat (sun, solarium, laser and IPL) or cold. Patients should refrain from sporting activities for a few days. The injection area should not be massaged in the days following the injection and not exposed to excessive pressure.
If the needle is clogged, replace it with a new one. Do not increase the pressure on the piston. Used syringes and needles should be treated as contaminated waste and must be disposed of in accordance with the generally accepted standards of medical practice.

Adverse effects

As with any invasive procedure, treatment with **HYAcorp MLF1 / MLF2** may also result in adverse effects. Treatment-related non-allergic reactions may occur such as itching, reddening, sensitivities and swelling at the puncture site, subcutaneous bleeding or haematoma as well as hardness or hypersensitivity reactions. In most cases these reactions occur immediately or up to one week after the injection and usually abate spontaneously within one or two weeks. Delayed side effects are very rare but can occur later after the injection. Known delayed side effects of dermal fillers are bacterial infections, biofilm formation, the formation of chronic inflammatory nodules, reactivation of herpes infections, migration of the filler material, skin necrosis, foreign body reactions and granuloma formation.
The injection technique can cause overcorrections or bluish discolorations (Tyndall effect). It is essential that side effects are diagnosed by an experienced doctor and appropriate treatment carried out and monitored.

In order to minimise the risk of side effects from the outset, a thorough anamnesis must be taken by the doctor carrying out the treatment and the use of a sterile injection technique rigorously maintained.

Application instructions

The areas to be treated must be marked before treatment begins. A local anaesthetic can be administered in order to carry out the implant as painlessly as possible. An antibiotic can be administered at the doctor's discretion to prevent infection. Remove the syringe from the blister pack, remove the cap covering the tip of the syringe and fit a suitable sterile needle to the Luer Lock port.

Implantation technique

The implantation technique in terms of the depth of the injection and the amount administered can vary from case to case and according to the different degrees of augmentation required. The doctor must select the technique appropriate to the case in hand. Correct only up to 100 % of the volume of augmentation required. Do not carry out overcorrections.
Explanations must be given to the patient before treatment is given about indications, warnings, intolerances as well as potential side effects and the results to be expected. The area to be treated must be carefully aseptically prepared before treatment.

Warning

The graduation on the syringe is intended as a guide for users based on the final volume. It does not perform any measuring function; it merely indicates the amount used in relation to the nominal volume of 10 ml. The doctor administering treatment should check visually and by touch that a sufficient amount of the material has been injected.

Scope of delivery

HYAcorp MLF1 / MLF2 is supplied in a 10 ml syringe with integrated Luer Lock Adapter in a blister pack for single use only. The contents of the syringe are sterile (steam sterilisation). Instructions for use as well as labels with the batch number and the expiry date together with the blister pack are packed in a cardboard box. Do not use the product after its expiry date. A label is given to the patient as well in order to guarantee the traceability of the product.

Important note

The product must not be resterilised. It must not be mixed with other injection materials or decanted. The product must not be used if the packaging and the blister pack are damaged.

Storage

Do not freeze or expose to extreme heat. Store at room temperature (2 °C – 25 °C).

Manufactured by

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Date of information: 12.2015