

APHRODITE GOLD®



Injectable implant



**STORE AT 2-8°C
DO NOT FREEZE**

CE 0344

contains needles approved
under CE 0086 and CE 0197

European Medical Contract Manufacturing by
Nijmegen, The Netherlands
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Composition

PMMA

The body of the microbeads in APHRODITE GOLD® is made of polymethylmethacrylate (PMMA). PMMA has been used safely in implants since the 1930s. The beads are very pure and produced by a suspension polymerization method, in contrary to crushing or grinding. The PMMA bodies are covered with bovine collagen from a 3.5% atelocollagen solution. The collagen layer is degraded by the body and replaced by the own body connective tissue. Pre-clinical and clinical studies demonstrate that also the size of the microbeads plays a role in the end result of the implantation by determining the amount of fibrous tissue stimulated by the injected implant. The distinct size of the microbeads avoids phagocytosis by macrophages and local dislocation of microbeads.

Atelocollagen

The substance used as a carrier for the microbeads is the collagen derivative atelocollagen. The gel-like properties (thixotropy) of the collagen and its derivatives make it an ideal carrier for APHRODITE GOLD® (under normal conditions the gel prevents microbeads precipitation, whereas under pressure it becomes liquid, thus enabling injection). Atelocollagen results from the enzymatic removal of the antigenic ends of the collagen molecule. It has been proven that this form of collagen minimizes the risk of allergic reactions. The collagen used as raw material in the preparation of APHRODITE GOLD® is extracted from bovine skins. Only skins from approved safe sources that have been analysed and declared BSE free by national

veterinary authorities are used for the extraction.

Additionally, research has demonstrated that skins are among the bovine tissues with no detected infectivity. The collagen used in the preparation of APHRODITE GOLD® is extracted under strict quality control and according to international standards (EN-ISO 13485 and EN 12442).

Lidocaine

Lidocaine is a local anaesthetic which causes numbness when applied to the skin.

Principle

APHRODITE GOLD® is an injectable implant for the lasting correction of wrinkles and other connective tissue imperfections or conditions. APHRODITE GOLD® uses the body's natural response to encapsulate foreign bodies and stimulate the formation of connective tissue. Due to the good biocompatibility of the microbeads, the connective tissue growth is normally completed within a few months. Over time, the imperfection or condition is filled with autologous connective tissue.

The microbeads remain in place for the duration of the patient's life. Overcorrection should therefore be avoided.

Areas of Application

- Nasolabial folds
- Mentolabial folds
- Deep wrinkles
- Traumatic scars
- Dermal and subcutaneous skin conditions/imperfections
- Lip augmentation, particularly suited for post cleft lip surgery
- Augmentation of bridge of the nose
- Small facial defects
- Acne scars

Application Instructions

- Only to be used by trained physicians.
- Thoroughly disinfect the implantation area prior to injection.
- Highly pain-sensitive patients may require local anaesthesia in addition to the anaesthetic present in APHRODITE GOLD®. This is especially recommended for lip augmentation.
- Check that the 26G needle is firmly placed on the syringe (firmly turn the needle CLOCKWISE on the syringe). If the 26G needle becomes blocked during the application, do not force the syringe by increasing the pressure as the needle may be forced out of the Luer lock adapter. In case of blockage, the needle should always be replaced.
- The injection must be carried out slowly! The needle should be moved backwards and forwards (tunnelling technique) under permanent pressure, filling the created tunnels. The injection pressure is correct if the implant flows slowly, evenly and without excessive pressure.
- The best cosmetic results are by moving the needle back and forth 3-5 times for each fold. Given constant flow, the implant distributes itself under the fold and up to 3 mm in a parallel direction within the vicinity. Placement of several single deposits can lead to irregular settlement of the microbeads (droplet technique).

- If necessary at the end of the injection procedure, the implants can be flattened by applying pressure with the fingertips or fingernails (in case of blanching).
- Overcorrection should always be avoided. The applied amount of APHRODITE GOLD® is calculated such that the growth of connective tissue roughly corresponds to the quantity of absorbed collagen.

Recommendations

- The application of APHRODITE GOLD® in folds and wrinkles should be performed at the junction between the dermis and the subcutaneous fat. Too deep implantation may cause the implant to sink into subcutaneous fat.
- For medium to small folds, the use of thin, short 26 G needles is recommended. For lip augmentation 30 G needles may be used to enhance patient comfort.
- If the injection is close to the surface, there is a risk that the implant will shine through (the so-called "blanch-effect") and that this lighter colour will be permanent. Moreover, the implant may then remain coarse to touch, despite the subsequent growth of connective tissue.
- For the treatment of larger bony defects, thicker needles up to 23G can be used. Thicker and shorter needles permit a lower injection pressure.
- High pressure may result in a separation of the solid component in APHRODITE GOLD® causing blockage of the needle. The syringe may be manually rolled to re-establish an even distribution and prevent possible needle blockage.
- A local anaesthetic may complicate determination of the amount of APHRODITE GOLD® required for the injection.
- To facilitate easier injection the viscosity of the product may be lowered by warming up to room temperature prior to the application.

Warnings

- Patients should be advised to mould the implantation area after the implantation in order to achieve an even distribution of the implant. Spreading and modelling by moulding is particularly necessary, should nodular build-up be felt during the first 3 days following the implantation.
- Pronounced facial movements may dislodge the implant from the area of injection into deeper layers, especially in the days immediately following the injection. For this reason, areas in which implantation has taken place may be supported by a transparent bandage (or by a rubber band if the upper lip is involved), during the first days.
- If implantation occurs too near to the skin surface the implant may appear as a light-coloured area. This colour difference can be permanent in the case of patients with very thin skin. In this case, removal could be considered or flattening by dermabrasion.
- After some years a new fold may develop next to the implant area as a result of repeated facial movements. A second injection next to the first area could then be considered. The physician will inform the patient of possible side effects and contra-indications.
- Where too little growth of connective tissue occurs, the fold or other treated imperfections/ conditions may well appear again after some time, though these should be less pronounced. This phenomenon is especially noticeable in patients who previously absorbed collagen injections exceptionally fast. An additional injection on top of the first implant could be considered.

- If APHRODITE GOLD® is injected too superficially, the risk of granuloma formation increases significantly.
- The safety of APHRODITE GOLD® for use during pregnancy or in infants and children has not been established.
- An interval of 6 to 8 weeks must be maintained in between multiple injections.

Contra-Indications

APHRODITE GOLD® should not be administered in case of:

- known allergy to collagen or bovine products
- known allergy to lidocaine
- known (auto-)immune diseases
- susceptibility to keloid formation
- current cortisone treatment, as the growth of connective tissue fibres might be inhibited

Side effects

- Slight swelling and redness usually follow the implantation. This normally lasts for 1-2 days, though it can be of longer duration in exceptional cases.
- Being non-absorbable, APHRODITE GOLD® will probably remain palpable as a thickening under the skin for the duration of the patient's life.
- After absorption of the collagen the implant may feel somewhat hard at first, although it will soften again during the following months with the growth of connective tissue.
- In less than 0.01% of the patients foreign body granulomas have been reported. Treatment is recommended using betamethason injections intra-lesionally, following the instructions of the manufacturer of the drug.
- Anaphylactic shock may occur after multiple implantations of APHRODITE GOLD®.
- In less than 0.1% of the patients, an allergic reaction has been reported.
- Testing prior to treatment may be considered in consultation with the physician.

Literature

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