

FOLLOWING IS INFORMATION ON BIOALCAMID, PRESENTED BY DR. MICHAEL GOTTLIEB OF LOS ANGELES. IDE PROTOCOLS ARE BEING DESIGNED NOW. CONTACT INFO IN WWW.CLINICESTETICA.COM

CORRECTIVE and COSMETIC IMPLANT MATERIALS FOR FACE AND BODY

What is BIO-ALCAMID®

BIO-ALCAMID® is an injectable endoprosthesis. The innovation lies not only in the fact that it is a synthetic biopolymer (comprising 97% apyrogenous water; the remaining 3% is polyalkylimide based), but above all in its unique features it combines all the requisites necessary to obtain an optimum implant, i.e.:

1. The implant is biocompatible with the tissues.
2. It is non-mutagenic.
3. It is non-allergenic (does not require any test).
4. It is radio-transparent (a necessary and fundamental requisite for making a differential diagnosis between the implant and the various types of tissues).
5. It is permanent (it is not re-absorbed and is therefore classified as a Class IIb Medical Device).
6. It is easy to remove (absolutely new for an injectable implant).
7. It does not migrate.
8. It remains chemically and physically stable (does not release monomeric units).
9. Its consistency is similar to that of the tissue into which it is implanted (it is almost imperceptible to the touch as it comprises 97% apyrogenous water).
10. Considerable quantities can be implanted (even more than 500 ml! A unique feature for any type of implant).

These features make BIO-ALCAMID® the first injectable water endoprosthesis for soft tissues.

INDICATIONS

BIO-ALCAMID® is an injectable medical substance specially created for filling soft tissues; it must therefore be used for correcting congenital or acquired deficits of such tissues.

Due to its high degree of biocompatibility and its permanent effect, BIO-ALCAMID® is recommended also in cases of significant deficits: such as facial hemiatrophy, severe tissue deficits as in the case of Poland syndrome, Pectus Excavatum, etc. However, it is not recommended for correcting fine wrinkles and for filling the mucosa (lips) area.

HISTOLOGICAL DATA

In order to evaluate the biocompatibility of BIO-ALCAMID® biopsies were done on mammalian tissues for over five years, with controls carried out from the third day for up to more than a year following the implant.

The results showed a high degree of biocompatibility, with minimum inflammatory response, only slight edema, and regular neutrophil response in the period immediately following the implant. Macrophagic migration begins later and, after about fifteen days, a very thin connective tissue capsule is formed. There is no infiltration of cells into the prosthesis.

Subsequently, the connective tissue capsule is replaced by fine collagen fibers, together with a few macrophages and fibroblasts without either fibroplastic activity or the presence of lymphocytes, thus becoming a stable and permanent, although very thin (less than 0.2 mm), fibrocellular capsule.

The implant is thus transformed into a "natural" prosthesis (endoprosthesis) containing only BIO-ALCAMID® (and thus comprising 97% water) which, if perforated, allows the implant to be completely removed if necessary (using an appropriate technique).

The effect obtained will correspond to that actually seen immediately after the substance is injected