**BIOFIBRE® HAIR IMPLANT**

**THE EVOLUTION OF ARTIFICIAL HAIR**

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**History Remarks**

**Yesterday**

In the USA, already at the beginning of 1900 there is notice of patents for artificial hair implant instruments. Around the 70’s this technique spreads from Japan into the US and Brazil. Unqualified not medical operators, dangerous materials and methods lacking the adequate scientific medical grounds, provoked serious complications to the end users, which in the USA lead to decree the ban to implant human hair and artificial fibers made of modacrylic, polyacrylic, polyesther, etc., which were used at that time.

**Today**

The new Era of Implantation starts in Europe in 1996, with the UMDNS classification of artificial hair as medical devices (ruled by Directive 93/42/EEC). The respect of international safety standard for medical device and the application of right medical protocol performed by qualified trained doctors guarantee the safety for the patient’s health and the suitability for the use of this hair surgery technique. Biofibre® a CO-Polyamide Italian fibers marked CE0373/TGA possess all the safety requirements envisaged in the present norms.

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**Biofibre® Hair Implant Protocol**

Hair implant protocol is based on selection of suitable patient, correct implant procedure including proper after care and periodical medical check-ups.

**Patient Selection**

- Patients in good health/psychological condition and healthy scalp
- Tolerance test: pre-implantation of 100 – 200 fibers to evaluate sensitivity to the material

**Implant Procedure**

- Local anesthesia (lidocaine + adrenaline)
- Avoid temporal area or too low on the front
- Around 1000 fibers per session at 4 weeks interval
- Fibers density must be not more than 50 per cm²
- Implant depth is under galea capitis
- Fibers inclination is around 45 degrees
- Antibiotic prophylaxis after any implant session
- After-care protocol to the patient

**Post-Implant Check-Ups**

- 4 weeks after implantation test (or before in case of need).
- every 3-6 months according to the needs

**Clinical and Histological Studies**

Clinical-histological studies at 2, 3 and 5 years confirm that Biofibre® Biocompatible Artificial Hair achieves high quality and safety standards, such as negligible discomfort and inflammation levels, a high biocompatibility and resistance to chemical, physical and mechanical stress and stimulate the production of keratin shield that is a barrier for the bacteria. Thanks to the good and immediate aesthetic results and the positive psychological effects the large majority of patients are highly satisfied by the quality of the procedure and final result.

**Research Achievements**

**Experimentation**

The multiannual process of scientific testing and clinical studies carried out in collaboration by research accredited institutes and university and expert medical practitioners allowed to identify an excellent medical fiber, to realize suitable implant instruments and a targeted medical protocol for artificial hair implant procedure.

**Safety of Materials**

Biofibre® is an artificial hair inert and well tolerated by the human body. It is manufactured in conformity with iso GMP and GLP norms, with FDA AUTHORIZED POLYMIDES AND PIGMENTS.

From Pre-Clinical and clinical tests Biofibre® as shown:

- No carcinogenicity
- No Mutagenicity
- No Capillarity
- No bacterial adhesion
- No tissue Dispersal
- No tissue Traumatus

Further Safety is given by the anchorage of Biofibre® which is an extractable root (ER) allowing to pull out the fiber completely with restitution ad integrum of the explanted skin.

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**Indications**

- Androgenetic alopecia at any age and stage
- Post-surgical alopecia, trauma and burns - scar areas
- Male and Female alopecia
- Other irreversible alopecias
- Hair transplant completion in case of insufficient density after donor area exhaustion