NEW BIOFIBRE 4.0

Biofibre

HAIR IMPLANT

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4.0

Biofibre



High Technology Hair Implant System

Company Highlights





 Medicap is a certified company, specialized in the production of biocompatible artificial hair (trade name: Biofibre®) and implant devices and equipment, used for the treatment of male and female pattern baldness.

• Thanks to 30 years of experience, scientific and clinical research on the technique that uses biocompatible materials and thanks to the collaboration with worldleading medical experts in the sector, Medicap has developed its own know-how as far as:

- Implant methodologies and techniques
- Manufacturing of artificial hair
- Manufacturing of implant devices and equipment

HISTORY REMARKS - Old Experience



• **'70s and '80s**: the technique is spread worldwide but without any regulation

Biofibre

High Technology Hair Implant System

- **1983**: FDA restriction caused by:
 - use of unsuitable fibers (cut human hair, polyacrylic, modacrylic, polycarbonate, polyester, etc.);
 - technique often performed from Nonmedical operators (hairdressers) in unsuitable environments;
 - lack of medical protocol and no proper after-care;
 - no patient's information (commercial fraud)

HISTORY REMARKS - New Standards



- from 1990 onwards scientific research has improved in Europe thanks to Medicap Italy (in collaboration with University and medical associations)
- 1995: the hair implant technique is recognized as medical act and only trained doctors can perform it
- 1996: Biofibre[®] by Medicap hair implant fibers are CE marked and approved as medical device (UMDSN)



SCIENTIFIC BACKGROUND THE FUTURE IS NOW

Biofibre® High Technology Hair Implant System

Scientific Research, in cooperation with eminent international professionals from high prestigious universities of dermatology, plastic surgery and biotechnologies, enable company Medicap to design **Biofibre® 4.0** and put that on the market in **2020**



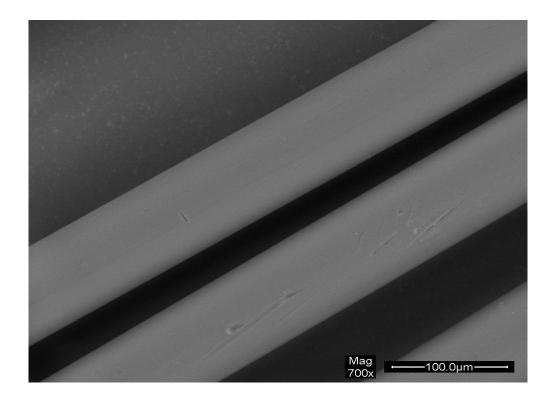


NEW BIOFIBRE 4.0[®] HOW IT'S MADE

• New Biofibre® generation is produced with Biocompatible Medical Grade 6 (highest level) Polymers approved for medical use and by developing new specific manufacturing processes to ensure best quality of fibers.

• All pigments used ensure maximum safety and additional exclusive treatments are performed to increase stability during years and improve the biocompatibility.

• New Biofibre® generation comply with all Safety present International Standards and all Biocompatible tests were held in collaboration with Namsa US.



NEW BIOFIBRE 4.0® FEATURES

Higher biocompatibility

- Natural aesthetic appearance
- Long duration of the result (7-8 years)
- Lower tissue trauma
- Absence of bacterial adhesion
- High resistance to traction





CERTIFICATIONS

BIOFIBRE® is a Medical Device Certified by CE, TGA, ISO 13485, etc.

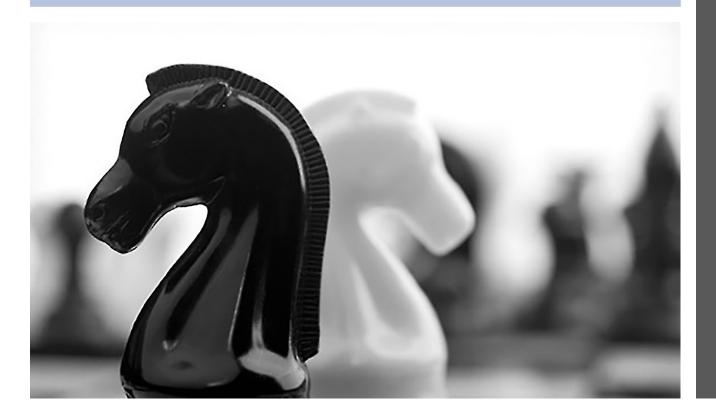
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NEW BIOFIBRE® 4.0 - AESTHETIC APPEARANCE



- **Soft** and **thin** for natural aesthetic result
- Available in 3 different lengths: 15, 30 and 45 cm
- Available in 5 different shapes: straight, wavy, curly, tight curl, afro
- Available in 13 colors
 + white
- Also available as triple fibers: one knot/three fibers outside the scalp, for higher density in shorter time

Artificial Hair -Market's Players



• To date there are only 2 players in the world specialized in artificial hair implant:

- ✤ Medicap Italy
- Nido Japan

• **MEDICAP**: produces and sells to clinics and distribution partners covering many countries. It promotes scientific activity and commercial information into the international congress and through the web. It organizes training to qualify doctors in this technique and ensure overall support to its partners. To improve services and products, the company invests an average of 50% of its revenues in R&D every year.

• **NIDO**: their main focus is represented by a franchising network of clinics in Japan with some occasional customer clinics abroad. The company has a conservative policy. They do not participate in congresses and do not carry out activities to expand the market.



	MEDICAP	NIDO
Product	Larger color range (14 colors, almost double than Nido)	Less extensive color range (only 8 colors)
	Finest and most refined hair	Hair less natural
	Wide range of hair types (in terms of length, shape and density)	Range limited to just short and medium smooth hair
Technique	Possibility of using multiple systems (manual and automatic)	Only manual system available
Results	Hair loss statistics on a year basis of only 10-15% (30% less compared to Nido)	Hair loss statistics on a year basis of 15-20%

The 2 players in comparison

Artificial Hair Market's Players

Medicap presents more advantages both on the product and the technique.



BIOFIBRE® NUMBERS

Over the last year Medicap Italy produced more than 3,000,000 Biofibre ®

More than 7,000 treatments all over the world

The current trend in Biofibre® implants is growing

The consumption of fibers has increased by <u>+ 30%</u> over the last year





High Technology Hair Implant System

BIOFIBRE® IN THE WORLD

Biofibre[®] CE 0373/TGA and Implant instruments CE 0373 are marketed by Medicap srl in over 50 countries:



Algerie Australia Austria Bahrain Belgium Bulgaria Cyprus Colombia Cameroon Cote D'Yvoire Czech Republic Ecuador Egypt Finland France Germany

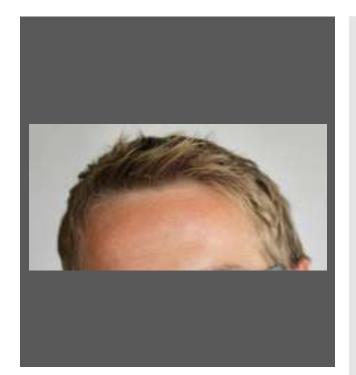
Greece Morocco Guatemala Norway Honduras Panama Hungary Peru India Philippines Indonesia Poland Iran Portugal Israel ROC Italy Romania Japan Russia Jordan Saudi Arabia Kazakhstan Serbia Kuwait South Africa Lebanon Spain Malaysia Sri Lanka Mexico Sweden

Switzerland Thailand The Netherland Tunisia UAE Uganda Ukraine United Kingdom Uzbekistan Vietnam

FUE, BIOFIBRE[®] 4.0 OR BOTH?

The best choice for baldness solution depends on the individual pathologies and personal expectations. Implant and transplant are very effective procedures with some significant differences that address patients to one choice rather than another according to their feeling and needs. Several times both solution are used in combination to increase final result.

	Technique	Pros	Cons
Fue/Fut	Use of own hair	 Improved compared to the past It often offers good results No need for after-care The hair grows back 	 Needs sufficient donor area High invasiveness Esthetic result extended over time Result not always satisfactory
Implant	Use of artificial hair	 Reduced invasiveness (simple and pain free) Immediate aesthetic result The hair does not age Reversible technique 	 Not definitive technique Requires periodic adjustments and checks It requires good personal hygiene The hair does not grow back



FUE BIOFIBRE® 4.0 OR BOTH? Doctors are able to work with both methods because it's often necessary to combine them -> No limit to perfection

• Regenerative scalp treatment, oligopeptide, LED, Laser, PRP, Stem cells treatment, rebalance of steroid receptors, etc. ...

are additional treatments to be **combined** with **Biofibre 4.0 Hair Implant**

BIOFIBRE® 4.0 HAIR IMPLANT Indications



- Diffuse hair loss or hair thinning
- For male alopecia and as first solution for female patients
- As **integration** to other hair restoration treatments
- To correct scars
- Alopecia Universalis on trial



BIOFIBRE[®] 4.0 HAIR IMPLANT

Requirements for a Successful Result

- Biocompatible fiber
- High Technology Implant instruments
- Qualified trained doctor
- Correct implant technique
- Patient selection
- Regular follow-up



BIOFIBRE® 4.0 HAIR IMPLANT

Procedure

- The doctor follows a mandatory training non Biofibre technique
- Patients selection and screening is required before proceeding with implant
- □ The doctor can use <u>two different systems</u>:
 - Manual instrument (so-called Implanter)
 - Automatic machine

The implant takes place in the <u>Galea</u> (subcutaneous layer) using a <u>sterile disposable needle</u> and in <u>more</u> <u>sessions</u> (2/3) lasting about 2 hours each after a <u>100</u> fibers initial implant test.

Careful monitoring is planned **for 30 days** postimplantation with specific after care.

<u>After 5 weeks</u> a new implantation session is possible.



BIOFIBRE[®] 4.0 Hair Implant - CORRECT AFTER CARE

- Regular follow up
- Correct scalp hygiene
- Suitable products (Biofibre Hair Care Set)
- Avoid dangerous products or treatments as:

hair dyes with ammonia, hair bleaching, permanent waving, excessive heat, hair curler, violent brushing, keratin powder



Cars.

BIOFIBRE®

Biofibre air Implant@ sively performed in clinics specialized tology, plastic surgery esthetic medicine ensure optimal uits to patients worldwide

9 arf - Via A. Lincein, 15 - 41012 Carpi (MO) - (TALY - Tel. + 30.058.002142 intr@bicfbrs.com www.3kdfbrs.com biofibre After care

SOME EASY SUGGESTIONS

by BIOFIBRE*



BIOFIBRE 4.0[®] HAIR CARE SET

 The Biofibre Hair Care Set has been specially devised to satisfy the needs of Biofibre patients. In this way, they will have readyto-use products, which are the best solution to maximize the results and the duration of the Biofibre hair implant

The BIOFIBRE HAIR CARE SET contains:
 BIOFIBRE Hair Comfort – cleansing foam to wash the scalp
 BIOFIBRE DermaClean – sanitizing spray for the hygiene of the scalp
 BIOFIBRE SeboCare – an antisebum spray to prevent the formation of sebum plugs



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BIOFIBRE[®] 4.0 Hair Implant -Causes of Problem

- Lack of hygiene
- Excessive density of implanted fibers
- Excessive quantity of implanted fibers in one session
- Lack of time interval between 2 Implant sessions
- Fibers intolerance (2%)
- Wrong implant area and wrong patient selection
- Wrong after care (wrong products or treatments)



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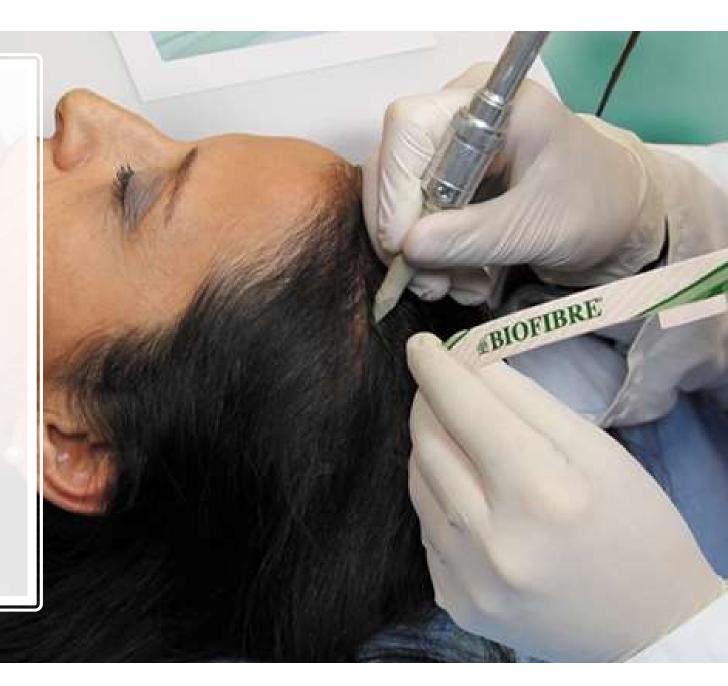
LM1 Laura Malavasi; 08/01/2021

BIOFIBRE® 4.0 HAIR IMPLANT

Biofibre[®] Hair Implant Devices comply with the highest standards for rapidity and accuracy of results:

- **Easy execution**
- □ Non-invasive procedure
- Duration of patient's result

This innovative automatic technique accounts the **prompt success** of this treatment **worldwide**.

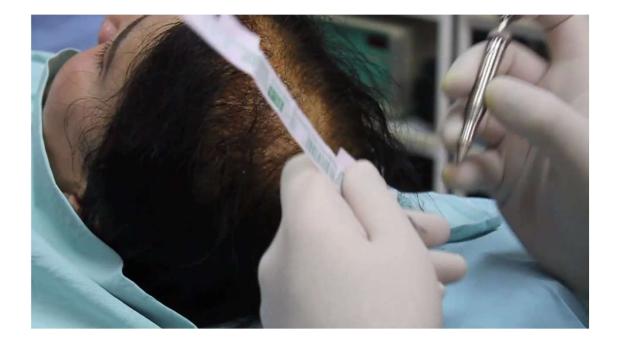




AUTOMATIC BIOFIBRE 4.0 HAIR DEVICE

- It is the most modern solution for artificial hair implant. It allows the implant until to 800 fibers/hour
- The session is pleasant both for the doctor and for the patient, who can see the result immediately after one hour







This soft manual hair implant solution allows to implant 600 Biofibre® per hour.

The patient can see the result immediately after the implant session without pain or discomfort.

BIOFIBRE® 4.0 HAIR IMPLANT

Technique





Faster cicatrization and high comfort for the patients allows to achieve best aesthetic result and immediate psychological benefit

BIOFIBRE® 4.0 HAIR IMPLANT

Psychological BENEFIT





To ensure a natural front-line a **zig zag staggered implant** has to be performed

BIOFIBRE® 4.0 HAIR IMPLANT

FRONT LINE





BIOFIBRE[®] hair is implanted under local anesthesia and features a special reversible anchorage allowing, in case of needs, total removal without leaving any lasting scars

BIOFIBRE® 4.0 HAIR IMPLANT



BIOFIBRE[®] HAIR IMPLANT Publications

More than 230 lectures and articles about Biofibre® Hair Implant System technique have been presented worldwide Paceived: 3 January 2019 Revised: 14 March 2019 Accepted: 3 June 2019 DOI: 10.1111/rdb.12965

THERAPEUTIC HOTLINE: SHORT PAPER



Biofibre[®] artificial hair implant: Retrospective study on 1,518 patients with alopecia and present role in hair surgery

Francesca Satolli¹ | Miriam Rovesti¹ | Al Bzour Bogdan Moran² | Giampiero Griselli³ | Manjul Agarwal⁴ | Said Amr Abdel-hakim Rateb⁵ | Serena Gianfaldoni⁶ | Ilia Lozev⁷ | Ivan Pidakev⁷ | Claudio Feliciani¹ | Georgi Tchernev⁸

³Department of Dematology, University of Pama, Pama Italy *Department of Demutology, University Cui-Napoca, Cluj-Napoca, Romania *Clinic of Dermatology, Forrara, Baly "Department of Dematology, Fort's Hospital, Shalimar Bash, India ¹Department of Dematology, University of Cairo, Giza, Egypt. "Department of Dematology, University G. Marconi of Rome, Rome, Italy "Department of General Vascular and Abdominal Surgery, Medical institute of Mobility of Interfor, Sofia, Bulgaria Department of Dematology, Venersology, and Dermatologic Surgery, Medical institute of Ministry of Interior, Sofia, Bulgaria

Consepandance Miniam Rovest, Department of Dematology, University of Parma, Parma, Italy. Enall miniam rovest Restudent unior 21. To treat alopecia, there are many surgical and nonsurgical treatments available nowadays. In the surgical one, the Biofibre® hair implantation system represents an important innovation with artificial hair with special physical, chemical, and mechanical features and the new Biofibre® Automatic device. Implant on 1,518 patients has been reported in this study where the Biofibre® hair implant technique is performed on men and women with varying degrees of bathness and for the treatment of various causes of alopeda such as androgenetic alopecia, burns, and scars. According to our experience, this technique gives immediate and visible results without scaring or hospitalization and the aesthetic results are very encouraging for both male and female patients with a rapid recovery of set-esteem and psychological well-being.

KEYWORDS Jopecia, biofibre, hair implant

Abstract

Baldness often causes psychological disorders and emotional stress with possible loss of self-esteem (Williamson, Gonzalez, & Finlay, 2001). Alopecia is not a single pathology but covers different etologles. With regard to the androgenetic form, the most common type of progressive hair loss disorder, novedsys, there are many nonsurgical treatments analiable.

The results of a recent network meta-analysis (Gupta et al., 2014) indicate the emergence of new nonhomonal hair loss thempies. New etheles, this review emphasizes that the quality of evidence supporting these new thempies is generally low because there are no high-quality randomized controlled trias. On the other hand, when nonsugical thempies are not possible or tail, surgery becomes the solution.

The most common surgical treatments to correct alopecia are hair transplants (follicular unit transplantation [FUT]/follicular unit

Ab breviations: FUE, to Review unit extraction; FUE, to Review unit transplantation.

Detmatokgik Therapy, 2019;s12985. https://doi.org/10.1111/dth.12985 © 2019 Wiley Periodicals, Inc. 1 of 4

ingly practiced with good results, these techniques are not without

risks and complications. In fact, extensive keloid formations on the

donor site or other complications are possible (Garg, Kumar,

sive dermatological procedure consisting in thin needles rolling over

the skin to puncture the stratum corneum in order to induce collagen

today and as with all techniques, there are controversies regarding

formation (Fertig, Gamret, Cervantes, & Tosti, 2018).

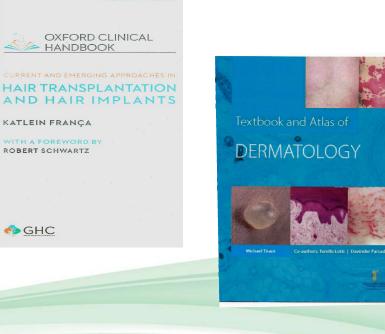
Another new surgical technique includes microneeding, an inva-

Unfortunately, a perfect hair transplant surgery does not exist

Tuknavat & Thami 2017).

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BIOFIBRE® HAIR IMPLANT Text books / Quality of Life/ Clinical Evidence







Rateb Said¹, Bogdan Morad Albzour², Martangela Santiago³, Manjul Agrawa

Open Access Neced J Med Eci electronic publication alread of print,

	Abstract
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Sector Children States Children State	second year. Any adverse effects were recorded during these visits.
Reprint 6 and nor new many facts that have the Alexan backgoes being they are the Alexan back to be to be any back and the set of the set are the set of t	RESULTS: At the consistence of the study period, as table of 146 packets concluded the table and the meads were instructed may weaked. Doth Heration scelar granding and convector users parametil inspected at the end of the study and adjustive and objective exclusions meaning and endowed the study and adjustive weak approximation only 15 cases (0.27%) which were sensity controlled by after building of any statement table and table day.
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THERAPEUTIC HOTLINE: LETTER

WILEY

Clinical updating study at 3 years on 278 patients treated by modern artificial hair implant technique (automatic biofibre®)

Torello Lotti¹¹⁰ | Michael Tirant² | A. Rateb Said³ | Bogdan Morad Altizour⁴ Mariangela Santiago⁵ | Manjula Agrawal⁶ | Ash Dutta⁷ | Van Thuong Nguyen¹ Mary Vadalá⁹ | B. Palmien⁹ | Akisandra Vojvodic¹⁰ | Massimo Fioranelli¹¹

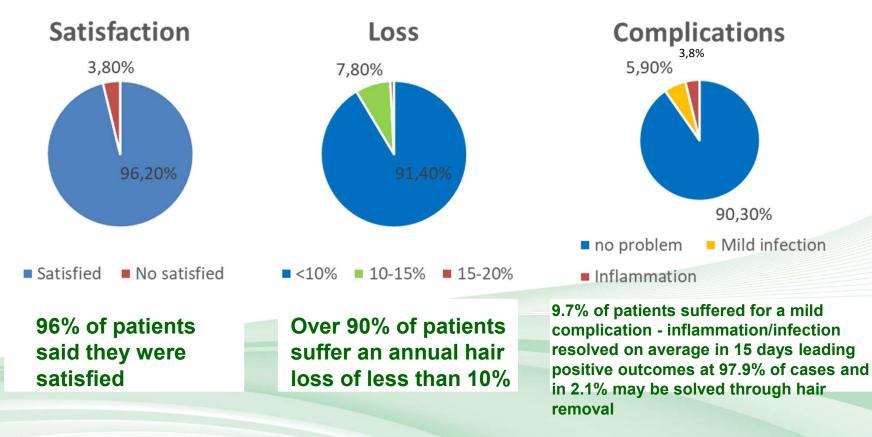
Department of Demarkings, University of Dates G. Marceri, Barris Table	Abstract
University of Bone G. Manurel Rome, Lab	In this study, we report our multicentric experience of synthetic medical certified
Department of Demarkings, University of Gen., Give, Named	polyanide hair implants in male androgenetic, female memopausa; and chronic aloge- cia. Biofibre hair instantiation and performed by means of a standardized mini-
Department of Domarkings, University Chip Ispena, Chip Napona, Bonarila	is assessed by regular postoperative care along 3 years. From May
Department of Peols Surgery, Hapital of Inco Delivite, Sac Peols, Breet	2015, 278 patients were enrolled and 253 completed the trial; 202 men (78.9%) ver- son 51 verses (20.1%). The average age was 43(a 4.2%): 179 patients (20.1%) had
Department of Demarkings, Rock Hospital, Indirect Rep. India	takes 51 women (20,1%). The average age was 44(5,422) 177 patients (20,1%) nad taken previous treatments for alogecia. We evaluated efficacy (as judged by Hamil-
Trice also Conveils a member of Works Realismy of Cashedic Surgery (WADCS	ton scale grading, covered area percent, surgeon, and patient's subjective evaluation and safety (as lodged by adverse events). The overall scale surface restored with arti-
Dometology and Veneracingy, National Headbal, Hereil, Vistram	and safety (as judged by adverse events). The overall scalp surface restored with arti- ficial hair (mm ² spaced) and pre-postoperative general customers' satisfaction
Department Surgary, University of Modera Antikal School, Modera, Selv	by Hamilton scale grading) are reported, showing a significant (FILSEN) subjective and objective improvement of the self-image. Twenty-two cases (0.75%) declared
Department of Demotology and favor unings, Milliony Malkal Academy,	minor side effects generally counteracted by topical or short course systemic antibi-
Mgen, Setia	ofic and anti-inflammatory treatment. The average number of implanted fibers was
Department of Nuclear Physics, Sub-Nacioar rel Radiation, G. Marcuel University, Ramo,	2,295 (SD 2,805; SE 200.9) ranging from 300 to 16,000. The average duration of pain
*	and tenderness at the implant area was 2.2 days (SD 4.09); SE 0.2933 ranging from
Companyation	1 to 20 days. A diagrammatic comparison of the Hamilton scale grading before and
General Parameter, Congentineent of Nuclear	after the trial showed a dramatic improvement with the majority of the patients being
Parce, un nuclear and subation & Manual University, Rome, Edg. Book massives for with granizon	in Hamilton grade II after implantation.
	KEYWORDS
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Statistics data source 2018





"The implant of Biofibre® can be considered an **efficient** surgical technique that allows **immediate aesthetic results**.....In our study, hair implant technique demonstrated to be **safe** and **well tolerated** by patients"

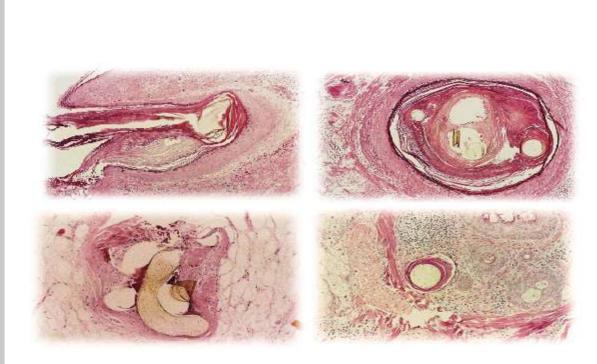
*Source Prof A. Rateb et al , OAMJM, s.i. Gloabal Dermatology, Jan 2018

HISTOLOGICAL STUDIES

BIOFIBRE® 4.0 HAIR IMPLANT

Within the pseudo-infundibula, a compact **keratin layer** adheres closely to the fibers.

In the middle and deep reticular dermis, the fibers are surrounded by a small amount of focally granulomatous chronic infiltrate. In the deepest dermis and hypodermis, the fibers are surrounded by **fibroplasia** and no **inflammatory infiltrate** is noted.



Courtesy of Dr. Pier Alessandro Fanti, Laboratory of Dermatologic Histopathology, University of Bologna, Italy





Qualified Clinic



• Medical operators performing the **Biofibre Hair Implant** technique have to be previously **trained and qualified**.

• A diploma and a company plaque will be issued to qualified clinics as quality hallmark

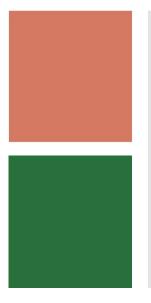
Medicap® provides Biofibre Qualified Clinics with the following support:



- Advertisement campaign through our international network
- forward patients to the closest qualified clinic;
- continuous technical and scientific assistance;
- cooperation in conference, workshops and events related to Biofibre
- immediate **updating** on any hair implant innovation.



BIOFIBRE PROMOTION



We provide our partners with complete **technical**, **scientific**, **promotional material** about Biofibre Hair Implant as:

videos, posters, roll-up, pre- and postpictures, leflets, etc. to be used in their clinic and on their web site.

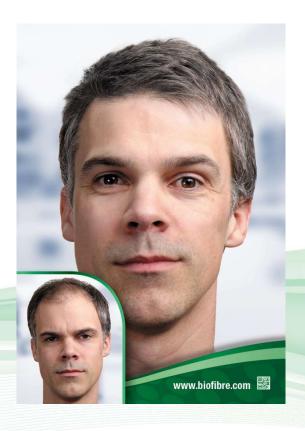




AND WE BET YOU CANNOT TELL THE DIFFERENCE between **BIOFIBRE** and real hair ...















CONCLUSIONS



- Safe and reversible procedure
- Not traumatic technique
- Immediate aesthetic result
- Large quantity of hair in short time

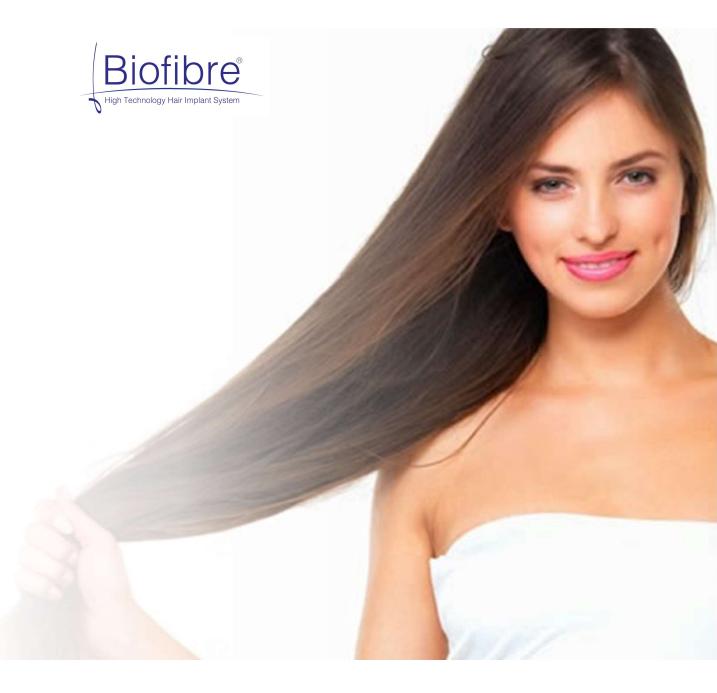
Can be used:

- as a single technique
- or in combination with other hair restoration techniques

NEW AUTOMATIC BIOFIBRE® 4,0 HAIR IMPLANT

«Nowadays, advancements in technology allow more inorganic materials to be used in dermatology and plastic surgery with **tested successful results** and a low complication rate».

Prof. N. Serdev, et al: *Journal of Biological Regulators & Homeostatic Agents*, 2015 Jan-Mar; 29 (1 Suppl):103-9.





AUTOMATIC BIOFIBRE 4.0 ARTIFICIAL HAIR IMPLANT AN INNOVATIVE TECHNIQUE