



NEW BIOFIBRE 4.0

HAIR IMPLANT

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 world-leading 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
- 1983: FDA restriction caused by:
  - use of **unsuitable fibers** (cut human hair, polyacrylic, modacrylic, polycarbonate, polyester, etc.);
  - technique often performed from **Non-medical 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

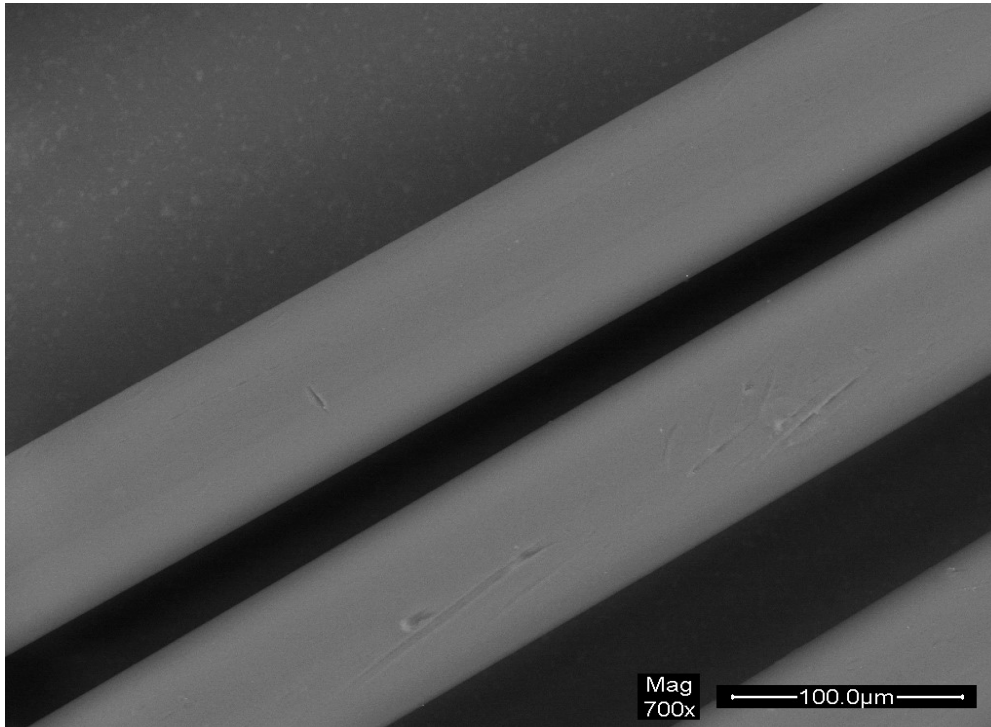
Scientific Research, in cooperation with eminent international professionals from high prestigious universities of dermatology, plastic surgery and biotechnologies, enable company Medicap to design **Biofibre® 4.0** and put that on the market in **2020**





## 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<sup>®</sup>

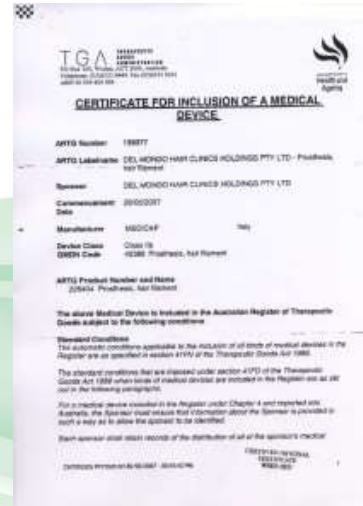
## *FEATURES*

- 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.**





# 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
<b>Product</b>	<p>Larger color range (14 colors, almost double than Nido)</p> <p>Finest and most refined hair</p> <p>Wide range of hair types (in terms of length, shape and density)</p>	<p>Less extensive color range (only 8 colors)</p> <p>Hair less natural</p> <p>Range limited to just short and medium smooth hair</p>
<b>Technique</b>	Possibility of using multiple systems (manual and automatic)	Only manual system available
<b>Results</b>	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%

## Artificial Hair Market's Players

### The 2 players in comparison

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 **+ 30%** over the last year



## BIOFIBRE® IN THE WORLD

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



Algerie	Greece	Morocco	Switzerland
Australia	Guatemala	Norway	Thailand
Austria	Honduras	Panama	The Netherland
Bahrain	Hungary	Peru	Tunisia
Belgium	India	Philippines	UAE
Bulgaria	Indonesia	Poland	Uganda
Cyprus	Iran	Portugal	Ukraine
Colombia	Israel	ROC	United Kingdom
Cameroon	Italy	Romania	Uzbekistan
Cote D'Yvoire	Japan	Russia	Vietnam
Czech Republic	Jordan	Saudi Arabia	
Ecuador	Kazakhstan	Serbia	
Egypt	Kuwait	South Africa	
Finland	Lebanon	Spain	
France	Malaysia	Sri Lanka	
Germany	Mexico	Sweden	

## 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
<b>Fue/Fut</b>	Use of own hair	<ul style="list-style-type: none"><li>• Improved compared to the past</li><li>• It often offers good results</li><li>• No need for after-care</li><li>• The hair grows back</li></ul>	<ul style="list-style-type: none"><li>• Needs sufficient donor area</li><li>• High invasiveness</li><li>• Esthetic result extended over time</li><li>• Result not always satisfactory</li></ul>
<b>Implant</b>	Use of artificial hair	<ul style="list-style-type: none"><li>• Reduced invasiveness (simple and pain free)</li><li>• Immediate aesthetic result</li><li>• The hair does not age</li><li>• Reversible technique</li></ul>	<ul style="list-style-type: none"><li>• Not definitive technique</li><li>• Requires periodic adjustments and checks</li><li>• It requires good personal hygiene</li><li>• The hair does not grow back</li></ul>



**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 two different systems:
  - **Manual instrument** (so-called Implanter)
  - **Automatic machine**

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

**Careful monitoring** is planned **for 30 days** post-implantation with specific after care.

After 5 weeks 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

**Biofibre®**  
High Technology Hair Implant System

**BIOFIBRE®**  
in the world



Biofibre  
Hair Implant®  
is exclusively performed in  
clinics specialized in  
cosmetology, plastic surgery  
and aesthetic medicine  
to ensure optimal  
results to patients  
worldwide

biofibre® - 0800 11 11 11

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**biofibre**  
**AFTER CARE**  
SOME EASY suggestions

by **BIOFIBRE®**





# BIOFIBRE 4.0<sup>®</sup>

## 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 **ready-to-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 anti-sebum spray to prevent the formation of sebum plugs



# BIOFIBRE 4.0<sup>®</sup> *HAIR CARE SET*

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**BIOFIBRE SeboCare** – an anti-sebum spray to prevent the formation of sebum plugs



## **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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## Diapositiva 22

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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**

**REVERSIBLE  
knot**

# BIOFIBRE® HAIR IMPLANT Publications

More than **230 lectures**  
and **articles**  
about **Biofibre® Hair  
Implant System**  
technique have been  
presented worldwide

Received: 3 January 2019 | Revised: 14 March 2019 | Accepted: 3 June 2019  
DOI: 10.1111/dth.12985

THE THERAPEUTIC HOTLINE: SHORT PAPER

DERMATOLOGIC  
THERAPY WILEY

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

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### Abstract

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 baldness and for the treatment of various causes of alopecia such as androgenetic alopecia, burns, and scars. According to our experience, this technique gives immediate and visible results without scarring or hospitalization and the aesthetic results are very encouraging for both male and female patients with a rapid recovery of self-esteem and psychological well-being.

### KEYWORDS

alopecia, biofibre, hair implant

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 etiologies. With regard to the androgenetic form, the most common type of progressive hair loss disorder, nowadays, there are many nonsurgical treatments available.

The results of a recent network meta-analysis (Gupta et al., 2018) indicate the emergence of new nonhormonal hair loss therapies. Nevertheless, this review emphasizes that the quality of evidence supporting these new therapies is generally low because there are no high-quality randomized controlled trials. On the other hand, when nonsurgical therapies are not possible or fail, surgery becomes the solution.

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

extraction [FUE]). The FUE consists in collecting the graft by using various types of punches to remove the follicular units from the donor region one at a time; this technique can be combined with other procedures, such as scalp micropigmentation or injections of plasma full of growth factors, to reduce the number of techniques and total costs of the hair restoration process. Although FUE procedures are increasingly 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, Tuknayak, & Tham, 2017).

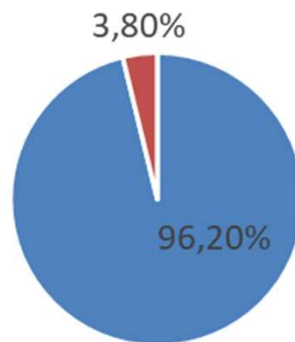
Another new surgical technique includes microneedling, an invasive dermatological procedure consisting in thin needles rolling over the skin to puncture the stratum corneum in order to induce collagen formation (Fertig, Garmat, Cervantes, & Tosti, 2018).

Unfortunately, a perfect hair transplant surgery does not exist today and as with all techniques, there are controversies regarding



# Statistics data source 2018

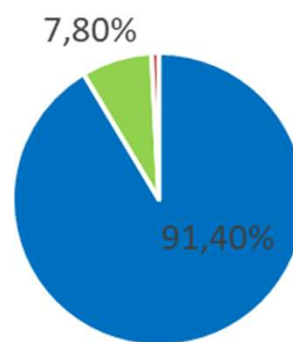
## Satisfaction



■ Satisfied ■ No satisfied

**96% of patients said they were satisfied**

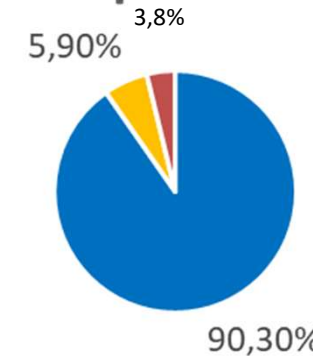
## Loss



■ <10% ■ 10-15% ■ 15-20%

**Over 90% of patients suffer an annual hair loss of less than 10%**

## Complications



■ no problem ■ Mild infection  
■ Inflammation

**9.7% of patients suffered for a mild complication - inflammation/infection resolved on average in 15 days leading positive outcomes at 97.9% of cases and in 2.1% may be solved through hair removal**

*"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

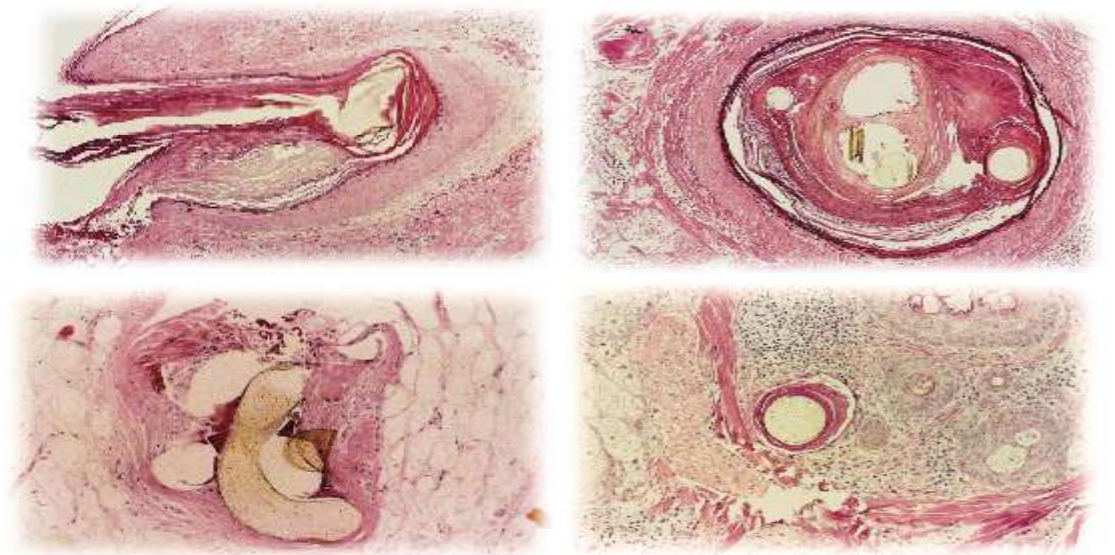


# HISTOLOGICAL STUDIES

## 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



- 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 post-pictures, leflets, etc.** to be used in their clinic and on their web site.



**BIOFIBRE®**  
HIGH TECHNOLOGY HAIR IMPLANT SYSTEM

Immediate and Natural Aesthetic Result

Large Quantity of Hair in very short time

Soft and Safe outpatient procedure

It allows an Active, Sporty Lifestyle

Optimal Integration with other techniques

**BIOFIBRE® in the world**

Biofibre Hair Implant® is exclusively performed in specialised clinics to always ensure excellent results

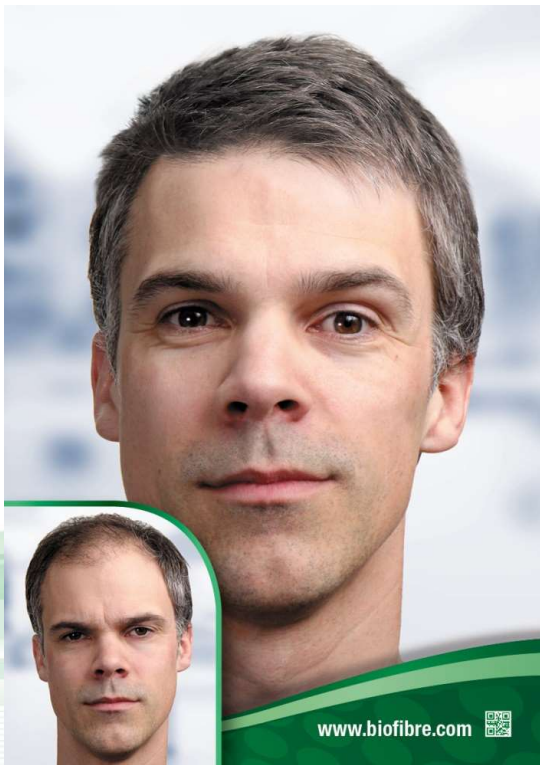
The poster features a green background with circular patterns. It includes several circular images of people with hair implants, arranged in a vertical sequence. The text is in white and green, providing key benefits and information about the system.



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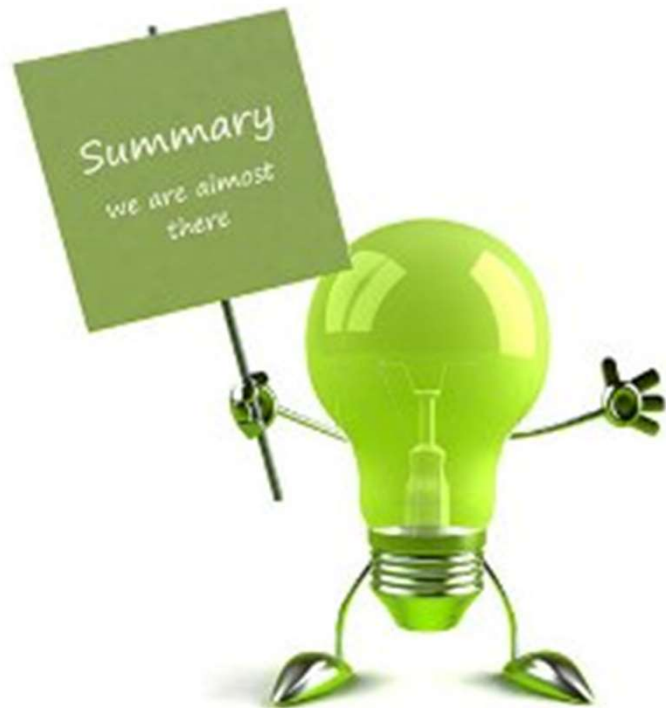
**AND WE BET  
YOU CANNOT TELL THE DIFFERENCE**  
between **BIOFIBRE** and real hair ...

Biofibre®  
High Technology Hair Implant System





# 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**





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## NEW AUTOMATIC BIOFIBRE® 4,0 HAIR IMPLANT

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«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**

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*Thank  
you*