PART 1 – SSCP INTENDED FOR HEALTHCARE PROFESSIONALS

This summary of safety and clinical performance (SSCP) is intended to provide public access to an up-to-date summary of the main safety aspects and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use, the main document to ensure the safe use of the device, nor does it intend to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for healthcare professionals. Part 2 is dedicated to the patient summary.

1 DEVICE IDENTIFICATION AND GENERAL INFORMATION

Table1 Device identification and general information

1.1. Trade name(s) of the device	Biofibre 4.0 / Medicap High Density 4.0
1.2. Name and address of the manufacturer	Medicap Ltd. Via A. LINCOLN, 15 - 41012 CARPI (MO) - ITALY
1.3. Unique Manufacturer Registration Number (SRN)	IT-MF-000007995
1.4. Basic UDI-DI	0805715896TF05HF
1.5. Nomenclature of EMDN medical devices - description	EMDN P9099 - DEVICES FOR IMPLANTS PROSTHETICS AND OSTEOSYNTHESIS
1.6. Device class	IIB
1.7. Year in which the first certificate (EC) relating to the device was issued	Sept. 2020 in accordance with the Medical Devices Directive 93/42/EEC Dec. 2022 in accordance with the Medical Devices Regulation (EU) 2017/745
1.8. Authorized representative if applicable; name and SRN	Not applicable
1.9. Name of the NO / Unique identification number of the AN	ON0373 - Istituto Superiore di Sanità

2 INTENDED USE OF THE DEVICE

Table2 Device identification and general information

2.1. Intended purpose	Biofibre 4.0 and Medicap High Density 4.0 are long-term implantable medical devices indicated to temporarily cover thinning and/or bald areas of the scalp
2.2. Target indication(s) and population(s)	Biofibre 4.0 and Medicap High Density 4.0 are intended to be implanted exclusively on adult male or female patients. Medical devices can satisfy any geographic taxonomy.
2.3. Contraindications and/or limitations	The devices are not indicated in case of reversible alopecia and for thickening of eyebrows, mustaches, beard, chest and pubis.

3 DEVICE DESCRIPTION

3.1 DEVICE DESCRIPTION

Biofibre 4.0 e Medicap High Density 4.0 are:

- implantable artificial hair;
- biocompatible;
- disposable;
- manufactured in polybutylene terephthalate;
- steam sterilized.

Biofibre 4.0 and Medicap High Density 4.0 exist in different lengths, colors, and shapes.

3.2 BIOLOGICAL COMPOSITION

Substance
PBT
PELD
Yellow pigment 180
Iron oxide
Carbone black

3.3 REFERENCE TO PREVIOUS GENERATIONS AND VARIANTS

In May 1996, Medicap obtained the first CE Certification for Biofibre.

The first generation of Biofibre artificial hair by Medicap S.r.l is produced in Polyamide 6, as well as Medicap High Density variant certified since 2005. Medicap High Density is a variant made to obtain 3 artificial hairs with a single implanted root (node).

Thanks to the development of medical grade polymers in recent years, Biofibre 4.0 & Medicap High Density 4.0, in Polybutylene terephthalate (PBT) are the new generation of artificial hair, similar to polyamide hair and created to improve its biocompatibility.

The identification of this new variant can be traced with the devices' reference and with the assignement of the trade name Biofibre 4.0 & Medicap High Density 4.0.

3.4 DESCRIPTION OF ANY ACCESSORIES INTENDED TO BE USED IN CONJUNCTION WITH THE DEVICE

Biofibre 4.0 and Medicap High Density 4.0 must be implanted using implantation tools manufactured by Medicap S.r.l:

- **adjustable implanter,** titanium or peek, CE medical device, assembled with **the sterile**, medical device CE0373, **needle for adjustable implanter**, made of steel, or;
- **disposable implanter,** CE0373 medical device.

To facilitate the implantation technique, it is also possible to use the active CE-marked medical device Automatic Biofibre Hair Device connected to the disposable implanter or to the Adjustable Implanter and Needle for Adjustable Implanter devices.

3.5 DESCRIPTION OF ANY OTHER DEVICES AND PRODUCTS INTENDED TO BE USED IN COMBINATION WITH THE DEVICE

Other devices and products intended for use in implantation sessions are those indicated in the implant protocol given to the user during implantation training. These are the materials that allow disinfection of the implant area and local anesthesia under hygienic conditions suitable for implantation (disinfectants, sterile gauze, anesthesia material, steel scissors, wide-toothed steel comb, glass or steel trays).

4 RISKS AND WARNINGS

4.1 WARNINGS AND PRECAUTIONS

The following paragraph contains all the general warnings regarding the devices, the specific warnings concerning the use of the device are available in the instructions for use accessible at the following link: https://www.biofibre.com/july_2021_ifu_medici/.

4.1.1 GENERAL WARNINGS

- Disposable device, do not reuse;
- Do not resterilize;
- Keep away from light;
- Keep dry;
- Do not use if the sterile barrier system of the product or its packaging are damaged and consult the instructions for use;
- Carefully read the instructions for use https://www.biofibre.com/july_2021_ifu_pazienti/
- The devices are not indicated in case of reversible, autoimmune alopecia and for thickening of eyebrows, mustaches, beard, chest and pubis;
- The device can only be used by doctors authorized to implant by Medicap S.r.l or by tutors authorized by Medicap S.r.l The implant is to be carried out in an outpatient setting, after local anesthesia. Carefully follow the implantation protocol;
- Patients eligible for treatment should have good overall health, a healthy scalp, and a good degree of cleanliness.

Patient must undergo all the tests prescribed by the doctor to check his health condition.
Implant center must inform the patient about the characteristics and limitations of the Biofibre® 4.0 & Medicap® High Density 4.0 implant. The patient must sign an informed consent;

- Do not use the device on patients at risk (see list in the instructions for use);
- Do not use substances that could compromise the success of the implant (see list in the instructions for use);
- Check the patient's compatibility with the device (see the protocol in the instructions for use).

4.1.2 RESIDUAL RISK

After the implantation of Biofibre® 4.0 or Medicap® High Density 4.0, some phenomena may occur in the scalp. These are infectious phenomena and inflammatory phenomena. If they are treated with adequate drug therapy, they normally olve in about ten days without sequelae. In the absence of a response to the therapeutic treatments performed, it will be essential to remove the fibers that cause problems. The total extraction of fibers, accompanied by an adequate pharmacological treatment, determines a *restitutio ad integrum* of the scalp.

Attention! If the above phenomena are not treated quickly and adequately, complications of a certain severity (pyoderma and granulomatous nodules) may arise. Untreated infections can cause defluvium of the patient's natural hair and/or fibers and can cause skin scarring around the implanted fibers.

In addition, the use of prohibited substances or treatments with excessive heat can cause changes to the appearance of Biofibre® & Medicap® High Density (curl, dryness, breakage).

4.2 OTHER RELEVANT ASPECTS OF SAFETY, INCLUDING A SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION (FSCA INCLUDING FSN) IF APPLICABLE

No field safety corrective action has been published.

5 SUMMARY OF CLINICAL EVALUATION AND POST-MARKETING CLINICAL FOLLOW-UP (PMCF)

5.1 SUMMARY OF CLINICAL DATA REGARDING EQUIVALENT DEVICE

In 2020, conformity has been initially assessed and approved by the notified body based on equivalence with:

- Biofibre & Medicap High Density, CE0373 in polyamide produced by Medicap S.r.l (UDI-DI base 0805715896TF01HF)
- Nido Hair, CE0373 in PBT produced by Nido L.t.d.

Between 2020 and 2022, Medicap collected clinical data on Biofibre 4.0 that confirm the effectiveness and safety of the device.

Published clinical data on the similar devices are summarized in § 5.1.1 while those relating to the Biofibre 4.0 device are summarized in § 5.1.2.

5.1.1 SUMMARY OF CLINICAL DATA RELATED TO SIMILAR DEVICES

5.1.1.1 DATA ON SAFETY AND CLINICAL EFFICACY

Table 1 Data on the safety and clinical efficacy of similar devices 1994-2003-2007

Identity (publication)	**A. d'Ugo – 1994**	**B. Palmieri – 2003**	**M. Santiago – 2007**
Device identity	Biofibre CE0373	Biofibre CE0373	Biofibre CE0373
Intended use	Used for implantation on the scalp to replace natural hair	Used for implantation on the scalp to replace natural hair	Used as an alternative to the use of wigs
Study Objective	To evaluate the efficacy of Biofibre on patients suffering from androgenetic alopecia.	To evaluate the safety and efficacy of Biofibre® in patients with androgenetic alopecia.	Evaluating the usefulness of artificial hair for the treatment of scalp scars
Study design	Open monocenter clinical trial 3 anni di follow-up	Open multicenter study Surgical procedures performed by 5 different doctors.	Open multicenter retrospective study Follow-up da 4 a 7 anni
Primary and secondary endpoint	**EFFECTIVENESS EVALUATION**	**EFFECTIVENESS EVALUATION** **SAFETY ASSESSMENT**	**EVALUATION OF THE EFFECTS OF THE IMPLANT**
Inclusion/exclusion criteria for subject selection	Not specified	**INCLUSION CRITERIA** • age from 30 to 50 years • dermatologically confirmed diagnosis of androgenetic alopecia and evaluation with Hamilton's syndrome • good overall health without scalp pathology • patients willing to return for follow-up • informed consent **OPT-OUT CRITERIA** • psychological disorders • dermatitis or dermatosis of the scalp • metabolic disorders, immunodeficiencies, allergies • alopecia for which medical therapy is possible • hypersensitivity to device substances	Not specified

Identity (publication)	A. d'Ugo – 1994	B. Palmieri – 2003	M. Santiago – 2007
		• patients unwilling to return for follow-up or with reduced treatment compliance • work where hygiene cannot be guaranteed or maintained • Sebum output: >35% • Humidity test: <2 and >7 (scale 0-10) • Test del pH: <4 e >5,5 • Thermal output: >32 °C **EXCLUSION CRITERIA** • patient decision, even without justification • Investigator's decision, for patient safety non-compliance with post-operative care recommendations	
Number of subjects enrolled	503 patients enrolled 16 patients excluded after implantation test	212 patients enrolled 16 patients were excluded from the study for the following reasons: • n 5 patients undergoing trial implantation without further surgery • n 6 patients lost at follow-up • n 4 Patient decision n 1 hypersensitivity reaction after implant test	48 patients enrolled (data lost for 4 patients)
Study population	460 men - 27 women Age group between 30 and 60 years	191 men - 5 women Age group between 30 and 50 years	36 men - 8 women Age group between 17 and 64 years Total of 54 scalp scars treated: • 30 scars from surgery • 24 scars from other causes Position of the scar: frontal (12), parietal (24) and occipital (18)

Identity (publication)	**A. d'Ugo – 1994**	**B. Palmieri – 2003**	**M. Santiago – 2007**
Summary of study methods	Implant test Surgical procedures – Average of3,000 implanted units in 5/6 implantation sessions • < 2,000 (42.6%) • 2.001– 4.000 (46,1%) • 4.001 – 6000 (7,8%) • >6.000 (3,5%) Follow-up : • Monthly (90.5% of patients) • Every 30-120 days (5.2%) • > 120 days (4.3%)	Collection of demographic and medical information Preliminary dermatological check-up to confirm clinical diagnosis and exclusion of skin diseases. **Hypersensitivity test** at the test implant of 100 fibers. Repeated surgical procedures until a satisfactory aesthetic result is obtained (average number of fibers implanted 3,222) Operational information collected at each intervention. Postoperative evaluation criteria included efficacy (judged by the Hamilton scale, percentage of area covered, surgeon, patient and photographic assessment) and safety (judged by possible adverse events). The clinical evaluation was repeated monthly for the first year and bimonthly for the second year of follow-up. Clinical evaluation was also performed in each case of adverse events. **Histological assessments** were performed at 3, 6, 12 and 24 months of follow-up in 12 volunteer patients. All patients were instructed to seek medical attention for follow-up with scheduled periods for follow-up checks and scalp hygiene.	Choice of subjects and data collection. Implant test procedure: 2 test sessions of 100 fibers performed at intervals of 30-40 days. Planting procedures: • from 2 to 9 sessions – average 4.3; • 200 to 5000 fibers implanted – average 1580 Follow up every 30 – 90 days Maintenance session 6 – 12 months
Summary of results	**EFFECTIVENESS** Patient satisfaction: 93.2% <u>Fiber loss / year</u> • < 10%: 91.4% • 20%: 7,8% • 30%: 0,8%	**EFFECTIVENESS** <u>Classification improvement according to Hamilton scale</u>: before 4.52 - after: 2.33 Average area covered rate: before: 61.5% - after: 85.3% Average patient rating: 2.54 on a 3-degree scale Average surgeon rating: 2.53 on a 3-degree scale	**EFFECTIVENESS** <u>Fiber loss / year</u> • frontal-parietal region 18% • Occipital region 23% • spontaneous high nr.2

Identity (publication)	A. d'Ugo – 1994	B. Palmieri – 2003	M. Santiago – 2007
	CASE I CLINICI No pathology 79.8% Septic disorders 3.8% Chemical diseases 12.3% Fiber curl and 2.6% Other problems 1.5% **RESOLUTION** Local steroids: 61.2% Local antibiotics: 15.3% Local and systemic antibiotics: 7.1% Removal of fibers without scars: 2.1%.	Average photo rating: 2.34 on a scale of 3 degrees Fibers loss/year: 10.61% **CASE I CLINICI** Accident-free 86.23% Insignificant adverse events 1.53% (fiber curled) Mild adverse events 11.22% (mild infections/inflammatory reactions), *Note: Poor scalp hygiene, excessive sweating, dirty headgear, secondary seborrhea, inadequate skin care have been identified as the main provoking factors. These reactions were all local and were completely healed with an average healing time of 10.8 days.* Moderate adverse events 1.02%: (pustular inflammatory skin infection) with fiber removal when abscess or inflammation has not been controlled by topical treatments. A microbiological buffer culture revealed Staphylococcus aureus infection. Systemic antibiotic therapy was added to local treatment to relieve symptoms of infection. **RESOLUTION** No residual or permanent healing damage was observed in follow-up. The fibers proved to be strong enough to stay in place for a long time. **HISTOLOGY**	Level of satisfaction: • Excellent 25% • Good 63.6% • poor 9.1% • Negative 2.3% **SAFETY** Serious adverse events 0%. No adverse events 90.7% Inflammation and infection 1.9% - resistant to standard topical and systemic steroids and antibiotic treatments - fiber removal (the skin has returned to its original appearance both in color and texture after 30-60 days). Mild non-serious adverse events 7.4%: superficial and mild inflammations-infections successfully treated with topical cortisone and local/systemic antibiotics. The skin has always returned to its initial state.

Identity (publication)	**A. d'Ugo – 1994**	**B. Palmieri – 2003**	**M. Santiago – 2007**
		Histological findings show a progressive decrease in macrophage cells around the fibers up to 12 months after surgery. These cells subsequently remained unchanged, while fibroblasts showed a progressive increase. Three months after surgery, there is a fibrotic reaction that helps keep the fibers in place. The fall rate is likely related to the degree of individual fibrosis. In accordance with the study protocol, in no case was there a replacement of the fiber.	
Possible limitations of the study	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
Any defect in the device and any replacement of the device related to safety and/or performance during the study.	NOT APPLICABLE	NOT APPLICABLE	Maintenance session 6 – 12 months

Table 2 Data on the safety and clinical efficacy of similar devices 2008-2015-2019

Identity (publication)	**M. Agrawal – 2008**	**Serdev N. – 2015**	**Satolli - 2019**
Device identity	Biofibre CE0373	Biofibre CE0373	Biofibre CE0373
Intended use	Method for hair restoration in case of androgenetic alopecia	Devices to be implanted under local anesthesia	Biofibre artificial hair is safe, well accepted by the human body, and completely removable in case of need. These fibers are produced from medical-grade non-absorbable polymers suitable for human use.
Objective of the study	To establish the safety and efficacy of the implantation of co-polyamide artificial fibers	Report the efficacy and safety of implantable hair fibers	The article is a collection and update of several studies published in Scientific review and shared in international congresses.
Study design	Open monocenter clinical trial Follow-up 3 anni	Open monocenter clinical trial Follow-up 3 anni	Filling of single-center open clinical trials
Primary and secondary endpoint	**EVALUATION OF IMPLANT EFFECTS**	**EFFICACY AND SAFETY EVALUATION**	**REPORTING EFFICACY AND SAFETY**
Inclusion/exclusion criteria for subject selection	**Exclusion criteria:** Scalp with seborrhea, infection, dermatological disease (psoriasis, eczematous dermatitis) Immunocompromised subject	**Inclusion criteria** • good health, • healthy scalp, • diligent people in cleaning the scalp. **Exclusion criteria** • Patients with atopic dermatitis, • lupus, • seborrheic dermatitis, • skin diseases.	**Inclusion criteria** • Ages 20-70 • Diagnosis of androgenetic alopecia (dermatological evaluation and evaluation according to the Hamilton scale) or other type of alopecia • Patients willing to return for follow-up • Informed consent

Identity (publication)	M. Agrawal – 2008	Serdev N. – 2015	Satolli - 2019
			Exclusion criteria • Patients diagnosed with psychological or metabolic disorders, immunodeficiency, or allergies • Dermatitis or dermatosis of the scalp • Alopecia for which medical therapy is available • Known hypersensitivity to substances in the device or patients who have experienced inflammation or skin reactions after compatibility testing • Work where hygiene cannot be guaranteed or maintained
Number of subjects enrolled	10 patients	133 patients	The article analyzes the results of Biofiber implantation in 1,518 patients included in different clinical trials (D'Ugo, 1995; Gonzalez, 2002; Palmieri, Griselli, D'ugo, Palmieri, & Salti, 2000; Rateb et al., 2017; Santiago et al., 2007; Serdev et al., 2015; Zhilina, Igytyan, & Antonova, 2000)
Study population	10 people who have failed previous conventional therapies and all with androgenetic alopecia 7 men – 3 women Age range between 27 and 43	98 men - 38 women The most represented group was made up of men aged between 30 and 60	1,104 men – 414 women
Summary of study methods	Selection of subjects	Selection of patients	Selection of patients

Identity (publication)	**M. Agrawal – 2008**	**Serdev N. – 2015**	**Satolli - 2019**
	Implant test (100 fibers) Planting sessions: up to 500 fibers every 4-6 weeks followed by a 5-day course of oral antibiotics; other implantation procedures up to 4,000 fibers (average 1000) Follow-up every 2 months for a minimum of 3 years	Information and education on the correct after-therapy and periodic dermatological check-up Implantation procedure (up to 6,000 fibers, average of 5-6 implantation sessions in three months) Clinical evaluation after 1 month, 4 months and every 2 months after implantation.	Compatibility test with 100 artificial hairs Further implantation sessions (if no reaction) Media of 2,300 implanted fibers. Post-implantation treatment: • Use of systemic/local antibiotics for 10 days • local disinfectant sprays for 3-4 weeks • possibly antihistamine therapy to avoid itching • In long implantation sessions, the use of local or systemic anti-inflammatory therapies has been suggested. Biopsies and histological examinations on 13 patients Scalp investigation with ultrasound at 21-25 MHz to analyze the effect of hair implantation on the subgaleal layer of the scalp in some patients
Summary of results	**EFFECTIVENESS** Fiber loss/year < 15-20% Insignificant drop of fibers in the first 3-6 months after each implantation session. Subsequently, the fall continued at the rate of about 2% per month. **SAFETY** 1 local foreign body reaction after implantation test: erythema, crusting, nodule formation, pain and itching within 3 weeks of test implantation.	**EFFECTIVENESS** Fiber loss/year • < 10% over 91.4% • 15% for 7.8% • 20% to 0.8% Satisfaction • 93.2% satisfied • 3.8% not satisfied	**EFFECTIVENESS** Satisfaction 95% **SAFETY** Inflammatory/infectious complications 13.04% Unresolved, fiber extraction required 2.10% Resolved with local or systemic therapy 10.94% Side effects: fiber curl 1.30%

Identity (publication)	M. Agrawal – 2008	Serdev N. – 2015	Satolli - 2019
	Reaction resolved by fiber extraction and short course of antiallergics and antibiotics Fibers with pustules at the point of entry can be easily pulled out by grasping the fiber as close as possible to the scalp with tweezers by applying a light but steady zigzag pull in the direction of the initial implant. However, the few fibers incorporated into the granulomatous nodules had to be surgically explanted under local anesthesia by complete excision of the nodule followed by suture. For this patient, further implantation sessions were suspended. 3 mild recurrent folliculitis around the entry point of the implanted fibers (<10 pustules at the same time), resolved with topical antibiotics and antiseptic shampoos only. **Presence of sebum** plugs around the entry point of most of the implanted fibers after about 3 months in all subjects. Periodic extraction of the blackhead was necessary during the scheduled checks. **Small cavities** were also observed at the site of a few comedones in all subjects, mainly in the frontal and temporal areas. It has been observed that each pit closes and allows complete restoration of integrity within 3-6 months after the fall of the fibers. **Slight curls at the end of fibers** were observed in half of the patients, but moderate curl was only observed	**SAFETY** No pathology 90.3% Average infectious diseases 5.9% Inflammatory diseases 3.8% **Resolution** local systemic antibiotic and/or steroid therapy 97.9% (+ Local and systemic antibiotics and steroids for 7.1%) Removal of fibers without leaving scars 2.1%	Maximum average of side effects (year 1994) 20.8% Minimum average side effects (year 2018) 9.27% **RESOLUTION** Inflammatory/infectious complications resolved with local or systemic therapy 10.94% Unresolved, fiber extraction required 2.10% **Other** The ultrasound appearance and dermatoscopic appearance after 2 months from the implantation session show no signs of interaction or damage between the natural hair follicles and the implanted Biofiber® hair. Healing of the dermis and subcutaneous tissue shows no signs of inflammation. A hyperechoic thickening on the subgaleal space, compared to fresh implantation, indicates the fibrosis process that keeps the fibers implanted.

Identity (publication)	**M. Agrawal – 2008**	**Serdev N. – 2015**	**Satolli - 2019**
	in one patient who used hair dye to color his natural gray hair. 0 Serious complications		
Possible limitations of the study	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
Any defect in the device and any replacement of the device related to safety and/or performance during the study.	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

Table 3 Data on the safety and clinical efficacy of similar devices 2019 – 2005 (Nido)

Identity (publication)	**Loti – 2019**	**Sydney – 2005**
Device identity	Biofibre CE0373	Artificial hair Z-type Nest (PBT)
Intended use	To be implanted under local anesthesia using a standardized and minimally invasive technique followed by regular postoperative care	To be implanted in the galley
Objective of the study	Evaluation of efficacy (according to the evaluation of the Hamilton scale and according to a subjective evaluation of the percentage of coverage of the area by the surgeon and the patient) and evaluation of safety (according to the judgment of adverse events) Update Serdev N. – 2015 [8]	Not specified
Study design	Open monocenter clinical trial Follow-up 3 anni	OPEN MULTICENTER CLINICAL TRIAL
Primary and secondary endpoint	**EVALUATION OF EFFICACY AND SAFETY**	**EVALUATION OF EFFICACY AND SAFETY**
Inclusion/exclusion criteria for subject selection	**Inclusion criteria** • Age 20-70 years • Good overall health without other scalp pathologies, • Clinical diagnosis of androgenetic alopecia and classification with Hamilton score • Patients willing to return for follow-up • Signature of informed consent	Not specified

Identity (publication)	**Loti – 2019**	**Sydney – 2005**
	Exclusion criteria • Psychological disorders • Dermatitis or any dermatosis of the scalp • Chronic metabolic disorders, immunodeficiency, allergies • Patients unwilling to return for follow-up or with reduced treatment compliance • Work where hygiene cannot be guaranteed and maintained • Alopecia for which medical therapy is available	
Number of subjects enrolled	278 patients enrolled 253 completed the study	9,511 patients
Study population	202 men - 51 women average age 43 (± 4.29); male androgenetic alopecia, menopausal and chronic female alopecia 179 patients (70.1%) had previously received treatment for alopecia	Not declared
Summary of study methods	Patient selection Information and education on correct post-implantation therapy and periodic dermatological check-up Planting procedure (300 to 16,000 fibers, average 2,295) Clinical evaluation after 1 month, 4 months and every 4 months after implantation.	Not declared

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Identity (publication)	**Loti – 2019**	**Sydney – 2005**
Summary of results	**EFFECTIVENESS** Fiber loss/year • < 10% over 91.4% • 15% for 7.8% • 20% to 0.8% Effectiveness satisfaction (average on a three-grade scale for 3 centers): 2.54; 2.53 and 2.34) Satisfaction Overall psychological satisfaction 98.14% **SAFETY** No pathology 91.31% 22 Adverse events (8.69%) 3 insignificant adverse events: Curling (1.18%) 15 mild inflammation and infection (5.92%) 4 moderate adverse events (1.58%) **Resolution** 18 adverse events resolved with topical and systemic therapy: antibiotic and/or steroid 4 resolved by removing the fibers without leaving scars (1.58%)	**EFFECTIVENESS** Study of the fixation rate Average fixation rate after: • 6 months 93.2% • 12 months 89.8% • 16 months 86.3% • 24 months 82.2% **CLINICAL CASES** • 171 Mild side effects (1.80%) • 18 Moderate side effects (0.19) • 0 serious side effects

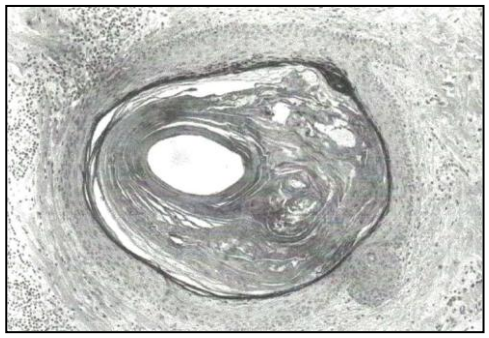
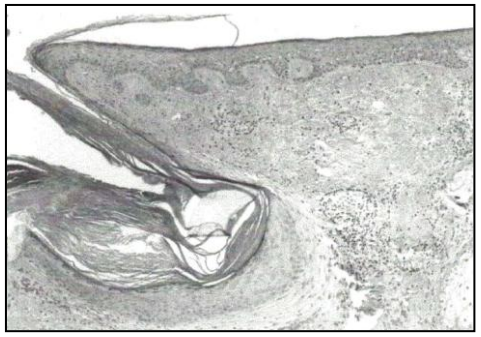
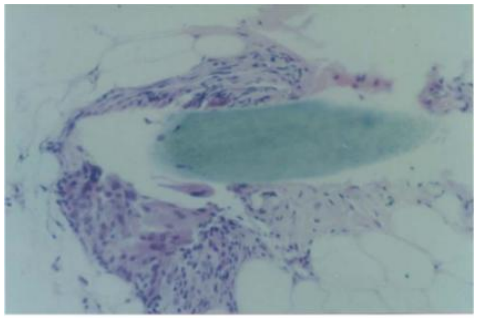
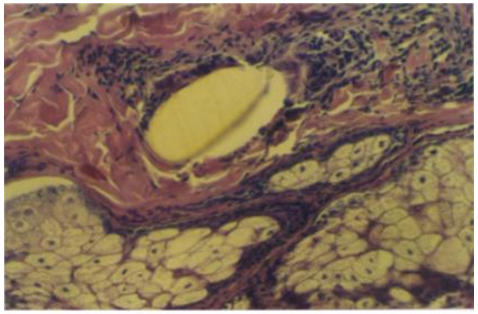
Identity (publication)	**Loti – 2019**	**Sydney – 2005**
Possible limitations of the study	NOT APPLICABLE	Not declared
Any defect in the device and any replacement of the device related to safety and/or performance during the study.	NOT APPLICABLE	Not declared

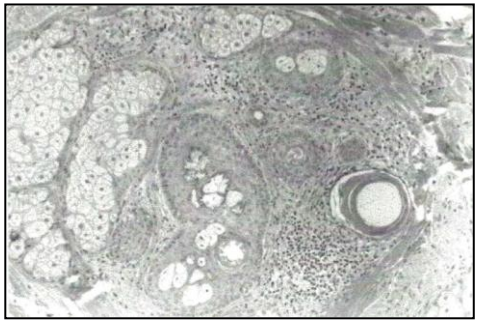
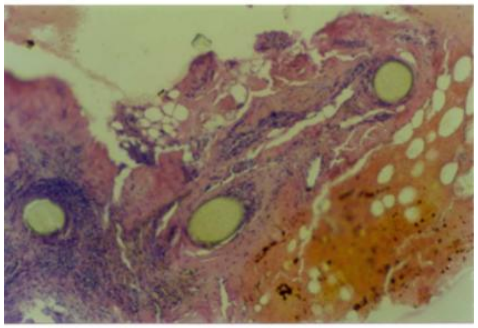
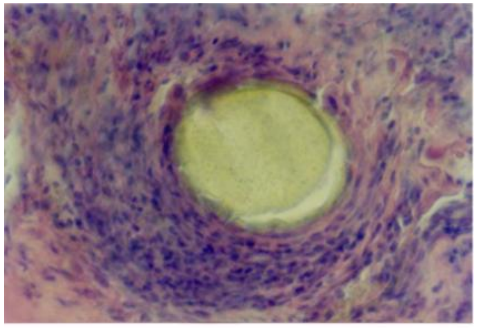
5.1.1.2 HISTOLOGICAL DATA

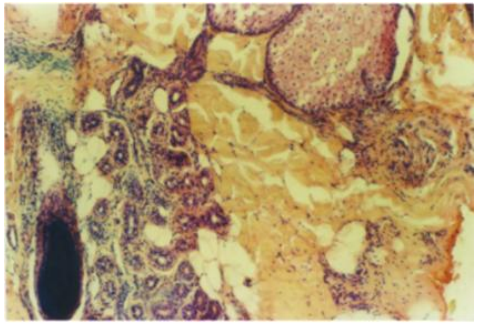
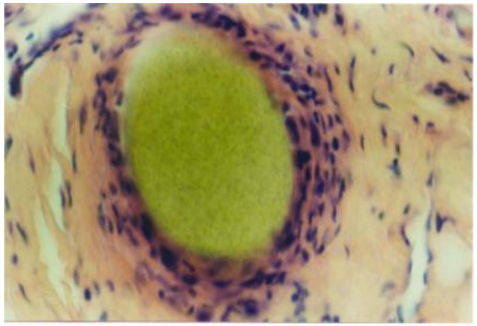
Tabella 4 Histological data similar devices 1995-2007-2015

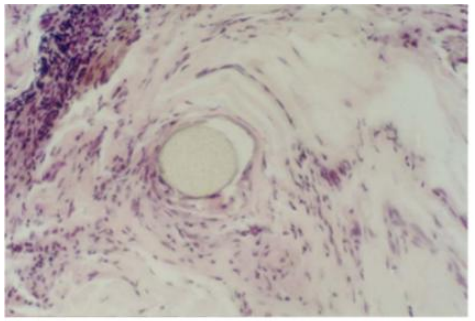
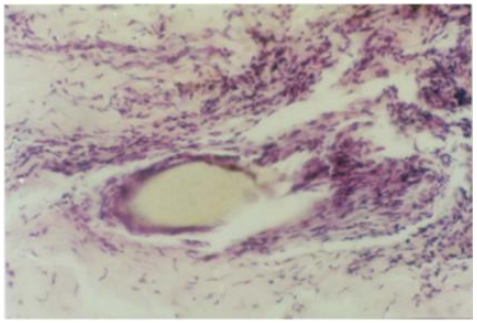
Identity (publication)	PA Fanti – 1995	M. Santiago – 2007	Serdev N. – 2015
Device identity	Colored PA6 fibers (Biofibre)	Biofibre CE0373	Biofibre CE0373
Intended use	Not specified	Complement for the treatment of both male and female pattern baldness	To be implanted under local anesthesia
Objective of the study	Histological study	Assess the duration of inflammatory reactions	Report the efficacy and safety of implantable hair fibers
Study design	Open monocenter clinical trial	Open monocentric explanatory clinical trial 5 anni di follow-up	Open monocenter clinical trial Follow-up 3 anni
Primary and secondary endpoint	**HISTOLOGICAL STUDY**	**EVALUATION OF THE EFFECTS OF THE IMPLANT**	**HISTOLOGICAL STUDY**
Inclusion/exclusion criteria for subject selection	Patients undergoing artificial hair implantation without complications	Not specified	**Inclusion criteria** • good health, • healthy scalp, • diligent people in cleaning the scalp. **Exclusion criteria** • Patients with atopic dermatitis, • lupus, • seborrheic dermatitis, • skin diseases.
Number of subjects enrolled	5 patients	4 patients	4 patients
Study population	Age group between 28 and 42	4 men –	Not specified

Identity (publication)	PA Fanti – 1995	M. Santiago – 2007	Serdev N. – 2015
		Age group between 23 and 50	
Summary of study methods	Implantation of artificial hair without clinically noticeable inflammatory complications Surgical procedures began 3 years before observation – about 1,800 to 8,000 fibers implanted. 2 biopsy samples of scalp around the implantation site, using 5 mm diameter punches: 1 cross-sectional sample and one vertical section sample Samples fixed in formalin, normally processed, including paraffin and colored with hematoxylin and eosin	Biopsies performed on the 4th, 8th, 30th day and 3rd, 6th, 12th, 18th month and 2nd, 3rd, 4th, 5th year after surgery	Patient selection Information and education on the correct after-therapy and periodic dermatological check-up Implantation procedure (up to 6,000 fibers, average of 5-6 implantation sessions in three months) Histological evaluation in 4 patients performed after 30 days and after 3.6, 12 and 24 months with punch of 5 mm in diameter.
Summary of results	Artificial hair is surrounded by hyperplastic epidermis at the level of the papillary layer of the dermis and in the highest part of the reticular dermis This proliferation of the epidermis forms a structure similar to the normal follicular infundibulum, known as pseudo-infundibulum. The section shows that these pseudo-infundibula merge with normal infundibula, from which they probably derive.	**EFFECTIVENESS** • 4-8 days - infiltration of lymphocytes and neutrophils around the fibers is observed; • 30 days: histoid cells and filaments of concentric fibroblasts appear; • 3 to 6 months: a network of fibrosis begins to surround the fiber; • 12-18 months: the fiber is surrounded by collagen and fibrotic tissue; • 2,3,4 and 5 years: persistence of fibrosis and collagen is observed. No dyes or pigments were detected outside the fibers at any of the stages mentioned above.	Giant histiocytes decrease until the 12th month The fibroblast increased inversely proportionally. Fibrosis increased until month 3 and remained unchanged until month 24. The artificial caps were surrounded by hyperplastic epidermis both at the level of the papillary layer of the dermis and in the highest part of the reticular dermis. This proliferation of the epidermis forms a structure similar to the normal follicular infundibulum, known as pseudo-infundibulum. In the deeper dermis and hypodermis, the fiber was surrounded by fibroplasia and no inflammatory infiltrate was noted. However, there are no obvious clinical signs of inflammation.

Identity (publication)	PA Fanti – 1995	M. Santiago – 2007	Serdev N. – 2015
	 Inside the pseudo-infundibula, the fibers are surrounded by a keratin layer that appears compact and well adherent to the fibers in the upper tracts and separated from them with a basket structure at the bottom.  Around the pseudo-infundibulum there is a small acute inflammatory infiltrate, see figure below.		A decrease in giant histiocytes and an increase in fibroblasts can be observed in histological features 30 days, 3 and 6 months after implantation.  30 DAYS  3 MONTHS

Identity (publication)	PA Fanti – 1995	M. Santiago – 2007	Serdev N. – 2015
	 The pseudo-infundibula reach the upper portions of the reticular dermis, where they gradually thin and disappear. Below the pseudo-infundibulum, the fibers are "bare" and are in direct contact with the collagens of the middle and deep reticular dermis. Here the fibers are surrounded by a small amount of chronic focal granulomatous infiltrate. In the deepest dermis and hypodermis, the fibers are surrounded by fibroplasia and no inflammatory infiltrate is noted. Although the changes vary depending on the anatomical structures in the fiber pathway, inflammatory phenomena are extremely limited and do not produce clinically evident signs of inflammation.		 6 MONTHS  6 MONTHS Around the fibers after 12 and 24 months there are some giant histiocyte cells. In the deeper dermis and hypodermis the fibers were surrounded by fibroplasia and no inflammatory infiltrate was noted.

Identity (publication)	PA Fanti – 1995	M. Santiago – 2007	Serdev N. – 2015
			 12 MONTHS  12 MONTHS

Identity (publication)	PA Fanti – 1995	M. Santiago – 2007	Serdev N. – 2015
			 24 MONTHS  24 MONTHS
Possible limitations of the study	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
Any defect in the device and any replacement of the device related to safety and/or performance during the study.	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

5.1.2 SUMMARY OF CLINICAL DATA RELATED TO BIOFIBRE 4.0

Tabella 5 Data on the safety and clinical efficacy Biofibre 4.0

Identity (publication)	**A. Rateb Said. 2022**	**G. Mokthar. 2023**
Device identity	Biofibre 4.0, CE0373	Biofibre 4.0 CE0373
Intended use	Biocompatible artificial hair implantation has multiple indications, including treatment of androgenetic alopecia, depletion of a donor area, scarring or scalp burns. It can be used alone or with other hair restoration techniques such as FUE and FUT. It can also be used in combination with other hair treatments such as PRP, mesotherapy. Laser etc. It is indicated for male and female patients to ensure immediate aesthetic results with psychological benefit and improvement of quality of life 18-26.	Cover thinning and/or bald areas of the scalp.
Objective of the study	Evaluate the efficacy, safety and performance of the Biofibre 4.0 medical device	Evaluate the efficacy of implantable biocompatible artificial hair in patients with androgenetic alopecia
Study design	Open multicenter study	Monocentric clinical study
Primary and secondary endpoint	**EVALUATION OF SAFETY AND PERFORMANCE**	**Evaluate effectiveness**
Inclusion/exclusion criteria for subject selection	Not specified	Inclusion criteria Clinical diagnosis of androgenetic alopecia and grading with Hamilton scoring Patient with AGA grade I-V of modified Hamilton-Norwood or grade I-II of Ludwig scale, Good general health without any other pathology of the scalp, Patients willing to return for follow up, Signed informed consent. Exclusion criteria Severe insulin dependent diabetes, Dermatitis or any dermatosis of the scalp, Other chronic metabolic and autoimmune diseases, Severe cardiovascular and kidney insufficiency, Cancer or chemotherapy or immunosuppressive drugs,

Identity (publication)	A. Rateb Said. 2022	G. Mokthar. 2023
		Psychiatric problems, trichotillomania, maniac depressive moods, Skin problems, previous keloids in any area of the body surface, psoriasis, chronic skin eczema or chronic infectious inflammations, skin cancers, Allergies, Patient who has tendency to form keloid, Pregnant women
Number of subjects enrolled	1337 patients enrolled	682 patients
Study population	Not specified	488 men - 184 women age between 25 and 70 years
Summary of study methods	Implant test of 100 fibers Local anesthesia in aseptic conditions. Surgical procedures Treatment of the implanted area with ice wrapped in gauze for 5-10 minutes to reduce inflammation of the implant Administration of broad-spectrum antibiotic and disinfection of the implanted area. At home, cleaning and disinfection of the scalp with the prescribed products and 7-10 days of taking antibiotics is required. The patient can start washing his hair from the third day onwards. A medical shampoo with ketoconazole is recommended twice a week, at least for the first month after implantation, then once a week. The first check-up is required at 4-5 weeks or earlier in case of need. The use of local anti-inflammatory therapies and systemic antihistamine therapy is recommended in large implant sessions or in case of sensitive skin.	Sensitization and signing of informed consent on the pros and cons of the procedure Inclusion based on defined criteria. Assignment of the degree of alopecia Preventive antibiotic therapy Local anesthesia Disinfection of the scalp 100 fibers test facility After 5 weeks, additional implantation of 500 to 1,200 fibers per session at a minimum interval of 5 weeks until the required aesthetic result is achieved. Automatic Implant session Implantation of fibers at a distance of 2 mm with inclination between 45° and 60° with respect to the scalp The front-line implant performed in a zigzag pattern to obtain a more natural final result. At the end of the procedure, application of a sterile gauze with ice pack for 5 minutes on the implanted area Disinfection of the implanted area

Identity (publication)	A. Rateb Said. 2022	G. Mokthar. 2023
		Prescription topical (bacitracin, fusidic acid) and systemic antibiotics, + antiseptic shampoo every other day for a week. Post-implantation clinical examination and evaluation of scalp hygiene at each monthly session for the first year and every three months for the second year. Any adverse events were recorded. Each patient completed a short medical findings survey questionnaire (SF-36) form at baseline and after two years.
Summary of results	**EFFECTIVENESS** Patient satisfaction: 96% Fiber loss / year: 12% **CLINICAL CASES** No pathology 96% Mild pathologies 5.5% Moderate pathologies 1.4% Fiber curl <1% **RESOLUTION** Mild pathologies 5.5% resolved all with therapies Moderate pathologies 1.4% of which 68% resolved with therapies and partial fiber extraction and 32% with total fiber extraction.	**EFFECTIVENESS** Satisfaction 95% The main efficacy endpoints, assessed by the SF-36 questionnaire, testify to significant improvements in physical and emotional score, overall health, social activities, or vitality. Changes in emotional state have been observed, through the reduction of typical alopecia symptoms including social anxiety and self-esteem. **SAFETY** No pathology 95.5% Mild infectious or inflammatory diseases 3.5% Medium infectious or inflammatory diseases 1% Fiber curl <1% **Resolution** Mild infectious or inflammatory pathologies resolved with local therapy: fusidic acid plus hydrocortisone cream and chlorhexidine. Average healing time 8 days.

Identity (publication)	**A. Rateb Said. 2022**	**G. Mokthar. 2023**
		Infectious or inflammatory diseases resolved with therapies 71% and partial fiber extraction and 28% Treated with systemic antibiotic and steroid prophylaxis with betamethasone in addition to local therapy as before. Average healing time: 3 weeks, except for two cases that had recurrent problems, leading the doctor to fiber extraction.
Possible limitations of the study	NOT APPLICABLE	NOT APPLICABLE
Any defect in the device and any replacement of the device related to safety and/or performance during the study.	NOT APPLICABLE	NOT APPLICABLE

5.2 SUMMARY OF CLINICAL DATA FROM INVESTIGATIONS CONDUCTED ON THE DEVICE PRIOR TO CE MARKING, IF APPLICABLE

The materials used for the manufacture of Biofibre® 4.0 and Medicap® High Density 4.0 devices are well characterized and/or have a history of clinical use in medical devices.

Biofibre 4.0 and Medicap High Density 4.0 medical devices comply with the required biocompatibility tests, namely:

- US Pharmacopoeia: Biological Reactivity Test, USP Plastic Class VI (USP VI),
- ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Testing for genotoxicity, carcinogenicity, and reproductive toxicity
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: In vitro cytotoxicity tests
- ISO 10993-6:2016 Biological evaluation of medical devices - Part 6: Testing for local effects after implantation
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for skin irritation and sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Systemic toxicity testing
- ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of materials

5.3 SUMMARY OF CLINICAL DATA FROM OTHER SOURCES

Not applicable

5.4 GENERAL SUMMARY OF CLINICAL PERFORMANCE AND SAFETY

The clinical data collected on Biofibre® 4.0 & Medicap® High Density 4.0 and similar medical devices on the market, demonstrate the performance of artificial hair to help people against the effects of alopecia and alleviate their psychological condition.

The safety data, collected on Biofibre® 4.0 & Medicap® High Density 4.0 and similar medical devices on the market, did not show safety risks related to their use, other than those foreseeable, considered and minimized.

Compliance with the implantation protocol, adequate post-implantation follow-up and adherence to the post-implantation protocol by the patient are necessary to achieve satisfactory long-term results.

For this reason, Medicap S.r.l is attentive to the training of the doctor and gives everyone a written protocol to follow.

5.5 POST-MARKET CLINICAL FOLLOW-UP IN CORSO O PIANIFICATO

Medicap S.r.l carries out the post-market clinical follow-up:

- at least once a year;
- according to a post-market clinical follow-up plan;
- according to:
  - MDCG 2020-5 Guidance on clinical evaluation – Equivalence
  - MDCG 2020-7 Guidance on PMCF plan template April 2020
  - MDCG 2020-8 Guidance on PMCF evaluation report template April 2020
  - MDCG 2020-13 Clinical evaluation assessment report template July 2020.

6 POSSIBLE THERAPEUTIC ALTERNATIVES

From the analysis of current knowledge on alopecia it emerges that:

- There are very different categories of alopecia, with different clinical conditions;
- there are very different risk factors;
- alopecia can be psychologically harmful and cause intense emotional suffering;
- There are three families of alopecia solution:
  - medical treatment;
  - hair transplant;
  - hair implant.

There is no validated medical treatment for alopecia.

Hair transplant could be a solution, but it is limited to certain types of alopecia and the quality of the donor transplant.

Hair implantation could be a solution for the healthy patient if the artificial hair is biocompatible and if the surgical technique and post-implantation protocol are well respected.

7 SUGGESTED PROFILE AND USER TRAINING

Users are doctors trained and authorized in implantation technology:

- by Medicap S.r.l;
- by tutors authorized by Medicap S.r.l.

The training course is carried out by Medicap personnel and / or by an implantologist tutor, at suitable facilities.

During a standard course the following explanations and practical tests are provided:

- Operation, cleaning and maintenance of the adjustable implanter and needle
- correct implantation technique
- practical test on different types of simulators
- Use of automatic machine
- Live patient demonstration
- information on health and surgical aspects.

Medicap S.r.l, in agreement with the implantologist tutor, may decide not to enable the doctor who has not acquired the minimum skills after training.

Doctors trained and qualified in implantation technique must sign an ethical contract committing to:

- faithfully follow all the indications suggested by the Plant Protocol;
- correctly inform the patient about the possible characteristics related to the implant (informed consent) and deliver to the patient the post-implantation protocol containing the post-intervention rules;
- work with a dermatologist for proper post-implantation management, if necessary
- stop the implants and contact Medicap S.r.l in case of unexpected complications;
- fill in the appropriate medical record for each patient, reporting all the data relating to each implant and each post-implantation control;
- keep the medical record and its attachments (informed consent and patient post-implantation protocol) for an unlimited period, so that they are available in case of request by Medicap S.r.l and / or the Health Authority.

8 REFERENCE TO ANY INTERNATIONAL AND CS STANDARDS APPLIED

UE Medical Devices Regulation 2017/745

Regarding clinical investigation and evaluation:

• MDCG 2024-3	Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices	March 2024
• MDCG 2024-3 Appendix A:	Clinical Investigation Plan Synopsis Template	March 2024
• MDCG 2023-7	Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR and on sufficient levels of access' to data needed to justify claims of equivalence	December 2023
• 2023/C 163/06	Commission Guidance on the content and structure of the summary of the clinical investigation report	May 2023
• MDCG 2021-28	Substantial modification of clinical investigation under Medical Device Regulation	December 2021
• MDCG 2021-20	Instructions for generating CIV-ID for MDR Clinical Investigations	July 2021
• MDCG 2021-8	Clinical investigation application/notification documents	May 2021
• MDCG 2021-6 - Rev.1	Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation	December 2023
• MDCG 2020-13	Clinical evaluation assessment report template	July 2020
• MDCG 2020-10/1 Rev.1	Guidance on safety reporting in clinical investigations	October 2022
• MDCG 2020-10/2 Rev.1	Appendix: Clinical investigation summary safety report form	October 2022
• MDCG 2020-8	Guidance on PMCF evaluation report template	April 2020
• MDCG 2020-7	Guidance on PMCF plan template	April 2020
• MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices Background note on the relationship between MDCG 2020-6 and MEDDEV 2.7/1 rev.4 on clinical evaluation	April 2020
• MDCG 2020-5	Guidance on clinical evaluation – Equivalence	April 2020
• MDCG 2019-9 - Rev.1	Summary of safety and clinical performance	March 2022

Regarding Post-Market Surveillance and Vigilance (PMSV)

• MDCG 2024-1	Device Specific Vigilance Guidance (DSVG) Template	January 2024
• MDCG 2023-3	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices	February 2023
• MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745	December 2022

- UNI CEI EN ISO 13485:2021 Medical devices. Quality management systems. Regulatory requirements.
- UNI CEI EN ISO 15223-1:2021 Medical devices. Symbols to be used on medical device labels, labelling and information to be provided. Part 1: General requirements.
- UNI CEI EN ISO 20417:2021 Medical Devices, Information provided by the manufacturer of the medical device.
- UNI EN ISO 14155:2020 Clinical investigation of medical devices for human subjects. Good clinical practice.
- UNI CEI EN ISO 14971:2022 Medical Devices - Application of risk management to medical devices.
- UNI EN ISO 10993-1:2021 Biological evaluation with a risk-based approach
- EN ISO 62366:2015+AMD 2020: Medical devices — Part 1: Application of usability engineering to medical devices.

9 REVISION HISTORY

SSCP Revision Number	Date issued	Description of the change	Revision validated by the notified body
00	12.08.2021	First edition	Yes, validation language: ITALIAN
01	18.01.2024	Insertion of new clinical data on Biofibre 4.0 Standards updates	Yes, validation language: ITALIAN

PARTE 2 - SSCP INTENDED FOR PATIENTS

Document revision: Rev 01

Issue date: January 18th 2024

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an up-to-date summary of the device's clinical safety and performance key aspects. The information presented below is intended for patients or non-professionals. A more extensive summary of its safety and clinical performance is available for healthcare professionals. The SSCP is not intended to provide general advice on treating a medical condition. Please contact your physician if you have any questions about your medical condition or the use of the device in your specific situation. This SSCP is not intended to replace the implant bearer card, or the Instructions for Use intended to provide information on the safe use of the device.

1 DEVICE IDENTIFICATION AND GENERAL INFORMATION

Table 3 Device identification and general information

Trade name (s) of the device	Biofibre 4.0 / Medicap High Density 4.0
Name and address of the manufacturer	Medicap S.r.l Via A. LINCOLN, 15 - 41012 CARPI (MO) - ITALY
Basic UDI-DI	0805715896TF05HF
Year in which the first (CE) certificate on the device was issued	Set. 2020 in accordance with the Medical Devices Directive 93/42/EEC Dic. 2022 in accordance with the Medical Devices Regulation (EU) 2017/745

2 INTRODUCTION TO THE MEDICAL DEVICE AND ITS INTENDED USE

From the analysis of the current knowledge on alopecia it is known that:

- there are very different categories of alopecia, with different clinical conditions (see figures 1 and 2);
- there are very different risk factors;
- alopecia can be psychologically harmful and cause intense emotional suffering;
- there are three families of alopecia solution:
    - medical treatment;
    - hair transplant;
    - hair implant.

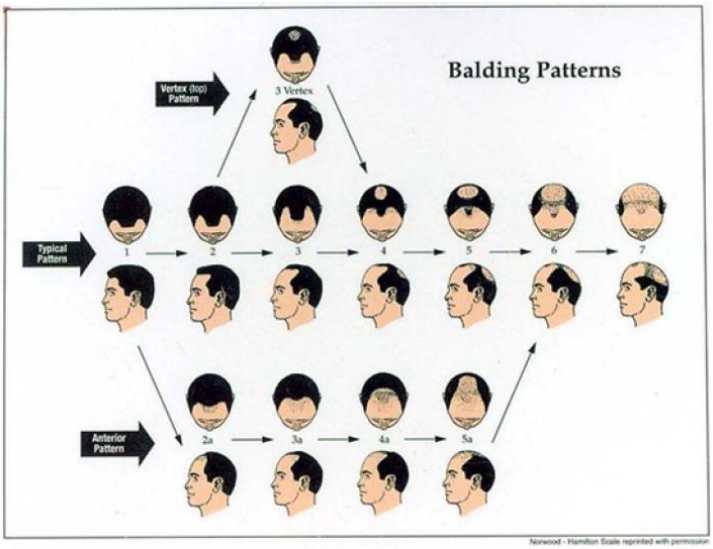


Figure 1 Hamilton-Norwood classification of male alopecia

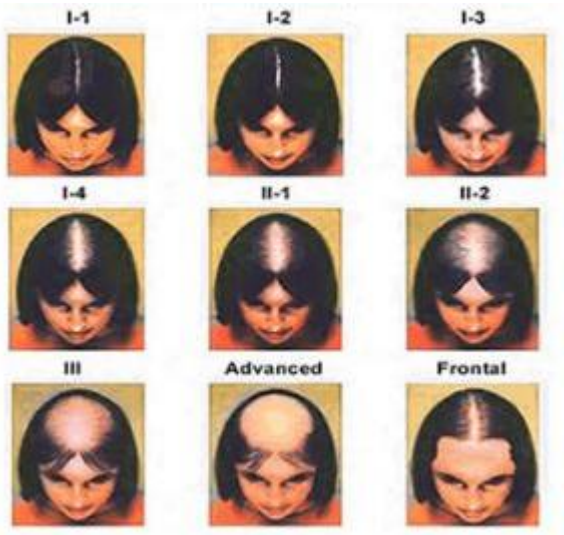


Figure 2 Ludwig scale classification of hair loss progression in female pattern

The experience of alopecia can be psychologically damaging, cause intense emotional distress, and lead to personal, social, and work-related problems.

People with severe hair loss are more likely to experience psychological distress and have lower self-esteem.

3 INTENDED USE OF THE DEVICE

Table 4 Device identification and general information

Intended purpose	Biofibre 4.0 & Medicap High Density 4.0 are long term medical devices indicated to cover thinning and/or bald areas of the scalp.
Indication (s) and target population (s)	Biofibre® & Medicap® High Density medical devices are intended for implantation only on adult patients of both sexes. Medical devices can satisfy any geographic taxonomy.
Contraindications and / or limitations	The devices are not indicated in case of reversible alopecia and for eyebrows, mustache, beard, chest and pubis thickening.

4 DEVICE DESCRIPTION

Biofibre 4.0 and Medicap High Density 4.0 are:

- implantable artificial hair;
- biocompatible;
- sterile;
- manufactured in polybutylene terephthalate (98%), polyethylene, yellow pigment 180, iron oxide, carbon black.

Biofibre 4.0 and Medicap High Density 4.0 exist in different lengths, colors and shapes.

The following photos show the implant effect on different patients.

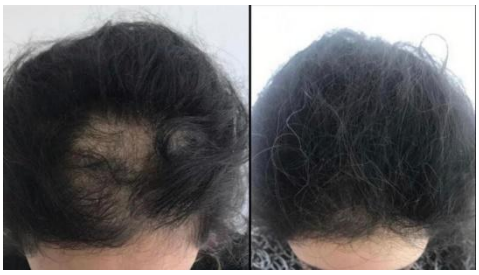


Fig. 1 No. 500 Biofibre implanted on female

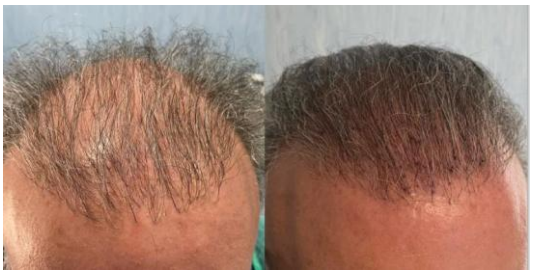


Fig. 2 No 1000 Biofibre implanted on male who already had HT

Fig. 3 No 1500 Biofibre implanted on male

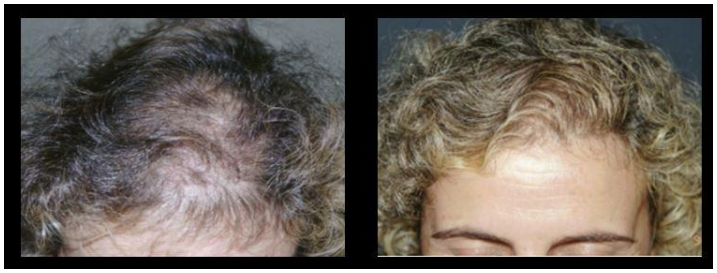


Fig. 4 No 1500 Biofibre wavy implanted on female

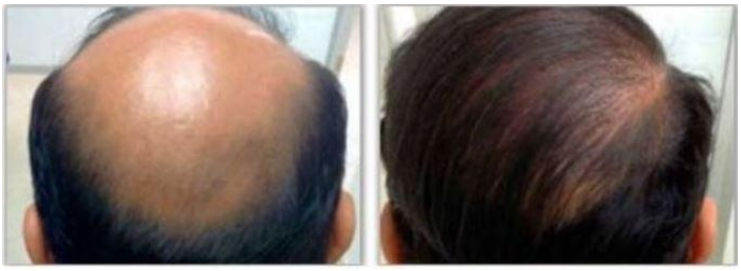


Fig. 5 No 2500 Biofibre implanted on male

Fig. 6 No 3500 Biofibre implanted on male

5 RISKS AND WARNINGS

Moderate scalp discomfort and swelling up to a few hours after implantation is possible as a normal consequence of the procedure and anesthesia.

After the implantation of Biofibre® 4.0 or Medicap® High Density 4.0, some phenomena may occur in the scalp. These are infectious phenomena and inflammatory phenomena. If treated with adequate drug therapy, they usually resolve in about ten days without sequelae. In the absence of a response to the performed therapeutic treatments, it will be essential to remove the fibers that cause problems. The total extraction of the fibers, accompanied by an adequate pharmacological treatment, determines a *restitutio ad integrum* of the scalp.

Attention! If the above phenomena are not treated quickly and adequately, complications of even a certain severity may arise (pyoderma and granulomatous nodules). Untreated infections can cause *defluvium* of the patient's natural hair and/or fibers and cause scarring of the skin around the implanted fibers.

In addition, the use of prohibited substances or treatments with excessive heat can cause changes to the appearance of Biofibre® & Medicap® High Density (curling, dryness, breakage). Follow the post-implantation protocol carefully.

Contact your doctor if you think you have any side effects related to the device or its use, or if you are concerned about the risks. This document is not intended to replace a consultation with your doctor if necessary.

In the event of a serious accident occurring in connection with the Biofibre® 4.0 or Medicap® High Density 4.0 device, please report:

- to MEDICAP S.r.l, e-mail address: info@medicaphair.com
- to the regulatory authority responsible for medical devices in your country (outside the EU),
  - for Australia, repot to https://www.tga.gov.au

6 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

The materials used to manufacture Biofibre® 4.0 and Medicap® High Density 4.0 devices have a history of clinical use in implantable medical devices.
Biofibre 4.0 and Medicap High Density 4.0 medical devices have passed the biocompatibility tests required by current regulations.

Clinical data collected on Biofibre 4.0 and Medicap High Density 4.0 and similar medical devices on the market demonstrate the performance of artificial hair to help people against the effects of alopecia and alleviate their psychological condition.

The latest studies show the successful implantation of Biofiber 4.0 and Medicap High Density 4.0 for more than 99% of patients with 96% satisfaction.

The degree of implant retention is over 88% per year for most patients.
The safety data, collected on Biofibre 4.0 and Medicap High Density 4.0 and on similar medical devices on the market, did not highlight any safety risks related to their use, other than those foreseeable, considered and minimized.
Compliance with the implantation protocol, adequate post-implantation follow-up and compliance with post-implantation protocol by the patient are necessary to obtain satisfactory long-term results.
Medicap S.r.l carries out at least one post-market clinical follow-up per year through the collection of production and post-production information, to obtain information on the use of the devices and collect significant information on their safety.

7 POSSIBLE THERAPEUTIC ALTERNATIVES

There is no validated medical treatment for alopecia.

Hair transplantation could be a solution, but it is limited to some types of alopecia and the quality of the donor transplant. Contact your healthcare provider to assess your individual situation.

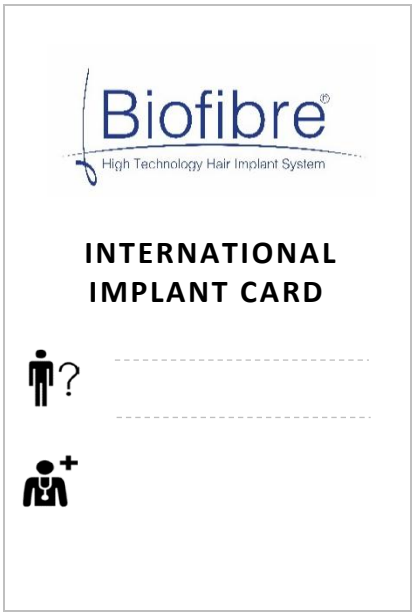
8 IMPLANT BEARER CARD

After treatment, the doctor provides the patient with an implant bearer card.

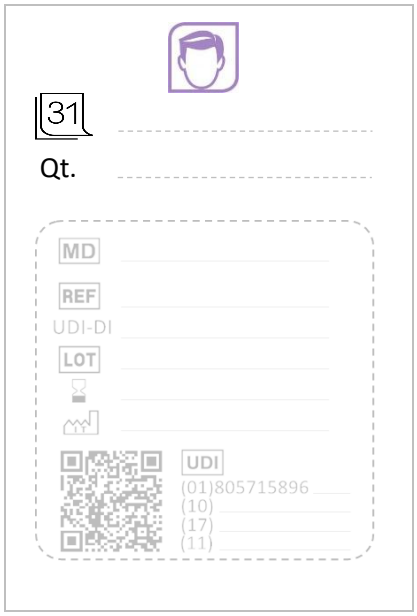
The patient must keep the individual implant card with him, as essential information about the implant is recorded.

The purpose of the implant card is to allow the user to identify the implanted device and to access other information regarding it, but also to allow the emergency clinical staff or first responder to be informed about special care/needs in the event of emergency situations.

Below is the drawing defined by Medicap S.r.l, and the symbols' legend.



Implant card Front



Implant registration space (x6)

Back of the implant card

Legend

SYMBOLS	MEANING
	Patient's name
	Name and address of the health facility
	Name and address of the manufacturer
	Website with information for patients
	Date of implantation
Qt.	Amount