INSTRUCTIONS FOR USE

Device name	Biofibre® 4.0 & Medicap High Density® 4.0
Instructions' revision and date	Ed. I, Rev 04 of 2022-11-16
Manufacturer's name and address	Medicap Srl, Via A. Lincoln, 15 - 41012 Carpi (MO) - ITALY

1 BIOFIBRE ® 4.0 AND MEDICAP HIGH DENSITY® 4.0 GENERAL CHARACTERISTICS

Implantable, sterile, and disposable artificial hair Biofibre® 4.0 & Medicap High Density® 4.0 are manufactured in polybutylene terephthalate.

At one end they have a small knot called " *knot*". Thanks to the reversibility characteristic of this knotting, the knot is also called "*removable root* ".

The general warnings and information that are always shown on the labeling along with their meaning are reported on the following table.

SYMBOLS	MEANING
CE 0373	CE marking and Notified Body identification
	Single use, do not reuse
	Do not resterilize
	Sterile device, steam sterilized
	Unique sterile barrier system with internal protective packaging
	Caution
	Keep away from light
	Keep dry
	Do not use if the sterile product's system barrier or its packaging is compromised and consult the instructions for use
	Non-pyrogenic
MD	Medical device It is flanked by the device name: Biofibre 4.0 or Medicap High Density 4.0
UDI	Unique Device Identification. The UDI vector is placed on the left. Below is the UDI in "HRI" format (Human Readable Interpretation)
REF	Catalog number
LOT	Batch code
	Expiration date
	Manufacturing date of and country identification code showing where the device was manufactured
	Consult the instructions for use

SYMBOLS	MEANING
	QR code that allows the user to download the instructions for use online
	Manufacturer
	Stamp certifying that all required checks have been carried out

The following table shows the composition of Biofibre® 4.0 & Medicap High Density® 4.0 devices.

Substance
PBT
PE
Inorganic pigments

2 SAFETY AND CLINICAL PERFORMANCE

The positive impact of medical devices on the health of the population is linked to:

- positive clinical outcome, with minimal probability of adverse events;
- easy management of mild side effects and total restoration of the scalp after removing the fibers;
- immediate, lasting results and without hospitalization.

The clinical data collected on Biofibre® 4.0 & Medicap High Density® 4.0 and on similar medical devices on the market, demonstrate the performance of artificial hair in helping people to counteract the effects of alopecia and alleviate their psychological condition.
The safety data, collected on Biofibre® 4.0 & Medicap High Density® 4.0 and on similar medical devices on the market, did not reveal any safety risks related to their use, other than those foreseeable, considered and minimized.
The SUMMARY RELATED TO SAFETY AND CLINICAL PERFORMANCE (SSCP) is available on Eudamed Portal with the basic device UDI-DI code 805715896TF05HF.

3 BIOFIBRE ® 4.0 AND MEDICAP HIGH DENSITY® 4.0 INTENDED USE

Biofibre® 4.0 & Medicap High Density® 4.0 are long-term implantable medical devices indicated for covering thinning and/or bald scalp areas. The devices are not indicated in case of reversible, autoimmune alopecia and for the thickening of eyebrows, mustache, beard, chest, and pubis.
The device can only be used by doctors authorized for implantation by Medicap Srl or by medical tutors authorized by Medicap Srl Implant is to be carried out in an outpatient setting, after administering local anesthesia.

TARGET USERS

Users are doctors **trained** and **qualified** in the implantation technique by Medicap Srl or by tutor doctors qualified for implantation by Medicap Srl.

RECIPIENT PATIENTS

Biofibre® 4.0 & Medicap High Density® 4.0 medical devices are intended for implantation only on adult patients of both genders. Medical devices can satisfy any geographic taxonomy.

Patients eligible for treatment must be in good health and have a healthy scalp with a good degree of cleanliness.
ATTENTION! Patients must undergo all the tests prescribed by the doctor to check their health conditions.

ATTENTION! The implantation center must inform the patient about Biofibre® 4.0 & Medicap High Density® 4.0 implant features and limitations.
Patient must sign an **informed consent** in which he/she:

- declares to be informed about Biofibre® 4.0 & Medicap High Density® 4.0 implant characteristics and limits and the post-implantation protocol;
- authorizes the intervention.

4 CONTRAINDICATIONS, RESIDUAL RISK

PATIENTS AT RISK

Patients at risk are considered those who:

- may manifest or show allergies to synthetic materials or local anesthetics;
- present alterations in the psychic area;
- are suffering from immune system diseases;
- have ongoing scalp diseases;
- have unrealistic expectations;
- are suffering from metabolic diseases;
- carry out activities in unsuitable environments;
- are subjected to constant drug therapies for health reasons;
- are not available to follow the post-implantation protocol.

FORBIDDEN SUBSTANCES FOR BIOFIBRE ® 4.0 AND MEDICAP HIGH DENSITY® 4.0

- acid substances in concentrations higher than 5%;
- benzyl alcohol and pure isopropanol;
- benzaldehyde and formaldehyde.
- phenol and derivatives: cresol, thymol and resorcinol (e.g., hair dye);
- ammonia (e.g., many hair dyes);
- substances with iodine;
- oxidants: hydrogen peroxide, benzoyl peroxide, etc. .;
- halogen substances: alcoholic iodine tincture, chlorine, etc. ;
- steroid-based substances;
- keratin powder.

ATTENTION! Some of the above-mentioned products such as hydrogen peroxide and povidone iodine, can be used for scalp disinfection during the implantation session, but frequent use can compromise the stability of Biofibre ® & Medicap High Density®.

TREATMENTS/CONDUCT PROHIBITED FOR BIOFIBRE® 4.0 AND MEDICAP HIGH DENSITY® 4.0

- dyes with ammonia, bleaches and perms;
- excessive heat (more than 50 ° C) and close proximity of the hair dryer, use of the curling iron, of the straightener;
- sauna without wet turban;
- excessive traction (e.g., violent brushing);
- use of helmets or constricting headgear that can cause traction;

- continuous exposure in dusty or dirty environments;
- scratching the scalp;
- poor personal hygiene;
- sunburn of the scalp.

SPECIAL WARNINGS

In order to obtain a natural and pleasant effect, choose one or more colors similar to those of the patient's natural hair.
The minimum implantation distance of the fibers must be 2 mm (approximately 40 fibers per cm2).
Implants can be done every 5 weeks on different areas of the scalp.
ATTENTION! A too close distance and/or the implantation of more fibers in the same introduction hole creates a hole that is too wide which favors the introduction of bacteria and inflammatory reactions. It is therefore necessary to remove the excessive fibers, recreating the normal condition of 1 fiber implanted for each new follicle.

Premature fiber shedding can occur because of:
- excessive traction of the knot and/or of the fiber in the implantation phase;
- introduction of 2 or more fibers into the same hole;
- insufficient implantation depth;
- lack of after-care.

The fiber implanted in a blood vessel causes a small, prolonged hemorrhage that stops immediately with the extraction of the fiber and with firm pressure on the area.

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 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 therapeutic treatments performed, 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 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.

Furthermore, the use of prohibited substances or treatments with excessive heat can cause changes in the appearance of Biofibre® & Medicap High Density® (curling, dryness, breakage).

5 CHECK OF THE DEVICE SUITABILITY

Biofibre® 4.0 & Medicap High Density® 4.0 are sterilized by saturated steam.
The expiry date is indicated on the package. Do not use the devices beyond the indicated expiration date.
The sterile package (envelope) should only be opened at the time of surgery.
Before opening, check that the package is perfectly intact. Any damage could compromise the sterility of the fibers and therefore the success of the operation.

Attention! Only the sealed pouch allows to maintain sterility, therefore Biofibre® 4.0 or Medicap High Density® 4.0 must never be stored and reused left over from previous implants, even if they were stored in medical paper holders.

6 METHOD OF USE

Carefully perform the implantation technique taught by Medicap Srl, or by the medical tutor trained by Medicap Srl
The implantation protocol illustrates each phase in detail.
Biofibre® 4.0 & Medicap High Density® 4.0 are implanted exclusively with the special implant tools manufactured by Medicap Srl
Implant can be made manually or assisted by the Automatic Biofibre Hair Device machine. For the preparation of the tools or the use of the automatic machine, carefully consult the instructions or the user manual.

Biofibre® 4.0 & Medicap High Density® 4.0 are disposable devices, their reuse is not possible as after the first hooking with the needle, the knot is deformed.
The implantation of Biofibre® 4.0 & Medicap High Density® 4.0 is carried out under local anesthesia.
Before proceeding, it is necessary to carefully disinfect the implantation area, selecting the appropriate implantation area, carefully avoiding the areas at risk (see implantation protocol). Medicap High Density® 4.0 must be used exclusively on the vertex area of the scalp.

ATTENTION! Check the compatibility of the patient with the device.

In compliance with the implantation protocol in force, before the first implantation session, it is necessary to implant 100 fibers to verify the patient's tolerance to the fibers. 4 weeks after implantation, it is necessary to perform a medical check-up and verify the outcome of the implantation test.

IMPORTANT! In case of doubt, repeat the tolerance test.

In case of skin reaction or if the fiber has undergone changes in appearance, do not proceed with the implantation session and contact Medicap Srl.

The implantation procedure foresees the placement of 500-800 fibers for the first session. After 5 weeks it is possible to foresee further sessions, implanting up to 1000-1200 fibers per session, in another area of the scalp.

FIBERS PREPARATION

1. take out a card from the envelope;
2. hold the Biofibre® 4.0 or Medicap High Density® 4.0 cardboard and remove the tube from the knots;
3. peel off or bend the card stock tab.

IMPLANTER CORRECT POSITION

1. grab the sachet of Biofibre® 4.0 or Medicap High Density® 4.0 ;
2. hold the implanter;
3. the inclined plane must face the palm of the hand holding the instrument;
4. place the implantation tool perpendicular to the fiber knots;
5. push the needle out completely.

CORRECT HOOKING OF THE KNOT

1. keep the needle completely out;
2. lower the instrument perpendicular to the knot and insert the needle into the knot of the fiber;
3. keep the fiber always in light traction to allow it to hook correctly;
4. in this position the fiber must form an angle of about 45° with respect to the inclined plane of the implanter.

FIBER ANGLE

1. retract the needle completely into the implanter

2. maintain the angle of approximately 45° between the fiber and the inclined plane of the implanter;
3. when hooked correctly the knot remains held by the hook.

INCLINATION OF THE FIBER

1. bring the instrument close to the patient's scalp;
2. the angle of the implanter with respect to the support surface must follow the orientation of the nearby natural hair or the type of hairstyle chosen.

PLACEMENT OF THE KNOT ON THE GALEA CAPITIS

1. let the needle to come out completely from the implanter so that it reaches the *galea capitis*;
2. while inserting the needle into the scalp, keep the instrument firmly, without putting pressure on the skin;
3. with a gentle hand movement, remove the sachet containing the fiber already implanted from the implantation area.

WITHDRAWAL OF THE NEEDLE FROM THE GALEA CAPITIS

1. return the needle to its rest position;
2. lift the implanter from the implantation area;
3. the fiber now remains positioned on the *galea capitis* .

Repeat the actions described above until the implantation session is completed. Remove the newly implanted fibers using a wide-toothed comb with gentle movements to have the operating field free.

END OF THE IMPLANT

At the end of the implant, disinfect or wash the implanted area without any excessive pulling of the fibers.
Adopt the necessary pharmacological and general prescriptions. Comb the implanted fibers with a disinfected wide-toothed comb.
If the patient wears a headgear, cover the implanted area with gauze, in or der to avoid contact with dirty surfaces. This warning will also apply to the weeks following implantation.

DISPOSAL PROCEDURES

Attention!

Implant instruments (needle or disposable implanter) present a physical cut risk and a risk of biological contamination.

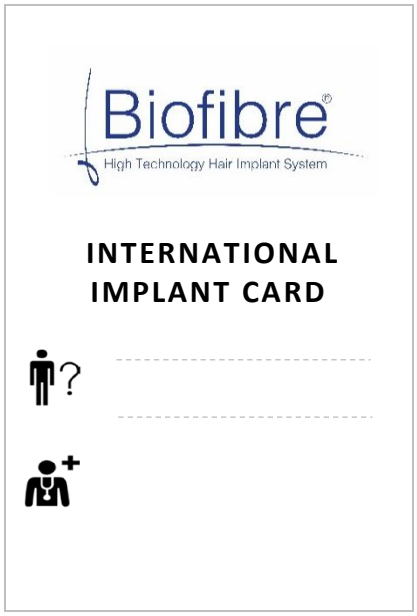
Dispose of consumables according to local regulations.

7 PREPARATION OF THE IMPLANT CARRIER CARD

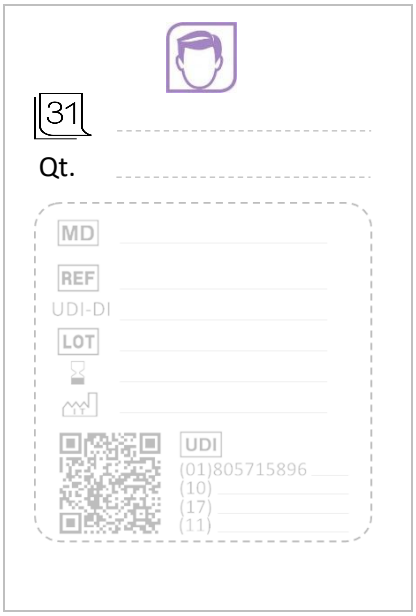
After the implantation session, the implantation center must prepare the implant card and explain their contents to the patient who will have to keep it.

The cards for implant bearers are delivered by Medicap along with the devices. The card is prepared with basic general information, fields to be filled in and fields for the application of labels provided by Medicap Srl

It is set up with a front space, to report information regarding the patient and the implant clinic, six spaces for the implant sessions registration and a back side with generic information on the device and on the manufacturer. A QR code allows patients to obtain information for post implant management.



Fronte della tessera d'impianto



Pagina di registrazione dell'impianto (x6)

Retro della tessera d'impianto

Legend

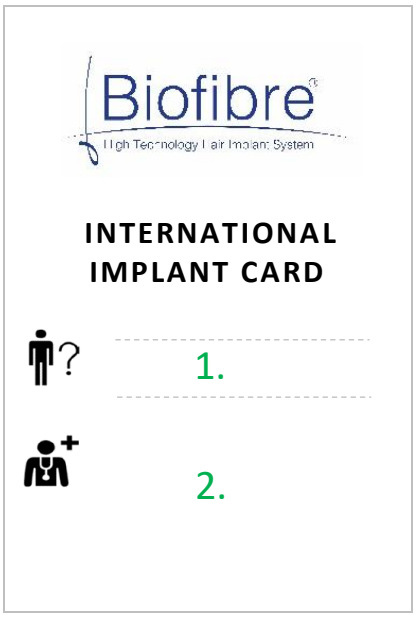
SYMBOLS	MEANING
	Patient name
	Clinic name and address
	Manufacturer name and address
	Website with information for patients
	Implantation date
Qt.	Quantity

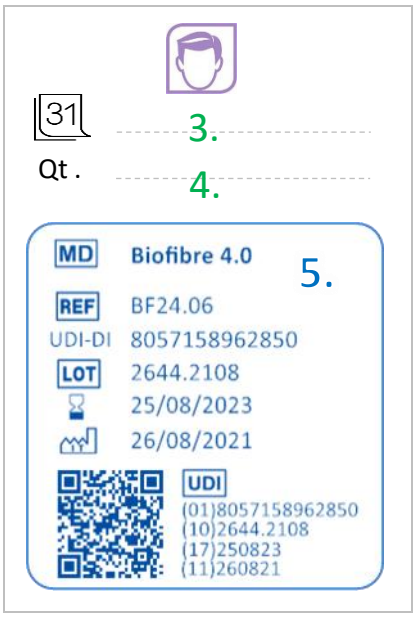
The clinic must fill in the card as follows:

1. patient's name;
2. clinic name and address;
3. implant date;
4. implanted quantity;
5. Apply on the card the label taken from the envelope of the implanted fibers.

Attention: in case of more ref REF and/or lots LOT used in the same implant session, apply the corresponding labels on the appropriate registration spaces .

6. Repeat steps 3. 4. and 5. for each implantation session





Legend

SYMBOLS	MEANING
	Information to be filled in by hand
	Information prepared by Medicap Srl
	Pre -printed text

8 BIOFIBRE® 4.0 AND MEDICAP HIGH DENSITY® 4.0 POST-IMPLANT MAINTENANCE OF

In the days following the implant, patient will have to follow a post implantation protocol, in order to reduce the likelihood of complications summarized in point 4. The protocol is available to patients online, following the QR code on the Implant card.

9 FIBER EXTRACTION

If an intolerance/rejection reaction to the fiber occurs, it must be removed as follows:

1. reduce inflammation, if present, with appropriate steroid and antibiotic therapy;
2. soften with vaseline oil and treat the implanted area with moist heat in order to make it easier to open the follicles and remove the fiber;
3. grasp the fiber with tweezers at the level of the scalp and extract it following the direction of introduction, with a decisive, waving movement without tearing;
4. disinfect the explanted area and adopt the appropriate drug therapy;
5. continue the appropriate therapy on the explanted area, until the skin is completely healed.

If removed from the patient's galea capitis, Biofibre® 4.0 or Medicap High Density® 4.0, are biological waste that must be disposed of according to local regulations.

10 IN THE EVENT OF AN ACCIDENT

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

- to MEDICAP Srl at the e-mail address info@biofibre.com
- to the competent medical devices' regulatory authority in your country.