INSTRUCTIONS FOR USE

Name of Device	Needle for Adjustable Implanter, sterile
Revision and date of instructions	Ed. I of 15/07/2021
Name and address of the Manufacturer	Medicap S.r.l, Via A. Lincoln, 15 - 41012 Carpi (MO) - ITALY

1 GENERAL CHARACTERISTICS OF THE NEEDLE FOR ADJUSTABLE IMPLANTER, STERILE

The Needle for Adjustable Implanter is a sterile, disposable medical device used for the implantation of artificial hair manufactured by Medicap S.r.l. It is sold in single pack.

The following table shows the general warnings and information that are always given on the labeling and their meaning.

SYMBOLS	SIGNIFICATE
CE 0373	CE marking and Notified Body identification
	Sterile device, steam sterilized
	Unique sterile barrier
	Not pyrogenic
	Caution
	Disposable, 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 is compromised and consult the instructions for use
MD	Medical device
UDI	It is accompanied by the name of the device: Needle for Adjustable Implanter
REF	Unique Device Identifier.
LOT	Lot code
	Expiration date
	Date of manufacture and country code identification where the device was manufactured
	Consult the instructions for use

SYMBOLS	SIGNIFICATE
	QR code that allows the user to download the instructions for use online
	Address of the manufacturer
	Stamp certifying the execution of all the foreseen controls

2 PERFORMANCE OF THE NEEDLE FOR ADJUSTABLE IMPLANTER, STERILE

The Needle for Adjustable Implanter, sterile is an implantation tool:

- developed to be used with the adjustable implanter manufactured by Medicap S.r.l;
- for the implantation of artificial hair manufactured by Medicap S.r.l.

Once assembled on the adjustable implanter, its specific design allows to hook the artificial hair manufactured by Medicap S.r.l and to implant it in the patient's scalp, in particular on the galea capitis. The Needle for Adjustable Implanter, sterile has been developed to allow for an entire implantation session (up to 1,000-1,200 hairs).

3 INTENDED USE OF THE NEEDLE FOR ADJUSTABLE IMPLANTER, STERILE

The Needle for Adjustable Implanter, sterile can only be used for the implantation of artificial hair manufactured by Medicap S.r.l.

The device can only be used by doctors authorized for implantation by Medicap S.r.l. or by medical tutors authorized by Medicap S.r.l.

The implant must be performed in an outpatient setting, subject to local anesthesia.

TARGET USERS

The users are doctors trained and enabled for the implant technique by Medicap S.r.l or by tutor doctors enabled for the implant by Medicap S.r.l.

RECIPIENT PATIENTS

The Needle for Adjustable Implanter, sterile is intended for the implantation of artificial hair into the scalp of adult male or female patients.

Patients suitable for treatment must have a good general state of health and a healthy scalp with a good degree of cleanliness.

ATTENTION! The patient must undergo all the tests prescribed by the doctor to check his health conditions.

4 CONTRAINDICATIONS AND RESIDUAL RISKS RELATED TO THE USE OF THE NEEDLE FOR ADJUSTABLE IMPLANTER IN THE IMPLANT PROCEDURE

PATIENTS AT RISK

Since the Needle for Adjustable Implanter, sterile is used exclusively for the implantation of synthetic hair manufactured by Medicap S.r.l, the patients at risk are the same as those at risk for receiving the implants, i.e. patients who:

- may show or show allergies to synthetic materials or local anesthetics;
- have alterations of the psychic area;
- are affected by diseases of the immune system;
- have scalp diseases in progress;
- have unrealistic expectations;
- are affected by metabolic disorders;
- carry out activities in unsuitable environments;
- are subjected to constant pharmacological therapies for health reasons;
- are not available to follow the post-implantation protocol

GENERAL WARNINGS FOR THE USER

Attention! The Needle for Adjustable Implanter presents a physical puncture risk and a biological contamination risk for the user. Wear disposable protective gloves until the device is disposed of.

SPECIAL WARNINGS

The minimum implantation distance of the fibers must be 2 mm (about 40 fibers per cm2).
The implants can be made every 5 weeks on different areas of the scalp.
ATTENTION! A too close distance and/or the implantation of several fibers in the same introduction hole creates a hole that is too large which favors the introduction of bacteria and inflammatory reactions. It is therefore necessary to explant the excess fibers, recreating the normal condition of 1 fiber implanted for each new follicle.
Early fiber loss can occur as a result of:
- excessive traction of the knot and/or fiber during implantation;
- introduction of 2 or more fibers in the same hole;
- insufficient implant depth;
- lack of after-care.

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

RESIDUAL RISKS

After the implantation procedure, some phenomena may occur on the scalp. These are infectious phenomena and inflammatory phenomena. If they are 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 phenomena indicated above are not treated quickly and adequately, complications of a certain seriousness 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.

5 DEVICE SUITABILITY VERIFICATION

The Needle for Adjustable Implanter is sterilized by saturated steam.
The expiry date is shown on the package. Do not use the tool 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 instrument and therefore the success of the operation.

Attention !
The needle for adjustable implanter is for single use only. It is used for the implantation of artificial hair on a single patient, for a single implantation session.
Do not wash, resterilize or reuse the Needle for Adjustable Implanter.

6 METHOD OF USE

Carefully follow the implant technique taught by Medicap S.r.l, or by the medical tutor trained by Medicap S.r.l.
The implantation protocol illustrates each stage in detail.

The Needle for Adjustable Implanter, sterile is to be used exclusively mounted on the adjustable implanter, for the implantation procedure of artificial hair manufactured by Medicap S.r.l.

The adjustable implanter must first be washed, disinfected and sterilized.
The implant can be done manually or assisted by the Automatic Biofibre Hair Device automatic machine.
For the preparation of the adjustable implanter, the preparation of the artificial hair and for the use of the automatic machine, carefully consult the instructions or the user manual.

The use of the adjustable implant needle takes place under local anesthesia.
Before proceeding, it is necessary to carefully disinfect the plant area, selecting the suitable plant area, carefully avoiding the areas at risk (see plant protocol).

PREPARING THE NEEDLE FOR ADJUSTABLE IMPLANTER

1. Wear disposable protective gloves;
2. open the bag containing the previously sterilized adjustable implanter;
3. grasp the implanter, unscrew the tip and extract it completely from the body of the implanter;
4. unscrew the ferrule of the tip;
5. open the bag containing the sterile, adjustable implant needle;
6. grasp the needle keeping the recognition sign on the needle guide cross towards the user;
7. grasp the tip of the adjustable implanter, keeping the plane inclined to the left;
8. insert the sterile needle into the canal;
9. screw the ring nut back into the sliding channel without tightening it excessively, in order to avoid blocking the needle;
10. insert the tip into the body of the implanter and screw it back on;
11. regulate the outflow of the needle by protruding only the long part of the hook.

CORRECT POSITION OF THE IMPLANTER WITH RESPECT TO THE ARTIFICIAL HAIR

12. grab the bag of synthetic hair;
13. grab the implanter, the inclined plane facing the palm of the hand that holds it;
14. position the implanter perpendicular to the nodes of the fibers;
15. push the needle out completely.

CORRECT HOOK OF THE KNOT

16. hold the needle completely out;
17. lower the implanter perpendicular to the node and insert the needle into the node of the fiber;
18 always keep the fiber in light traction to allow it to hook correctly;
19. in this position, the fiber must form an angle of approximately 45° with respect to the inclined plane of the implanter.

If the fiber is not retained by the needle:

- check the correct positioning of the needle;
- adjust the release of the hook from the inclined plane of the implanter.

FIBER ANGLE

20. retract the needle completely into the implanter;
21. maintain an angle of about 45° between the fiber and the inclined plane of the implanter;
22. the correctly hooked knot remains held by the hook.

INCLINATION OF THE FIBER

23. bring the tip of the implanter close to the patient's scalp;
24. the angle of the implanter must follow the orientation of the nearby natural hair or the type of hairstyle chosen.

PLACEMENT OF THE KNOT ON THE GALEA CAPITIS

25. make the needle of the implanter come out completely so that it reaches the galea capitis;
26. while inserting the needle into the scalp, keep the instrument very still, without putting pressure on the skin;
27. with a gentle movement of the hand, move the sachet containing the fiber already implanted away from the implantation area.

WITHDRAWAL OF THE NEEDLE FROM THE GALEA CAPITIS

28. return the needle to its rest position;
29. lift the implanter from the implant area;
30. the fiber now remains positioned on the galea capitis.

Repeat the actions described above until completion of the implant session.

AT THE END OF THE IMPLANT

At the end of the implant, disinfect or wash the implanted area.

Adopt the necessary pharmacological and general prescriptions. If the patient wears a headgear, cover the implanted area with gauze to avoid contact with dirty surfaces. This warning will also apply for the weeks following the implant.

Remove the tip, unscrew the ring nut and discard the needle. Immediately proceed with washing the adjustable implanter and with its disinfection and sterilization according to the protocol described in the instructions for use.

DISPOSAL PROCEDURES

Attention! The adjustable implant needle presents a physical puncture risk and a biological contamination risk.

Dispose of it according to local regulations.

7 MAINTENANCE POST PROCEDURE OF THE IMPLANT

In the days following the implant, the patient must follow the post-implant protocol prepared by Medicap S.r.l and provided by the implant centre.

8 IN THE EVENT OF AN ACCIDENT

In the event of a serious accident involving the device Needle for adjustable planter, sterile, please report:
- to MEDICAP S.r.l at the e-mail address info@biofibre.com
- with the relevant medical device regulatory authority in your country.