INSTRUCTIONS FOR USE

Name of Device	Disposable Implanter, sterile
Revision and date of instructions	Ed. I, Rev 01 of 11/10/2024
Name and address of the Manufacturer	Medicap S.r.l, Via A. Lincoln, 15 - 41012 Carpi (MO) - ITALY
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1 GENERAL CHARACTERISTICS OF THE DISPOSABLE, STERILE IMPLANTER

The Disposable, sterile 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 is always reported on the labelling and their meaning.

SYMBOLS	MEANING
CE 0373	CE marking and Notified Body Identification
	Sterile device, steam sterilized
	Unique sterile barrier
	No Pirogenic
	Attention
	Disposable, not re-use
	Don’t re-sterilize
	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 It is flanked by the name of the device: Disposable Implanter
UDI	Unique Identifier of the device The UDI vector is placed on the left. Below is the UDI in 'HRI' (human-readable interpretation) format
REF	Catalogue number
LOT	Lot code
	Expiration date
	Date of manufacture and identification of the code of the country where the device was manufactured
	Consult the instructions for use

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

2 PERFORMANCE OF THE DISPOSABLE IMPLANTER, STERILE

The Disposable, sterile Implanter is a ready-to-use tool, developed for the implantation of artificial hair manufactured by Medicap S.r.l; Its specific and ergonomic design allows to hook the artificial hair manufactured by Medicap S.r.l and to implant it in the patient's scalp, in particular in the galley capitis. The disposable, sterile implanter has been developed to allow simple and ergonomic use for an entire implant session (up to 1,000-1,200 hairs).

3 INTENDED USE OF THE DISPOSABLE, STERILE IMPLANTER

The Disposable, sterile Implanter can only be used for the implantation of artificial hair manufactured by Medicap S.r.l.
The device can only be used by doctors qualified 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.

TARGET USERS

Users are doctors trained and qualified in implantation technique by Medicap S.r.l or by doctors tutors qualified to implant by Medicap S.r.l.

RECIPIENT PATIENTS

The disposable, sterile implanter is used for implanting artificial hair on the scalp of adult male or female patients.
Patients eligible for treatment should have good overall health and a healthy, cleanliness scalp.
ATTENTION! The patient must undergo all the tests prescribed by the doctor to check his health condition.

4 CONTRAINDICATIONS AND RESIDUAL RISKS RELATED TO THE USE OF THE DISPOSABLE IMPLANTER IN THE IMPLANT PROCEDURE

PATIENTS AT RISK

Since the disposable, sterile implanter is used exclusively for the implantation of synthetic hair manufactured by Medicap S.r.l, patients at risk are the same as those at risk to receive implants, i.e. patients who:

- may manifest or manifest allergies to synthetic materials or local anesthetics;
- have alterations of the psychic area;
- are affected by diseases of the immune system;
- have ongoing scalp diseases;
- have unrealistic expectations;
- are affected by metabolic diseases;
- 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 Disposable Implanter presents a physical risk of puncture and a risk of biological contamination for the user. Wear disposable protective gloves until the device has been removed.

SPECIAL WARNINGS

The minimum implanting distance of the fibers must be 2 mm (about 40 fibers per cm2).
Implants can be performed every 5 weeks on different areas of the scalp.
ATTENTION! A too close distance and / or the implantation of several fibers in the same injection hole, creates a hole too wide that favors the introduction of bacteria and inflammatory reactions. It is therefore necessary to remove the excess fibers, recreating the normal condition of 1 fiber implanted for each new follicle.

Early fiber dropping may occur as a result of:
- excessive traction of the node and/or fiber during implantation;
- introduction of 2 or more fibers in the same hole;
- insufficient depth of planting,
- lack of after-care.

The fiber implanted in a blood vessel causes a small, prolonged bleeding that 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 in the scalp. These are infectious phenomena and inflammatory phenomena. If they are treated with adequate drug therapy, they normally 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 (pyoderma and granulomatous nodules) may arise. Untreated infections can cause defluvium of the patient's natural hair and/or fibers and cause skin scarring around the implanted fibers.

5 DEVICE SUITABILITY VERIFICATION

The Disposable 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 implanter is disposable. It is used for the implantation of artificial hair on a single patient, for a single implantation session.
Do not disassemble, wash, resterilize or reuse the disposable implanter.

6 METHOD OF USE

Carefully follow the implant technique taught by Medicap S.r.l, or by the tutor doctor trained by Medicap S.r.l.
The plant protocol explains each step in detail.
The disposable, sterile implanter is to be used exclusively for the implantation procedure of artificial hair manufactured by Medicap S.r.l. The implant can be made manually or assisted by the automatic Automatic Biofibre Hair Device.
For the preparation of artificial hair and for the use of the automatic machine, carefully consult the instructions or the user manual.
The use of the Disposable Implanter takes place under local anesthesia.
Before proceeding, it is necessary to carefully disinfect the planting area, selecting the suitable planting area, carefully avoiding risk areas (see plant protocol).

PREPARATION OF THE DISPOSABLE IMPLANTER

1. Wear disposable protective gloves;
2. open the bag and remove the disposable, sterile implanter;
3. if necessary, adjust the needle using a mm 1,27 grub screw.

CORRECT POSITION OF THE IMPLANTER WITH RESPECT TO THE ARTIFICIAL HAIR

4. grab the bag of synthetic hair;
5. grasp the disposable implanter, the inclined plane facing the palm of the hand holding it;
6. position the disposable implanter perpendicular to the nodes of the fibers;
7. push the needle out completely.

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CORRECT KNOT HOOKING

8. hold the needle completely out;
9. lower the disposable implanter perpendicular to the node and insert the needle into the node of the fiber;
10. always keep the fiber in a slight traction to allow it to hook correctly;
11. In this position, the fiber must form an angle of approximately 45° with respect to the inclined plane of the disposable implanter.

ANGLE OF THE FIBER

12. retract the needle completely into the disposable implanter;
13. maintain an angle of approximately 45° between the fiber and the inclined plane of the disposable implanter;
14. the correctly hooked knot remains held by the hook

INCLINATION OF THE FIBER

15. bring the tip of the disposable implanter close to the patient's scalp;
16. 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

17. fully push out the needle of the disposable implanter so that it reaches the galea capitis;
18. while inserting the needle into the scalp, keep the instrument very still, without putting pressure on the skin;
19. 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

20. return the needle to its rest position;
21. lift the disposable implanter from the implant area;
22. 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 plant, disinfector wash the implanted area.
Adopt the necessary pharmacological and general prescriptions. If the patient wears a headgear, cover the implanted area with gauze, in order to avoid contact with dirty surfaces. This warning will also apply for the weeks following implantation.

DISPOSAL PROCEDURES

Attention! The disposable implanter presents a physical risk of **puncture and a risk of biological contamination.**
Delete it according to local regulations.

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7 MAINTENANCE POST PROCEDURE OF THE IMPLANT

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

8 IN THE EVENT OF AN ACCIDENT

In the event of a serious accident in relation to the Disposable, sterile Implanter device, please send a report:

- to MEDICAP S.r.l at the e-mail address info@biofibre.com
- the regulatory authority responsible for medical devices in your country.