INSTRUCTIONS FOR USE

Device name	Adjustable implanter
References	IR01PB, IR01T
Revision and date of instructions	Ed. I of 15/07/2021
Name and address of the manufacturer	Medicap Srl, Via A. Lincoln, 15 - 41012 Carpi (MO) - ITALY

1 GENERAL CHARACTERISTICS OF THE IMPLANTER ADJUSTABLE

The Adjustable Implanter is a reusable medical device used for the implantation of artificial hair manufactured by Medicap Srl. It is sold in single, non-sterile packaging.

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

SYMBOLS	MEANING
CE	CE marking
NON STERILE	Non-sterile device
REF	Catalog number
LOT	Lot code
	Manufacturing date
	Expiration date
	Keep away from light
	Keep dry
	Attention
	Consult the instructions for use
MD	Medical device
UDI	Unique device identifier. The UDI vector is placed on the left Below is entered the UDI in «HRI» format (Human Readable Interpretation)
	Manufacturer
MEDICAP CQ	Stamp certifying the execution of all the foreseen checks

2 PERFORMANCE OF THE IMPLANTER ADJUSTABLE

The Adjustable Implanter is a reusable instrument:

- developed to be used with the Needle for Adjustable Implanter manufactured by Medicap Srl;
- for the implantation of artificial hair manufactured by Medicap Srl

Its specific design allows to guide the Needle for Adjustable Implanter to hook the artificial hair manufactured by Medicap Srl and implant it in the patient's scalp, in particular on the galea capitis .

The adjustable implanter has been developed to be reused and re -sterilized several times.

3 INTENDED USE OF THE ADJUSTABLE IMPLANTER

The Adjustable Implanter can only be used for the implantation of artificial hair manufactured by Medicap Srl

The device can only be used by doctors authorized for the implant by Medicap Srl or by tutor doctors authorized by Medicap Srl

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

TARGET USERS

The users are doctors **trained** and **enabled** for the implantation technique by Medicap Srl or by tutor doctors authorized for the implantation by Medicap Srl

RECIPIENT PATIENTS

The Adjustable Implanter is 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 DISPOSABLE IMPLANTER IN THE IMPLANT PROCEDURE

PATIENTS AT RISK

Since the Adjustable Implanter is used exclusively for the implantation of synthetic hair manufactured by Medicap Srl, 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 suffering from 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 drug therapies for health reasons;
- are not available to follow the post-implantation protocol

GENERAL WARNINGS FOR THE USER

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

SPECIAL WARNINGS

The device is supplied non-sterile and must be sterilized before use by the user physician.
The user is fully responsible in case of use other than that indicated.
Only assemble the needle on the sterilized Adjustable Implanter .
Disposal of the device must be done in accordance with normal medical waste disposal procedures.

5 DEVICE SUITABILITY VERIFICATION

Before using the device (first use), it is necessary to recondition it according to the protocol provided by Medicap and check that all the components are present: button, tip, body and ferrule.

Before each implantation session, verify that the Adjustable Implanter has undergone a sterilization procedure. Medicap recommends the use of envelopes with chemical color indicators.
sterilization deadline has not passed.

6 METHOD OF USE

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

The Adjustable implanter is to be used exclusively for the implantation procedure of artificial hair manufactured by Medicap Srl. The implantation can be performed manually or assisted by the Automatic Biofibre Hair Device automatic machine (model IR01PB only). For 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 Implanter 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).

PREPARATION OF THE DISPOSABLE 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 needle for adjustable implanter, sterile;
6. insert the sterile needle into the tip channel so that the longer tip of the needle is opposed to the inclined plane of the tip; when at rest, the needle must protrude imperceptibly from the inclined plane of the tip;
7. screw the ring nut back onto the sliding channel without tightening it excessively, in order to avoid blocking the needle's sliding;
8. insert the tip into the body of the implanter and screw it back on.
9. perform needle adjustment

CORRECT POSITION OF THE IMPLANTER WITH RESPECT TO THE ARTIFICIAL HAIR

10. grab bag of synthetic hair ;
11. grasp the implanter , the inclined plane facing the palm of the hand holding it;
12. place the implanter perpendicular to the nodes of the fibers;
13. fully extend the needle.

CORRECT HOOK OF THE KNOT

14. hold the needle completely out;
15. lower the disposable implanter perpendicular to the node and insert the needle into the node of the fiber;
16. always keep the fiber in light traction to allow for the right hooking;
17. in this position the fiber must form an angle of approximately 45° with respect to the inclined plane of the disposable implanter .

FIBER ANGLE

18. the needle completely into the disposable implanter ;
19. maintain an angle of approximately 45° between the fiber and the inclined plane of the disposable implanter ;
20. the correctly hooked knot remains held by the hook.

INCLINATION OF THE FIBER

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

PLACEMENT OF THE NODE ON THE GALEA CAPITIS

23. fully push out the needle of the disposable implanter so that it reaches the *galea capitis* ;
24. while introducing the needle into the scalp, keep the instrument very still, without putting pressure on the skin;
25. 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

26. return the needle to its rest position ;
27. lift the disposable implanter from the implant area;
28. 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 PLANT

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.
Proceed immediately with the reconditioning of the Implanter according to the methods described in the protocol attached to the instructions.

DISPOSAL PROCEDURES

Attention! If it is necessary to eliminate the blood polluted implanter It will be necessary to proceed with its disposal according to the regulations in force relating to health waste.

7 POST- PROCEDURE INSTALLATION MAINTENANCE

In the days following the implant, the patient must follow the post-implant protocol prepared by Medicap Srl and provided by the implant center.

8 IN THE EVENT OF AN ACCIDENT

In the event of a serious incident that has occurred in connection with the Adjustable Implanter device, please to send a report:
- to MEDICAP Srl at the e-mail address info@biofibre.com
- with the relevant medical device regulatory authority in your country.