AUTOMATIC BIOFIBRE HAIR DEVICE

USER MANUAL

CE

AUTOMATIC BIOFIBRE HAIR DEVICE

is manufactured by

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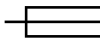
Read this manual carefully
before using
AUTOMATIC BIOFIBRE HAIR DEVICE

AUTOMATIC BIOFIBRE HAIR DEVICE

1 INDEX

2 LEGEND OF SYMBOLS USED IN THE MANUAL

	Fuse		General indications without danger to humans or objects
	Warnings (risk to people)		Press the button (ONE click)
	Warnings (device risk)		Keep the button pressed

3 INTENDED USE

This medical device is manufactured by Medicap S.r.l for Automatic Biofibre® implant (Automatic Biofibre®Hair Device) allowing a better performance for Biofibre® Implants - Biocompatible Artificial Hair.
Created to meet the demands of medical facilities that deal with hair implantation every day, Automatic Biofibre® Hair Device has several benefits that make it "a very valuable partner" for doctors.
In fact, thanks to constant pressure, the automatic implanter:

- allows an optimal result even after many hours of continuous activity;
- reduces implantation times and shortens the intervals between implant sessions;
- ensures perfect and tailored hair implant, for maximum patient satisfaction and for the prestige of the implant clinic.

4 WARNINGS

WARNING !

Use the device only in accordance with the intended use identified by the manufacturer; Medicap S.r.l. is not responsible for damage or injury caused by improper use of the device.

Only use the device with the original accessories listed in this manual and the spare parts supplied by the manufacturer. Failure to comply with these requirements may decrease the safety or effectiveness of the device.
Periodically check good condition of the supplied accessories; if they show damage, do not use them or try to repair them and contact Medicap S.r.l.
The device should only be used by trained medical personnel.
Modifications and alterations, even slight, release the manufacturer from any liability, voiding the warranty.
Make sure that the electric network complies with the power requirements required for the device, according to the indications given on the device label and in this manual.
Use a power cord certified for the country of use and periodically check its integrity.
Do not touch electrical outlets and adapters with wet hands.
Do not spill or introduce water or liquids on/into the device.
Do not disconnect the power cords before turning off the unit.
Do not connect or disconnect accessories while using the appliance or pull the power cord
Avoid exposed circuits.
Do not touch exposed connections or components.
Do not use in a potentially explosive atmosphere.
Do not use near radiofrequency devices.
Contact Medicap S.r.l. or its Distributor if the device does not work, even after following the instructions given in the PROBLEM SOLVER.

5 PRODUCT DESCTIPTION

OVERVIEW

- Control console equipped with side handles (figure 1).

Figure 1 Automatic Biofibre® Hair Device

FRONT

- Connection for frontal section accessories (Figure 2):
  - connection for the pedal on lower left;
  - handpiece cable connection on lower right.

Figure 2 Frontal view detail, insert the pedal on the left, insert the handpiece cable connection on the right

BACK

- Power cable connection;
- Main switch (ON/OFF)
- Device lable.

Figure 3 Back of the machine – unplugged

AUTOMATIC BIOFIBRE® HAIR DEVICE ACCESSORIES

N°	Automatic Biofibre® Hair Device Components	Photo and drawings	Quantity
1	Power cord (CA01)		1
2	Handpiece cable (CV01)		2
3	Pedal (PE01)		1
4	Ampoule to hold the implanter (AM01)		1
5	Handpiece (MA02A)		1

6 CHECKS BEFORE INSTALLATION

Before installing the machine, carry out the following checks:

After removing the packaging, check the integrity of the machine: in particular, that the machine is intact without visible damage that could be caused by transportation.

In case of doubt about integrity, do not use the device and contact the manufacturer. Do not leave the packaging material (plastic bags, cardboard, ...) within the reach of children and dispose them according to current regulations.

Make sure that the ground protection system is suitable and avoid connecting the device to an outlet to which one or more devices have already been connected using multiple or adapters.

Installation must be carried out according to the manufacturer's instructions. Wrong installation can cause damage to people or things, for which the manufacturer cannot be held responsible.

Avoid, as far as possible, installing the appliance near sources of water or liquids.
Avoid places subject to extreme temperatures, excess humidity or sudden changes in temperature.
Avoid direct exposure to sunlight.
Avoid places where large amounts of dust accumulate.

Pay close attention to the power and connection cables: excessively kinking or pulling them can cause damage.

DO NOT USE, even temporary, in places where fumes of flammable anesthetic mixture can occur with air or oxygen or with nitrous oxide.

All packing material must be stored and used in case the machine has to be returned.

7 DEVICE INSTALLATION

Hoe to operate the machine:

- Remove cardboard packaging;
- Place Automatic Biofibre® Hair Device on a flat surface;
- Connect the power cord;
- Connect the handpiece cable;
- Connect the pedal cable.

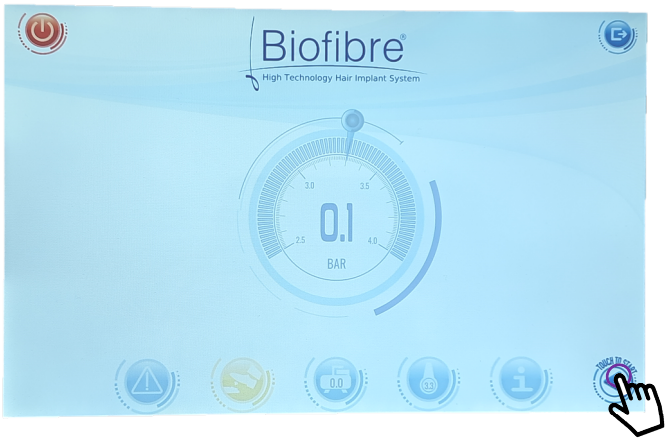
- Is twisted, return cables to their original condition, in order to facilitate implant procedure.

8 ISTRUCTIONS FOR USE

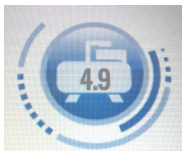
8.1 STARTING THE MACHINE

Turn on the machine. 

Press **"Touch to start"** to enable machine operation.



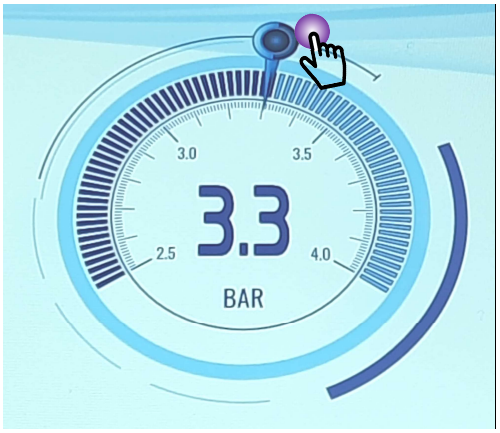
The compressor will start charging up to 5.0 bar. The progress of the charge level will be shown on this icon:



The machine is now ready to operate, the manufacturer supplies the device with the adjusted pressure of 3.3 Bar.

In case of patients with scars, it is possible to raise the working pressure till 4.0 bar.

To adjust working pressure, move the cursor with your finger till reaching the desired pressure level; once the cursor is released, the pressure level will be stored.

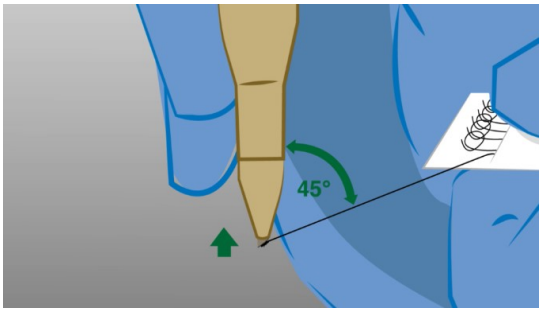


IMPORTANT ! During machine operation, when pressure reaches 0.1 bar above the set point, the compressor starts and recharges till reaching 5 bar. (For example: if the set point is 3.3 bar, once the pressure reaches 3.4 bar, the compressor starts again).

8.2 IMPLANT

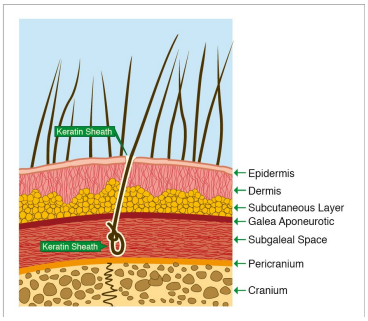
Handle the hand piece and the pedal with care to avoid injuries caused by the needle.

Press the pedal to extract the needle and take the fiber knot with the hooked needle, then release the pedal to retract the needle (Biofibre remains hooked to the needle).



Place the implanter on the spot where the fiber has to be implanted and press the pedal to let the needle penetrate the scalp.

Release the pedal, the needle goes back inside the implanter.



Repeat the procedure until the end of the planned implant session.

8.3 PLACE THE SYSTEM ON PAUSE AND TURN OFF THE MACHINE

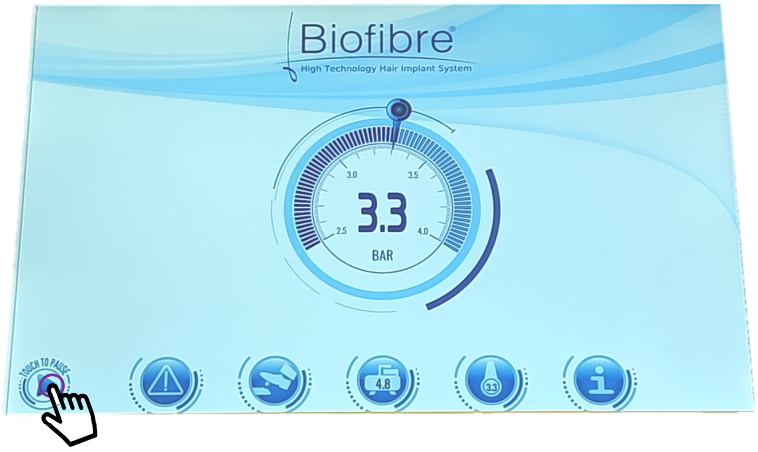
In order to temporarily stop the machine, Medicap recommends to pause the system (standby).

In case the machine needs to be re-used during the same day, Medicap recommends to temporarily turn off the system.

In case of prolonged non-use, turn off the switch.

8.3.1 ENTER IN PAUSE / RESTART THE SYSTEM

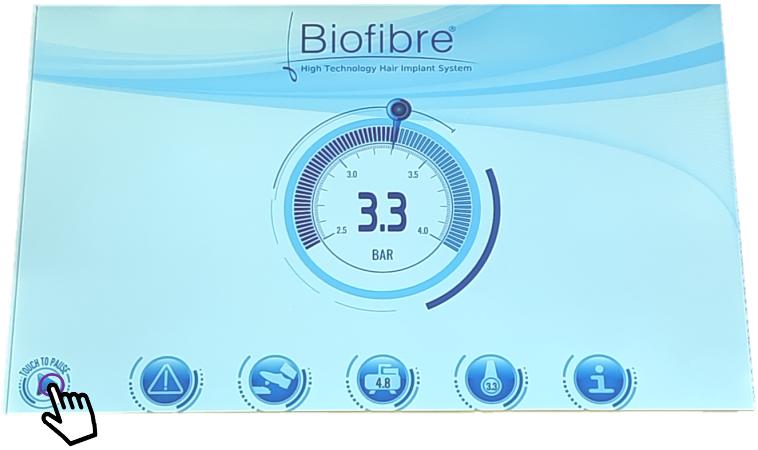
Press **"TOUCH TO PAUSE"** in order to pause the machine.



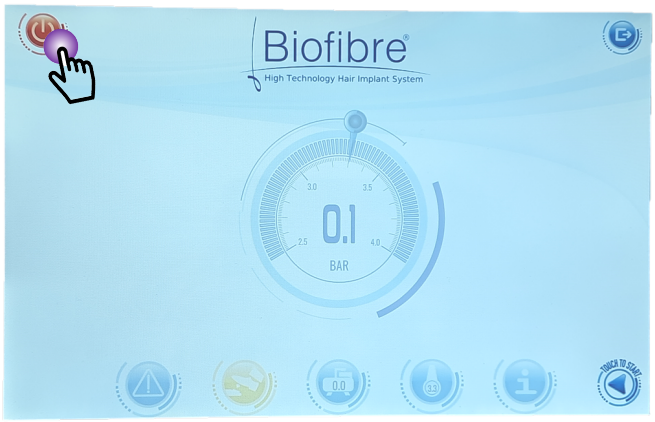
Press **"TOUCH TO START"** to re-start another cycle

8.3.2 TURN ON / TURN OFF THE SYSTEM (ON THE SAME DAY)

Press **"TOUCH TO PAUSE"** in order to pause the machine.



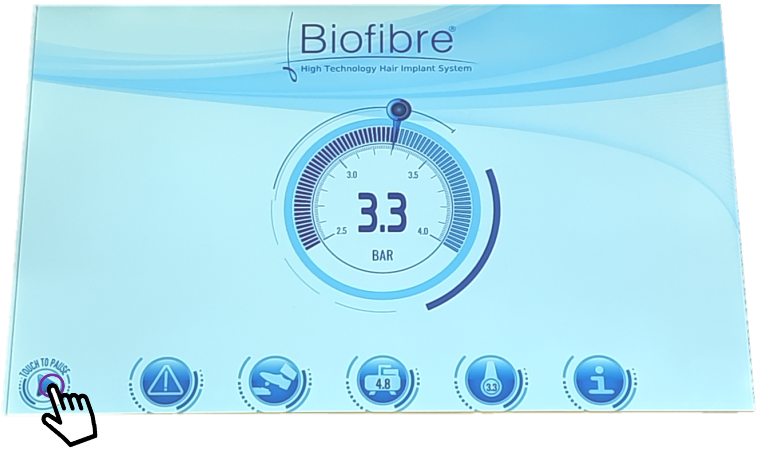
Press **"OFF"** for about 2 seconds to turn off and unload the device.



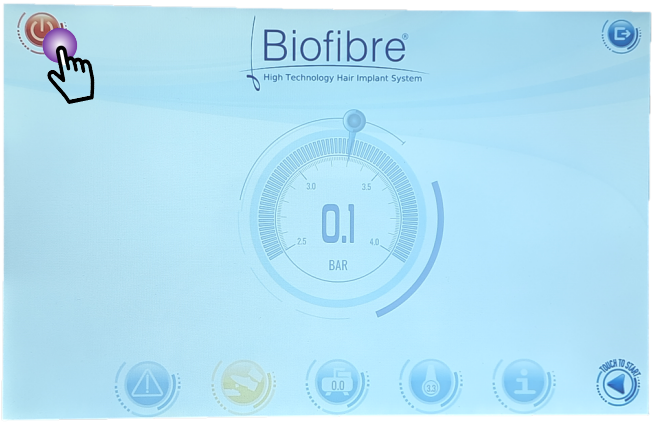
Press the white button on the left of the machine to turn the system on 

8.3.3 TURN OFF THE MACHINE (PROLONGED USE)

Press **"TOUCH TO PAUSE"**



Press **"OFF"** about 2 seconds to turn off and unload the device.



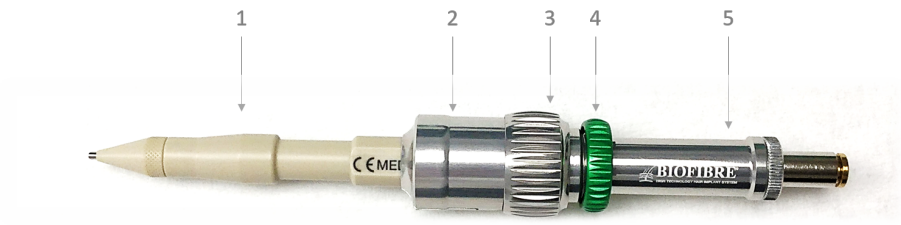
Switch off the device by pressing "0" on the back button switch 

WARNING !

The electric power is turned off only with the "I / O" button
Turn off the button before removing the electrical plug 

9 INJECTOR

The injector is made of 2 parts: the handpiece and the implanter - both patented.



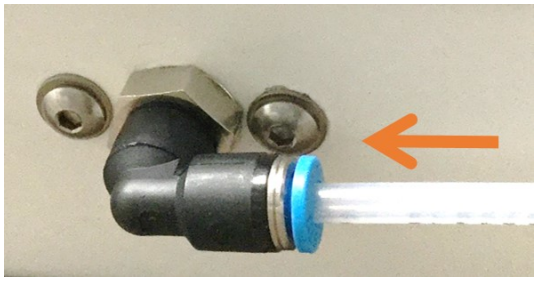
1 **Implanter**
2 Support/Holder
3 Ring nut 1
4 Ring nut 2
5 Injector chamber

Handpiece

9.1 HOW TO FIT THE INJECTOR

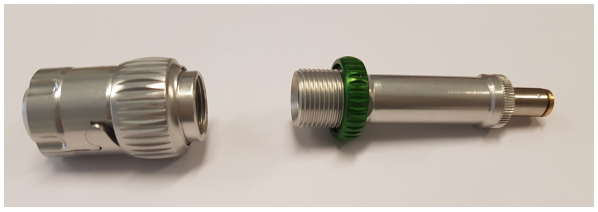
- Firmly push the cable inside the outlet placed at the bottom of the handpiece.

- Firmly push the other side of the cable inside the outlet placed on the front of the device

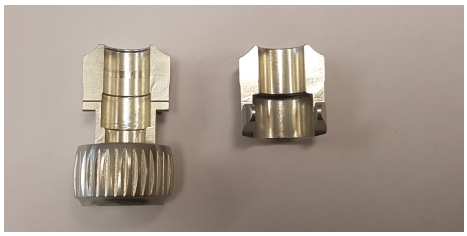


9.2 REPLACEMENT OF THE IMPLANTER INSIDE THE HANDPIECE

Unscrew (green) ring nut 2 to unlock and remove the holder from the injector chamber.



Unscrew (gray) ring nut 2 to open the two holder sections.

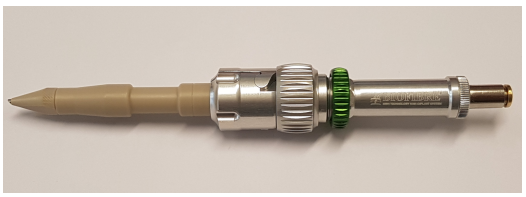


Insert the implanter into the holder, by fitting it to the holder cavity.

The button has to touch the bottom part of the holder; the upper part of the holder has to reach the implanter groove between letters E and D in MEDICAP writing.

Readjust the two holder sections.

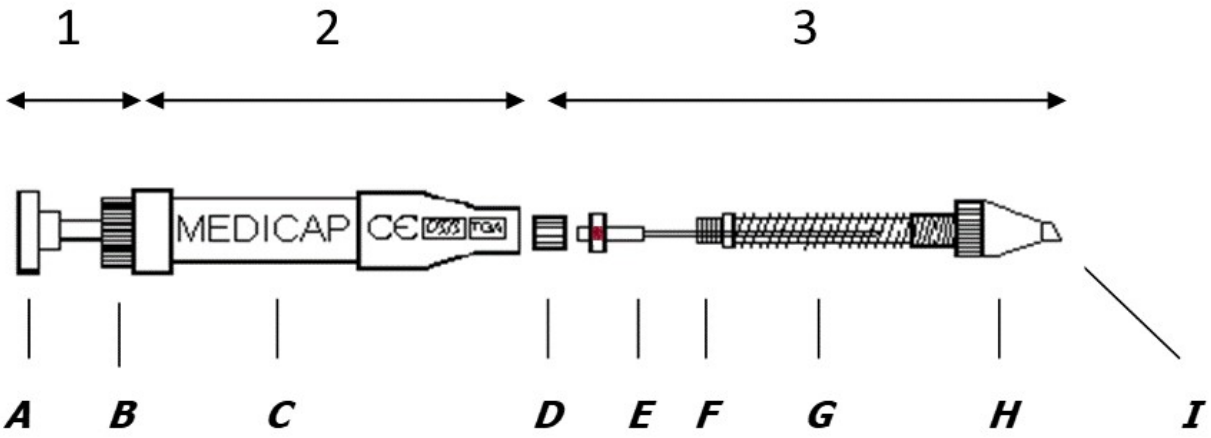
Screw ring nut 1 to fix the 2 sides of the holder
Screw the holder in the injector chamber



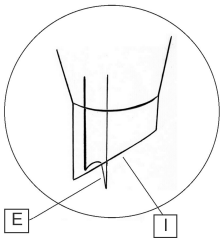
Adjust the correct position of the needle hook, with respect to the inclined plane of the implanter head, by unscrewing ring nut 2 and turning the injector chamber clockwise or anticlockwise.

Once properly adjusted, ring nut 2 has to be totally screwed up to fix correct position.

10 NEEDLE REPLACEMENT



- Unscrew the head **3** and remove it completely from the body of the implanter **2**
- Unscrew the ring nut **D** and remove the needle **E**
- Insert sterile needle in the sliding groove **F** so that the longest side/tip of the needle is opposite to the inclined plane **I** of the head*
- Without pressing the button A, the tip of the needle **E** should just emerge from the inclined plane **I** of the head



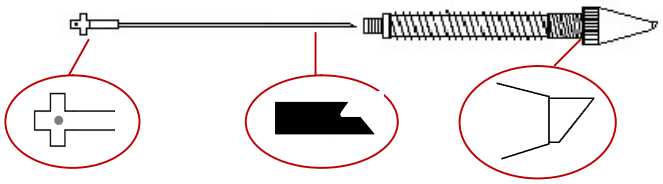
- Screw up the ring nut **D** to the sliding groove **F** without tightening excessively, in order to avoid blocking the needle
- Insert head **3** in the body of the implanter **2** and screw it up

AUTOMATIC BIOFIBRE HAIR DEVICE

A recognition sign/dot was placed on the cross needle guide to facilitate the replacement of the needle in the adjustable implanter. Replacement of the needle can be done in 3 ways:

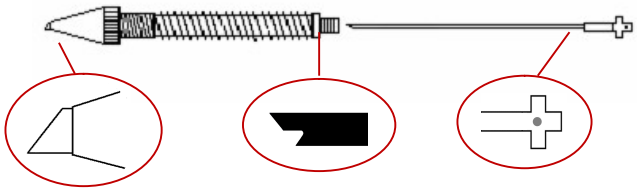
- Insertion of the needle into the implanter by holding the needle in the left hand and the implanter in the right hand: the long end of the needle is at the bottom and the long part of the head's inclined plane should be upwards.

  Needle sign/dot will be facing you.



- Insertion of the needle into the implanter holding the needle in the right hand and the implanter in the left hand: the long end of the needle is at the top and the long part of the head's inclined plane should be facedown.

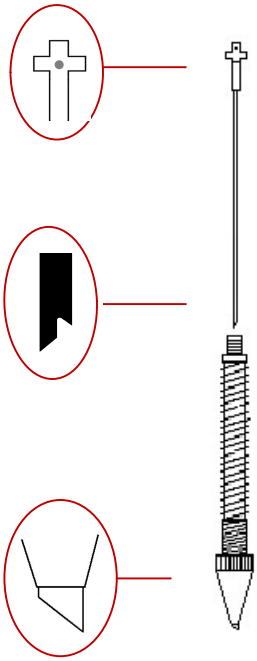
  Needle sign/dot will be facing you.



- **PREFERABLE NEEDLE INSERTION POSITION!**

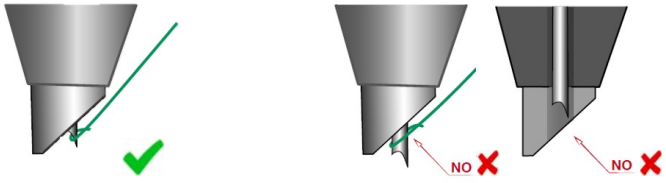
  Insertion of the needle into the implanter with the needle and implanter in an upright position: the long end of the needle is on the left and the long part of the head's inclined plane should be given to the right.

  Needle sign/dot will be facing you.



IMPORTANT !

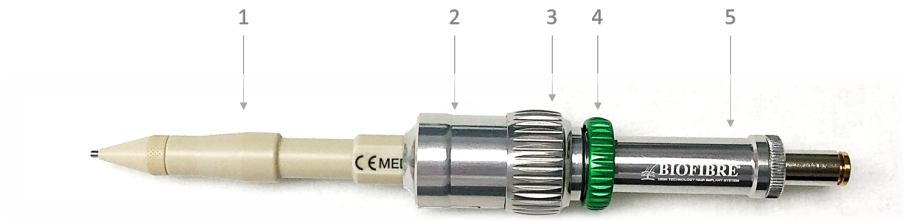
The knot is not held by the hook if the needle is placed in the opposite sense and if the hook emerges too far or too little from the inclined plane



11 CLEANING AND STERILIZATION

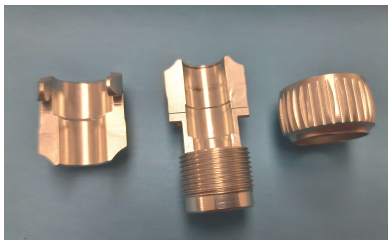
To restore the necessary hygienic conditions of the instruments. cleaning and sterilization are necessary at the end of each implant session.
The adjustable implanter must be cleaned of all traces of blood, washed, disinfected, rinsed and sterilized.
The **handpiece holder** must be cleaned of all traces of blood, washed, disinfected and rinsed.
The **injector chamber** must be disinfected with disinfecting wipes.

- The tip of the implanter and the support must be cleaned quickly by soaking them in hydrogen peroxide;
- **Blood shall not dry inside the implanter, or it will be difficult to clean it properly which will compromise the proper functioning of the implanter itself.**

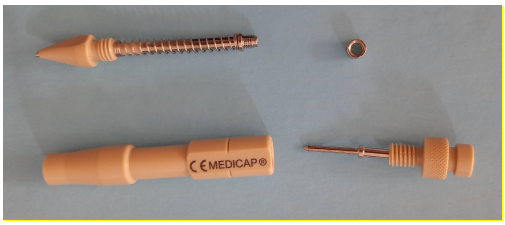


1 Implanter
2 Support/Holder
3 Ring nut 1
4 Ring nut 2
5 Injector chamber

- Unscrew the injector chamber (4 and 5) and disinfect with disinfecting wipes;
- **Never soak the injecting chamber in water or cleaning solutions to avoid damaging its internal parts.**



- Fully unscrew the injector chamber support (2 and 3);
- Pour around 100ml of peroxide oxide 3% (10 volumes) in a glass bowl;
- Soak support components in this solution to remove potential blood residues;
  Soak for 5 minutes;
- Carefully rinse each components under drinkable water for 2.3 seconds;
  Dry the components on a sterile gauze for at least 30 minutes.



- Disassemble the implanter and eliminate the needle.
- Recondition the adjustable implanter by following the instructions reported hereafter (see also our Medical Protocol).

12 WARNINGS FOR REUSE OF ADJUSTABLE IMPLANTER

(ACCORDING TO UNI EN ISO 17664:2005)

Device **Adjustable Implanter**

Manufacturer
Medicap S.r.l.
Via A. Lincoln, 15
41012 Carpi (Mo) – Italia
info@biofibre.com

Method Sterilization by saturated steam

Symbol

WARNING:	The adjustable implanter has a specific intended use. Any other improper use can cause rapid deterioration of the instrument.
Limitations on reprocessing:	Reprocessing has a negligible effect on the device. The shelf life of the implanter is determined by any damage caused by its incorrect use and wear.
ISTRUCTIONS	
Point of use:	It is recommended to clean the implanter right after its use or as soon as possible.
Containers and transportation:	No particular requisite.
Preparation for cleaning:	Rinse the instrument under warm water to remove blood residues and verifying that the sliding canal is not clogged up. If cleaning is not done correctly after rinsing, the instrument must be submerged in a pH neutral solution of water and detergent.
Automated cleaning:	The implanter can be cleaned with an ultrasound basin: disassemble all the components of the implanter (see point A), eliminate the needle which was used and submerge all instrument components in an ultrasound basin for as long as recommended by the manufacturer (usually 5-7 minutes). Parts shall be completely covered by the cleaning solution. The cleaning solution must be changed often, or according to the manufacturer instructions. After ultrasound cleaning of components, rinse them carefully with running water in order to clean them from any residue from the cleaning solution.
Manual cleaning:	If cleaning with ultrasound is not possible, it is suggested to: • use sterile rigid brushes made of plastic or nylon (do not use steel wool or metallic brushes); • only use pH neutral detergents; • carefully brush all instrument components, by taking care that all surfaces are perfectly cleaned and rinse the components under running water.
Disinfection:	After cleaning and drying, submerge the device components in a disinfecting solution, by following instructions reported on the corresponding label. Once the submerging time has elapsed, rinse components with sterile distilled water.

Drying:	After rinsing, before individually packaging for sterilization, component parts of the implant instrument must be perfectly dried with a paper towel that leaves no residue.
Maintenance:	Proceed by reassembling the implanter and checking that all components are present (see point B).
Inspection and function testing:	Check if damage and signs of wear are visible.
Packaging:	Package the implanter individually in medical type pouch, which are designed for steam sterilization. The instrument shall not stress on the sealing borders.
Suggested sterilization:	It is suggested to sterilize with autoclave by saturated steam: • follow the instructions supplied by the autoclave manufacturer; • do not overload the sterilization chamber as steam might not do through correctly; • the sterilization cycle validated by Medicap foresees the following minimum parameters: temperature 121° C (+3° C), pressure 1.06 bar, length 16 minutes. Other sterilization cycles may also be used, by following the autoclave specification. • to avoid burns be careful when taking out the implanter from the sterilization chamber or wait that it cools down.
Storage:	Keep the device in a sterile package in a clean environment, away from heat and humidity. Do not use the device if package is damaged.
Additional information:	Periodically check that the equipment used (e.g.: ultrasound and autoclave) are functioning correctly.
Manufacturer contact:	For any information please contact Medicap Ltd.: phone 0039/059/692142 – fax 0039/059/642400 – e-mail: info@biofibre.com

Above provided instructions were validated by the medical device manufacturer as the one being capable of preparing a medical device for re-use. It is the responsibility of the processor to ensure that the repeated processing are actually performed by using equipment, materials and personnel to achieve final result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

13 MAINTENANCE

13.1 CLEANING THE DEVICE

Use a cloth dampened with a mild detergent, it is not necessary to rinse but it is appropriate to dry.

DO NOT use aggressive detergents, acids, solvents, abrasives, steel wool, sprays or alcohol.

Protect the device from improper use.

Do not leave the appliance exposed to excessive dust or temperatures below -20 ° C (if stored at temperatures below -20° C, it must be placed in an environment at 20-25° C for 1 to 2 hours before use).

Any intervention on Automatic Biofibre® Hair Device must always be performed when the machine is switched off, and only after unplugging the power cord from the electrical outlet.

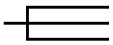
Maintenance operations affect the compliance of cables, fuses and power source. Faults can be caused by knotted / twisted and / or accidental fall of the hand piece.

13.2 ASSISTANCE

13.2.1 FUSESE

If the device does not turn on after verifying the integrity of all connections and position "1" of the main switch light, check the **fuses** located in the fuse box placed inside the power supply socket.

Fuses replacement must take place when the machine is turned off.



Fuses are 2 x 2.5A 250 V.

How to replace fuses:

- Open the source supply socket with a screw driver
- Pull out the fuse box and open the cover
- Change the fuses
- Close the cover and push the fuse box inside the socket
- Screw up the power supplly socket

13.2.2 FURTHER ASSISTANCE

Contact Medicap S.r.l. or your distributor for further assistance or repair on the device.

14 LABELLING

14.1 IDENTIFYING LABEL

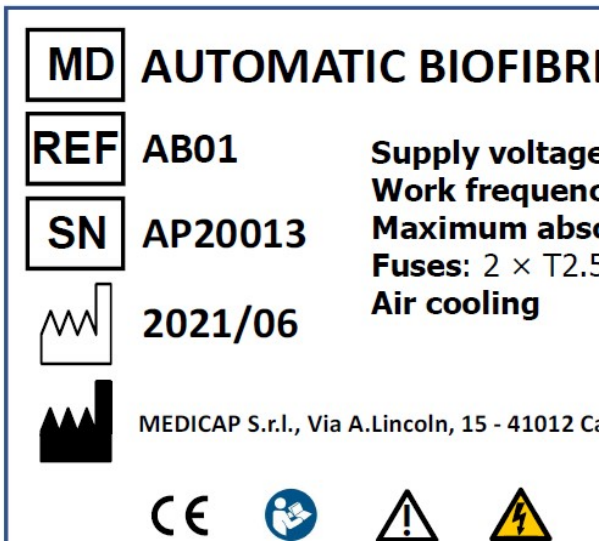


Tabella 1 spiegazione dei simboli riportati in etichetta

MD	**M**edical **D**evice	REF	***REF**erence*
SN	**S**erial **N**umber		Manufacturing date
	Manufacturer	CE	Complies with regultion (EU) 2017/745
	Leggere le istruzioni per l'uso		Warning
	Warning, high voltage		BF type applied part
	Prohibition to dispose as urban waste	UDI	**U**nique **D**evice **I**dentification

14.2 IDENTIFYING LABEL FOR ACCESSORIES

AUTOMATIC BIOFIBRE HAIR DEVICE *COMPONENTE AMOVIBILE / REMOVABLE COMPONENT* REF **CV01** **Cavo *per manipolo*** ***Handpiece cable*** **Q.tà / *Q.ty 2*** Medicap S.r.l - ITALY	**AUTOMATIC BIOFIBRE HAIR DEVICE** *COMPONENTE AMOVIBILE / REMOVABLE COMPONENT* REF **CA01** **Cavo di alimentazione** ***Power Cable*** **Q.tà / *Q.ty 1*** Medicap S.r.l - ITALY	**AUTOMATIC BIOFIBRE HAIR DEVICE** *COMPONENTE AMOVIBILE / REMOVABLE COMPONENT* REF **MA02** Manipolo / *Handpiece* Q.tà / *Q.ty 1* Medicap S.r.l - ITALY
AUTOMATIC BIOFIBRE HAIR DEVICE *COMPONENTE AMOVIBILE / REMOVABLE COMPONENT* REF **AM01** **Ampolla supporto per implanter** ***Ampoule to hold the implanter*** **Q.tà / *Q.ty 1*** Medicap S.r.l - ITALY	**AUTOMATIC BIOFIBRE HAIR DEVICE** *COMPONENTE AMOVIBILE / REMOVABLE COMPONENT* REF **PE01** Pedale / *Pedal* Q.tà / *Q.ty 1* Medicap S.r.l - ITALY	

15 TECHNICAL FEATURES

- Power supply: 100/240Vac 50/60Hz
- Absorption: 150W
- Panel control Voltage: 24Vdc
- Pressure (max): 5,0 Bar
- Fuses: 2 x 2.5A 250 V
- Safety Class: I
- Height (base included): 230mm
- Lenght: 380mm
- Width: 480mm
- Weight: 14kg
- Internal pressure: 5 bar
- Working pressure: 3.3 bar*
- Working frequency: 50 Hz/60 Hz

* the most suitable pressure for use can be chosen by the doctor, but the device is supplied with pressure set at 3.3 bar.

16 ENVIRONMENTAL USE CONDITIONS

Temperature: from 5°C to 40°C.
Relative humidity: from 10% to 80% without condensation.

17 STORAGE CONDITIONS

Temperature: from -20 °C to +60 °C.

18 INFORMATION ON ELECTROMAGNETIC COMPATIBILITY

Guide and manufacturer's declaration – electromagnetic emissions		
Automatic Biofibre Hair Device is intended for use in the electromagnetic environment specified below. The customer or the user of the AUTOMATIC BIOFIBRE HAIR DEVICE should assure that it is used in such kind of environment.		
Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	AUTOMATIC BIOFIBRE HAIR DEVICE uses RF energy only for its internal operation. As a result, its RF emissions are very low and is likely to cause no interference in nearby electronic devices
RF emissions CISPR 11	Class A	AUTOMATIC BIOFIBRE HAIR DEVICE is suitable for use in all environments other than domestic and those directly connected to the public low-voltage power supply that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration – electromagnetic immunity			
AUTOMATIC BIOFIBRE HAIR DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of the AUTOMATIC BIOFIBRE HAIR DEVICE should assure that it is used in such kind of environment			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD)	contact ± 8kV	contact ± 8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
IEC 61000-4-2	air ± 2; 4; 8; 15 kV	air ± 2; 4; 8; 15 kV	
Electrical fast transient/burst	±2kV for power supply lines	± 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	± 1 kV for input/output lines	± 1 kV for input/output lines	
Surge	± 1kV lines to lines	± 1kV lines to lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	± 2kV lines to earth	± 2kV lines to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines	0% U_T for 0,5 cycle	0% U_T for 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Automatic Biofibre Hair Device intensifier requires continued operation during power mains interruptions, it is recommended that the Automatic Biofibre Hair Device Image Intensifier be powered from an uninterruptible power supply or a battery. Power frequency.
	0% U_T for 1 cycle	0% U_T for 1 cycle	
IEC 61000-4-11	70% U_T for 25 cycles	70% U_T for 25 cycles	
	0% U_T for 250 cycles	0% U_T for 250 cycles	
Power frequency (50/60Hz) magnetic field	3 A/m	Not applicable, the device does not contain components susceptible to magnetic fields.	Network frequency magnetic fields should have characteristic levels of a typical location in a commercial or hospital environment.
IEC 61000-4-8			
NOTE U_T is the mains voltage a.c. prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity				
AUTOMATIC BIOFIBRE HAIR DEVICE is intended for use in the electromagnetic specified below environment. The customer or the user of the AUTOMATIC BIOFIBRE HAIR DEVICE should assure that it is used in such an electromagnetic environment. Portable and mobile RF communications equipment should not be used closer to any part of AUTOMATIC BIOFIBRE HAIR DEVICE, including cables, than the recommended separation distance calculated with the equation applicable to the transmitter frequency.				
IMMUNITY test	IEC 60601 TEST LEVEL		Compliance level	**Recommended separation distance d:**
RF Conducted IEC 61000-4-6	3 Veff 150kHz to 80 MHz		3 Veff	**d**= 30 cm
RF Irradiate IEC 61000-4-3	3 V/m from 80 MHz to 2,5 GHz		3 V/m	**d**= 30 cm
Immunità a campi di prossimità da dispositivi di comunicazione RF wireless IEC 61000-4-3	TETRA 400 380 – 390 MHz	27 V/m	27 V/m	**d**= 30 cm
	GMRS 460 FRS 460 430 – 170 MHz	28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz	28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz	9 V/m	9 V/m	

Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range. [b]

Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the AUTOMATIC BIOFIBRE HAIR DEVICE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

WARNING !

Use of this equipment near to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING !

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Automatic Biofibre Hair Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.