SUMMARY ON SAFETY AND CLINICAL PERFORMANCE (SSCP)

SSCP INTENDED FOR PATIENTS

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This Summary on Clinical Safety and Performance (SSCP) is intended to provide public access to an up-to-date summary of the device's clinical safety and performance key aspects. The information presented below is intended for patients or non-professionals. A more extensive summary of its safety and clinical performance is available for healthcare professionals. The SSCP is not intended to provide general advice on treating a medical condition. Please contact your physician if you have any questions about your medical condition or the use of the device in your specific situation. This SSCP is not intended to replace the implant bearer card, or the Instructions for Use intended to provide information on the safe use of the device.

1 DEVICE IDENTIFICATION AND GENERAL INFORMATION

Table 1 Device identification and general information

Trade name (s) of the device	Biofibre / Medicap High Density
Name and address of the manufacturer	Medicap Srl Via A. LINCOLN, 15 - 41012 CARPI (MO) - ITALY
Basic UDI-DI	0805715896TF01
Year in which the first (CE) certificate on the device was issued	1996 under Medical Devices Directive 93/42/EEC

2 INTRODUCTION TO THE MEDICAL DEVICE AND ITS INTENDED USE

From the analysis of the current knowledge on alopecia it is known that:

- there are very different categories of alopecia, with different clinical conditions (see figures 1 and 2);
- there are very different risk factors;
- alopecia can be psychologically harmful and cause intense emotional suffering;
- there are three families of alopecia solution:
    - medical treatment;
    - hair transplant;
    - hair implant.

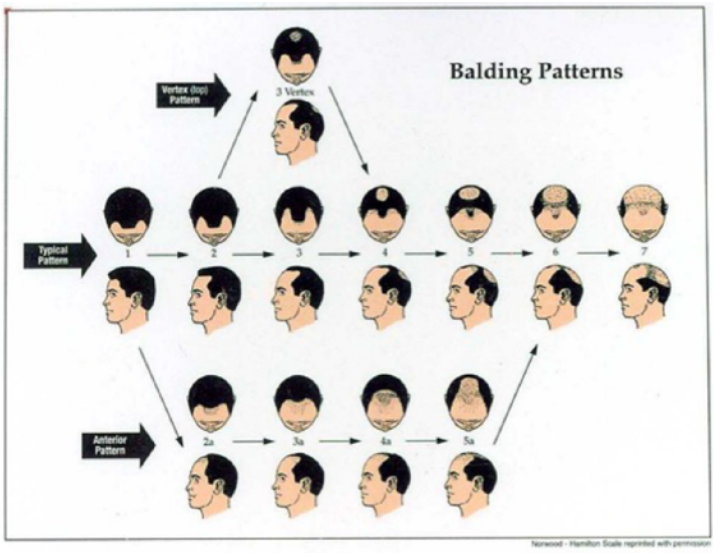


Figure 1 Hamilton-Norwood classification of male alopecia

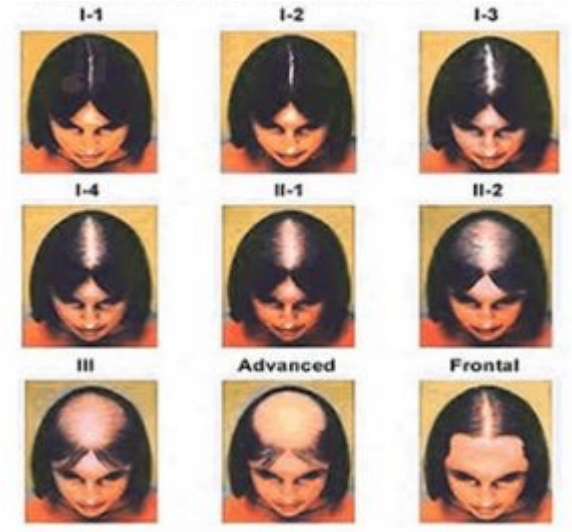


Figure 2 Ludwig scale classification of hair loss progression in female pattern

The experience of alopecia can be psychologically damaging, cause intense emotional distress, and lead to personal, social, and work-related problems.

People with severe hair loss are more likely to experience psychological distress and have lower self-esteem.

3 INTENDED USE OF THE DEVICE

Table 2 Device identification and general information

Intended purpose	Biofibre & Medicap High Density are indicated to temporarily cover thinning and/ or bald areas of the scalp
Indication (s) and target population (s)	Biofibre® & Medicap® High Density medical devices are intended for implantation only on adult patients of both sexes. Medical devices can satisfy any geographic taxonomy.
Contraindications and / or limitations	The devices are not indicated in case of reversible alopecia and for eyebrows , mustache, beard, chest and pubis thickening.

4 DEVICE DESCRIPTION

Biofibre and Medicap High Density are:

- implantable artificial hair;
- biocompatible;
- sterile;
- manufactured in polybutylene polyamide 6, yellow pigment 110, iron oxide, carbon black, titanium dioxide (only light colors) and additives (antioxidant and u.v filter).

Biofibre and Medicap High Density exist in different lengths, colors and shapes.

Figure 3 Biofibre colors and shapes

The following photos show the implant effect on different patients.

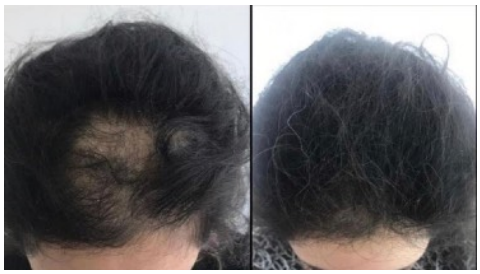


Figure 4 No. 500 Biofibre implanted on female

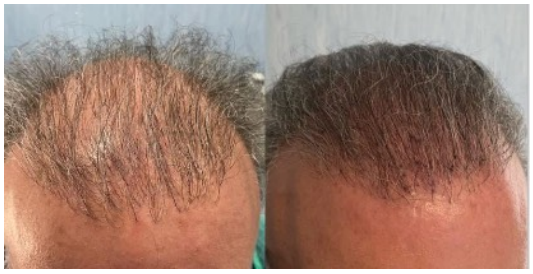


Figure 5 No 1000 Biofibre implanted on male who already had HT

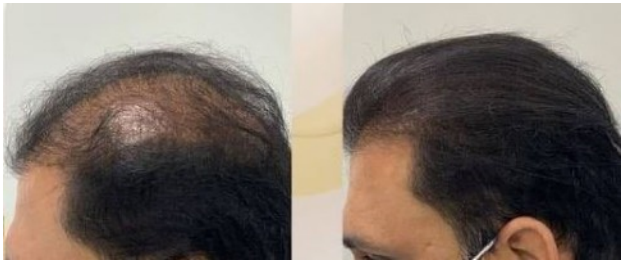


Figure 6 No 1500 Biofibre implanted on male

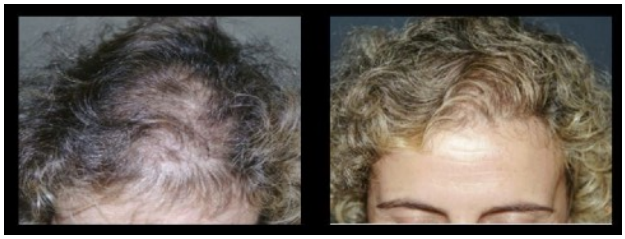


Figure 7 No 1500 Biofibre wavy implanted on female

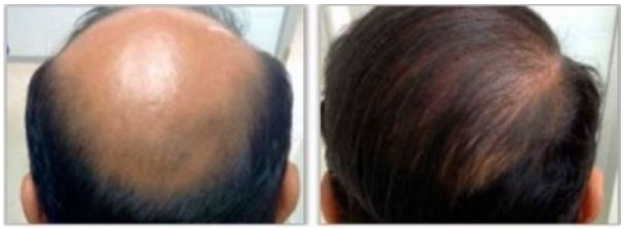


Figure 8 No 2500 Biofibre implanted on male

Figure 9 No 3500 Biofibre implanted on male

5 RISKS AND WARNINGS

Moderate scalp discomfort and swelling up to a few hours after implantation is possible as a normal consequence of the procedure and anesthesia.

After the implantation of Biofibre® or Medicap® High Density, some phenomena may occur in the scalp. These are infectious phenomena 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 performed therapeutic treatments, 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 even 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.

In addition, the use of prohibited substances or treatments with excessive heat can cause changes to the appearance of Biofibre® & Medicap® High Density (curling, dryness, breakage). Follow the post-implantation protocol carefully.

Contact your doctor if you think you have any side effects related to the device or its use, or if you are concerned about the risks. This document is not intended to replace a consultation with your doctor if necessary.

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

- to MEDICAP S.r.l, e-mail address: info@biofibre.com
- to the regulatory authority responsible for medical devices in your country (outside the EU),
    - for Australia, repot to https://www.tga.gov.au
    -

6 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

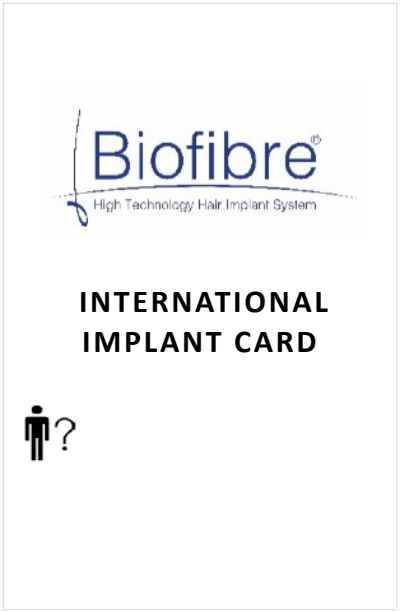
The materials used to manufacture Biofibre® and Medicap® High Density devices have a history of clinical use in implantable medical devices.
Biofibre and Medicap High Density medical devices have passed the biocompatibility tests required by current regulations.
Medicap carried out a clinical evaluation, considering the clinical data of Biofibre and Medicap High Density CE0373 certificate under medical device directive 93/42/CEE.
The clinical data demonstrate artificial hair performance to help people against the effects of alopecia and alleviate their psychological condition.
The latest studies demonstrate the success of the implant for 98% of patients with 95% satisfaction.
The degree of maintenance of the implants is over 90% per year for most patients.
The safety data, collected on Biofibre and Medicap High Density and on similar medical devices on the market, did not highlight any safety risks related to their use, other than those foreseeable, considered and minimized.
Compliance with the implantation protocol, adequate post-implantation follow-up and compliance with post-implantation protocol by the patient are necessary to obtain satisfactory long-term results.
Medicap Srl carries out at least one post-market clinical follow-up per year through the collection of production and post-production information, to obtain information on the use of the devices and collect significant information on their safety.

7 POSSIBLE THERAPEUTIC ALTERNATIVES

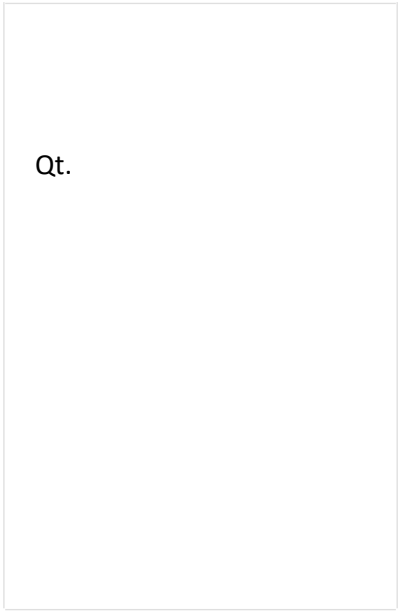
There is no validated medical treatment for alopecia.
Hair transplantation could be a solution, but it is limited to some types of alopecia and the quality of the donor transplant.
Contact your healthcare provider to assess your individual situation.

8 IMPLANT BEARER CARD

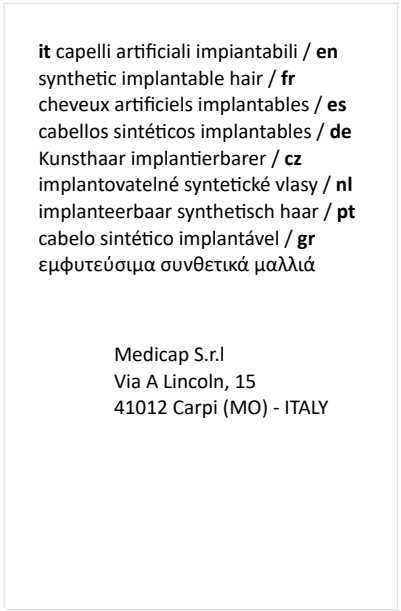
After treatment, the doctor provides the patient with an implant bearer card.
The patient must keep the individual implant card with him, as essential information about the implant is recorded.
The purpose of the implant card is to allow the user to identify the implanted device and to access other information regarding it, but also to allow the emergency clinical staff or first responder to be informed about special care/needs in the event of emergency situations.
Below is the drawing defined by Medicap Srl, and the symbols' legend.



Implant card Front



Implant registration space (x6)



Back of the implant card

Legend

SYMBOLS	MEANING
	Patient's name
	Name and address of the health facility
	Name and address of the manufacturer
	Website with information for patients

SYMBOLS	MEANING
	Date of implantation
Qt.	Amount