GB: Dental prosthetic components for transient use and for laboratory
Dental prosthetic components for short term use

1. PRODUCT IDENTIFICATION
The products covered by this instructions for use are dental prosthetic components for transient use, short-term use and for temporary use such as analogues, transfers, related screws, transgingival healing caps and laboratory scan transfers for CAD CAM technique relating to the implant systems manufactured by Sweden & Martina.
The devices forming the subject matter of these user's instructions must be used with other prosthetic components or implants manufactured by Sweden & Martina. Use of non-original components limits the responsibility of Sweden & Martina S.p.A. and renders the product warranty void (see the "Responsibility for defective products and warranty terms" section below).
Prosthetic components must be fastened to the implants or analogues using dedicated instruments. Always use original screwdrivers/driver accessories manufactured by Sweden & Martina. Sweden & Martina declines all responsibility for use of any non-original instruments.
2. DESCRIPTION
The prosthetic components covered by this Instructions for Use are the following:
a. implant analogues (not for single use)
Used to reproduce, in laboratory cast models, the exact position of the implant connection transferred via the transfers. They faithfully reproduce the entire implant platform. Some analogues reproduce the connection platform and, in case of certain prosthetic solutions (e.g. ball attachments, abutments, solid one-piece abutments, etc.) some analogues reproduce the position of the prosthetic component. Consult product catalogues for full details. Implant analogues are colour-coded according to the implant code, to facilitate platform identification.
b. Transgingival healing caps (not for single use)
Small, direct screw-retained posts, that are usually short (1 to 7 mm long, depending on the implant system) and are used to recondition the mucosa's protrusion profile, prior to restoration loading. They are invasive, surgical devices designed for long-term use. The transgingival healing caps can be identified by a laser-etched marking indicating the diameter, protrusion profile (if other than cylindrical) and height).
c. Transfers for impression taking (model for open tray, pull up and closed tray techniques) (not for single use)
Used to transfer the exact position of the implant connection, in terms of height, inclination and indexing, from the mouth to the study model.
There are different types of transfer for the closed tray, open tray and pull-up techniques. Some transfers are used to transfer the position of the implant platform, others to reproduce the position of the restoration components that are screwed into the implants. They are supplied complete with the screws required for fastening to the dental implants.
This category also includes impression taking caps used to transfer the position of posts or closed tray transfers to the laboratory. Not all solutions are available in all implant systems. Consult the individual catalogues for details on availability.
d. Transfer screws (not for single use)
Screws used to fasten the transfers to the implants during impression-taking and, subsequently, to fasten them back onto the plaster analogues. They are sold both together with the transfers and individually, as a spare part.
Since they are used with transfers, they are classified as a medical device accessory.
e. Echo laboratory transfers for cad-cam technique scanning (not for single use)
These elements are made of ERGAL 7075 aluminium alloy, since they are designed for use on study models rather than contact with the patient and ERGAL guarantees extreme precision. Once the ERGAL surface has been sandblasted, its opacity is ideal for precision detection with the optical scanners used to detect 3D solid models in CAD techniques. They are provided complete with their fastening screws.
3. INTENDED USE
Sweden & Martina declares that it is the manufacturer of the prosthetic components for Sweden & Martina dental implants and identifies their risk class as indicated in table 01. For non-disposable components, the maximum permitted use is ten uses.
The product must only be used and handled by dentists and dental technicians with the necessary qualifications and professional experience.
4. IDENTIFICATION OF THE MANUFACTURER

Device	Pack
Laboratory transfers for cad and cam techniques	Not for single use, complete with relative fastening screws
Transfer screws	Not for single use, not sterile
Analogues	Not for single use, not sterile
Spare castable sleeves and pre-made castable bars/ ball connections	Not for single use, not sterile, without fastening screws

The manufacturer of the prosthetic components for dental implants dealt with in these User's Instructions is:
Sweden & Martina S.p.A.
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e-mail: info@sweden-martina.com - www.sweden-martina.com
5. RAW MATERIALS USED
The materials used to manufacture the prosthetic components for Sweden & Martina dental implants were selected according to the properties indicated for their intended use in accordance with Regulation (EC) 2017/745.
They are manufactured, depending on the type of component, using:
- Aluminium alloy, abbreviated to ERGAL (prosthetic components such as ECHO transfers for CAD and CAM techniques)

The materials satisfy harmonised standards.
The restoration components manufactured by Sweden & Martina do not contain any material of human or animal origin or phthalates.
Remember to ask patients whether they are allergic to any of the substances used.
Although very rare, titanium allergy is possible. Patients should therefore always be asked whether they are allergic to this material before use.
6. WARNINGS
Modern implantology, with immediate or delayed loading, is a well-tested and reliable discipline able to solve almost all edentulism problems, both functional and cosmetic. Restoration can replace a single tooth (implant-supported crown), a group of neighbouring teeth (implant-supported bridge) or an entire arch.
Implant-supported prosthetic rehabilitation must meet certain fundamental criteria:
- the presence of a certain amount of bone,
- the primary stability of the implants after insertion,
- good periodontal (gingival) support,
- no bruxism (teeth grinding) or serious malocclusion,
- the presence of good occlusal balance (correct masticatory occlusal plane).

The prosthesis must always be planned in advance. Pre-prosthetic planning must be carried out in cooperation with the dental technician.
The guided prosthetic insertion of implants makes the task of the prosthetist easier and is a better guarantee of its duration. It is advised to collect and keep on file a complete clinical, radiological and x-ray documentation
Each pack indicates the code, description of the contents and batch number. These same details are also indicated on the labels to be attached to the patient's records and must be referred to by the doctor whenever necessary.
When handling the devices destined to come into contact with the patient, both during use and during cleaning and sterilisation, practitioners should use surgical gloves for personal protection against bacterial contamination.
The packaging conforms to European standards.
7. CONTRAINDICATIONS
It is contraindicated to fit implants and implant prosthetics in patients with poor general or oral health, those who are unable to monitor their general conditions properly or those who have had organ transplants. Psychologically unstable patients, alcohol or drug abusers, and poorly motivated or uncooperative patients should also be considered unsuitable for this kind of treatment. Patients with poor periodontal health should first be treated and allowed to recover. In the presence of a lack of bone substance or poor quality of the receiving bone, such as to compromise the stability of the implant, suitable guided tissue regeneration must be performed prior to implant treatment. Contraindications also include: allergy to titanium or other materials used, acute or chronic infectious diseases, sub-acute chronic maxillary osteitis, systemic diseases, endocrine disorders, diseases resulting in microvascular disorders, pregnancy, breastfeeding, previous exposure to radiation, haemophilia, neutropenia, steroid use, diabetes mellitus, kidney failure and fibrous dysplasia.
Implants designed to support prosthetics are medical devices that are introduced into the mouth during surgical procedures and as such they involve further restrictions to use, details of which can be found in the User's Instructions for the implant fixtures.
8. SPECIAL WARNINGS
When tightening screws always use the torque force indicated below:
- Transgingival healing screws: 8-10 Ncm
- Transfer screws: not exceed 8 Ncm

Excessive tightening torques can weaken the screws' mechanical structure and compromise restoration stability, with potential damage to the implant connection.
9. CLEANING / STERILISATION / STORAGE
Caution!!! All restoration components for dental implants are sold NON-STERILE.
The products are supplied washed according to appropriate procedures at the end of the production cycle. Immediately before use, the prosthetic components must be cleaned, disinfected and sterilized following the following procedure validated by Sweden & Martina S.p.A. Repetition of the processes described in this paragraph does not alter the characteristics of these devices. Failure to follow these instructions may cause cross-infection.
Containers and transport to be used for washing: there are no special requirements.
In case of automatic cleaning, use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times.
Use demineralised water to prevent the formation of stains and marks.
When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.
When cleaning manually, use a suitable neutral detergent and follow the manufacturer's user instructions. Brush the products with a soft-bristled brush under plenty of running water. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure plenty of running water passes through any holes.
After rinsing, dry the devices thoroughly and place them inside suitable sterilisation bags.
Do not exceed 121°C when performing a drying cycle in a washing and disinfection appliance.
b. Sterilisation
Place in a vacuum autoclave and sterilise as follows:
- Temperature = 121°C, with autoclave cycle of at least 18 minutes and drying cycle of 4 minutes.

c. Storage
After sterilisation, the product must remain in the sterilisation bags. The bags should only be opened immediately prior to reuse. In normal conditions, sterilisation bags maintain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and resterilise in new bags before using them again. The storage time of products sterilised inside the bags should not exceed that
recommended by the manufacturer of the bags.
The product must be stored in a cool dry place, away from direct sunlight, water and heat sources.
10. REFERENCE STANDARDS
Laboratory components are designed and manufactured in accordance with the latest directives and harmonised standards as regards the materials used, production processes, information supplied and packaging.
11. DISPOSAL PROCEDURES
The laboratory components dealt with in these user's instructions do not pose any particular problems with regard to disposal, since they are small pieces made of polymer or metal. They can be disposed of as recyclable waste (plastic and metal) or, if soiled during use, as non-recyclable residual waste. Dispose of in compliance with local regulations.
12. RESPONSIBILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS
The instructions provided by Sweden & Martina are available at the time of the treatment and are accepted as normal dental practice. They must be followed and applied in all treatment phases.
The warranty only covers manufacturing defects as long as the faulty piece is identified by the article code and batch number and returned within the validity period of the warranty. The warranty terms are available on the website www.sweden-martina.com.
13. DATE AND VALIDITY OF THESE USER'S INSTRUCTIONS
These user's instructions are valid and effective from May 2023.

EXPLANATION OF SYMBOLS

	Caution! See instruction for use	✓
	Batch number	✓
	Code	✓
	Manufacturer	✓
	Country of manufacture	✓
	UDI code, Unique Device Identification	✓
	Medical Device	✓
	Consult instruction for use www.sweden-martina.com	✓
	CE marking *Where applicable: The identification number of the Notified Body shall follow this symbol.*	✓
	American federal law restricts this device to sale by or by order of a professional practitioner	✓
	Do not use if the packaging in damaged	✓
	Non-sterile product	✓

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IFUP-CE-GB rev.05-23