CE 0476

GB: Implant system prosthetic components

1. PRODUCT IDENTIFICATION
The restoration components designed for use with Sweden & Martina implant systems are medical devices intended for use inside the oral cavity.
The functions of the restoration components are:
- gum reconditioning,
- anchorage to dental implants to support dental restorations.

The restoration components manufactured by Sweden & Martina are intended to be anchored to dental implants also 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).
Restoration components must be fastened to the implants using dedicated instruments. When tightening restoration components, use original instruments manufactured by Sweden & Martina. Sweden & Martina declines all responsibility for use of any non-original instruments.

2. DESCRIPTION
The restoration components can be divided into the following categories:

a. Temporary posts
Temporary posts, usually consisting of a titanium base with an upper rod on which the dentist or dental technician trims acrylic restorations. Some versions come with a pre-assembled PEEK jacket that can be trimmed either in the laboratory or by the practitioner while the patient is in the chair. As PEEK cannot be trimmed in resin, these posts are normally used for single crown rehabilitation by means of crown cementing.
They are sold complete with the screws needed to fasten them to the implants.

b. Preformed posts
- Straight, preformed posts, complete with the screws needed for fastening to the implants, for cement-retained restorations.
- Angled, preformed posts, complete with the screws needed for fastening to the implants, for cement-retained restorations.
- Straight, preformed, direct screw-retained posts, used to perform intraoral welding (using commercial devices) on titanium stabilisation bars.

In some cases, the fastening screws are colour-coded to match the implant system they belong to, in order to facilitate the identification of the connection platform.
Final straight and angled preformed posts for two-phase implants are golden yellow for cosmetic reasons.

c. Customisable posts
- Castable sleeves, complete with the screws needed for fastening to the implants. They are used by dental technicians to obtain customised posts for cemented crown, by casting, or to cast overdenture sleeves or structures for screw-retained Toronto Bridges.
- Castable sleeves with a preformed alloy base, complete with the screws needed for fastening to the implants. They serve the same function as the posts indicated above, however, instead of casting; they require the over-casting of the individual model at the base of the preformed connection.
- Millable posts, complete with the screws needed for fastening to the implants. Customised by milling performed by the technician or using CAD CAM techniques by a milling machine.
- In some cases, the fastening screws are colour coded to match the implant system they belong to, in order to facilitate the identification of the connection platform.
- Titanium bases fitted with an implant connection ("T-Connect") that has a standard coupling cone in the upper part and whose ".stl" format is compatible with commercially available CAD systems. These bases are assembled to the implants with the relative fastening screws.

d. Components for screw-retained crowns, for both straight and disparallel implants
- Posts and abutments that are usually used to fasten multiple prosthesis (Toronto bridges). These include:
- conventional, straight components with a castable sleeve for modelling the over-structure and fastening screws with a single through hole, or those manufactured with a threaded guide to be screwed directly onto the implants without requiring through screws, with a threaded hole in the upper part for the two-phase tightening of the over-structure. In these cases, the castable sleeve for the modelling of the over-structure is provided separately, complete with the screw needed to fasten it to the abutment. In some cases, a titanium sleeve is also provided for the preparation of provisional structures.
- for the P.A.D. technique (disparallel screwed prosthesis) to compensate significant parallelism defects. Shapes and functions vary according to whether the implants being used are parallel or not. These posts are used with the relevant components for the creation of the over-structures. Straight P.A.D. abutments are screwed directly to the implants, whereas angled abutments require special screws (provided) for fastening to the implants. The over-structures for P.A.D. abutments can be made using a series of titanium or castable sleeve and are fastened to the abutment with prosthetic screws, which are normally provided with the components for the fabrication of the same over-structures. Consult the individual catalogues for specification details.

e. Fastening screws for posts, abutments and over-structures
The screws needed to fasten posts, abutments and over-structures. They are sold with posts, abutments and over-structure components. They are available both individually and as spares.
As they are used with posts, abutments and over-structures, they are classified as medical device accessories.
For final fastening in the patient's mouth, use the screws provided with prosthetic components ONLY. For the in-mouth trial and fastening to study model phases, use spare working screws. Loosening and retightening the final screw frequently may weaken the structure and cause a loss of precision, with a consequent loosening of the components.

f. Components for anchoring removable overdentures
- ball attachments, screwed to the implants, which act as "studs" for total restoration stabilisation.
- the ball attachments require a suitable male portion to be positioned inside the prosthesis, at the connection, to engage with it. These male portions are composed of polyamide, gold alloy or titanium caps or O-ring type ring connections. Consult the individual catalogues for detailed specifications.

g. Components for creating bars and mounters for anchoring overdentures
- preformed alloy components for the fabrication of bars (Dolder type) and alloy mounters for attaching overdentures to the bars.

3. INTENDED USE
Sweden & Martina declares that it is the manufacturer of the restoration components and identifies their risk class as shown in table 01,
Products must only be used and handled by dentists and dental technicians with the necessary qualifications and professional experience.

4. IDENTIFICATION OF THE MANUFACTURER
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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5. RAW MATERIALS USED
The materials used to manufacture the restoration components for Sweden & Martina dental implants were selected according to the properties indicated for their intended use in accordance with Regulation (EU) 2017/745.
They are manufactured, depending on the type of component, using:
- grade 5 titanium (preformed straight and angled posts, millable posts, temporary posts, abutments, ball attachments, mounters for overdenture anchorage).
- gold alloy (preformed bases for overcastable solutions, caps for ball attachments, mounters for anchoring the overdentures to the bars).
- Polyamide (ball attachment retainer caps, pink) and AISI 303 steel for the containing caps for the same attachments.
- Silicone and nitrile gum for O-Ring-type male part systems for ball attachments and AISI 303 steel for the container ring for the male portions.

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. Restorations can replace a single tooth (implant-supported crown), a group of neighbouring teeth (implant-supported bridge) or an entire arch. Restoration components can be used to stabilise pre-existing full dentures.
Implant-supported restoration rehabilitation must meet certain fundamental criteria:
- the presence of a certain amount of bone,
- 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).

Restoration work must always be planned in advance. Restoration planning must be performed in concert with the dental technician.
The restoration-guided placement of implants facilitates the practitioner's work and provides better guarantees in terms of duration.
It is recommended to collect and file all the clinical, radiological and radiographic records.
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, both during use and during cleaning and sterilisation, practitioners should use surgical gloves for personal protection against bacterial contamination. Failure to comply with these warnings may lead to cross-infection.
The packaging conforms to European standards.

7. CONTRAINDICATIONS
It is contraindicated to place implants and implant restorations 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 infective 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 restorations 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. SINGLE USE DEVICES
Restoration components are single use products. Single use means that each individual device may be used just once, on a single patient. It is common practice for restoration components to be tried in the patient's mouth several times and then sent back to the dental technician for final restoration. This practice is valid and does not alter the single-use concept, provided the same restoration component is always used by the same patient and him/her alone. In the case of multiple restorations, it is important that the same component is always used in the same position and connected to the same implant, i.e. that the components are not switched within the same restoration project.
Failure to comply with these indications may compromise the precision of the work. . Any reuse in other patients must be considered off-label use and in such cases Sweden & Martina declines all responsibility.

9. SPECIAL WARNINGS
When tightening post screws or restoration screws, always use the torque force indicated below:
- Screws for fastening posts and abutments to the implants: 20-25 Ncm
- Screws for fastening over-structures to the abutments: 20-25 Ncm
- Fastening of components that screw directly into the implants (e.g. ball connections, certain types of abutment that do not have separate screws but form a single body with it): 30 Ncm
- Screws for fastening over-structures directly onto the implants (without using intermediate abutments): 20-25 Ncm

Excessive tightening torques can weaken the screws' mechanical structure and compromise restoration stability, with potential damage to the implant connection.

10. MAINTENANCE
There are no implant restoration-related complications reported in literature. These complications may lead to a loss of osteointegration and implant failure. Correct maintenance by the patient, good home dental care and regular appointments with a professional hygienist increase the device's service life.
Complications such as the pull-out of screws that fasten the restoration to the implants or bone reabsorption causing the loss of the mucosal contact in removable restorations can be easily prevented with regular check-ups. Whenever it is necessary to fasten superstructures by means of any type of connecting screws, these fastening operations must be performed by the practitioner using suitable torque-controlled devices. The calibration of these devices should be checked regularly.
In the event of unscrewing or loosening complications, patients should contact their practitioner as soon as possible, so that their prosthesis can be restored. A delay in contacting the practitioner may lead to the failure of the fastening screw and the restoration, in the former case, and to a loss of the implant in the latter, which could impair the result of rehabilitation. Practitioners must make this clear to their patients.
Complications can be of a biological nature (loss of integration) or mechanical nature (fracture of a component due to overloading). If there are no complications, duration depends on the devices and the whole restoration system depends on mechanical resistance in relation to the fatigue accumulated by the device.
Any decementation of cement-retained crowns or bridges secured using non-temporary cement, such as to transmit shocks to the implant structures, can lead to the failure of the same.
Sweden & Martina has conducted 5,000,000-cyle fatigue resistance tests on its implant-post-fastening screw systems. The systems passed the test.
Fatigue tests are conducted according to applicable standards and further assessed by means of finite element calculations.

11. CLEANING / STERILISATION / STORAGE
Caution !!! All restoration components for dental implants are sold NON-STERILE.
Before use, all restoration components must be cleaned, disinfected and sterilised according to the following procedure validated by Sweden & Martina S.p.A.
These processes must also be performed before intraoral use, i.e. before each use for any test phases and in any case before final restoration loading.
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.

a. Cleaning
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.

12. REFERENCE STANDARDS
The restoration 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.

13. DISPOSAL PROCEDURES
If removed from the mouth due to biological or mechanical failure, the restoration components must be disposed of as biological waste according to local regulations.

14. RESPONSIBILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS
Optimal patient care and attention to their needs are necessary conditions for the success of implantation

procedures and, therefore, patients must be carefully selected and informed of the associated risks and obligations connected with the treatment and encouraged to cooperate with the practitioner in the interests of the success of the same treatment.
The patient must, therefore, maintain good hygiene, which should be confirmed during check-up appointments, guaranteed and recorded and the practitioner's instructions and orders shall be observed.
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: from taking the patient's medical history to post-surgery check-ups.
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.

15. DATE AND VALIDITY OF THESE USER'S INSTRUCTIONS

These user's instructions are valid and effective from May 2023.

Table 01

Device	Pack
Temporary posts, for provisional restoration making	Single use, non-sterile, complete with fastening screws
Abutments and components for screw-retained crowns, using conventional or P.A.D. techniques	Single use, non-sterile, complete with fastening screws
Preformed posts	Single use, non-sterile, complete with fastening screws
Customisable posts (including T-Connect bases for creating individual zirconium posts using CAD-CAM systems)	Single use, non-sterile, complete with fastening screws
Fastening screws for posts, abutments and over-structures	Single use, non-sterile. Sold together with the corresponding posts or individually, in single or multiple packs
Components for removable overdenture anchorage (ball attachments; titanium, polyamide or gold alloy caps; O-ring devices)	Single use, non-sterile, complete with fastening screws
Preformed bars, and bar attachments for overdentures	Single use, non-sterile

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	✓
	Disposable product, do not reuse	✓
	Do not use if the packaging in damaged	✓
	Non-sterile product	✓

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