sweden & martina

CE 0476

GB - Dental Implants

GLOBAL

1. PRODUCT IDENTIFICATION

Global dental implants are implantable devices for the rehabilitation of patients affected by total or partial edentulism. The implants are intended to be inserted into the mandibular or maxillary bone (that is, as implant fixtures) via a surgical operation. The fixtures have a connection in the crown part to hold the abutment implant which acts as a support for the dental prosthesis. The purpose of dental prostheses is to restore the dental function to patients from an aesthetic, phonetic and masticatory point of view.

In implantoprosthetic rehabilitation using Global implants, exclusively original Sweden & Martina prosthetic components must be used. Use of components that are not produced by Sweden & Martina limits their liability and renders the product Warranty void (see the later section "Liability for Defective Products and Terms of Warranty").

For surgical insertion of the fixture, appropriate surgical instruments must be used, available either singularly or in kits. Use of original surgical accessories manufactured by Sweden & Martina is recommended. Sweden & Martina does not have any liability if non-original instruments are used.

Global implants can be inserted in various sites in the oral cavity employing different techniques, and then connected to the prosthesis at a later time. The implants (more correctly, implant bodies or fixtures) have a conical form. They are screw-shaped with an external thread and an internal octagonal connection that serves for connecting the prosthetic components ("implant abutments"). Depending on the type of surgical protocol, they can be implanted following a "submerged" or "non-submerged" protocol. Depending on operating time (for functionality restoration), they can be rehabilitated with immediate or deferred loading. Global implants can be inserted in sites that are already edentulous, or in post-extraction sites both immediately (the implant is inserted immediately following tooth or root removal) or at a deferred time (a period of about 3 weeks is normally allowed to pass between extraction and insertion of the implant fixture).

2. INTENDED USE

Global implant fixtures are medical devices intended for long term implantations. All the fixtures are sold in single-use sterile packaging. The purpose of the fixtures is to replace the missing roots of the tooth.

All the fixtures are sold complete with their respective cap screws (also called surgical screws). The cap screws are also implantable medical devices of surgical type, designed to remain in the oral cavity for a duration that can exceed 30 days. The cap screws, which are coloured by anodising according to the diameter of the implant platform for which they are used (3,80 mm GREEN, 4,30 mm BLUE, 4,80 mm LILAC, and 5,5 mm LIGHT BLUE) are also available in individual packs.

The Global implant system fixtures are packaged pre-assembled with a device called 'mounter' that also performs the impression transfer and provisional abutment functions: for aesthetic reasons, when used as a provisional abutment, the 'mounter' device is YELLOW in colour (for all platforms) by anodising it. These components are medical devices that are also available on sale individually, classified as surgically invasive medical devices of temporary duration.

Sweden & Martina declares that it is the manufacturer of the Global implants and attributes the risk classes given in Table 01. The dental implants, although intended for implantation in all subjects who satisfy the appropriate therapeutic indications, must be used exclusively by professional medically-qualified personnel having the necessary qualifications and approvals.

3. MANUFACTURER'S DETAILS

The Manufacturer of Global implant fixtures is:

Sweden & Martina S.p.A.
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e-mail: info@sweden-martina.com
www.sweden-martina.com

4. RAW MATERIALS USED

IThe materials used for manufacturing the Global dental implants were selected on the basis of the properties required for their intended use, in accordance with Regulation (EU) 2017/745.

The implants are produced in grade 4 titanium, according to the harmonised normatives.

Numerous experimental studies confirm the bio-compatibility of Global implants. Please refer to the abstracts of the numerous publications on this subject available on the website www.sweden-martina.com.

Allergies to titanium are very rare but nevertheless possible. For this reason, it is always necessary to check in advance with patients that they do not suffer from this type of allergy.

5. DESCRIPTION

The information contained in these Instructions for Use complete the indications given in the catalogues and manuals. If you do not have copies, they can be requested from Sweden & Martina S.p.A..

Global implants (Fig. 01) are screw implants with a number of features that have been specially designed to optimise the results obtained from the various clinical analyses, and to make the surgical procedure easier according to the most up-to-date implant protocols.

The Global dental implant system features a screw fixture with a conical body and an double internal octagon connection.

Global implants are an extremely versatile solution, ideal for solving all implantoprosthetic problems. The range covers lengths from 8.5 mm to 15 mm in four diameters: 3.80, 4.30, 4.80 and 5.50 mm.

The implant has a variable taper: slight in the neck and in the first central portion, more accentuated in the apical part. The distinctive profile of the Global implant makes it particularly suitable for use in different surgical techniques.

The neck of the implant has a micro-threaded part that confers greater primary stability and prevents natural post-surgery re-absorption of the bone.

The thread has a conical profile with a 0.6 mm pitch and a 0,4 mm 0,3 mm depth. In the central part of the implant, the depth of the thread is 0.4 mm to provide a greater contact surface where the bone is spongier.

The long apical incisions allow adequate self-tapping of the bone, providing two decompression and release areas for coagulations and improving primary stability making the implant less susceptible to rotation during manoeuvres for tightening and untightening the screws of the components attached to it.

Pre-tapping of the bone is always appropriate in the case of very dense bone (D1).

The implant has a double internal octagon connection and an end collar. The octagon nearest to the crown is the 'working' area, that is, the torque forces generated during the phases for positioning the implant are applied on this octagon. The octagon below on the other hand represents the 'precision' area, constructed in such a way that it is not subjected to mechanical stress. In fact, it is on this octagon that all the prosthetic solutions are guided with tolerances of a few microns. The end collar serves as a guide, allowing the connection to achieve a total length of 3,5 mm, which provides greater stability and a correct distribution of masticatory forces (Fig. 02).

The deep connection allows the head of the abutment screw to be sunk into the implant neck, which has the following advantages:

- the abutment screw is subjected to less stress and consequently there is a reduced risk of the screw loosening or breaking:
- the head of the abutment screw does not present an obstacle to the prosthetist while modelling the prosthesis (Fig. 03)

The implant is sold already assembled with its mounter (fig 04 and fig 05); its particular dimensions and design make it practical, functional and versatile. As well as performing its usual role of 'carrier' for positioning 'in situ' the implant, the shape of the mounter also allows it to be used both for taking a precise impression and for creating immediately the provisional abutment (to be used with a special plastic cap).

Mounter pre-assembled with implant: the mounter works exclusively on the upper plane of the connection, in this manner preventing the connection plane that is to hold the final post being deformed.

The hex screws for screwing the implant are situated in the precise internal octagon in the upper part of the mounter.

The measurement of the implant diameters always refers to spiral diameter measured at the widest point of the spiral. The measurement of the prosthetic platform means the diameter measured at the junction point with the prosthetic posts. By implant length is always intended the length of the fixture, calculated from the point of connection with the posts to the apex of the implant.

Global implants are available with Zirti (sandblasted, acid etched body, neck polished) surface treatment.

The implants are packaged inside a special vial inside which, by means of the mounters, the fixtures are "hung" on special titanium rings. These rings are also coloured by means of a galvanising procedure in the colour coding of the system. The fixtures are hung in a way that they do not to touch other surfaces during the storage and transport phases, thereby avoiding potential contaminations through contact (Table 02).

6. METHOD OF USE

Modern implantology, whether using immediate or deferred loading, is largely an experimented, reliable discipline, able to resolve almost all problems related to edentulism, whether they be functional or aesthetic in nature.

Implantology methodologies use primarily two types of surgical technique:

• two stage: consisting of two phases - the first "submerged", that is, the implant is inserted and the connection hole closed with a cap screw (or surgical or cover screw), suturing takes place, the mucosa is re-opened after 2 to 6 months and the actual prosthesis is inserted;

• one stage: insertion of the implant that is left uncovered with the head of the implant emerging. It can be left to heal like this for bone integration (again for 2-6 months) or loaded immediately with a specific dental post, provisionally or definitively, depending on the case. Submerged implants can be used with the one-stage technique, closing the connection with a transmucosal healing screw instead of the cap screw.

• Implants are inserted into the bone following surgical protocols that must take into account the quantity and quality of the receiving bone, the implant type, and the possible need for regenerative therapies. A site is created in the patient's bone (corresponding to the site for the tooth to be replaced or built anew altogether) using a series of calibrated bone millers, or appropriate instruments such as bone-expanders, bone compactors etc. In order for the implant to osseointegrate, a good primary stability is required with little or no movement - if movement is present it must not exceed a few microns. The bone-implant interface is therefore to the order of milli-microns, otherwise the implant risks being fibrointegrated with no osseointegration.

In general, the masticatory load with the fixed prosthesis takes place in a second phase, after 2-3 months for the mandibular bone or 4-6 months for the upper maxillary bone. In certain cases, immediate loading of the implant is possible, however certain fundamental criteria must be met:

• presence of a certain amount of bone
• primary stability of implants after insertion
• good paradental (gingival) support
• absence of bruxism (tooth greying) or serious malocclusion
• presence of a good occlusal balance (correct masticatory occlusal plane).

A serious assessment is therefore required of the specialist who, carrying out the necessary examinations with the help of appropriate instruments, must verify the coexistence of all these factors. If not, the choice must fall on "traditional" techniques (of "submerged" or "non-submerged" type), that is, using implants that require a longer waiting time but that are stronger for supporting the masticatory load.

Implants can be used to replace a single tooth (crown on implant), a group of teeth close together (bridge on implant) or a whole dental arch, or they can be used to stabilise a full upper or lower overdenture prosthesis.

The Global implants have been tested in a wide range of clinical situations:

- standard surgical procedures involving either the double or single surgical phase;
- early, immediate loading;
- contextual employment with regenerative therapies
- post-extraction situations, also with immediate loading.

The clinical indications determining the specific type of Global implant depend on the site for which the implant is intended, the anatomy of the receiving bone, the number of implants, and the technically-motivated choice of protocol from those mentioned above. This decision must be taken exclusively by the doctor performing the operation, who must have a suitable preparation, and plan in advance the appropriate prosthetic rehabilitations.

Where possible, implants with the largest diameter possible for the crest thickness must always be used. Bear in mind the usage limitations for short implants (height 8,5 mm), and narrow implants (diameter 3,80 mm) described in the previous paragraph.

6.1 Pre-surgery Planning and Preparation

During the phase preceding the intervention, the following is required:

- General medical and dental history, general medical examination, clinical examinations (full blood tests) and radiological examinations, TAC and consultation with family doctor
- Patient information (indications, counter-indications, clinical situation, expectations, normal percentages of success and failure, necessity for periodical post-surgery check-ups)
- Hygiene programme, with periodontal interventions (if any)
- Adoption of the necessary pharmacological prescriptions
- Pre-prosthetic surgical planning in collaboration with dental technician
- Assessment of risks relating to inadequate treatments of soft and hard tissues
- Choice of anaesthetic and sedation techniques, and amount of monitoring necessary
- Prosthetic planning in collaboration with dental technician.

6.2 Surgical Intervention

The surgical techniques for implants are taught in University establishments to students graduating in dentistry. Nevertheless, the following factors must be born in mind:

- Hard and soft tissue, must be treated with extreme care, taking all the necessary precautions in order to obtain a good integration of the implant
- The normal biological principles for osseointegration must be respected
- Thermal traumas must be avoided, they could cause necrosis and reduce the possibility of osseointegration. For this reason, an adequately reduced drilling speed must be used (100-150 rpm) and milling tools with cutters in optimum conditions. Drilling must be carried out intermittently, cooling the site adequately with the irrigation necessary, and widening the hole using milling tools with gradually increasing specific diameters
- It is advisable to gather and keep on file a complete clinical, radiological and x-ray documentation
- It is indispensable to respect the healing times recommended for implant surgery, and to check periodically - also by means of radiographic controls - the state of progression of osseointegration.

6.3 Instructions relating to Product Handling and Storage

Implantological interventions must be carried out in a suitable, adequately aseptic environment. It is recommended to always: cover surfaces with sterile drapes; to cover the dental unit and the micromotor with appropriate coverings; to isolate the operating field covering the patient with appropriate surgical gowns; to wear sterile gloves and open the sterile packages containing the instruments only just before their use.

Global implants are packaged in sterile vials, placed inside a blister with a Tyvek seal. This blister is in turn contained in a little box that forms the external enclosure. The package also contains the adhesive labels for use on the patient's medical card.

The blister preserves the sterile conditions and is shaped and pre-formed in a way to prevent the vial from moving as much as possible, while at the same time making it easy to extract. The blister is sealed with a Tyvek film

The sterile blister must only be opened in controlled asepsis conditions. Remove the vial from its seat.

The vials containing the implants must be opened only in a sterile environment, immediately before insertion of the fixtures into their sites. Inside the sterile vials, the fixtures are enclosed in special sleeves in titanium and kept straight with the connection visible, ready to be taken up by the surgical instruments.

A special surgical kit is provided for surgery involving Global implants. The kit contains all the instruments necessary for extracting the fixtures from the vials via the mounters, without the need for them to come into contact with hands or other instruments, and in this way avoid potential contamination before use.

Any contact, even accidental, with the surfaces of the implant before its insertion into the surgical site nullifies the ideal surface conditions produced by the surface treatment procedure.

Should it be necessary to manipulate the implant to insert it into the prepared site, you must use only clean and sterilised tweezers in titanium.

All contacts between the surfaces of the implant and the epithelial and connective tissue must be avoided because they could prejudice the success of the intervention.

At the end of the intervention, if the implant is to be submerged, before closing the flaps, the connection must be sealed well using the special cap screw.

The cap screw is located in a special location, inside the light blue cap (Fig. 05) used to close the vial. A small label indicates its presence.

The cap screw can be extracted using the appropriate electrical screw driver and carried directly into the implant (Fig. 06).

At the end of the intervention, the flaps must be repositioned and closed. Suturing should be performed as normal.

Every package displays the code and a contents description, the batch number, the 'sterile' label and its expiry date. This same data is also indicated on the labels for use on the patient's medical card, and must always be stated by the doctor in any communication in its relation.

The packaging is in compliance with European regulations.

Implants must be stored in a cool dry place, protected from direct sunlight, water and heat sources.

7. STERILISATION

Global implants are sterilised using Beta rays. The expiry date is given on the packaging. The sterile blister must be opened only at the moment it has to be used in the operation. Before opening, make sure that the packaging is perfectly intact. Any damage could compromise the sterility of the implant, and therefore the success of the intervention. Implants that have already been used, or that are not in a sterile condition, must never be reused.

The device is for single-use only: its reuse is not permitted as it could lead to loss of the implant and cross-infections.

On the bottom of the vial there is a round label (or sticker). This label certifies that sterilisation has been obtained through radiation. In fact, this label is yellow in the beginning and turns red under the effect of the radiation, thereby confirming that sterilisation has taken place.

8. COUNTER-INDICATIONS

Insertion of implants and prosthesis implants is counter-indicated in patients presenting a poor general health condition, scarse or inadequate oral hygiene, or where it is impossible or difficult to monitor their general conditions, or in patients who have previously been subjected to organ transplants. Patients with psychiatric problems must also be excluded, as well as those prone to alcohol or drugs abuse, who are little motivated or not sufficiently co-operative. Patients whose gums are in a bad condition must be treated and their condition recuperated in advance. In cases where the receiving bone contains insufficient material or is of such a poor quality that the implant stability could be jeopardised, an appropriate guided regeneration of the tissue must be carried out in advance. Other counter-indications include: allergies to titanium, acute or chronic infective diseases, chronic sub-acute maxillary osteitis, systemic diseases, endocrine disorders, diseases leading to microvascular disorders, pregnancy, breastfeeding, previous exposures to radiation, haemophilia, granulocytopenia, use of steroids, diabetes mellitus, renal insufficiency, bone fibrous dysplasia. All the normal counter-indications for oral surgical operations must also be taken into account. Patients must not be subjected to interventions if they are undergoing anticoagulant, anticonvulsant or immunosuppressive therapies, if inflammatory-infectious processes are present in the oral cavity, or if their creatinine or BUN values are outside the normal range. Other patients who must be excluded are those with cardiovascular disease, hypertension, thyroid or parathyroid diseases, malignant tumours encountered within the 5 years preceding intervention, or node enlargements. Failures of implants inserted in sites where a root canal therapy have been previously performed, are reported in the literature. Planning implant placements, any previous endodontic therapies should be carefully evaluated in the patient's medical history. Unexpected implant failures have been reported in the literature related to patients who regularly assume, or even only for repeated periods, proton pump inhibitors. Planning implant-prosthetic rehabilitations, carefully evaluate the possible assumption of such drugs by the patient. Cases of failures of implants inserted in sites previously subjected to root canal treatments have been reported in the literature.

Any previous endodontic therapies should therefore be carefully evaluated in the patient's medical history when planning implant surgery. Unexpected implant failures have been reported in the literature in patients who take proton pump inhibitors regularly, or even only for repeated periods. It is therefore recommended to carefully consider the possible intake of these drugs by patients for whom implant-prosthetic rehabilitations are planned.

9. SPECIAL WARNINGS

As a precaution, after the intervention, the patient must avoid activities requiring physical effort.

When tightening the cap screws, post screws or prosthetic screws, you must adhere strictly to the tightening torque recommended in the related Instructions for Use. Too high a tightening torque could weaken the mechanical structure of the

screw and compromise the prosthetic stability, causing possible damage to the implant connection.

10. SECONDARY EFFECTS

After dental implant operations the following could occur: bone crest loss, permanent numbness, dysaesthesia, local or systematic infections, exfoliation, hyperplasia, oroantral and oronasal fistula. Temporary complications can occur such as pain, swelling, pronunciation problems and gingivitis. The risks related to an implantological intervention include: perforation of the lip plate or tongue, bone fractures, implant fractures, fractures of the upper structures, aesthetic problems, accidental perforation of sinus, nerve damage and compromission of natural dentition. The following pathophysiological complications can increase the degree of risk: cardiovascular insufficiency, coronary disorders, arrhythmia, chronic respiratory or lung diseases, gastrointestinal diseases, hepatitis, intestinal inflammations, chronic kidney insufficiency and urinary system disorders, endocrine disorders, diabetes, thyroid diseases, blood disorders, anaemia, leukaemia, coagulation disorders, osteoporosis or musculoskeletal arthritis, heart attacks, neurological disorders, mental retardation, paralysis.

11. MAINTENANCE

Complications linked to implant prostheses are documented in the related literature. These complications can lead to a lack of osseointegration and a failure of the implant. A correct up-keep on the part of the patient, following a regular level of hygiene at home, combined with periodic checks and visits to a professional hygienist lengthen the useful life of the device.

Complications such as, for example, loosening of the screws securing the prosthesis to the implant, or bone re-absorption causing loss of mucosa support for removable prostheses, can easily be detected through regular control visits.

Should it be necessary to tighten the abutment or the prosthetic screws, these operations must be carried out by the doctor using appropriate devices that are able to verify the tightening torque. Devices must be calibrated on a regular basis.

Should the patient become aware that any of the conditions above have occurred, they should contact their doctor as soon as possible so that the prosthesis can be restored to its proper functional condition. Any delay in requesting medical intervention could, in the first instance, lead to the fastening screw or the prosthesis fracturing and, in the second instance, to loss of the implant altogether, affecting the rehabilitation result achieved. Doctors must therefore prepare patients for these circumstances.

Complications can be biological (no integration) or mechanical (component fracture due to excessive load). If no complications occur, the duration of the devices and of the prosthesis as a whole depends on the mechanical resistance of the device with respect to the accumulated fatigue.

Sweden & Martina has subjected Global implants to the required fatigue resistance tests at 5,000,000 cycles, and the implants passed the test.

Fatigue tests are carried out in compliance with the specific normative, and the results assessed by a calculation performed on the finished elements.

12. EXPIRY DATE

Implants must not be used after the expiry date indicated.

13. LEGAL REFERENCES

The design and production of Global implant fixtures is carried out in conformity with the directives and most up-to-date harmonised normatives regarding the materials used, production processes, sterilisation, information provided and packaging.

14. WASTE DISPOSAL PROCEDURES

Fixture implants, if removed from the oral cavity as a result of a biological or mechanical failure, must be treated as organic waste for their disposal, according to the laws applying at local level.

On the other hand, if the implants are sent to Sweden & Martina with a request for execution of a Surf Test, the protocol given on the website www.sweden-martina.com must be followed.

15. LIABILITY FOR DEFECTIVE PRODUCTS AND TERMS OF WARRANTY

Excellent patient care and attention to their needs are necessary conditions for success of the implant. It is therefore necessary to select the patient carefully, inform them of the inherent risks and of the duties associated with the treatment, encouraging them to co-operate with the dentist to achieve a good outcome from the treatment.

The patient must therefore maintain a good level of oral hygiene - confirmed by means of regular check-ups and control visits – that must be guaranteed and documented, as also the pre- and post-surgical directions and prescriptions.

The instructions provided by Sweden & Martina are available at the moment of treatment, and have been accepted by the Dental Practice. These instructions must be observed and applied during all the care phases: from the patient medical history stage to the post-surgery check-ups.

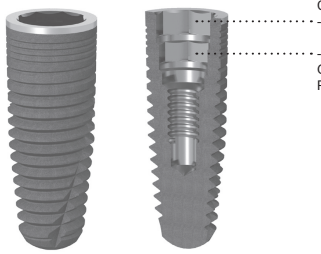
The Warranty covers exclusively defects that can be attributed to production and provided that the piece is submitted - identified by its article and batch code - within the period of validity of the Warranty. The Warranty Conditions are available on the website www.sweden-martina.com.

The Fidelity Service is a service set up to offer customers of Sweden & Martina implantology systems the possibility of replacing implants at discounted prices, implants that have failed, or that are simply not usable any longer because they have been opened and/or mishandled. The conditions governing the Fidelity Service are also available on the website www.sweden-martina.com.

16. DATE AND VALIDITY OF INSTRUCTIONS FOR USE

These Instructions for Use have validity and effect from the month of July 2021.

picture 01 **picture 02**



Connection with double internal octagon:
- coronal octagon on which torsional forces are applied,
- deeper octagon for precise repositioning of prosthetic components: Greater stability and correct distribution of masticatory forces. Prosthetic solution tolerances of a few microns.

picture 03


Cap of the surgical cover screw


Surgical cover screw


Blue vial cap


Fixture


Fixture carrying basket

Vial

Table 01

Device	Packaging	Regulation (EU) 2017/745	Classification Rule	Risk Class
Implant fixtures for dental use, belonging to the Global implantological system	Sterile, single-use packages. Fixtures come complete with cover screw and mounter that also provides impression transfer function and provisional abutment	Implantable devices intended for long term use (over 30 days)	8	IIb
Cover screws	Sold either complete with appropriate fittings or individually (disposable and sterile package). Coloured by a galvanic process using the system's colour code (3,80 mm GREEN, 4,30 mm BLUE, 4,80 mm LILAC, 5,50 mm LIGHT BLUE)	Implantable devices intended for long term use (over 30 days)	8	IIb
Mounters for Global fixtures. Perform also the impression transfer function and provisional abutment	Sold complete with their appropriate fastening screws, and pre-assembled with fixtures, in single-use, sterile packages). Available on sale also individually, complete with fastening screws. Coloured YELLOW by means of a galvanic process	Both for mounter and transfer function are surgically invasive medical devices of a duration that can exceed 30 days (provisional use)	8	IIb

Table 02

Ø 3.80 mm	Ø 4.30 mm	Ø 4.80 mm	Ø 5.50 mm
Green	Blue	Violet	Light blue

EXPLANATION OF SYMBOLS

	Caution! See instruction for use
LOT	Batch number
REF	Code
	Manufacturer
IT	Country of manufacture
UDI	UDI code, Unique Device Identification
MD	Medical Device
	Consult instruction for use www.sweden-martina.com
CE	CE marking *Where applicable: The identification number of the Notified Body shall follow this symbol.*
Rx Only	American federal law restricts this device to sale by or by order of a professional practitioner
	Do not resterilize
	Disposable product, do not reuse
	Do not use if the packaging in damaged
STERILE R	Sterilized with ionizing radiation
	Single sterile barrier system with protective packaging inside
	Expiry date after which the product must not be used

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IFUI-U2-GB rev.07-21