sweden & martina

CE 0476

GB: Prama Dental Implants

PRAMA

1. PRODUCT IDENTIFICATION

PRAMA 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 ("post") 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 PRAMA 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.

PRAMA implants can be inserted in different sites of the oral cavity with various techniques and subsequently connected to the prostheses at different times. The implants (more correctly called implant bodies, or fixtures) are available in both conical and cylindrical shapes (fig. 01 and 02). They take the form of a screw with an external thread and have a hexagonal internal connection for connecting the prosthetic components. They may be implanted with a submerged protocol, or not, as dictated by the surgical protocol; depending on the time frame of use (functionalisation), they can be rehabilitated with immediate loading or deferred loading. PRAMA implants can be inserted in both edentulous and post-extraction sites, with either immediate insertion (at the same time as the removal of the tooth or root), or deferred insertion (normally leaving about 3 weeks between extraction and insertion of the implant fixture).

2. INTENDED USE

PRAMA 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 cover screws (also called surgical screws). The cover screws are also implantable medical devices of surgical type, designed to remain in the oral cavity for a duration that can exceed 30 days. Cover screws are also available in individual packs. In this case also the pack is sterile.

Sweden & Martina declares that it is the manufacturer of the PRAMA 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 the PRAMA implant fixtures is:

Sweden & Martina S.p.A.
Via Veneto 10 - 35020 Due Carrare (Padua) - Italy
Tel. +39 049.91.24.300 - Fax + 39 049.91.24.290
e-mail: info@sweden-martina.com - www.sweden-martina.com

4. RAW MATERIALS USED

The materials used for manufacturing the PRAMA 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 "commercially-pure" titanium, according to the harmonised normatives.

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 provided in these user instructions complements the directions provided in catalogues/manuals. If you do not have this documentation, you may request a copy from Sweden & Martina.

PRAMA implants have a series of characteristics designed to optimise the results of various clinical findings and to facilitate surgical procedures, in line with the latest implant protocols.

The PRAMA implant system presents a transgingival neck characterized by a straight cylindrical section and an hyperbolic geometry section and either a cylindrical or conical ("root form") body as required by individual specifications.

The implants are available, as required by individual specifications, with diameters of 3.30, 3.80, 4.25 and 5.00 mm and heights ranging from 6 to 22 mm. The complete range can be found in the relevant catalogue.

All the Prama implants have the characteristic hyperbolic geometry neck which, from the platform of 3.30, 3.80, 4.25 and 5.00 mm, shrinks to 3.40 mm.

PRAMA implants are available with three lengths of the neck, short, standard and long, in order to meet the different clinical needs:

- "short neck": implants with reduced size of the transmucosal tract are indicated for prosthetic solutions in the frontal aesthetic sectors;
- "standard neck";
- "long neck": the longer neck is used to guarantee the availability of a greater transgingival stretch at the crestal level.

The apical notches, diametrically opposite each other, increase cutting capacity while also allowing decompression and release of bone fragments and the non-rotational quality of the implant when screwing and unscrewing the components connected to it in the second surgical phase.

However, pre-emptive bone tapping is always required in cases of very compact bone (D1).

The same connection is used as in the Premium/Kohno system (manufactured by Sweden & Martina), so it is fully compatible.

All the implants have an internal hexagon (with 2.30 mm key) that ensures the non-rotational quality of the over-structure.

The implant length always refers to the length of the fixture measured inclusively from the connection point at the posts to the implant apex. Prama implants are available with Zirti (sandblasted and acid etched body) surface treatment and UTM (Ultrathin Threaded Microsurface) neck.

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 techniques:

- 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 2-6 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 to 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 and 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 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.

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

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

The clinical indications determining the type of implant PRAMA and its measurement, 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.

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 who are 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 trauma that would necrotise, and compromise possible osseointegration, must be avoided. For this reason, reduced drilling speeds must be used (100-115 rpm) and the cutting edges of the drills must be in excellent condition. Drilling should be carried out intermittently, cooling the site, as required, with sufficient irrigation. The hole should be widened using drills of specific, and increasingly large, 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

Implant procedures must be performed in a suitable environment with appropriate aseptic conditions. It is recommended that surfaces be covered with a sterile sheet, that the dental unit and micromotor be covered with suitable coverings, that the site of the operation be isolated by covering the patient with suitable gowns, that sterile gloves be worn, that instruments be removed from their sterile wrapping immediately prior to their use.

PRAMA implants are packaged in sterile vials, which are placed in a blister with a Tyvek seal; this blister is in turn contained in a box which forms the outer packaging. The package also contains adhesive labels to be attached to the patient's records. The blister pack preserves sterility. It is shaped and pre-formed in such a way as to limit the movement of the vial as much as possible, but allow ease of access when extracting the vial. The blister is sealed with a sheet of Tyvek (fig. 03).

It is recommended that the sterile blister only be opened in controlled, aseptic conditions. Remove the vial from its packaging (fig. 04).

The vials containing the implants must only be opened in a sterile environment, immediately prior to inserting the fixtures in their sites. Inside the sterile vials, special titanium discs support the fixtures and keep them straight, with the connection visible, ready to be engaged by the surgical instruments.

PRAMA implants have been designed for a mountless surgical procedure. In common with the Premium/Kohno system, the PRAMA system uses easy-Insert drivers which, by engaging directly with the internal connection hexagons, make it possible to remove the implants from the ampullas without touching them directly with the hands or other instruments, thus avoiding the risk of contamination prior to use. The drivers have been specifically designed to prevent deformation to the connections or over-engagement during the surgical phase, thus limiting mechanical damage.

Should it be necessary to manipulate the implant while inserting it in the prepared site, it is recommended that only clean, sterilised, titanium forceps be used.

Avoid any contact between the surface of the implant and the epithelial and connective tissue as this could be prejudicial to the success of the operation.

At the end of the operation, if the implant is submerged, the connection well must be closed with the surgical cover screw before closing the flaps. The surgical cover screw is stored in a special cavity within the blue vial cap. There is a small label indicating its location. The surgical cover screw can be removed by friction with the suitable driver and transferred directly into the implant (fig.05).

At the end of the operation the flaps must be repositioned and closed. Normal suturing is recommended.

Each package is marked with the product code, a description of the contents, the batch number, the indication "sterile" and the expiry date. The same details are printed on the labels provided for attaching to the patient's records. The doctor should quote them in any related communication.

The packaging conforms to European standards.

The implants must be stored in a cool, dry place, away from direct sunlight, water and sources of heat.

7. STERILISATION

PRAMA 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. Chemotherapies reduce or counter osseointegration capability, therefore patients undergoing such treatments must be accurately evaluated before implantoprosthetic rehabilitations. In the literature, numerous cases of perimplant osteonecrosys were reported in patients that had been administered with biphosphonates, in particular in the lower jaw and mainly in case of intravenous administration. 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 or tongue plate, 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, with a regular attention to dental hygiene at home, combined with periodic check-ups 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 by 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 the 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, affecting the rehabilitation result achieved. Doctors must therefore prepare patients for these circumstances.

Complications can be biological (integration loss) 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 PRAMA 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 performing calculations 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 PRAMA implant fixtures are 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 that apply locally.
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 the 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, along with 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 are established to be attributed production-related and on submission of the piece identified by item and batch code, within validity period of the Warranty.
The Warranty Conditions are available on the
www.sweden-martina.com website.

16. DATE AND VALIDITY OF INSTRUCTIONS FOR USE

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

Table 01

Device	Packaging	Regulation (EU) 2017/745	Classification Rule	Risk Class
Implant fixtures for dental use, belonging to the Prama implantological system	Sterile, single-use packages. Fixtures come complete with cover screw	Implantable devices intended for long term use (over 30 days)	8	IIb
Cover screws	Sold either complete with appropriate fittings or individually (single-use, sterile package)	Implantable devices intended for long term use (over 30 days)	8	IIb

Table 02

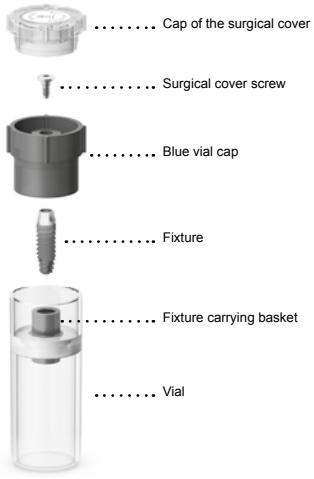
Ø 3.30	Light blue
Ø 3.80	Green
Ø 4.25	Blue
Ø 5.00	Magenta

picture 01

picture 02

picture 03-04

picture 05



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
2 STERILIZE	Do not resterilize
2	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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