sweden & martina

CE 0476

GB: Dental Implants

SHELTA

1. PRODUCT IDENTIFICATION

Shelta dental implants are implantable devices suitable for the rehabilitation of patients affected by total or partial edentulism. They are intended to be inserted surgically in the mandibular or maxillary bone (e.g. implant fixtures),

The fixtures have a connection in the crown part for receiving an implant post aimed at supporting a dental prosthesis. The aim of the dental prostheses is to restore the patients' aesthetic, phonetic and masticatory function.

In implant-prosthetic rehabilitation with Shelta implants, exclusively original prosthetic components by Sweden & Martina must be used. 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).

Suitable surgical instruments must be used to insert the fixtures surgically. These instruments are sold individually or in kits. It is recommended to use original surgical accessories manufactured by Sweden & Martina. Sweden & Martina declines all responsibility for use of any non-original instruments.

Shelta implants can be inserted in different sites of the oral cavity with various techniques and then connected to the prosthesis at different times. Implants (more specifically, implant body or fixture) have a conical shape. They are screw shaped with an external thread and have a hexagonal internal connection for connecting the prosthetic components ("implant posts"). Based on the surgical protocol, they can be implanted with the submerged and non-submerged technique; based on the times of use (functionalization), they may be rehabilitated with immediate or deferred loading. Shelta implants can be inserted in both edentulous and post-extraction sites, either immediate (insertion of the implant at the same time as the removal of the tooth or root), or deferred (normally about 3 weeks between extraction and insertion of the implant fixture).

2. INTENDED USE

Shelta implant fixtures mesh are long-term implantable medical devices. All the fixtures are sold in single-use sterile packs. The function of the fixtures is to replace missing dental roots.

All the fixtures are sold with the respective closing cover screws (also called, surgical screws). The surgical cover screws are also medical devices that can be implanted surgically. They are designed to remain in the oral cavity for more than 30 days. The surgical cover screws can also be sold individually. Even in this case the package is sterile.

Sweden & Martina declares to be the manufacturer of Shelta devices and identifies the risk classes shown in table 01.

Normally, dental implants, even though they can be implanted in all patients who have the suitable therapeutic indications, must only be used by professional dentists or surgeons with the necessary qualifications and training.

3. MANUFACTURER'S DETAILS

The manufacturer of Shelta implant fixtures is:

Sweden & Martina S.p.A.
Via Veneto 10 - 35020 Due Carrare (Padova) - 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 Shelta implants were selected based on the properties indicated for their intended use according to Regulation (EU) 2017/745.

They are made of Grade 4 titanium and conform to the harmonised standards.

Although very rare, titanium allergy is possible. Patients should therefore always be asked whether they have allergies of this type.

5. DESCRIPTION

TThe information provided in these user instructions complements the indications provided in catalogues/ manuals. If you are not in possession of this documentation, you may ask Sweden & Martina to provide you with a copy.

Shelta implants have a series of characteristics designed to optimise the results of the various clinical findings and to bring the surgical procedure in line with the latest implant protocols.

The Shelta dental implant system is characterised by a cylindrical screw fixture with different types of thread: one with a wide spire and one with a narrow spire.

With reference to Figure 01, the following versions of the Shelta implant can be distinguished:

1. "Narrow spire" implant;
2. "Wide spire" implant;

Shelta implants are extremely versatile, suitable for resolving all types of oral implantoprosthetic problems: they originate in the narrow spire version, but in the case of immediate loading and/or post-extraction, according to recent studies on the matter, the wide spire is a means for obtaining greater primary stability.

All the implants are available in the diameters 3.80, 4.25 and 5.00 and in heights 8.5, 10, 11.5, 13 e 15 mm.

The thread always has a constant pitch of 1.5 mm and a triangular profile (40° angle). In the case of the wide spire this gives an increased thickness of the thread crest in the direction of the crown of the implant; this helps obtain greater stability during insertion of the implant.

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

However, preventive self-tapping of the bone is always required in case of highly compact bone (D1).

The connection is the same as the systematic Premium/Kohno connection (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 aspect of the over-structure.

The size of the implant diameter, calculated in the crown part of the implant, is normally the same as the diameter of the prosthetic platform which is understood as the diameter measured at the point where it joins the prosthetic posts. The implant length always refers to the length of the fixture measured from the connection point at the posts to the implant apex, inclusive.

Shelta implants are available with Zirti (sandblasted, acid etched body, neck polished) surface treatment. The implants are packed in a special vial in which the fixtures are inserted in titanium "discs", also colour-coded with a galvanic process to match the implant system, so that the fixtures do not touch other surfaces during storage and transport and to prevent potential contaminations by contact (table 02).

6. METHOD OF USE

Modern implantology, with immediate or deferred loading, is a well-tested and reliable discipline capable of solving almost all edentulism problems, both functional and aesthetic.

The implantology methods can be divided into two main surgical techniques:

- two-stage: the first stage is "submerged" i.e. where the plant is inserted under the mucosa, and the connection well is covered with a surgical cover screw (or closing screw), which is then sutured. Then, after 2-6 months, the mucosa is reopened and the prosthesis is inserted;
- one-stage: the implant is inserted, but with its head protruding out of the mucosa, so that it can be left to heal (always from 2 to 6 months) by bone integration, or it can be loaded immediately with an appropriate temporary or permanent dental post, depending on the case. The "submerged" implants can be used with the one-stage technique by closing the connection with a transgingival healing screw, instead of a surgical cover screw.

Implants are inserted in the bone based on surgical protocols that must be considered according to the quantity and quality of the receiving bone, the type of implant, and the possible need for regenerative therapies. The "implantologist" or dental surgeon creates a site in the patient's bone (corresponding to the new tooth to be placed or replaced), by using a series of calibrated burs or suitable instruments such as bone expanders, bone compactors or similar instruments. Good primary stability, with no mobility or movement limited to a few microns, is necessary for the implant to osseointegrate. The bone-implant interface is of the order of a few millimicrons, otherwise there is the risk of fibrous integration with consequent non-integration of the bone.

Generally, masticatory loading with a fixed prosthesis occurs at a second stage, after 2 to 3 months for the mandible and after 4 to 6 months for the upper jaw. In some cases, but not all, it is also possible to load the implants immediately, but some fundamental criteria must be followed:

- 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).

Of course, a serious evaluation is needed by the specialist, who must use suitable examinations and instruments to verify whether all these factors exist, otherwise the choice will fall on a "traditional" technique (e.g. submerged or non-submerged), or using implants that require a longer, but safer, waiting time for masticatory loading.

Implants can replace a single tooth (crown on an implant), a group of contiguous teeth (bridge on implants), a full dental arch, or they may be used to stabilise complete upper or lower over-dentures.

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

- standard operating procedures involving the double or single surgical phase;
- immediate and early loading;
- simultaneous use with regenerative therapies
- post-extraction situations, even combined with immediate loading

The clinical indication for choosing the Shelta implant depends on the site in which the implant is to be inserted, on the anatomy of the receiving bone and on the technique chosen from among those mentioned above. The choice must be made exclusively by the doctor, who must have the suitable training and experience and must plan the prosthetic rehabilitations beforehand. It is also recommended to always use, whenever possible, implants with the largest diameter possible depending on the thickness of the crest.

6.1 Pre-surgery Planning and Preparation

The preparation involves:

- general medical and dental history of the patient, general medical exams, clinical tests (complete blood count) and X-rays, CAT scans and consultation with the family doctor
- information to the patient (indications, contraindications, clinical profile, expectations, normal success and failure rates, need for periodic check-ups)
- hygiene plan, with any periodontal treatments
- adoption of the necessary pharmaceutical prescriptions
- pre-prosthetic surgical planning in collaboration with the dental technician
- assessment of the risks associated with inadequate treatment of the soft and hard tissues
- choice of anaesthetic and sedative techniques and monitoring to the extent necessary.
- prosthetic planning in collaboration with the dental technician

6.2 Surgical Intervention

The operating techniques for implants are taught at a university level to dentistry graduates. However, the following factors should be taken into account:

- both the soft and hard tissues should be treated with extreme care, taking all the necessary precautions to obtain good integration of the implant
- the normal biological principles of osseointegration must be followed
- Thermal trauma must be avoided which would necrotize, compromising the possibility of osseointegration. For this reason low drilling speeds must be used (100-115 rpm) and drills with cutting edges in excellent condition. Drilling must be carried out intermittently, suitable cooling the site with the necessary irrigation, and the hole must be widened using drills with increasingly larger specific diameters
- it is recommended to collect and file all the clinical, radiological and radiographic records.
- it is essential to respect the healing times recommended in implant surgery and to check periodically the progressive state of osseointegration, even with x-rays.

6.3 Instructions relating to Product Handling and Storage

The implant procedures must be performed in a suitable environment with appropriate aseptic conditions. It is recommended to cover the surfaces with a sterile sheet, to cover the dental unit and micromotor with suitable covering, to isolate the operating area by covering the patient with suitable gowns, to wear sterile gloves, and to open the sterile bags of the instruments just before their use.

Shelta implants are packaged in sterile vials, in a blister with a Tyvek seal; this blister is in turn contained in a box which forms the outer wrapping. Inside the pack are the adhesive labels to be attached to the patient's records. The blister pack protects the conditions of sterility, it is shaped and pre-formed in such a way as to limit movements of the vial as much as possible, but to allow easy access for removing the vial. The blister is sealed with a sheet of Tyvek.

It is recommended to open the sterile blister in controlled aseptic conditions. Remove the vial from its seat.

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

Shelta implants have been designed for a mountless surgical procedure. Easy-Insert drivers are used, in common with the Premium/Kohno system which, engaging themselves directly in the internal connection hexagons, allow them to be taken out of the ampullas without the use of hands or other instruments, thus preventing the risk of recontamination before use. The drivers have been specifically designed to prevent deformation to the connections or over-engagements 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 to use exclusively clean and sterilised titanium forceps.

Avoid all 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, before closing the flaps the connection well must be closed with the surgical cover screw. The surgical cover screw is in a special lodging inside the blue cap of the vial. A small label indicates its presence. The surgical cover screw can be removed by friction with the suitable driver and transferred directly into the implant (fig.03).

At the end of the operation the flaps must be repositioned and closed. It is recommended to suture as usual.

Marked on each package are the code and description of the content, the batch number, the indication "sterile" and the expiry date. 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.

The packaging conforms to European standards.

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

7. STERILISATION

Shelta implants are sterilised with beta rays. The expiry date is indicated on the package. The sterile blister must be opened only at the moment of the operation. Before opening, make sure that the package is perfectly intact. Any damage could compromise the sterility of the implant and therefore the success of the operation. Implants that have already been used or are not sterile must never be reused.

It is a single-use device: reuse is not allowed and may lead to loss of the implant and cross infections.

There is a round label (sticker) on the bottom of the vial. This label indicates sterilisation by irradiation. The label is originally yellow and changes to red during irradiation, confirming that sterilisation has taken place.

8. COUNTER-INDICATIONS

It is contraindicated to fit 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, 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. The normal contraindications common to all oral surgery must also be observed. Surgery is not recommended for patients on anti-coagulant, anti-convulsant and immunosuppressant therapies, with active inflammatory-infective processes of the oral cavity, and patients with BUN and creatinine values outside the norm. Patients with cardiovascular disease, hypertension, thyroid or parathyroid diseases, malignant tumours found in the 5 years preceding the operation, or nodular swellings must also be rejected.

Chemotherapies reduce or eliminate the ability of osseointegration, therefore patients undergoing these treatments must be carefully screened before being rehabilitated with oral implantoprostheses. Numerous cases of bisphosphonate-associated peri-implant osteonecrosis of the mandible have been reported in the literature. This problem particularly applies to patients treated intravenously.

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 post-operative precaution, the patient must avoid any kind of strenuous physical activity.

When tightening surgical cover screws, post screws or restoration screws, always use the tightening torque recommended in the instructions for use. Excessive tightening torques can weaken the screws' mechanical structure and compromise restoration stability, with potential damage to the implant connection.

10. SECONDARY EFFECTS

The following may occur after operations with dental implants: loss of bone crest, permanent paresthesia, dysesthesia, local or systemic infections, exfoliation, hyperplasia, and oronasal and oroantral fistulas. Temporary complications such as pain, swelling, speech problems and gingivitis may also be experienced. The risks of an implant operation include: perforation of the labial or lingual plate, bone fractures, implant fractures, fractures of the over-structures, aesthetic problems, unnoticed perforation of the nasal sinus, nerve injuries, impairment of natural dentition. The following pathophysiological problems can increase the risks: cardiovascular failure, coronary disease, arrhythmia, pulmonary or chronic respiratory disease, gastrointestinal disease, hepatitis, inflammatory bowel disease, chronic kidney failure and disorders of the urinary system, endocrine disorders, diabetes, thyroid diseases, hematologic disorders, anaemia, leukaemia, coagulation problems, osteoporosis or musculoskeletal arthritis, stroke, neurological disorders, mental retardation, paralysis.

11. MAINTENANCE

There are no implant restoration-related complications reported in literature. These complications may lead to a loss of osseointegration and implant failure. Correct maintenance by the patient, good home dental care and regular sessions 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 resting surface in patients with removable restorations can be easily prevented with regular check-ups.

If post or prosthetic connecting screws are needed, these operations must be performed by the doctor using suitable devices equipped with torque control. The calibration of these devices should be checked regularly.

In the event of complications of this kind, patients should contact their practitioner as soon as possible, so that the restoration can be repaired and functionality restored. A delay in contacting the doctor may lead to fractures in the connecting screw and the prosthesis, in the first case, and to implant failure in the second case, which could impair the rehabilitative result.

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.
Sweden & Martina has conducted 5,000,000-cycle fatigue resistance tests on Shelta implants. The implants passed the test.
Fatigue tests are conducted according to the standards and evaluated further with finite element calculations.

12. EXPIRY DATE

It is recommended not to use the implants after the indicated expiry date.

13. LEGAL REFERENCE

Shelta implant fixtures are designed and manufactured in accordance with the most recent directives and harmonised standards regarding the materials used, production processes, sterilisation, information supplied and packaging.

14. WASTE DISPOSAL PROCEDURES

If removed from the oral cavity due to biological or mechanical failure, the implant fixtures must be disposed of as biological waste according to local regulations.
If they are sent to Sweden & Martina with a request to carry out a Surf Test, follow the procedure indicated on the site www.sweden-martina.com

15. LIABILITY FOR DEFECTIVE PRODUCTS AND TERMS OF WARRANTY

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 odontologist 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 pre and post-operative indications instructions must 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

16. DATE AND VALIDITY OF INSTRUCTIONS FOR USE

These user instructions are valid and effective from July 2021.

Table 01

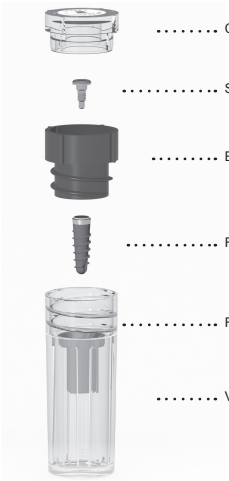
Device	Packaging	Regulation (EU) 2017/745	Classification Rule	Risk Class
Implant fixtures for dental use, belonging to the Shelta implantological system	Sterile, single-use packages. Fixtures come complete with cover screw	Implantable devices intended for long term use (over 30 days)	8	IIb
Cover screws	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 3.80	Ø 4.25	Ø 5.00
Green	Blue	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	✓
STERILIZE	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	✓

sweden & martina
Sweden & Martina S.p.A.
Via Veneto, 10 - 35020 Due Carrare (Padova) - Italy
Tel. +39.049.9124300 - Fax + 39.049.9124290
e-mail: info@sweden-martina.com
www.sweden-martina.com