sweden & martina

CE 0476

GB: Dental Implants

OUTLINK²

1. PRODUCT IDENTIFICATION

Outlink² 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 the support for the dental prosthesis. The purpose of dental prostheses is to restore the dental function to patients from the aesthetic, phonetic and masticatory points of view.

In implantoprosthetic rehabilitation using Outlink² 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.

Outlink² implants can be inserted in different sites in the oral cavity employing various techniques, and then connected to the prosthesis at a later time. The implants (more correctly, implant bodies or fixtures) have a cylindrical form. They are screw-shaped with an external thread and an external hexagonal connection 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, anticipated or deferred loading. The Outlink² implants can be inserted in sites that are already edentulous, or in post-extraction sites both immediately (insertion of the implant takes place at the same time as tooth or root is removed) or deferred (a period of about 3 weeks is normally allowed to pass between extraction and insertion of the implant fixture).

2. INTENDED USE

Outlink² 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 fixtures are sold complete with their respective cap screws (also called surgical screws), pre-assembled on practical mounters and screwed to the connections by means of special 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. Cover screws are also available in individual packs. The fixtures of the Outlink² implantological system are packaged pre-assembled with a device called 'mounter', that performs also the transfer impression function for intraoperative use with closed flaps for reference impressions. These components are medical devices that are also available on sale individually, and are classified as surgically invasive medical devices of temporary duration.

Sweden & Martina declares that it is the manufacturer of the Outlink2 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 Outlink² 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 the Outlink² 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 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.

Outlink² implants (Fig. 01) are screw implants with a number of features that have been especially 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 thread has a pitch of 0.6 mm and a triangular, symmetrical profile.

This profile avoids the bone being subjected to trauma when the load is applied, creating the perfect conditions for complete osseointegration. The apical incisions allow the bone to be tapped, providing three decompression and release areas for bone fragments, and improve primary stability, helping also prevent rotation of the implant during the second surgical phase while performing the manoeuvres for screwing and unscrewing the components connected to it.

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

The implants are on sale pre-assembled with practical devices called 'mounters' for direct insertion into the surgical site. These mounters are also sometimes used to take an intraoperative reference impression. For this purpose, the mounters are also available on sale individually - in this case the packages are not sterile.

The Outlink² system offers two different prosthetic platforms: one with a 2.40 mm external hexagon of height 1.0 mm and thread M 1.8 that can be used with implants of diameters of 3.30 mm and 4.10 mm SP (Switching Platform); the other with a standard 2.70 mm hexagon, height 0.70 mm and thread M 2.0 that can be used with implants of diameters 3.75, 4.10 and 5.00 mm.

Both platforms guarantee an elevated level of precision and allow every type of prosthetic solution to be adequately served.

The features described also allow the concept of switching platform to be applied, mounting posts that are narrower than the implantoprosthetic platform. The "switching platform" technique can be used for:

- Ø 4.10 mm SP (Switching Platform) implants, using ø 3.30 mm prosthetic components on them
- Ø 5.00 mm implants using ø 4.10 mm prosthetic components on them.

In this manner, it is possible to take advantage of the horizontal component of the biological width, reducing to a minimum the loss of crestal bone.

Given their diameter, the implants of ø 3.30 mm lend themselves to being used in cases where there is little bone thickness. However, due to their reduced dimensions, they are not recommended for use in rehabilitating single crowns in molar positions. In these positions, the fixtures can only be used if rehabilitation involves bars or bridges and in the presence of implants of larger diameter.

The connection platforms have different measurements depending on the diameter of the implant. The female thread also, designed to receive the fastening screws of the superstructure, has a different pitch and size depending on the diameter of the implant.

Within this scheme, fixtures of reduced height are available (5, 7 and 8.5 mm) that complete the implantoprosthetic solution, and can be used in accordance with the most recent clinical protocols in all the cases where the vertical bone is of reduced dimension. The slight tapering of the apex makes insertion of the fixture easier, while the thread pitch and depth guarantee optimum primary stability. Given the reduced dimension of these implants, they should only be used for supporting multiple prostheses, together with implants of greater dimensions.

The measurement of the implant diameters always refers to the spiral diameter measured at the widest point of the spiral. By measurement of the prosthetic platform is intended the diameter measured at the jointure 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.

Outlink² implants are available with Zirti (sandblasted, acid etched body, neck polished) surface treatment.

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 2-6 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.

Outlink² 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 Outlink2 implant 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. Bear in mind the usage limitations of short implants (heights 7 and 8.5 mm), and narrow implants (diameter 3.30 mm) described in the previous paragraphs.

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 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, a reduced drilling speed must be appropriate 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.

Outlink² 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 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, special rings in titanium support the fixtures keeping them straight, pre-assembled on their mounters that are presented with the upper hexagon visible, ready to be taken up by the surgical instruments.

A special surgical kit is provided for surgery using Outlink² implants.This kit contains all the instruments necessary for extracting the fixtures from the phials where they are housed by means of the mounters, without having to touch them by hand or with other instruments, so avoiding any risk of 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 (Fig. 02). The cap screw can be extracted using an appropriate electric screw driver and carried directly into the implant.

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

Outlink² 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 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, 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 (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 Outlink^2 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 REFERENCE

The design and production of Outlink^2 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 on the provision 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.

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

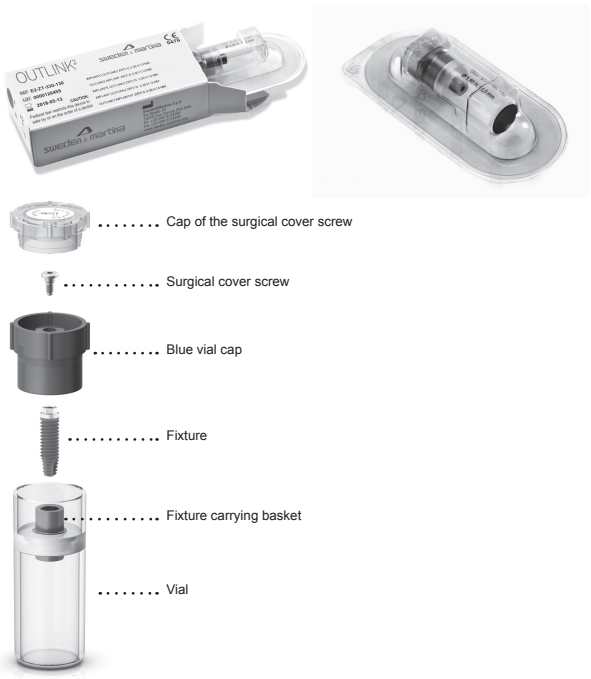

Table 01

Device	Packaging	Regulation (EU) 2017/745	Classification Rule	Risk Class
Implant fixtures for dental use, belonging to the Outlink^2 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
Mounters for Outlink^2 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	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 3.30	ø 3.75	ø 4.10	ø 5.00
Light blue	Green	Blue	Magenta

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	✓

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