sweden & martina
IMPLANTOLOGY

CE 0476

## GB - Dental Implants

# ISY

**INSTRUCTION FOR USE**

Carefully read the instructions before use and always preventively plan interventions to be made on the patient.

**1. INDICATIONS**

ISY mini implants can be used for all oral endosteal implant indications and aesthetic rehabilitation of partially or totally edentulous patients. ISY mini implants can be provided with a spherical head that can be used to anchor mobile prosthesis by means of assembly with the proper retentive caps or with a square head that can be easily worked to make bars and provisional bridges or provisional single crowns. Restoration can consist of provisional single crowns or temporary bridges (considering that mini implants cannot be loaded) as well as overdentures (for the latter it is advisable to use at least 4 mini implants); the prosthetic solutions are inserted in the implants with the proper sovrastructures. Furthermore, mini implants must only be used to improve the retention of the overdenture, but from the biomechanical point of view they cannot and must not bear all the load stress. In order to lighten the load on the implants as much as possible the prosthesis must be made according to the concepts of removable total prosthesis, respecting support and stabilization criteria.

Attention: ISY mini implants can only be used by dentists, physicians and surgeons who have undergone the relevant training. For more information on ISY mini implants, the range of implants available, prosthetic components and more, please refer to the respective catalogues and brochures

**2. MATERIALS**

ISY mini implants are produced in titanium alloy grade 5 with a sandblasted surface. They are decontaminated by the argon plasma system, scaled in a double-sterile package and sterilized by beta-ray treatment.

**3. CONTRAINDICATIONS**

ISY mini implants and implant prosthesis are contraindicated in the presence of the following conditions: patients with poor general medical condition and poorly controlled dental conditions, with poor or inadequate oral hygiene, or who have undergone organ transplants. Insufficiently motivated, uncooperative and psychologically unstable patients or patients with alcohol, drug or tobacco abuse.

Patients with poor periodontal state must be treated beforehand. Patients with a lack of bone substance or inadequate bone quality, which could endanger the securer stability of the implant, should first undergo bone tissue regeneration. Allergy to titanium, aluminium or vanadium, acute or chronic infections, subacute chronic osteitis of the jaw, systematic diseases, endocrine disorders, diseases leading to microvascular disorders, pregnant or lactating women, history of radiation, hemophilia, ganulocytopenia, brittle diabetes, kidney failure, fibrous dysplasia.

Furthermore the normal contraindications of all oral surgery.

Patients undergoing anticoagulant, anticonvulsive and immunosuppressive therapies, with active inflammatory-infective processes in the oral cavity. Patients with abnormal creatinine and BUN laboratory values. Patients with cardiovascular, thyroid or parathyroid diseases, hypertension, malign tumours diagnosed in the past 5 years or swollen nodes.

**4. WARNINGS**

- Any activities subjecting the body to physical stress must be avoided after the operation.
- Loading time for ISY mini implants must be evaluated by the professional based on bone quality, the treatment plan and patient expectations.
- Sweden & Martina is responsible only for original Sweden & Martina products.

**5. SIDE EFFECTS**

Complications associated with mini implants can be: bone loss, permanent parasthesia, dysesthesia, localized or systematic infections, exfoliation, hyperplasia, and oroantral or oronasal fistula. Temporary conditions such as pain, swelling, speech problems, and gingivitis. Risks that may result from implant placement include perforation of labial or lingual plate, bone, implant or dental prosthesis fractures, cosmetic problems, inadvertent perforation of the nasal sinus, and nerve damage. The natural dentition may be compromised. The following physiopathological problems may increase risks: the natural dentition may be compromised. The following physiopathological problems may increase risks: cardiovascular failure, coronary artery disease, arhytmia, chronic lung or respiratory disease, gastrointestinal disease, hepatitis, inflammatory bowel disease, chronic kidney failure, urinary or endocrine disorders, diabetes, thyroid disease, hematologic problems, anemia, leukemia, blood clotting disorders, osteoporosis, musculoskeletal arthritis, stroke, neurologic disorders, mental retardation, and paralysis.

**6. PREOPERATIVE PLANNING AND PREPARATION**

Preoperative planning involves:

- Dental and general anamnesys, general medical visit, clinical examination, complete blood analysis, radiological examination, CAT, consultation with a family dotor.
- Information to the patient (indications, contraindications, clinical picture, expectations, standard success and failure rate, need of regular follow-up)
- Hygiene plan, periodontal treatments, when necessary.
- Adoption of any necessary pharmacological prescriptions
- Pre-prosthetic surgical plan, carried out in cooperation with dental technician
- Risk analysis of inadequate soft and hard tissue treatments
- Choice of anaesthetic, sedative and control techniques, as required
- Prosthetic plans in cooperation with dental technician

**7. HANDLING**

**A. Packaging**

ISY mini implants are packaged in sterile vials, which are inside a blister sealed with Tyvek. This blister is inside a box that is the external wrapping.

Inside the box there are instructions for use and an adhesive label to attach on the patient's record sheet. On each package there is an article code and a description of the contents, a lot number, and an expiration date. This information is also on the adhesive label for the patient record sheet and must always be quoted by the doctor for any communication as regards this subject. ISY mini implant is a medical device certified in compliance with the 93/42/CEE directive and marked CE0476.

**B. Sterilization**

ISY mini implants are beta-ray sterilized. The expiration date is on the package. The sterile blister must only be opened immediately prior to implantation. Before opening the package, check it for damage, which could adversely affect sterility and consequently the success of the operation. Any dental implant that has been implanted previously or is not sterile must never be re-implanted.

**C. Removal of fixtures from the sterile package and handling**

ISY mini implants are supplied complete with a pre-assembled mounting device, so that they can be removed and placed in the implant site without ever being touched by hands. Any contact, even if accidental, would alter the ideal surface conditions formerly obtained through the surface treatments. Should it become necessary to handle the fixture prior to its insertion in the site, it is strongly recommended to touch the implant only with titanium tweezers.

**8. SURGICAL TECHNIQUE**

Initially the type and number of ISY mini implants to be used, their ideal position and orientation for the type of prosthetic solution chosen must be defined in the

preoperative phase (keep in mind that the norm requires maintaining a distance of at least 5 mm between the implants perimeter). Before proceeding to the drilling phase, it is advisable to mark the insertion point(s) by making an incision in the gengiva that causes slight bleeding.

**A. Drilling**

Set the surgical micromotor at a value of maximum torque, rotation speed at 800 rpm (g/min) and abundant sterile external irrigation, place the pilot drill in correspondence with the previously marked point(s) and with slight pressure proceed to drilling the bone to the depth of the threaded part of ISY mini implants to be inserted (N.B. the length of the threaded part of ISY mini implants is always 2 mm less than the effective length). Always use drills with the tip in excellent shape.

**B. Withdrawl and placement in the implant site**

Remove the double vial from the sterile blister, open the cap of the big vial and remove the small vial that is inside of it; carefully remove the cap of the small vial which also acts as a digital mounter for the ISY mini implant and proceed to manually fasten the mini implant by inserting the point in the hole(s) previously made. Once there is enough stability to enable removing the plastic cap from the implant head and proceed to fastening all the threaded part inside the bone by connecting the proper manual butterfly driver to the head of the mini implant or the hand driver with hex connection to the dynametric ratchet with a maximum torque of 35 Ncm. Make sure the tool being used for the final fastening of the mini implant is correctly and completely inserted in the square part of the implant head. If during the final fastening phase, due to very dense bone, it is impossible to insert the mini implant at a torque equal to 35 Ncm, unfasten it, pass the hole again using the drill and following the indications reported in the DRILLING section and finally reinsert the mini implant.

Do not use after the indicated expiration date.

**16. DATE AND VALIDITY OF INSTRUCTIONS FOR USE**

These Instructions for Use have validity and effect from the month of December 2011.

**Key of the symbols used**

| | |
|---|---|
|  | Attention, read instructions for use |
|  | Batch number |
|  | Code |
|  | Sterilization with ionizing radiations |
|  | Best before |
|  | Do not re-use |
|  | Manufacturer |
|  | Consult instruction for use |
|  | Do not use if package is damaged |
| CE 0476 | European Union CE conformance marking |
| Rx Only | U.S. federal law restricts this device to sale by or on the order of a licensed dentist |


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**


IFUI-ISY-GB rev.02-15