GB: Surgical guides

1. PRODUCT IDENTIFICATION
The surgical guides designed for use with the implant systems manufactured by Sweden & Martina S.p.A are medical devices intended for transient use in the oral cavity (no more than 60 minutes at a time), supplied in NON-STERILE packaging.
The function of the surgical guides is:
- Guide the surgical instruments in preparing the site for Sweden & Martina implants. S.p.A.

The surgical guides manufactured by Sweden & Martina S.p.A. are intended for use with surgical instruments also manufactured by Sweden & Martina S.p.A. The use of surgical guides for operations with instruments other than those manufactured by Sweden & Martina S.p.A. limits the liability of Sweden & Martina S.p.A. and voids the product warranty (see section “Product liability and warranty terms”, below). Sweden & Martina declines all responsibility for use of any non-original instruments.

2. DESCRIPTION AND USE
The information provided in these user’s instructions complements the indications provided in catalogues/manuals.

REALIZATION OF OCCLUSAL INDEX
MANDATORY IN CASE OF COMPLETE EDENTULIA


Fix cast models to the articulator. Pay attention to use models used for Evobite.


Prepare Silicone for bite registration (maximum extension).


Replace the cast model with 3d-printed RealMODEL and mount RealMODEL on the articulator using silicone for bite registration.


Mount RealGUIDE on the RealMODEL. On the articulator, realize the correct occlusal registration wax using silicone minimum 75 shore.

3. INTENDED USE
Surgical guides: medical devices, Dispositivi Medici, supplied in NON-STERILE packs,, Risk Class 1.
The use and handling of the product is reserved for medical and dental personnel with the necessary qualifications and professional training.

4. IDENTIFICATION OF THE MANUFACTURER
The manufacturer of the surgical guides referred to in these User’s Instructions is:
Sweden & Martina S.p.A.
Via Veneto 10 - 35020 Due Carrare (Padova) - Italia
Tel. +39 049.91.24.300 - Fax + 39 049.91.24.290
e-mail: info@sweden-martina.com - www.sweden-martina.com

5. RAW MATERIALS USED
The materials used to manufacture the surgical instruments for Sweden & Martina dental implants were selected according to the properties indicated for their intended use in accordance with directive and regulations.
They are manufactured in resin for dental use.
Remember to ask patients whether they are allergic to any of the raw materials. Go to www.sweden-mar-tina.com for detailed data sheets for all the materials used, to check the relative chemical compositions and the physical and mechanical properties.

6. WARNINGS
Sweden & Martina S.p.A. surgical instruments are sold in NON-STERILE packs. Before use, they must be cleaned, disinfected and sterilised according to the instructions reported below. Failure to follow these warnings may expose the patient to infection.
It is recommended to collect and file all the clinical, radiological and radiographic records.
Each pack indicates the code, description of the contents and batch number. The doctor must communicate these details as necessary.
When handling the devices, both during use and during cleaning and sterilisation, it is recommended to use surgical gloves for personal protection against bacterial contamination. The packaging conforms to European standards

7. CONTRAINDICATION
When assessing the patient, in addition to his/her eligibility as regards implant-restoration rehabilitation, it is usually necessary to consider the contraindications that apply to oral surgery procedures in general. These include:
- Clotting disorders, anticoagulant therapy.
- Healing or bone regeneration disorders such as, for example: decompensated diabetes mellitus
- metabolic or systemic diseases that compromise tissue regeneration with a particular influence on healing and bone regeneration
- alcohol abuse, smoking and use of drugs
- Immunosuppressive therapy, such as: chemotherapy and radiotherapy
- Infections and inflammations, such as: periodontitis, gingivitis
- Poor oral hygiene
- Inadequate motivation
- Occlusion and/or articulation disorders as well as an inadequate interocclusal space
- Inadequate alveolar process
- Bone expanders should be used instead of drills when preparing sites in poor quality bone.

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 infective 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. Implants designed to support restorations are medical devices that are introduced into the mouth during surgical procedures and as such they involve further restrictions to use, details of which can be found in the User’s Instructions for the implant fixtures.

8. SIDE EFFECTS
The following may present after surgical procedures:
- Temporary local swelling, oedema and haematoma.
- Temporary sensitivity alterations.
- Temporary masticatory limitations.
- Post-surgical micro-haemorrhages in the following 12-24 hours.

9. CLEANING / DISINFECTION / STERILISATION / STORAGE
Attention! All the surgical accessories for dental implants are sold NON-STERILE. Before use, they must be cleaned, disinfected and sterilised according to the following procedure validated by Sweden & Martina S.p.A. These processes must be performed before use. Instruments should always be checked before use to ensure they are in good working order. Failure to follow these instructions may cause cross-infection and intraoperative complications.

a. Cleaning
Containers and transport to be used for washing: there are no special requirements.
In case of automatic cleaning, use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer’s instructions concerning concentrations and washing times. Use demineralized water to prevent the formation of stains and marks.
When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.
When cleaning manually, use a suitable neutral detergent and follow the manufacturer’s user instructions. Wash under plenty of running water. Apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure plenty of running water passes through any holes.
After rinsing, dry the devices thoroughly and place them inside suitable sterilisation bags.
Do not exceed 50 °C when performing a drying cycle in a washing and disinfection appliance.

b. Sterilisation:
For sterilization, the guides must be wrapped in autoclavable bags Place in a vacuum autoclave and sterilise as follows:
Method 1
- Autoclave (Gravity Steam) temperature = 121 - 124 °C, with autoclave cycle of 20 minutes and drying cycle of 15 minutes.

Method 2
- Autoclave (Pre-vacuum Dynamic-Air-Removal Cycles) temperature = 134 °C, with autoclave cycle of 4 minutes and drying cycle of 20 minutes.

c. Storage:
After sterilisation, the product must remain in the sterilisation bags. The bags should only be opened immediately prior to reuse. In normal conditions, sterilisation bags maintain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and resterilise in new bags before using them again. The storage time of products sterilised inside the bags should not exceed that recommended by the manufacturer of the bags.
The product must be stored in a cool dry place, away from sunlight, water and sources of heat.

10. REFERENCE STANDARDS
The surgical guides are designed and manufactured in accordance with the most recent directives, regulation and harmonised standards regarding the materials used, production processes, information supplied and packaging.

11. DISPOSAL PROCEDURES
If used, dispose of the surgical guides as biological waste, according to the local regulations.

12. RESPONSIBILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS
Optimal patient care and attention to their needs are necessary conditions for the success of a implantation procedures and, therefore, patients must be carefully selected and informed of the associated risks and obligations connected to the treatment and encouraged to cooperate with the practitioner in the interests of the success of the treatment itself.
The patient must, therefore, maintain good hygiene, which should be confirmed during check-up appoint-ments, guaranteed and recorded and the practitioner’s instructions and orders shall 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.

13. DATE AND VALIDITY OF INSTRUCTIONS FOR USE
These user’s instructions are valid and effective from Februay 2021.

KEY OF THE SYMBOLS USED

	Attention, read instructions for use
	Batch number
	Code
	Manufacturer
	Non-sterile product
	Consult instruction for use https://www.sweden-martina.com/en_gb/

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