CE 0476

sweden & martina

GB: Accessory kit for Shorty milling tools for implant systems and related spares

SHORTY

1. PRODUCT IDENTIFICATION

The Shorty milling tool kit and its components manufactured by Sweden & Martina S.p.A. are medical devices intended to be used for a temporary duration in the oral cavity (continuous duration not exceeding 60 minutes), supplied in non sterile packaging.

The purpose of the Shorty milling tool kit is to prepare sites for short implants or to prepare guide holes to facilitate subsequent use of standard milling tools for long implants in distal sites or limited oral opening.

The tools contained in the kit are intended to be used with dental implants that are also made by Sweden & Martina S.p.A. and with all implants not made by Sweden & Martina S.p.A., provided they have equivalent technical and dimensional characteristics.

The use of products that do not conform to the indications given, limits the liability of Sweden & Martina S.p.A. and the product Warranty rendered void (see the "Liability for Defective Products and Terms of Warranty" section below).

2. DESCRIPTION AND USE

These Instructions for Use refer to the accessories described below.

When using Shorty milling tool kits with dental implants made by Sweden & Martina S.p.A. we recommend consulting the product catalogues and the surgical manuals that contain all the technical details and directions related to the most appropriate surgical procedures.

All accessories are identified via an instrument code indicated by a laser marking on the accessory body. A colour coding system is used that helps identify the diameters of the instruments to use on the basis of the implant diameter or of the dimensions of the platform.

The legend for the colour codes is explained in table 01.

Complete kit

The Shorty milling tool kit for implant systems, fig. 01 contains all the tools for preparing the implant site for plants with a submerged section length of between 5 and 8,5 mm. The contains only the tools described and is therefore to be considered as an aid for the individual implant systems, to which the operator must refer for inserting implants. The instruments forming the subject matter of these user's instructions are intended for mechanical use, i.e. they have a shaft with a contra-angle connection and must be used with a suitable micromotor. Incorrect insertion of the instruments in the handpiece will cause instrument vibration, eccentric rotation, early wear and shaft buckling. Suitable surgical micromotors only should be used. Micromotors should be checked regularly by their manufacturers, according to the indications given by the same, to prevent potential malfunctions (e.g. axle shifts for transmission shafts, worn or faulty forceps, etc.). Failure to follow the instructions provided may cause surgical problems and damage to the patient's health.

Drills

These are cutting instruments used for preparing the surgical sites for implants. They are cylindrical in shape. They have depth notches that allow you to determine the working depth, and are prepared to allow a depth stop to be attached.

The depth measurements for the holes determined by the milling tools are shown in table 02.

For the purposes of a surgical approach that favours safety, the depths of the holes are prepared at two tenth of a millimetre steps.

We recommend using a rotation speed for the milling tools covered by this manual of between 900 and 1100 rpm, depending on the diameter of the milling tool and bone density. If the milling tool is used in the end phase of preparing the implant site, we recommend using a rotation speed of 900 rpm.

Levering movements increase the risk of the instruments fracturing, therefore they must be avoided. In general, any sudden changes of speed must also be avoided. Pressure must never be applied to stop the tool rotating by force. This could result in an excessive rise in heat in the tissue affected by the cut and ruin both the tool and the equipment used (micro motor). This could also result in the tool itself breaking. It is further recommended to work intermittently, so as to avoid the working part becoming overheated or worn, and also to avoid an undesired increase in heat of the tissue being operated on. Use of an appropriate cooling liquid is recommended.

Exclusively surgical micro motors appropriate for this type of operation must be used. Ask the producers of micro motors to test them on a regular basis - according to their specifications - so as to detect in advance any possible malfunctioning (e.g. shifting of the axes of the transmission shaft, wear or malfunctioning of the pincers etc.).

In order to adopt a safer, more prudent approach with respect to wear resistance of devices, milling tools must not be used for more than 20 work cycles, or less if their cutting capacity deteriorates. The residual cutting capacity should be checked after every intervention. The use of milling tools with cutting capacity reduced due to wear may cause bone necrosis due to overheating.

The 20 cycles recommended represent an average figure. Wear on the milling tools depends to a large extent on the type and density of the milled bone. Harder bone leads to faster wear of the tools.

Milling tools must never be re-sharpened before use. Damaged, bent or worn tools must never be used.

Milling tool stops

These are devices that can be inserted onto cylindrical milling tools. They make it possible to limit the working length to a predetermined depth. The measurements are shown in the previous table.

We recommend always checking that the stop is fitted at the required depth. Incomplete insertion may reduce the preparation depth or cause it to fall accidentally. Any difficulty encountered when inserting the stop can be resolved by loosening slightly the stop flaps using a pair of tweezers. Also check that the stop is fixed sufficiently tightly to avoid it falling accidentally.

Intermediate widening milling tools are not fitted with stops, since they must always be used at the same depth.

Parallel pins

These are tools fitted with two cylindrical sections with rounded points, one thinner 2 mm diameter and one thicker, 3 mm diameter, which are normally inserted into the holes prepared using milling tools, to allow the operator to check that the preparations are parallel. Depending on the diameter of the hole, they are inserted in the narrower or wider part. With depth markings they are also used to determine the insertion depth achieved using the milling tools.

Instrument tray

This is a practical radel tray that can be used to lay out all the instruments described above in an ergonomic manner.

3. INTENDED USE

Sweden & Martina declares that it is the manufacturer of the Shorty milling tool kits for dental implants and their individual components, and has attributed the risk classes as shown in Table 03.

These products are medical devices and are manufactured according to the UNI EN ISO 9001:2015 / UNI EN 13485:2016 standards.

The product must be used and handled exclusively by medical and dental staff having the necessary authorisation and professional preparation.

4. MANUFACTURER'S DETAILS

The manufacturer of the surgical accessories for the dental implants which are the subject of these Instructions for Use 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 for making the Shorty milling tool kits for the dental implants have been selected on the basis of the properties required for their intended use, in compliance with Regulation 2017/745.

Depending on the type of component, they are made of:

- Titanium, grade 5
- Tool steel 1.4197

Patients must always be consulted in advance to ascertain if they are allergic to any of the substances used.

The surgical trays are made of Radel.

6. WARNINGS

Shorty milling tool kits for implant systems made by Sweden & Martina S.p.A. are sold in non sterile packs. Therefore, they must be cleaned, disinfected and sterilised before use, following the directions given below. Non-observance of this warning could cause the patient infections.

It is advised to collect and keep on file a complete clinical, radiological and x-ray documentation for the patient.

The code, contents description and batch number are given on every package. This same data is also indicated on the labels used on the patient's medical card and must always be quoted by the doctor in any communication in its relation.

Whenever handling the devices, both during their employment and when performing cleaning and sterilisation operations, it is recommended to always wear surgical gloves for personal protection from bacterial contaminations.

If the Shorty tools and kit are used to prepare implant sites not made by Sweden & Martine, the user is responsible for checking the adequacy of the sizes of the milling tools for the dimensions of the sites to be prepared. If the user does not do these checks, there is a risk of inadequate preparation.

The packaging complies with European standards.

7. COUNTER-INDICATIONS

During patient assessment, as well as evaluating the appropriateness of a prosthetic implant, it is also necessary to take into account certain recognised counter-indications for dental surgery operations.

Among these can be mentioned:

- Alterations to blood coagulation processes, therapies using anticoagulants
- Healing or bone regeneration disorders such as e.g.:
  - Uncompensated diabetes mellitus
  - Replacement metabolic or systematic diseases that compromise tissue regeneration, affecting in particular healing and bone regeneration processes
  - Alcohol or tobacco abuse, drugs use
- Immunosuppressive therapies such as for example chemotherapy and radiotherapy
- Infections and inflammatory conditions such as for example periodontitis, gingivitis
- Scarse oral hygiene
- Insufficient motivation
- Occlusion and/or articulation defects such as an insufficient interocclusal space
- Inadequate alveolar process
- Milling tools must be used prudently in the case of low bone density, and the sites must be adequately prepared underneath preferably using bone condensers.

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 in advance and their condition recuperated.

In cases where the receiving bone contains insufficient material, or is of such 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.

Implants for the purpose of supporting the prostheses are medical devices that are inserted into the oral cavity during surgery. For this reason, they are subject to further restrictions on use, which are given in the Instructions for Use related to the implant fixtures.

8. COLLATERAL SYMPTOMS

Amongst the symptoms that could accompany surgery, the following could occur:

- Temporary local swellings, edema, hematomas
- Transient reduction in sensitivity
- Transient reduction in masticatory function
- Post-surgery microhemorrhages during the next 12-24 hours.

9. CLEANING / DISINFECTING / STERILISATION / STORAGE

Warning! The Shorty milling tool kit for implant systems is sold in a NON STERILE state. Before use, it must therefore be cleaned, disinfected and sterilised following the procedure indicated below and verified by Sweden & Martina S.p.A.

These procedures must be carried out before initial use, and before every subsequent operation.

The repetition of the procedures described in this paragraph has a minimal effect on the related devices.

Repetition of the processes described in this paragraph has a negligible effect on the devices. Instruments should always be checked before use to ensure they are in good working order. Any instruments showing signs of wear must be immediately replaced with new devices. It is particularly important to check that the drivers grip properly inside the connection wells on the heads of the screws to be lifted and tightened with the same. Failure to follow these instructions may cause cross-infection and intraoperative complications.

a. Cleaning: Containers and transportation to use for washing: no particular requirements exist.

For automated cleaning: use an ultrasound tank together with an appropriate cleaning solution. Exclusively neutral cleaning solutions should be used. The concentration of the solution and duration of the washing must be in observance of the manufacturer's instructions. Use demineralised water to prevent stains and haloes.

When emptying out, check the recesses of the devices, holes and so on, to ensure that all residues have been completely removed. If necessary, repeat the cycle or clean by hand.

For manual cleaning: use an appropriate neutral cleaning solution, paying attention to the manufacturer's Instructions for Use. Use a brush with soft bristles and brush the product under plenty of running water. Still using the brush, apply the cleaning solution to the surfaces. Rinse with distilled water for at least 4 minutes. Make sure that the flow of water passes copiously through any holes.

In the case of milling tools with internal irrigation, use the special pins provided with the handpieces to make sure that the irrigation holes are completely clean and free from any bone fragments or organic tissue.

After rinsing, dry the devices completely and pack them into suitable bags for sterilisation.

In cases where a drying cycle is carried out as part of a machine washing and disinfection cycle, do not exceed 120 °C.

b. Sterilisation:

For sterilization, the kits must be packed inside autoclavable bags.

Sterilization can be done as follows:

- Method 1: Autoclave (Gravity Steam)
  temperature of 121-124 °C, exposure of 20 minutes and drying of 15 minutes;
- Method 2: Autoclave (Pre-vacuum Dynamic-Air-Removal Cycles)
  temperature of 134 °C, exposure of 4 minutes and drying of 20 minutes.

c. Storage:

After sterilisation the product must be kept in the bag that was used for sterilisation. These bags must only be opened just before use. Bags used for sterilisation are normally able to conserve the inside sterile unless the wrapping is damaged. It must be emphasised therefore that if the bag in which the products are conserved is damaged they must not be used, but re-sterilised in new bags before being used. The conservation period for sterilised products inside the bags must not exceed the period recommended by the bag manufacturer. The product must be conserved in a cool dry place, protected from direct sunlight, water and from heat sources.

10. LEGAL REFERENCES

The design and production of the prosthetic components is carried out in conformity with the most up-to-date directives and harmonised norms in relation to the materials used, production procedures, information supplied and packaging.

11. WASTE DISPOSAL PROCEDURES

If surgical accessories are used, they must be disposed of in the same way as organic waste, according to the laws that apply locally.

12. LIABILITY FOR DEFECTIVE PRODUCTS AND TERMS OF WARRANTY

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 appointments, guaranteed and recorded and the practitioner's instructions and orders shall be observed.

The directions provided by Sweden & Martina S.p.A. are supplied at the moment of treatment, and have been accepted by the Dental Practice. They must be observed and applied during all phases of use. 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.

13. DATE AND VALIDITY OF INSTRUCTIONS FOR USE

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

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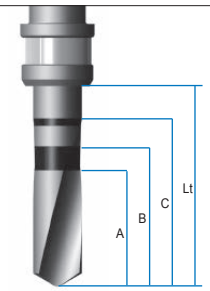
Table 01

Colour	Milling tool diameter
White	2.00 mm
Green	3.00 mm
Blue	3.40 mm
Magenta	4.25 mm
Petrol	5.40 mm

Table 02



Ref. Size	Depth
A	5.00 mm
B	6.00 mm
C	7.00 mm
Lt	8.50 mm

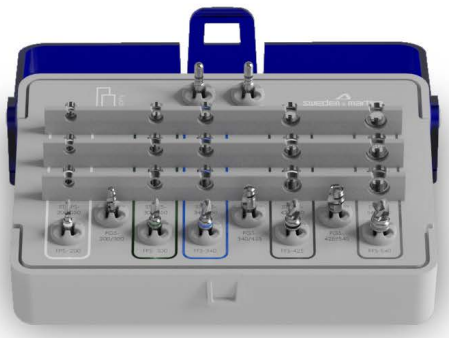
Table 03

Device	Packaging	Classification based on Rules in Annex IX	Risk Class
Milling tools	Non-sterile packages	6	IIa
Milling tool stops			IIa
Parallel pins			I
Tray			I
Complete Shorty milling tool kit			IIa

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	✓
	Do not use if the packaging in damaged	✓
NON STERILE	Non-sterile product	✓

Fig. 01



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