

GB: Instruments kit for feather edge preparation

1. PRODUCT IDENTIFICATION

The rotary instruments contained in the Preparation Drill and Preparation and finishing drills for temporary bridges kits by Sweden & Martina S.p.A., are medical devices intended to be used in the oral cavity, for temporary use (continuous duration not exceeding 60 minutes), reusable, sold in non-sterile packaging.

The drills of the Preparation Drill kit are used for the preparation of natural abutments; the rotary instruments of the Preparation and finishing drills for temporary bridges kit are instead used in the finishing and adaptation steps of the resin provisionals, according to the same technique.

The rotary instruments manufactured by Sweden & Martina S.p.A. are intended for use with dental implants also manufactured by Sweden & Martina S.p.A. The use of these instruments for surgery with dental implants other than those manufactured by Sweden & Martina limits the liability of the company and voids the product warranty. We do not respond to the use of non-original equipment.

2. INTENDED USE AND RISK CLASS

The Preparation Drill and Preparation and finishing drills for temporary bridges kits contain rotary instruments suitable for the preparation of natural abutments, from the mesio-distal separation of the dental element from its adjacent ones, up to the preparation of all the orthodontic planes, and to face all the finishing and adaptation steps of temporaries prosthesis made of resin for the restoration of vertically prepared abutments.

Both trays are produced in sterilizable and autoclavable stainless steel and allow you to organize the rotary instruments inside them in an ergonomic way.

The Preparation Drill kit contains 17 diamond drills of different shapes and grits that allow you to work so as not to generate steps or gutters that prevent the correct and natural adaptation of the mucous membranes and guarantee an excellent surface finish.

The Preparation and finishing drills for temporary bridges kit includes:

- N° 5 tungsten carbide drills with different shapes and cuts
- N° 1 superfine grit diamond disc
- N° 1 soft boar bristle toothbrush
- N° 2 steel mandrels
- N° 100 disposable Moore discs in medium grain corundum
- N° 1 polishing rubber with diamond grain in the mixture.

The kits are sold in a complete package with all the tools. It is also possible to order only the empty trays and also the individual instruments as spare parts.

The kits and tools included within them are sold non-sterile. The instruments are reusable, after washing and sterilization which must be carried out by the users before the first use and after each use.

The Preparation Drill and Preparation and finishing drills for temporary bridges kits must be used exclusively by medical and dental personnel with the necessary qualifications and must be used only in accordance with the indications and instructions for use, according to the general rules of dental treatment and / or surgical and in compliance with accident prevention and occupational protection regulations. Failure to comply with the instructions provided can cause surgical problems and damage to the patient's health. Dentists who use the kits must be well trained in bone regeneration and oral surgery.

Both trays and instruments are classified as medical devices and fall within the scope of the Regulation (EU) 2017/745 in the risk classes as shown in table 1.

3. IDENTIFICATION OF THE MANUFACTURER

The manufacturer of the kits: Preparation Drill and Preparation and finishing drills for temporary bridges and their components is:

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4. RAW MATERIAL USED

The materials used for the production of the Preparation Drill and Preparation and finishing drills for temporary bridges kits and the instruments that are part of them have been selected on the basis of the properties indicated for their intended use, in compliance with Regulation (EU) 2017 / 745, Annex I Essential Requirements, point 10.1.

All the rotary instruments contained in the Preparation Drill kit are made of AISI630 (17-4-PH) stainless steel, in compliance with the international standards on surgical steels American Society for Testing and Materials ASTM F 899. The kit Preparation and finishing drills for temporary bridges contains different types of tools, each of which is made of specific materials:

- The drills are made of tungsten carbide
- The mandrels are made of special wolfram vanadium steel
- The diamond disc is produced in electrodeposited diamond
- The toothbrush has soft boar hair bristles

- The rubber has a working part consisting of a flexible binder impregnated with a fine diamond grain.

The surgical trays are in sterilizable and autoclavable stainless steel. It is recommended to check with patients for any allergy to the substances used. Please refer to the website www.sweden-martina.com for the detailed technical data sheets of all the materials used, for the verification of the relative chemical compositions and for the physical-mechanical characteristics.

5. PRODUCT DESCRIPTION

1. Preparation Drill Kit

The drills belonging to the Preparation Drill kit allow to face all the clinical steps for the preparation of the natural abutment.

The different morphologies of the drills allow to work in such a way as not to generate steps or gutters that prevent the correct and natural adaptation of the mucous membranes. The different grits, on the other hand, allow a perfect smoothing of the abutment in order to guarantee a better seal after the cementation of the crown.

The Preparation Drill kit consists of a sterilizable and autoclavable stainless steel tray, containing the diamond burs arranged diagonally in the three grits and easily identifiable thanks to the ISO code. The color of the silicone supports indicates the grain of the cutter and corresponds to the colored ring on the shank of the same. The tray also allows the professional who uses it a better working ergonomics, given the angle of the base of the bur holder that is obtained by opening the lid (fig.01).

2. Rotary Instruments of the kit Preparation and finishing drills for temporary bridges

The selection of the rotary instruments belonging to the Preparation and finishing drills for temporary bridges kit allows to face all the finishing and adaptation steps of the resin provisionals for the restoration of the abutments prepared vertically.

Of the five tungsten carbide burs present in the kit, the two with small heads allow you to easily model the surfaces of the temporaries, the two with larger dimensions are suitable for quickly removing the excesses caused by the resin relining from the temporaries and the ball head is excellent for removing the internal interference of the provisional pre-shaping and for lightening the friction of the relined provisional.

The pink rubber has a fine diamond grain in the mixture that allows excellent surface smoothing.

The two steel mandrels are already pre-assembled with the relative Moore abrasive discs in corundum, for finishing the provisionals.

The soft-bristled boar hair brush can be used both dry and with suitable polishing pastes. The diamond disc has a diamond coating on both working sides, to facilitate the entry and exit of the instrument from the interproximal spaces of the provisionals.

The Preparation and finishing drills for temporary bridges kit consists of a sterilizable and autoclavable stainless steel tray, containing in an orderly and intuitive manner the assortment of rotary instruments inside. All the instruments in the kit are easily identifiable thanks to the ISO code shown on the tray near them. The tray also allows the professional who uses it a better working ergonomics, given the angle of the base of the box that is obtained by opening the lid (fig. 4). The kit is sold complete with all the instruments that compose it; the empty tray can in any case be ordered as a spare part with a specific code present in the catalog.

6. CLEANING/DISINFECTION/STERILIZATION/STORAGE

Proper cleaning, disinfection and sterilization of instruments plays a fundamental role in risk reduction and prevention. Rotary instruments are sold in a non-sterile condition. Therefore, before use, they must be properly cleaned and sterilized, according to the following indications:

- Avoid using too aggressive detergents (e.g. bleach, hydrogen peroxide, etc.) or those containing high concentrations of chlorine, to avoid unwanted oxidation effects.
- After use, remove major organic residues with a disposable cloth or paper. Then immerse the medical devices in a disinfectant bath, following the product manufacturer's instructions. There are no particular prescriptions on the containers to be used.
- Subject tools to a cleaning process immediately after use. Disassemble multi-part tools. You can choose between an ultrasonic or manual washing. In the first case, prepare a tray containing a bactericidal solution according to the manufacturer's instructions.
- The duration of washing depends on the solution. The bactericidal solutions must be replaced between one wash and the next when there are fixed residues present in them. In any case, the solution must be replaced no later than 5 washing cycles. At the end of the cycle, the pieces must be rinsed in demineralized water,

making sure that all bactericidal residues are eliminated. The instruments being washed should not overlap once immersed in the solution. To wash the trays, immerse the components of the cassette inside the tank in a dedicated cycle and proceed with the same cycles as above. At the end of the cycles, rinse in demineralized water, making sure that all bactericidal residues are eliminated. If necessary, repeat the cycle or use manual cleaning.

- In manual washing it is recommended to use the same detergent mentioned above, always following the manufacturer's instructions for use. Brush the devices with soft bristles, under plenty of running water. Using the brush, apply the cleaning solution to all surfaces. Rinse with distilled water for at least 4 minutes. Make sure that the running water passes in abundance through the holes in the tray. After washing, check the complete removal of any visible residue from the instruments. If necessary, repeat the cleaning cycle.
- At the end of the washing phase, proceed with a complete cycle in the autoclave, previously placing the instruments in Steri-fit bags. The cycle specifications to be adopted are as follows:

- Operating temperature: 121 ° C
- Duration of the autoclave cycle: 20 minutes
- Duration of drying cycle: 15 minutes

Surgical kits must be sterilized with the instruments inserted inside them. Rotary tools of different types, groups or families must always be packaged separately as, being made of different materials, there could be problems of oxidation-reduction and subsequent corrosion of the metal. Always keep ultrasound cleansed products separate and appropriately identified from those cleansed manually.

The end of the life span of an instrument is generally determined by wear and damage due to use, and not much from the repetition of the above processes.

After sterilization, the product must remain in the bags used for sterilization. The pouches should only be opened immediately before the instruments are reused. The bags for sterilizing instruments are normally able to maintain sterility inside them, unless the wrapping is damaged. Therefore, be careful not to use the kit or individual instruments if the bags in which they were stored show damage and to re-sterilize them in new bags before re-use. The storage period of sterilized products inside the bags must not exceed that recommended by the manufacturer of the bags themselves.

7. CONTRAINDICATIONS

When evaluating the patient, it is generally necessary to take into account the contraindications valid for dental surgery.

These include:

- Alterations of the blood coagulation chain, therapies performed with anticoagulants.
- Disorders of scarring or bone regeneration such as:
 - Uncompensated diabetes mellitus
 - Metabolic or systematic metabolic diseases that compromise tissue regeneration with particular incidence on scarring and bone regeneration
 - Alcohol and tobacco abuse and drug use
 - Immunosuppressive therapies such as: chemotherapy and radiotherapy
- Taking bisphosphonates for oral or intravenous use
- Infections and inflammations such as: periodontitis, gingivitis
- Parafunctionality not treated such as: bruxism
- Poor oral hygiene
- Inadequate motivation
- Defects of the occlusion and / or of the joint as well as insufficient interocclusal space
- Inadequate alveolar process in the specific of the surgical technique described below, in addition to the aforementioned contraindications, the following are mentioned:
 - Bone density D4
 - Initial bone height less than 3 mm
 - Presence of pathologies affecting the sinus mucosa.

8. METHOD OF USE

For a correct and safe use of the rotary instruments present in the Preparation Drill and Preparation and finishing drills for temporary bridges kits, Sweden & Martina recommends that you strictly follow the recommendations below. Lever movements of the instruments increase the risk of fracture of the instruments and must therefore be avoided. Sudden changes in speed or the use of speeds higher than those scrupulously indicated for each type of instrument in the appropriate tables in the catalog must also be avoided. Speeds higher than those recommended, although they allow to increase the cutting capacity of the tools, develop greater heat increase in the elements affected by the cut and reduce the life of the devices.

Incorrect insertion of the instruments in the handpieces, turbines or contra-angles can lead to vibrations of the same, to eccentric rotations, to premature wear, and to bending of the stem.

It is recommended to use only equipment (micromotors, turbines, contra-angles) suitable for use. It is recommended that the equipment be checked periodically by the manufacturers, according to their individual indications, to prevent possible malfunctions (eg axis displacements of the transmission shafts, malfunctioning calipers, etc.).

The tools must never be used if damaged, bent or worn, but must be used until they maintain an adequate cutting capacity and then thrown away.

Rotary tools must be protected from corrosive agents: as regards tungsten carbide burs, it is recommended not to clean, spray or immerse them in hydrogen peroxide (hydrogen peroxide), as this would lead to the dissolution of the carbide.

The rubber tips must be protected from direct exposure to sunlight, too high temperatures and dry air currents for prolonged times, as this could lead to excessive drying of the raw material and lead to premature crumbling of the instrument.

9. WARNINGS

The tools from the Preparation Drill and Preparation and finishing drills for temporary bridges kits must be employed only in optimal conditions. In case of doubts or uncertainties about the indications or methods of use, use must be avoided or interrupted until all doubts are clarified.

Not being able to control the correct use of the product, we are not liable for any damage caused by incorrect use. The responsibility lies exclusively with the operating doctor.

Before each use, make sure that all the necessary components, tools and auxiliary means are available in a complete, functional way and in the required quantity. The availability of a partially incomplete kit can lead to the impossibility of correctly concluding a surgical procedure. Make sure that all components used in the mouth are not aspirated or swallowed.

Sweden & Martina S.p.A. surgical accessories they are sold in NON-STERILE packaging. Before using them, they must be cleaned, disinfected and sterilized according to the instructions given. When handling the devices, both during use and during cleaning and sterilization, it is recommended to always use surgical gloves for individual protection from bacterial contamination. Failure to comply with these warnings can cause infections and consequent pain, inflammation and bone loss for the patient and / or operator and / or lead to cross infections.

If washing and sterilization procedures other than those recommended with these instructions for use are used, they must be validated by the user. The adoption of different procedures can lead to premature wear of the tools. Complete clinical, radiological and radiographic documentation should be collected and archived.

The code, the description of the contents and the lot number are shown on each package. These data must always be quoted by the doctor for any communication on the matter.

The packaging complies with European standards.

10. DISPOSAL PROCEDURE

If used, dispose of the instruments as biological waste, according to the local regulations.

11. REFERENCE STANDARDS

The instruments are designed and manufactured in accordance with the most recent directives and harmonized standards regarding the materials used, production processes, information supplied and packaging.

12. RESPONSIBILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS

The instructions provided by Sweden & Martina are available at the time of treatment and accepted by the file dentistry; they must be observed and applied at all stages of use. The warranty covers defects only verified production, after sending the piece identified by item code and lot, within the validity period of the warranty. The warranty clauses are available on the website www.sweden-martina.com.

13. DATE AND VALIDITY OF THESE USER'S INSTRUCTIONS

These instructions for use are valid and effective from July 2021.

EXPLANATION OF SYMBOLS		
	Caution! See instruction for use	✓
	Batch number	✓
	Code	✓
	Manufacturer	✓
	Country of manufacture	✓
	UDI code, Unique Device Identification	✓
	Medical Device	✓
	Consult instruction for use www.sweden-martina.com	✓
	CE marking Where applicable: The identification number of the Notified Body shall follow this symbol.	✓
	American federal law restricts this device to sale by or by order of a professional practitioner	✓
	Do not use if the packaging is damaged	✓
	Non-sterile product	✓

Tabel 01

Device	Classification	Classification rule	Risk Class
Empty stainless steel tray	Non-invasive medical device	1	I
Complete surgical kit	Reusable surgical instruments	6	Ila
Diamond drills	Reusable invasive surgical instruments for use temporary (for less than 60 minutes)	6	Ila
Tungsten carbide drills	Reusable invasive surgical instruments for use temporary (for less than 60 minutes)	6	Ila
Superfine grit diamond disc	Reusable invasive surgical instruments for use temporary (for less than 60 minutes)	6	Ila
Soft boar bristle brush	Reusable invasive surgical instruments for use temporary (for less than 60 minutes)	6	Ila
Steel mandrels	Reusable invasive surgical instruments for use temporary (for less than 60 minutes)	6	Ila
Disposable Moore discs	Reusable invasive surgical instruments for use temporary (for less than 60 minutes)	6	Ila
Rubber for polishing	Reusable invasive surgical instruments for use temporary (for less than 60 minutes)	6	Ila

Fig. 01
Preparation Drill kit



Fig. 02
Preparation and finishing drills for temporary bridges kit

