

EN: kit for the removal of  
broken screws inside  
Sweden & Martina implants

# REMOVAL SCREW KIT

## 1. PRODUCT IDENTIFICATION

The surgical instruments designed for use with the implant systems manufactured by Sweden & Martina are medical devices intended for temporary use in the oral cavity (no more than 60 minutes at a time).

The surgical instruments manufactured by Sweden & Martina are intended for use with dental implants also manufactured by Sweden & Martina S.p.A.

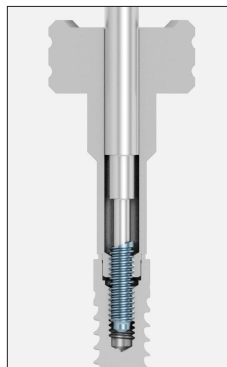
## 2. PRODUCT DESCRIPTION

These instructions for use refer to the accessories described below.

All the accessories are identified by the instrument code, which is applied with laser marking on the instrument body. If the complete code cannot be applied due to lack of space, elements that will allow the device to be unambiguously identified are however provided (e.g. diameter or length).

Within the implantological systems of Sweden & Martina S.p.A. a colour code is defined helping to identify the diameters of the instruments to be used according to the implant diameter or platform size. The colour-coding legend is explained in the catalogues and surgical manuals of the individual implant systems.

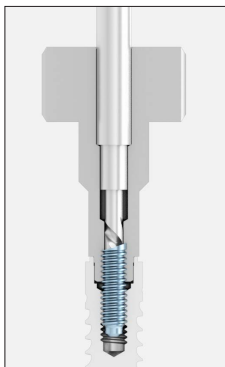
With the Sweden & Martina S.p.A. **RSK - REMOVAL SCREW KIT** systems it is possible to extract the broken screw from the implant when screw is not fixed with special types of cement or has not been damaged when trying to remove it.



**Figure 1.** Clutch drill, with related guide, in contact with the broken screw



**Figure 2.** Broken screw during removal, hooked to the clutch drill



**Figure 3.** Spiral drill, with related guide, in contact with the broken screw

By inserting the guide inside the implant and using the "clutch" drill (*figure 1*), it will be possible to unscrew the residues of the broken screw stuck inside the implant (*figure 2*). If it not possible to remove the screw in this way, one has to use, always by means of the related guide, the special "spiral" drill (*figure 3*) with which it will be possible to wear away the stuck screw piece. Once the screw has been worn away, the shavings can be removed from the implant cavity with abundant irrigation, removing the bigger screw residues with a normal probe if required.

**For the detailed use of the accessories, consult the text on the back of these instructions.**

## 3. INTENDED USE

In accordance with Directive 93/42/EEC adopted in Italy with Law Decree 46/97 dated 26 March 1997, Annex IX, Sweden & Martina S.p.A. declares that it is the manufacturer of the surgical instruments for Sweden & Martina S.p.A. dental implants, and identifies their risk class as follows:

Device	Annex IX rule	Risk class
Drills	6	2a
Guides for drills, implant analogs, manual drivers	6	I

The use and handling of surgical instruments is intended for professional medical staff with the necessary qualifications and accreditation.

## 4. IDENTIFICATION OF THE MANUFACTURER

The manufacturer of the surgical instruments for dental implants referred to in these Instructions for Use is:

**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

## 5. WARNINGS

Sweden & Martina surgical instruments are sold in NON-STERILE packs. Before use they must be cleaned, disinfected and sterilised following the instructions given below. Failure to follow this warning may expose the patient to infection.

A complete clinical, radiological and radiographic documentation should be collected and filed.

Every product pack shows the product code, a description of contents and the batch number. These details, which are also indicated on labels included in the packs, must always be mentioned by the clinician in any correspondence regarding the products.

The product pack conforms with European standards.

When handling these devices, both during actual use and during cleaning and sterilisation procedures, surgical gloves must always be worn for personal protection from bacterial contamination.

## 6. CLEANING / DISINFECTION / STERILISATION / STORAGE

**Caution!** All Sweden & Martina surgical instruments for implants are sold in **NON-STERILE** condition.

Before use, they must be cleaned, disinfected and sterilised using the following procedures validated by Sweden & Martina S.p.A.

These processes must be performed prior to the first use and before each subsequent operation.

### a. Cleaning

Containers and transport to be used for washing: no special requirements.

In case of automated cleaning: use an ultrasound bath with a suitable detergent solution. It is recommended to use only neutral detergents. The concentration of the solution and duration of washing must comply with the manufacturer's instructions. Use demineralised water to avoid the formation of stains and marks.

When draining washing water, check the recesses of the instruments, holes, etc. to check that all residues have been completely removed. If necessary, repeat the cycle or use manual cleaning.

In case of manual cleaning: use a suitable neutral detergent and follow the manufacturer's instructions for use. Brush products with a soft-bristled brush under abundant running water. Using the brush, apply the detergent to all the surfaces. Rinse with distilled water for at least 4 minutes. Make sure that the running water passes abundantly through any holes. In case of drills with internal irrigation, use the special pins supplied with the handpieces to ensure that the irrigation holes are completely clean and free from residual bone fragments and biological tissues.

After rinsing, dry the devices thoroughly and pack them in appropriate sterilisation bags. Do not exceed 120°C when performing a drying cycle in a washing and disinfection appliance.

**b. Sterilisation:** in a vacuum autoclave, sterilising as follows:

- autoclave (gravity displacement cycle) at a temperature of 121°C with a minimum exposure of 30 minutes and drying cycle of 15 minutes;
- autoclave (dynamic air removal cycle) at a temperature of 132°C with a minimum exposure of 4 minutes and a drying cycle of minimum 20 minutes.

**c. Storage:** after sterilisation, products must remain in the bags used for sterilisation. Bags must only be opened immediately before reuse. The product must be used immediately after sterilisation.

## 7. DISPOSAL PROCEDURES

If used, surgical instruments must be disposed of as biological waste, in accordance with existing local regulations.

## 8. USING THE PRODUCT

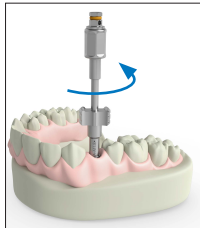
### a) Use of the guide with the clutch drill



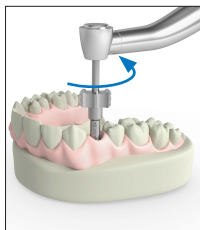
1. Insert the guide inside the fixture, making sure that the hexagon fits precisely to the implant platform;



2. Keeping the guide completely still with one's fingers, insert the related drill inside the centring hole and lower until it comes into contact with the broken screw;



3. using the contra-angle manual driver for instruments, compress the drill firmly by manually rotating the driver **ANTICLOCKWISE**. After a few rotations it will be sufficient to remove the guide and easily extract the piece of broken screw which has remained engaged with the clutch drill;

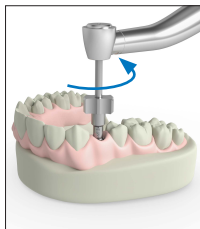


4. it is possible to use the clutch drill mounted on a contra-angle handpiece, using the micromotor for implantology. Insert the drill inside the guide keeping the handpiece motor **STILL** until touching the tip of the broken screw. Press hard and only now actuate the instrument anticlockwise at the lowest number of rotations (never more than 20) and at the maximum programmable torque. After a few rotations, it will be possible to remove the screw as illustrated in the previous paragraph.

### b) Use of the guide with the spiral drill



1. Should it not be possible to remove the broken screw with the clutch drill, the use of the special spiral drill (left-handed) will be necessary to wear away the broken screw.



2. This drill must be used only with the micromotor handpiece, fitting the drill into the guide and making the motor turn **ANTICLOCKWISE** at a speed of 2000 rpm. Above all, an abundant irrigation is recommended: hold down and release the drill continuously, thus avoiding the overheating of the fixture and at the same time the breaking of the drill. At the end of the operation, eliminate the residues of the broken screw which have remained inside the implant with an abundant irrigation.

## 9. LIABILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS

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 the usage phases.

The warranty covers ascertained manufacturing defects only, upon the return within the warranty period of the faulty product identified by the article code and batch number. The warranty clauses are available on the website [www.sweden-martina.com](http://www.sweden-martina.com).

## 10. LEGAL REFERENCE

The design and production of the prosthetic components is carried out in accordance with the latest directives and harmonised standards applicable to the used materials, the production processes, the provided information and packaging.

## 11. DATE AND VALIDITY OF THESE INSTRUCTIONS FOR USE

These instructions for use are valid and effective as of January 2018.

### Key to symbols

	Caution, see instruction for use
	Batch number
	Code
	Manufacturer
	Consult the instructions for use
	CE conformity mark
	CE conformity mark
	Non-sterile product

### Kit components

CODE	DESCRIPTION
<b>RSK-A</b>	<b>for the implants: PREMIUM KOHNO, PREMIUM KOHNO ONE, SHELTA</b>
ANA-330	Implant analog Hex. 2.00 mm with thread M1.6
A-ANA-330	Implant analog Hex. 2.30 mm with thread M1.8
A-ANA-425	Implant analog Hex. 2.50 mm with thread M2
AVV-CA-DG-EX	Contra-angle driver for instruments
FA-EXTRACTOR	Clutch drill
FC-EXTRACTOR	Spiral drill
GUA-A-EX230M18	Guide for clutch drill Hex. 2.30 mm with thread M1.8
GUA-A-EX200M16	Guide for clutch drill Hex. 2.00 mm with thread M1.6
GUA-A-EX250M20	Guide for clutch drill Hex. 2.50 mm with thread M2
GUI-A-EX230M18	Guide for spiral drill Hex. 2.30 mm with thread M1.8
GUI-A-EX200M16	Guide for spiral drill Hex. 2.00 mm with thread M1.6
GUI-A-EX250M20	Guide for spiral drill Hex. 2.50 mm with thread M2
<b>RSK-E</b>	<b>for the implants: OUTLINK<sup>2</sup>, SYRA</b>
E-ANA-330	Implant analog Hex. 2.40 mm with thread M1.8
E-ANA-410	Implant analog Hex. 2.70 mm with thread M2
AVV-CA-DG-EX	Contra-angle driver for instruments
FA-EXTRACTOR	Clutch drill
FC-EXTRACTOR	Spiral drill
GUA-E-EX240M18	Guide for clutch drill Hex. 2.40 mm with thread M1.8
GUA-E-EX270M20	Guide for clutch drill Hex. 2.70 mm with thread M2
GUI-E-EX240M18	Guide for spiral drill Hex. 2.40 mm with thread M1.8
GUI-E-EX270M20	Guide for spiral drill Hex. 2.70 mm with thread M2
<b>RSK-U</b>	<b>for the implants: GLOBAL</b>
U-ANA-380	Implant analog Oct. 3.05 mm with thread M1.8
AVV-CA-DG-EX	Contra-angle driver for instruments
FA-EXTRACTOR	Clutch drill
FC-EXTRACTOR	Spiral drill
GUA-U-OT305M18	Guide for clutch drill Oct. 3.05 mm with thread M1.8
GUI-U-OT305M18	Guide for spiral drill Oct. 3.05 mm with thread M1.8
<b>RSK-CSR</b>	<b>for the implants: CSR</b>
VSR-ANA	Implant analog Hex. 2.00 mm with thread M1.6
VSR-ANA-N	Implant analog Hex. 2.30 mm with thread M1.8
AVV-CA-DG-EX	Contra-angle driver for instruments
FA-EXTRACTOR	Clutch drill
FC-EXTRACTOR	Spiral drill
GUA-CSR-EX200M16	Guide for clutch drill Hex. 2.00 mm with thread M1.6
GUA-CSR-EX230M18	Guide for clutch drill ad Hex. 2.30 mm with thread M1.8
GUI-CSR-EX200M16	Guide for spiral drill Hex. 2.00 mm with thread M1.6
GUI-CSR-EX230M18	Guide for spiral drill Hex. 2.30 mm with thread M1.8

The analog contained in the kit and shown in the above table is an example of a connection for implant systems and must be used only to test the guides and drills before using them on a patient.

**sweden & martina**

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