CE 0476

GB: Minimally invasive sinus elevation system
Sinus Lift M.I.S.E. EVO (Minimal Invasive Sinus Elevation - Evolution)

1. PRODUCT IDENTIFICATION
The M.I.S.E. EVO kit related to the maxillary sinus lift technique manufactured by Sweden & Martina S.p.A. is a medical device intended to be used in the oral cavity, for temporary use (continuous duration not exceeding 60 minutes), reusable, in NON-STERILE packaging. The function of the instruments in the kit is: site preparation for sinus lift.
The M.I.S.E. EVO kit manufactured by Sweden & Martina S.p.A. is intended for use with dental implants manufactured by Sweden & Martina S.p.A. The use of surgical instruments for interventions with implants 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 “Responsibility for defective products and warranty terms”, below). We are not liable for the use of non-original equipment.
2. INTENDED USE AND RISK CLASS
The M.I.S.E. is an instruments kit that allows you to lift the maxillary sinus floor by 5-10 mm with respect to the vestibular position, allowing you to insert an implant without opening the vestibular porthole. The bending of the cortex and the overcoming of the elastic deformation phase up to its rupture in order to insert a reconstructive biomaterial and the implant are guaranteed with gradual, atraumatic, step by step passages (1 mm each), by means of a depth stop.
The M.I.S.E. EVO kit is composed of an autoclavable, reusable surgical tray, which contains the following instruments:
N°7 drills
- N°13 depth stops
- N°1 bilateral hand instrument: depth gauge / compactor d. 3 mm
- N°1 bilateral hand tool: compactor d. 3.4 mm / compactor d. 4 mm
- N°1 instrument holder box consisting of a box and an internal tray

The kit is sold in a complete package with all the instruments. The surgical tray and all the instruments are also available in single, unitary packs as spare parts. All the devices, both the kit and the spare parts, 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 M.I.S.E. EVO must be used exclusively by medical and dental personnel with the necessary qualifications and must only be used in accordance with the instructions for use, according to the general rules of dental and/or surgical treatment and in compliance with accident prevention and protection regulations at work. Failure to comply with the instructions provided can cause surgical problems and damage to the patient’s health. Dentists who use the kit must be well trained in bone regeneration and oral surgery. The use of the kit, although tested, designed to be safe and to prevent and reduce errors, is unsuitable for inexperienced operators.
Both the kit and the instruments are medical devices. The risk class of the devices is defined in table 01.
3. IDENTIFICATION OF THE MANUFACTURER
The manufacturer of the M.I.S.E. EVO kit and its components is:
SWEDEN & MARTINA S.p.A.
Via Veneto 10, 35020 Due Carrare PD, Italy.
Tel. 049.91.24.300 - Fax 049.91.24.290
email: info@sweden-martina.com - www.sweden-martina.com
4. RAW MATERIAL USED
The materials used for the production of the M.I.S.E. EVO kit and instruments were selected on the basis of the properties indicated for their intended use, in compliance with the Regulation (EU) 2017/745, Annex I Essential Requirements, point 10.1.
All the instruments for sinus lift contained in the M.I.S.E. EVO 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 surgical tray that contains the instruments is made of Radel, a very high performance plastic material that can be sterilized in an autoclave without deteriorating.
The devices belonging to the M.I.S.E kit do not contain phthalates, nor materials of human or animal origin, nor drugs. 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. Drills
The drills for sinus lift are designed as instruments which are intended to be used in conjunction with angled handpieces (fig. 1). They have the working part structured in different shapes and diameters: Rounded apex (ø 3.0 / ø 3.4 / ø 4.0), Chamfered apex (ø 3.0), BreakUp apex (ø 3.0) and cylindrical (ø 2.00 and 2.50 mm). These instruments are indicated exclusively for inserting threaded and non-threaded cylindrical implants, whose size of the implant body corresponds to the diameter of the working part of the rotating instruments. The first drill (Rounded) has no sharp bevels, the second (Chamfered) instead has apical bevels that produce displacement effects on the cortex, the third (Break up) has sharp bevels. The cylindrical drills, on the other hand, guarantee an effective cut in the phase of creating the invitation to the other cutters. Laser markings and a color code identify the diameters of the instruments making up the series. Appropriate depth marks on the working part of the instrument indicate the depth reached from time to time as the instrument advances in the implant site.
The depth notches represent a distance, between one and the other, of 1 mm (fig. 2). The first notch detects the depth of 1 mm, the others gradually add a millimeter, and indicate the depth reached from time to time as the instrument advances into the implant site. The notches are distinguished from each other being represented alternately as follows:
- the first notch is 1 mm deep and is engraved
- the second notch is 2 mm and is represented by a dark ring marked with laser technique
- the third notch is represented by a 1 mm high laser marked black band starting at 3 mm depth e ends at 4 mm
- the following notches follow the same pattern as the first three (5 mm machined notch, 6 mm lasered thin notch, then 1 mm thick band between 7 and 8 mm deep, and then again machined notch at 9 mm, thin laser-cut notch at 10 mm, laser-cut band 1 mm high between 11 and 12 mm, machined notch at 13 mm).

This scheme allows the user to recognize the notches without the need to count the millimeters at each use. The drills must be used at the rotation speed indicated in the Method of Use, reported below. Using different speeds can compromise the result of the surgery and cause harm to the patient.**2. Depth stop**
To help the user, the kit contains 13 depth stops, called spacers, with progressive incremental lengths of 1 mm, to be used in combination with the drills and compactors (fig.3).
The stops are inserted and removed through the front of the rotating instrument. These safety devices limit any possible movement that can cause injuries and accidents.
Also make sure that the stop provides sufficient retention. Weak retention may cause the instrument to fall out of the drill. The retention between the stops and the body of the drill is guaranteed by the 4 tabs present at the end of the stops (fig. 4). To increase (decrease) the interference between the stops and the body of the drill, exert a slight pressure on the opposing tabs from the outside towards the inside (vice versa).
After inserting the depth stops on the drills or compactors (see below), always check that the working part of the drill or compactor outside the stop coincides with the desired working length (i.e. make sure the stop is inserted at the desired length). The insertion of a stop that is too short can cause excessively long preparations, which in turn may cause damage to the sinus membrane.
Attention:
After about 25 operations based on the compactness and quality of the bone, the cutting instruments must be replaced with new ones.
Such pressure must never be applied to forcefully stop the rotation of the instrument. This could lead to excessive heat increase in the tissues affected by the cut, and damage both the tool and the device used (micromotor). This could also lead to the breakage of the instrument itself. It is recommended to work intermittently, to avoid overheating and wear of the working part and undue heat increase in the tissues affected by the cut. The use of appropriate refrigeration liquid is recommended. Incorrect insertion can lead to instrument vibrations, eccentric rotations, premature wear and bending of the stem. It is recommended to use only surgical micromotors suitable for use. It is recommended that the micromotors and handpieces be checked periodically by the manufacturers, according to their individual indications, to prevent possible malfunctions (eg axis displacements of the transmission shafts, worn or malfunctioning grippers, etc.). The use of micromotors o improperly maintained handpieces can lead to eccentric operation of the instruments, with consequent vibrations and unsuitable preparations. The 25 recommended cycles represent an average figure. The wear of the drills largely depends on the type and density of the milled bone: harder bone leads to greater wear of the instruments. For greater safety and caution with respect to the wear resistance capacity of the device, it is recommended that the cutters be used for no more than 25 work cycles or sooner if the tools lose their cutting capacity. It is recommended to check the maintenance status of the residual cutting capacity after each intervention. Sweden & Martina S.p.A. assumes no responsibility in case of excessive use. The drills must never be re-sharpened before use. Never use damaged, bent or worn tools
2. Depth stops
To protect the user, the kit includes 13 depth stops, defined spacers, of progressive lengths with fixed increments of 1 mm, to be used in conjunction with the cutters and compactors (fig. 3).
Stops are inserted and removed through the front of the rotary instrument. These safety devices limit any possible maneuver that could cause risks and accidents. Also check that the stop performs sufficient retention.
Too weak retention can cause the depth stop to fall off the bur. Retention between the stops and the drill is ensured by the 4 fins present at the ends of the stops (fig. 4). To increase (decrease) the interference existing between the stops and the body of the drill, it is necessary to exert a slight pressure on the opposing fins from the outside to the inside (vice versa).
After inserting the depth stops on the drills or compactors (see below), it is always necessary to check that the working part of the cutter or compactor remaining outside the stop coincides with the desired working length, i.e. having inserted the stop at the desired length. The insertion of a stop that is too short can cause too long preparations, and cause damage to the sinus membrane.
3. Manual Instruments
The kit contains two bivalent manual instruments.
The first (fig. 5), consists of a handle with two terminals representing respectively a depth gauge (on the right in the image fig. 5) and a compactor of d. 3.00 mm (on the left in the image fig. 5).
The second instrument (fig. 6) consists of a handle with two terminals respectively representing a compactor of d. 3.40 mm and one of d. 4.00 mm.
The depth marks of both the depth measuring tip and the compacting tips are represented in the same way as those present on the drills.
The same depth stops used to check the working length of the drills must be assembled on the compactors. Also in this case, after having inserted the stop, check that the residual working length corresponds to the desired one.
4. Complete Kit and Surgical Tray
In the M.I.S.E. EVO the instrumentation is placed inside a sterilizable surgical tray in autoclavable radel.
The kit is sold complete with all the instruments that compose it.
The tray is sold, as well as as part of the complete kit, in unitary, empty packaging, as a spare. The codes and sales descriptions of the empty tray and the complete kit are as follows:
- ZMISE-INT kit complete with all the instruments (followed by a letter and a number to indicate the revision of the kit).
- MISE-TRAY-INT surgical tray in radel, empty, M.I.S.E EVO instrument holder.

Fig.7 shows an image of the complete kit, and fig.8 shows the internal part of the tray (the instrument holder lid).
The housings of the drills are identified by the same color code present on the shank of the respective drills. The presence of this color code helps the identification of the instruments and prevents errors when removing the instruments from the kit during the operating phase.
The 3.00 mm break Up drill has a WHITE color code. The 3.00mm Chamfered Bur is color coded BLACK. The 3.00, 3.40, and 4.00 mm Rounded drills are color coded GREEN, BLUE and MAGENTA respectively.
6. CLEANING / DISINFECTION / STERILISATION / STORAGE
The instruments of the M.I.S.E. EVO are supplied assembled inside the surgical tray.
Attention! The M.I.S.E. EVO and all its components are sold in NON-STERILE condition. Before use, they must be cleaned, disinfected and sterilized following the following procedure validated by Sweden & Martina.
Repeating the processes described in this paragraph has little effect on these devices. The end of life is generally determined by wear and damage due to use.
Cleaning: Remove major organic residues with a disposable cloth or paper.
After use, immerse the medical devices in a disinfectant bath. The disinfectant solution must be used in accordance with the manufacturer’s instructions
Containers and transport: There are no special requirements. It is recommended that tools be subjected to a cleaning process as soon as reasonably practicable immediately after use. Disassemble multi-part tools
In case of automated cleaning: use an ultrasonic bath using a suitable detergent solution. It is recommended to use only neutral detergents. The concentration of the solution and the duration of the washing must comply with the instructions of the manufacturer of the same. The use of ultrasonic tanks facilitates the removal of the most stubborn residues. Use demineralized water to prevent the formation of stains and halos.
When unloading, check the recesses of the tools, holes, etc. to verify the complete removal of each
visible residue. If necessary, repeat the cycle or use manual cleaning.
In case of manual cleaning: Use a suitable neutral detergent, following the manufacturer’s instructions for use. Brush the products 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 depth stops and through the holes in the tray. Check instruments carefully and replace damaged ones. Visually inspect for damage and wear. The cutting edges should be free from notches and have a solid edge. Check for any distortions suffered by the instruments. Replace worn tools. The use of worn, distorted and more generally damaged instruments can lead to surgical complications and bone necrosis. Generally, the temperature at the site should not exceed 36-37 ° C.
Check that the stops have maintained the correct friction and do not fall off the drills. If they are loose, reactivate the flaps as explained above. Slack stops risk falling from the drills during surgery. After rinsing, dry the instruments completely, put them back in the tray, check that the tray is closed correctly. and pack it all in suitable sterilization bags. If a drying cycle is performed as part of the cycle of a washing and disinfection equipment, not
exceed 120 ° C.
Sterilization: In vacuum autoclave, and sterilize in the following way:
- Temperature = 121 ÷ 124 C °, with a minimum autoclave cycle of 20 minutes and a drying cycle of 15 minutes.

To sterilize multiple instruments in a single autoclave cycle, ensure that the maximum sterilizer load is not exceeded. If you sterilize single instruments outside the tray, it is recommended to pack the different instruments separately to prevent the instruments from being damaged in contact with each other.
It is recommended not to place the radel cassette against the walls of the autoclave chamber during the sterilization cycles, since prolonged contact can cause permanent deformation of the cassette itself.
Conservation: After sterilization, the product must remain in the bags used for sterilization. The bags must be opened only immediately before using the tools. The pouches 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 chain of coagulation, 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 specifically of the surgical technique described below are mentioned in
- the following are added to the contraindications already mentioned:
- Bone density D4
- Initial bone height less than 3 mm
- Presence of pathologies affecting the sinus mucosa

8. METHOD OF USE
Indications
To be able to perform the MISE surgical technique with the atraumatic rotary instruments for sinus lift it is necessary to follow carefully the following indications:
- Bone density D2-D3
- Bone height: measurement of bone height through the use of intraoral x-rays performed with the Rinn centering device
- in order to have a 1: 1 ratio or through the use of the T.C. Dentascan, which allows us to highlight:
- The precise measurement of the distance between the bone crest and the cortical plane of the maxillary sinus floor
- Bone density
- The bucco-lingual bone thickness
- The possible presence of hypertrophy of the sinus mucosa or other sinus pathologies
- The initial bone height must be no less than 3 mm

- The maximum lift we can achieve with this crestal approach osteotomy technique is 5 mm.

The M.I.S.E. EVO can be used for the preparation of surgical sites for all cylindrical, threaded implants, which have a body with a diameter compatible with that of the drills in the kit. The drills prepare holes of 3.00, 3.40 and 4.00 mm. These diameters are among the most used by implant systems on the market. Refer to the indications of the individual implant manufacturers to verify the consistency of the preparation diameter.

Attention! In the event of perforation of the maxillary sinus or the nasal floor, the operation must be stopped immediately and the urgency treated appropriately for the case in question.

The goal of the surgical technique is to raise the maxillary sinus floor by max. 5 mm with respect to the original position, and then insert an implant without opening a buccal port.

After incision of the soft tissues, uncover the crestal bone plane and use the 2.00 mm drills to start the Preparation. Using the depth probe included in the kit, measure the implant socket prepared with the drill from 2.00 mm. Continue preparation with the 2.50 mm drill. Both drills must be used at 800 rpm. Prepare the implant socket up to 2 mm from the cortex of the sinus floor.

In this regard, it is useful to measure bone height with intraoral x-rays performed with the Rinn technique or with CT. Dentascan. Please note: all drills must be used intermittently, with adequate irrigation. Otherwise, there is the risk of overheating of the site and consequent bone necrosis. The temperature should not exceed 36-37 ° C. The torque of the micromotor must be set to the maximum value. The micromotors currently on the market do not exceed, on average, 68 Ncm of torque. Higher torques have not been tested. If the micromotor delivers a higher torque, then bring it back to these values.

Sinus floor lift for max. 2 mm

Use the Rounded drill of d. 3.00 mm or Chamfered ø 3.00 mm of the Sinus Lift Kit by applying the depth stop corresponding to the depth detected by the probe, which will bring the working length of the drill to 2 mm from the cortex of the floor. Use the handpiece at a speed of 800 rpm, ensuring adequate external irrigation.

Then move on to the 2nd depth stop which will increase the working height by 1 mm, compared to the 1st stop. By proceeding with this system, the operator will already be able to perceive the cortical plane with the 3rd stop of depth. Then apply the 4th and 5th stops always on the same drill. During these last steps, a substantial bending of the cortex is determined without rupture with the lifting of the maxillary sinus floor by about 2 mm. If an implant diameter greater than the conditions determined is planned during the design phase, enlarge the implant site laterally with the Rounded drill with a diameter of ø 3.4 mm and possibly the one with a diameter of ø 4.0, applying the 5th stop. Before inserting the implant, pass the crestal drill if the surgical protocol of the implant system is provides.

Lifting of the maxillary sinus floor over 2 mm

If you wish to lift the maxillary sinus floor beyond 2 mm, the steps previously described must necessarily be carried out with the Chamfered drill of d.3.00 mm of the Sinus Lift Kit. After the cortical bending phases carried out with the 4th and 5th stops it will always be necessary with the aid of the Chamfered drill, applying the 6th stop, to arrive at the rupture of the cortex itself, which will be perceived by the operator as a sensation of penetration in the void. At the time of the cortex rupture, the stop will guarantee penetration beyond the sinus floor, extremely limited (on average about 0.5 mm); this avoids significant damage to the Schneiderian membrane.

In case of thick cortex, the Chamfered bur may not be sufficient; in this case it will be necessary to further drill with the Break Up drill, which has a greater cutting incidence, with the same stop used previously on the Chamfered drill. Once the cortex has been passed, a double phase of reaming at reduced speed (100 rpm) of the fractured cortex is carried out using the Rounded drill ø 3.0 mm, first applying the same stop used in the rupture phase and then the stop greater than 1 mm. Failure to use this drill risks generating postoperative pain for the patient. This last phase of reaming the area overcoming the sinus cortex creates the necessary space to facilitate the insertion of filling material through the corresponding compactor KM-C-PROF-300 (compactor side).

On this instrument it will be necessary to insert the depth stop 2 mm lower than the one used at the moment of the cortical rupture.

This will allow the material to be pushed, never going beyond the cortex of the floor with the instrument (for example: if the sinus floor cortex was broken at a working depth of 12 mm, place a depth stop of 10 mm on the compactor. mm).

Initially insert some collagen, which, by soaking up blood, will lift the mucous membrane of the breast. This will then be followed by some repeated loads of autogenous bone and bone substitutes inserted always using the compactor kept at the same size.

To insert implants with a larger diameter, use the Rounded drill with a diameter of ø 3.4 mm in two steps: applying the last stop used at the time of the cortex rupture and subsequently at a reduced rate (100 rpm) with a stop greater than 1 mm .

If you want to further widen the site, repeat the two steps with the Rounded drill with a diameter of ø 4.0.

Depending on the diameter of the last drill used, use the KM-C-340-400 compactor respectively in the parts with a diameter of ø 3.4 mm or ø 4.0 mm, for the insertion of materials through the implant socket. The choice of the implant and therefore any final crestal preparation is left to the operator. This technique allows, following the step by step protocol, to lift the floor and the mucosa of the maxillary sinus from 1 to 5 mm compared to the original position, reserving the technique of vestibular access with porthole for complex cases.

Attention! During the surgical technique, the axis of the rotating instruments must be kept suitable both from the point of surgical view than prosthetic. Sideways movements should be avoided.

9. WARNINGS

The M.I.S.E. EVO instruments must only be used 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. These instructions for use may not be sufficient to ensure correct application of the instruments for surgical or implantology procedures by inexperienced operators. In this regard, it is recommended to participate in specific training courses and to read the existing bibliography on sinus lift surgical techniques before using the instruments. 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 harmonised 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.

Fig. 01
Sequence of drills in the M.I.S.E. Evo kit

Fig. 02
Diagram of the depth lines on the drills and other instruments contained in the M.I.S.E. Evo kit

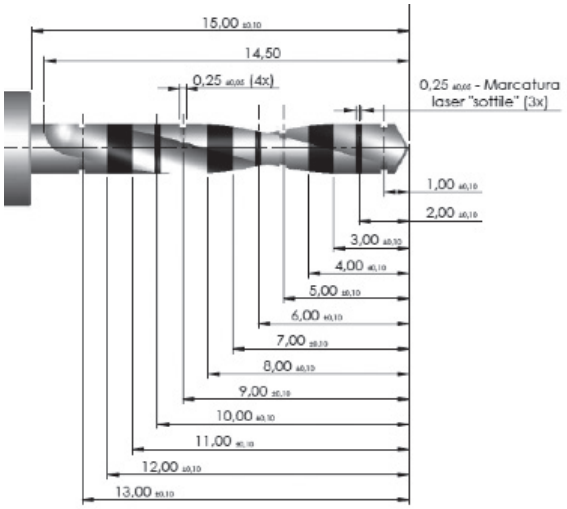


Fig. 03
Progression of the 13 depth stops for rotating Sinus Lift instruments

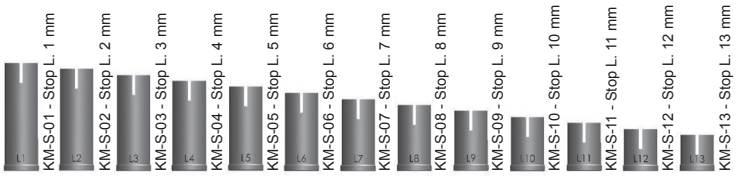


Fig. 04
How to activate the tabs of the safety stops or spacers ft

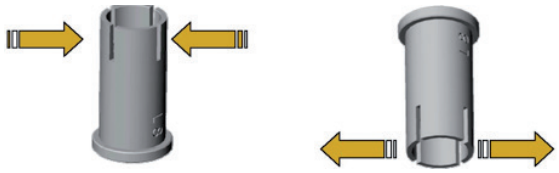


Fig. 05
Double-sided manual instrument that acts as a depth meter on one side and a ø 3 mm compactor on the other. Ref: KM-C-PROF-300

Fig. 06
Double-sided manual instrument that acts as a ø 3.4 mm compactor on one side and a ø 4 mm compactor on the other. Ref: KM-C-340-400

Fig. 07
Complete M.I.S.E. Evo kit

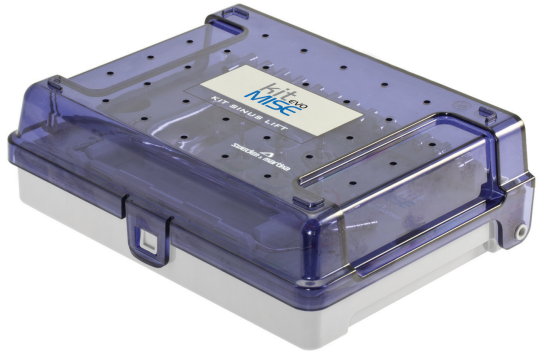
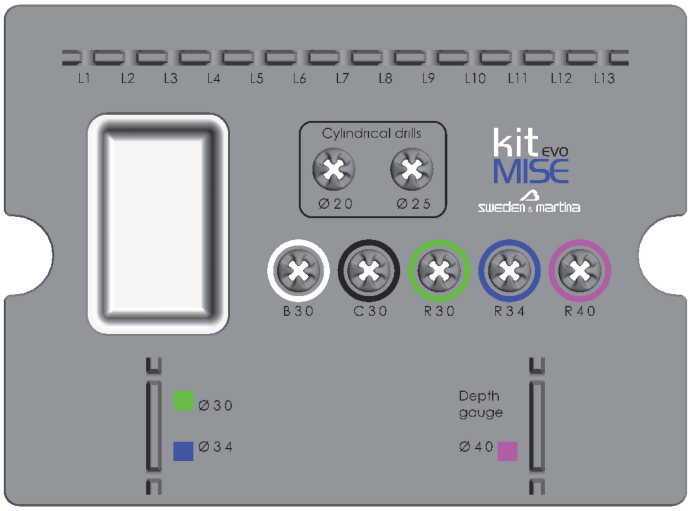


Table 01

Device	Features	Classification rule	Risk Class
Drills and stops	Invasive surgical devices intended for transient use in the oral cavity (continuously on the same patient for less than 60 minutes). They are used connected to an active medical device (surgical motor)	6	IIa
Surgical tray, empty, designed to hold the devices contained in the kit	An accessory designed for being used with the devices contained in the kit (it is an organiser that allows sterilising and storing the devices). It is a non-invasive device	1	I
Manual instruments with two working sides (depth meter/ compacter ø 3 and compactor ø 3/4 and compactor ø 4)	They are invasive surgical devices intended to be used manually and are reusable surgical instruments	6	I
Evo M.I.S.E. Kit complete with all the instruments	Since the kit contains several devices, the risk class is the same as that of the device with the highest risk class included within it	6	IIa

Fig. 08
Instrument tray: a handy instrument organiser



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	✓

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