

Surgical manual

MINIMAL INVASIVE
SINUS ELEVATION
M.I.S.E. EVO Kit



M.I.S.E. EVO KIT CONTENTS



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Introduction to the M.I.S.E. EVO Kit

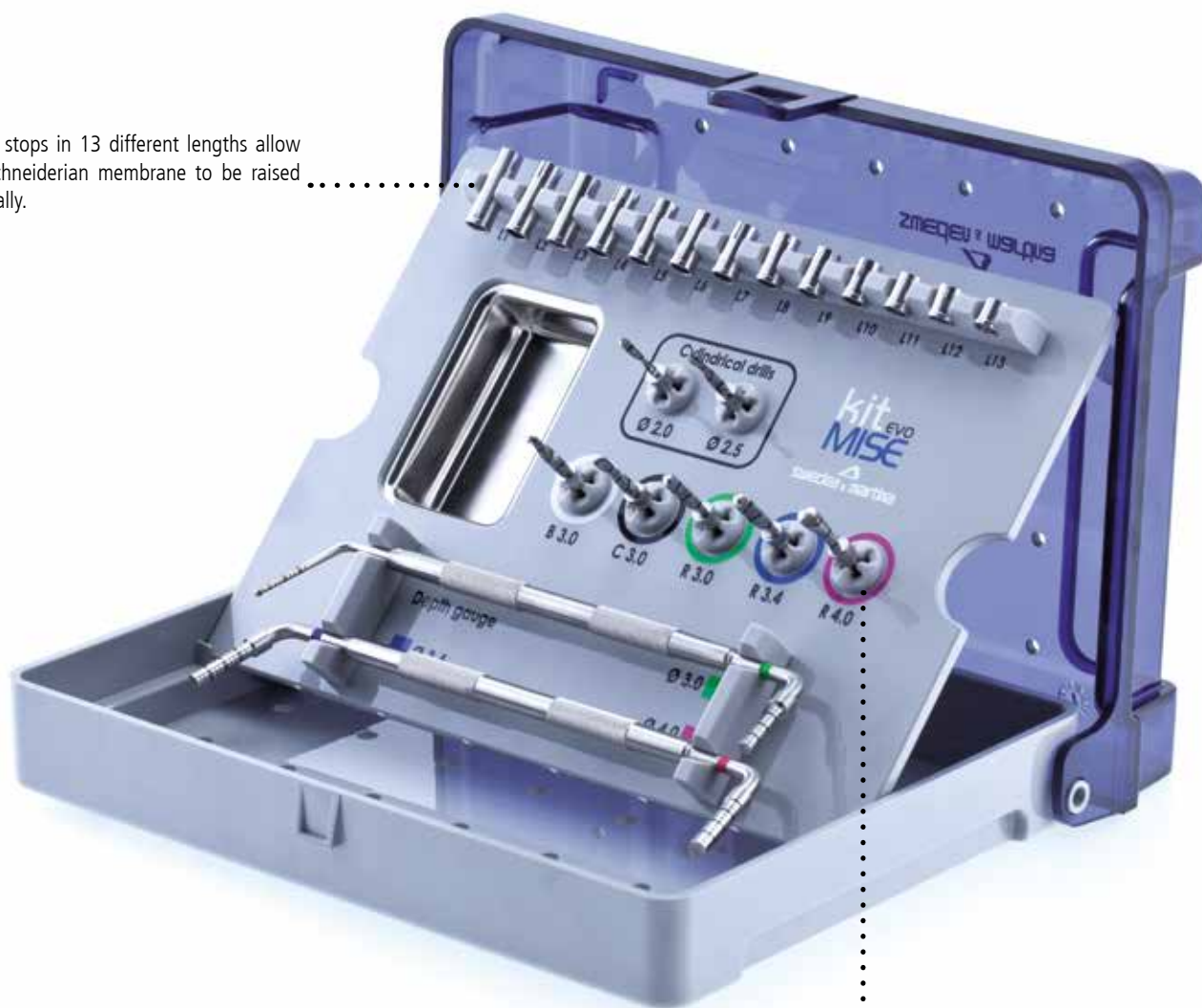
The M.I.S.E. EVO Kit is a system that allows the maxillary sinus to be augmented atraumatically and gradually to a height of 5–10 mm above its initial level. The bending of the cortical bone and the overcoming of the phase of elastic deformation until the bone breaks to allow the insertion of a reconstruction biomaterial and an implant are guaranteed by gradual and atraumatic series of steps of 1 mm each, using depth stops.

The significant advantage of this system with respect to conventional osteotomy techniques is the use of drills that when used with depth stops make it possible to gradually and predictably raise the Schneiderian membrane in steps of 1 mm at a time, conserving its integrity. This technique also avoids the need to open a lateral window.

Stops can be assembled and removed directly over the tip of the drill, with no need to remove it from the contra-angle handpiece. The lateral tabs on the stops ensure safe and secure fixation to both the drill and condensers, which are supplied preassembled on handles.

The M.I.S.E. EVO Kit can be used to prepare the site for threaded and unthreaded implants, in which the size of the implant body corresponds to the diameter of the working part of the rotary instruments.

Depth stops in 13 different lengths allow the Schneiderian membrane to be raised gradually.



The drills, can be recognized by the coloured rings at the base of the shank, which follow a colour code to guide the sequence of use.

Surgical tray and complete kit

The codes and sales descriptions of the empty tray and the complete kit are as follows:

code	description
 <p data-bbox="240 842 323 869">ZMISEB1</p>	Complete kit with all instruments
 <p data-bbox="236 1189 331 1216">MISETRAY</p>	Empty surgical tray in Radel plastic for M.I.S.E. EVO instruments
 <p data-bbox="209 1413 360 1440">GROMMET-MISE</p>	Kit of 5 spare silicone supports for surgical trays, for drills

SURGICAL INSTRUMENTS

DEPTH STOPS

KM-S-01 KM-S-02 KM-S-03 KM-S-04 KM-S-05 KM-S-06



CYLINDRICAL INITIAL DRILLS

KM-F-200 KM-F-250



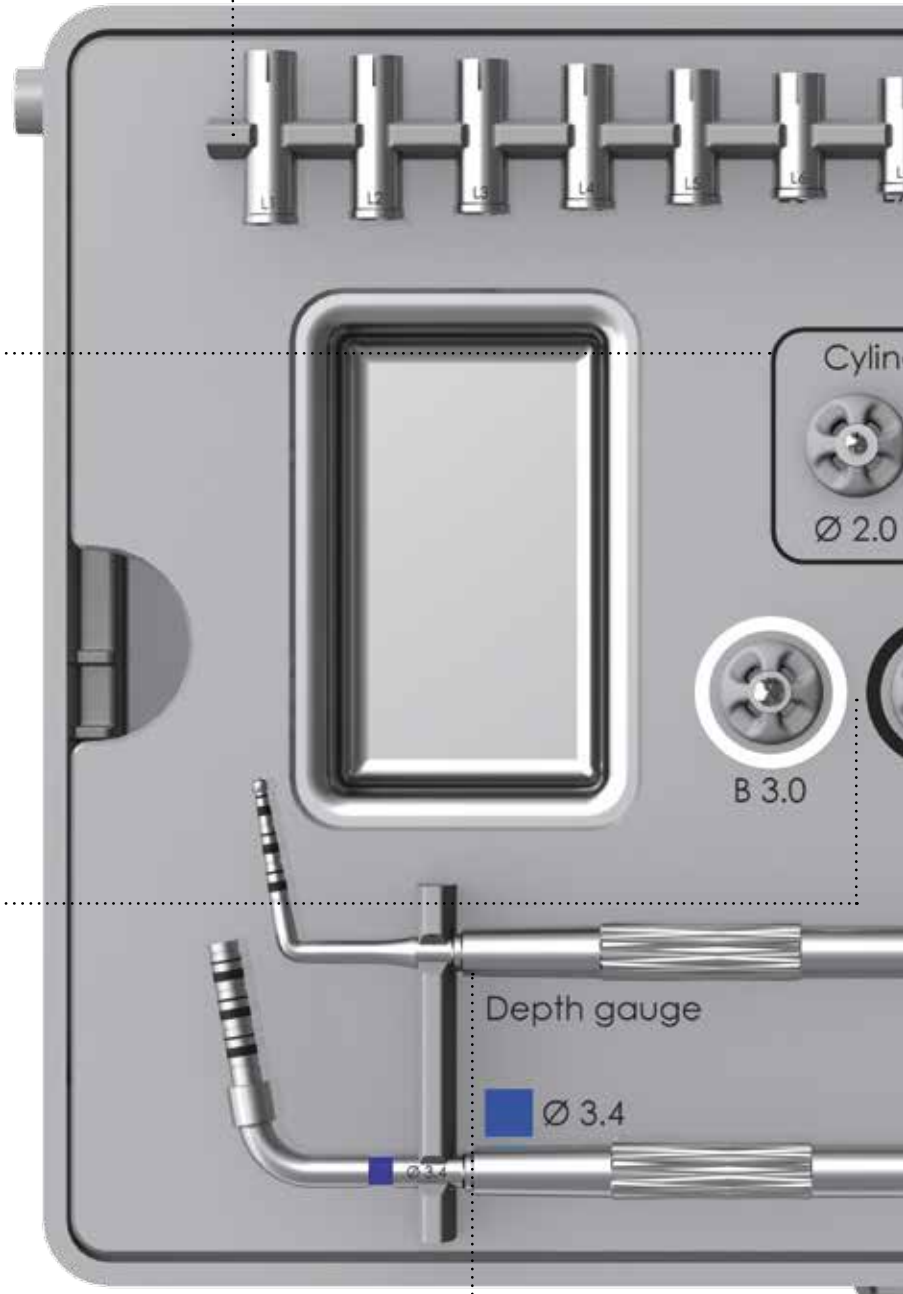
BREAK-UP DRILL

KM-F-B300



CHAMFERED DRILL

KM-F-C300



CONDENSER Ø 3.00 mm

DEPTH GAUGE



KM-C-PROF-300

KM-S-07 KM-S-08 KM-S-09 KM-S-10 KM-S-11 KM-S-12 KM-S-13



KM-F-R300

ROUNDED DRILLS
KM-F-R340

KM-F-R400



CONDENSER Ø 3.40 mm

CONDENSER Ø 4.00 mm

KM-C-340-400



General indications

The MISE Kit contains the following instruments:

- 7 drills with various profiles
- 13 depth stops
- 1 manual instrument with a depth gauge at one end and a \varnothing 3.0 mm condenser at the other end
- 1 manual instrument with a \varnothing 3.4 mm condenser at one end and a \varnothing 4.0 mm condenser at the other end
- 1 instrument case with a case and an internal tray

These are reusable medical devices intended for temporary use in the oral cavity (no more than 60 consecutive minutes).

The M.I.S.E. EVO Kit is sold complete with its components, and the single instruments and the tray are also sold individually as spare parts. The kit, the instruments and the tray are sold in NON-STERILE packs. Before use they must be cleaned, disinfected and sterilized following the instructions to be given later. Failure to follow this precaution may expose the patient to infections.

The product must be used and handled only by medical and dental clinicians with the necessary accreditation and professional training.

The materials used for production of the devices were selected on the basis of the properties indicated for their intended use, in compliance with Directive 93/42/EEC, implemented in Italy with Law 46/97, Annex I – Essential Requirements, point 7.1.

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 packs, must always be cited by the practitioner in any correspondence regarding the products.

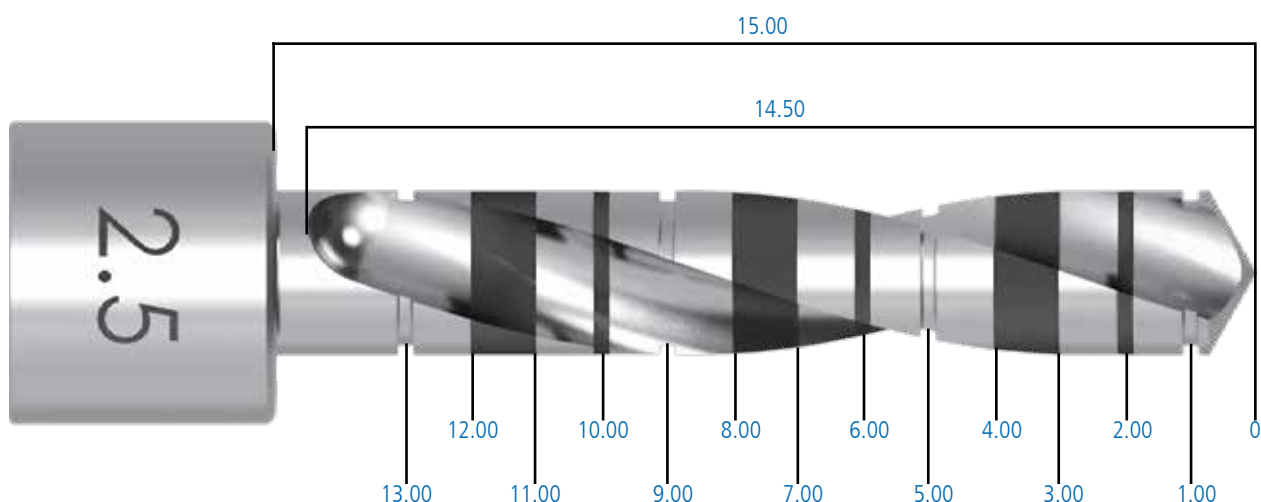
Drills

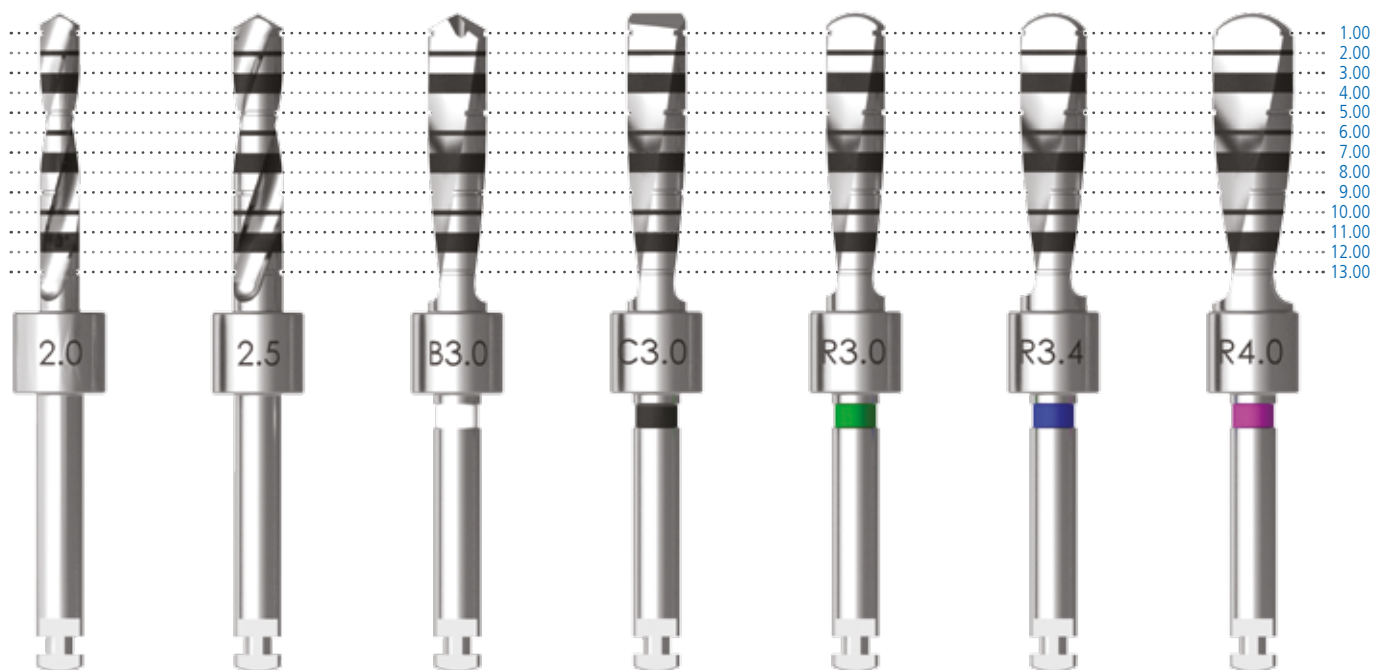
Drills are made of **steel** specifically for surgical use with **high resistance to corrosion and wear**. They are intended for mechanical use, i.e. they have a shank with a right angle attachment and must be used with a suitable micromotor. The extreme accuracy of design and production allows use **free from vibrations and oscillations**. However, 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 manufacturers, 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 complications and consequent damage to the patient's health.

It is recommended to use the rotation speeds indicated in the procedures on page 16 to prevent the development of bone necrosis. Lever movements increase the risk of instrument breakage and should therefore be avoided. Changes in speed should be avoided in general. Never apply pressure such as to force the instrument to stop rotating. This could lead to an excessive increase in heat in the tissues being drilled, with consequent bone necrosis, and damage both the instrument and the appliance (micromotor) used. This could also lead to breakage of the instrument. Using an intermittent approach, with a back and forth movement in a vertical direction, prevents overheating and wear of the working part and an undesirable increase in the temperature in the tissues being cut. Suitable coolant should be used. Inadequate irrigation can lead to bone necrosis.

Drill wear depends to a large extent on the type and density of the drilled bone: harder bone leads to greater instrument wear. For greater safety and caution, given the device's capacity for resistance to wear, drills should not be used for more than 20 work cycles and should be replaced earlier if the instruments lose their cutting ability. These recommended 20 cycles should be considered a rough guide. Always check the instrument's residual cutting capacity after each procedure. Sweden & Martina decline responsibility for the use of blunt instruments. Never sharpen drills before use. Never use damaged, buckled or worn instruments.

A laser marking on instrument shanks indicates their diameter.





The depth lines, common to all drills, show distances of 1 mm apart. The first line indicates a depth of 1 mm, and the others add 1 mm at a time to this measurement, showing the depth reached as the instrument moves progressively further into the osteotomy. The depth lines differ in type, alternating as follows:

- The first line is at a depth of 1 mm, and consists in a machined notch.
- The second line is at a depth of 2 mm, and consists in a dark laser-engraved ring.
- The third line consists in a black laser-engraved band with a height of 1 mm, starting at a depth of 3 mm and ending at 4 mm.
- The other lines are arranged in the same way as the first three (machined notch at 5 mm, a thin laser-engraved line at 6 mm, a band with a height of 1 mm between the depths of 7 and 8 mm, and then another machined notch at 9 mm, a thin laser-engraved line at 10 mm, laser-engraved band with a height of 1 mm between 11 and 12 mm, and a machined notch at 13 mm).

This layout makes it possible to recognize the depth lines without needing to count the millimetres every time a drill is used.

SURGICAL INSTRUMENTS

Initial drills

The initial drills of the MISE Kit are cylindrical, and have spiral geometries with two cutting edges. The working part of the KM-F-200 drill bores a hole with a diameter of 2.00 mm. The KM-F-250 drill bores a hole with a diameter of 2.50 mm.



KM-F-200



KM-F-250

BreakUp drill KM-F-B300

The BreakUp drill has a very sharp tip that allows the cortical bone of the sinus floor to be broken when it is particularly thick and resistant. The morphology of the working part, with a diameter of 3.00 mm, has two spiral cutting edges.



Chamfered drill KM-F-C300

With the special blunted profile of its tip, the Chamfered drill makes it possible to bend the cortical bone of the sinus floor or to break it if necessary if the layer of cortical bone is particularly thin. The morphology of the working part, with a diameter of 3.00 mm, has two spiral cutting edges.



Rounded drills

The three Rounded drills have a blunt spherical tip. The working part has two spiral cutting edges that allow the preparation hole to be progressively broadened from 3.00 to 3.40 mm, and then to 4.00 mm.



KM-F-R300



KM-F-R340
















KM-F-R400

IMPORTANT WARNING

The MISE Kit can be used to prepare sites to receive cylindrical implants with diameters between 3.00 and 5.00 mm. Refer to the specific protocols for the insertion of the single implants to determine the most suitable dimensions for surgical preparation of the site.

Depth stops

The kit includes 13 depth stops with lengths increasing progressively in steps of 1 mm, to be used with both rotary and manual instruments.

code	description
 KM-S-01	Stop for MISE instruments leaving the working part free for 1.00 mm
 KM-S-02	Stop for MISE instruments leaving the working part free for 2.00 mm
 KM-S-03	Stop for MISE instruments leaving the working part free for 3.00 mm
 KM-S-04	Stop for MISE instruments leaving the working part free for 4.00 mm
 KM-S-05	Stop for MISE instruments leaving the working part free for 5.00 mm
 KM-S-06	Stop for MISE instruments leaving the working part free for 6.00 mm
 KM-S-07	Stop for MISE instruments leaving the working part free for 7.00 mm
 KM-S-08	Stop for MISE instruments leaving the working part free for 8.00 mm
 KM-S-09	Stop for MISE instruments leaving the working part free for 9.00 mm
 KM-S-10	Stop for MISE instruments leaving the working part free for 10.00 mm
 KM-S-11	Stop for MISE instruments leaving the working part free for 11.00 mm
 KM-S-12	Stop for MISE instruments leaving the working part free for 12.00 mm
 KM-S-13	Stop for MISE instruments leaving the working part free for 13.00 mm

Stops must be fitted over the tip of the instrument. These safety devices limit all possible maneuvers that may cause risks or accidents.



Stops are secured to drills by the four tabs present at the top end of each stop. To increase the grip between a stop and the drill body, as may be necessary as a result of wear caused by repeated fitting and removal, a slight pressure should be applied towards the interior on opposite pairs of tabs. This simple procedure can prevent the detachment of the stop from the drill while working.

If the stop falls off and one or more of the tabs is bent too far internally, insert a tapered instrument (e.g. an osteotome) to restore the original condition of the instrument.



Manual instruments

The kit contains two dual-purpose manual instruments.

The first (KM-C-PROF-300) consists in a handle with a depth gauge at one end and a \varnothing 3.00 mm condenser at the other, used to push filling material into the surgical site so that it expands beneath the Schneiderian membrane.

The depth lines both on the depth gauge and on the condenser have the same layout as the depth lines present on the drills.



The second instrument (KM-C-340-400) consists in a handle with a condenser at each end, with \varnothing 3.40 mm and \varnothing 4.00 mm respectively. Coloured rings on the handle indicate the reference diameter, following the same colour code as used for the Rounded drills.

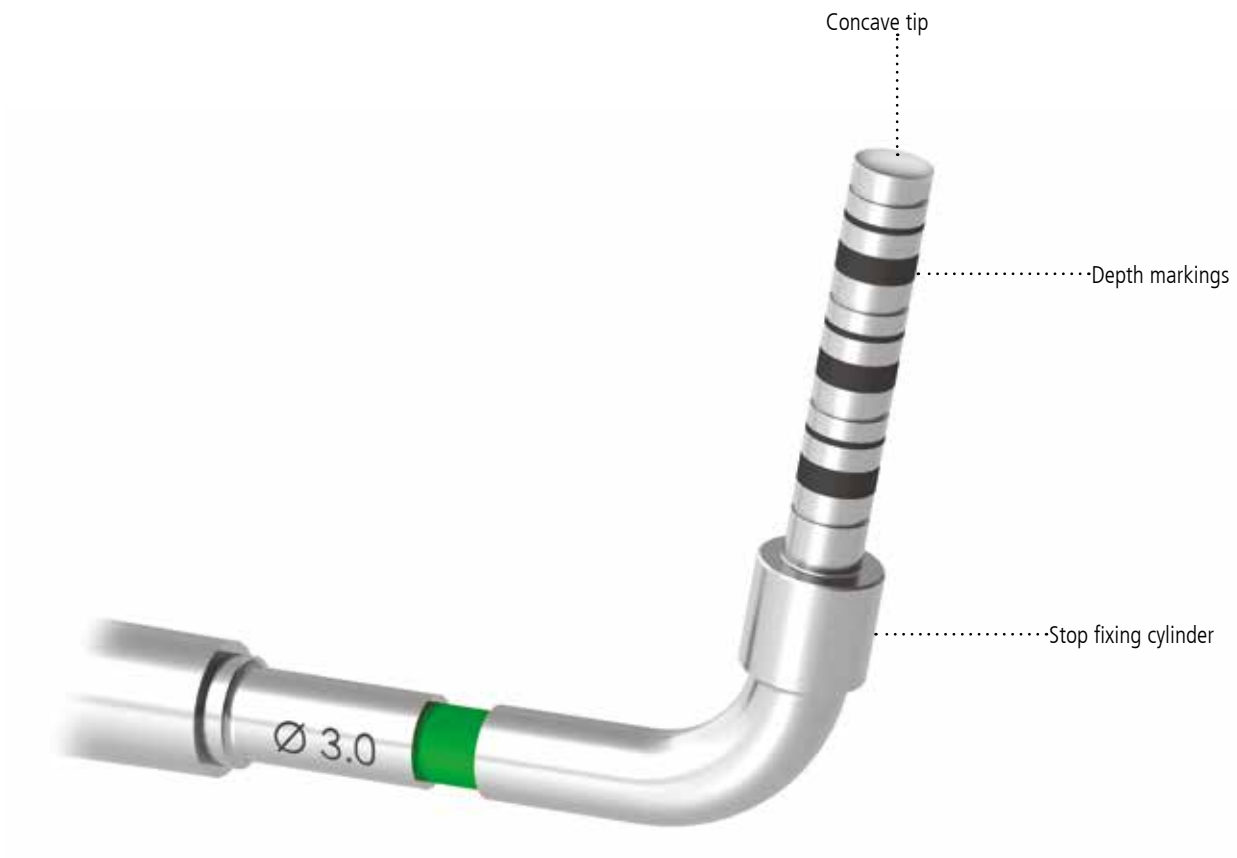
In this case as well, the depth lines have the same layout as on the drills.



The same stops that can be fitted to all the drills can also be used on the condenser tips.



The concave recess on the condenser tips is designed to insert filling material during surgical preparation.



Protocol for use

The aim of the surgical technique is to raise the maxillary sinus floor by 5–10 mm with respect to its original level, and to then insert an implant with a length of at least 11–12 mm, without opening a vestibular window.

To perform the MISE surgical technique with atraumatic rotary instruments for sinus augmentation, the following indications must be carefully followed:

- Bone density D2–D3.
- Bone height: measurement of bone height using intraoral X-rays performed with a Rinn holder to obtain a ratio of 1:1, or using a CT Dentascanner, which makes it possible to observe the following:
 - The precise measurement of the distance between the bone crest and the cortical level of the maxillary sinus floor;
 - Bone density;
 - Buccolingual bone thickness;
 - Any possible presence of hypertrophy of the sinus mucosa or of other sinus pathologies.
- The initial bone height must be no less than 3 mm.

The M.I.S.E. EVO Kit can be used to prepare surgical sites for all threaded and unthreaded cylindrical implants, with a body diameter compatible with the diameter of the drills of the kit. The drills prepare holes with diameters of 3.00, 3.40 and 4.00 mm. **Refer to the indications of the single implant manufacturers to verify the congruity of the preparation diameter.**

IMPORTANT WARNING

In case of perforation of the membrane of the maxillary sinus or the nasal floor, the operation must be immediately interrupted and the emergency must be appropriately treated.

Preliminary phase

After incising the soft tissues, uncover the crestal bone level and use the **initial drill** with \varnothing 2 mm at a speed of **800 rpm** to bore the guide hole for the subsequent drills. With the help of the pre-operative diagnostics choose a suitable stop to ensure that the preliminary preparation reaches 2 mm from the maxillary sinus floor.



Use the same stops on the intermediate drill with \varnothing 2.50 mm at 800 rpm to make the preliminary preparation wider. The stop guarantees that the residual bone thickness of 2 mm beneath the sinus floor remains unaltered.



In this phase, it is advisable to measure bone height with intraoral X-rays performed with a Rinn holder or a CT Dentascan. Then measure the implant socket prepared with the cylindrical drills using the depth gauge of the MISE Kit.



IMPORTANT WARNING

All drills must be used intermittently, with adequate irrigation. Otherwise there may be a risk of overheating of the site and consequent bone necrosis. The temperature must not exceed 36–37°C.

Maximum torque must be set, but no greater than 70 Ncm.

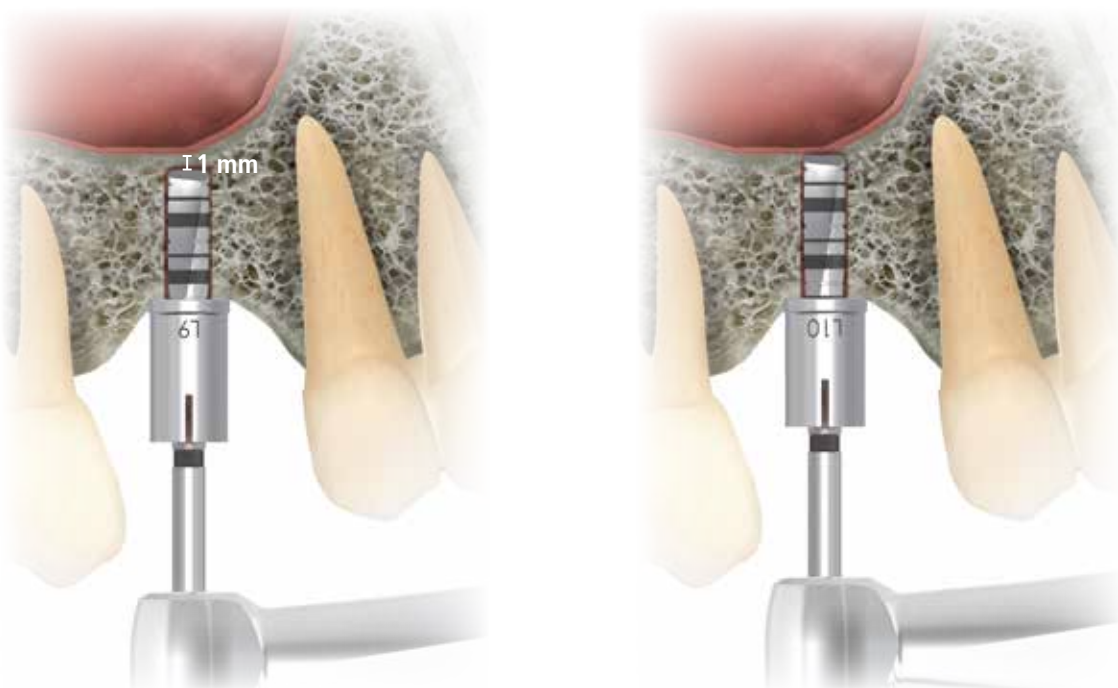
Lifting the maxillary sinus floor

Augmentation up to 2 mm

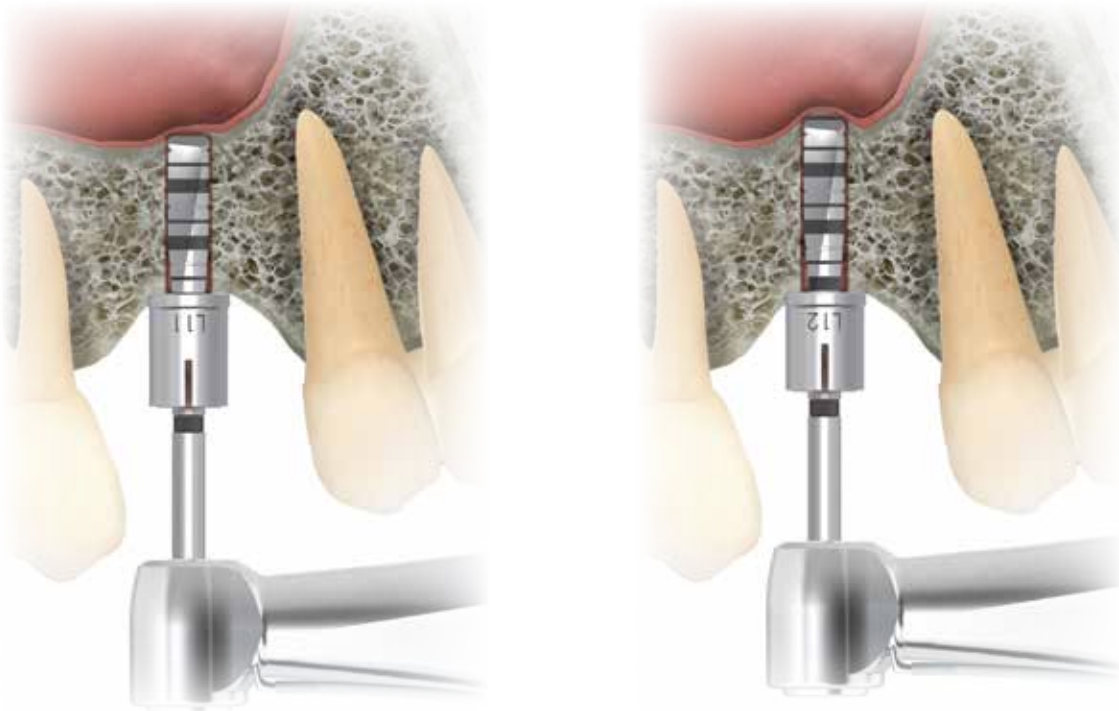
Use the **Chamfered drill with \varnothing 3.0 mm (C3.0)**, fitting it with the depth stop corresponding to the depth measured with the depth gauge, which will bring the working length to 2 mm from the cortical floor. Use the handpiece at a speed of **800 rpm**, ensuring adequate external irrigation.



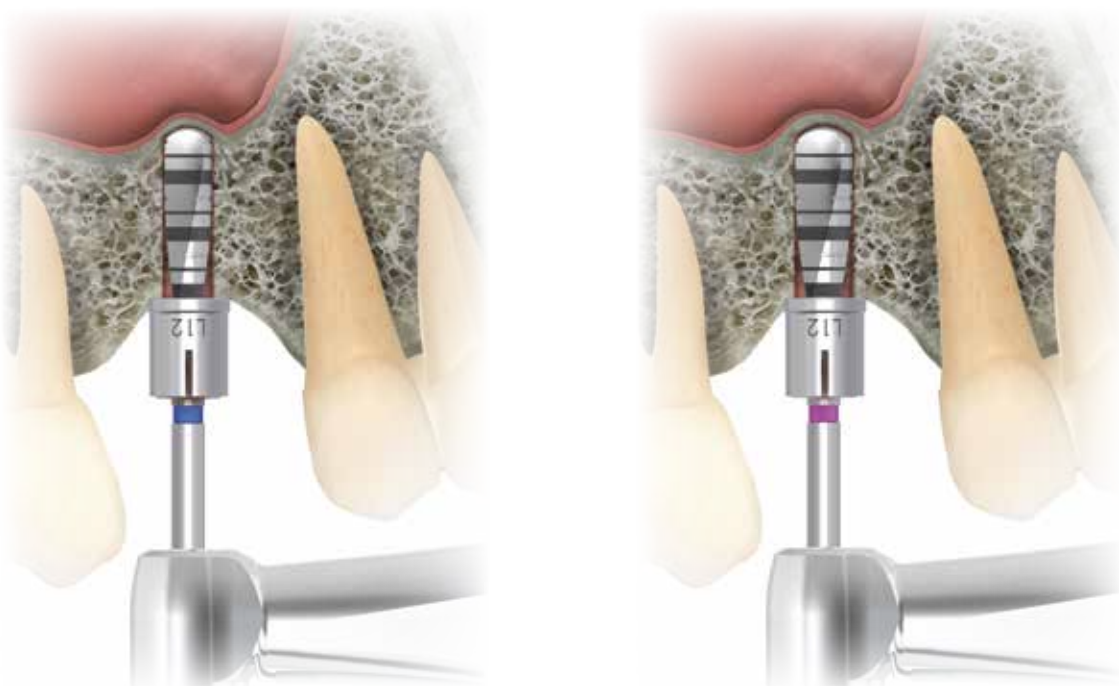
Then move on to the second depth stop, which will increase working height by 1 mm with respect to the first stop. Proceeding with this sequence, the clinician will be able to feel the cortical floor with the third depth stop.



Next fit the fourth stop and then the fifth stop onto the same drill. During these final steps, a substantial bending of the cortical bone is generated without breakage, lifting the maxillary sinus floor by about 2 mm.



If a greater implant diameter than the diameter obtained has been planned in the preliminary phase, make the implant site wider using the Rounded drill with \varnothing 3.4 mm (R3.4), and if necessary the Rounded drill with \varnothing 4.0 mm (R4.0) at 100 rpm, fitting the fifth stop.

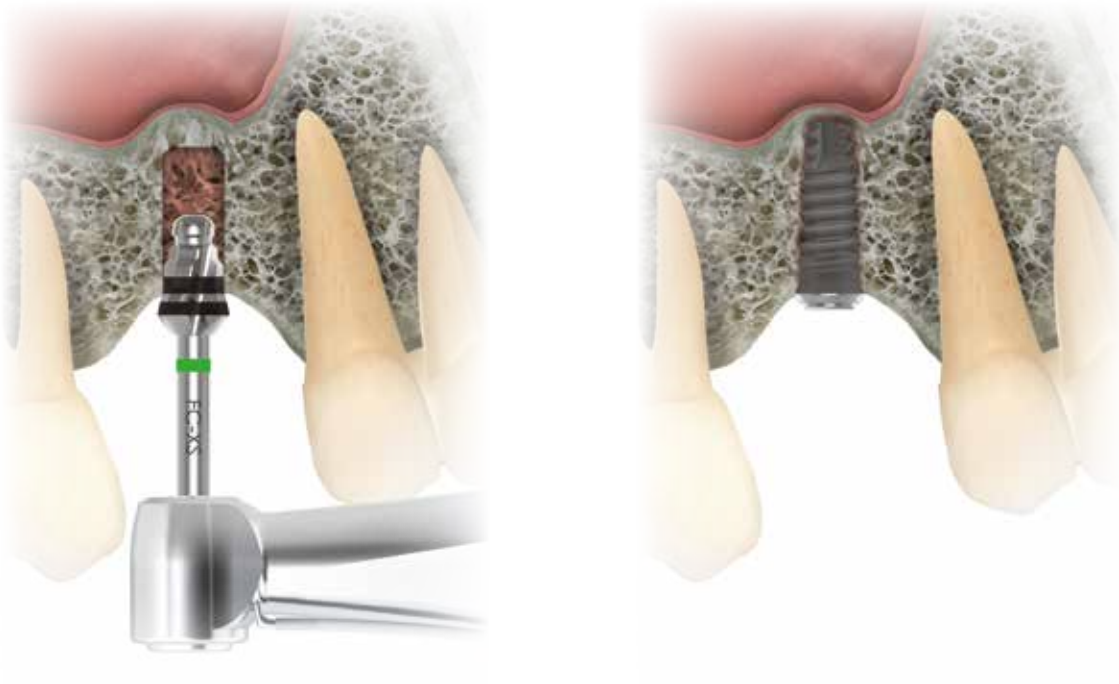


SURGICAL PROCEDURES

Insert the implant using the instruments indicated by the producer in the specific instructions.



If the quality of cortical bone does not permit the complete insertion of the implant, use the crestal drill of the implant system with extreme care to create a slight guide hole. In the following example, for the insertion of a Premium Platform Switching implant, the respective FC-XS drill is used.



Augmentation over 2 mm

If the maxillary sinus floor is to be raised more than 2 mm, the initial surgical procedures will be the same as those described on pages 18–19. In the explanatory case illustrated below, a bone thickness of 8 mm is considered.



SURGICAL PROCEDURES

After the phases of cortical bone bending with the fourth and fifth stops (L10 and L11), it will be necessary, still using the Chamfered drill (C3.0) and fitting the sixth (L12), to break the cortical bone itself, which will be felt by the clinician as a sensation of penetrating into an empty space.



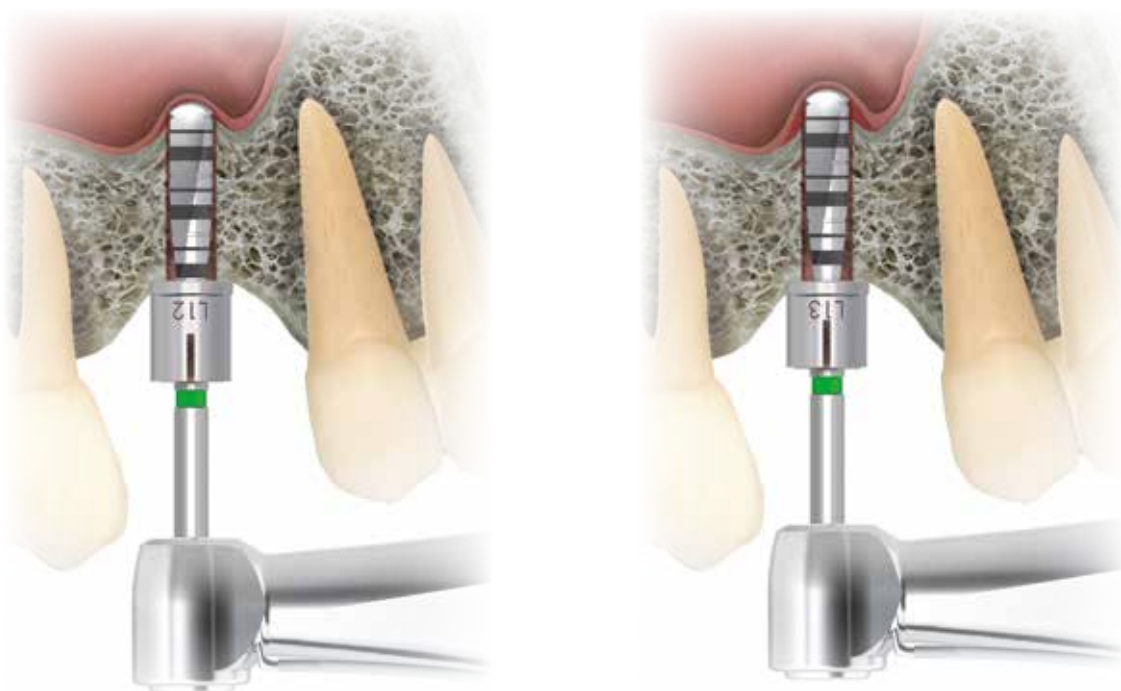
Given the particular shape of the tip, the Chamfered drill is able not only to deform the cortical bone of the sinus floor, but also to break it if it is particularly thin. At the moment of breakage of the cortical bone, the stop will guarantee extremely limited penetration beyond the sinus floor, of about 0.5 mm on average. This will avoid significant damage to the Schneiderian membrane.



In the case of thick cortical bone, the Chamfered drill (C3.0) may not be sufficient. In this case, further drilling with the BreakUp drill (B3.0) will be necessary. This drill, which has a higher cutting angle, must be fitted with the same stop used previously on the Chamfered drill (C3.0).

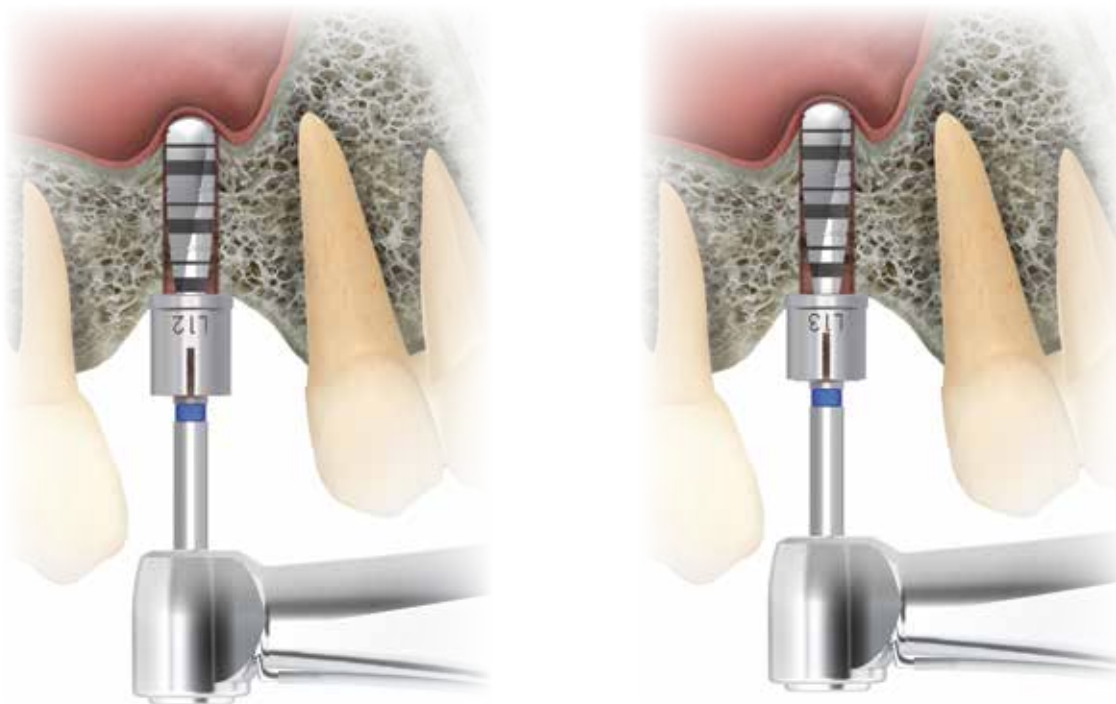


After breaking through the cortical bone, proceed with a double phase boring of the fractured cortical bone at low speed (100 rpm), using the Rounded drill with \varnothing 3.0 mm (R3.0) and fitting first the same stop used in the phase of breakage and then the stop with a length greater by 1 mm.

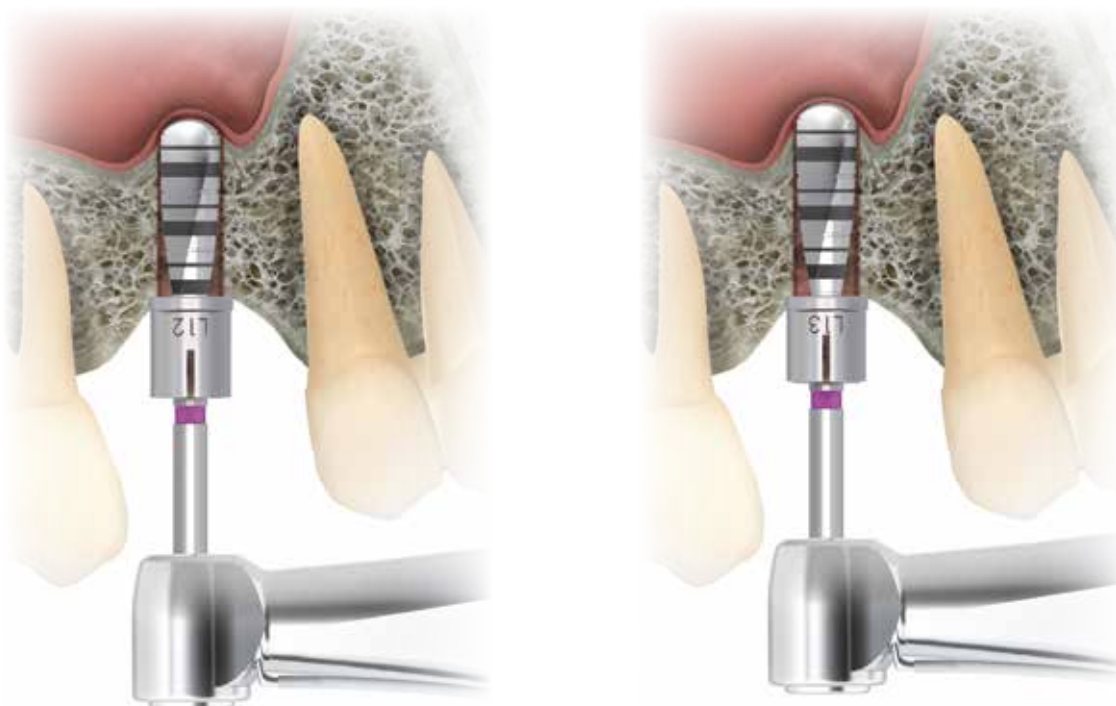


SURGICAL PROCEDURES

To insert implants with a greater diameter, use the Rounded drill with \varnothing 3.4 mm (R3.4) in two steps, first applying the last stop used at the moment of breakage of the cortical bone and then a stop with a length greater by 1 mm, still proceeding at low speed (100 rpm).



If the site must be further broadened, repeat the same two steps with a drill with \varnothing 4.0 (R4.0).



IMPORTANT WARNING

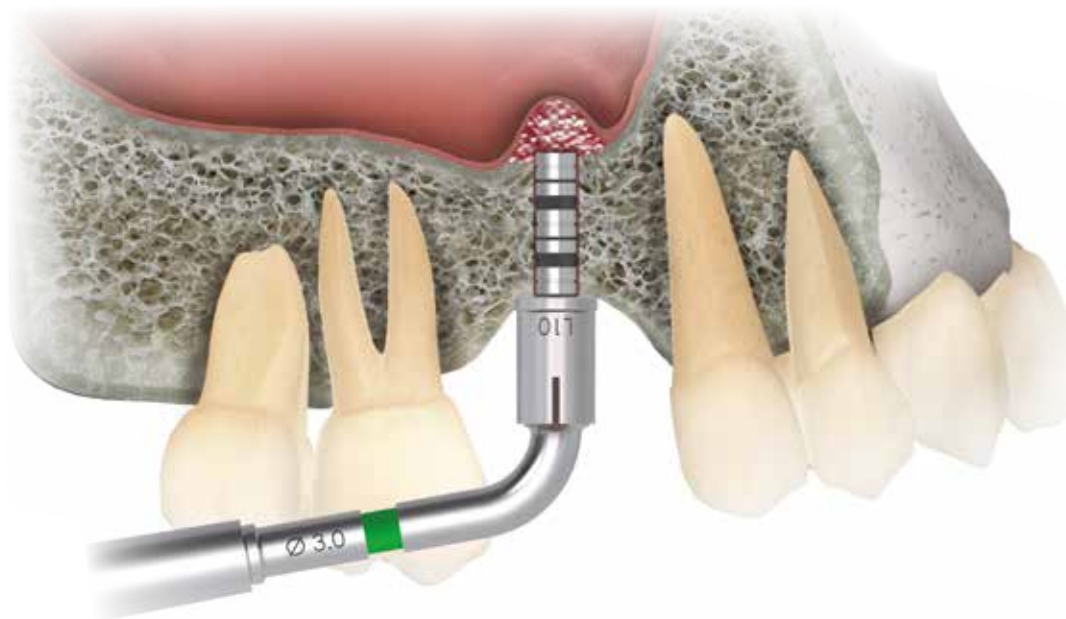
During the surgical procedure, the axis of rotary instruments must be kept in suitable alignment for both surgical and prosthesis requirements. Lateral movements must be avoided.

This final phase of drilling in the area of breakage of the sinus cortical bone creates the space necessary to facilitate the insertion of filling material using the corresponding condenser.

A depth stop of 2 mm less than that used at the moment of cortical bone breakage must be fitted to this instrument.

This will allow the filling material to be pushed in without ever going beyond the floor of the cortical bone (e.g. if the cortical bone of the sinus floor is broken at a working depth of 12 mm, fit the condenser with a 10 mm depth stop).

Insert collagen initially, which will lift the mucosa of the sinus as it absorbs blood. Follow this with repeated additions of autogenous bone and/or bone substitutes, always inserted using the condenser at the same measurement. According to the diameter of the last drill used, use the condenser with \varnothing 3.4 mm (blue) or 4.0 mm (magenta) to insert filling material through the implant socket.



The type of implant must be chosen by the clinician. The implant will push the filling material even further beneath the Schneiderian membrane, so that it acts as a scaffold for neo-ossification around the implant apex. If the clinician chooses an implant morphology that requires a special crestal preparation, follow the indications given on page 20.



Clinical case 1



Pre-operative X-ray: residual bone height 3 mm in area 1.5 and 4 mm in area 1.6.



Insertion of one 13 mm Premium implant at position 1.4 and two 11.5 mm Premium implants at positions 1.5 and 1.6, with sinus floor lifting of 8.5 and 7.5 mm respectively.



Follow-up X-ray after 5 years. The increase of bone density (grade 1) can be noted in the area of sinus augmentation with the MISE technique.

Clinical case 2



Pre-operative X-ray.



Insertion of a Premium implant with a height of 13 mm in the sinus septum.

Clinical case 3



Pre-operative X-ray, with an initial crestal height of 2.8 mm.



Insertion of a Premium implant with a height of 10 mm.

Clinical case 4



Pre-operative X-ray.



X-ray at 5 months.



X-ray at 7 years.

Clinical case 5



Pre-operative X-ray, with an initial crestal height of 4 mm.



Insertion of a Premium implant with a height of 11.5 mm in area 1.5.



Clinical check-up at 5 years.

Clinical case 6



X-ray of dental element 2.6 before avulsion.



Post-operative X-ray.



X-ray at 6-month check-up.



X-ray at 5-year check-up.



OPT X-ray at 5-year check-up.

Clinical case 7



X-ray of dental element 2.6 before avulsion.



Post-operative X-ray.



OPT X-ray at 5-year check-up.

Clinical case 8



Pre-operative X-ray.



Post-operative X-ray.



Follow-up at 5 years.

Clinical case 9



Pre-operative X-ray.



Pre-operative X-ray with measurements.



Sinus lifting with the MISE technique associated with vertical GBR of element \varnothing 1.5, with a 5.00 mm Premium implant height 11.50 mm.

Clinical case 10



Pre-operative X-ray.



Post-operative X-ray at position 1.6.

Clinical case 11



Pre-operative OPT X-ray.



Post-operative X-ray at position 1.6.



Post-operative X-ray at position 2.6.



OPT X-ray at 5-year check-up.

Clinical case 12



Pre-operative X-ray.

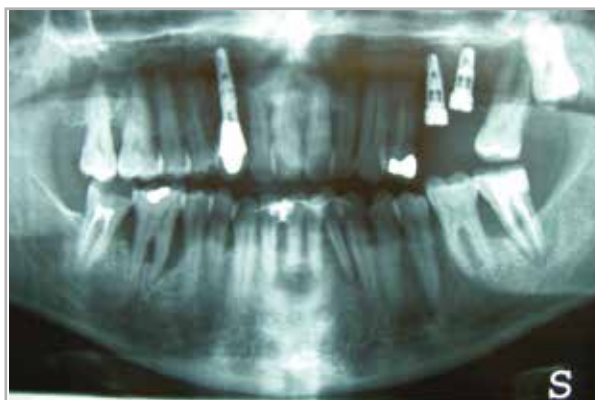


Post-operative X-ray.

Clinical case 13



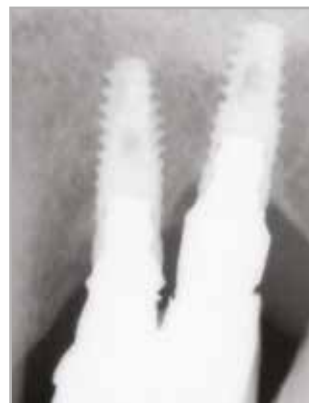
Pre-operative OPT X-ray.



Post-operative OPT X-ray, with implant insertion at position 2.6 using the MISE technique.



OPT X-ray at 5-year check-up.



X-ray at 5-year check-up.

Indications

The instruments of the M.I.S.E. EVO Kit must be used only in optimal conditions. In case of doubts or uncertainty on the methods of use, use of the instruments must be avoided or interrupted until all doubts have been clarified.

These instructions for use may not be sufficient to ensure the correct use of the instruments for surgical or implantology procedures by clinicians without the necessary expertise in their use. To this end, we recommend attendance at specific training courses and thorough reading of the existing bibliography on surgical techniques for sinus augmentation before using the instruments. Since we are unable to monitor correct use of the product, we are unable to assume liability for any injuries or damage caused by its incorrect use. Any liability for the same remains the sole liability of the operating clinician.

Before any use of the product, ensure that all components, instruments and items of auxiliary equipment are completely available, are fully operative and are present in the required quantity. The availability of a kit that is even partially incomplete may make it impossible to correctly complete a surgical procedure. Ensure that no components used in the oral cavity are sucked in or swallowed by the patient.

Sweden & Martina surgical accessories are sold in NON-STERILE packs. Before use they must be cleaned, disinfected and sterilized following the instructions reported later. When handling these medical devices, both during actual use and during cleaning and sterilization procedures, surgical gloves must always be worn for individual protection against bacterial contamination. Failure to respect these precautions may cause infections leading to pain, inflammation and bone loss for the patient and/or operator, and/or may cause cross-infections.

If washing and sterilization procedures other than those recommended in these instructions for use are used, these must be validated by the user. The use of different procedures may lead to premature wear on the instruments.

Complete clinical, radiological and radiographic documentation should be collected and stored on file.

Every product pack shows the product code, a description of contents and the batch number. These details must always be cited by the practitioner in any correspondence regarding the products.

Packaging conforms to European standards.

Contraindications

When assessing patients, it is necessary to take into account any contraindications of dental surgery.

These may include:

- Clotting disorders, anticoagulant therapies in progress.
- Healing or bone regeneration disorders, such as:
 - decompensated diabetes mellitus;
 - metabolic or systemic diseases that compromise tissue regeneration, and with effects in particular on tissue healing and bone regeneration;
 - alcohol abuse, smoking and use of drugs.
- Immunosuppressive therapy, such as chemotherapy and radiotherapy.
- Treatments with oral or endovenous bisphosphonates.
- Infections and inflammations, such as periodontitis and gingivitis.
- Untreated disorders such as bruxism.
- Poor oral hygiene.
- Insufficient motivation.
- Occlusion and/or articulation disorders, and also inadequate interocclusal space.
- Inadequate alveolar process. In addition to the contraindications already referred to, in the specifications for the surgical technique described below the following contraindications must also be mentioned:
 - Bone density D4.
 - Initial bone height less than 3 mm.
 - Presence of pathologies of the sinus mucosa.

Side effects

The following phenomena may accompany surgical operations:

- Temporary local swelling, edemas or hematomas.
- Temporary alterations in sensitivity.
- Temporary limitations in masticatory functions.

Complications

The following complications have been very occasionally observed:

- Micro-hemorrhages in the 12–24 hours after surgery.
- Post-operative infections, with possible bone loss.

Cleaning, disinfection, sterilization and storage

The instruments of the M.I.S.E. EVO Kit are supplied assembled inside the surgical tray.

IMPORTANT WARNING

The M.I.S.E. EVO Kit and all its components are sold in NON-STERILE conditions. Before use, they must be cleaned, disinfected and sterilized using the following procedures validated by Sweden & Martina.

Repetition of the processes described in this paragraph has only a minimal effect on these devices. The end of the service life of instruments is usually caused by wear and damage due to use.

CLEANING

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

In case of automatic cleaning, use an ultrasound bath with a suitable detergent solution (as DURR ID212, DC1 or equivalent). Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralised 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 detergent solution (as DURR ID212, DC1 or equivalent) and follow the manufacturer's user instructions. Brush the products with a soft-bristled brush under plenty of running water. Use the brush to 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.

Do not exceed 120°C when performing a drying cycle.

b. Steam sterilisation: in a vacuum autoclave, proceeding as follows:

autoclave (Gravity-Displacement Cycles) at a temperature of 121°C with a minimum exposure of thirty (30) minutes and a drying of fifteen (15) minutes;

autoclave (Dynamic-Air-Removal Cycles) at a temperature of 132°C -134°C with a minimum exposure of five (5) minutes and a drying of twenty (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.

REFERENCE STANDARDS

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

DISPOSAL PROCEDURES

If used, dispose of the surgical accessories as biological waste, according to the local regulations

WARNINGS










Responsibility for defective products and warranty terms

Optimal patient care and attention to their needs are necessary conditions for the success of treatment procedures and, therefore, patients must be carefully selected and informed of the associated risks and obligations connected with the treatment and encouraged to cooperate with the odontologist in the interests of the success of the same treatment. The patient must, therefore, maintain good hygiene, which should be confirmed during check-up appointments, guaranteed and recorded and the practitioners instructions and orders shall be observed.

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.

Date and validity of these instructions for use

These instructions for use are valid and effective as of November 2015.

symbol	description
	Caution! See instructions for use
	Batch number
	Code
	Non-sterile product
	Manufacturer
	Consult instructions for use
	CE conformity mark for class 1 products
	CE conformity mark for class 2a products
	American federal law restricts this device to sale by or by order of a professional practitioner

Identification of the manufacturer

The manufacturer of the M.I.S.E. EVO Kit system is:

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The products contained in this manual are Medical Devices and are manufactured by Sweden & Martina S.p.A. They conform to the ISO 9001 and ISO 13485 standards and are certified with the CE Mark (Class I) and CE 0476 mark (Class IIA) in compliance with European Medical Device Directive No. 93/42 and European Directive No. 2007/47/CE.

We have met the good manufacturing standards (GMP) set forth by many countries worldwide, including the United States FDA.



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The contents are updated at the time of publication. Check with the company for any subsequent updates.