sweden & martina

CE 0476

EN: Transcrestal maxillary sinus lift system with fluid dynamic technique FLUSILIFT EVO Kit

1. PRODUCT IDENTIFICATION

The FLUSILIFT EVO kit for the maxillary sinus lift technique manufactured by Sweden & Martina S.p.A. is a medical device intended for use in the oral cavity, for temporary use (continuous use not exceeding 60 minutes), reusable, in NON-STERILE packaging. The function of the instruments in the kit is to prepare the site for the maxillary sinus lift. The FLUSILIFT EVO kit manufactured by Sweden & Martina S.p.A. is intended for use with dental implants also manufactured by Sweden & Martina S.p.A. The use of surgical instruments for procedures 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 the section “Liability for defective products and warranty terms” below). The use of non-original instruments is not responsible.

2. INTENDED USE AND RISK CLASS

The FLUSILIFT EVO kit is a set of instruments that allows the maxillary sinus floor to be raised 5-10 mm from the vestibular position, allowing for implant insertion without opening the vestibular port. Bending of the cortical bone and overcoming the elastic deformation phase until its rupture, allowing for the insertion of a reconstructive biomaterial and the implant, are ensured with gradual, atraumatic, step-by-step steps (0.5-1 mm each), using depth stops. Sinus floor elevation can be followed by lifting the Schneiderian membrane using a fluid-dynamic system that allows for the injection of fluid collagen into the space between the sinus floor and the membrane itself. This fluid is not part of/contained in the FLUSILIFT EVO kit and can be freely selected by the clinician based on their experience. The FLUSILIFT EVO kit consists of an autoclavable, reusable surgical tray containing the following instruments:

- 7 drills
- 18 depth stops
- 1 bilateral hand instrument: depth gauge/compactor, 3 mm dia.
- 1 bilateral hand instrument: compactor, 3.4 mm dia./compactor, 4 mm dia.
- 2 double pluggers
- 1 PEEK osteotome tip, 3.80 mm dia.
- 3 steel osteotome tips, 4.25 mm dia. and 5.00 mm dia.
- 1 instrument holder 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, single packages as spare parts. All devices, both the kit and the spare parts, are sold NON-STERILE. The instruments are reusable, subject to washing and sterilization, which must be performed by the users before first use and after each use. The FLUSILIFT EVO kit must be used exclusively by medical and dental personnel with the necessary qualifications and authorizations and must be used only in accordance with the indications and instructions for use, according to general dental and/or surgical treatment standards, and in compliance with accident prevention and workplace safety regulations. Failure to follow the instructions provided may cause surgical problems and damage to the patient's health. Doctors and dentists using the kit must have extensive training in bone regeneration and oral surgery. Although tested and designed to be safe and to prevent and reduce errors, the kit is intended for oral use only. The use of the kit, although tested and designed to be safe and to prevent and reduce errors, is not suitable for inexperienced or poorly trained operators. Both the kit and the instruments, including the tray, are medical devices. The risk class of the devices is defined in Table 1.

3. MANUFACTURER

The manufacturer of the FLUSILIFT EVO kit and its components is:

SWEDEN & MARTINA S.P.A.
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4. MATERIALS

The materials used to produce the FLUSILIFT EVO kit and the instruments included therein, manufactured by Sweden & Martina S.p.A., have been selected based on the properties indicated for their intended use, in compliance with Regulation (EU) 2017/745, Annex I Essential Requirements, point 10.1. All sinus lift instruments contained in the kit are made of: AISI630 (17-4-PH) or W1.4197 stainless steel, in compliance with the international standards on surgical steels American Society for Testing and Materials ASTM F 899; Gr.5 Titanium in compliance with international standards (ASTM F136); PEEK plastic material. The surgical tray containing the instruments is made of Radel, a high-performance plastic material that can be sterilized in an autoclave without deteriorating. The devices in the FLUSILIFT EVO kit do not contain phthalates, materials of human or animal origin, or drugs. It is recommended that patients be consulted for any allergies to the substances used. Please visit www.sweden-martina.com for detailed technical data sheets for all materials used, their chemical compositions, and their physical and mechanical characteristics.

5. PRODUCT DESCRIPTION

1. Cutters

Sinus lift drills are designed for use with angled handpieces (Fig. 1).
Their working parts are available in various shapes and diameters: spherical/rounded (ø 3.0/ø 3.4/ø 4.0), chamfered (ø 3.0), sharp/break-up (ø 3.0), and cylindrical (ø 2.00 and 2.50 mm).
These instruments are intended exclusively for inserting threaded and non-threaded implants, whose implant body size corresponds to the diameter of the working part of the rotary instruments. The first drill (Rounded) has no cutting bevels, the second (Chamfered) has apical bevels that produce displacing effects on the cortical bone, and the third (Break-up) has cutting bevels. The cylindrical drills, on the other hand, ensure effective cutting when creating the pre-drill for the other drills. Laser markings and a color code identify the diameters of the instruments in the series. Depth markings on the working part of the instrument indicate the depth reached each time as the instrument advances into the implant site.
The depth markings represent a distance of 1 mm between each other (Fig. 2). The first marking indicates a depth of 1 mm, the others progressively add one millimeter and indicate the depth reached each time as the instrument advances into the implant site. The markings are distinguished from each other by being represented alternately as follows:

1. The first notch is 1 mm deep and is engraved.
2. The second notch is 2 mm deep and is represented by a dark ring marked with a laser.
3. The third notch is represented by a 1 mm high black laser-marked band that starts at 3 mm deep and ends at 4 mm.
4. The subsequent notches follow the same pattern as the first three (a machined notch at 5 mm, a thin laser-marked notch at 6 mm, then a 1 mm thick band between 7 and 8 mm deep, then a machined notch at 9 mm, a thin laser-marked notch at 10 mm, a 1 mm high laser-marked band between 11 and 12 mm, and a machined notch at 13 mm). This pattern allows the operator to recognize the notches without having to count the millimeters with each use. The drills must be used at the rotation speed indicated in the Technique of Use, given below. Using different speeds can compromise the outcome of the surgery and cause harm to the patient.

Attention: After approximately 25 procedures, depending on the firmness and quality of the bone, cutting instruments
should be replaced with new ones. Never apply pressure that forcefully stops the rotation of the instrument. This could lead to excessive heat buildup in the tissues involved in the cut, damaging both the instrument and the device used (micromotor). This could also result in breakage of the instrument itself. Intermittent operation is recommended to avoid overheating and wear of the working part and undue heat buildup in the tissues involved in the cut. The use of a suitable coolant is recommended. Improper insertion can lead to instrument vibration, eccentric rotation, premature wear, and bending of the shaft. It is recommended to use only surgical micromotors suitable for this purpose. It is recommended that micromotors and handpieces be periodically inspected by the manufacturers, according to their individual instructions, to prevent possible malfunctions (e.g., misaligned drive shafts, worn or malfunctioning collets, etc.). Using improperly maintained micromotors or handpieces can cause eccentric operation of the instruments, resulting in vibrations and unsuitable preparations. The recommended 25 cycles represent an average. Bur wear depends largely on the type and density of the bone being milled: harder bone results in greater instrument wear. For greater safety and prudence with respect to the wear resistance of the device, it is recommended that burs be used for no more than 25 work cycles before the instruments 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 the event of excessive use. Burs should never be resharpened before use. Never use damaged, bent or worn tools.

2. Depth stop

For user protection, the kit includes 18 depth stops, called spacers, of progressive lengths with fixed increments of 0.5-1 mm, to be used in conjunction with the burs and compactors (Fig. 3).
The stops are inserted and removed through the front of the rotating instrument. These safety devices limit any possible maneuvers that could cause risks and accidents.
Also check that the stops provide sufficient retention. Too little retention can cause the instrument to fall from the bur. Retention between the stops and the bur is ensured by the 4 tabs at the ends of the stops (Fig. 4). To increase (decrease) the interference between the stops and the bur body, apply light pressure on the opposing tabs from the outside towards the inside (vice versa).
After inserting depth stops on drills or compactors (see below), always be careful to check that the working part of the drill or compactor remaining outside the stop coincides with the desired working length, i.e., that the stop has been inserted at the desired length. Inserting a stop that is too short can result in excessively long preparations and cause damage to the sinus membrane.

3. Dual-purpose hand tools

The kit contains two dual-purpose hand tools.
The first (fig. 5) consists of a handle with two ends representing a depth gauge (on the right in the image, fig. 5) and a 3.00 mm diameter compactor (on the left in the image, fig. 5). The second tool (fig. 6) consists of a handle with two ends representing a 3.40 mm diameter compactor and a 4.00 mm diameter compactor, respectively. The depth markings on both the depth measuring tip and the compactor tips are represented in the same way as those on the cutters. The compactors must be fitted with the same depth stops used to control the working length of the cutters. Once again, after inserting the depth stop, check that the remaining working length corresponds to the desired length.

4. Manual tools for fluid dynamic lifting

The kit contains some manual instruments for fluid dynamic elevation: two osteotome handles (one straight and one pre-curved), 4 osteotome tips of variable size and 1 fixing ring. The two osteotome handles (fig. 7) are made up (on the right in the image fig. 7) of a straight cylindrical body (or pre-curved for the distal sectors) equipped with a terminal suitable for the insertion of two functional elements (Fig. 8):
1. A lateral threaded hole for screwing in a Luer-lock connector (not included in the kit) and a corresponding connector for assembly with a syringe (not included in the kit) for injecting fluid through the internal channel of the handle and the most suitable tip based on the preparation performed with the bur.
2. An axial connection geometry with the handle suitable for inserting the appropriate tip and securing it via a ring nut that screws onto the external thread of the handle.
The tips (fig. 9) are available in two variants: three in steel, calibrated to the size of the drill preparation, whose function is to expand the hole and one in PEEK whose function, thanks to an increased size, is to seal the hole to prevent the flow of the fluid during the injection of the fluid itself. All the tips are provided with laser marking to reference the insertion depth (as shown in fig. 8).

5. Complete Kit and Surgical Tray

- In the FLUSILIFT EVO kit, the instruments are placed inside a sterilizable surgical tray made of autoclavable Radel. The kit is sold complete with all the instruments it comprises. The tray is sold not only as part of the complete kit, but also in a single, empty package as a spare part. The sales codes and descriptions of the empty tray and the complete kit are as follows: ZFLU-EVO-INT complete kit with all the instruments (followed by a letter and a number indicating the kit revision).
- FLU-EVO-TRAY-INT surgical tray in radel, empty, instrument holder FLUSILIFT EVO.

Fig. 10 shows an image of the complete kit, and Fig. 11 shows the inside of the tray.
The drill housings are identified by the same color code found on the shaft of the respective drills. This color code helps identify the instruments and prevents errors when removing them from the kit during surgery. The 3.00 mm break-up drill is color-coded WHITE. The 3.00 mm chamfered drill is color-coded BLACK. The 3.00, 3.40 and 4.00 mm rounded drills are color-coded GREEN, BLUE, and MAGENTA, respectively. All other instrument housings are identified by a description printed on the upper surface of the kit's internal tray (as shown in Fig. 11).

6. CLEANING / DISINFECTION / STERILIZATION / STORAGE

The instruments of the FLUSILIFT EVO Kit are supplied assembled inside the surgical tray.
Attention! The FLUSILIFT EVO kit and all its components are sold NON-STERILE.
Before use, they must be cleaned, disinfected, and sterilized following the procedure validated by Sweden & Martina.
Repeating the processes described in this section has minimal effect on these devices. The end of their service life is generally determined by wear and tear and damage due to use.
Cleaning: Remove large organic residues with a disposable cloth or paper towel.
After use, immerse medical devices in a disinfectant bath. The disinfectant solution must be used according to the manufacturer's instructions.
Containers and transport: There are no specific requirements. It is recommended that instruments be cleaned as soon as reasonably possible after use. Disassemble instruments composed of multiple parts.
In case of automated cleaning: Use an ultrasonic cleaner using a suitable cleaning solution. We recommend using only neutral detergents. The solution concentration and cleaning duration must follow the manufacturer's instructions. Using an ultrasonic cleaner facilitates the removal of stubborn residues. Use demineralized water to prevent stains and streaks. When draining, check the recesses of the instruments, holes, etc. to ensure all visible residues have been removed. If necessary, repeat the cycle or use manual cleaning.
In case of manual cleaning: Use a suitable neutral detergent, following the manufacturer's instructions. Brush the products with soft bristles under abundant running water.
Using the brush, apply the cleaning solution to all surfaces. Rinse with distilled water for at least 4 minutes. Ensure that ample running water passes through the depth stops and the tray holes.
Inspect the instruments carefully and replace any damaged ones. Perform a visual inspection for damage and signs of wear. The cutting edges should be free of notches and have a continuous edge. Check for any distortion of the instruments. Replace worn instruments. Using worn, distorted, or generally damaged instruments can lead to surgical complications and bone necrosis. Generally, the temperature at the site should not exceed 36-37°C.
Verify that the stops have maintained proper friction and do not fall off the drills. If they are loose, re-engage the tabs as explained above. Loose stops risk falling from the drills during the procedure. After rinsing, dry the instruments completely, place them in the tray, check that the tray is closed properly, and package everything in suitable sterilization bags.
If performing a drying cycle as part of a washing and disinfection cycle, do not exceed 120°C.
Sterilization: For sterilization, the kits must be packaged in autoclavable pouches. Sterilization can be performed as follows:

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

7. CONTRAINDICATIONS

When evaluating a patient, it is generally necessary to consider contraindications for dental surgery.
These include:
- Alterations in the blood coagulation chain, and anticoagulant therapy.
- Healing or bone regeneration disorders, such as:
- Uncompensated diabetes mellitus
- Metabolic or systemic metabolic diseases that impair tissue regeneration, particularly affecting healing and bone regeneration
- Alcohol and tobacco abuse, and drug use
- Immunosuppressive therapies, such as chemotherapy and radiotherapy
- Oral or intravenous bisphosphonate use
- Infections and inflammation, such as periodontitis, gingivitis
- Untreated parafunctional disorders, such as bruxism
- Poor oral hygiene
- Inadequate motivation
- Occlusion and/or joint defects, such as insufficient interocclusal space
- Inadequate alveolar process. Specifically for 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 sinus mucosal pathologies

8. TECHNIQUE OF USE

Directions
To perform the MISE surgical technique with atraumatic rotary sinus lift instruments, the following guidelines must be carefully followed:

- Bone density (D2-D3-D4)
- Bone height: bone height measurement using Dentascan CT, which allows us to determine:
  - Residual bone height (the precise measurement of the distance between the bone crest and the cortical plane of the maxillary sinus floor)
  - Bone density

- Buccolingual bone thickness
- Maxillary sinus width
- Any presence of sinus mucosal hypertrophy or other sinus pathologies
- Initial bone height must be at least 3 mm.

The FLUSILIFT EVO kit can be used to prepare surgical sites for all cylindrical, threaded implants with a body diameter compatible with that of the drills in the kit. The drills prepare 3.00, 3.40, and 4.00 mm holes. These diameters are among the most widely used implant systems on the market. Please refer to the instructions of the individual implant manufacturers to verify the appropriateness of the preparation diameter.

Attention! In case of perforation of the maxillary sinus or nasal floor, the operation must be stopped immediately and the emergency treated appropriately. The goal of the surgical technique is to raise the sinus floor from its original position and then insert an implant without opening the vestibular porthole. After making an incision in the soft tissue, expose the crestal bone plane and use the 2.00 mm drills to begin the preparation until reaching 1 mm from the Schneiderian membrane. Using the depth probe provided in the kit, measure the implant socket prepared with the 2.00 mm drill. Continue the preparation with the 2.50 mm drill and the 3.00 mm drill (B300) to the same depth as the previous drill. The three drills should be operated at 800 rpm.

Please note: All drills must be used intermittently, with adequate irrigation. Otherwise, there is a risk of overheating the site and resulting bone necrosis.

The temperature should not exceed 36-37°C. The micromotor torque must be set to the maximum value. 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, set it back to these values.

Use the 3.00 mm diameter Chamfered drill from the Kit, applying the depth stop corresponding to that of the previous drills +1 mm, which will bring the working length of the drill to 2 mm from the cortical bone floor. Operate the handpiece at 800 rpm, ensuring adequate external irrigation. Then move to the second depth stop, which will increase the working height by 1 mm compared to the first stop. By proceeding with this approach, the operator can already achieve cortical fracture with the 4th depth stop, which will be felt by the operator as a sensation of penetrating into a void. During these final steps, a substantial bending of the cortical bone occurs without fracture, elevating the maxillary sinus floor by approximately 3 mm. Upon cortical fracture, the stop will ensure extremely limited penetration beyond the sinus floor (on average approximately 0.5 mm); this prevents significant damage to the Schneiderian membrane.

The choice of implant and therefore any final crestal preparation is left to the operator. This technique, following the step-by-step protocol, allows for a lifting of the maxillary sinus floor and mucosa by 1 to 5 mm from the original position, reserving the buccal access technique with a porthole for complex cases. Caution! During the surgical technique, the axis of the rotating instruments must be maintained appropriate from both a surgical and prosthetic standpoint. Lateral movements must be avoided.

Fluid dynamic membrane lifting

After having obtained, with the previous steps, an initial elevation of approximately 3mm and created a surgical socket with access to the membrane, the first tip (380) is assembled with handle, ring and saline syringe and inserted into the preparation until it fits into the socket and in any case with a depth no greater than that of the last stop used for perforation of the sinus. At this point, 1cc of saline is injected into the sinus and subsequently aspirated with the syringe to verify that the saline re-enters the same mixed blood as proof of the integrity of the membrane (in the event of perforation, air would re-enter during aspiration). The tip is then removed, allowing the saline solution to flow completely out. The saline syringe is replaced with one of the preferred gel biomaterial, the tip is re-inserted into the socket at the same depth as before and the desired quantity of biomaterial is injected into the sinus. The tip is then removed and the chosen implant is inserted. It is recommended to proceed with flap closure and healing by first intention.

9. WARNINGS

Flusilift EVO instruments should only be used under optimal conditions. If you have any doubts or uncertainties regarding the indications or instructions for use, use should be avoided or discontinued until all doubts have been clarified.

These instructions for use may not be sufficient to ensure the correct application of the instruments for surgical or implant procedures by inexperienced operators. Therefore, we recommend attending specific training courses and reading the existing literature on sinus lift surgical techniques before using the instruments. Since we cannot monitor the correct use of the product, we cannot be held liable for any damage caused by incorrect use. Responsibility lies solely with the operating physician. Before each use, ensure that all necessary components, instruments, and aids are available in complete, functional, and in the required quantities. A partially incomplete kit may prevent a successful surgical procedure. Ensure that all components used in the oral cavity are not aspirated or ingested. Sweden & Martina

S.p.A. surgical accessories are sold in NON-STERILE packaging. Before use, they must be cleaned, disinfected, and sterilized according to the instructions provided. When handling the devices, both during use and during cleaning and sterilization procedures, it is recommended to always wear surgical gloves for personal protection against bacterial contamination. Failure to follow these warnings may cause infections and subsequent pain, inflammation, and bone loss in the patient and/or operator and/or lead to cross-infection.

If cleaning and sterilization procedures other than those recommended in these instructions for use are used, they must be validated by the user. Adopting other procedures may lead to premature instrument wear.

It is advisable to collect and archive complete clinical, radiological, and radiographic documentation.

Each package contains the code, description of contents, and batch number. This information must always be cited by the physician in any related communications. The packaging complies with European standards.

10. DISPOSAL PROCEDURES

The instruments of the FLUSILIFT EVO kit, if used, must be treated as biological waste for their disposal, according to the regulations in force at a local level.

11. REGULATORY REFERENCES

The design and production of the FLUSILIFT EVO kit is carried out in compliance with the most up-to-date directives and harmonised standards regarding the materials used, the production processes, the information provided and the packaging.

12. LIABILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS

The instructions provided by Sweden & Martina are available at the time of treatment and are accepted by the dental practice; they must be observed and applied at all stages of use. The warranty covers only proven manufacturing defects, provided the piece identified by item code and batch number is returned within the warranty period. The warranty terms are available at www.sweden-martina.com.

13. DATE AND VALIDITY OF THESE INSTRUCTIONS FOR USE

These instructions for use are valid and effective from February 2025.

LEGEND OF SYMBOLS USED		
	Attention! See instructions for use.	✓
LOT	Batch number	✓
REF	Code	✓
	Manufacturer	✓
IT	Country of production	✓
UDI	UDI Code, Unique Device Identifier	✓
MD	Medical device	✓
	See instructions for use www.sweden-martina.com	✓
CE	CE Conformity Marking If applicable: The identification number of the notified body must follow this symbol	✓
Rx Only	Federal law restricts sales by or on the order of a professional	✓
	Do not use if the package is damaged	✓
NON STERILE	Non-sterile product	✓

Table 01

Device	Classification	Rule	Risk class	CE marking
Radel Instrument Tray	Non-invasive medical device	1	I	CE
Complete surgical kit	Reusable surgical instruments	6	IIa	CE0476
Surgical drills (cylindrical, Break up, Chamfer, Round) and stops	Reusable invasive surgical instruments for temporary use (less than 60 minutes)	6	IIa	CE0476
Plugger and depth gauge	Reusable invasive surgical instruments for temporary use (less than 60 minutes)	6	I r	CE0051

Fig. 01
Sequence of cutters in the FLUSILIFT EVO kit: Cylindrical, Break up, Chamfered, Rounded.

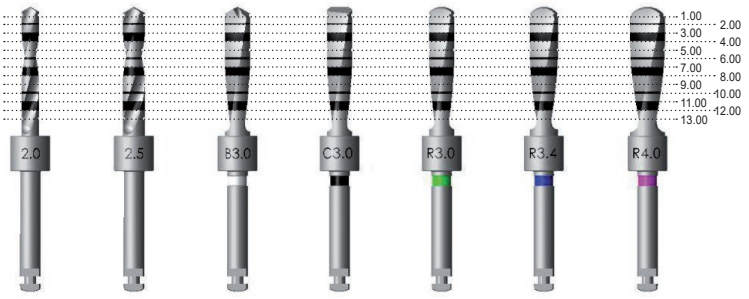

Fig. 02
Depth marking diagram for cutters and other tools in the FLUSILIFT EVO kit.

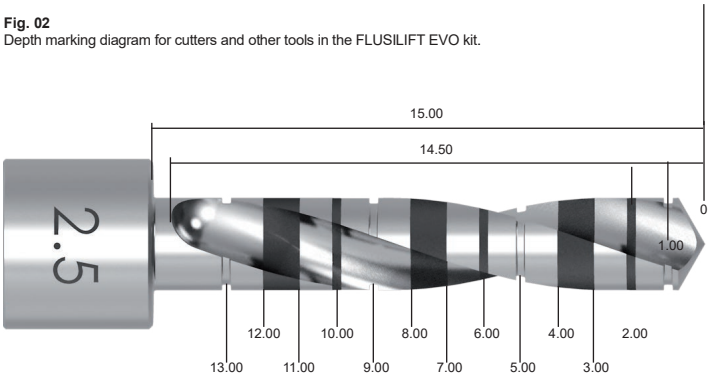

Fig. 03
13-stop depth progression for Sinus Lift rotary instruments

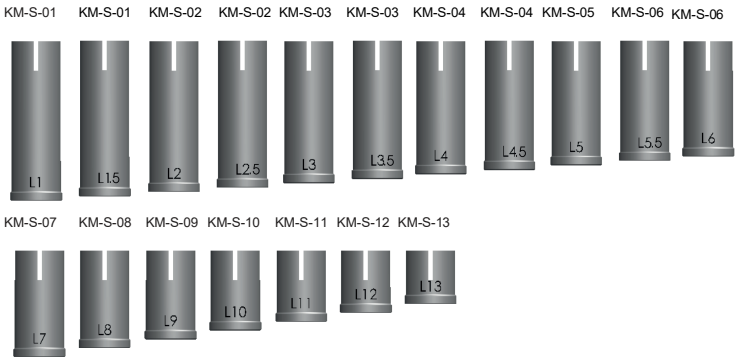

Fig. 04
Activation of the safety stop flaps or spacers

Fig. 05
Dual-purpose manual tool, depth gauge on one side and compactor on the other ø3.00 mm,
REF KM-C-PROF-300

Fig. 06
Dual-purpose manual tool, on one side compactor ø3.40 and on the other compactor ø400 mm,
REF KM-C-340-400

Fig. 07
Dual-purpose manual tool, on one side compactor ø3.40 and on the other compactor ø400 mm,
REF KM-C-340-400

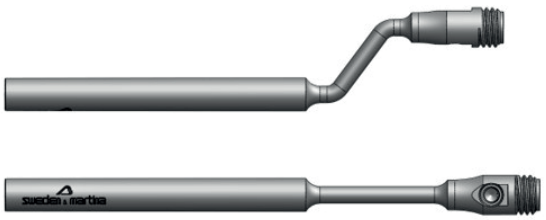

Fig. 08 Dual-purpose manual tool, on one side compactor ø3.40 and on the other compactor ø400 mm,
REF KM-C-340-400

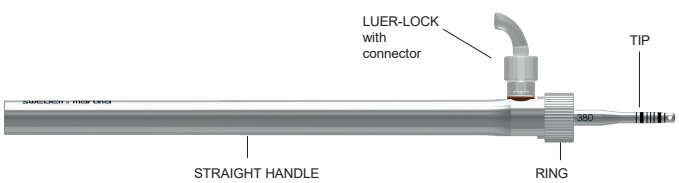

Fig. 09 Dual-purpose hand instrument, one end with a 3.40 mm diameter compactor and the other with a 400 mm diameter compactor, REF KM-C-340-400

Fig. 07
Kit complete FLUSILIFT EVO

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