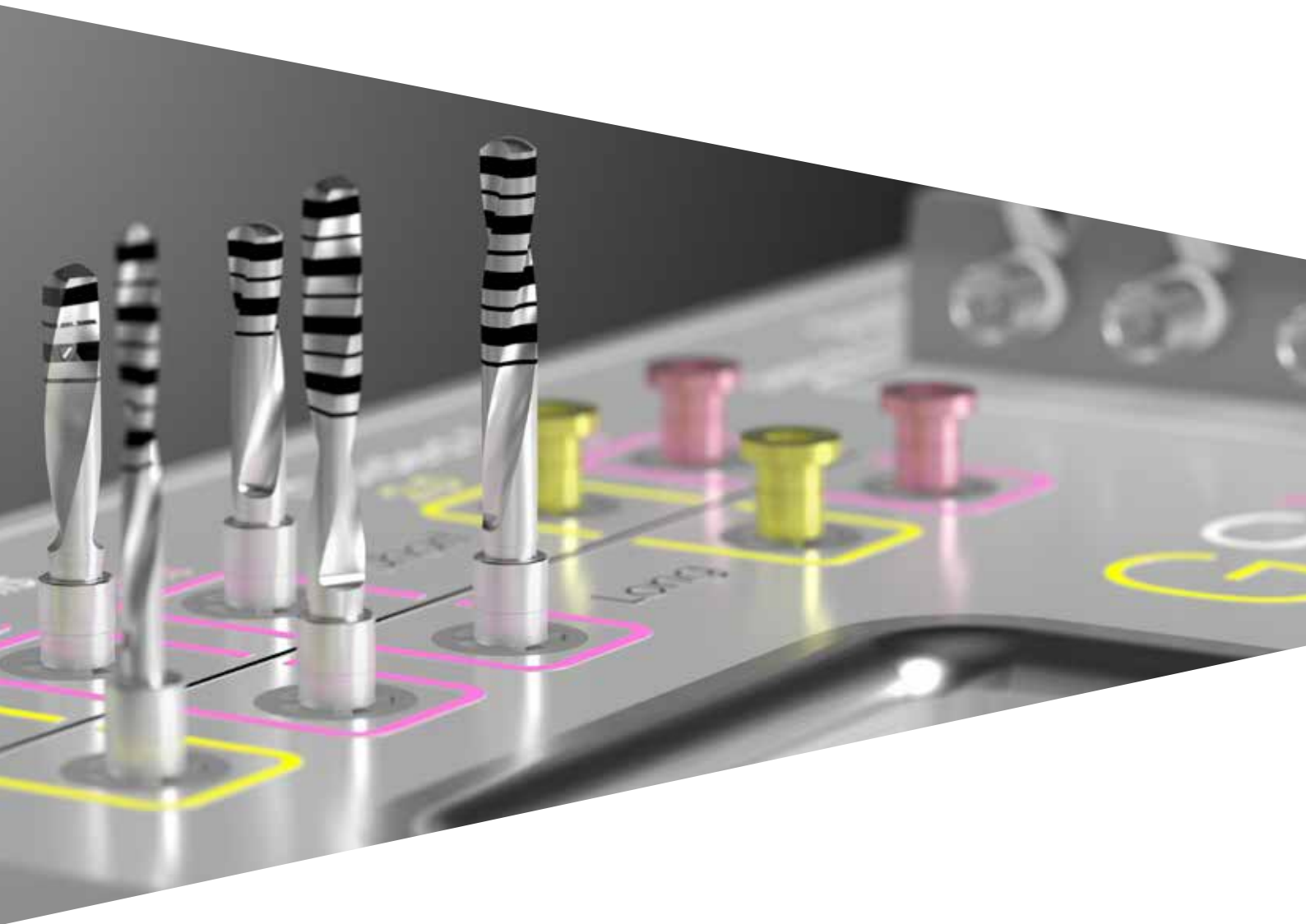


KIT GSL

Guided Sinus Lift
Surgical Manual



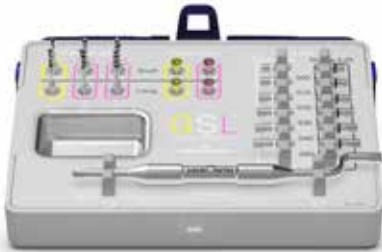
GSL

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GSL kit

The GSL kit provides a minimally invasive system, performed under guided surgery, which allows the gradual elevation of the maxillary sinus, using a fast, safe and simple technique.

Bending the cortical bone until its elastic deformation has been overcome so that it breaks, making way for the insertion of reconstructive biomaterial and the implant, is obtained with no trauma, using depth stops, in gradual step by step phases (1.00 mm each).



ZGSL-INT

complete kit with
all instrumentation

GSL-TRAY-INT

grommetless instrument
cases made of Radel

Important Warning

The GSL kit is used only to perform the sinus lift. One of the guided surgery kits is needed for preparation of the site. In the kit, there are no mucotomes, mounters or fixation pins for the templates.

Echoplan Pro C surgical kit



ZGS-PRO-C-INT

complete kit with
all instrumentation

GSPROC-TRAY-INT

grommetless
Radel instrument case

Echoplan Pro S surgical kit



ZGS-PRO-S-INT

complete kit with
all instrumentation

GSPROS-TRAY-INT

grommetless
Radel instrument case

Echoplan Pro E surgical kit



ZGS-PRO-E-INT

complete kit with
all instrumentation

GSPROE-TRAY-INT

grommetless
Radel instrument case

Echoplan Pro A surgical kit

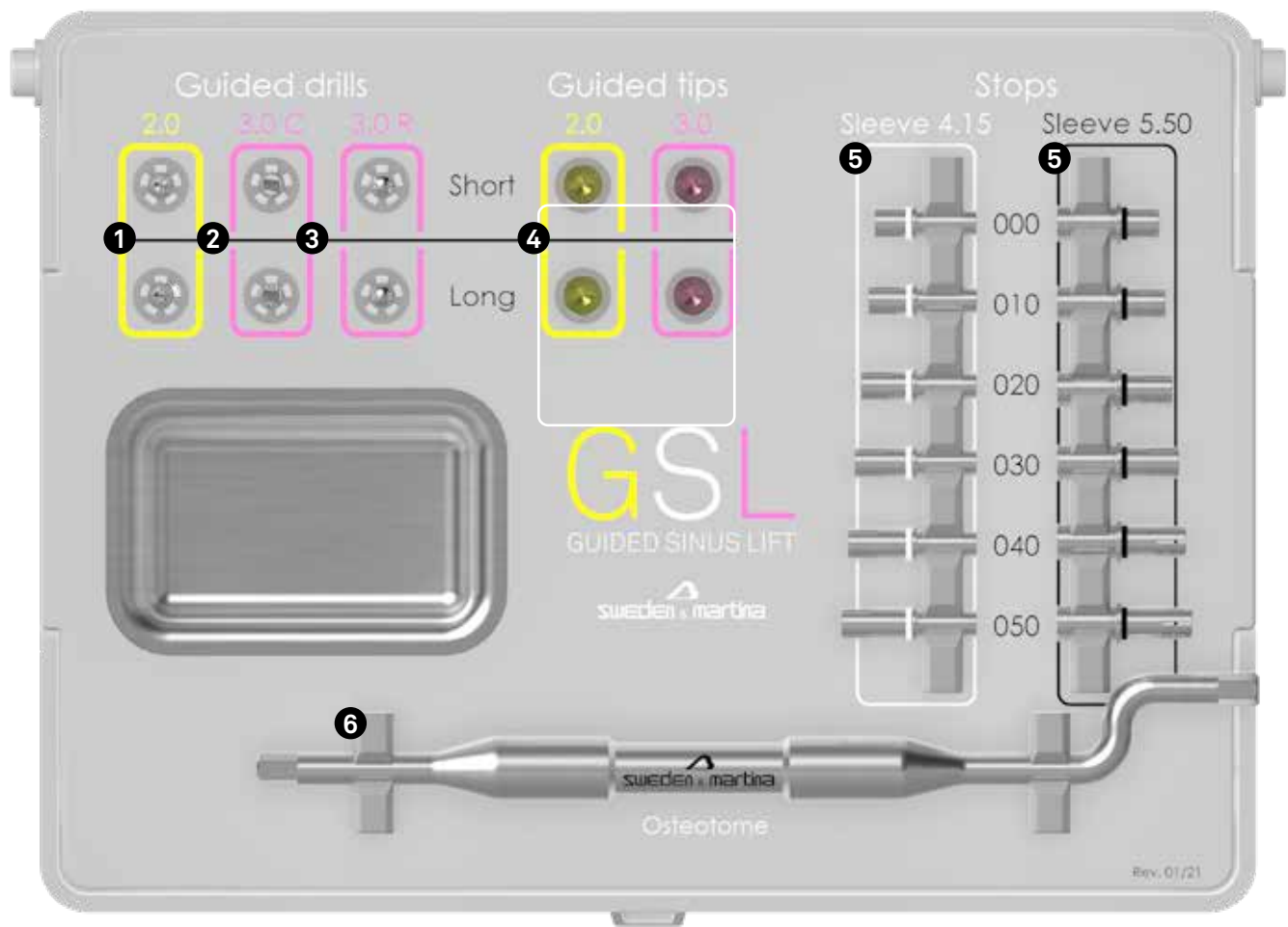


ZGS-PRO-A-INT

complete kit with
all instrumentation

GSPROA-TRAY-INT

grommetless
Radel instrument case



1

Cylindrical drills

GSL-F200-060
GSL-F200-120

2

Chamfered drills

GSL-FC300-060
GSL-FC300-120

3

Rounded drills

GSL-R300-060
GSL-R300-120

4

Guided tips

GSL-TIP-200-060
GSL-TIP-200-120
GSL-TIP-300-060
GSL-TIP-300-120

5

Stops

GSL-STOP-000-415
GSL-STOP-010-415
GSL-STOP-020-415
GSL-STOP-030-415
GSL-STOP-040-415
GSL-STOP-050-415

6

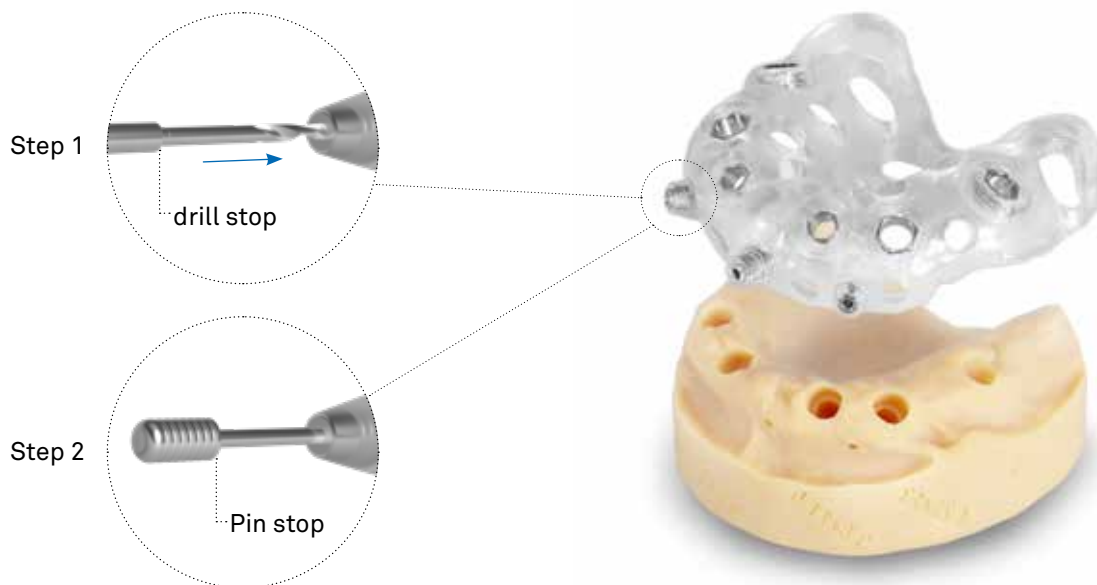
Multifunction handles

GSL-PLUG
GSL-CAP-PLUG

GSL-STOP-000-550
GSL-STOP-010-550
GSL-STOP-020-550
GSL-STOP-030-550
GSL-STOP-040-550
GSL-STOP-050-550

Fixation pins and drills

When the surgical template cannot be stabilized on the residual teeth, it is appropriate to adopt a protocol with a total-thickness flap that guarantees bone support. However, since the edentulous arch would allow tilting, the template needs to be stabilized using the Gr. 5 titanium bone pins included in the kit. In order to prepare the pin's recessed hole, the related GS-FPN-148 drill is provided, to be used at 800 rpm. The pins are guided into the appropriate dedicated sleeves which are provided by Sweden & Martina already inserted in the template without additional cost. Should the templates be made in laboratory, the sleeves can be purchased separately in packs of 6.



Important Warning

To correctly stabilise the template, it is essential that both the drills and the pins are brought to the stop.



GS-FPN-148

drill for fixation pins



GS-PIN

fixation pins 4-pack



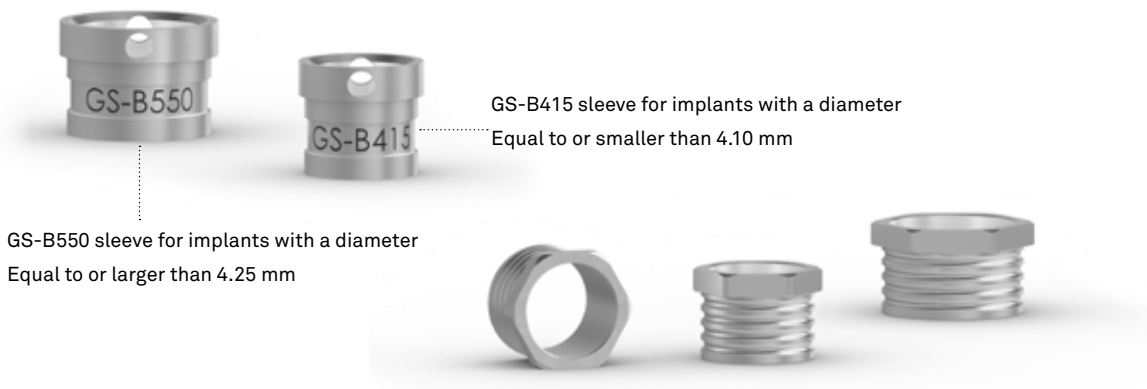
GS-B150-PIN-6

sleeves for pins 6-pack

Guide sleeves

The guide sleeves are AISI 630 stainless steel cylinders, with diameters of 4.15 mm or 5.50 mm, which are embedded in the polymer of the surgical template. Their purpose is to guide the rotating instruments during preparation whilst maintaining the working axis programmed with the planning software and providing a certain physical stop for all instruments at 9.00 mm from the plane of the implant connection platform.

Sweden & Martina produces a series of standard sleeves, which are not indexed: these are available to laboratories who manufacture surgical guides using software different from RealGUIDE. In addition, Sweden & Martina produces a series of indexed sleeves with an upper hexagon which means the positioning of the implant connection previously planned using RealGUIDE software can be respected. Due to this specific peculiarity, indexed sleeves can be positioned in Sweden & Martina surgical guides just using the appropriate software.



Important Warning

Whenever a 3D printer is available to make the templates, it is appropriate to use the flow to bond the sleeves and not use cyano-methacrylate because the latter tends to oxidize them.

implant	implant ø	sleeve		mounter		screw	
Premium One	3.30 mm		GS-B415			GS-MOU-A330	
	3.80 mm		GS-B415			GS-MOU-A380	
	4.25 mm		GS-B550			GS-MOU-A380SP	
	5.00 mm		GS-B550			GS-MOU-A380SP	
							GS-VTMOU-180
Prama	3.80 mm		GS-B415			GS-MOU-L415	
Prama RF	4.25 mm		GS-B550			GS-MOU-L550	
	5.00 mm		GS-B550			GS-MOU-L550	
							GS-VTMOU-180
Shelta	3.80 mm		GS-B415			GS-MOU-A380	
Shelta SL	4.25 mm		GS-B550			GS-MOU-A380SP	
	5.00 mm		GS-B550			GS-MOU-A380SP	
							GS-VTMOU-180
Syra	3.80 mm		GS-B415			GS-MOU-E410	
	4.25 mm		GS-B550			GS-MOU-E500	
	5.00 mm		GS-B550			GS-MOU-E500	
							GS-VTMOU-200

*The indexed sleeves are available in packs of 6, not individually.

Easy mounters

Easy mounters are guided surgery instruments that, in one single piece, combine the functions of a classic mounter and a driver, with all the functionalities of an Easy Insert. Unlike the current system used for guided surgery, which requires a mounter to be screwed into the connections and the use of the Easy insert to pick up the implant and screw it in, this new solution does not require a fixation screw. In one single piece this system provides both the guide inside the sleeve and the driver function for screwing down.

They therefore have the advantage of ensuring greater simplicity and rapidity when used.

The upper ring identifies the diameter of the sleeve.

White for the \varnothing 4.15 mm sleeve and
black for the \varnothing 5.50 mm sleeve.



Though the torque control ratchet version has no band identifying the sleeve, it is indicated by a laser mark at the top of the hexagon.

The two coloured rings indicate the implant line.

The one coloured ring on the body of the device identifies the implant line.

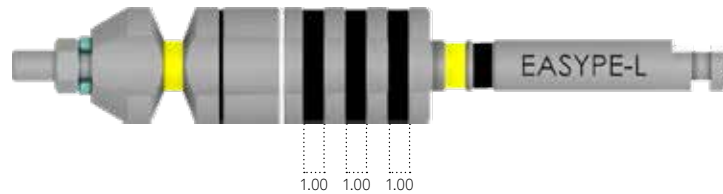
implant	implant \varnothing	sleeve		mounter		
Premium One	3.30 mm		GS-B415			GS-EASY-AS-415-CA
	3.80 mm					GS-EASY-AS-415-EX
	4.25 mm		GS-B550			GS-EASY-AS-550-CA
	5.00 mm					GS-EASY-AS-550-EX

implant	implant \varnothing	sleeve		mounter		
Prama	3.80 mm		GS-B415			GS-EASY-L-415-CA
						GS-EASY-L-415-EX
	4.25 mm		GS-B550			GS-EASY-L-550-CA
						GS-EASY-L-550-EX
	3.80 mm		GS-B415			GS-EASYPE-L-415-CA
						GS-EASYPE-L-415-EX
	4.25 mm		GS-B550			GS-EASYPE-L-550-CA
						GS-EASYPE-L-550-EX

implant	implant \varnothing	sleeve		mounter		
CSR	3.00 mm		GS-B415			GS-EASY-CSR-N-415-EX
	3.50 mm					GS-EASY-CSR-N-415-CA
	3.80 mm					GS-EASY-CSR-N-415-EX
	4.20 mm		GS-B550			GS-EASY-CSR-N-415-CA
						GS-EASY-CSR-550-EX
	5.00 mm		GS-B550			GS-EASY-CSR-550-CA

*Indexed guide sleeves are not sold individually but are available in packs of 6.

The Easy Mounters for Collex connections are made only with the 2.3 mm hexagon for the ONE platforms (3.30, 3.80, 4.25 ONE and 5.00 ONE). Therefore the Easy Mounters are not available for either the old 4.25 or the 5.00 NON ONE connections.



These Easy Mounters were designed to provide clinicians with greater freedom in implant insertion in post-extraction cases. This freedom is given by the fact that these instruments are entirely cylindrical, thus they have no shoulder to act as a stop. The absence of a physical stop and the depth notches at each millimetre are also useful when, due to anatomical necessity, the guide sleeve is positioned at a greater height than the standard 9.00 mm reference used for Sweden & Martina guided surgical procedures.

General overview

The instruments in the GSL kit are as follows:

- 6 drills, in different designs;
- 12 depth stops;
- 4 guided tips in different sizes;
- 1 hand instrument with a straight working axis on one side and an “L” on the other side, which makes operating in the lateral posterior sectors easier;
- One autoclave-safe instrument box with an internal tray.

These are reusable medical devices intended for temporary use in the oral cavity (continuous duration not exceeding 60 minutes).

The GSL kit is offered for sale including all of its components, whilst the individual instruments and tray can also be purchased individually as spare parts. Both the kit and the instruments and tray are sold in NON-STERILE packaging. Before use, the instruments must be cleaned, disinfected and sterilised according to the instructions below.

Lack of compliance may result in patient infection.

Use and handling of these products are restricted to medical and dental personnel with the necessary qualifications and professional training.

The materials used for production have been selected on the basis of the properties indicated for their intended use, in compliance with Regulation (EU) 2017/745. Each package bears the code, a description of the contents and the batch number. These same data, which can also be found on labels inside the packages, are to always be quoted by the doctor in any communications about the products.

Drills

Sweden & Martina drills are made of surgical steel. They are intended for mechanical use, i.e., they have a shank with a contra-angle attachment and must be used with a suitable micromotor. The extreme accuracy of their design and manufacture means that their operation is absolutely free of vibrations and oscillations.

Nevertheless, any improper insertion of the tools into the handpiece can lead to instrument vibration, eccentric rotation, premature wear and bent shanks. Only surgical micromotors that are suitable for these applications should be used. To prevent any malfunctions (e.g. axis shifts of drive shafts, worn or malfunctioning collets, etc.), it is strongly suggested that your micromotors be periodically inspected by their manufacturers, according to instructions. Failure to follow these instructions may lead to intraoperative surgical problems.

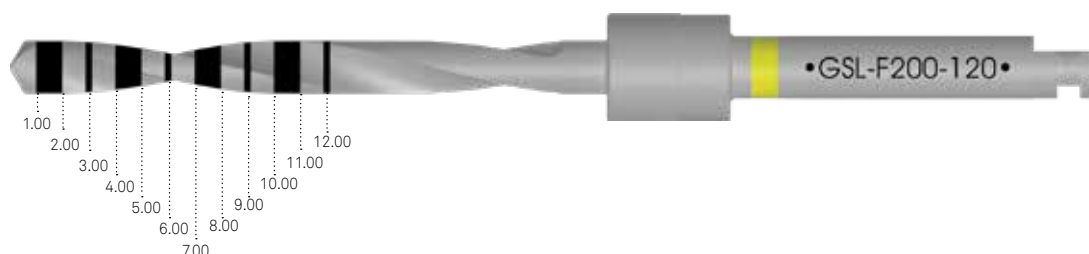
It is recommended that the rotation speeds, which are indicated in the procedures on Page 14 et seq., be used to avoid the development of bone necrosis. Lever movements augment the risk of tool fracture and should therefore be avoided. In general, sudden changes in speed should be avoided. Never apply sufficient pressure to forcefully stop the rotation of the instrument. This could cause excessive heat to build-up in the tissues being cut, which can result in bone necrosis, and which can ruin both the tool and the drive used (micromotor). This can also lead to the tool breaking.

Furthermore, an appropriate coolant should also be used. Bone necrosis may occur without adequate irrigation. Drill wear largely depends on the type and density of the bone being cut: harder bone leads to greater tool wear. It is recommended, for greater safety and caution with respect to the wear capacity of the device, that drills be used for no more than 20 work cycles or less if the tools begin to lose their cutting capacity. The suggested 20 work cycles is an average figure. The tools' residual cutting capacity should be checked after each surgical procedure.

Sweden & Martina shall bear no liability for excess usage.

Drills should never be resharpened before use. Never use tools that are either damaged, bent or worn.

A laser marking on the shank of each instrument identifies its diameter.



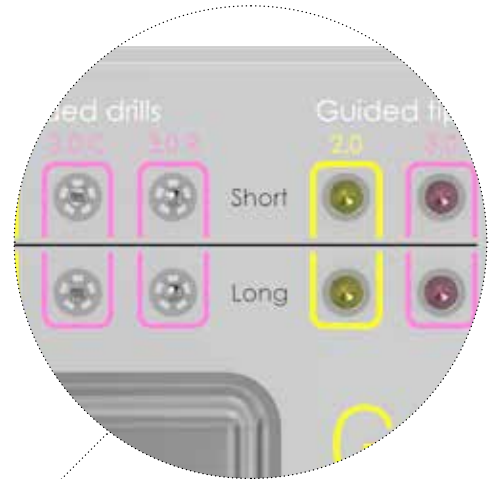
The depth notches, common to all drills, are at a distance of 1 mm between each of them.

The first notch marks a depth of 1.00 mm, each of the others progressively adds one millimetre, and indicates the depth reached as the instrument advances into the implant site.

The notches are alternately distinguished from one another as follows:

- the **first notch** is a 1.00 mm high laser-marked black band that starts at a depth of 1.00 mm and ends at 2.00 mm;
- the **second notch** is a dark laser-marked ring that starts at 3.00 mm;
- the **next notches** follow the same pattern as the first two
 - 1.00 mm thick bands at a depth of between 4.00 mm and 5.00 mm;
 - then again, there is a thin laser-marked notch at 6.00 mm;
 - then there is a 1.00 mm thick band between 7.00 and 8.00 mm
 - then a thin notch at 9.00 mm,
 - with a 1.00 mm band between 10.00 and 11.00 mm,
 - and a thin notch at 12.00 mm.

This pattern allows the operator to recognise the notches without having to count millimetres each time they are used.



Cylindrical drills

The drills have two working lengths: SHORT at 6.00 mm and LONG at 12.00 mm. Their use depends on the amount of native bone in the case being treated.



Chamfered drills

Thanks to its special profile with bevelled angles and apices, the chamfered drill allows the cortical layer of the sinus floor to be bent or broken if the cortical layer is thin.



Rounded drills

The two rounded drills are characterised by a non-cutting spherical tip. The working part has two helical cutting edges that allow the preparation hole to be enlarged to \varnothing 3.00 mm.








Depth stops

For the user's protection, the kit includes 12 depth stops in progressive lengths in fixed 1.00 mm increments, for use with either rotary or manual instruments.

Important Warning

The stops work by subtraction, please refer to the use protocol on page 14.

	GSL-STOP-000-415		GSL-STOP-000-550
	GSL-STOP-010-415		GSL-STOP-010-550
	GSL-STOP-020-415		GSL-STOP-020-550
	GSL-STOP-030-415		GSL-STOP-030-550
	GSL-STOP-040-415		GSL-STOP-040-550
	GSL-STOP-050-415		GSL-STOP-050-550



Important Warning

If the stop fins are too tight or too loose, please adjust them manually as required.

Handle

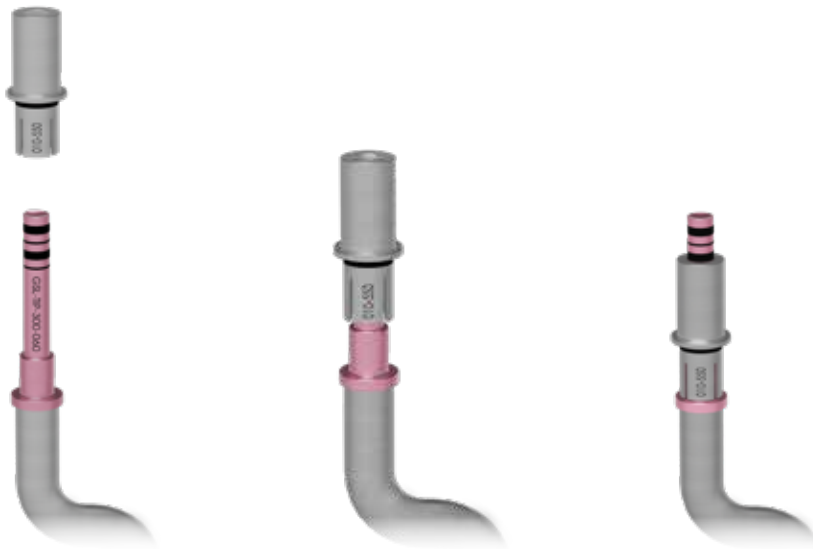
The handle is a multifunction tool with interchangeable tips that can become either a plugger or osteotome.





Guided tips can be used as depth gauges, pluggers and osteotomes for mixed Summers technique. In some cases is it possible to use the smaller one as an osteotome. On the other hand, the Long one is used to push the regenerative material into the site where you are operating.

To use the instrument with the surgical hammer, insert the special cap so that the thread on the tip will not be damaged.



Manual Instruments



	GLS-TIP-200-060	tip ø 2.00 mm h 6.00 mm	works as a probe
	GLS-TIP-200-120	tip ø 2.00 mm h 12.00 mm	
	GLS-TIP-300-060	tip ø 3.00 mm h 6.00 mm	works as a Plugger, an osteotome and as a probe
	GLS-TIP-300-120	tip ø 3.00 mm h 12.00 mm	

Use Protocol

by dr. Bruno Emanuele (Padua)

Let us consider, for the case selected, that the patient with 5.00 mm of residual bone, turns out to be suitable for reconstructive/regenerative therapy, to be rehabilitated by implant-prosthesis, with CBCT performed under stable conditions, with extractions (where necessary) already performed and bone healing time sufficiently respected. The implant that is planned to be inserted is 10.00 mm long.

Important Warning

Steps to be taken before proceeding with sinus augmentation:

- Local-regional anaesthesia
- Position the surgical template
- Perform the mucotomy
- Remove the template to ensure that the site is clean, i.e., free of fragments of mucous (clean as needed)
- Reposition the surgical template

Bring the 6.00 mm long initial SHORT cylindrical drill GSL-F200-060 to 2.00 mm from the sinus using the 3.00 mm stop GSL-STOP-030-415.

Check the working level with the depth gauge GSL-TIP-200-060 and the same GSL-STOP-020-415 stop.



drill/tip	instrument length	stop	working length	working speed
GSL-F200-060	6.00 mm	GSL-STOP-030-415	3.00 mm	800 rpm

Bring the chamfered SHORT drill GSL-FC300-060 to the same working level (2.00 mm from the sinus) and with the stop GSL-STOP-030-415.



drill/tip	instrument length	stop	working length	working speed
GSL-FC300-060	6.00 mm	GSL-STOP-030-415	3.00 mm	800 rpm

Mount the 2.00 mm stop
GSL-STOP-020-415 on the
chamfered drill GSL-FC300-060 and
start advancing to 1.00 mm from the
sinus.

Check the working level with the
depth gauge GSL-TIP-300-060 and
the stop GSL-STOP-020-415.



drill/tip	instrument length	stop	working length	working speed
GSL-FC300-060	6.00 mm	GSL-STOP-020-415	4.00 mm	800 rpm
GSL-TIP-300-060	6.00 mm	GSL-STOP-020-415	4.00 mm	800 rpm

Advance to the floor of the sinus
with the drill GSL-FC300-060 using
the 1.00 mm GSL-STOP-010-415
stop.

Measure the working level with
GSL-TIP-300-060 and the stop
GSL-STOP-010-415.



drill/tip	instrument length	stop	working length	working speed
GSL-FC300-060	6.00 mm	GSL-STOP-010-415	5.00 mm	800 rpm
GSL-TIP-300-060	6.00 mm	GSL-STOP-010-415	5.00 mm	800 rpm

Recommended step

After having checked the working length,
it is recommended to give a light blow
with the surgical hammer to then proceed
with lifting the membrane.



Use the SHORT rounded drill first GSL-R300-060 with the stop GSL-STOP-000-415 to optimise the patency of the osteotomy. To proceed with lifting the membrane, you will have to switch to the LONG rounded drill, since you have already arrived at 5.00 mm and will need to arrive at the planned implant length, i.e., 10.00 mm.



Important Warning
From this step onwards it is preferable to reduce the speed according to the receiving bone.

drill/tip	instrument length	stop	working length	working speed
GSL-R300-060	6.00 mm	GSL-STOP-000-415	6.00 mm	300 rpm

Advance 1.00 mm by mounting the 5.00 mm stop GSL-STOP-050-415 on the LONG rounded drill, GSL-R300-120.



drill/tip	instrument length	stop	working length	working speed
GSL-R300-120	12.00 mm	GSL-STOP-050-415	7.00 mm	300 rpm

Proceed with the 4.00 mm stop GSL-STOP-040-415, reaching a depth of 8.00 mm.



drill/tip	instrument length	stop	working length	working speed
GSL-R300-120	12.00 mm	GSL-STOP-040-415	8.00 mm	300 rpm

Proceed with the 3.00 mm stop GSL-STOP-030-415, reaching a depth of 9.00 mm.



drill/tip	instrument length	stop	working length	working speed
GSL-R300-120	12.00 mm	GSL-STOP-030-415	9.00 mm	300 rpm

Proceed with the 2.00 mm stop GSL-STOP-020-415, reaching a depth of 10.00 mm.



drill/tip	instrument length	stop	working length	working speed
GSL-R300-120	12.00 mm	GSL-STOP-020-415	10.00 mm	300 rpm

Insert a collagen sponge to protect the membrane and then the filler material afterwards.

At this point the membrane has been lifted. The biomaterial should now be inserted through the template, using the Plugger with the tip GSL-TIP-300-060 and with the stop GSL-STOP-010-415, which should start working at 2.00 mm from the sinus floor and progress millimetre by millimetre.



drill/tip	instrument length	stop	working length	working speed
GSL-TIP-300-060	6.00 mm	GSL-STOP-010-415	5.00 mm	300 rpm

Insert the implant: Premium
 ø 3.80 h 10.00 mm. If the raised
 height is greater than the amount
 of residual bone, a contra-angle
 implant insertion is recommended.

Important Warning

The guided sinus lift performed with the
 GSL kit is to be finalised with the insertion
 of the implant.

working speed

60 rpm



Watch the video of one of
 dr. Bruno Emanuele's clinical cases

Summary of working lengths with the GSL kit

drill/tip	stop	drill working part
6.00 mm	0.00 mm	6.00 mm
	1.00 mm	5.00 mm
	2.00 mm	4.00 mm
	3.00 mm	3.00 mm
	4.00 mm	2.00 mm
	5.00 mm	1.00 mm

drill/tip	stop	drill working part
12.00 mm	0.00 mm	12.00 mm
	1.00 mm	11.00 mm
	2.00 mm	10.00 mm
	3.00 mm	9.00 mm
	4.00 mm	8.00 mm
	5.00 mm	7.00 mm

Cleaning/sterilisation/storage of prosthetic components and instruments

Warning! All surgical instruments for dental implants are sold in non-sterile condition. Before use, the instruments must be cleaned, disinfected and sterilised according to the following procedure validated by Sweden & Martina. These processes are to be performed before first use, and before each subsequent re-use.

Repeating the processes described in this section has a minimal effect on these devices' wear and tear.

Make sure to always check the functionality of the instruments before use. Any instrument showing signs of wear should be replaced with a new device immediately. Specifically, it is recommended that the correct retention of the screwdrivers inside the engagement wells on the heads of the screws that are to be taken out and screwed in with those tools always be checked. Failure to comply with these instructions may result in cross infection and intraoperative complications.

a. Cleaning

Containers and transport to be used for cleaning have no special requirements. If automated cleaning is applied: use ultrasonic bath with a suitable cleaning solution. It is recommended that only neutral detergents be used. The concentration of the solution and the duration of the cleaning process should be in accordance with the solution manufacturer's instructions. Use demineralised water to prevent the formation of stains and marks.

When draining, check that residues have been completely removed from recesses, holes, etc., in the devices. If necessary, repeat the cycle or clean manually.

If manual cleaning is performed, use a suitable neutral detergent, following the manufacturer's instructions for use. Brush the products with soft bristles under running water. Using the brush, apply the cleaning solution to all surfaces. Rinse with distilled water for at least 4 minutes.

Ensure that plenty of running water flows through any holes. When cleaning drills with internal irrigation, use the pins provided with the handpieces to ensure that the irrigation holes have been thoroughly cleaned and cleared of any residual bone chips or biological tissue. After rinsing, dry the devices completely and pack them in suitable sterilisation bags. If a drying cycle is performed as part of the washing and disinfection machine cycle, do not exceed 120 °C.

b. Sterilisation

When using a vacuum autoclave, sterilise using the following procedures:

- autoclave (Gravity-Displacement Cycles) at the temperature of 121 °C with a minimum of 30 minutes of exposure and a 15-minute drying cycle;
- autoclave (Dynamic-Air-Removal Cycles) at the temperature of 132 °C with 4 minutes of exposure and at least a 20-minute drying cycle.

c. Storage

After sterilisation, the product should remain in the pouches used for sterilisation. The pouches should only be opened immediately prior to reuse. Sterilisation pouches are normally capable of maintaining sterility inside the pouch unless the pouch is damaged. Care should therefore be taken to not use components if the pouches in which they were stored are damaged and to re-sterilise them in new pouches before re-use. The shelf life of sterilised products in pouches should not exceed that recommended by the pouch manufacturer. The product should be stored in a cool, dry place, away from direct sunlight, and from sources of water and heat.

For information on maintenance, cleaning/sterilisation/storage, and the symbols on the packaging of prosthetic components and surgical instruments, see the website https://www.sweden-martina.com/en_gb/ifu/

THE LAST REVISION DATE OF THIS MANUAL IS JULY 2022.

The design and manufacture of the devices covered by this manual has been undertaken in compliance with the most up-to-date directives and harmonised standards with regard to materials used, manufacturing processes, sterilisation, information provided and packaging.



rev. 07-22



Sweden & Martina S.p.A.

Via Veneto, 10
35020 Due Carrare (PD), Italy
Tel. +39.049.9124300
Fax +39.049.9124290
info@sweden-martina.com

www.sweden-martina.com

Sweden & Martina Ltd

Unit 1b
Amberley Court, Whitworth Road
Crawley, West Sussex, RH11 7XL
Toll free 0800 1123575
info.uk@sweden-martina.com

Customer Service Digital Workflow

Tel. 08007747542
customerserviceDWF@sweden-martina.com

Sweden & Martina Mediterranea S.L. - España

info.es@sweden-martina.com

Sweden & Martina Lda - Portugal

info.pt@sweden-martina.com

Sweden & Martina Inc. - Distributor for U.S.

info.us@sweden-martina.com

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The Sweden & Martina plant manufactures Medical Devices in compliance with the CGMPs in force in the USA and in other countries worldwide.



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