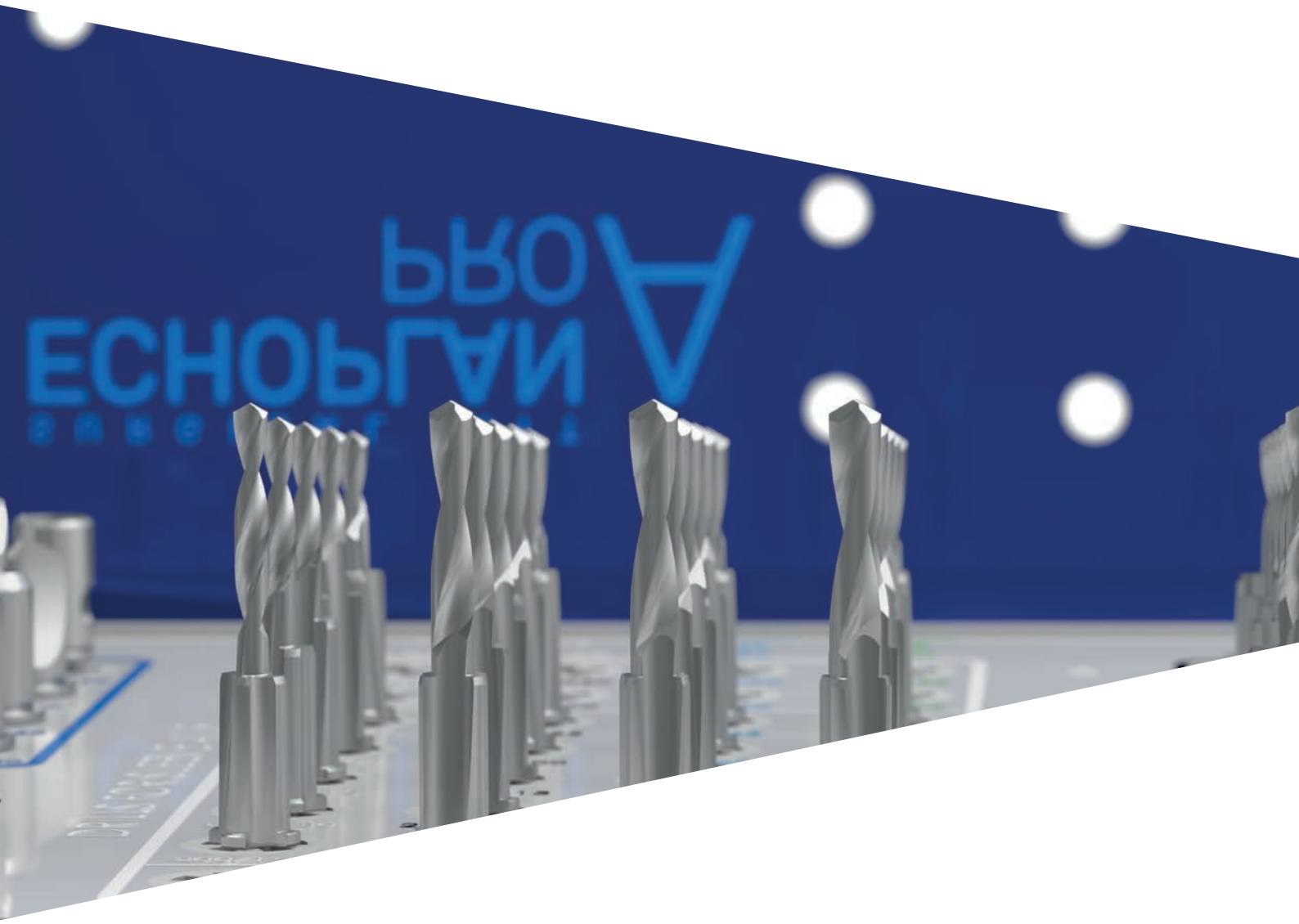
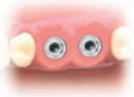
Surgical manual

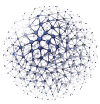
ECHOPLAN PRO A



sweden & martina

Kit Echoplan PRO A





Clinical indications for resorting to implantoprosthetic therapies

When assessing the patient, in addition to his/her eligibility with regards to implant-prosthetic rehabilitation, it is usually necessary to consider the contraindications that apply to oral surgery procedures in general. These include:

- clotting disorders, anticoagulant therapy;
- healing or bone regeneration disorders;
- decompensated diabetes mellitus;
- metabolic or systemic diseases that compromise tissue regeneration with a particular influence on healing and bone regeneration;
- alcohol abuse, smoking and use of drugs;
- immunosuppressive therapy, such as: chemotherapy and radiotherapy;
- infections and inflammations, such as periodontitis and gingivitis;
- poor oral hygiene;
- inadequate motivation;
- occlusion and/or articulation disorders as well as an inadequate interocclusal space;
- inadequate alveolar process.

It is contraindicated to fit implants and implant restorations in patients with poor general or oral health, those who are unable to monitor their general conditions properly or those who have had organ transplants. Psychologically unstable patients, alcohol or drug abusers, and poorly motivated or uncooperative patients should also be considered unsuitable for this kind of treatment. Patients with poor periodontal health should first be treated and allowed to recover. In the presence of a lack of bone substance or poor quality of the receiving bone, such as to compromise the stability of the implant, suitable guided tissue regeneration must be performed prior to implant treatment.

Contraindications also include: bruxism, allergy to titanium (extremely rare), acute or chronic infectious diseases, sub-acute chronic maxillary osteitis, systemic diseases, endocrine disorders, diseases resulting in microvascular disorders, pregnancy, breastfeeding, previous exposure to radiation, haemophilia, neutropenia, steroid use, diabetes mellitus, kidney failure and fibrous dysplasia. The normal contraindications common to all oral surgery must also be observed. Surgery is not recommended for patients on anti-coagulant, anticonvulsant and immunosuppressant therapies, with active inflammatory-infective processes of the oral cavity, and patients with BUN and creatinine values outside the norm. Patients with cardiovascular disease, hypertension, thyroid or parathyroid diseases, malignant tumours found in the 5 years preceding the operation, or nodular
swellings must also be rejected.

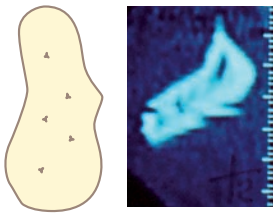
Chemotherapies reduce or eliminate the ability of osseointegration, therefore patients undergoing these treatments must be carefully screened before being rehabilitated with oral implantoprostheses. Numerous cases of bisphosphonate-associated periimplant osteonecrosis of the mandible have been reported in the literature. This problem particularly applies to patients treated intravenously.
As a post-operative precaution, the patient must avoid any kind of strenuous physical activity.

Side and secondary effects

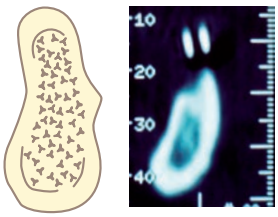
Situations that may occur after surgical procedures include temporary local swelling, edema, hematoma, temporary sensitivity alterations, temporary masticatory limitations, post-surgical microhemorrhages in the following 12-24 hours. The patient may also experience pain, speech problems, gingivitis, loss of bone crest, permanent paresthesia, dysesthesia, local or systemic infections, exfoliation, hyperplasia, and oronasal and oroantral fistulas, perforation of the labial or lingual plate, perforation of the Schneidarian membrane, bone fractures, implant fractures, fractures of the overstructures, aesthetic problems, unnoticed perforation of the nasal sinus, nerve injuries, impairment of natural dentition. The following pathophysiological problems can increase the risks: cardiovascular failure, coronary disease, arrhythmia, pulmonary or chronic respiratory disease, gastrointestinal disease, hepatitis, inflammatory bowel disease, chronic kidney failure and disorders of the urinary system, endocrine disorders, diabetes, thyroid diseases, hematologic disorders, anaemia, leukaemia, coagulation problems, osteoporosis or musculoskeletal arthritis, stroke, neurological disorders, mental retardation, paralysis.

Before proceeding, it is important to perform a careful pre-operative analysis of the patient's medical history to verify his or her suitability for the implant treatment. It is also recommended to collect and file all the clinical, radiological and radiographic records.

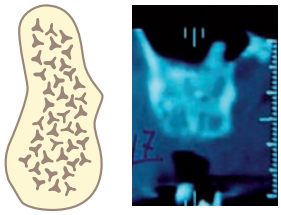
In addition to both clinical and radiographic oral examination, it is also advisable to conserve the CT of the area affected. Once the radiographic and tomographic documentation has been obtained, the specialist can identify the most suitable implant for the case with the help of reference software.
The pre-operative study of the CT scan allows the identification of the type of bone present in the insertion point of the implant. The choice of the surgical procedure must take into consideration the type of bone present. The bone is normally classified into 4 types according to the density. The classification (according to Carl Misch) is the following:



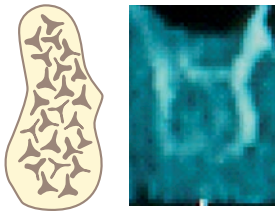
BONE D1: all cortical bone.



BONE D2: a core of bone marrow enclosed in a shell of cortical bone.



BONE D3: all bone marrow without cortical bone.



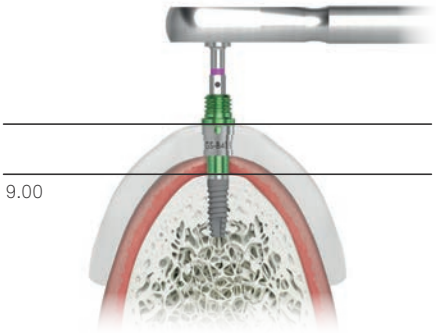
BONE D4: all bone marrow with very poor mineralization.

General indication

The guided surgery implant treatment technique includes diagnosis, planning and positioning.
The main advantage is being able to plan the intervention by working with a complete 3D view of the radiological and prosthetic anatomy of patients and so evaluate the dimensions and final position of the dental implant precisely, also in accordance with the prosthetic study (wax-up), and using surgical guides capable of guiding the implant positioning according to this same planning.
The Echoplan PRO A surgical kit has been studied and developed for the preparation of surgical sites using the guided surgery with cylindrical implants Premium One produced by Sweden & Martina.
The Echoplan PRO A and the surgical instruments contained in it have been designed so that they are compatible for use with the main guided surgery techniques currently available on the market (three-dimensional diagnostic software and surgical guides).
Sweden & Martina has an up-to-date list available upon request.

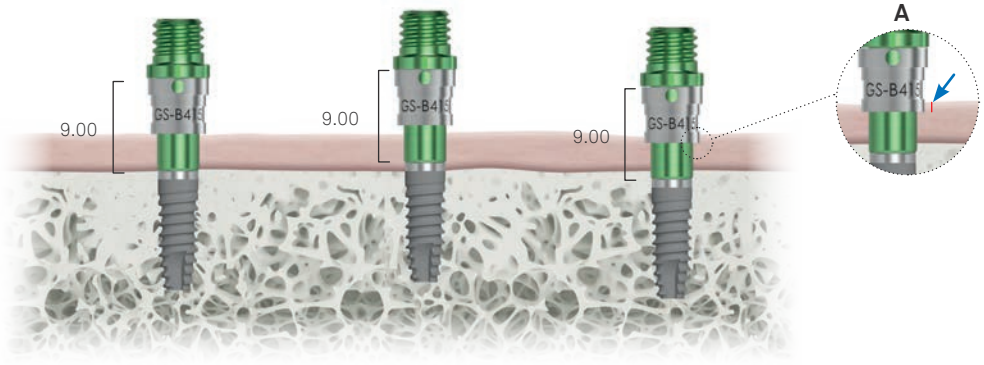
Introduction to the Echoplan PRO A system

There is a **fixed relationship** between the instruments involved in guided surgery which facilitates congruence between the implant position and its planned position.
The ratio according to which the Echoplan PRO A system has been designed is **9.00 mm** between the level of the mechanical stop of instruments on the sleeve, the metal cylinder inserted in the surgical guide (which functions to guide the axis of the instruments' insertion but also to determine its place of rest at a determined length) and the implant connection plane.



Premium One implant bone level

When a surgical protocol provides for a different positioning of the implant platform from the juxtaosseous as in the XA* technique, the digital planning automatically calculates the position of the sleeve's upper edge at exactly 9.00 mm from the connection plane. The thickness of the soft tissues in such cases may interfere with the ideal position of the sleeve so rather than adopting a flapless approach, the flap needs to be opened (**A**).



The opportunity to manage submerged positioning of implants is particularly helpful because the Premium One implant range also includes 7.00 mm heights and their dedicated drills are available as an option and can be added to the kit. In this case, please request the correct insertion sequence from Sweden & Martina.

**For further information on the XA technique, please go to www.sweden-martina.com*

Guide sleeves

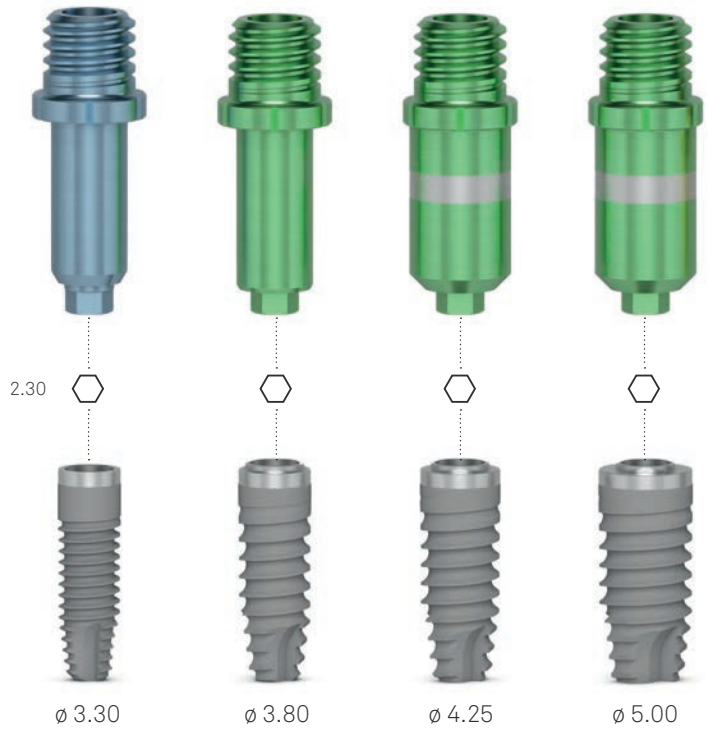
Guide sleeves are the cylinders present in the surgical template that are used to guide instruments during preparation.
Sweden & Martina produces a series of standard sleeves, which are not indexed: these are available to laboratories who manufacture surgical guides. Sleeves have a height of 5.00 mm, and the internal hole has a diameter of 4.15 mm or 5.50 mm. Sleeves are used to correctly guide surgical instruments in accordance with the predetermined axis, they provide a safe stop at a distance of 9.00 mm from the bone crest edge for all instruments.

implant	ø implant	sleeve	mounter
Premium One	**3.30** **3.80**	**GS-B415**  	**GS-MOU-A330**  **GS-MOU-A380** 
	4.25 **5.00**	**GS-B550**  	**GS-MOU-A380SP** 

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.

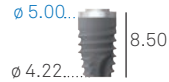
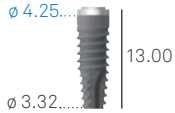
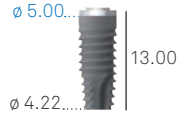
Implant mounters and connections

Premium One implants have the Collex One connection, with an internal prosthetic support hexagon that makes the prostheses robust and stable and acts as a guide when engaging the mounters. The connection is the same for all implant diameters but mounters differ according to the diameters of the reference guide sleeves (see the side table) within which the mounters must be guided for the 9.00 mm of their length. Please see pages 30-31 for all the codes and details of the interaction between mounters and the handpiece or the driver they must be used with.



**Please see details of the Collex One connection inside the manuals MP-IMP-PREKOSH-ONE-E at www.sweden-martina.com.*

Premium One implants

implant ø and color code on the packaging	3.30	3.80	4.25 ONE	5.00 ONE
7.00	-	-	**AS-ZT-425-070** 	**AS-ZT-500-070** 
8.50	**A-ZT-330-085** 	**A-ZT-380-085** 	**AS-ZT-425-085** 	**AS-ZT-500-085** 
10.00	**A-ZT-330-100** 	**A-ZT-380-100** 	**AS-ZT-425-100** 	**AS-ZT-500-100** 
11.50	**A-ZT-330-115** 	**A-ZT-380-115** 	**AS-ZT-425-115** 	**AS-ZT-500-115** 
13.00	**A-ZT-330-130** 	**A-ZT-380-130** 	**AS-ZT-425-130** 	**AS-ZT-500-130** 
15.00	**A-ZT-330-150** 	**A-ZT-380-150** 	**AS-ZT-425-150** 	**AS-ZT-500-150** 
18.00	-	**A-ZT-380-180** 	**AS-ZT-425-180** 	-
Surgical cover screws*	**A-VT-330** 	**A-VT-380** 	**SH-VT-425-BL** 	**SH-VT-500-VI** 

**Each implant is sold with the respective 4 Gr. titanium surgical cover screws. Individual surgical cover screws are also available in sterile packs and are tightened at 8-10 Ncm.*

See technical characteristics of Gr. 4 titanium on page 53.

General indications

The surgical instruments designed for use with the implant systems manufactured by Sweden & Martina are reusable medical devices intended for temporary use in the oral cavity (no more than 60 minutes) . The functions of the surgical instruments are to prepare sites for Sweden & Martina implants, to insert the implants in the sites, to tighten and unscrew all the connecting screws (surgical cover screws, healing abutments, screws for posts, abutments, prosthesic screws, transfer screws, etc.).

The surgical instruments manufactured by Sweden & Martina are designed for use with dental implants manufactured by Sweden & Martina. Use of surgical instruments for operations with other implants than those manufactured by Sweden & Martina limits the responsibility of Sweden & Martina and renders the product warranty void. Sweden & Martina declines all responsibility for use of any non-original instruments. Sweden & Martina surgical instruments are sold in **NON-STERILE packs**. Before use, they must be cleaned, disinfected and sterilized according to the instructions reported below. Failure to follow these warnings may expose the patient to infections. The materials used for production of the surgical instruments manufactured by Sweden & Martina were selected based on the properties indicated for their intended use according to Regulation (EU) Medical Devices n. 2017/745.

Each packaging indicates the code, description of the contents and batch number. These same details, which are also indicated on the labels inside the packs, must always be provided by the practitioner in any relevant correspondence.
All the devices are identified by an instrument code, which is laser marked onto the body of each instrument. If there is not enough space to include the full code, the elements for unequivocally identifying the device (e.g. diameter or length) are provided. When handling the devices, both during use and during cleaning and sterilization procedures, it is recommended to use surgical gloves for personal protection from bacterial contaminations. Failure to follow these instructions may cause cross-infection.

Key to codes: surgical instruments

Implants are coded with “mnemonic” codes that allow easy identification of the piece. Below is a table showing how the mnemonic codes work using various types of instruments as examples.

examples	component type and implant type	diameter	length	sleeve
The range of instruments is vast, we indicate some examples of the main families of instruments	The letters “GS” mean the instruments dedicated to guided surgery, designed to be guided inside the sleeves inserted in the surgical template	Normally it is the ø of the implant for the insertion or of the preparation for which the instrument should be used	This measurement is normally linked to the height of the component, or to other important measurements that characterise it, or it is a value that defines the preparation length of a drill	Indicates the internal diameter of the sleeve guiding the instrument
GS-F200-100-415	GS-F: drill for guided surgery	200: 2.00 mm	100: for the preparation of 10.00 mm high implants	415: for sleeves of 4.15 mm diameter
GS-MUC-550	GS-MUC: mucotome for guided surgery	-	-	550: for sleeves of 5.50 mm diameter
GS-FPN-148	GS-FPN: drill for insertion of the surgical template retention pins	148: 1.48 mm	-	-

Echoplan PRO A surgical kit

The Echoplan PRO A surgical kit has been designed and produced to offer simplicity and immediacy of use for the correct sequence of the instruments. The instruments are all made of stainless steel for surgical use. They have the descriptions screen printed on the tray so that the user can easily identify each instrument and put it back in the correct place in the kit after the cleansing and cleaning phases thanks to the help of a system of color codes that track the appropriate surgical procedures for the various implant diameters.

Important warning
The Echoplan PRO A kit and the surgical instruments contained in it are sold in a NON-STERILE pack. Before being used, they must be cleaned, disinfected and sterilized according to the instructions provided below. Not respecting this warning may cause infections to the patient.

The kit has holders for the optional drills used to prepare the 6.00 mm and 7.00 mm short implants and the 18.00 mm long implants.

description	code
Grommetless surgical kit complete with the Instruments required for guided insertion of Premium One implants	**ZGS-PRO-A-INT** 
Grommetless instrument cases made of Radel for the guided surgery instruments, empty	**GSPROA-TRAY-INT**

Important warning
The kit does not contain mounters which must be bought separately before the surgical operation. Mounters can be stored and organized in an appropriate organizer. For details see pages 28-29 and 32.

1 **Mucotomes**
GS-MUC-415
GS-MUC-550

2 **Bone profilers**
GS-LC-415
GS-LC-550

3 **Initial drills and progressive drill**
GS-F200-415
GS-F200-550
GS-F2030-550

4 **Drivers**
HSM-20-EX HSML-20-EX HSM-20-DG HSML-20-DG HSM-20-CA

20 **Optional drill for H 18.00 mm implants and ø 5.50 mm sleeve**
GS-F200-180-550
GS-F340-180-550

19 **Optional drill for H 18.00 mm implants and ø 4.15 mm sleeve**
GS-F200-180-415
GS-F300-180-415

18 **Pins and drill for pins**
GS-FPN-148 GS-PIN (4 pcs)

17 **Hand knob**
AVV3-MAN-DG

16 **Torque control ratchet**
CRI5-KIT

15 **Drivers for mounters**
EASY4-EX250-EX EASYC4-EX250-CA

14 **Countersink drills**
GS-FCS-A380
GS-FCS-A425
GS-FCS-A500

5

Optional drills for H 6.00 mm
ø 3.80 mm implants*
GS-F200-060-415
GS-F250-060-415
GS-F280-060-415
GS-F300-060-415

6

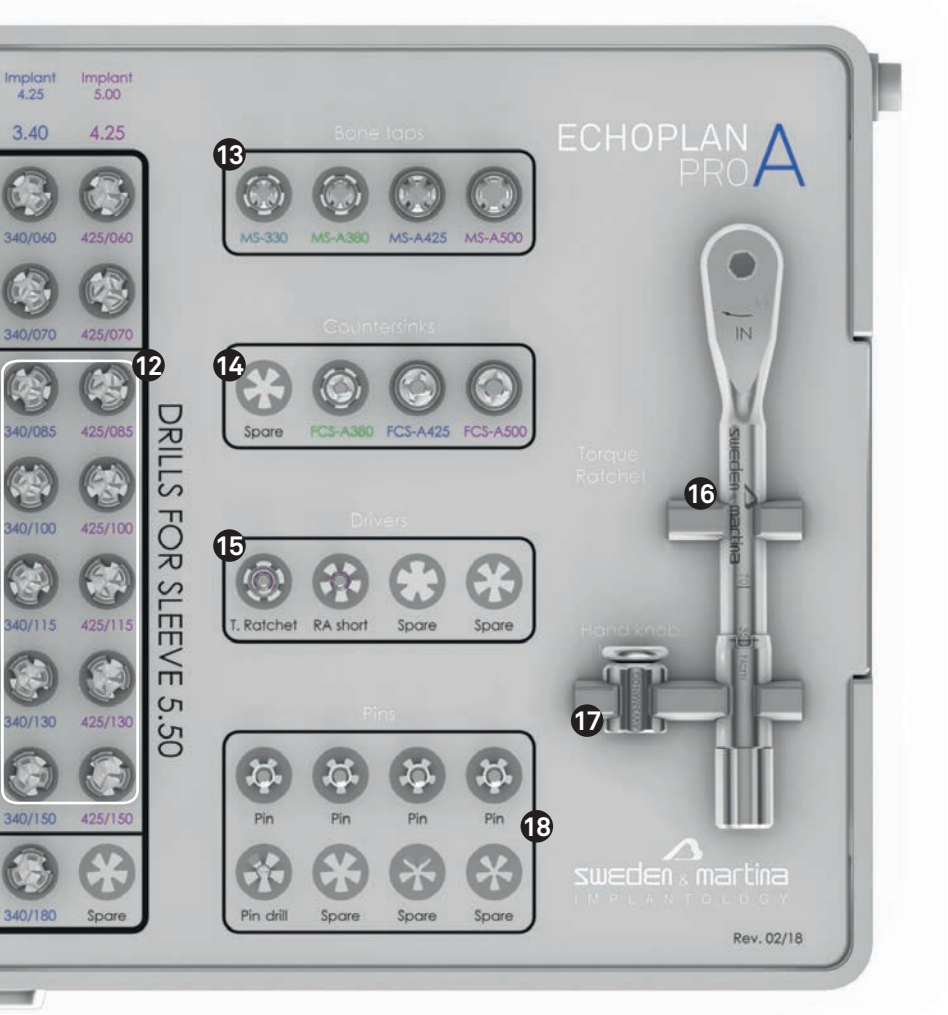
Optional drills for H 6.00 mm
ø 4.25 and 5.00 mm implants*
GS-F200-060-550
GS-F300-060-550
GS-F340-060-550
GS-F425-060-550

7

Optional drills for H 7.00 mm
ø 3.80 mm implants
GS-F200-070-415
GS-F250-070-415
GS-F280-070-415
GS-F300-070-415

8

Optional drills for H 7.00 mm
ø 4.25 and 5.00 mm implants
GS-F200-070-550
GS-F300-070-550
GS-F340-070-550
GS-F425-070-550



9

Intermediate drills
for ø 4.15 mm sleeve
GS-F200-085-415
GS-F200-100-415
GS-F200-115-415
GS-F200-130-415
GS-F200-150-415

GS-F250-085-415
GS-F250-100-415
GS-F250-115-415
GS-F250-130-415
GS-F250-150-415

10

Final drills for
ø 4.15 mm sleeve
GS-F280-085-415
GS-F280-100-415
GS-F280-115-415
GS-F280-130-415
GS-F280-150-415

GS-F300-085-415
GS-F300-100-415
GS-F300-115-415
GS-F300-130-415
GS-F300-150-415

13

Bone taps
GS-MS-330
GS-MS-A380
GS-MS-A425
GS-MS-A500

12

Final drills for ø 5.50 mm sleeve
GS-F340-085-550
GS-F340-100-550
GS-F340-115-550
GS-F340-130-550
GS-F340-150-550

GS-F425-085-550
GS-F425-100-550
GS-F425-115-550
GS-F425-130-550
GS-F425-150-550

11

Intermediate drills for
ø 5.50 mm sleeve
GS-F200-085-550
GS-F200-100-550
GS-F200-115-550
GS-F200-130-550
GS-F200-150-550

GS-F300-085-550
GS-F300-100-550
GS-F300-115-550
GS-F300-130-550
GS-F300-150-550

*Since the surgical kit allows the insertion of implant systems not released for sale in all markets, it also includes drills not required for guided insertion of Premium One implants.

Rotating instruments

All Sweden & Martina drills are made of **surgical steel** 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 **completely 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.).

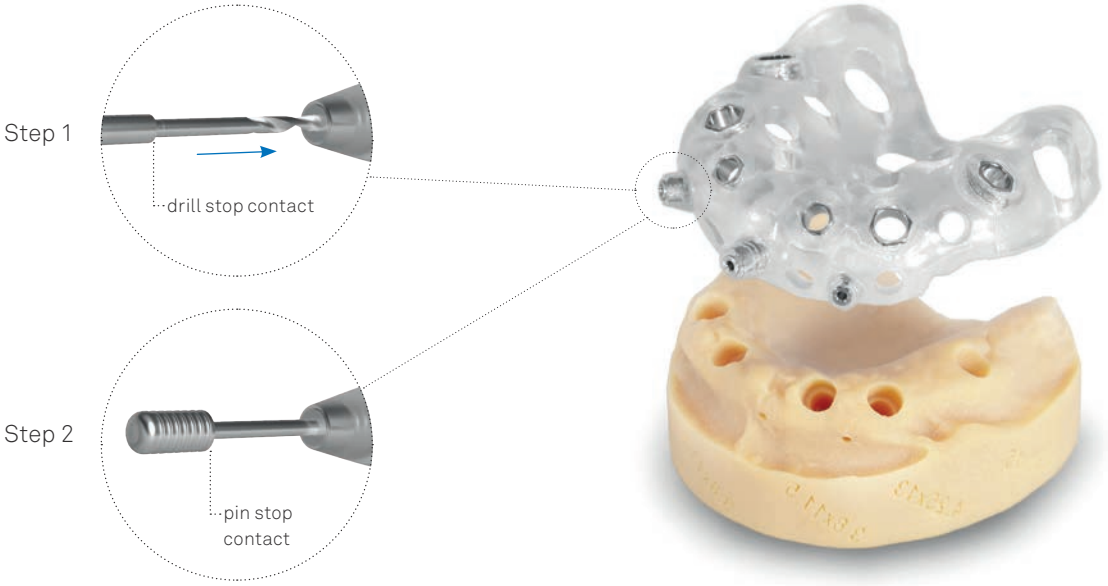
Failure to follow the instructions provided may cause surgical complications and consequent damage to the patient‘s health. It is recommended to use the rotation speeds indicated in the procedures on page 58 and following to prevent the development of bone necrosis.
Lever movements increase the risk 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 used (micromotor). 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 liquids must be used. Inadequate irrigation can lead to bone necrosis. Drill wear depends on 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 declines all responsibility in cases of excessively intense use. Never sharpen drills before use. Never use damaged, buckled or worn instruments.

Drills for guided surgery have been designed to work inside the sleeves produced by Sweden & Martina and inserted inside the surgical guides by the respective manufacturer. Sweden & Martina is not liable for any malfunctioning or damage caused by the use of guided surgery drills with non-original sleeves or incompatible with the size of instruments, which could get stuck, may not be guided correctly, or produce a different implant preparation from that planned by the clinician if the sleeve’s height is not correct.

Important warning
The Echoplan PRO A kit and the surgical instruments contained in it are sold in a NON-STERILE pack. Before being used, they must be cleaned, disinfected and sterilized according to the instructions provided below. Not respecting this warning may cause infections to the patient.

Fixation pin 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 that can be purchased separately in packs of 6. They are not sold individually.



Important warning
In order to stabilize the template correctly, both the drill and the pin must reach the final stop contact.

description	code
Drill for fixation pin	**GS-FPN-148** 
Fixation pin 4 item pack	**GS-PIN** 
Sleeves for pins 6 item pack	**GS-B150-PIN-6** 

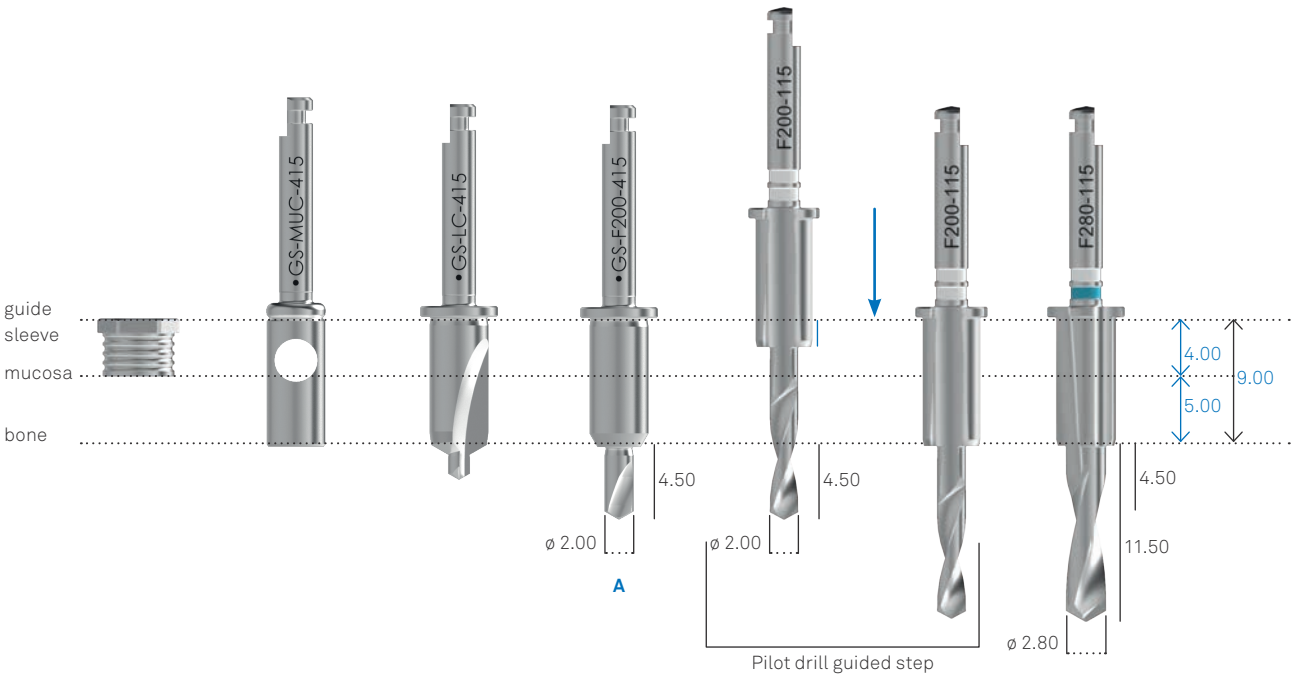
See the specifications of the 5 Gr. titanium on page 54.

From planning to implant insertion: stages in Echoplan guided surgery

Thanks to the potential of 3D simulation, the clinician is able to define exactly the diameter and height of the implant to be inserted using one of the numerous softwares on the market. The correct implant positioning is referred to the operator's clinical experience and to the accuracy of the chosen software. The Echoplan PRO A kit can be used with all softwares respecting a stop contact distance for the instruments fixed at 9.00 mm from the implant platform.

The choice of the guide sleeve to be inserted in the template is made by the template manufacturer and is bound by the diameter of the implant chosen. See page 8 for information about the sleeves that Sweden & Martina manufactures for the production of the surgical templates. After identifying the diameter of the sleeve to be used, it is possible to prepare the surgical site using the appropriate surgical instruments from the Echoplan PRO A kit for the sleeve diameter.

Site preparation **must** proceed with the sequential use of three surgical accessories included in the kit, which are the following: mucotome (unless a full thickness flap is utilized), the bone profiler and the initial drill. The shape of the drill tips allows a hole with a diameter of 2.00 mm and a depth of 4.50 mm (**A**) to be bored. In this way the final drills that are used subsequently are guided from the first millimetres onwards at the tip (for 4.50 mm by the hole bored by the initial drill) and in the guide sleeve. The illustration below visually helps to understand the importance of these three initial steps.
All three instruments are included in the kit in both the versions for the ø 4.15 mm and the ø 5.50 mm sleeve.



Surgical instruments for the initial phase

GS-MUC-415 and GS-MUC-550 Mucotomes

The kit contains two mucotomes, one for each sleeve diameter. Representing the first operational stage and only having to cut the mucosa, they do not have a predetermined stop. Mucotomes have a circular notch that forms a visual reference for the depth of 9.00 mm. The two mucotomes create a slight overpreparation of the mucosa to avoid direct contact with drills.

description	for ø 4.15 mm sleeve	for ø 5.50 mm sleeve
Mucotomes for guided surgery	**GS-MUC-415** 	**GS-MUC-550** 

GS-LC-415 and GS-LC-550 bone profilers

The bone profilers have the function of preparing a hole of much reduced height that will guide the tip of successive instruments, moreover they eliminate crest irregularities.
This is precisely why the oblique profile at the end of the portion guided into the sleeve also has cutting ability.

description	for ø 4.15 mm sleeve	for ø 5.50 mm sleeve
Bone profiler for guided surgery	**GS-LC-415** 	**GS-LC-550** 

Initial drills GS-F200-415 and GS-F200-550

The third compulsory stage involves two initial drills, one for each sleeve diameter, to be used always regardless of the implant system.
The drills create a hole with a depth of 4.50 mm, so that the subsequent drills can be guided doubly, both at the tip, because this is inserted in the guide hole already drilled, and by the stop that is guided inside the sleeve at a higher position.

description	for ø 4.15 mm sleeve	for ø 5.50 mm sleeve
Initial drills for guided surgery	**GS-F200-415** 	**GS-F200-550** 

GS-F2030-550 progressive drill

A progressive drill is available to widen the preparation from ø 2.00 mm to ø 3.00 mm so that the ø 3.00 mm intermediate drills for a ø 5.50 mm sleeve can be guided. The drill is used after the ø 2.00 mm intermediate drill. The correct sequence for using the progressive drill is shown on page 39.

description	for ø 5.50 mm sleeve
ø 2.00 - 3.00 mm Progressive drill	**GS-F2030-550** 

Intermediate and final drills

All of the drills in the Echoplan PRO A system are cylindrical with helical geometry: those up to a diameter of 3.00 mm are characterized by two cutting edges while the drills over 3.00 mm in diameter have three blades.

Each drill has two indications on its shaft: on the one side, the diameter of the sleeves with which it is used (**side B**) and on the other side, a code composed of the cutting edges diameter and the height of the corresponding implant, in this order (**side A**).
The image below shows how for example the first part in the code F425-115 identifies the width of the preparation, that is, the diameter of the working part of the 4.25 mm drill which is used as the final drill for a ø 5.00 mm implant, while the second part states the implant's length of 11.50 mm.

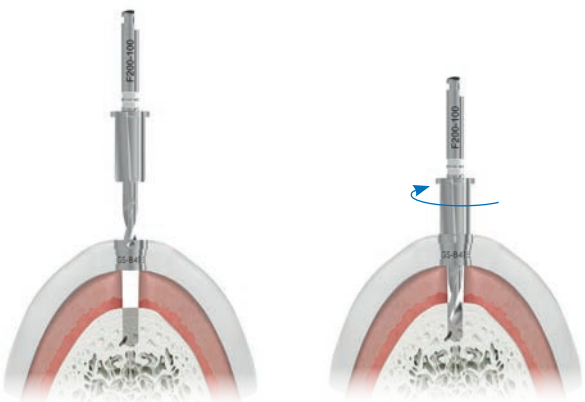
Drills are also characterized by a colored double ring at the foot of the shaft. This color is a code that along with the upper band identifies the sleeve's diameter (**ring A**: white for the ø 4.15 mm sleeve and black for the ø 5.50 mm sleeve) and with the lower band identifies the diameter of the cutting edge that in the case of the final drills refers to the color of the sticker on the fixture's pack (**ring B**). See the headings of the tables on pages 8-9 for the implant diameters corresponding to the color codes.

Intermediate drills have black and white rings only. Please find all the details in the tables on the following pages.

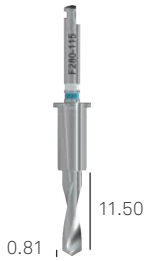
Stops are integrated into the drills' shaft for a faster and more ergonomic work. Where possible, **the rotation of the drill should only be started when the stop is engaged into the sleeve**.

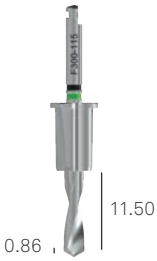
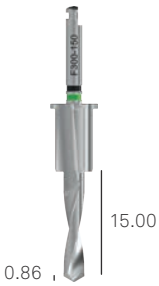
In order to guarantee maximum accuracy, it is advisable to irrigate the implant site abundantly with a sterile physiological solution (NaCl) during and after the preparation to facilitate the expulsion of bone residues that may obstruct the correct functioning of the instruments. The irrigation will also help prevent the drill from overheating and consequently the surrounding tissues: to facilitate the passage of the liquid, the intermittent drilling technique is probably the most useful.

Before each intervention, check that the drills are in good condition and substitute them if necessary.



Drills provided with the Echoplan PRO A kit

description	for ø 4.15 mm sleeve			
Drills for preparing H 8.50 mm implants	**GS-F200-085-415** 	**GS-F250-085-415** 	**GS-F280-085-415** 	**GS-F300-085-415** 
Drills for preparing H 10.00 mm implants	**GS-F200-100-415** 	**GS-F250-100-415** 	**GS-F280-100-415** 	**GS-F300-100-415** 
Drills for preparing H 11.50 mm implants	**GS-F200-115-415** 	**GS-F250-115-415** 	**GS-F280-115-415** 	**GS-F300-115-415** 
Drills for preparing H 13.00 mm implants	**GS-F200-130-415** 	**GS-F250-130-415** 	**GS-F280-130-415** 	**GS-F300-130-415** 
Drills for preparing H 15.00 mm implants	**GS-F200-150-415** 	**GS-F250-150-415** 	**GS-F280-150-415** 	**GS-F300-150-415** 

description	for ø 5.50 mm sleeve			
Drills for preparing H 8.50 mm implants	**GS-F200-085-550** 	**GS-F300-085-550** 	**GS-F340-085-550** 	**GS-F425-085-550** 
Drills for preparing H 10.00 mm implants	**GS-F200-100-550** 	**GS-F300-100-550** 	**GS-F340-100-550** 	**GS-F425-100-550** 
Drills for preparing H 11.50 mm implants	**GS-F200-115-550** 	**GS-F300-115-550** 	**GS-F340-115-550** 	**GS-F425-115-550** 
Drills for preparing H 13.00 mm implants	**GS-F200-130-550** 	**GS-F300-130-550** 	**GS-F340-130-550** 	**GS-F425-130-550** 
Drills for preparing H 15.00 mm implants	**GS-F200-150-550** 	**GS-F300-150-550** 	**GS-F340-150-550** 	**GS-F425-150-550** 

Optional drills for 6.00 and 7.00 mm heights

The surgical kit contains all of the instruments for inserting implants of lengths between 8.50 mm and 15.00 mm. It also includes empty slots to insert the optional drills to prepare sites 6.00, 7.00 and 18.00 mm in length. Such optional drills can be purchased individually or in sets that cover all of the implant diameters for each special height. Since the surgical kit allows the insertion of implant systems not released for sale in all markets, it also includes drills not required for guided insertion of Premium One implants, like drills for preparing implants 6.00 mm high.

sleeve	ø 4.15 mm			
Drill for preparing H 6.00 mm* ø 3.80 mm implants	**GS-F200-060-415** 	**GS-F250-060-415** 	**GS-F280-060-415** 	**GS-F300-060-415** 
Drill for preparing H 7.00 mm** ø 3.80 mm implants	**GS-F200-070-415** 	**GS-F250-070-415** 	**GS-F280-070-415** 	**GS-F300-070-415** 

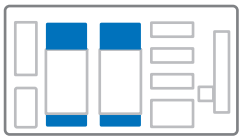
The drills for preparing implants 6.00 mm high can also be ordered in a full set using the code **GS-PROA-INTEGRA-060.*

***The drills for preparing implants 7.00 mm high can also be ordered in a full set using the code **GS-PROA-INTEGRA-070**.*

Optional drills for 18.00 mm heights

sleeve	ø 4.15 mm	
Drill for preparing H 18.00 mm ø 3.80 mm implants	**GS-F200-180-415** 	**GS-F300-180-415** 

N.B. in contrast to the sets of drills for the 6.00 and 7.00 mm high implants, the drills for preparing implants 18.00 mm high can only be purchased individually.



sleeve	ø 5.50 mm			
Drill for preparing H 6.00 mm* ø 4.25 and 5.00 mm implants	**GS-F200-060-550** 	**GS-F300-060-550** 	**GS-F340-060-550** 	**GS-F425-060-550** 
Drill for preparing H 7.00 mm** ø 4.25 and 5.00 mm implants	**GS-F200-070-550** 	**GS-F300-070-550** 	**GS-F340-070-550** 	**GS-F425-070-550** 

The drills for preparing implants 6.00 mm high can also be ordered in a full set using the code **GS-PROA-INTEGRA-060.*

***The drills for preparing implants 7.00 mm high can also be ordered in a full set using the code **GS-PROA-INTEGRA-070**.*

sleeve	ø 5.50 mm	
Drill for preparing H 18.00 mm ø 4.25 and 5.00 mm implants	**GS-F200-180-550** 	**GS-F340-180-550** 

N.B. in contrast to the sets of drills for the 6.00 and 7.00 mm high implants, the drills for preparing implants 18.00 mm high can only be purchased individually.

Bone taps

These are bladed instruments able to prepare bone to receive the implants' thread, in very compact or cortical bone in order to alleviate the compression and decrease the insertion torque. All of the bone taps have a total length of insertion in the bone of 6.00 mm and are composed of a guide section that does not cut, and a cutting section of 5.50 mm, indipendent from the length of the implant to be inserted. Each implant diameter has a dedicated bone tap.

description	ø 3.30	ø 3.80	ø 4.25	ø 5.00
Bone taps for Premium One implants	**GS-MS-330**  6.00	**GS-MS-A380**  6.00	**GS-MS-A425**  6.00	**GS-MS-A500**  6.00

Important warning
Even in very mineralized bone it is not advisable to bone tap the preparations for 7.00 mm height implants.

Countersink drills

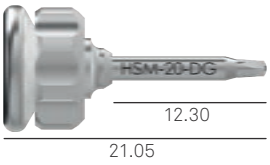
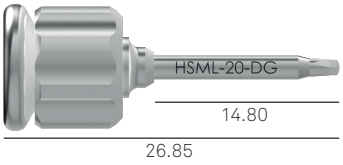
In the case of excessive friction caused by the coronal cortical bone, the neck of the implant can be prepared using the appropriate four-edged countersink drills included in the surgical kit. The countersink drills are universal because they can be used for both a cylindrical preparation for the neck of Premium One implants.

description	ø 3.30	ø 3.80	ø 4.25	ø 5.00
Countersink drills for Premium One implants	-	**GS-FCS-A380** 	**GS-FCS-A425** 	**GS-FCS-A500** 

Important warning
Even in very mineralized bone it is not advisable to use the countersink drill for the preparations of 6.00 mm height implants.

Drivers for connecting screws

The surgical kit contains several useful screwdrivers for tightening and unscrewing mounter fixation screws, healing abutments, transfer screws, post and abutments screws. All of the screwdrivers are made of stainless steel for surgical use. The design of the tip of all of the screwdrivers is the same so they are all interchangeable. They are available in different total lengths and in digital and one-piece version, that is to say, solid with a handpiece that can be gripped, or equipped with a hexagonal connector compatible with the ratchet.
The one-piece hand drivers in the kit are available in two different heights.

description	code
Hand driver for surgical cover screws and fixation screws, digital, short	**HSM-20-DG** 
Hand driver for surgical cover screws and fixation screws, digital, long	**HSML-20-DG** 

Important warning
It is recommended to pass a thread through the hole on the top of the digital screwdriver to prevent it from falling.

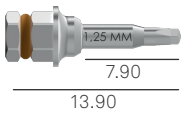
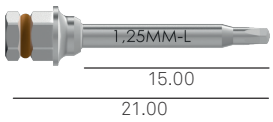
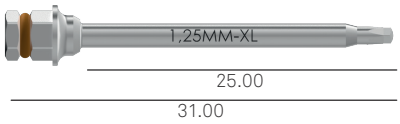
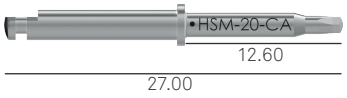
Important warning
Lever movements should be avoided as they increase the risk of breakage. Before tightening, make sure the hexagon socket screw head on the driver tip is correctly inserted into the screws to be tightened. Incorrect insertion is likely to pare off the hexagonal connection of the screwdriver or the screw to be tightened. Drivers have a slightly conical profile, able to guarantee the hexagonal connection on the tip of the driver grips inside the hexagonal connection on the head of the screws, making it possible to carry the screw to the patient's mouth correctly, without dropping it. Replace drivers regularly to reduce the risk of wear to the hexagon connection.

Important warning
Excessive torque can strip the fixation screws' slots and round off the corners of the screwdrivers causing intraoperative or prosthetic complications that can be serious. The recommended torques for tightening the various components are summarized in the following table:

description	recommended torque
surgical cover screws, healing abutments	(manually) 8-10 Ncm
all of the prosthetic screws	20-25 Ncm
all of the prosthetic components with direct screw retention on the implant	25-30 Ncm
transfer fixation screws	(manually) 8-10 Ncm

Prosthetic screwdrivers

In order to facilitate the engagement of the screws or the threaded portions of the prosthetic components, tightening can be started using the digital screwdrivers. Nevertheless, given the importance of the tightening torque, it is advisable to use screwdrivers with hexagonal connectors in this phase, keeping the torque under control with the applied use of the torque wrench.

description	code
Screwdriver for fixation screws, with hexagonal connector for torque control ratchet or hand knob, short	**HSM-20-EX** 
Screwdriver for fixation screws, with hexagonal connector for torque control ratchet or hand knob, long	**HSML-20-EX** 
Screwdriver for fixation screws, with hexagonal connector for torque control ratchet or hand knob, extra long*	**HSMXL-20-EX** 
Screwdriver, with right angle shank for fixation screws	**HSM-20-CA** 

**Optional instrument not included in the surgical kit but purchased separately*

Important warning
All the ratchet drivers have a red polymer O-ring in the connecting hexagon that guarantees friction between the instruments and therefore a correct grip of the components. This O-ring must be checked periodically and replaced when worn or when no longer able to exert the correct friction. A kit of 5 spare O-rings is available, which can be ordered with code **ORING180-088**.

Hand knob

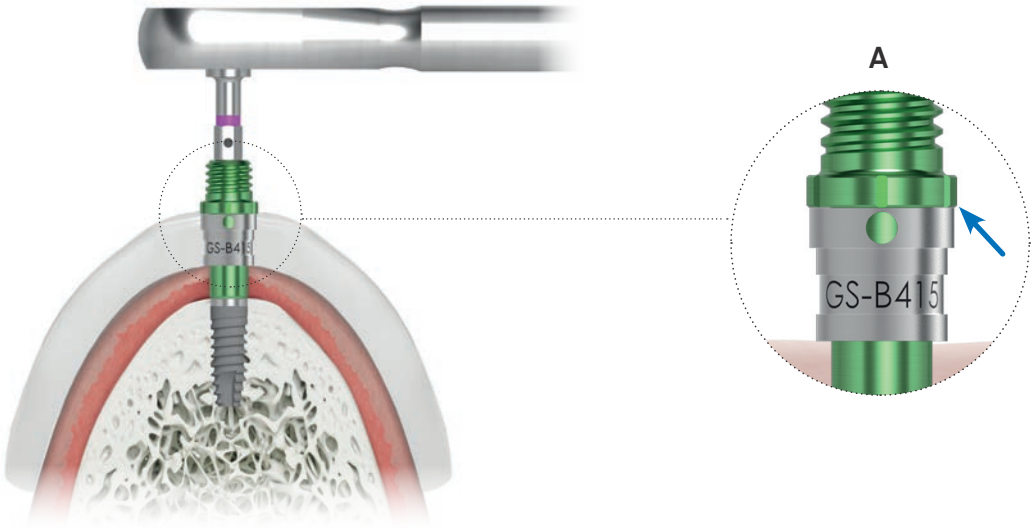
description	code
Hand knob for bone taps, mounters, drivers and manual drivers	**AVV3-MAN-DG** 

Mounters

Mounters are used to ensure that final implant insertion is also guided, not only in terms of angle and depth but also of orientation. In fact, mounters have a hexagonal landmark with faces aligned with the faces of the implant connections (**A**). They are made in Grade 5 titanium, anodized according to the color code shown in the table below and are supplied together with the specific screw, the same for all implant diameters, to be tightened manually with a torque no greater than 10 Ncm.

Mounters can be organized, sterilized and preserved in the dedicated Mounter Organizer illustrated on page 32.

Mounters for Premium One implants



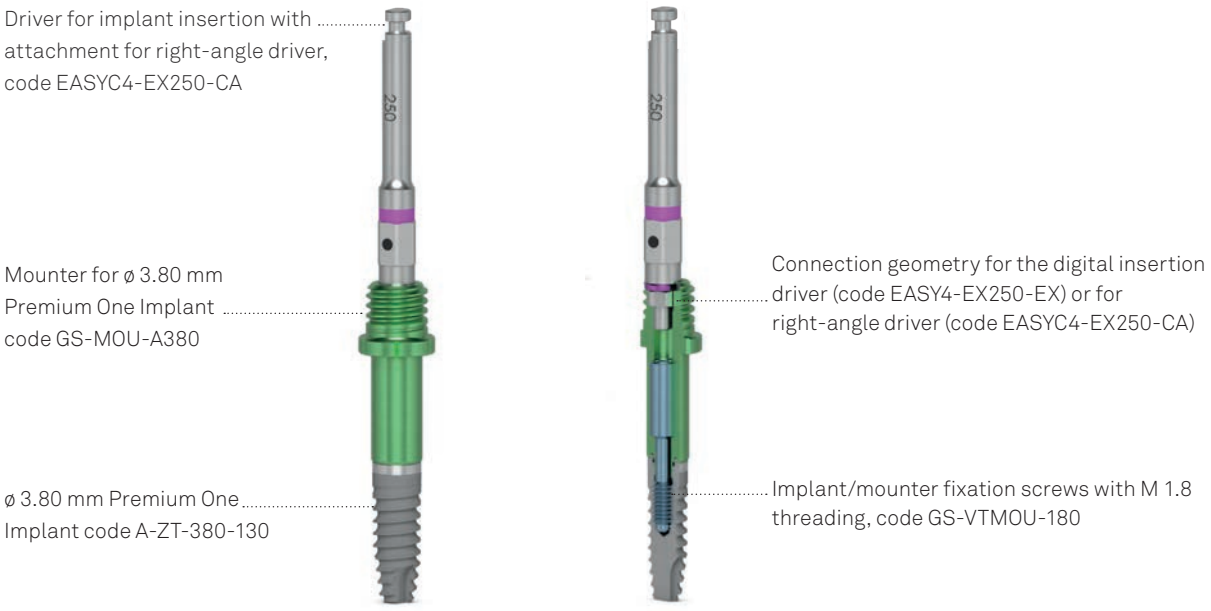
Important warning
In order to meet the clinical needs of every individual case, both Premium One implants can be positioned more deeply (see page 7). For help in advance in the planning stage of these cases, it is advisable to call Sweden & Martina personnel dedicated to guided surgery. The support service for guided surgery can be contacted by phone on +39 049 9124248.

ø Premium One	3.30	3.80	4.25	5.00
implant color code				
mounter color code	**GS-MOU-A330** 	**GS-MOU-A380** 	**GS-MOU-A380SP** 	**GS-MOU-A380SP** 
fixation screws supplied as standard	**GS-VTMOU-180** 	**GS-VTMOU-180** 	**GS-VTMOU-180** 	**GS-VTMOU-180** 

See technical specifications of 5 Gr. Titanium on page 54.

Easy Insert Driver for mounters

The Echoplan PRO A surgical kit includes two Easy Insert drivers with a metal O-ring that clicks inside the upper end of all of the mounters, making certain of the assembled implant-mounter's transport into the sleeve and of the surgical insertion phases.
These drivers have been tested up to a torque of 70 Ncm. Greater insertion torque can cause mechanical criticality. It is advisable to use Easy Insert with hexagon in all of the later inserting phases.



description	code
Easy Insert Driver for guided surgery mounters with hexagonal connector for torque control ratchet	**EASY4-EX250-EX** 
Easy Insert Driver for guided surgery mounters with right-angle attachmen	**EASYC4-EX250-CA** 

Important warning
The Easy Insert drivers for mounters cannot be used to directly engage Premium One implants: their dimensions only allow them to be used with guided surgery mounters.
They are supplied pre-mounted with the appropriate titanium O-ring. Being mechanical components, these small retention rings are subject to wear and can lose their elasticity and functionality with the passage of time and cannot be replaced. On the other hand, the instrument in its entirety can be replaced.
Easy Inserts have been tested to resist up to 50 uses in the most unfavorable use conditions. Consequently, this limit can vary according to the conditions of use. They have a guiding pin on the tip that facilitates insertion into the mounter. Lever movements can cause the driver to bend or fracture with intraoperative surgical complications being possible.

Hand knob for removal of the GS-MOU-DG mounter

This optional hand knob can be useful after the implant insertion and mounter screw removal for a guided extraction and removal of the mounter, whithout compromising primary stability of the the implant. The hand knob can be sterilized and kept in the appropriate slot inside the Mounter Organizer (page 32).

GS-MOU-DG hand knob

Threading for anchoring the hand knob

Guide diameter calibrated for the sleeve

Connection hexagon for the implants

Index hexagon: the faces are aligned with those of the internal hexagon of the implant consequently allowing it to be oriented during the insertion phase

Important warning
The connecting screw between the implant and the mounter must be removed prior to the hand knob being employed.

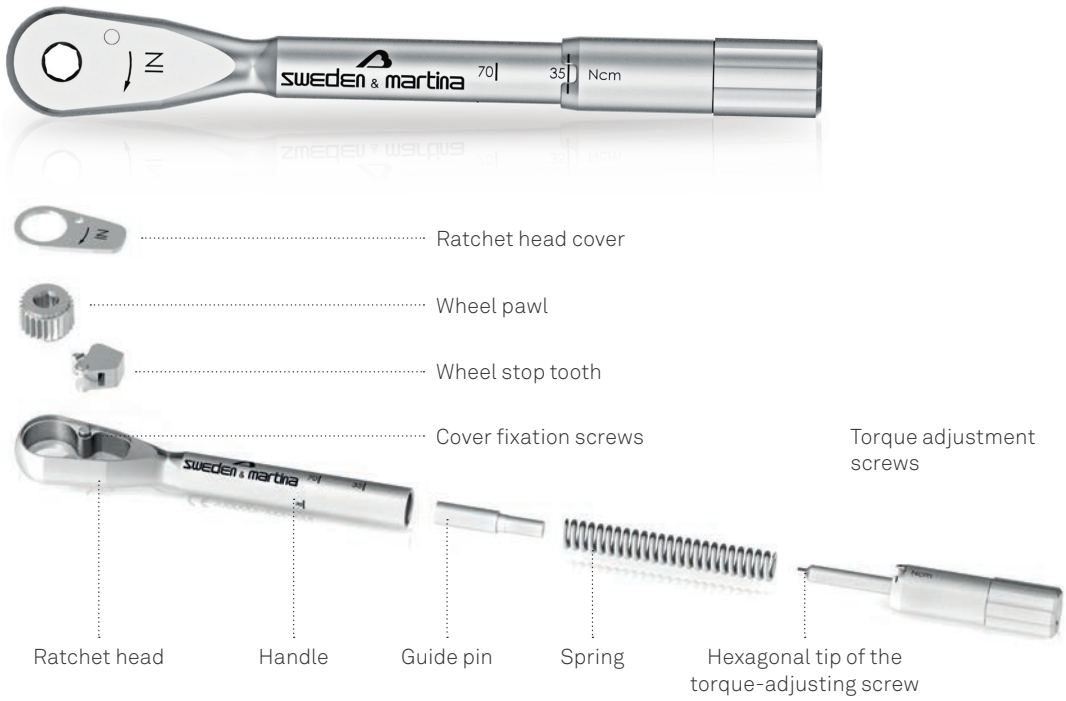
GSMOUNT-TRAY-INT Mounter Organizer

The Mounter Organizer is an autoclavable tray made of radel for organizing, sterilizing and housing the mounters for guided surgery. The upper half has two areas of 20 slots each to subdivide the instruments according to the size of the sleeve that they must be used with. There is a removable stainless steel surgical bowl in the middle of the tray to put the used mounters back after they have been removed.
The lower part has a retainer for the hand knob, 4 slots to house instruments with hexagonal connector and with right-angle shaft and 7 retentive slots to house the implant vials that make the phases of assembling the mounter to the fixture easier.

Important warning
The Mounter Organizer is a tray which is sold empty and does not include any instruments. It is appropriate to remove and clean the surgical stainless steel bowl before the sterilization phase and then to put it back.

CRI5-KIT torque control ratchet

A specific ratchet (CRI5-KIT) is included inside the Echoplan PRO A surgical kit together with the adjustment key that is used to rapidly turn the torque adjustment sleeve. A gel lubricant for maintenance is also included. The ratchet can be used with torque adjustment from 10 to 70 Ncm or otherwise in a blocked position without torque control.
If using it as a prosthetic ratchet to tighten the screws, reference should be made to the torque values shown in the table on page 26. The CRI5-KIT counter torque ratchet is a multiuse dismantlable instrument sold non-sterile.



Before each use, this instrument must be cleaned and sterilized according to the instructions on pages 49-50. Appropriate maintenance is fundamental to the correct functioning of the device so that its reliability and operating life are not affected. This is carried out by following all of the phases in dismantling and correct reassembly of the device in detail step by step during its cleaning.
Personnel who operate this instrument must be trained appropriately and have read the instructions in this manual before handling this instrument.
Once sterilized, the ratchet is ready for use. A test verifying the correct assembly and functioning of the ratchet is necessary before each and every time it is operated, whether surgically or prosthetically.

The torque is adjusted by aligning the marking of the value required in the circular opening in the handle. The “IN” arrow on the head seen from above indicates the ratchet position that allows the screw to be tightened. The “OUT” arrow on the head visible from above indicates the loosening position. An unlimited torque position is obtained by positioning the torque adjustment device to the notch marked “R” on the handle of the ratchet body.

The sleeve can be screwed and unscrewed manually but to speed up these operations, the kit also contains a driver that allows you to rotate it quickly.
Any deterioration in the screw retention, insertion and coupling mechanisms must be checked by personnel responsible for the use and maintenance of this dental instrument. The parts in this mechanism are not interchangeable. A part of a ratchet cannot be taken to substitute another as each ratchet is calibrated INDIVIDUALLY. Should a part be lost, please return the instrument affected to Sweden & Martina so that it can be repaired. No component for the assembly of the ratchet is sold separately. Not respecting the instructions provided may cause problems with the stability and maintenance of the prosthesis.

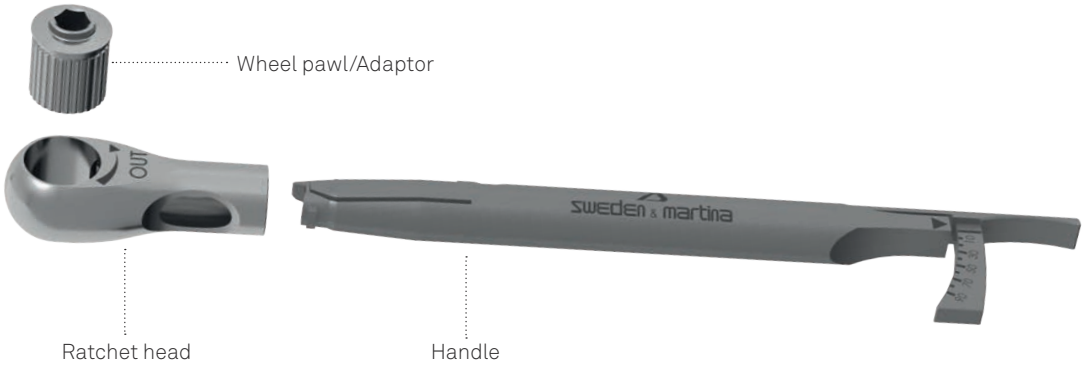
Important warning
The torque is always adjusted by tightening/unscrewing the sleeve placed at the bottom the instrument's handle. The torque must always be adjusted by increasing the value, starting by screwing at a lower value up until arriving to the desired torque, that is to say, tightening the sleeve in a clockwise direction. Consequently, whenever a torque below the last one used needs adjusting, a two turn screwing must be used below the value of the new torque desired and then increased to the desired value, re-screwing the sleeve clockwise.

To adjust the torque to increase it, the sleeve simply needs to be rotated in a clockwise direction.

To adjust the torque to a value below that previously used, the sleeve must be turned anticlockwise no less than two turns below the desired value and then proceed to screw in a clockwise direction until reaching the value of torque required.

Dynamometric key with TWL control lever

A specific TWL dynamometric key with control lever is available to buy separately.
The dynamometric key can be used to indicate the value of torque applied during the surgical phases of screw retention and unscrewing, with marked values from 10 to 90 Ncm. It is supplied with a dedicated adaptor that means it can be used with the surgical instruments with hexagonal attachments.
The TWL dynamometric key with control lever is a dismantlable multipurpose instrument sold non-sterile.



Before each use, this instrument must be cleaned and sterilized according to the instructions on pages 51-52.
Appropriate maintenance is fundamental to the correct functioning of the device and so that its reliability is not affected. This is carried out by following all phases in dismantling and correct reassembly of the device step by step in detail during its cleaning.
Personnel who operate this instrument must be trained appropriately and have read the instructions in this manual before handling this instrument.

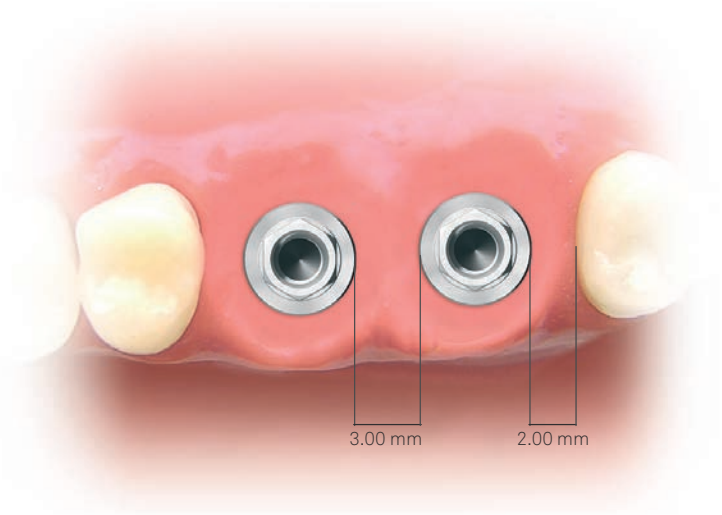
After sterilization and before using it, make sure that the first notch on the scale is aligned with the arrow. A test to check correct mounting and functioning of the ratchet needs to be carried out before each time it is used.

Important warning
During the use of the dynamometric key's lever, it must not pass the graduated scale as this can cause imprecise reading of the torque and damage the instrument.

The dynamometric key can be used as a fixed key or without using the dynamometric scale by levering the whole handle. In this case it is recommended not to subject it to a load greater than 150 Ncm.
Any deterioration in the screw retention, insertion and coupling mechanisms must be checked by personnel responsible for the use and maintenance of this instrument.
The parts of this dynamometric key are not interchangeable so a part cannot be used to substitute another in the key. Should a part be lost, please return the instrument affected to Sweden & Martina so that it can be repaired. No component for assembling the dynamometric key with control lever can be sold separately. Not respecting the instructions provided can cause the patient to have esthetic problems and may damage the patient's health.

Preparation of the implant site

During the software-assisted planning it is best as a rule to keep a distance of 3.00 mm between the perimeters of the implants and at least 2.00 mm between implants and adjacent natural teeth. Numerous clinical trials and experimental studies state that it is appropriate to position the implants more lingually or palately in order to obtain better esthetic results since such positioning helps to preserve the level of the soft and hard tissues coronally to the implant. It is also essential to check that the thickness of the residual osseous wall is not less than 1.00 mm.
The best esthetic results are obtained with buccal walls of no less than 2.00 mm. The risk of bone resorption and exposure of the threads increases if thicknesses are thinner.



The appropriate preparation sequences for the Premium One implants are described in the following pages. These procedures have been developed through clinical experience and information from numerous clinical trials and protocols for implants with this endosseous morphology. However, it must always be taken into consideration that types of bone with different densities need different surgical approaches and the instructions that follow cannot and are not meant to substitute the required training, medical knowledge nor personal experience that sometimes suggests different indications. The sequences that follow, however, refer to specific bone types.

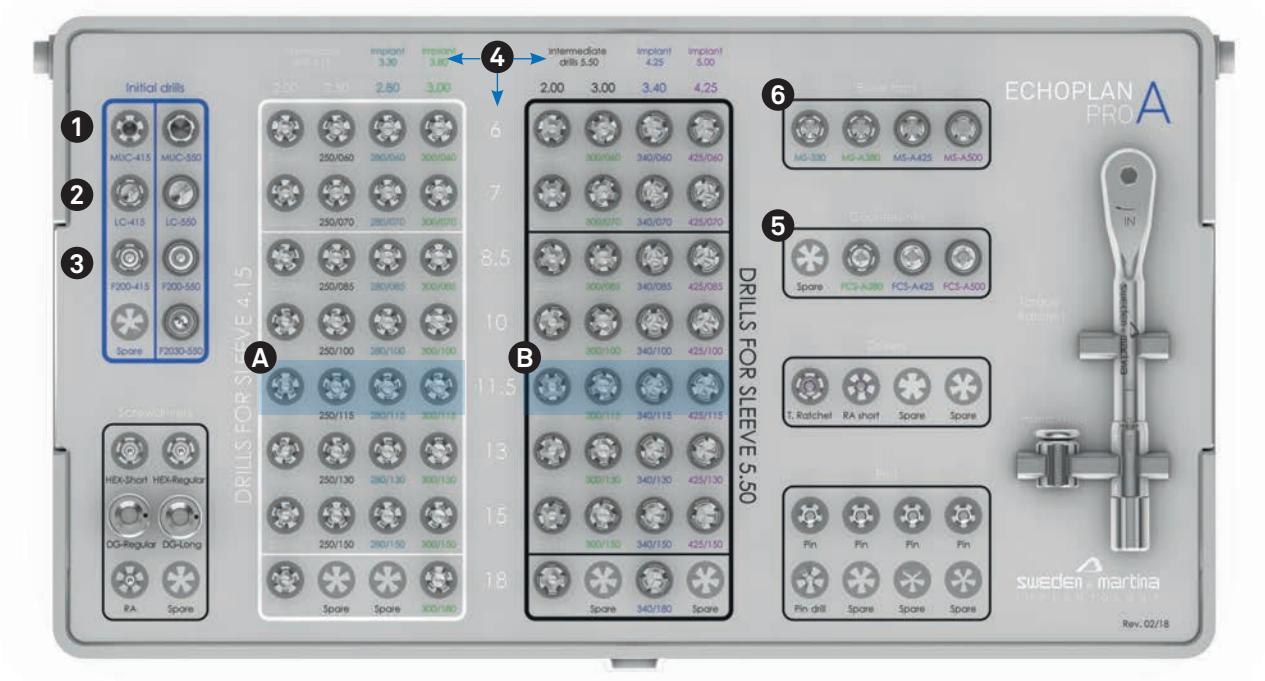
It should be borne in mind that standard drills always prepare a hole longer than the implant. Please see pages 20 and following for the dimensions of the overpreparation. The preparations must be atraumatic and the most gradual possible as well as be carried out quickly and accurately. The bone must not be overheated.

It should also be borne in mind that the surgical micromotor needs to be set to the correct torque, reduction and rotation values accordingly to the intervention that needs to be carried out.
In particular:

- **drills** must be used at the speed stated in each single sequence, with maximum torque and irrigated abundantly with cold sterile physiological solution, better if it has been cooled in a refrigerator;
- the **bone taps** must only be used when stated in the procedures.

Incorrect insertion of the instruments in the handpieces can lead to vibrations, eccentric rotation, precocious wear and bending of the shaft. It is recommended that only the surgical micromotors suitable to this application are used. It is also recommended that the micromotors are periodically checked by their manufacturer according to each individual instructions in order to prevent possible malfunctioning (e.g. movement of the transmission shaft axis, worn forceps, poor functioning, etc.). Not respecting the instructions provided can cause surgical problems and damage the patient's health.

The sequence for using the instruments in the kit is simple and intuitive. As explained on pages 38-39, it is mandatory the preliminary use of a mucotome, unless a flapless approach is used (**1**), bone profiler (**2**) and initial drill (**3**) for the sleeve on the template. After that it is sufficient to identify on the surgical tray the height and diameter of the implant to be inserted (**4**) and use the 4 drills of the corresponding line in the white field for the ø 4.15 mm sleeves (**A**) or in the black field for the ø 5.50 mm sleeves (**B**). Whenever necessary, on completion of the preparation the countersink drill is used (**5**) and/or the bone tap (**6**) of the diameter of the implant to be inserted.



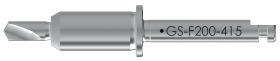
The following pages present these sequences subdivided by sleeve and diameter, **taking the insertion of an implant 11.50 mm in height (A-B)** as an example. It is simply a matter of changing the black field of the codes shown for all other heights with the height desired in order to have the correct sequence for the insertion of each implant length.

Surgical sequences - Premises

The initial phases of the insertion of any implant provide for the use of the following instruments in the order indicated:

A. Mucotome
(Use of the mucotome is only obligatory for flapless surgery)

B. Bone profiler



C. Initial drill

These first three steps must always be carried out before any other drill is used.
Otherwise, correct guidance of the final drills cannot be guaranteed.

Important warning
The steps described below must always be taken before the final and/or intermediate drills are used. These steps must NEVER be skipped. The use of fewer surgical instruments could compromise a good result being obtained from the surgery. In fact, the correct guide of the final drills would not be guaranteed. Sweden & Martina advise that the drills should not be used for type D4 bone.

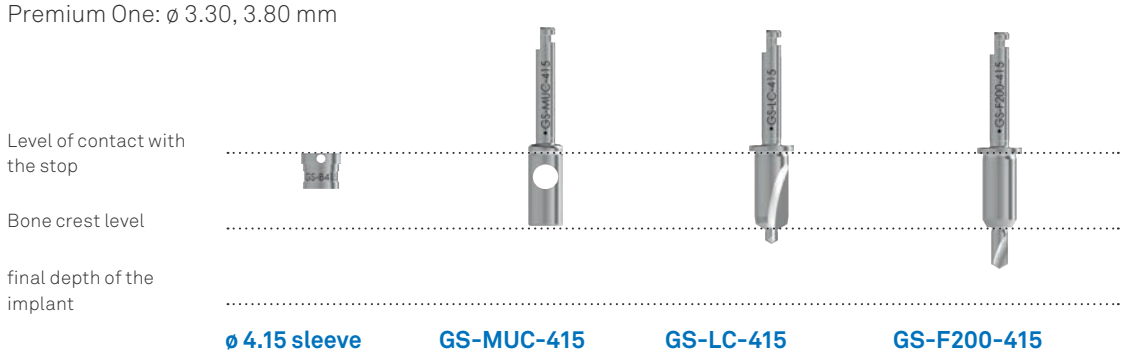
The sequences that follow refer to specific bone types.
However, it must always be taken into consideration that types of bone with different densities need different surgical approaches and the instructions that follow cannot and are not meant to substitute the training and medical knowledge required nor the personal experience that sometimes suggests different instructions.
The rotation speeds indicated must be respected.

It is not advised in both traditional and guided surgery to use rotating instruments in D4 quality bone. The use of osteotomes and/or bone compactors is preferable in order to conserve as much of the bone as possible (all of the instruments available are in the MC-IMP-PREMIUM-ONE-E and manual which can be downloaded from Sweden & Martina's web site).
In this case only the obligatory stage can be guided up until the initial drill is used, which acts as a pilot hole for the osteotomes which not present integrated stops, must be used according to the traditional surgical protocols, that is, by removing the surgical template.

Preliminary surgical sequences

OBLIGATORY preliminary sequence for inserting the Premium One implants using the Echoplan PRO A kit, dedicated to guided implantology, in the case of a ø 4.15 mm sleeve

Valid for implants:
Premium One: ø 3.30, 3.80 mm

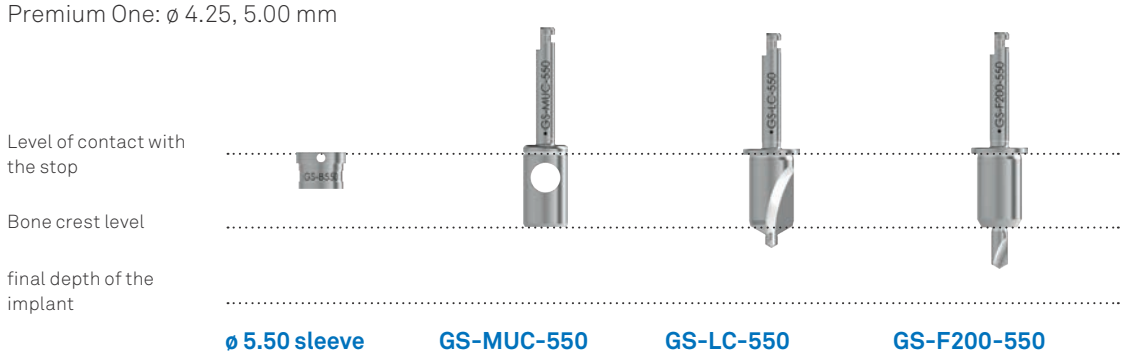


ø 4.15 sleeve | **GS-MUC-415** | **GS-LC-415** | **GS-F200-415**

	work until contact with the bone	integrated stop	integrated stop
BONE D1	800 rpm	800 rpm	800 rpm
BONE D2	800 rpm	800 rpm	800 rpm
BONE D3	800 rpm	800 rpm	800 rpm
BONE D4	-	-	-

OBLIGATORY preliminary sequence for inserting the Premium One implants using the Echoplan PRO A kit, dedicated to guided implantology, in the case of a ø 5.50 mm sleeve

Valid for implants:
Premium One: ø 4.25, 5.00 mm



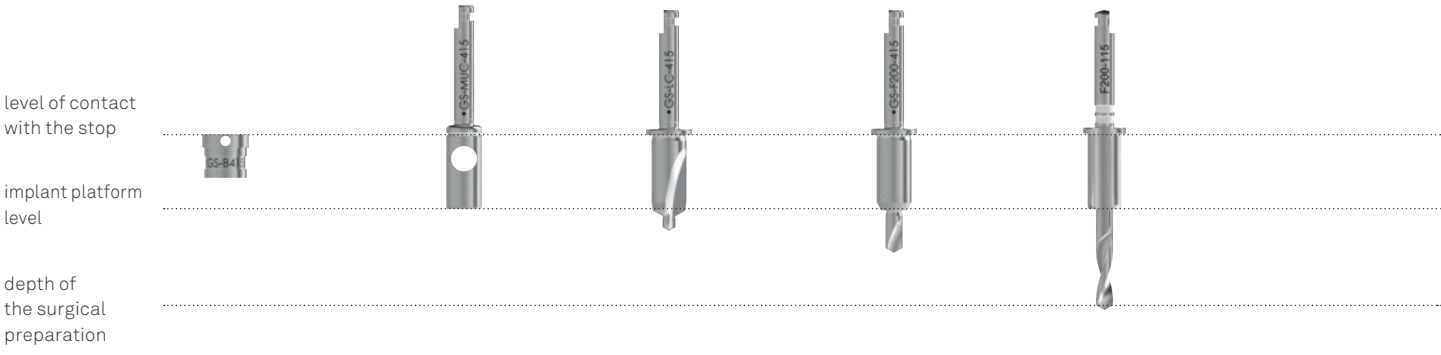
ø 5.50 sleeve | **GS-MUC-550** | **GS-LC-550** | **GS-F200-550**

	work until contact with the bone	integrated stop	integrated stop
BONE D1	800 rpm	800 rpm	800 rpm
BONE D2	800 rpm	800 rpm	800 rpm
BONE D3	800 rpm	800 rpm	800 rpm
BONE D4	-	-	-

Surgical sequences – ø 4.15 mm sleeve

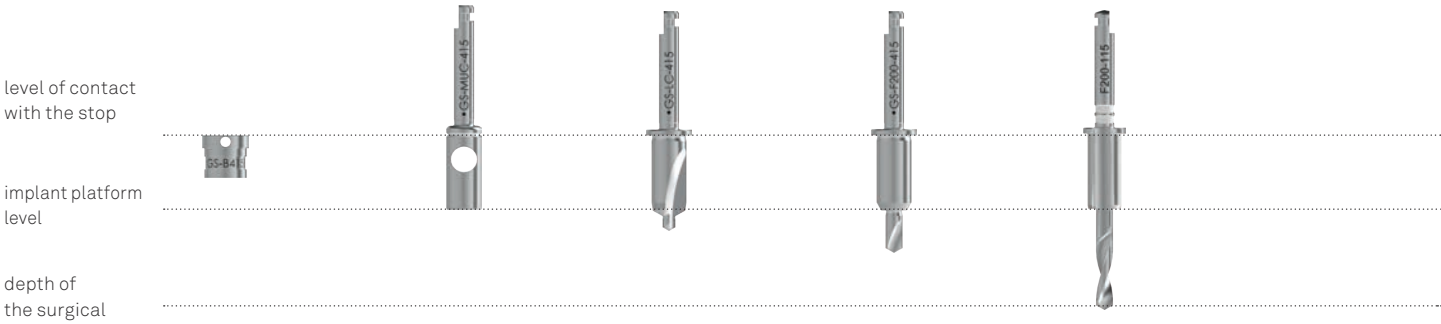
It should be borne in mind that drills overprepare the length for a measurement reported in the table on pages 20 and following. **The graphic sequence refers to the 11.50 mm high implants**: for all other heights, all that needs to be done is to replace the part with the code in black in the following table with the length of the implant.

Surgical sequence for ø 3.30 mm Premium One implants



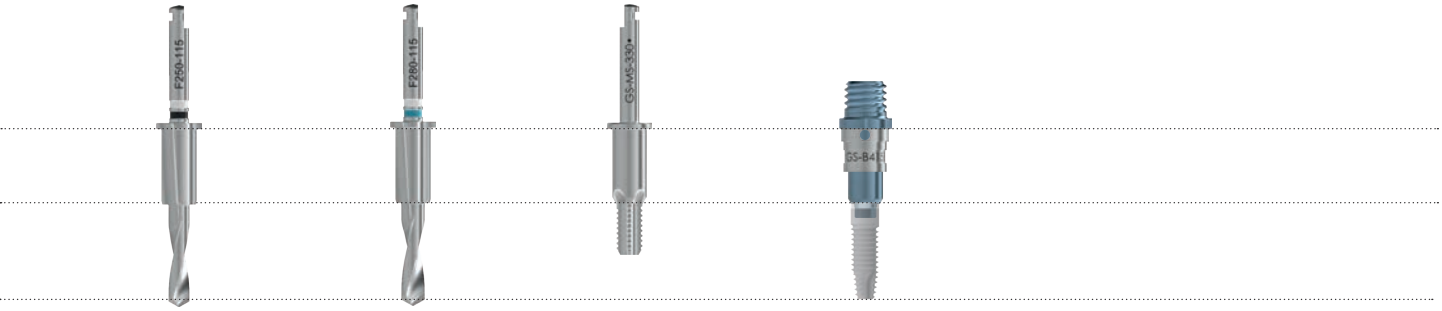
ø 4.15 sleeve	GS-MUC-415	GS-LC-415	GS-F200-415	GS-F200-115-415
ø 3.30 mm				
BONE D1	800 rpm	800 rpm	800 rpm	800 rpm
BONE D2	800 rpm	800 rpm	800 rpm	800 rpm
BONE D3	800 rpm	800 rpm	800 rpm	800 rpm
BONE D4	-	-	-	-

Surgical sequence for ø 3.80 mm Premium One implants



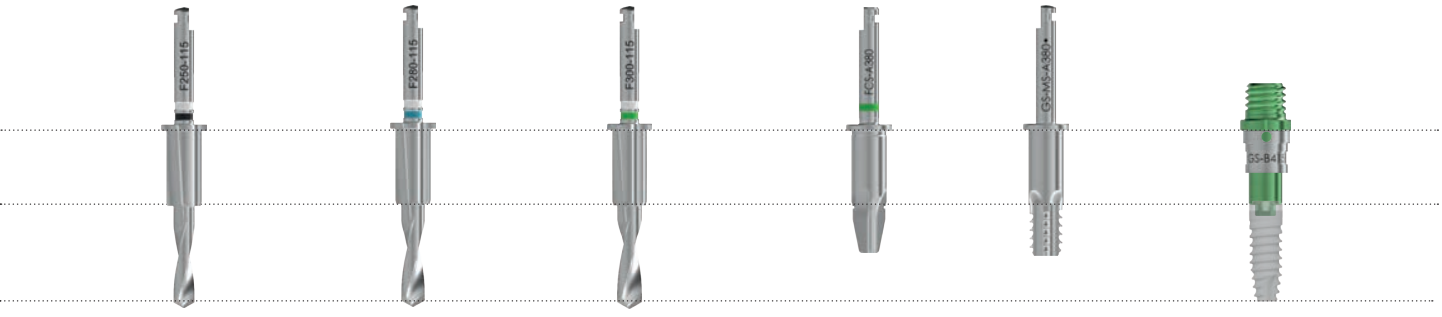
ø 4.15 sleeve	GS-MUC-415	GS-LC-415	GS-F200-415	GS-F200-115-415
ø 3.80 mm				
BONE D1	800 rpm	800 rpm	800 rpm	800 rpm
BONE D2	800 rpm	800 rpm	800 rpm	800 rpm
BONE D3	800 rpm	800 rpm	800 rpm	800 rpm
BONE D4	-	-	-	-

Important warning
To insert implants more than 11.50 mm in height, it may be useful to carry out the intermediate phases including using the 8.50 mm or 10.00 mm drills so that the longer corresponding drills find space enough to get in contact with the sleeve through the integrated stop and so be guided for all of their use.



GS-F250-115-415 **GS-F280-115-415** **GS-MS-330** **GS-MOU-A330**

		max 50 Ncm	max 50 Ncm
800 rpm	800 rpm	20 rpm	20 rpm
800 rpm	800 rpm	-	20 rpm
800 rpm	800 rpm	-	20 rpm
-	-	-	-



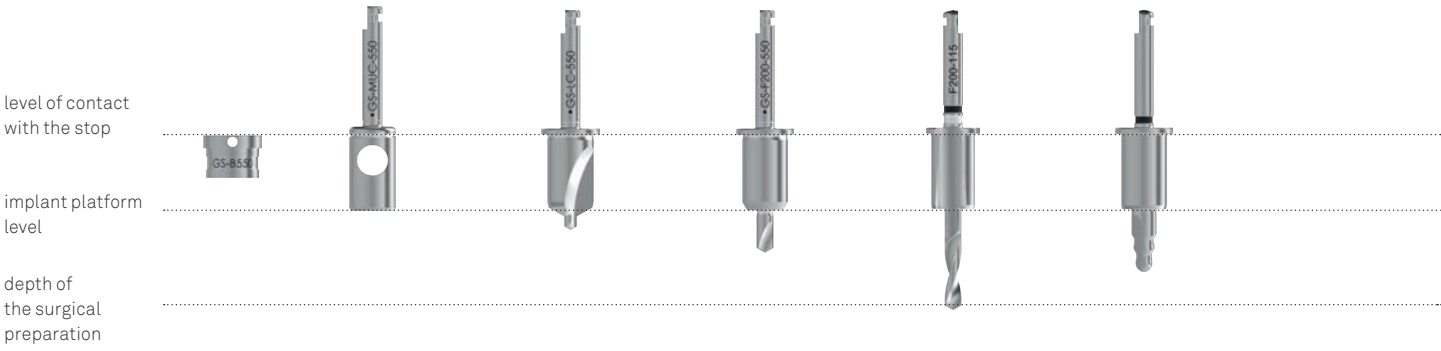
GS-F250-115-415 **GS-F280-115-415** **GS-F300-115-415** **GS-FCS-A380** **GS-MS-A380** **GS-MOU-A380**

				max 50 Ncm	max 50 Ncm
800 rpm	800 rpm	800 rpm	800 rpm	20 rpm	20 rpm
800 rpm	800 rpm	800 rpm	800 rpm	-	20 rpm
800 rpm	800 rpm	800 rpm	800 rpm	-	20 rpm
-	-	-	-	-	-

Surgical sequences – ø 5.50 mm sleeve

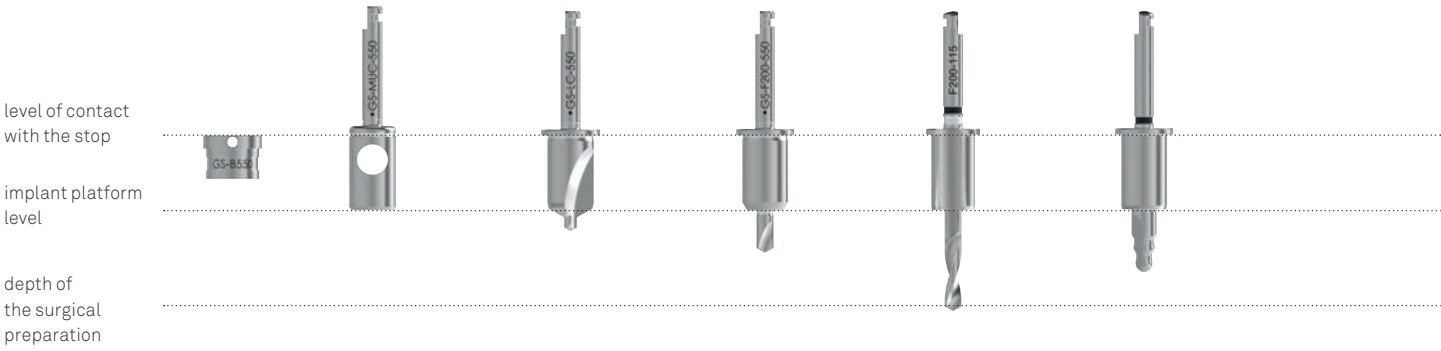
It should be borne in mind that the drills overprepare the length for a measurement reported in the table on pages 20 and following. **The graphic sequence refers to the 11.50 mm high implants**: In order to obtain the correct sequence of instruments to be used for all of other heights, all that needs to be done is substitute the length of the implant with the part with the code in black in the following table.

Surgical sequence for ø 4.25 mm Premium One implants



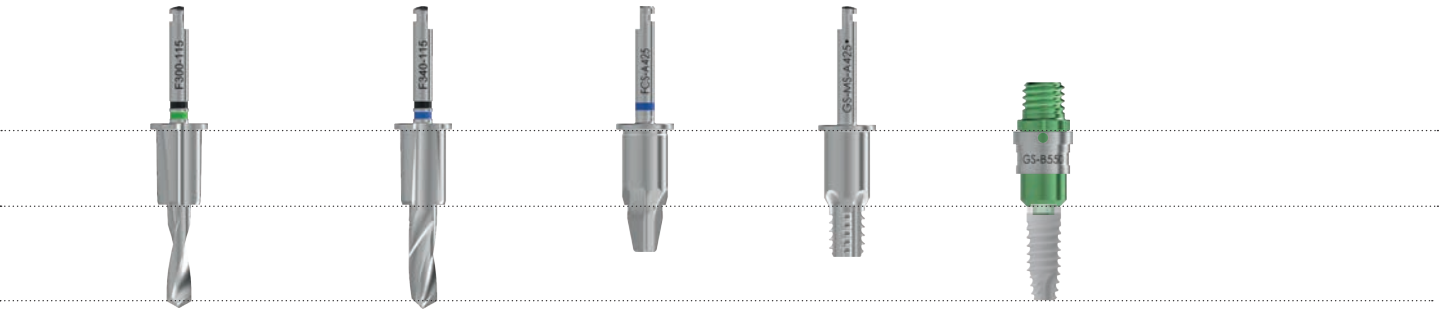
ø 4.25 mm						
	BONE D1	800 rpm	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D2	800 rpm	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D3	800 rpm	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D4	-	-	-	-	-

Surgical sequence for ø 5.00 mm Premium One implants

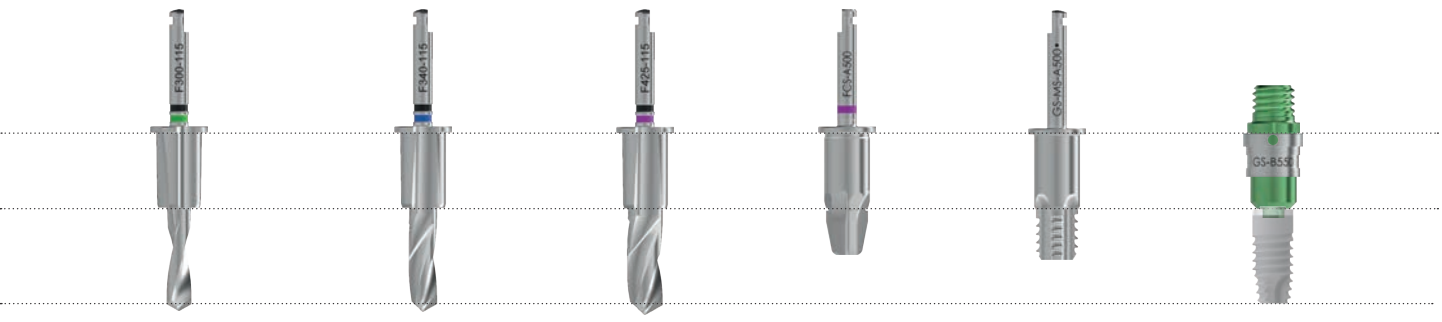


ø 5.00 mm						
	BONE D1	800 rpm	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D2	800 rpm	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D3	800 rpm	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D4	-	-	-	-	-

Important warning
To insert implants more than 11.50 mm in height, it may be useful to carry out the intermediate phases including using 8.50 mm or 10.00 mm drills so that the longer corresponding drills have space to use the sleeve with the integrated stop and so be guided for all of their use.



GS-F300-115-550	GS-F340-115-550	GS-FCS-A425	GS-MS-A425	GS-MOU-A380SP
			max 50 Ncm	max 50 Ncm
800 rpm	800 rpm	800 rpm	20 rpm	20 rpm
800 rpm	800 rpm	800 rpm	-	20 rpm
800 rpm	800 rpm	800 rpm	-	20 rpm
-	-	-	-	-

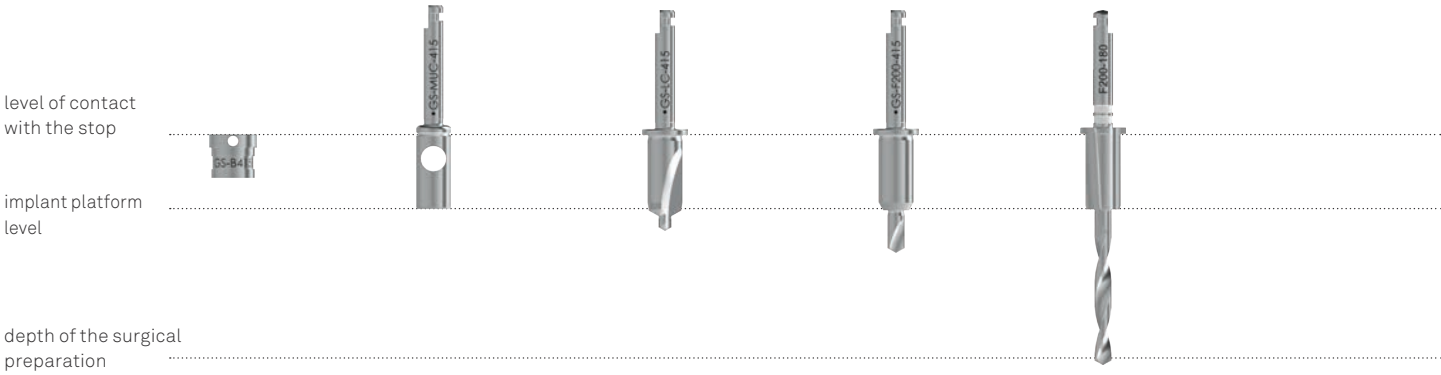


GS-F300-115-550	GS-F340-115-550	GS-F425-115-550	GS-FCS-A500	GS-MS-A500	GS-MOU-A380SP
				max 50 Ncm	max 50 Ncm
800 rpm	800 rpm	800 rpm	800 rpm	20 rpm	20 rpm
800 rpm	800 rpm	800 rpm	800 rpm	-	20 rpm
800 rpm	800 rpm	800 rpm	800 rpm	-	20 rpm
-	-	-	-	-	-

Surgical sequences – 18.00 mm height implants

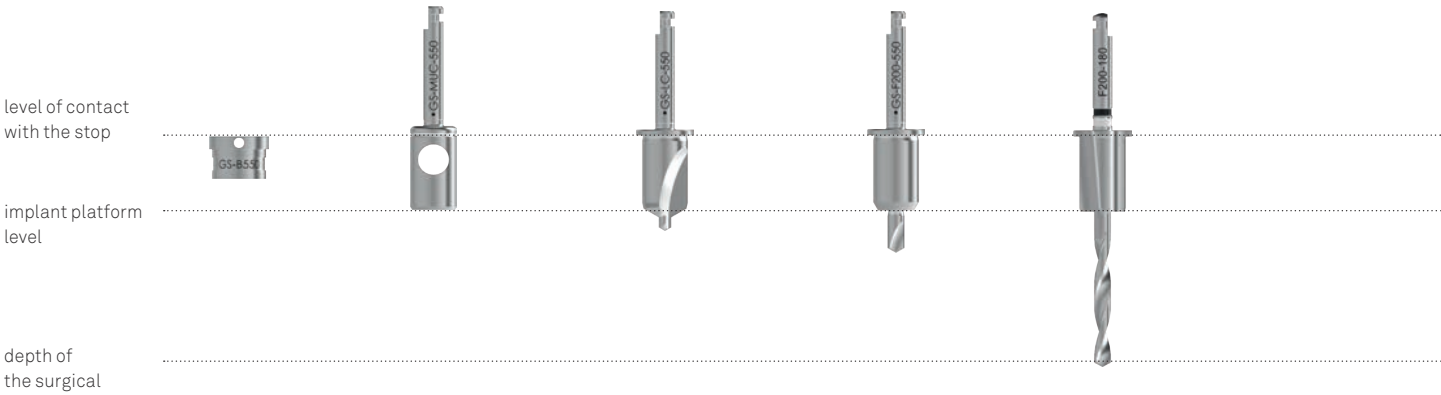
Since the 18.00 mm high implants have a insertion protocol that differs slightly from the logic just explained, the sequence is described in details for greater clarity. It should be borne in mind that drills overprepare the length as per specific measurements reported in the tables on pages 24-25.

Surgical sequence for 18.00 mm high ø 3.80 mm Premium One implants

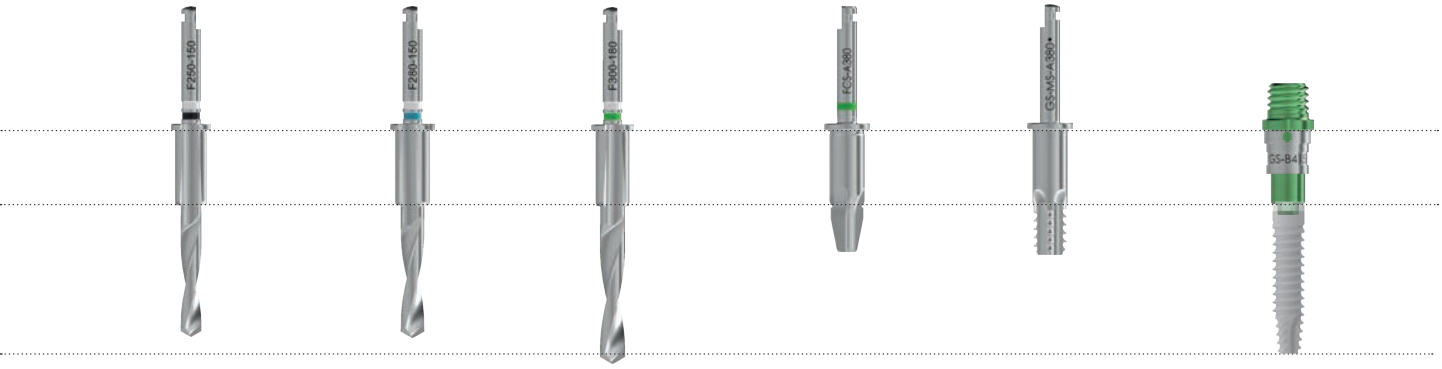


	ø 4.15 sleeve	GS-MUC-415	GS-LC-415	GS-F200-415	GS-F200-180-415
ø 3.80 mm	BONE D1	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D2	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D3	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D4	-	-	-	-

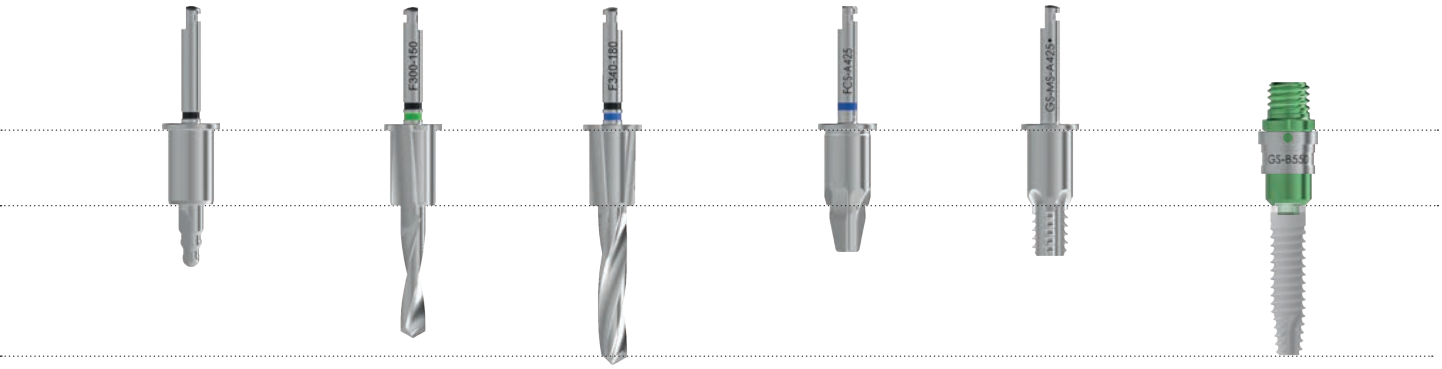
Surgical sequence for 18.00 mm high ø 4.25 mm Premium One implants



	ø 5.50 sleeve	GS-MUC-550	GS-LC-550	GS-F200-550	GS-F200-180-550
ø 4.25 mm	BONE D1	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D2	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D3	800 rpm	800 rpm	800 rpm	800 rpm
	BONE D4	-	-	-	-



GS-F250-150-415	GS-F280-150-415	GS-F300-180-415	GS-FCS-A380	GS-MS-A380	GS-MOU-A380
				max 50 Ncm	max 50 Ncm
800 rpm	800 rpm	800 rpm	800 rpm	20 rpm	20 rpm
800 rpm	800 rpm	800 rpm	800 rpm	-	20 rpm
800 rpm	800 rpm	800 rpm	800 rpm	-	20 rpm
-	-	-	-	-	-



GS-F2030-550	GS-F300-150-550	GS-F340-180-550	GS-FCS-A425	GS-MS-A425	GS-MOU-A380SP
				max 50 Ncm	max 50 Ncm
800 rpm	800 rpm	800 rpm	800 rpm	20 rpm	20 rpm
800 rpm	800 rpm	800 rpm	800 rpm	-	20 rpm
800 rpm	800 rpm	800 rpm	800 rpm	-	20 rpm
-	-	-	-	-	-

Insertion of the implant

1 Use the patient use label found inside the pack for the patient's medical records and apply it to the Dental Card: this makes the recording of the patient's treatment plan simpler and helps trace the batch used.

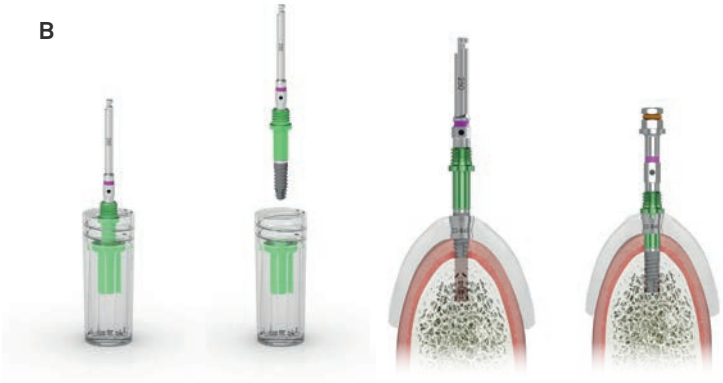
2 Open the blister and place the vial contained in it on a sterile surface (a single-use towel or a sterile cloth) or insert in one of the appropriate Mounter Organizer compartments, also previously sterilized, near the operating field.

3 Immediately before the insertion into the oral cavity, remove the blue cap of the vial, making sure not to remove the transparent cap containing the surgical cover screw. The implant holding cylinder inside the vial and the surgical cover screw are coloured according to a colour code that allows the rapid identification of the implant diameter.

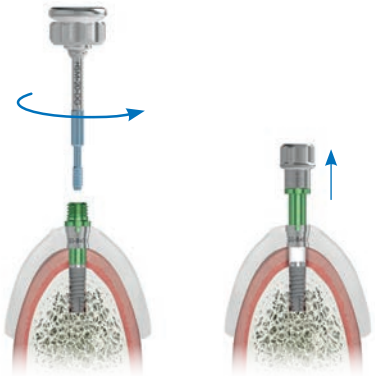
(**A**) Open the small vial containing the implant (in the example a Premium One (code A-ZT-380-130) and assemble the mounter (code GS-MOU-A380) on to the implant itself using the appropriate screw (code GS-VTMOU-180, supplied with the mounter) and the screwdriver (code HSM-20-DG).
(**B**) Select the appropriate Easy Insert from those included in the kit and fit it by applying light manual pressure inside the mounter in order to extract the implant from the vial and transport it into the mouth. It should be borne in mind that the implant insertion must be carried out using the torque control so it is always advisable to complete the operation using the torque control ratchet and the Easy Insert with hexagon connection.
(**C**) After the unscrewing of the mounting screw, the mounter can be removed without tilting thanks to the GS-MOU-DG handpiece.

A

B



C



Phase after the implant insertion

Healing times

It is essential to respect the healing times recommended in implant surgery and periodically verify the progress of the osteointegration with x-rays. Preliminary healing times before loading an implant are influenced by the quality of the receiving bone.
Whenever it is decided to defer loading, in order to minimize the discomfort conditioned by respecting the biological time for osteointegration, temporary mobile prostheses must be used prudently, avoiding functional load of these mobile prostheses.

After healing, surgical cover screws are removed from the implants. After this, according to the protocol adopted, tissue profiles are adapted through an appropriate temporary restoration or using suitable healing abutments. It is recommended that healing screws are tightened using a torque of no more than 10 Ncm.

Cleaning, disinfection, sterilisation and storage of surgical kits 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.

Cleaning, disinfection, sterilisation and storage of the CRI5-KIT torque ratchet

The processes described below are to be carried out before the first use, and before any subsequent use. Repeating the processes described in this section has a minimal effect on these devices' wear and tear. Failure to comply with these instructions may result in cross infection. Containers and transport to be used for cleaning have no special requirements. As soon as possible after each use of the wrench, place it in a container filled with a disinfectant/detergent solution and cover everything with a cloth. The purpose of this operation is to prevent that contaminants from the patient dry out, by dissolving them, and to then make cleaning easier and more effective. Completely disassemble the wrench as indicated below.

Completely unscrew the torque adjustment screw and pull out the spring inside the ratchet body handle. Do not separate the spring from the pin that acts as a stop.

Using the hexagonal bit at the base of the torque adjustment screw, unscrew and completely remove the cover fastening screw from the side marked OUT. Apply light pressure to avoid damaging the hexagonal bit.

After removing the cover, remove the two components inside the ratchet head: the notched pawl wheel and the wheel stop tooth.

For manual cleaning, mechanically clean all of the tool's external and internal surfaces with a soft bristle brush under warm water. Rinse the poorly accessible holes in the head and around the pawl wheel and wheel stop tooth by injecting hot water using a syringe without the needle. If necessary, do the same for the inside of the handle and torque adjuster. Use a suitable neutral detergent, following the manufacturer's instructions for its use. Using the brush, apply the cleaning solution to all surfaces. Rinse with distilled water for at least 4 minutes. Make sure that plenty of running water flushes through all the passages. 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. During this cycle, avoid that the parts make contact with one another as this can cause deterioration of the machined surfaces, and a resulting loss of torque measurement accuracy. When draining, check that residues have been completely removed from recesses, holes, etc., in the devices. If necessary, repeat the cycle or clean manually.

Observation: Blood residues or other deposits reduce the effectiveness of sterilisation, which is why it is important to thoroughly clean all the parts. During all cleaning cycles, avoid that the liquids spurt or splash and work with appropriate personal protection. Avoid contact between this instrument and other nickel-plated instruments.
The parts must be reassembled before sterilisation. Dry the parts and lubricate the functional areas moderately and reassemble the wrench as shown in the figures below.
Excess lubricant will cause it to come up on the instrument's surface during sterilisation.
Use only the lubricant supplied.

After having lubricated the parts shown in the figures, assemble the two elements that make up the ratchet head in the following sequence: toothed pawl wheel and then the wheel stop tooth.

Lubricate the areas that make contact between the pawl wheel tooth and the wheel stop tooth pin.

Once parts 2 and 3 have been lubricated and assembled in the ratchet head, position the cover and rotate the ratchet body from the OUT side. Tighten the screw with the hexagonal tip of the torque adjustment screw.

Lubricate the spring inside the ratchet handle as shown in the figure. Assemble the torque adjustment screw, checking that the instrument is working properly by manually activating the pawl wheel.

Sterilization: Before sterilisation, the wrench must be fully assembled and adjusted to its minimum torque. The medical device must undergo steam sterilisation.
Recommended cycle: 3 (4 for the US market) pre-vacuums,
18 minutes at 134°C / 273°F at 2 bars and drying for 20 minutes.
We recommend the use of devices fitted with vacuum pumps (type B) to reduce the risk of air pockets forming. This recommendation is particularly important for hollow tools and to guarantee perfect drying. The hot air steriliser is not recommended as it can accelerate the ageing of the spring and consequently cause modification of the torque.
This procedure is essential to maintain the precision of the instrument within a tolerance range of ± 3.5 Ncm. Operate the torque and insertion mechanism to check its correct operation.
Remove all traces of lubricant from the external surfaces of the key. Place the device in a suitable sterilization bag. Disassembly and reassembly operations must be carried out following the instructions provided.

Cleaning, disinfection, sterilization and preservation of the TWL torque control ratchet

The processes described below must be carried out before the first use and before each subsequent surgical operation. The repetition of the processes described in this paragraph has minimal wear on the device. Non-observation of these instructions may lead to cross-infection.

a. Cleaning
Containers and transports to be used for washing: there are no particular requirements. As soon as possible after each use of the ratchet, place it in a container filled with a disinfectant/ detergent solution and cover both container and ratchet with a cloth.
The purpose of this operation is to prevent the drying of contamination agents from the patient, to dissolve them and then facilitate cleaning and make it more effective.

Fully dismantle the ratchet by following these instructions:

Press the hand driver and take it out from the ratchet's head, then remove the head by pressing Inside the socket, taking it out very carefully. The three parts separated are ready for cleaning.

In the case of automated cleaning using ultrasound: Use an ultrasonic tank and a suitable detergent solution. It is recommended that only neutral detergent is used.
The concentration of the solution and the duration of washing must follow the solution manufacturer's instructions. Use demineralized water to prevent the formation of marks and rings. Avoid contact between the parts during this cycle because this causes the surfaces worked to deteriorate and consequently the torque measurements to be less precise.

Immediately after rinsing, check that all of the residues in the recesses, holes, etc. in the devices have been removed. If necessary, repeat the cycle or manual cleaning.
Observation: Residual blood or other deposits reduce the sterilization's effectiveness which is why it is important to effect precise cleaning. Avoid liquid spurting or splashing during all cleaning cycles and work with appropriate protection from spurting and splashing. Avoid contact between this instrument and other nickel-plated instruments.

The parts are re-assembled before proceeding to sterilization.

This procedure is important in maintaining the instrument's accuracy within the following tolerances:

10 Ncm	± 0,75 Ncm
30 Ncm	± 1,5 Ncm
50 Ncm	± 2,5 Ncm
70 Ncm	± 3,5 Ncm
90 Ncm	± 4,5 Ncm

After cleaning, connect the ratchet's head to the body, pushing the components together and rotating them in the opposite direction until you hear the terminal spring closing.

Push the hand driver into the ratchet until you hear the terminal spring closing. The arrow on the ratchet's head indicates the direction of functioning.

Place the device in appropriate sterilization pouch bags. It is advisable to follow the instructions in this manual during the disassembly and re-assembly operations.

b. Sterilization

Sterilize in vacuum autoclave using the following method:

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

c. Preservation

After being sterilized, the product must remain in the pouch bags used for the sterilization.
The pouch bags must only be opened immediately before re-use. The sterilization pouch bags are normally able to maintain the sterility inside them unless damaged by the recessed holder. Consequently, be careful not to use components if the pouch bags in which they were preserved have been damaged and re-sterilize them in new pouch bags before re-use.
The period of preservation of sterilized products inside the pouch bags must not exceed the pouch bag manufacturer's recommendation.
The product must be preserved in a cool dry place out of direct sunlight and away from water and sources of heat.

Composition of the materials

Implants
The implants are made of 4 Gr. titanium in conformity with harmonized European standards. Allergic reaction to titanium is rare but possible. Consequently, preventively verifying with the patients that they do not have an allergy of this type is always necessary. The specifications of the 4 Gr. titanium used are shown below.

4 Gr.* titanium (Cold worked)*

chemical composition	maximum permitted values (%)	tolerance
nitrogen	0.05	+/- 0.02
carbon	0.10	+/- 0.02
hydrogen	0.015	+/- 0.002
iron	0.25	+/- 0.10 (%<0.25) +/- 0.15 (%>0.25)
oxygen	0.20	+/- 0.02 (%<0.20) +/- 0.03 (%>0.20)
titanium	remainder	-

*This technical information is faithful to all that is expressly specified in the regulations in force for the use of 4 Gr. titanium in implantology:
- ASTM F67-13: current edition.
- ISO 5832-2: 2018: current edition.

Surgical instruments
The surgical instruments are manufactured in the following materials as a function of the type of component:
- 5 Gr. titanium
- 1.4197 steel
- 1.4542 steel
- 1.4305 steel (AISI 630)
- 1.4108 steel (AISI 303)
- 1.4108 steel
- 1.4112 steel

It is recommended that any allergy to the raw materials is checked with the patient.

5 Gr.* titanium

chemical composition	maximum permitted values (%)	tolerance
nitrogen	0.05	+/- 0.02
carbon	0.08	+/- 0.02
hydrogen	0.012	+/- 0.002
iron	0.25	+/- 0.10
oxygen	0.13	+/- 0.02
aluminum	5.5÷6.5	+/- 0.40
vanadium	3.5÷4.5	+/- 0.15
titanium	remainder	-

** This technical information is faithful to all that is expressly specified in the regulations in force for the use of 5 Gr. titanium in implantology:*

- *ASTM F 136-13: current edition;*
- *ISO 5832-3: current edition*

Key to symbols on the packaging

		Implant packaging	Surgical instrument packaging	Prosthesis packaging
	Warning! See the instructions for use	✓	✓	✓
	Batch number	✓	✓	✓
	Code	✓	✓	✓
	Manufacturer	✓	✓	✓
	Country of manufacture	✓	✓	✓
	UDI code (Unique Device Identification)	✓	✓	✓
	Medical device	✓	✓	✓
	See the instructions for use www.sweden-martina.com	✓	✓	✓
	CE Mark of conformity *If applicable: the identification number of the notified body must follow this symbol.*	✓	✓	✓
	U.S. federal law restricts this product to sale by or on the order of a professional.	✓	✓	✓
	Do not resterilize	✓		
	Do not reuse: disposable products	✓		✓
	Do not use if the container is damaged	✓	✓	✓
	Non-sterile products		✓	✓
	Sterilised with ionising radiation	✓		
	Sterile single barrier system with protective packaging inside	✓		
	Expiry date after which the product should not be used	✓		

THE LAST REVISION DATE OF THIS MANUAL IS MAY 2022.

The development and manufacture of the device described in this manual was carried out in conformity with the latest EU directives and harmonized regulations governing the materials used, the production processes, sterilization, information provided and packaging.

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The implants, standard prosthetic components and surgical instruments contained in this catalogue 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 and class IIB) in compliance with Regulation (EU) Medical Devices n. 2017/745.

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