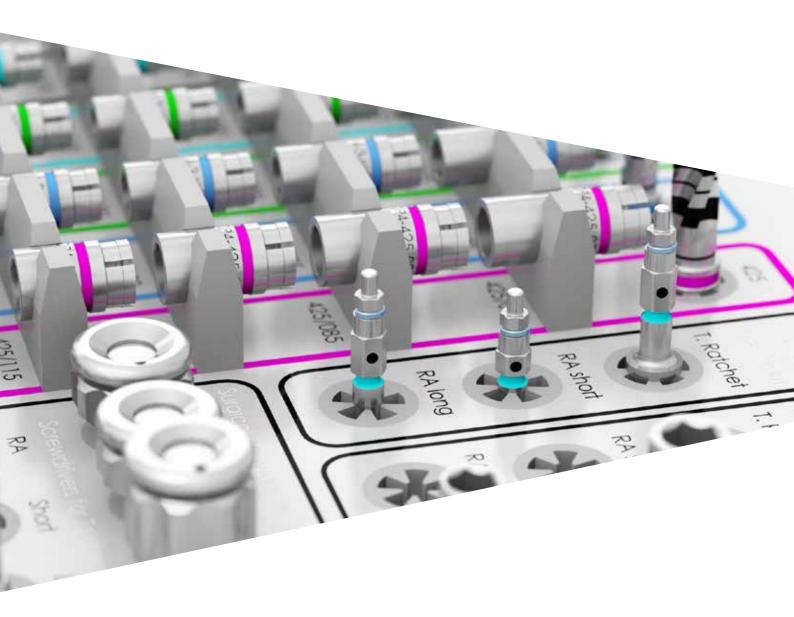
Surgical manual

PREMIUM ONE





Premium One



The implants

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The range

Premium One implants Table of colour codes



Surgical instrumentation

Premium One surgical kit Premium One kit Combined surgical kits Premium Kohno One the surgical kit Premium Shelta surgical kit General indications Drills Precision drill FS-230 Pilot drill FPT3-200-LXS Intermediate cylindrical drill Other intermediate drills Final cylindrical drills Drills for distal sectors Bone profilers Countersink drills Bone taps Osteotomes Parallelism pins PROF3 depth gauge Mounter and mounter stop key Easy Insert Drivers Drivers for fixation screws and extraction tools Torque control ratchet CRI5-KIT Torque wrench with control lever TWL Cleaning, disinfection, sterilization and storage of the kit and of the surgical instruments Shorty Drilling kit Instruments contained in the Shorty Drilling Kit



Surgical sequences

Preparation of the implant site Surgical sequences for Premium One implants

Surgical procedures

Insertion of the implant Intraoperative removal of implants if necessary The use of bone profilers for the insertion of P.A.D. abutments



General indication

Intraoperative removal of implants if necessary Maintenance of the prosthesis Responsibility for defective products and warranty terms Disposal Composition of the materials Identification of the manufacturer

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 micro-hemorrhages 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.

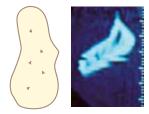
Before proceeding, it is important to perform a careful pre-operative analysis of the patient's medical history to verify his or her suitability for the implant treatment. It is also recommended to collect and file all the clinical, radiological and radiographic records.

After making models of the two arches, the best position and orientation of the chosen implants will be evaluated based on the occlusal plane and on a correct distribution of the forces. In this phase, a surgical stent may be created to guide the specialist to correctly position the implants during the operation. Depending on the specific case, a decision will be made on whether to use a single or double phase surgical procedure, using titanium cylinders (code DIM) to make the radiological/surgical stent.

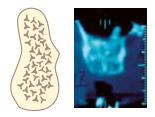


A radiological and surgical stent can be made by using the special cylinders in titanium (code DIM), which can be used to obtain an ideal positioning of the implants in terms of biomechanics and aesthetics.

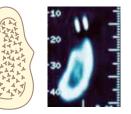
In addition to an oral examination, both clinical and with x-rays, it is recommended to take a CT scan of the interested area; once the x-rays and scans have been obtained, the specialist can identify the most suitable implant with the help of convenient transparent radiographic guides. The pre-operative 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:



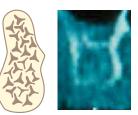
BONE D1: all cortical bone.



BONE D3: all bone marrow without cortical crest.



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



BONE D4: all bone marrow with very poor mineralization.

General indications

Premium One fixtures are long-term implantable medical devices. All the fixtures are sold in singleuse sterile packs. The function of the fixtures is to replace missing dental roots.

The implants have a connection in the crown part for receiving a post aimed at supporting a dental prosthesis. Original Sweden & Martina, S.p.A. prosthetic components must exclusively be used with Premium One implants for the implant-prosthetic rehabilitation. The use of non-original components limits the responsibility of Sweden & Martina S.p.A. and renders the product warranty void. The implants have a hybrid morphology, they are screw-shaped with an external thread and have a conical internal connection for connecting the prosthetic components. Premium One implants can be inserted in both edentulous and post-extraction sites, either immediate (insertion of the implant at the same time as the removal of the tooth or root), or deferred (normally about 3 weeks between extraction and insertion of the implant fixture).

All the fixtures are sold with the respective surgical cover screw. The surgical cover screws are also medical devices that can be implanted surgically, designed to remain in the oral cavity for even more than 30 days. The surgical cover screws can also be sold individually.

Key to Premium One implant codes

Implants are coded with "mnemonic" codes that allow easy identification of the piece. Below is a table showing how the mnemonic codes work using AS-ZT-425-115 as an example:

implant type A-	surface ZT	diameter 380	length 115-
A: Premium One implants ø 3.30 or ø 3.80 mm AS: Premium One implants ø 4.25 or ø 5.00 mm	ZT : ZirTi surface	330 : 3.30 mm 380 : 3.80 mm 425 : 4.25 mm 500 : 5.00 mm	070: 7.00 mm 085: 8.50 mm 100: 10.00 mm 115: 11.50 mm 130: 13.00 mm 150: 15.00 mm 180: 18.00 mm
		This is the dimension of the endosseous diameter of the implant, measured at the coronal level	

All measurements are in mm, unless otherwise indicated.

Important note: on the 4.25 and 5.00 implants packs there is a Premium One brand to differentiate them from the previous version, which connection was different. 3.30 and 3.80 implants do not show the same brand because they did not change.

Method of use

The methods of use can be divided into two main surgical techniques:

- Two stages: an initial "submerged" stage, with implant insertion, covering of the connection with a surgical cover screw, suturation and subsequent reopening of the mucous membrane 2–6 months later, followed by prosthesis insertion;
- One stage: implant insertion and closure of the connection with a healing abutment instead of a surgical cover screw. Alternatively, in presence of suitable therapeutic indications, it can be loaded immediately with an appropriate temporary or permanent dental post, depending on the case.

Implants are inserted in the bone following surgical protocols that must be considered according to the quantity and quality of the receiving bone, the implant and any possible need for regenerative therapies. A site is created in the patient's bone at the position of the new tooth to be replaced or inserted, using a series of calibrated bone drills or other suitable instruments, such as bone expanders, bone profilers or similar.

The necessary conditions for the success of the implant are:

- the presence of a certain quantity of bone;
- good periodontal (gingival) support;
- the absence of bruxism (tooth grinding) and serious malocclusions;
- the presence of good occlusal balance (correct masticatory occlusal plane).

Premium One implants have been tested in a wide range of clinical situations:

- standard operating procedures involving the double or single surgical phase;
- immediate and early loading;
- simultaneous use with regenerative therapies;
- post-extraction situations, even combined with immediate loading.

Generally, masticatory loading with a fixed prosthesis occurs at a second stage, after 2 to 3 months for the mandible and after 4 to 6 months for the upper jaw. In some cases, but not all, immediate loading of the implants is possible; to do this it requires good primary stability, with no mobility or movement limited to a few microns. The bone-implant interface must therefore be of the order of a few millimicrons, otherwise there is the risk of fibrous integration. The clinical indication for choosing the Premium One implant depends on the site in which the implant is to be inserted, on the anatomy of the receiving bone and on the technique chosen from among those mentioned above. The choice must be made exclusively by the doctor, who must have the suitable training and experience and must plan the prosthetic rehabilitations beforehand.

Sweden & Martina has conducted 5,000,000-cycle fatigue resistance tests on Premium One implants. The implants passed the test. Fatigue tests are conducted according to the standards and evaluated further with finite element calculations.

Premium One morphologies

The different morphologies that characterize the entire family of Premium One implants mean that the correct implant design can always be selected to suit the site in which they are to be fitted.

ø 3.30 mm

Implants with diameter 3.30 mm are available with a 0.80 mm UTM neck. Only the thread of the implants with diameter 3.30 mm has a pitch of 0.60 mm and a triangular profile characterized by a 50° angle and a depth of 0.30 mm.

Straight ø 3.80 - 4.25 - 5.00 mm

All Premium One implants have a UTM straight neck 0.80 mm high. The standard thread of Premium One implants has a pitch of 1 mm and a depth of 0.40 mm.

Shorty ø 4.25 - 5.00 mm

A range of fixtures with reduced heights is also available: they can be used, according to the most recent clinical protocols, in all cases where there is small vertical bone dimension. Shorty implants are available from height 7.00 mm.

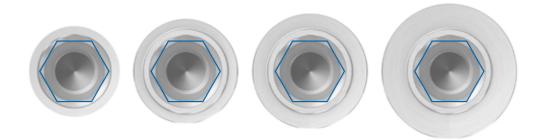


Important warning

It is recommended to use Shorty implants combined in multiple rehabilitations, better if with longer fixtures, specially when placing them in scarcely mineralized bone and in all those cases when a sufficient primary stability cannot be reached.

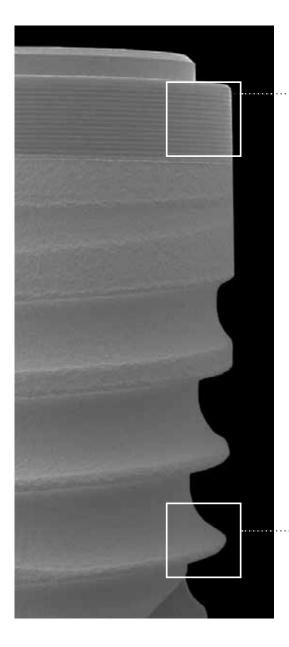
Collex One connection

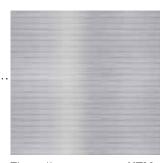
All Premium One implants share the same Collex One connection with an internal hexagon supporting and repositioning of the prosthesis, that gives strength and stability to the prosthesis and helps Easy Insert drivers in guiding and engaging. The connection is common to all diameters to simplify user experience.



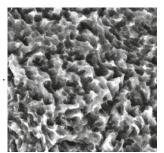
Implant surfaces

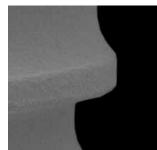
Premium One implants are available with a **UTM neck** (Ultrathin Threaded Microsurface) and a **ZirTi body**, treated with sand-blasting with zirconium oxide and etching with mineral acids.





The collar presents a **UTM surface** that allows perfect control of the connection diameter and **prevents the accumulation of plaque** on the connection with the post





Sand-blasting with zirconium oxide and etching with mineral acids give surfaces a characteristic micromorphology capable of significantly increasing the bone-to-implant contact area and and promoting osseointegration

Premium One implants

implant ø	3.30	3.80	4.25	5.00
7.00	-	-	AS-ZT-425-070	AS-ZT-500-070
			ø 4.25 7.00 ø 3.32	ø 5.00 7.00 ø 4.22
8.50	A-ZT-330-085	A-ZT-380-085	AS-ZT-425-085	AS-ZT-500-085
	ø 3.30 ø 2.52	ø 3.80 ø 2.97	ø 4.25 ø 3.32	ø 5.00 ø 4.22
10.00	A-ZT-330-100	A-ZT-380-100	AS-ZT-425-100	AS-ZT-500-100
	ø 3.30 10.00 ø 2.52	ø 3.80 ø 2.97	ø 4.25 10.00 ø 3.32	ø 5.00 10.00 ø 4.22
11.50	A-ZT-330-115	A-ZT-380-115	AS-ZT-425-115	AS-ZT-500-115
	ø 3.30 ø 2.52	ø 3.80	ø 4.25 ø 3.32	ø 5.00 ø 4.22
13.00	A-ZT-330-130	A-ZT-380-130	AS-ZT-425-130	AS-ZT-500-130
	ø 3.30 13.00 ø 2.52	ø 3.80**** ø 2.97	ø 4.25 ø 3.32	ø 5.00 13.00 ø 4.22
15.00	A-ZT-330-150	A-ZT-380-150	AS-ZT-425-150	AS-ZT-500-150
	ø 3.30 15.00 ø 2.52	ø 3.80 ø 2.97	ø 4.25 ø 3.32	ø 5.00 ø 4.22
18.00	-	A-ZT-380-180	AS-ZT-425-180	-
		ø 3.80 ø 2.97	ø 4.25 18.00 ø 3.32	
Surgical cover screw*	A-VT-330	A-VT-380	SH-VT-425-BL	SH-VT-500-VI

* Every implant is supplied with its own Titanium Gr.4 surgical cover screw.

Surgical cover screws are also available individually in sterile packs, and must be tightened to 8–10 Ncm. When starting with a platform Switching protocol, narrower surgical cover screw can be purchased separately. See technical characteristics of Gr. 4 titanium on page 81.

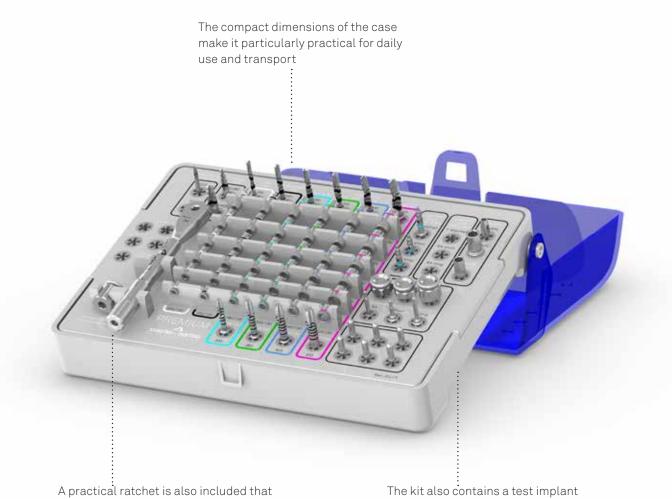
Table of colour codes

A colour code system has been defined in the Premium One implant system to identify the endosseous diameter of the implant. Transfers for taking impressions, laboratory analogs, final drills and the sequence on the surgical tray are also identified by the colour code.

implant ø	3.30	3.80	4.25	5.00
Colour code on the packaging	•		ONE	ONE
Reference colour code on the surgical tray				
Connection platform ø	ø 3.30	ø 3.80 2.30	o 4.25 ↓ 2.30	ø 5.00 2.30
Final drill	V	ţ	ţ	
Pick-up transfer colour code and laser mark	Ī	Į	Į	ŧ
Pull-up transfer colour code	Ţ	Ţ	ļ	ļ
Analogue colour code	Į	Į	ļ	

Premium One surgical kit

The Premium One surgical kit is designed for maximum simplicity of use and immediacy for the correct sequence of the instruments required. Made of surgical stainless steel, the instruments descriptions are screen-printed on the tray to allow an easier identification and to correctly replace them after cleaning and sterilization procedure, marked with a system of colour codes that follow the most suitable surgical procedures for the different implant diameters. The surgical kits are supplied with x-ray templates for the graphic representation of all the Premium One implant system measurements to allow choosing the most suitable implant diameters and lengths by means of radiographic or tomographic methods.



A practical ratchet is also included that acts as a dynamometric key for checking the torque of the prosthetic screws and as a surgical key for inserting the implants The kit also contains a test implant which is not to be clinically used, entirely anodised in blue to make it easily recognizable

description	code
Complete grommetless surgical kit of the instruments necessary for Premium One implants	ZPREMIUM-ONE-INT
Radel instrument grommetless tray for the instruments necessary for Premium One implants	A-TRAY-INT

Important warning

The surgical kit also contains a non-sterile test implant that must not be used clinically, and can be easily recognized because it is entirely anodized in blue; it is recommended to use this implant for trials on models before starting to use implants clinically, so as to become familiar with the implant system and its respective instruments.



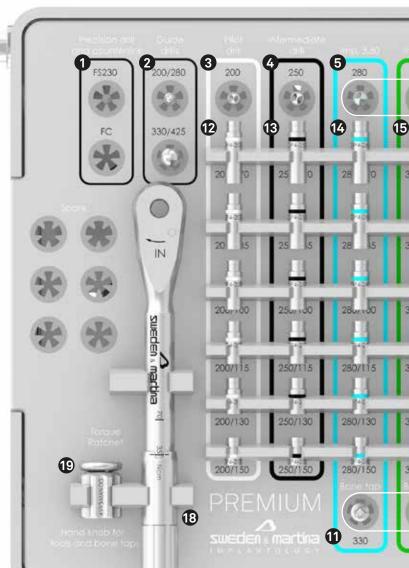
Premium One kit







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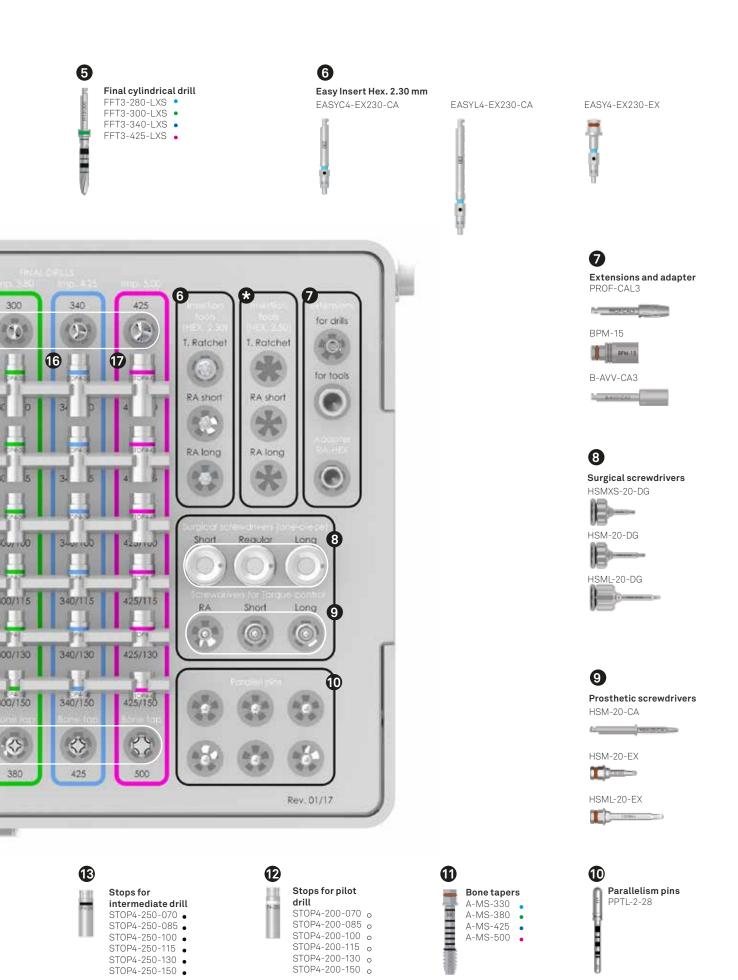








🛠 Premium One surgical kit includes spaces for 2.50 mm Easy Inserts but not the instruments because they cannot be used to transport and place Premium One implants, but only the previous version of Premium implants ø 4.25 mm and ø 5.00 mm.



STOP4-250-130 • STOP4-250-150 •

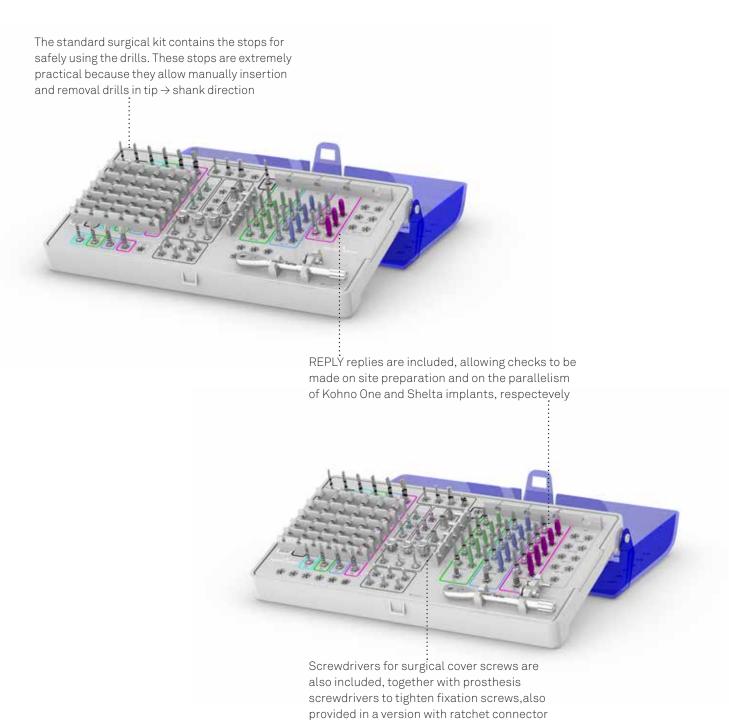
15

Combined surgical kits

Combined surgical kits for Premium Shelta and Premium Kohno One contain the instruments for the surgical and prosthetic phases of the fixtures of both implant systems.

The instrument tray is made in autoclavable Radel plastic and offers simplicity and immediacy for the correct sequence of the instruments required, marked with a system of colour codes that follow the most suitable surgical procedures for the various implant diameters. Descriptions of these instruments are indicated on the tray, allowing users to easily identify all instruments and to replace them in the correct position after cleansing and sterilization procedures.

The surgical kit also contains X-ray templates for the implants, to allow the most suitable implant diameters, lengths and morphologies to be chosen using radiographic or tomographic analyses.



description	code
Surgical kit containing the instruments necessary for Premium One and Kohno One implants	ZPREKOH-ONE-INT
Radel empty instrument tray for Premium One and Kohno One implants	AK-TRAY-INT
Surgical kit containing the instruments necessary for Premium and Shelta implants*	ZPRESH-INT
Radel empty instrument tray for for Premium and Shelta implants*	ASH-TRAY-INT

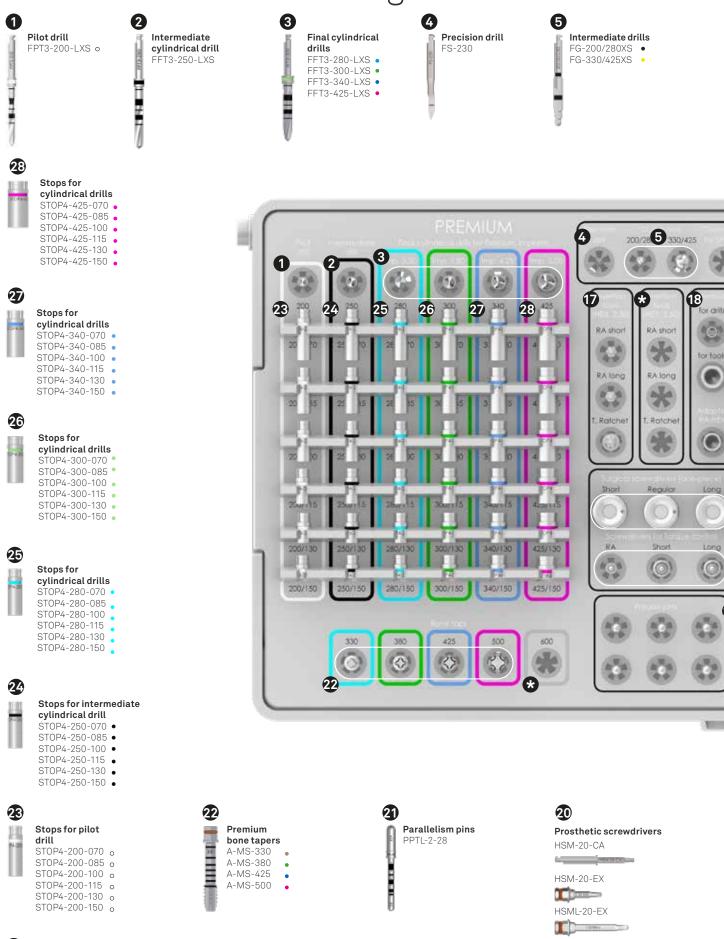
*In some countries the Premium Shelta surgical kit could be available in a different version.

Important warning

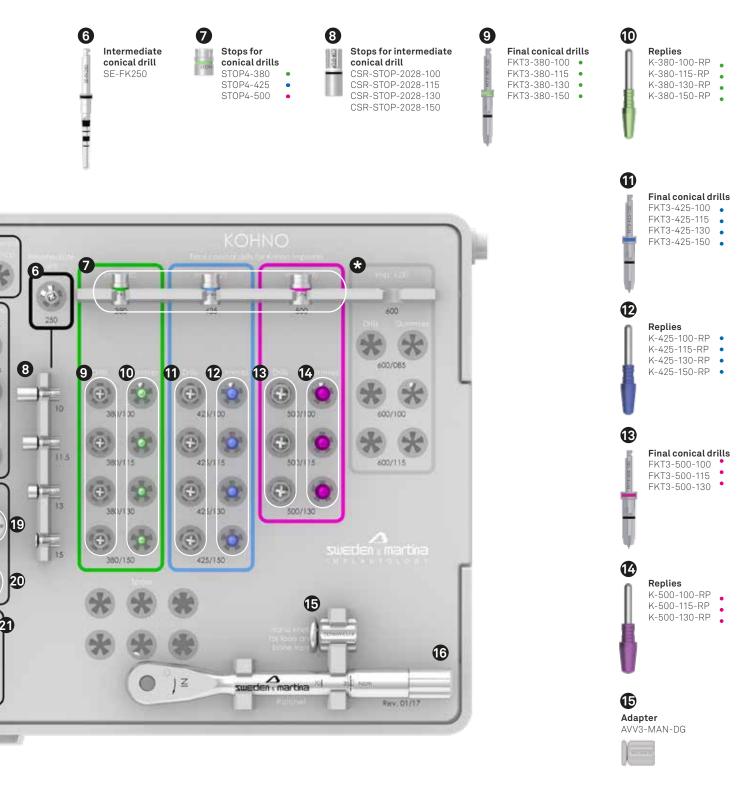
Each surgical kit also contains a non-sterile test implant that must not be used clinically, and can be easily recognized because it is entirely anodized in blue; it is recommended to use this implant for trials on models before starting to use implants clinically, so as to become familiar with the implant system and its respective instruments.



Premium Kohno One the surgical kit



Premium Kohno One surgical kit includes spaces for 2.50 mm Easy Inserts but not the instruments because they cannot be used to transport and place Premium One implants, but only the previous version of Premium implants ø 4.25 mm and ø 5.00 mm. It also includes spaces for diameter 6.00 of the previous version of Kohno implants, but not the instruments.



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Surgical screwdrivers



Extensions and adapter PROF-CAL3

BPM-15

B-AVV-CA3

Easy Insert Hex. 2.30 mm EASYC4-EX230-CA

EASYL4-EX230-CA

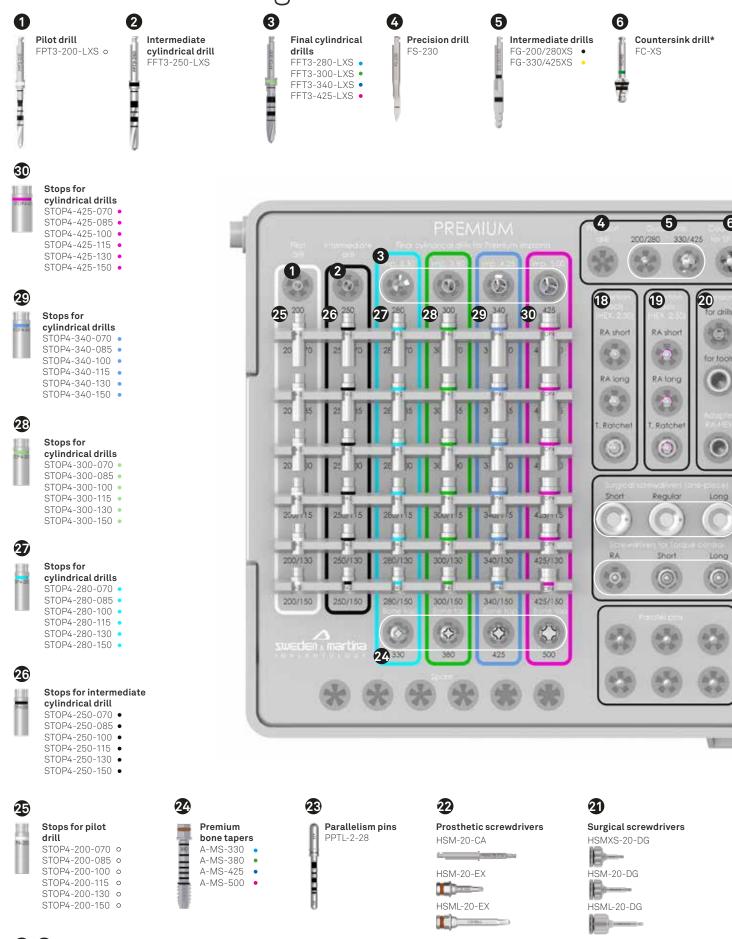
EASY4-EX230-EX

Torque control ratchet

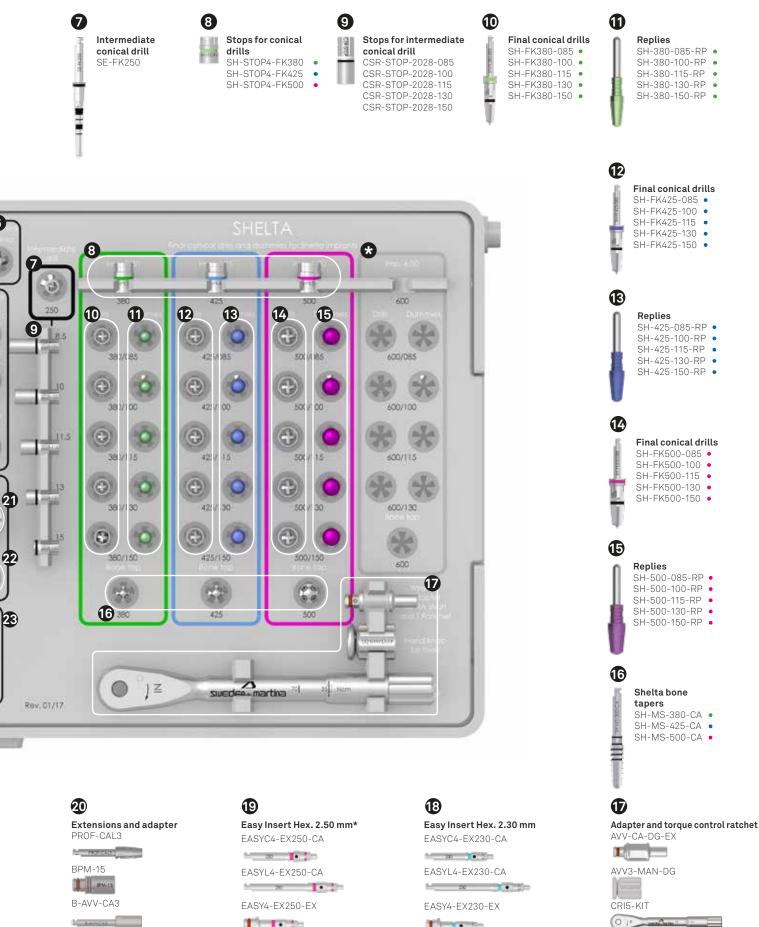


19

Premium Shelta surgical kit



6 (D) Premium Shelta surgical kit includes 2.50 mm Easy Inserts (19): they cannot be used to transport and place Premium One implants, but only the previous version of Premium implants ø 4.25 mm and ø 5.00 mm. Also the old countersink drill (6), designed to prepare Premium SP neck, is not suitable for Premium One implants.



🛠 Premium Shelta surgical kit includes spaces for diameter 6.00 of Shelta implants, but not the instruments.

- BANNCAS

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), re-usable. 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 Directive 93/42/EEC, implemented in Italy with Law 46/97, Annex I – Essential Requirements, point 7.1.

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 the implant 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
The range of instruments is vast, we indicate some examples of the main families of instruments.		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.
FFT3-300-LXS	FFT3: final cylindrical drill	300: 3.00 mm, for the preparation of a fixture with ø 3.80	
STOP4-200-085	STOP4: stop for pilot drill	200: 2.00 mm	085: 0.85 mm
PPTL-2-28	PPTL: parallelism pin with laser-etched notches large version	2-28: from 2.00 mm to 2.80 mm	-

Drills

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 60 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. 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.



Precision drill FS-230

The precision drill is made of surgical stainless steel. It is used to cut the cortical bone, so it is very sharp and pointed. The design of the blades ensures efficient cutting with both the tip and the edge. It has a maximum diameter of 2.30 mm.

The laser marking at 4.80 mm indicates the maximum depth of insertion of the drill to obtain an adequate guide hole for subsequent drills.



Important warning

The precision drill is supplied complete with a protective silicone sheath to protect it during transport, and it must be removed before the first use. Since this drill is extremely sharp, special caution is required during handling.

Pilot drill FPT3-200-LXS

The pilot drill is cylindrical and has a diameter of 2.00 mm. It is designed for the preparation of the hole that will receive the implant. The drill is easy to identify, thanks to the presence of a white ring and a laser-etched code on the drill shank. It has laser-etched depth marks and a spiral shape with two cutting edges. It must be used with abundant external irrigation.



Important warning

The drills always make a hole that is longer than the implant to be inserted. The oversizing (LS) is equal to the difference between the length of the working part of the drill and the nominal height of the implant.

code	Ø	LS	Ц
FPT3-200-LXS	2.00	0.58	19.30

Pilot drill stops

Stops are devices to be fitted in tip \rightarrow shank direction on drills suited to receive them. They make it possible to restrict the working length of a drill to a pre-set height.

height	7.00 mm	8.50 mm	10.00 mm	11.50 mm	13.00 mm	15.00 mm
Stop	STOP4-200-070	STOP4-200-085	STOP4-200-100	STOP4-200-115	STOP4-200-130	STOP4-200-150
	P4-20	94-20	94-20	P 4-201	74-20	24-205

Always check that the stop is inserted at the desired height. Incomplete insertion may reduce the preparation height. Any insertion difficulties can be resolved by loosening the stop tabs slightly, using forceps. It is also recommended to check the retention exerted by the stop, as if retention is too weak the instrument will fall off the drill during operation. In the event of reduced retention capacity, simply tighten the tabs by hand or using forceps.



Intermediate cylindrical drill

A cylindrical drill made in surgical stainless steell with a diameter of ø 2.50 mm is available, useful for underpreparation protocols of 3.30 mm implants. The related stops are available, meant to guarantee a safe preparation.

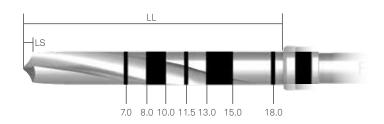


cylindrical drill ø 2.50 mm and related stops						
FFT3-250-LXS cylindrical drill	STOP4-250-070 stop 7.00 mm for cylindrical drill	STOP4-250-085 stop 8.50 mm for cylindrical drill	STOP4-250-100 stop 10.00 mm for cylindrical drill	STOP4-250-115 stop 11.50 mm for cylindrical drill	STOP4-250-130 stop 13.00 mm for cylindrical drill	STOP4-250-150 stop 15.00 mm for cylindrical drill
FFT3-250						
ø 2.50	Ш	1911		6796		
0.72	94-25	2P4/25	94-25	0P4-28	024-25	DP 4-238

Important note: the drills always make a hole that is longer than the implant to be inserted. The oversizing

(LS) is equal to the height of the tip of the drill that is being used. See drawing on the side.

- LL: Total length of the working part, including the tip.
- **LS**: Length of the tip. This measurement must be calculated in addition to the length of the preparation hole.

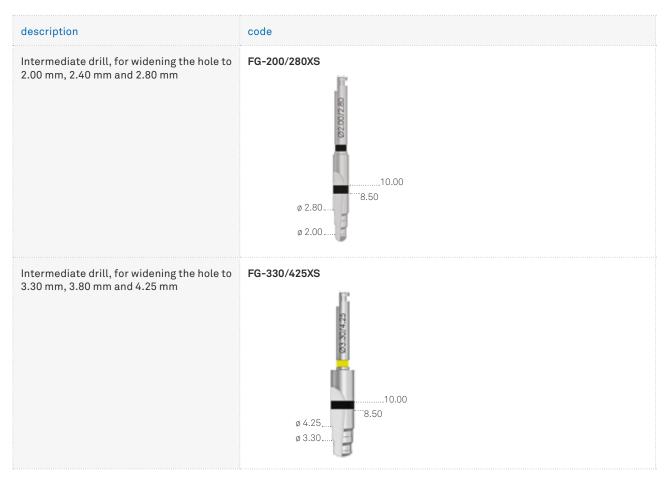


Other intermediate drills

Intermediate drills are drills with two cutting edges suitable for progressively widening the preparations in relation to the diameter of the drills to be used in succession. They have two small steps with an initial guide with a progressive diameter and final diameter, respectively equal to 2.00/2.80 and 3.30/4.25 mm. They have reference laser markings that range from a height of 8.50 to 10.00 mm. For shorter preparations, they must be used until the end stop (the guide is not a cutting edge).



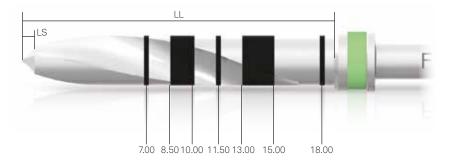
8.50 10.00

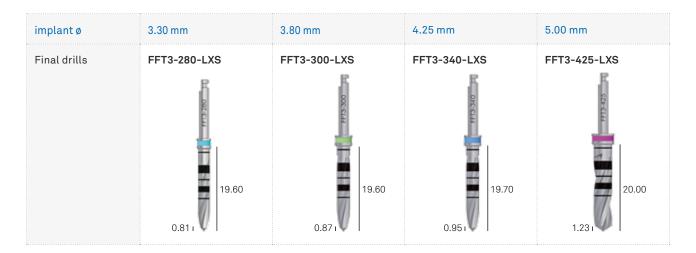


Final cylindrical drills

Made of steel with high resistance to corrosion and wear, Premium One final drills present a number of cutting edges proportional to the hole diameter, so as to allow a continuous and homogeneous cutting movement and greater instrument stability during operation. All this enables high-precision implant preparations to be obtained, with consequent ease in inserting the implant. It is recommended to use these drills with the related depth stops, also included in the surgical kit.

- **LL**: Total length of the working part, including the tip.
- LS: Length of the tip. This measurement must be calculated in addition to the length of the preparation hole.





Important warning

The drills always make a hole that is longer than the implant to be inserted. The oversizing (LS) is equal to the height of the tip of the drill that is being used.

Stops for final cylindrical drills

implant ø	3.30 mm	3.80 mm	4.25 mm	5.00 mm
Stop for H. 7.00 mm preparation	STOP4-280-070	STOP4-300-070	STOP4-340-070	STOP4-425-070
Stop for H. 8.50 mm preparation	STOP4-280-085	STOP4-300-085	STOP4-340-085	STOP4-425-085
Stop for H. 10.00 mm preparation	STOP4-280-100	STOP4-300-100	STOP4-340-100	STOP4-425-100
Stop for H. 11.50 mm preparation	STOP4-280-115	STOP4-300-115	STOP4-340-115	STOP4-425-115
Stop per H. 13.00 mm preparation	STOP4-280-130	STOP4-300-130	STOP4-340-130	STOP4-425-130
Stop for H. 15.00 mm preparation	STOP4-280-150	STOP4-300-150	STOP4-340-150	STOP4-425-150
	2428	D74.5	IDP430	-425-150

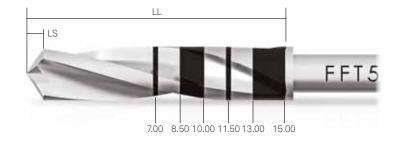
It is advisable to always check that the stop is fitted at the desired height. Incomplete insertion may reduce the preparation height. Any insertion difficulties can be solved by loosening the stop tabs slightly, using forceps. It is also recommended to check the retention exerted by the stop, as if retention is too weak the instrument will fall off the drill during operation.

If the retention capacity of the stops is reduced, simply tighten the tabs by hand or using forceps.

Drills for distal sectors

As an option, shorter drills are available that are very practical in distal sectors with limited oral opening. They come in a wide range of diameters and are also useful for preparations in extremely compact bone where, in the most coronal portion, it is desired to widen the preparation diameter by 0.10 mm with respect to the size of the standard drills to facilitate the insertion of the implants. On the other hand, in low-density bone they can be used to under-prepare the implant site so as to obtain optimum primary stability.

- LL: Total length of the working part, including the tip.
- **LS**: Length of the tip. This measurement must be calculated in addition to the length of the preparation hole.



Important note: the drills always make a hole that is longer than the implant to be inserted. The oversizing (Ls) is equal to the height of the tip of the drill that is being used. See drawing on the side.



* The drills for distal sectors are not included in any surgical kit and must be purchased separately.

Bone profilers

Bone profilers can be very useful when a very irregular bone crest coronal levelling is desired or needed, specially for a following P.A.D. abutment rehabilitation. Bone profilers must be used in combination with their guide.

For the use of bone profilers please see pg. 79.



description	3.30	3.80	4.25	5.00
Narrow bone profiler for P.A.D. abutments Transgingival height 5.00 mm	A-PAD-PS330-S	A-PAD-PS380-S	A-PAD-PS425-S	A-PAD-PS500-S
Wide bone profiler for P.A.D. abutments Transgingival height 3.00 mm	A-PAD-PS330-L	A-PAD-PS380-L	A-PAD-PS425-L	A-PAD-PS500-L
Guide cylinder for bone profilers	A-PAD-GUI-PS-230	Use A-PAD-GUI-PS-230	Use A-PAD-GUI-PS-230	Use A-PAD-GUI-PS-230

Bone profilers are optional instruments not included in the surgical kit, and can be ordered singularly for separate.

Countersink drills

Countersink drills are optionally available. They allow to prepare the neck of Premium One implants in presence of a very thick cortical bone. The drills are characterized by an apical portion that is guided into the hole created by the final cylindrical drill and by a standard height of the working part of 6.60 mm.



Drills are available with 3.80, 4.25 and 5.00 mm diameters

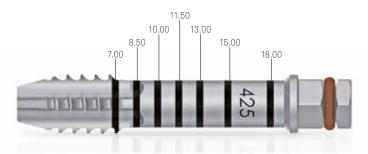


The particular morphology of the countersink drills allows to widen the initial part of the hole bored by the final cylindrical drills to prepare the cortical bone portion, that will be in contact with the neck of the implant. The maximum recommended speed is 1,000 rpm. Each drill has to be used only for the implant of equal diameter.



Bone taps

Premium One implants are self-tapping implants with excellent cutting and insertion capabilities; however the use of a bone tap is recommended in all cases where the type of bone requires it to facilitate the fixture insertion. Bone taps are available both with right-angle shank and with hexagonal attachment for torque control ratchet.



implant ø	3.30 mm	3.80 mm	4.25 mm	5.00 mm
Right-angle bone taps for Premium One implants	A-MS-330-CA	A-MS-380-CA	A-MS-425-CA	A-MS-500-CA
Standard bone taps with hexagonal attachments for Premium One implants*	A-MS-330	A-MS-380	A-MS-425	A-MS-500
Short bone taps with hexagonal attachments for Premium One implants*	A-MSC-330	A-MSC-380	A-MSC-425	A-MSC-500

*Optional instruments not included in the surgical kit, and can be ordered singularly for separate.

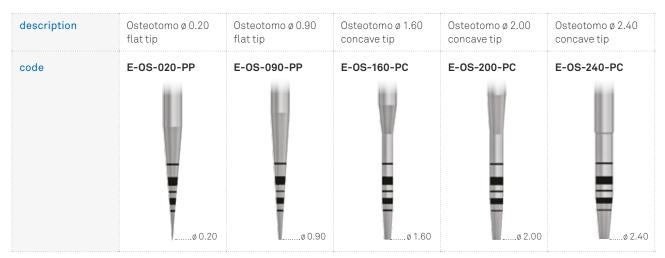
Important warning

The surgical kit only includes right-angle bone taps. They can also be used manually, connecting them to the torque control ratchet CRI5-KIT thanks to AVV-CA-DG-EX adapter. It is recommended not to exceed an insertion torque of 60 Ncm. If a higher torque is required, it is recommended to use bone taps with hexagonal attachment, optionally available.

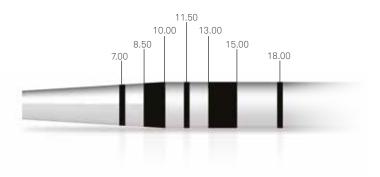


Osteotomes

A complete set of osteotomes, optionally available, has been designed for expansion protocols. The laser-etched codes on the handles indicate the osteotome diameter, to make it easier to recognize the correct surgical sequence. The laser marking on the point mark all the available heights. A practical universal instrument case for storing and organizing them is available.



Osteotomes are optional instruments not included in the surgical kit, and can be ordered singularly for separate.

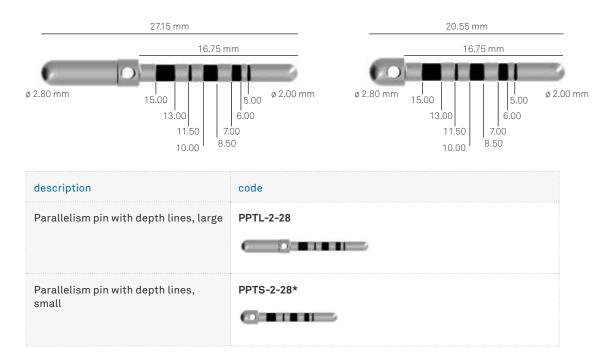


description	code	
Universal case in Radel for osteotomes Can hold up to 12 instruments	OS-TRAY	

Parallelism pins

Parallelism pins can be used to check the insertion axis of the implants and the parallelism between more fixtures. Parallelism pins with depth notches allow the control of the preparation height during the first surgical step, thanks to the notches provided on the side with a diameter of ø 2.00 mm. As the notches have a slightly smaller diameter than the body of the pin, they can be clearly noted on intraoperative X-rays.

The other side of the pin has a diameter of ø 2.80 mm and it has a hole in which a safety thread can be inserted. The small version of the pin, with the side with diameter ø 2.80 mm shorter than on the large version, may be useful with patients with a limited space in the oral cavity or for distal sectors.



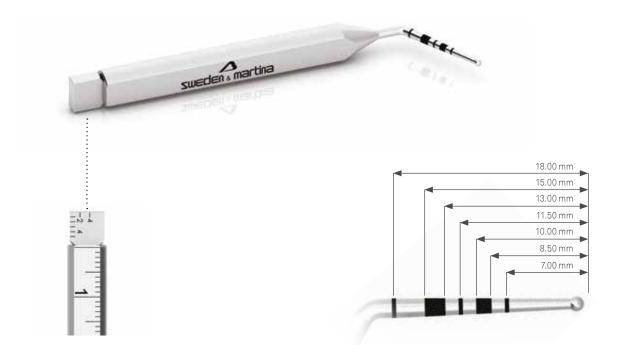
As an option, plain parallelism pins are available, which reduced partial lenght can help in case of difficult to reach distal sectors or small oral openings.



*Optional instruments, not included in the surgical kit

PROF3 depth gauge

It is a practical instrument which allows to verify the depth of the preparation holes and the distance between the implants. It is not included in any surgical kit, it can be ordered separately.



Mounter and mounter stop key

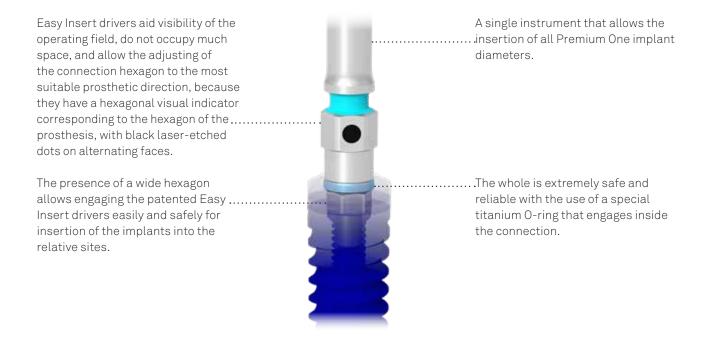
In the case of inserting Premium One implants without the Easy Insert driver, an optional mounter suitable for this procedure is available. Also available is a mounter stop key, useful for the screwing/unscrewing of the mounter itself.

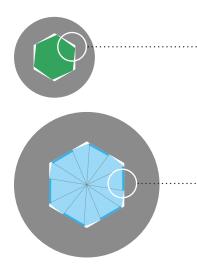
description	code
Mounter for Premium One implants	MOU-EX230
Mounter stop key	CM2 success martine

Easy Insert Drivers

The Premium One implant does not require a mounter for the insertion into the implant site, it is engaged directly inside the connection by practical Easy Insert drivers, designed to guarantee a safe grip, to prevent deformations to the corners of the connections and at the same time to allow easy removal from the implant.

The use of these drivers makes the surgical procedure of insertion extremely simple.





The photo on the left shows how a traditional instrument (in green) edges itself into the connection (in grey). This geometry inevitably determines the grip and deformation of the actual internal connection.

The special design of the Easy Insert drivers (in light blue in the section on the right) enables the driver and implant to interact on a portion of the surface in the centre of the connection hexagon.

The **dodecagonal design** of the drivers prevents deformations to the implant connection, thus guaranteeing extremely high prosthetic stability and precision.

When using the Easy Insert driver with the torque wrench with control lever or ratchet, as when using any other instrument for inserting implants with a dynanometric key, it is likewise advisable to take care to keep the working axis as perpendicular as possible. It is also fundamental for the movement performed with the ratchet during tightening to be slow and uniform, avoiding brusque movements as much as possible. If the precautions of use are not followed and the maximum torque is exceeded, the instrument could be broken: for this reason there is a **default breaking point** located over the dots, to allow the operator to remove the driver from the implant without any difficulties.

It is recommended to grip the ratchet in the part closest to the connection and to maintain a light and constant pressure with one finger, to allow greater stability during tightening.

description	code	included in the following kits
Short driver with shank for right angle	EASYC4-EX230-CA	Premium One, Premium Kohno One, Premium Shelta
Long driver with shank for right angle	EASYL4-EX230-CA	Premium One, Premium Kohno One, Premium Shelta
Driver with connector for dynamometric key	EASY4-EX230-EX	Premium One, Premium Kohno One, Premium Shelta

Maintenance and care of Easy Insert drivers

The Easy Insert drivers are supplied prefitted with specific titanium O-rings.

Since they are mechanical components, the retainer rings are subject to wear over time and can lose their functionality.

The O-rings cannot be replaced, but it is necessary to replace the instrument. The Easy Inserts were tested to be good for 40 uses in the worst conditions of use.

This limit may however be subject to variations, depending on conditions of use.

It is however always recommended to check the correct functionality of Easy Insert drivers every time they are cleaned and sterilized. For this reason, and to allow the practitioner to become familiar with the use of Easy Insert drivers, the surgical kit contains an untreated non-sterile "test implant", which can be easily recognized because it is entirely anodized in blue.

Important warning

It is recommended to use the Easy Insert drivers with a torque between 50 Ncm and 70 Ncm. Thanks to tests performed on models, it has been observed that from 70 Ncm to 100 Ncm slight frictions between the instrument and the implant connection are possible, which can be avoided with a slight shaking movement of the Easy Insert in the connection. From 100 Ncm to 200 Ncm higher frictions are possible, which can be solved with a simple counter-rotation movement (at 40 Ncm) in order to remove the instrument from the connection. Moreover it is recommended to end the bone tapping phase using the dynamometric key with control lever TWL.

Drivers for fixation screws

All the drivers are made of stainless steel for surgical use. The design of the tip is studied to join a screw with internal hexagonal connection: the slightly conical coupling between the driver and the screw allows an appropriate retention when carrying the screw in the oral cavity. Drivers are available in different shank lengths, in order to facilitate the ergonomics depending on the patient anatomy. They are available also in the hand one-piece version, this means they are integral with the hand knob which allows the grip. **Regularly verify that this functionality have not been lost due to wear.**



Important warning

Excessive torques can damage the internal thread of the implant or of the sharp edges of the connecting screws and damage the thread of the DAT drivers, causing also severe intra-surgical and prosthetic complications. The recommended torque for the tightening of the different components are summarized in the following chart:

description	recommended torque
surgical cover screws, healing abutments	(manually) 8-10 Ncm
all prosthetic screws	20-25 Ncm
all prosthetic components screwed directly onto an implant	25-30 Ncm
transfer fixation screws	(manually) 8-10 Ncm

Given the importance of the tightening torque, it is recommended to use always the drivers with hexagonal connection, keeping always the exerted torque under control with the ratchet. To facilitate the joint of the screws or of the threaded sections of the prosthetic components, the screwing can be started with the hand drivers.

Digital surgical screwdrivers

The design of digital surgical screwdrivers makes them extremely practical for tightening surgical cover screws during surgery and when uncovering and handling healing abutments. They must not be used when working with definitive prostheses, as they do not allow tightening torque to be controlled.

description	code	included in the following kits
Screwdriver for surgical cover screws and fixation screws, digital, extra-short	HSMXS-20-DG	Premium One, Premium Kohno One, Premium Shelta
Screwdriver for surgical cover screws and fixation screws, digital, short	HSM-20-DG 12.30 21.00	Premium One, Premium Kohno One, Premium Shelta
Screwdriver for surgical cover screws and fixation screws, digital, long	HSML-20-DG 14.80 26.90	Premium One, Premium Kohno One, Premium Shelta

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 hex 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 hex connection.

Prosthesic screwdrivers

The screwdrivers with upper hexagonal connection have been designed to be used with the dynamometric ratchet with function of torque control. The kit contains short and long versions; an extra-long version is also available on request, necessary when the length of the hole for the screw to pass inside the posts is greater than 13.00 mm.

description	code	included in the following kits
Screwdriver for fixation screws, with hexagonal connector for ratchet or hand knob, short	HSM-20-EX <u>7.90</u> 13.90	Premium One, Premium Kohno One, Premium Shelta
Screwdriver for fixation screws, with hexagonal connector for ratchet or hand knob, long	HSML-20-EX	Premium One, Premium Kohno One, Premium Shelta
Screwdriver for fixation screws, with connector for dynamometric ratchet or digital connector, extra-long	HSMXL-20-EX	Not included in the surgical kit, available separately
Screwdriver, with right angle shank	HSM-20-CA 12.60 27.00	Optional instrument not included in the surgical kit, can be ordered for separate.
Screwdriver with right angle shank, extra short	HSMXS-20-CA HSMXS-20-CA 6.00 20.40	Not included in the surgical kit, available 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.

Important warning

Lever movements should be avoided as they increase the risk of breakage. Before tightening, make sure the hex 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 hex connection.

Other prosthesic screwdrivers

description	code	included in the following kits
Driver for ball attachments, with hexagonal connector for ratchet or hand knob	BASCC-EX	Not included in the surgical kit, available separately
Driver for straight P.A.D. abutments, with hexagonal connector for ratchet or hand knob	AVV2-ABUT	Not included in the surgical kit, available separately
Driver for screwing Locator abutments, with hexagonal connector for ratchet or hand knob	8926-SW	Not included in the surgical kit, available separately
Driver for screwing Locator abutment, with hexagonal connector for ratchet or hand knob	8927-SW	Not included in the surgical kit, available separately
Instrument for inserting, fitting and maintaining the titanium cap for CAPTIT-1 ball attachments	AVV-CAP-TIT-1	Not included in the surgical kit, available separately
Dynamic Abutment screwdriver 24 mm lenght	DSPDCLH-24	Not included in the surgical kit, available separately
Dynamic Abutment screwdriver 32 mm lenght	DSPDCLH-32	Not included in the surgical kit, available separately

Extraction tools

These are stainless steel instruments, indicated for removing implants already in position. It is recommended to use long and short drivers EXCLUSIVELY for removing the implants, and not for screwing them in.

description	code
Short driver to remove Premium One Implants	BC-EX230
Long driver to remove Premium One Implants	BL-EX230

Important warning

Since these drivers have a full hexagon, they may cause the deformation of the implant hexagon if used for screwing even from 40 Ncm, with the risk of influencing the whole subsequent phase of prosthetic rehabilitation. Moreover, also on account of the full hexagon, they get stuck much more easily in the implant hexagons, and often become very difficult to remove.

Adaptors and extensions

description	code	included in the following kits
Extension for drivers, screwdrivers and manual drivers, with hexagonal connector for ratchet	BPM-15	Premium One, Premium Kohno One, Premium Shelta
Extension for surgical drills	PROF-CAL3	Premium One, Premium Kohno One, Premium Shelta
Screwdriver for right angle instruments with hexagonal connector for ratchet, digital	B-AVV-CA3	Premium One, Premium Kohno One, Premium Shelta
Driver for right angle and manual instruments and instruments with hexagonal connection for ratchet	AVV-CA-DG-EX	Not included in the surgical kit, available separately
Hand knob for instruments with exagonal connection for torque-control ratchet	AVV3-MAN-DG	Premium One, Premium Kohno One, Premium Shelta

Important warning

The extension PROF-CAL3 must be used only together with the surgical drills. In case it is used with other instruments, it is essential to not exceed the torque value of 50 Ncm, to prevent deformations of the extension that could compromise its successive use.

Spare O-rings

descript	ion	code	included in the following kits
with hex	spare O-rings for all accessories agonal connection for metric key and ratchet		Not included in the surgical kit, available separately

X-ray templates

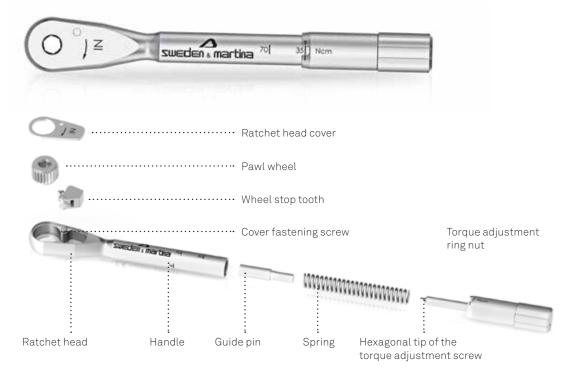
The surgical kits are supplied with x-ray templates for the graphic representation of all the implant measurements to allow choosing the most suitable implant diameters and lengths by means of radiographic or tomographic methods. The templates are available in three versions: in real dimensions, increased of 20% and 30%.

description	code	included in the following kits
X-ray template for Premium One implants Real dimensions		Premium One, Premium Kohno One
X-ray template for Premium One implants 20% increased dimensions		Premium One, Premium Kohno One
X-ray template for Premium One implants 30% increased dimensions		Premium One, Premium Kohno One

Torque control ratchet CRI5-KIT

A special ratchet (CRI5-KIT) is included in the surgical kits, with its own adjustment key, for quickly screwing the torque adjustment ring nut, and with gel lubricant for maintenance. The dynamometric key can be used with torque adjustment from 10 to 70 Ncm or in a locked position without torque control.

When using as a prosthetic ratchet for fastening the screws, refer to the torque values indicated for the fastening of the prostheses. The CRI5-KIT dynamometric key is a multipurpose instrument that can be dismantled, and it is sold as non-sterile.



Before each use, this instrument must be cleaned and sterilized according to the instructions on page 50. Adequate maintenance, carried out by scrupulously following all the steps indicated for dismantling and reassemblying of the torque wrench during cleaning operations is essential for its correct use and to prolong its shelf life. The personnel using this instrument must be suitably trained and must have read the instructions given in this manual before proceeding with any operations with it. After sterilization, the ratchet is ready for use. The instrument must be tested for correct assembly and correct funcionality every time it is used, whether for surgical and prosthetic procedures.

The torque is adjusted by aligning the marking of the desired torque in the circular opening of the handle. The "IN" arrow legible on the top of the head indicates the screwing position of the key. The "OUT" arrow legible on the top of the head indicates the loosening or unscrewing position. An unlimited torque position is obtained by positioning the torque adjustment device up to the line marked "R" on the handle of the ratchet body.



The ring nut may be screwed and unscrewed by hand, but to speed up these operations the kit also contains a driver that allows it to be turned quickly. Any deterioration of the screwing, insertion and torque mechanisms must be checked by personnel responsible for the use and maintenance of this dental instrument. The pieces of this mechanism are not interchangeable; one piece from one key cannot be replaced by a piece from another key as each ratchet is calibrated INDIVIDUALLY. If a piece is lost, please return the instrument to Sweden & Martina for repair. No components for assembling the ratchet can be sold individually. Failure to follow the instructions provided may cause problems of maintenance and stability of the prosthesis.



Important warning

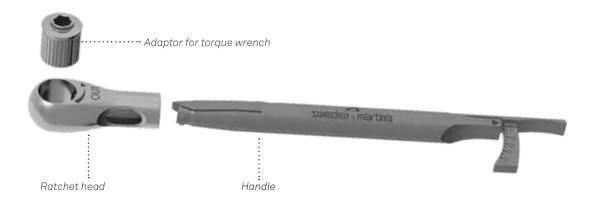
Torque is always adjusted by screwing in/unscrewing the sleeve at the end of the instrument handle. Torque must always be adjusted upwards, starting from a value lower than that required and tightening the adjustment sleeve in a clockwise direction until the desired value is reached. This means that if a torque value lower than that used previously is to be set, the adjustment sleeve must be slackened by two whole turns beneath the new torque value required, and then tightened again in a clockwise direction to the desired value.



In order to set a torque value, turn the ring nut in the clockwise direction until the wanted value. To turn down a torque value of work of the ratchet, first it is necessary to unscrew the ring nut in the anticlockwise direction until reaching a value inferior of the wanted one, then proceed with the clockwise direction screwing until the chosen torque.

Torque wrench with control lever TWL

The torque wrench can be used to indicate the value of the torque applied during the **surgical phases** of screwing and unscrewing, showing values from 10 to 90 Ncm. For this reason it is not recommended for prosthetic phases, which minimum torque starts from 8-10 Ncm. It is supplied complete with a specific adaptor that allows it to be used with surgical instruments with a hexagonal connection. The torque wrench with control lever TWL is a multipurpose instrument not included in the surgical kits. It can be can be dismantled, and it is sold as non-sterile.



Every time this instrument is used, it must first be cleaned and sterilized following the instructions on page 52.

Adequate maintenance, carried out by scrupulously following all the steps indicated for dismantling and reassemblying of the torque wrench during cleaning operations is essential for its correct use and to prolong its shelf life. The personnel using this instrument must be suitably trained and must have read the instructions given in this manual before proceeding with any operations with it.



After sterilization and before use, check that the first mark on the scale is aligned with the arrow. The instrument must be tested for correct assembly and correct funcionality every time it is used.

Important warning

The arm of the torque wrench must not move beyond the end of the scale, as this could lead to inaccurate torque readings.

The torque wrench can also be used as a fixed key, without using the scale, by using the entire handle as a lever. In this case, it must not exceed the torque value of 150 Ncm. The personnel responsible for the use and maintenance of this instrument must check it for possible signs of deterioration of the tightening, insertion and torque mechanisms. The single components of the torque wrench are not interchangeable, and it is not possible to use a component from one key to replace a component on another. If any component of the torque wrench is lost, always return the entire instrument to Sweden & Martina S.p.A. for all necessary repairs. Components for the assembly of the torque wrench with control lever are not sold individually. Failure to respect the instructions given may cause aesthetic problems and be damaging for the patient's health.

Cleaning, disinfection, sterilization and storage of the kit and of the surgical instruments

Attention! All the surgical instruments for dental implants are sold in NON-STERILE packs. Before use, they must be cleaned, disinfected and sterilized according to the following procedure validated by Sweden & Martina. These processes must be performed before use and before each subsequent reuse. Repetition of the processes described in this paragraph has minimal effect on the wear of these devices.

Instruments should always be checked before use to ensure they are in good working order. Any instruments showing signs of wear must be immediately replaced with new devices. It is particularly important to check that the drivers grip properly inside the engagement wells on the heads of the screws to be lifted and tightened with the same. Failure to follow these instructions may cause cross-infections and intraoperative complications.

a. Cleaning

Containers and transport to be used for washing: there are no special requirements. In case of automatic cleaning, use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralized water to prevent the formation of stains and marks. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually. When cleaning manually: use a suitable, neutral detergent and follow the manufacturer's user instructions. Brush the products with a soft-bristled brush under plenty of running water. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure plenty of running water passes through any holes. For drills with internal irrigation, use the special pins provided with the handpieces to ensure that the irrigation holes are completely clean and free of bone fragments or biological tissues. After rinsing, dry the devices thoroughly and place them inside suitable sterilization bags. Do not exceed 120°C when performing a drying cycle in a washing and disinfection appliance.

b. Sterilization

In a vacuum autoclave, proceeding as follows:

– Autoclave (Gravity - Displacement Cycles) Temperature of 121°C with a minimum autoclave cycle of 30 minutes and a drying cycle of 15 minutes.

– Autoclave (Dynamic - Air - Removal Cycles) Temperature of 132°C with a minimum autoclave cycle of 5 minutes and a drying cycle of 20 minutes.

c. Storage

After sterilization, the product must remain in the sterilization bags. The bags should only be opened immediately prior to reuse. In normal conditions, sterilization bags maintain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and resterilize in new bags before using them again. The storage time of products sterilized inside the bags should not exceed that recommended by the manufacturer of the bags. The product must be stored in a cool dry place, away from sunlight, water and sources of heat.

Cleaning, disinfection, sterilization and storage of the dynamometric key CRI5-KIT

The processes described below must be performed before use and before each subsequent operation. Repetition of the processes described in this paragraph has minimal effect on the wear of the device. The failure to follow these instructions may cause cross-infections. Containers and transport to be used for washing: there are no special requirements. As soon as possible after each use, the key must be placed in a container filled with a disinfecting/cleansing solution and covered with a cloth. This prevents the desiccation of the contaminating agents coming from the patient, and dissolves them, thus making cleaning easier and more effective. Completely disassemble the key as shown below:



Completely unscrew the torque adjustment screw and remove the spring inside the handle of the ratchet body. Do not separate the spring from the pin that acts as a stop. Use the hexagon tip at the bottom of the torque adjustment screw to unscrew and completely remove the connecting screw of the cover from the side marked "OUT". Exert a light pressure in order to avoid damaging the hexagon tip. After removing the cover, pull out the two components contained inside the ratchet head: the toothed pawl wheel and wheel stop tooth.

In case of manual cleaning, clean the outer and inner surfaces of the instrument mechanically under hot water with a soft bristled brush. Inject hot water using a needleless syringe to wash the hard-to-access holes of the head and the area around the pawl wheel and wheel stop. If necessary, proceed in the same way for the inside of the handle and of the torque adjustment device. Use a suitable neutral detergent and follow the manufacturer's user instructions. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure the running water passes abundantly through the passages. In case of automated ultrasound cleaning: use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralized water to prevent the formation of stains and marks. During this cycle, avoid contact between the pieces because this causes the machined surfaces to deteriorate, and consequently, loss of precision of the torque measurement. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.

Observation: blood residues or other deposits reduce the efficacy of the sterilization process, which is why it is important to clean thoroughly. During cleaning, avoid sprays or jets of liquid and adopt adequate protections. Avoid contact between this instrument and other nickel-plated instruments.

The pieces must be reassembled prior to sterilization.

Dry the parts, lubricate the functional areas lightly and reassemble the key as shown in the figures. Too much lubrication may cause the surfaces of the instrument to resurface during sterilization. Use only the lubricant supplied.



After lubricating the parts shown in the fugure, insert the two elements of the ratchet head acording to the following sequence: the toothed pawl wheel and then the wheel stop tooth.



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



Once parts 2 and 3 have been lubricated and inserted in the head of the ratchet body, position the cover and turn the ratchet body from the "OUT". Tighten the screw with hexagon tip of the torque adjustment screw.



Lubricate the spring inside the ratchet handle as shown in the figure. Assemble the torque adjustment screw, making sure the instrument functions properly. Manually activate 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 \pm 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 storage of the torque wrench with control lever TWL

The processes described below must be performed before use and before each subsequent operation. Repetition of the processes described in this paragraph has minimal effect on the wear of the device. The failure to follow these instructions may cause cross-infections.

a. Cleaning

Containers and transport to be used for washing: there are no special requirements. As soon as possible after each use, the key must be placed in a container filled with a disinfecting/cleansing solution and covered with a cloth.

This prevents the desiccation of the contaminating agents coming from the patient, and dissolves them, thus making cleaning easier and more effective.

Completely disassemble the key as shown below:



Press the driver and remove it from the head of the torque wrench, then remove the head by pressing inside the hollow, and delicately pull it out. The three separate components are now ready for cleaning.

In case of manual cleaning, clean the outer and inner surfaces of the instrument mechanically under hot water with a soft bristled brush. Use a suitable neutral detergent and follow the manufacturer's user instructions. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure the running water passes abundantly through the passages.

In case of automated ultrasound cleaning: use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralized water to prevent the formation of stains and marks. During this cycle, avoid contact between the pieces because this causes the machined surfaces to deteriorate, and consequently, loss of precision of the torque measurement.

When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually. Observation: blood residues or other deposits reduce the efficacy of the sterilization process, which is why it is important to clean thoroughly. During cleaning, avoid sprays or jets of liquid

and adopt adequate protections. Avoid contact between this instrument and other nickel-plated instruments.

Components must be reassembled before sterilization.

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

This procedure is important in order to preserve the precision of the instrument within the following tolerances:



After cleaning, connect the torque wrench head to the body, pushing the components together and rotating them in opposite directions until a click is heard. Press the driver into the torque wrench until a click is heard. The arrow on the torque wrench head indicates the direction of operation.

Place the device in a suitable sterilization bag. Disassembly and reassembly operations must be carried out following the indications provided here.

b. Sterilization

- In a vacuum autoclave, proceeding as follows:
- Autoclave (Gravity Displacement Cycles) Temperature of 121°C with a minimum autoclave cycle of 30 minutes and a drying cycle of 15 minutes.
- Autoclave (Dynamic –Air Removal Cycles) Temperature of 132°C with exposition of 4 minutes and a minimum drying cycle of 20 minutes.

c. Storage

After sterilization, the product must remain in the sterilization bags. The bags should only be opened immediately prior to reuse. In normal conditions, sterilization bags maintain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and resterilize in new bags before using them again. The storage time of products sterilized inside the bags should not exceed that recommended by the manufacturer of the bags.

The product must be stored in a cool dry place, away from sunlight, water and sources of heat.

Shorty Drilling kit

A kit of drills and stops dedicated short implants of Sweden & Martina systems is available, like Premium One, Prama and Outlink2. Using Shorty drills allows all the available bone to be used for seating the implant since they do not make any overpreparation of the implant site. In addition, the laser markings that report heights from 5.00 mm to 7.00 mm, together with the relative stops, allow safe and rapid preparation.

Compared to traditional drills, the overall length of Shorty drills is shorter (24.85 mm instead of 35.00 mm), making it possible to use them even in case of difficult-to-reach distal sectors or in case of patients with reduced oral opening.

In the following pages just the instruments used for the insertion of Premium One Shorty implants height 7.00 mm are explained.

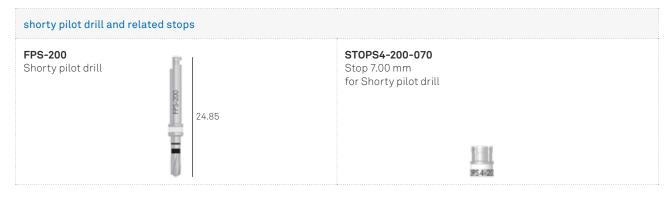


description	code
Drilling Kit for short implants	ZSHORTY-INT
Empty Drilling Kit Shorty tray	SHORTY-TRAY-INT
Kit with 5 spare silicon supports for surgical trays, for drills or instruments with right-angle shank	GROMMET-CA-1
Important warning	

The Shorty Drilling Kit contains only drills and two parallelism pins. It is not a complete surgical kit: to insert implants must be used all the other instruments included in the standard surgical kit (driver, ratchet, screwdrivers, etc.).

Instruments contained in the Shorty Drilling Kit

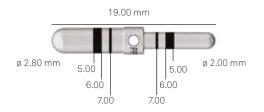
Pilot drill



Short guide drills



Parallelism pin





Final drills and related stops



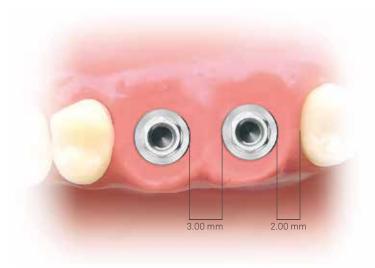


Important note: remember that the drills in the Shorty Drilling Kit do not over-prepare the surgical site. The working lengths include the portion related to the conical tip of the drill.

Preparation of the implant site

To obtain a three-dimensional view of the bone available, it is recommended to lift a mucoperiosteal flap. As already mentioned, pre-operative clinical and radiographic exams play an important role in determining the position and direction according to which the implants will be positioned; in this stage, a surgical stent will be helpful, acting as a guide during the marking of the cortical bone with the precision drill and in the drilling phase with the 2.00 mm pilot drill. As a rule a distance of 3.00 mm should be maintained between the perimeter of the implants, and at least 2.00 mm between implants and adjacent natural teeth. The numerous experimental and clinical studies carried out indicate that it is opportune to position the implants more in a lingual or a palatal direction to obtain the best aesthetic results, because this position helps preserve the level of the hard and soft tissues at the crown of the implant.

It is also essential to check that the thickness of the residual bone wall at buccal level is not less than 1.00 mm. The best aesthetic results are obtained with buccal walls of no less than 2.00 mm. If the thickness is smaller there is a high risk of bone reabsorption failure and exposure of the spires.



The following pages contain information on the drilling sequences for the adequate preparation of all implant types. These procedures come from clinical experience and recommendations taken from numerous studies and clinical protocols for implants of this type. However, it should be remembered that bone types with different densities require different surgical approaches, and the indications below cannot replace the necessary training and knowledge of the doctors, nor their personal experience, which can at times lead to different solutions and indications. The sequences that follow refer to specific bone types. In expansion techniques or in case of regenerative surgery, or when you want to increase the compaction in poor quality bone, the use of drills can be replaced with the relative osteotomes.

Remember to always use drills with stops correctly inserted. Remember that the drills always prepare a hole that is longer than the implant. For the overpreparation dimensions, refer to page 28. The preparations must be non-traumatic and as gradual as possible, and must be executed quickly and precisely. No overheating of the bone should be generated.

It should also be remembered to initially set the surgical micromotor with the correct torque, reduction and rotation values depending on the operation to be performed. In particular:

- the **drills** must be used at the speed indicated in each sequence, with the maximum torque and irrigated copiously with cold sterile physiological solution, better if cooled in a refrigerator;
- the **bone taps** must only be used when indicated in each procedure.

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 same, 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 problems and damage to the patient's health.

Sweden & Martina distributes **Impla6000** and **Impla7000**, a brushless micromotor for surgical and implant procedures. It perfectly combines reliability, high performances and easy to use procedures. Compact, practical with a basic design, they comes with all the requirements for maximum precision and safety.

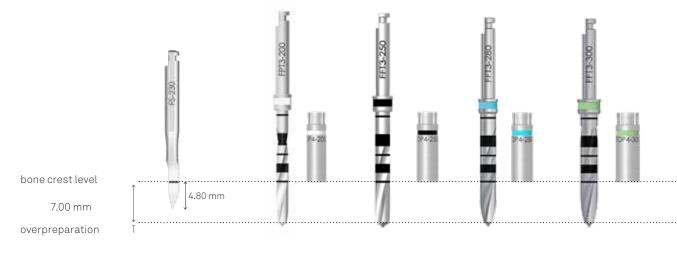




Surgical sequences for Premium One implants

Surgical sequence for Premium One implants height 7.00 mm with standard drills

The use of the stop is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility. Please remember that the drills overprepare the length for a measurement reported in the table on page 24 (for the pilot drill) and page 28 (for the final drills). The graphic sequence refers to ϕ 5.00 mm implants.



FS-230 FPT3-200-LXS

S FFT3-250-LXS

FFT3-280-LXS

FFT3-300-LXS

ø 4.25 mm	AS-ZT-425-070		use up to: marking 7.00 mm			
	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
6	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	osteotome*
	AS-ZT-500-070					
5.00 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	1,100 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	1,100 rpm	900 rpm	osteotome*	osteotome*	osteotome*

Important warning

The use of short implants in D3 and D4 bone is recommended only with a proper bone regeneration therapy, so that an ideal osseointegration can be guaranteed after a prompt healing time.

For surgeries in distal sectors and for limited oral opening reduced length drills are available, to be used without stops. For details see pg. 30.

* All the osteotomes have to be used at the reference notch of the implant to insert. For further details please see pg. 35



FFT3-340-LXS FG-330/425XS FFT3-425-LXS See chart below EASYC4-EX230-CA

use up to: marking 7.00 mm	use up to half of the last step	use up to: marking 7.00 mm	50 Ncm max	50 Ncm max
900 rpm	-	-	A-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
osteotome*	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
1,100 rpm	1,100 rpm	900 rpm	A-MS-500 (20 rpm)	20 rpm
1,100 rpm	1,100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
osteotome*	osteotome*	osteotome*	osteotome*	20 rpm

Important warning

For the preparation of a 7.00mm site the intermediate drill must be used only up to the middle of the larger step to guarantee the guide for the 2.80mm drill, and not up to the laser mark, since it is placed at 8.50mm.

Surgical sequence for Premium One implants height 7.00 mm with Shorty drills

The use of the stop is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility. The graphic sequence refers to Ø 5.00 mm implants.



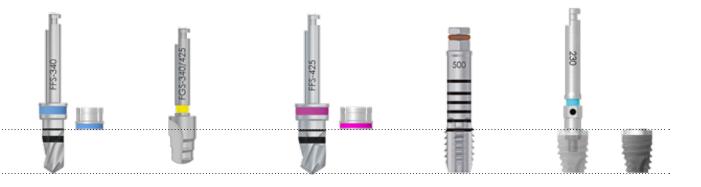
FFS-300

FS-230 FPS-200 FGS-200/300

	AS-ZT-425-070	-425-070 use up to: marking use up to hal 7.00 mm last step		use up to half of the last step	use up to: marking 7.00 mm
2 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
4.2	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	-	-	-	-
	BONE D4	-	-	-	-
	AS-ZT-500-070				
mm (BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
5.00	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
	DONEDZ	1,100101	, Is		
ø 5.	BONE D3	-	-	-	-

Important warning

The use of short implants in D3 and D4 bone is recommended only with a proper bone regeneration therapy, so that an ideal osseointegration can be guaranteed after an appropriate healing time.



FFS-340 FGS-340/425 FFS-425 See chart below EASYC4-EX230-CA

use up to: marking 7.00 mm	use up to half of the last step	use up to: marking 7.00 mm	50 Ncm max	50 Ncm max
1,100 rpm	-	-	A-MS-425 (20 rpm)	20 rpm
1,100 rpm	-	-	20 rpm	20 rpm
-	-	-	-	-
-	-	-	-	-
			50 Ncm max	50 Ncm max
1,100 rpm	1,100 rpm	900 rpm	A-MS-500 (20 rpm)	20 rpm
1,100 rpm	1,100 rpm	900 rpm	20 rpm	20 rpm
-	-	-	-	-
-	-	-	-	-

Surgical sequence for Premium One implants height 8.50 mm

The use of the stop is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility. Please remember that the drills overprepare the length for a measurement reported in the table on page 24 (for the pilot drill) and page 28 (for the final drills). The graphic sequence refers to Ø 5.00 mm implants.



FS-230 FPT3-200-LXS FFT3

FFT3-250-LXS

FFT3-280-LXS

FFT3-300-LXS

ε	A-ZT-330-085		use up to: marking 8.50 mm			
30 mn	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm	-
3.3	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm	-
154	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	-
	BONE D4	-	-	-	-	-
_	A-ZT-380-085					
80 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm
ι Έ	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm
8	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	osteotome*
_	A-ZT-425-085					
5 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
4.2	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	osteotome*
c	A-ZT-500-085					
u m n	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
5.00	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
8	BONE D3	1,100 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	1,100 rpm	900 rpm	osteotome*	osteotome*	osteotome*

For surgeries in distal sectors and for limited oral openingreduced length drills are available, to be used without stops. For details see pg. 30.



FFT3-340-LXS

FG-330/425XS

FFT3-425-LXS

See chart below

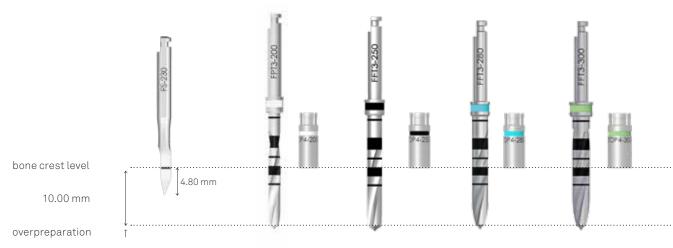
EASYC4-EX230-CA

use up to: marking 8.50 mm	use up to: marking 8.50 mm	use up to: marking 8.50 mm	50 Ncm max	50 Ncm max
-	-	-	A-MS-330 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	-
			50 Ncm max	50 Ncm max
-	-	-	A-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
900 rpm	-	-	A-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
osteotome*	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
1,100 rpm	1,100 rpm	900 rpm	A-MS-500 (20 rpm)	20 rpm
1,100 rpm	1,100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
osteotome*	osteotome*	osteotome*	-	20 rpm

* All the osteotomes have to be used at the reference notch of the implant to insert. For further details please see pg. 35

Surgical sequence for Premium One implants height 10.00 mm

The use of the stop is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility. Please remember that the drills overprepare the length for a measurement reported in the table on page 24 (for the pilot drill) and page 28 (for the final drills). The graphic sequence refers to Ø 5.00 mm implants.



FS-230 FPT3-200-LXS

FFT3-250-LXS

FFT3-280-LXS

FFT3-300-LXS

6	A-ZT-330-100		use up to: marking 10.00 mm			
3.30 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm	-
ø 3.3(BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm	-
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	-
	BONE D4	-	-	-	-	-
_	A-ZT-380-100					
3.80 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	osteotome*
	AS-ZT-425-100					
4.25 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
4.25	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	osteotome*
_	AS-ZT-500-100					
mm C	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
5.00	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	1,100 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	1,100 rpm	900 rpm	osteotome*	osteotome*	osteotome*

For surgeries in distal sectors and for limited oral openingreduced length drills are available, to be used without stops. For details see pg. 30.



FFT3-340-LXS

FG-330/425XS

FFT3-425-LXS

See chart below

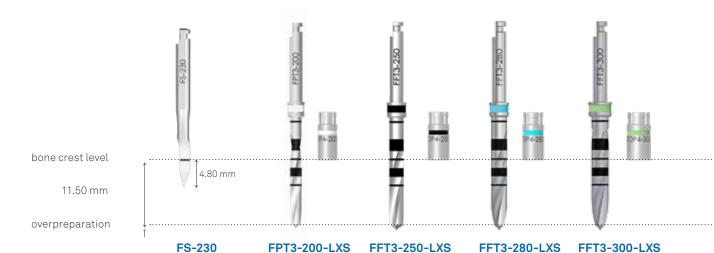
EASYC4-EX230-CA

use up to: marking 10.00 mm	use up to: marking 10.00 mm	use up to: marking 10.00 mm	50 Ncm max	50 Ncm max
-	-	-	A-MS-330 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	_	_	-	-
			50 Ncm max	50 Ncm max
-	-	-	A-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
900 rpm	-	-	A-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
osteotome*	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
1,100 rpm	1,100 rpm	900 rpm	A-MS-500 (20 rpm)	20 rpm
1,100 rpm	1,100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
osteotome*	osteotome*	osteotome*	-	20 rpm

* All the osteotomes have to be used at the reference notch of the implant to insert. For further details please see pg. 35

Surgical sequence for Premium One implants height 11.50 mm

The use of the stop is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility. Please remember that the drills overprepare the length for a measurement reported in the table on page 24 (for the pilot drill) and page 28 (for the final drills). The graphic sequence refers to ϕ 5.00 mm implants.



A-ZT-330-115 use up to: use up to: use up to: use up to: marking 11.50 mm marking 11.50 mm marking 11.50 mm marking 11.50 mm ø 3.30 mm BONE D1 1,100 rpm 1,100 rpm 1,100 rpm 900 rpm BONE D2 1,100 rpm 1,100 rpm 1,100 rpm 900 rpm _ BONE D3 900 rpm 900 rpm 900 rpm 900 rpm _ BONE D4 A-ZT-380-115 ø 3.80 mm BONE D1 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm 900 rpm BONE D2 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm 900 rpm BONE D3 900 rpm 900 rpm 900 rpm 900 rpm 900 rpm BONE D4 900 rpm 900 rpm osteotome* osteotome* osteotome* AS-ZT-425-115 ø 4.25 mm BONE D1 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm BONE D2 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm BONE D3 900 rpm 900 rpm 900 rpm 900 rpm 900 rpm BONE D4 900 rpm 900 rpm osteotome* osteotome* osteotome* AS-ZT-500-115 ø 5.00 mm BONE D1 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm BONE D2 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm 1,100 rpm BONE D3 1,100 rpm 900 rpm 900 rpm 900 rpm 900 rpm BONE D4 1,100 rpm 900 rpm osteotome* osteotome* osteotome*

For surgeries in distal sectors and for limited oral openingreduced length drills are available, to be used without stops. For details see pg. 30.

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FFT3-340-LXS

FG-330/425XS

FFT3-425-LXS

See chart below

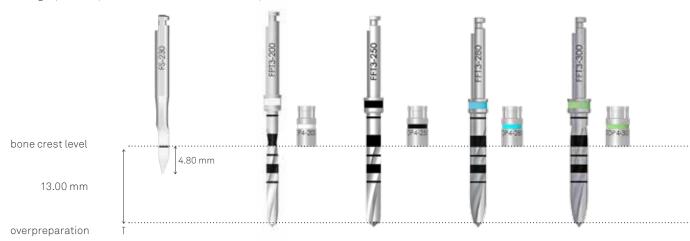
EASYC4-EX230-CA

use up to: marking 11.50 mm	use up to: marking 10.00 mm	use up to: marking 11.50 mm	50 Ncm max	50 Ncm max
-	-	-	A-MS-330 (20 rpm)	20 rpm
-	_	_	-	20 rpm
-	-	-	-	20 rpm
-	=	=	-	-
			50 Ncm max	50 Ncm max
-	-	-	A-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	_	_	-	20 rpm
			50 Ncm max	50 Ncm max
900 rpm	-	-	A-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
osteotome*	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
1,100 rpm	1,100 rpm	900 rpm	A-MS-500 (20 rpm)	20 rpm
1,100 rpm	1,100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
osteotome*	osteotome*	osteotome*	-	20 rpm

* All the osteotomes have to be used at the reference notch of the implant to insert. For further details please see pg. 35

Surgical sequence for Premium One implants height 13.00 mm

The use of the stop is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility. Please remember that the drills overprepare the length for a measurement reported in the table on page 24 (for the pilot drill) and page 28 (for the final drills). The graphic sequence refers to Ø 5.00 mm implants.



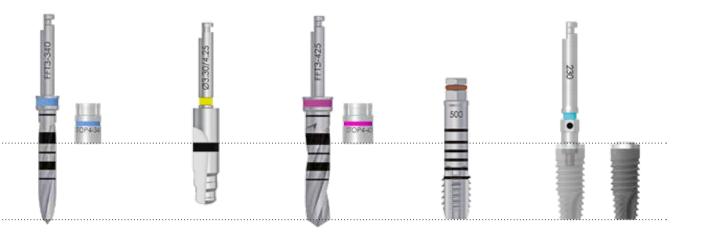
FS-230 FPT3-200-LXS FFT3-250-LXS

FFT3-280-LXS

FFT3-300-LXS

6	A-ZT-330-130		use up to: marking 13.00 mm			
3.30 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm	-
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm	-
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	-
	BONE D4	-	-	-	-	-
	A-ZT-380-130					
3.80 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	osteotome*
	AS-ZT-425-130					
4.25 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	osteotome*
	AS-ZT-500-130					
5.00 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	1,100 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	1,100 rpm	900 rpm	osteotome*	osteotome*	osteotome*

For surgeries in distal sectors and for limited oral openingreduced length drills are available, to be used without stops. For details see pg. 30.



FFT3-340-LXS

FG-330/425XS

FFT3-425-LXS

See

See chart below EASYC

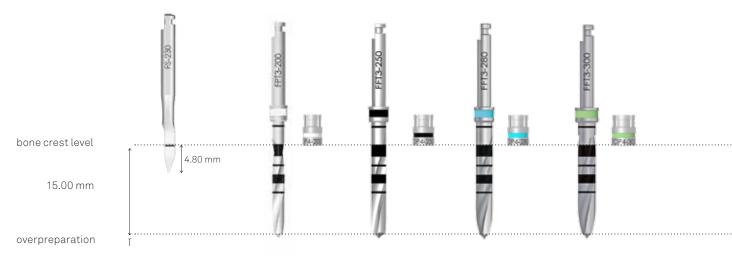
EASYC4-EX230-CA

use up to: marking 13.00 mm	use up to: marking 10.00 mm	use up to: marking 13.00 mm	50 Ncm max	50 Ncm max
-	-	-	A-MS-330 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	-
			50 Ncm max	50 Ncm max
-	-	-	A-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
900 rpm	-	-	A-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
osteotome*	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
1,100 rpm	1,100 rpm	900 rpm	A-MS-500 (20 rpm)	20 rpm
1,100 rpm	1,100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
osteotome*	osteotome*	osteotome*	-	20 rpm

* All the osteotomes have to be used at the reference notch of the implant to insert. For further details please see pg. 35

Surgical sequence for Premium One implants height 15.00 mm

The use of the stop is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility. Please remember that the drills overprepare the length for a measurement reported in the table on page 24 (for the pilot drill) and page 28 (for the final drills). The graphic sequence refers to Ø 5.00 mm implants.



FS-230 FPT3-200-LXS FFT3-

FFT3-250-LXS

FFT3-280-LXS

FFT3-300-LXS

- -	A-ZT-330-150		use up to: marking 15.00 mm			
3.30 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm	-
ø 3.3(BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm	-
8	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	-
	BONE D4	-	-	-	-	-
	A-ZT-380-150					
3.80 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	900 rpm
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	osteotome*
_	AS-ZT-425-150					
ø 4.25 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
4.25	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
19	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	osteotome*
c	AS-ZT-500-150					
5.00 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	1,100 rpm	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	1,100 rpm	900 rpm	osteotome*	osteotome*	osteotome*

For surgeries in distal sectors and for limited oral openingreduced length drills are available, to be used without stops. For details see pg. 30.



FFT3-340-LXS

FG-330/425XS

FFT3-425-LXS

See chart below

EASYC4-EX230-CA

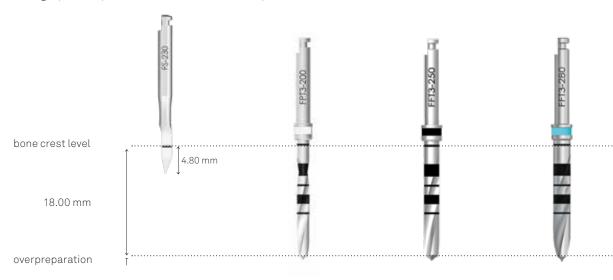
use up to: marking 15.00 mm	use up to: marking 10.00 mm	use up to: marking 15.00 mm	50 Ncm max	50 Ncm max
-	-	-	A-MS-330 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	-
			50 Ncm max	50 Ncm max
-	-	-	A-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
900 rpm	-	-	A-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
osteotome*	-	-	-	20 rpm
			50 Ncm max	50 Ncm max
1,100 rpm	1,100 rpm	900 rpm	A-MS-500 (20 rpm)	20 rpm
1,100 rpm	1,100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
osteotome*	osteotome*	osteotome*	-	20 rpm

* All the osteotomes have to be used at the reference notch of the implant to insert. For further details please see pg. 35

Surgical sequence for Premium One implants height 18.00 mm

FS-230

The use of the stop is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility. Please remember that the drills overprepare the length for a measurement reported in the table on page 24 (for the pilot drill) and page 28 (for the final drills). The graphic sequence refers to ø 5.00 mm implants.



FPT3-200-LXS

FFT3-250-LXS

FFT3-280-LXS

_	A-ZT-380-180		use up to: marking 18.00 mm	use up to: marking 18.00 mm	use up to: marking 18.00 mm
nm C	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
3.80	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*
	AS-ZT-425-180				
mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
4.25	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm
0	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*

For surgeries in distal sectors and for limited oral openingreduced length drills are available, to be used without stops. For details see pg. 30.

* All the osteotomes have to be used at the reference notch of the implant to insert. For further details please



FFT3-300-LXS

FFT3-340-LXS

See chart below

EASYC4-EX230-CA

use up to: marking 18.00 mm	use up to: marking 18.00 mm	50 Ncm max	50 Ncm max
900 rpm	-	A-MS-380 (20 rpm)	20 rpm
900 rpm	-	-	20 rpm
900 rpm	-	-	20 rpm
osteotome*	-	-	20 rpm
		50 Ncm max	50 No
		JUNCHI MAX	50 Ncm max
1,100 rpm	900 rpm	A-MS-425 (20 rpm)	20 rpm
1,100 rpm 1,100 rpm	900 rpm 900 rpm		
L			20 rpm

Important warning

The use of stops in implants with length 18.00 mm supported with existing drill stops, since the end of the working part of the cylindrical drills already corresponds to 18.00 mm. So in this case the use of the depth stop is not necessary.

Insertion of the implant

1

Use the patient label inside the pack for the patient's medical file, and apply it to the Dental Card. This will make it easier to record the patient's treatment plan and will keep a trace of the product batch used.



Important note: on the 4.25 and 5.00 implants packs there is a Premium One brand to differentiate them from the previous version, which connection was different. 3.30 and 3.80 implants do not show the same brand because they did not change.

2 Open the blister pack and place the vial inside it on a sterile surface (e.g. on a disposable towel or a sterile cloth) next to the operating area.

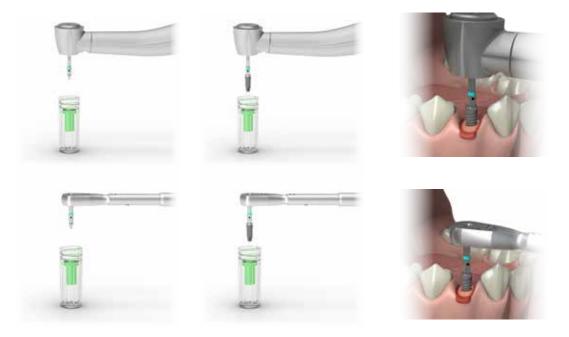


3 Immediately before the insertion into the oral cavity, remove the blue cap of the vial, making sure not to remove the transparent cap containing the surgical cover screw. The implant holding cylinder inside the vial and the surgical cover screw are coloured according to a colour code that allows the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



Standard procedure

When the vial is opened, the implant is exposed with the connection ready to be engaged. The implant can be picked up with the Easy Insert driver and then screwed mechanically in situ with the aid of a suitable surgical micromotor with torque control set at a insertion speed of 20 rpm and a maximum torque of 70 Ncm or manually with a compatible dynamometirc key. The driver has been tested up to 70 Ncm without showing signs of deformations or failures. Both mechanical and manual instruments with torque control must be calibrated regularly using a suitable calibration device.



After implant insertion

Healing times

It is essential to respect the healing times recommended in implant surgery, and periodically checking the progress of osseointegration with x-rays. The preliminary healing times of an implant are influenced by the quality of the receiving bone. In the case of immediate load, consider the warnings reported on pages 6-7. If deferred loading is chosen, temporary mobile prostheses must be used prudently, with a correct distribution of their load, to reduce discomfort during the biological times necessary for osseointegration.

After healing is completed, the surgical cover screws of the implants must be removed. If the right angle driver is used, the surgical micromotor must be set with the following parameters: 20 rpm and torque 10 Ncm. Subsequently, depending on the protocol adopted, tissue profiles must be adapted using a suitable temporary fitting or healing abutments. It is recommended to secure the healing abutments manually or with a torque no greater than 10 Ncm.

Intraoperative removal of implants if necessary

If a previously inserted implant needs to be removed, this can be done by directly engaging the hexagonal driver connection of the implant.

Accurately clean away blood and any other residues produced during insertion from the implant socket by irrigating the site.



Take the BC-EX230 or BL-EX230 driver not included in the surgical kit and insert the hexagonal tip of the driver inside the implant connection, being very careful that the instrument is on-axis with the implant and that it completely and closely engages the internal hexagon.



Block the head of the CRI5-KIT ratchet or of the TWL key and connect it with the hexagonal tip of the driver making sure that the laser-etched arrow on the ratchet head indicates an anticlockwise direction, and move it in this direction while keeping the driver/ratchet assembly onaxis with the index finger.

It is recommended to apply a higher torque than the one applied during the insertion phase.

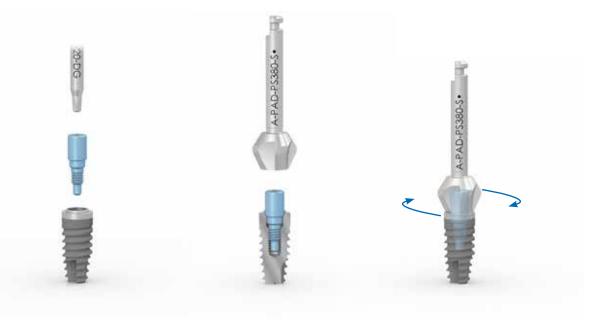
Once it has been unscrewed pick up the removed implant using sterile forceps.





The use of bone profilers for the insertion of P.A.D. abutments

The bone profilers can help levelling very irregular bone crests, particularly when using P.A.D. angled abutments. The bone profilers have to be used only jointly with the guide cylinder, that assures stability and allows their operation without damaging the implant connection in any way. For a correct use, firstly the guide cylinder has to be screwed to the implant with any of the screwdrivers at pg. 41-42, then the bone profiler can engage the guide cylinder. Bone profilers are available both in a wide version and in a narrow one.



The wide version of the bone profiler is used for P.A.D. abutments with a transgingival height of 3.00 mm with an angle of 17° or 30°. The image shows the preparation of the bone for the use of a P.A.D. inclined at 17° with a transgingival height of 3.00 mm.



The narrow version of the bone profiler is used for P.A.D. abutments with a transgingival height of 5.00 mm with an angle of 17° or 30°. The image shows the preparation of the bone for the use of a P.A.D. inclined at 30° with a transgingival height of 5.00 mm.



Maintenance of the prosthesis

Some implant restoration-related complications are reported in the literature. These complications may lead to a loss of osseointegration and implant failure. Correct maintenance by the patient, satisfactory home dental hygiene and regular sessions with a professional hygienist increase the device service life. Complications such as the unscrewing of the screws securing the prostheses to implants or bone reabsorption causing the loss of the gingival support surface in the case of removable prostheses can be easily prevented with regular check-ups. If post or prostheses screws need to be tightened, this must be done by the practitioner, using suitable instruments with control over tightening torque.

The calibration of these instrument should be checked regularly. In the event of complications of this kind, patients should contact their practitioner as soon as possible, so that the necessary work to restore correct orthodontic functionality can be carried out. Delays in consulting the practitioner may lead firstly to the fracture of the connection screw or of the prosthesis, and secondly to the loss of the implant, thereby compromising rehabilitation results. Practitioners must make this clear to their patients. Complications may be biological (impaired integration) or mechanical (fracture of a component due to excessive loads). If there are no complications, duration depends on the devices and the whole restoration system depends on mechanical resistance in relation to the fatigue accumulated by the device.

Responsibility for defective products and warranty terms

Optimal patient care and attention to their needs are necessary conditions for the success of implantation procedures and, therefore, patients must be carefully selected and informed of the associated risks and obligations connected with the treatment and encouraged to cooperate with the dentist in the interests of the success of the same treatment. The patient must, therefore, maintain good hygiene, which should be confirmed during check-up appointments, guaranteed and recorded and the practitioners instructions and orders shall be observed. The warranty only covers manufacturing defects as long as the faulty piece is identified by the article code and batch number and returned within the validity period of the warranty. The warranty terms are available on the website www.sweden-martina.com.

Disposal

If removed from the oral cavity due to biological or mechanical failure, the implant fixtures must be disposed of as biological waste. The surgical instruments are made of small components, mostly metal. They may therefore be disposed of as metal wastes. If dirty, they must be disposed of as biological wastes. In general, the local regulations apply.

Composition of the materials

The materials used for manufacturing the surgical instruments illustrated in this manual were selected based on the properties indicated for their intended use according to directive 93/42, implemented in Italy with Law 46/97, Annex I – Essential Requirements, point 7.1.

Implants

The implants are made of Gr. 4 commercially pure titanium, in compliance with harmonized standards. Although very rare, titanium allergy is possible. Patients should therefore always be asked whether they have allergies of this type.

The characteristics of the Gr. 4 titanium used are listed below.

Grade 4 titanium (Cold worked)* ASTM F67-13, ISO 5832-2:2012

chemical composition	maximum allowed 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	a bilancio	-

* This technical information complies with the express specifications of the regulations in force on the use of Gr. 4 titanium in implantology:

- ASTM F67-13: Standard Specification for unalloyed titanium, for surgical implant applications.
- ISO 5832-2: 2012: Implants for surgery Metallic materials Part 2: Unalloyed titanium.

Important note: the use of **cold worked** Gr. 4 titanium bars for the production of Sweden & Martina implants allows the exploitation of mechanical characteristics higher than those required by applicable standards. Furthermore, the excellent results documented during **20 years of clinical experience** corroborate the choice of the coldworking production process and of **ZirTi surface** treatments, which express and enhance the raw material potential selected by Sweden & Martina.

Surgical instruments

Depending on the type of component, surgical instruments are made of:

- Gr. 5 titanium
- 1.4197 steel
- 1.4542 steel
- 1.4305 (AISI 630) steel
- 1.4108 (AISI 303) steel
- 1.4108 steel
- 1.4112 steel

Patients must be asked if they are allergic to any of the materials used.

Identification of the manufacturer

The manufacturer of Premium One implants and of the respective surgical instruments is:

Sweden & Martina

Via Veneto 10 - 35020 Due Carrare (Padua) - Italy Tel. +39 049.9124300 - Fax + 39 049.9124290 e-mail: info@sweden-martina.com www.sweden-martina.com

In accordance with Directive 93/42/EEC implemented in Italy with L.D. 46/97 of 26/03/97, Annex IX, Sweden & Martina identifies the risk class of these products as indicated in Table 01. Even though they can be used with all patients who have suitable therapeutic indications, dental implants and the respective surgical instruments must be used only by professional dentists or surgeons with the necessary qualifications and training.

Table 01 - Risk classes

device	directive 93/42/EEC	packing	rule Annex IX	risk class
Implant fixtures for dental use belonging to the Premium One implant system	Implantable devices intended for long-term use (over 30 days)	Single-use sterile pack, fixture complete with surgical cover screw	8	llb
Surgical cover screws	Implantable devices intended for long-term use (over 30 days)	Sold in packs complete with the respective fixtures or sold individually (single-use sterile pack)	8	llb
Complete surgical kits	Re-usable surgical instruments	Sold in NON-STERILE packs	6	lla
Radel instrument tray and X-ray templates	Non invasive medical devices	Sold in NON-STERILE packs	1	1
Surgical drills (precision, final, for distal use); extension for drills; stops for drills; drivers and screwdrivers intended for use with a micromotor	Re-usable invasive surgical instruments for temporary use (for less than 60 minutes at a time)	Sold in NON-STERILE packs	6	lla
Osteotomes/bone expanders; screwdrivers; manual and digital drivers, hand knob, depth gauges, parallelism pins and cylinders for stents	Re-usable invasive surgical instruments for temporary use (for less than 60 minutes at a time), not intended to be connected to an active medical device	Sold in NON-STERILE packs	6	1

Key to symbols used on the implant packs:

description	symbol
Caution! See instructions for use	\triangle
Batch number	LOT
Code	REF
Manufacturer	
Consult instructions for use	Ĩ
CE conformity mark for class IIa/IIb products	C € 0476
American federal law restricts this device to sale by or by order of a professional practitioner	Rx Only
Do not resterilize	STERIAZE
Single use product, do not reuse	\otimes
Do not use if the packaging is damaged	\otimes
Sterile device, sterilization by radiation	STERILE R
Expiry date	

Key to symbols used on surgical instrument packs:

description	symbol
Caution! See instructions for use	\triangle
Batch number	LOT
Code	REF
Manufacturer	
Consult instructions for use	i
CE conformity mark for class IIa/IIb products	C E 0476
CE conformity mark for class I products	CE
American federal law restricts this device to sale by or by order of a professional practitioner	Rx Only
NON-STERILE device	

Key to symbols used on prosthetic component packs:

description	simbolo
Caution! See instructions for use	\triangle
Batch number	LOT
Code	REF
Manufacturer	
Consult instructions for use	ĺĺ
CE conformity mark for class IIa/IIb products	C € 0476
CE conformity mark for class I products	CE
American federal law restricts this device to sale by or by order of a professional practitioner	Rx Only
Single use product, do not reuse	\otimes
NON-STERILE device	NON

THIS MANUAL WAS LAST UPDATED IN MARCH 2018.

The medical devices contained in this manual have been designed and manufactured in accordance with the most recent directives and harmonized standards applicable to the materials used, the production processes, the sterilization, the information supplied and the 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. They are conform to the QSR and 21 CFR part 820 and are approved by FDA.

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



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