Surgical Manual

SHELTA

sweden & martina
IMPLANTOLOGY

SURGICAL MANUAL CONTENTS

In implant-prosthetic rehabilitation with Shelta implants, exclusively original prosthetic components by Sweden & Martina must be used.
Use of non-original components limits the responsibility of Sweden & Martina S.p.A. and renders the product warranty void.
Suitable surgical instruments must be used to insert the fixtures surgically. These instruments are sold individually or in kits. It is recommended to use original surgical accessories manufactured by Sweden & Martina. Sweden & Martina declines all responsibility for use of any non-original instruments.
Shelta dental implants are implantable devices suitable for the rehabilitation of patients affected by **total or partial edentulism**. They are intended to be inserted surgically in the mandibular or maxillary bone. They can be inserted in different sites of the oral cavity with various techniques and then connected to the prosthesis at different times.

This manual contains the instructions for use of Shelta dental implants and of the respective surgical instruments.

Clinical indications for resorting to implantoprosthetic therapies

When assessing the patient, in addition to his/her eligibility as regards 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.

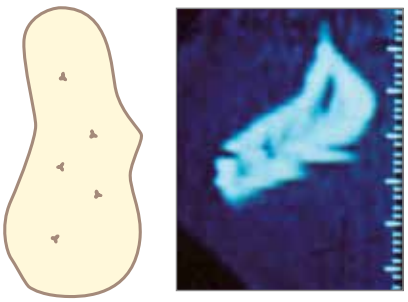
It is contraindicated to fit implants and implant restorations in patients with poor general or oral health, those who are unable to monitor their general conditions properly or those who have had organ transplants. Psychologically unstable patients, alcohol or drug abusers, and poorly motivated or uncooperative 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, anti-convulsant 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 peri-implant 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

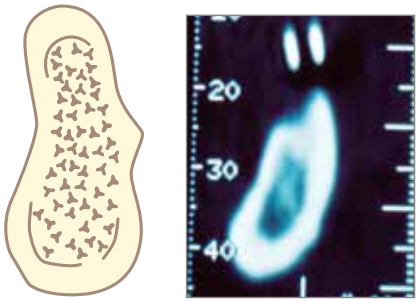
Situations that may occur after surgical procedures include temporary local swelling, oedema, haematoma, temporary sensitivity alterations, temporary masticatory limitations, post-surgical micro-haemorrhages in the following 12-24 hours. The patient may also experience pain, speech problems, gingivitis, 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 Schneider membrane, bone fractures, implant fractures, fractures of the over-structures, 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.

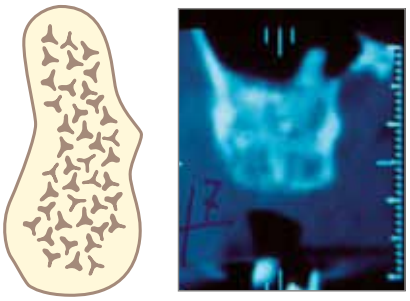
In addition to an oral examination, both clinical and with x-rays, it is recommended to take a T.C. scan of the interested area; once the x-rays and scans have been obtained, the specialist can identify the most suitable implant with the help of convenient transparent radiographic guides.
The pre-operative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



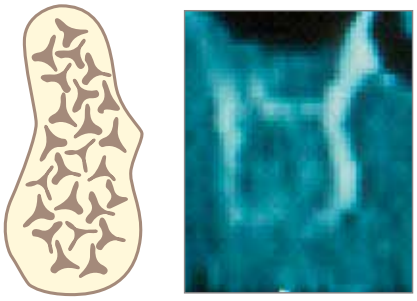
BONE D1: all cortical bone.



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



BONE D3: all bone marrow without crest cortical



BONE D4: all bone marrow with very poor mineralisation.

Dentalscan images by kind permission of Dr. Marco Csonka - Catania

General indications

Shelta implant fixtures mesh are long-term implantable medical devices. All the fixtures are sold in single-use sterile packs. The function of the fixtures is to replace missing dental roots. The fixtures have a connection in the crown part for receiving an implant post aimed at supporting a dental prosthesis.
In implant-prosthetic rehabilitation with Shelta implants, exclusively original prosthetic components by Sweden & Martina must be used.
Use of non-original components limits the responsibility of Sweden & Martina S.p.A. and renders the product warranty void.
The implants have a conical shape, they are screw shaped with an external thread and have a hexagonal internal connection for connecting the prosthetic components. Shelta 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 closing cover screws (also called, surgical screws). The surgical cover screws are also medical devices that can be implanted surgically. They are designed to remain in the oral cavity for more than 30 days.
The surgical cover screws can also be sold individually. In accordance with Directive 93/42/EEC adopted in Italy with L.D. 46/97 of 26 March 1997, Annex IX, Sweden & Martina declares to be the manufacturer of Shelta devices and identifies the risk classes shown in table 01 (see page 56). Normally, dental implants, even though they can be implanted in all patients who have the suitable therapeutic indications, must only be used by professional dentists or surgeons with the necessary qualifications and training.

Method of use

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

- **Two stage:** the first stage is "submerged" i.e. where the implant is inserted under the mucosa, and the connection well is covered with a surgical cover screw (or closing screw), which is then sutured. Then, after 2-6 months, the mucosa is reopened and the prosthesis is inserted;
- **One stage:** insertion of the implant, closure of the connection with a transgingival healing screw, instead of a surgical cover screw. Alternatively, in the 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 based on surgical protocols that must be considered according to the quantity and quality of the receiving bone, the implant, and the possible need for regenerative therapies. The "implantologist" or dental surgeon creates a site in the patient's bone (corresponding to the new tooth to be placed or replaced), by using a series of calibrated burs or suitable instruments such as bone expanders, bone compactors or similar instruments. The necessary conditions for the success of the implant are:

- the presence of a certain amount of bone;
- good periodontal (gingival) support;
- no bruxism (teeth grinding) or serious malocclusion;
- the presence of good occlusal balance (correct masticatory occlusal plane).

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.

Shelta 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.

The clinical indication for choosing the Shelta 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 Shelta implants. The implants passed the test. Fatigue tests are conducted according to the standards and evaluated further with finite element calculations.

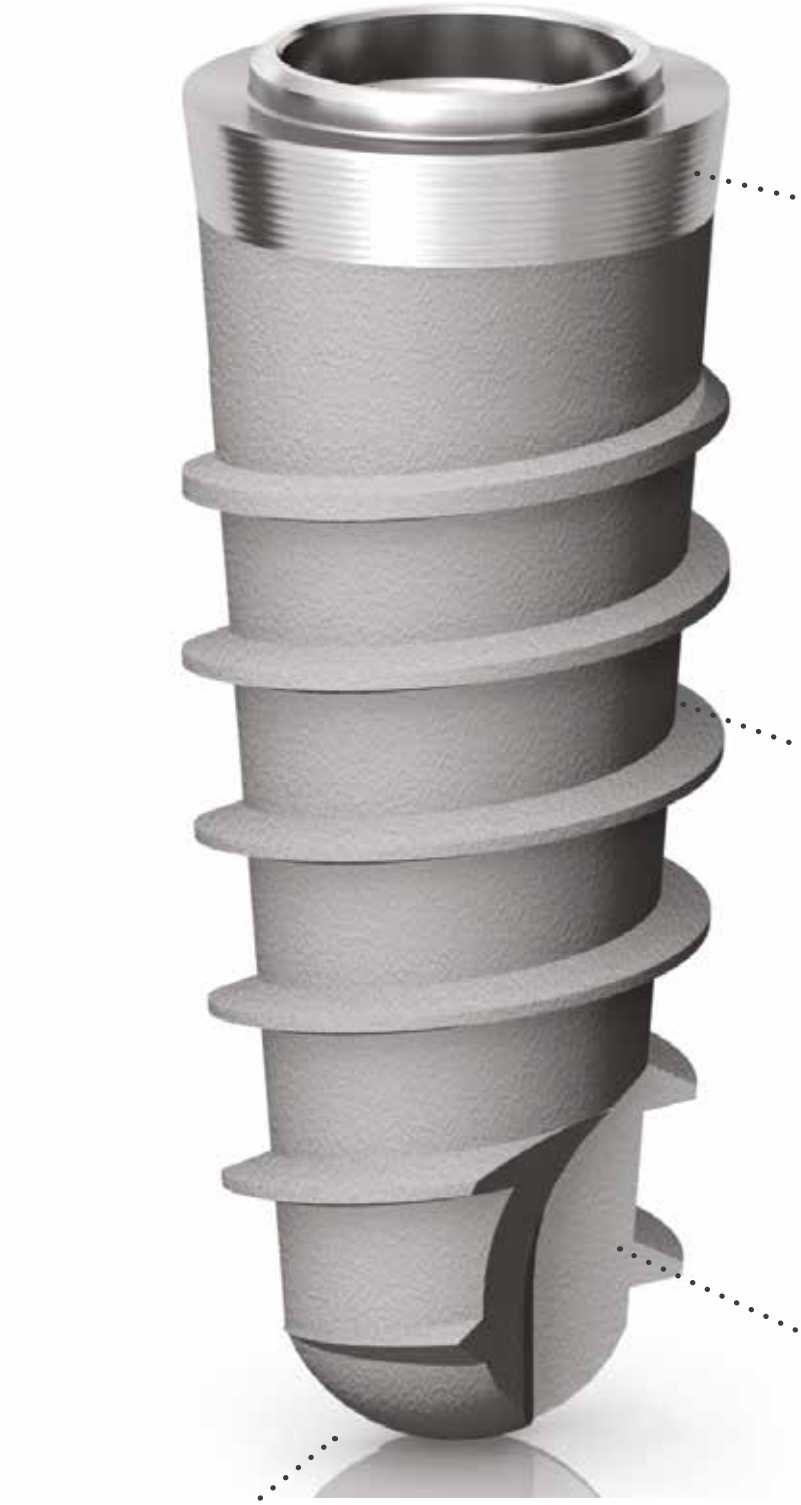
Key to the Shelta implant codes

The implant codes are so-called "mnemonic" codes, i.e. they allow easy identification of the piece. Below is a table showing how the mnemonic codes work using SH-ZT-380SL-115 as an example:

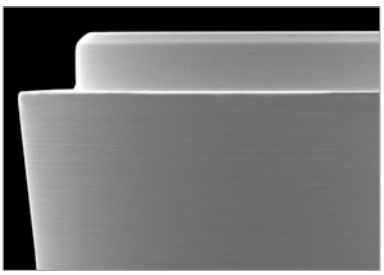
Type of implant SH-	Surface ZT-	Diameter 380	Thread SL-	Length 115
SH: Shelta Implant	ZT: ZirTi surface	380: 3.80 mm 425: 4.25 mm 500: 5.00 mm	SL: Wide Thread	085: 8.50 mm 100: 10.00 mm 115: 11.50 mm 130: 13.00 mm 150: 15.00 mm
		This is the size of the diameter of the implant connection	*If no specifications are available, it refers to a standard thread (that is a thread that maintains its geometry along the body of the implant)*	*Refers to the length of the implant*

All the measures in the catalogue are given in mm, unless indicated otherwise.

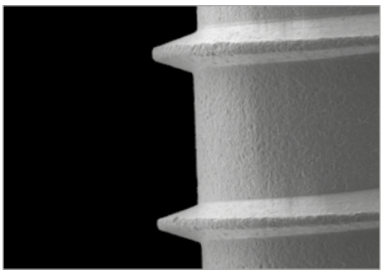
Shelta implants



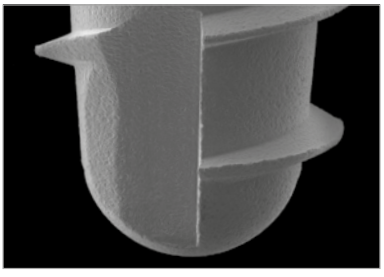
Shelta implants have a collar 0.35 mm high with the function of supporting the masticatory loads for prosthetic components; they also have a smooth neck 1.00 mm high.

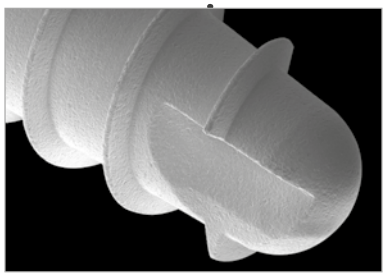


The thread of Shelta implants is characterised by a triangular profile, a pitch of 1.50 mm and a depth of 0.40 mm



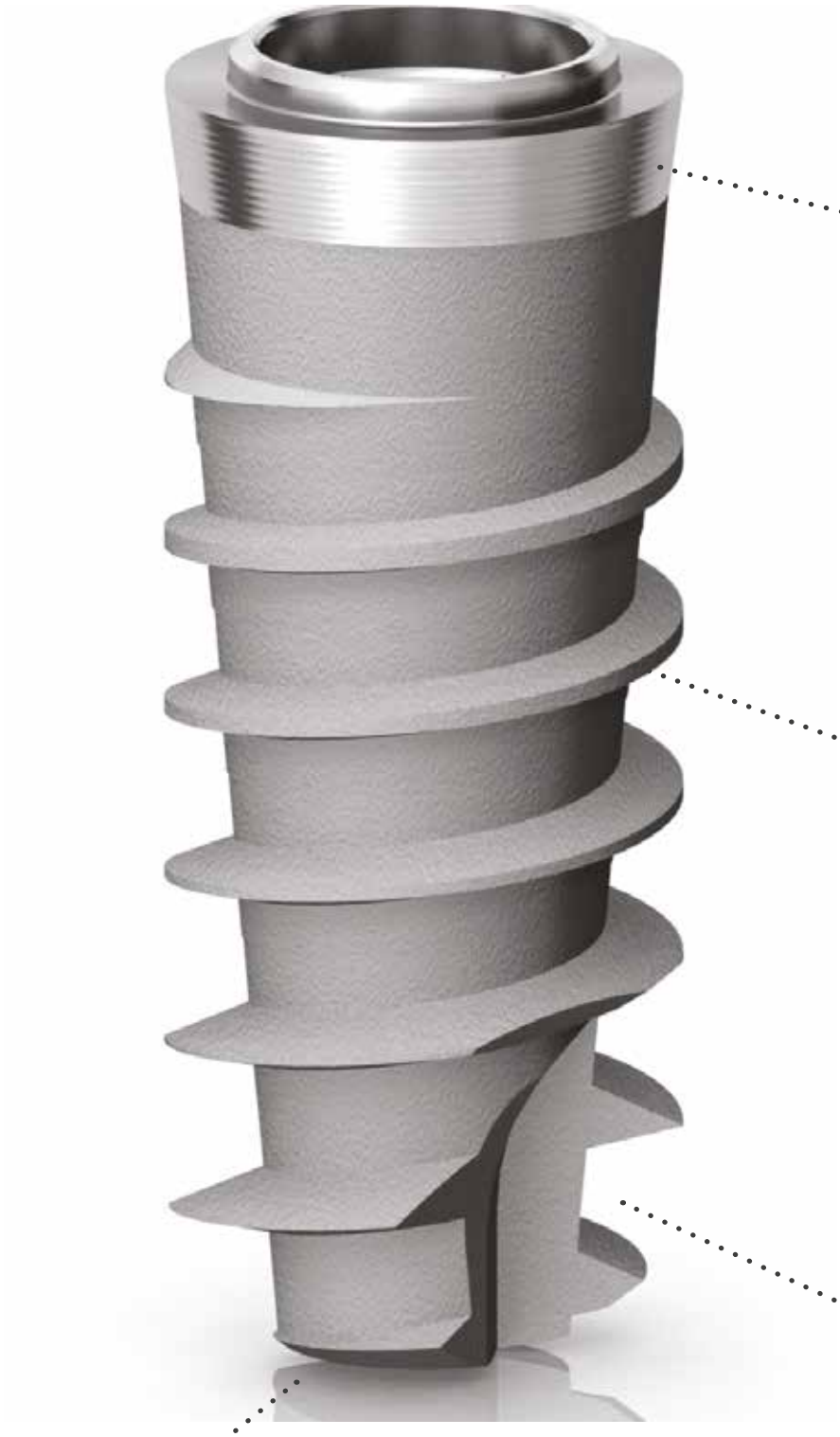
The thread of Shelta implants develops with the same geometry along the whole body of the implant.





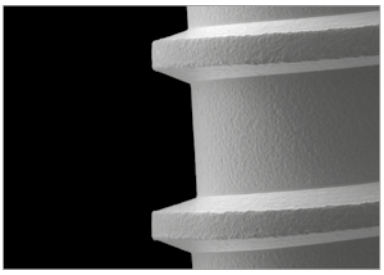
The apex of Shelta implants has two incisions that increase its penetration capacity and non-rotational property, useful for discharging the clot, a fundamental element for starting the osteogenesis cycle. The hemispherical apex makes Shelta implants ideal in sinus lift procedures.

Shelta SL implants (Wide Thread)

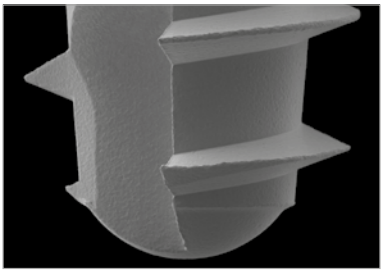


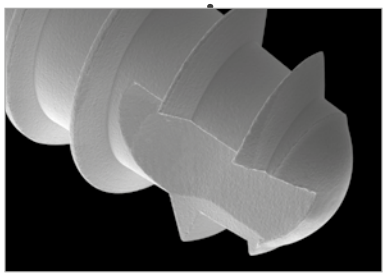
Shelta SL implants have the same prosthetic support collar and the same smooth neck as Shelta implants.

The thread of Shelta SL implants maintains a constant pitch of 1.50 mm, but the depth varies along the implant body.



The thread of Shelta SL implants develops keeping the maximum external profile constant. The result is a very pronounced and sharp apex.



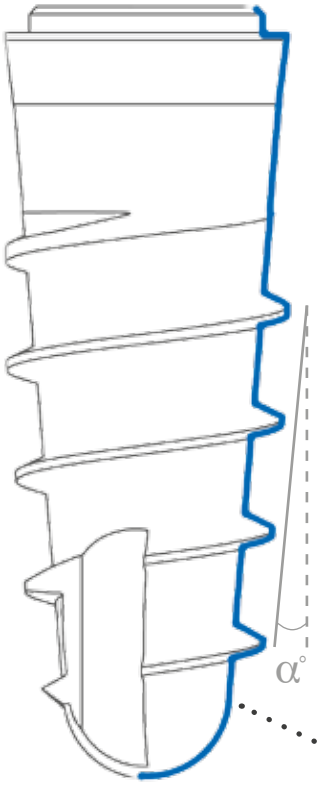


Also Shelta SL implants have a rounded apex, but the dimensions are reduced due to the more pronounced threading.

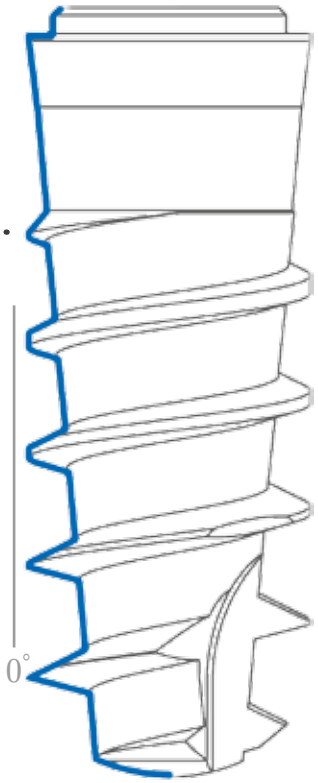
Choosing the thread

Shelta and Shelta SL implants differ in the morphology of the apical thread. These two possibilities allow the ideal morphology always to be available for achieving optimum primary stability depending on the surgical practice and on the clinical conditions of the individual case.

SHELTA



SHELTA SL



Shelta SL implants have a core with a conical geometric shape, though they maintain a constant cylindrical external diameter along the whole length of the implant.
This characteristics means that the threading at the apex is much more accentuated.
The resulting morphology is indicated in post-extraction surgery and in the case of low-density bone.

In **Shelta** implants both the core of the implant and the threading have a conical morphology. This type of implant is indicated where the bone volumes between the roots of the adjacent teeth do not allow the use of larger morphologies.
Furthermore, unlike Shelta SL implants, the apex is a complete hemisphere and the presence of a less aggressive thread makes them preferable in the case of sinus lift surgery.

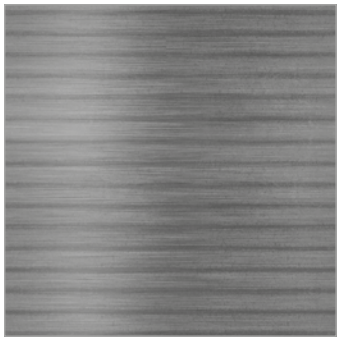
The crest of the thread of **Shelta SL** implants increases gradually in the coronal direction.
So in addition to the high cutting capacity of the most apical thread, there are wider coronal thread that ensure high stability.

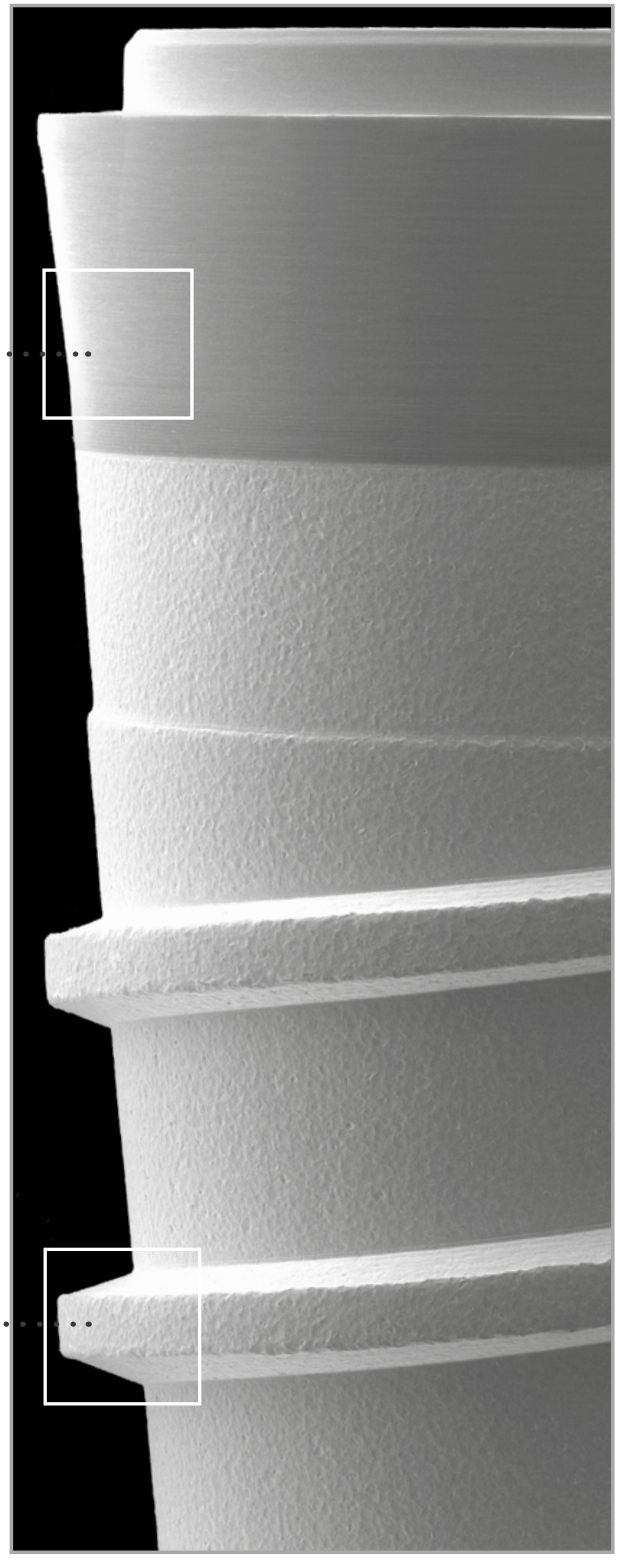
The crest of the thread of **Shelta** implants, on the other hand, is constant along the whole body of the fixture.

ZirTi Surface

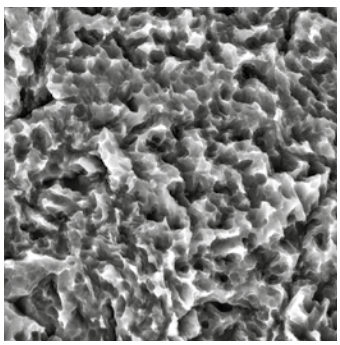
It has been widely demonstrated that the closer the roughness is to the size of the fibroblasts, the more influence it has on cell behaviour, causing the platelet activity to increase compared to a smooth surface, thus accelerating the repair and osseointegration processes: the roughness can guide the layout of the cells, alter their metabolism and proliferation, differentiate osteoblasts and modulate production of extra-cellular matrix. For **clinical findings** concerning Sweden & Martina surfaces refer to the paragraph in the bibliography (see from page 57) with the list of numerous *in-vitro* and *in-vivo* studies.

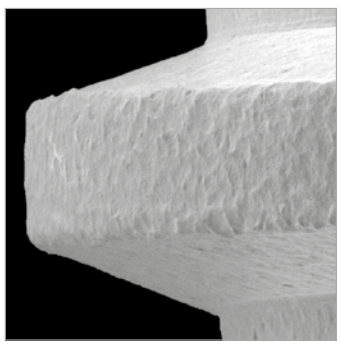
The **machined nek** allows the perfect quality control of the connection diameter in the production phase and prevents the accumulation of plaque in the area where it joins the post.





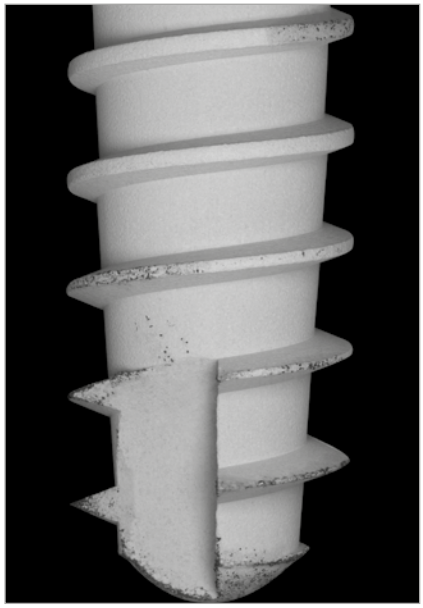
Shelta and Shelta SL implants are available with the ZirTi surface. The implant body is treated with appropriate subtraction techniques that give the surface the characteristic ZirTi morphology, able to significantly increase the bone-implant contact surface and ensure excellent primary stability. The ZirTi surface has shown to have a sub-layer that promotes cell regrowth, such as to adequately boost its differentiation and proliferation.



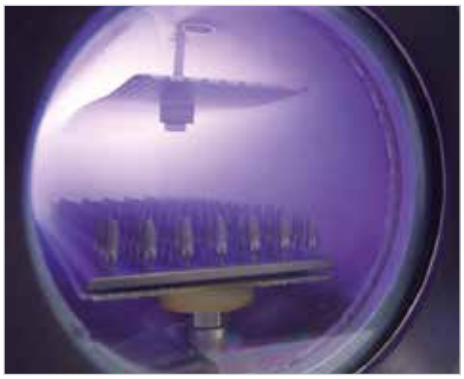


Cold plasma surface decontamination

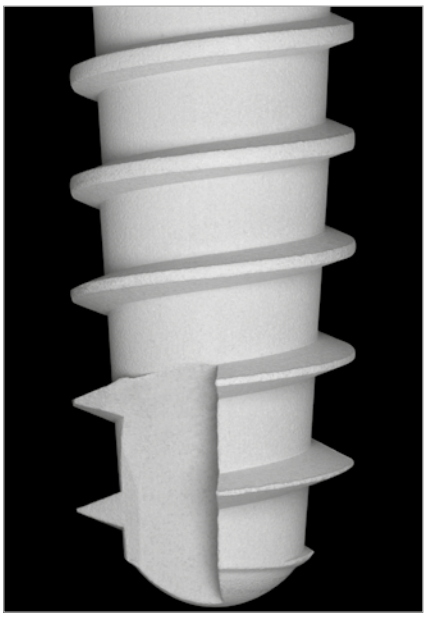
The better the processes of passivation, cleaning and decontamination of an implant surface, the greater the presence of pure titanium on its surface, which proportionally increases the possibilities of osseointegration.
At the end of the surface treatments, the implants are subjected to a careful cleaning and decontamination process by means of cold plasma triggered in argon after first being cleaned of the main processing residue with numerous washing cycles in specific solvents.
What is decontamination? It is the total removal of dirt and particle residue from the surface of the implants.
During the Argon treatment, the gas atoms are partially ionised, they acquire energy and "bombard" the surface of the fixture violently. This kind of "atomic sand-blasting" removes organic contaminants without leaving any traces or additional residuals.
All the fixtures are sold with the respective surgical cover screws. The surgical cover screws are also medical devices that can be implanted surgically. They are designed to remain in the oral cavity for more than 30 days.



Implant before the decontamination treatment



Working plasma reactor during surface decontamination of the implants



Implant after the decontamination treatment

As known, Argon is an inert gas that does not react with the titanium surfaces. The condition of surface decontamination is controlled regularly with randomised analyses of Bioburden residuals and a SEM visual examination on all the batches produced. This process activates the ionisation of the atoms on the surface of the titanium oxide which in turn increases the wettability of the fixture.

Implant packaging

The implants are packaged in PMMA vials in which they are held/housed in special titanium baskets that protect the surface of the fixture against possible recontaminations due to contact. All the materials comprising the packaging have been suitably tested to verify their suitability to sterilisation, preservation and medical use. All the fixtures are sold with the respective surgical cover screws, preassembled on practical mounters, secured to the connections with special screws. The surgical cover screws are medical devices that can be implanted surgically. They are designed to remain in the oral cavity for more than 30 days. The expiry date is indicated on the package. The sterile blister must be opened only at the moment of the operation. Before opening, make sure that the package is perfectly intact. Any damage could compromise the sterility of the implant and therefore the success of the operation. Implants that have already been used or are not sterile must never be reused. It is a single-use device: reuse is not allowed and may lead to loss of the implant and cross infections. There is a round label (sticker) on the bottom of the vial. This label indicates that it has been sterilised.
The packaging conforms to European standards.

The blister packs containing the implants are packed in cardboard boxes which also contain the labels for the patient records reporting the details for traceability of the product (code and batch number).

The vials are contained in a special PETG blister pack sealed by a Tyvek cover, which guarantees sterility of the product for 5 years. A label that changes colour is applied on the bottom of the vial. This label has the property of changing colour from orange to red during sterilisation. When an implant pack is opened, a red label is therefore proof that it has been sterilised.

Upon opening of the vial, the implants appear with the visible connection ready to be engaged by the drivers.

The surgical cover screw, supplied with every single implant, is housed in a special compartment in the top of a blue cap made of LDPE which closes the vial. In turn, a small transparent lid in PMMA closes the blue cap.

Sterilisation

Sterilisation is the total elimination of the residual microbial load present on the implant after the decontamination and packing process, it is carried out with the use of beta rays. The sterilisation procedures are carried out in accordance with the ISO 13485 and ISO 9001 quality standards. A beta ray sterilisation process was chosen because it has a variety of different advantages:

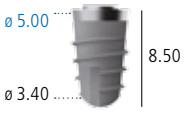
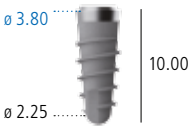
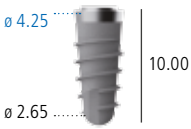
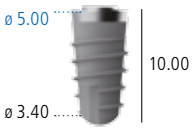
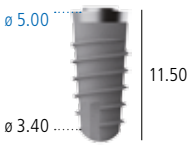
- the process occurs in a completely automatic way with computerised control of all the phases;
- the process is quick, reliable and extremely easy to repeat with safety and precision;
- the process is extremely eco-friendly, does not require the presence of radioactive sources and does not lead to the formation of toxic or radioactive products;
- beta rays are minimally invasive with regards to packaging due to the speed of the treatment. This guarantees preservation of the product's sterility over time (certified duration of 5 years).

IMPORTANT WARNING

It is recommended not to use the implants after the expiry date indicated on the pack. Use of the product after the expiry date may cause infections.

Shelta implants: the range

Shelta implants are characterised by tapering the gradually decreases as the length of the implants increases. The angle remains unchanged between implants of different diameters, but of the same length.

implant diameter	ø 3.80 mm	ø 4.25 mm	ø 5.00 mm
8.50			
	SH-ZT-380-085	SH-ZT-425-085	SH-ZT-500-085
10.00			
	SH-ZT-380-100	SH-ZT-425-100	SH-ZT-500-100
11.50			
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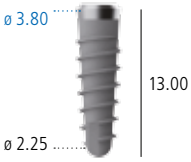
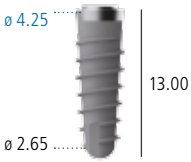
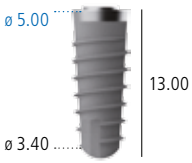
13.00			
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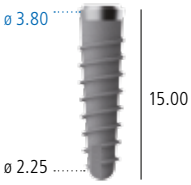
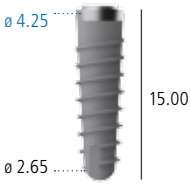
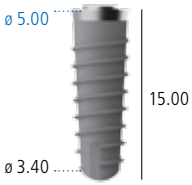
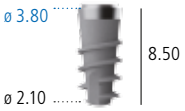
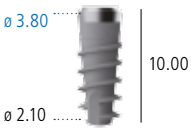
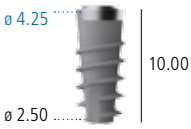
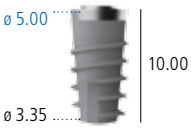
15.00			
	SH-ZT-380-150	SH-ZT-425-150	SH-ZT-500-150
Surgical cover screws*			
	SH-VT-380	SH-VT-380	SH-VT-380

** Each implant is sold with its own surgical cover screw. The surgical screws are also available on sale individually in a sterile pack and must be tightened to 10 Ncm.*

Shelta SL implants: the range

The conical geometry of Shelta SL implants replicates that of Shelta implants with a standard theread with the same length and connection diameter.

implant diameter	ø 3.80 mm	ø 4.25 mm	ø 5.00 mm
8.50			
	SH-ZT-380SL-085	SH-ZT-425SL-085	SH-ZT-500SL-085
10.00			
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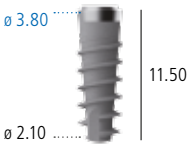
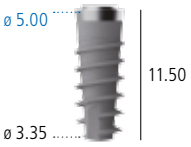
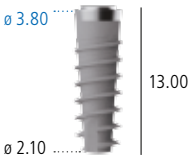
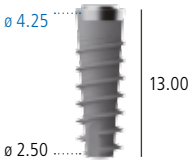
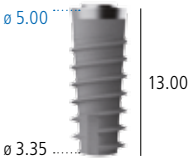
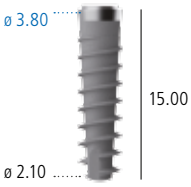
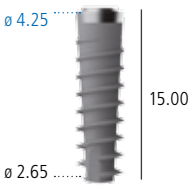
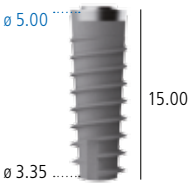
11.50			
	SH-ZT-380SL-115	SH-ZT-425SL-115	SH-ZT-500SL-115
13.00			
	SH-ZT-380SL-130	SH-ZT-425SL-130	SH-ZT-500SL-130
15.00			
	SH-ZT-380SL-150	SH-ZT-425SL-150	SH-ZT-500SL-150
Surgical cover screws*			
	SH-VT-380	SH-VT-380	SH-VT-380

** Each implant is sold with its own surgical cover screw. The surgical screws are also available on sale individually in a sterile pack and must be tightened to 10 Ncm.*

Surgical kit

The Shelta surgical kit has been designed and made to offer ease of use and immediate placing in the sequence of instruments. The instruments, all made of stainless steel, have their descriptions screen-printed on the tray to allow the user to identify each instrument more easily and to put it back after the cleansing and cleaning phases, with the aid of a colour code system that traces the suitable surgical procedures for the various implant diameters. The kit contains stops for safe use of the drills. These stops are extremely practical because they allow manually inserting and removing drills in tip → shank direction. The instruments contained in the kit are all made of stainless steel specifically for surgical use. To guarantee maximum duration of the pieces, it is advisable to follow the recommended cleansing and sterilisation procedures. The Shelta surgical kit is also supplied with the templates for the graphic representation of the implant measurements to allow choosing the most suitable implant diameters and lengths by means of radiographic or tomographic analyses.

The compact dimensions of the kit make it very practical in everyday use and in transport.

A practical ratchet is also included that acts as a dynamometric key for checking the closing torque of the prosthetic screws and as a surgical key for inserting the implants. The ratchet has a very small head, making it easy to use even in distal sectors.

The kit consists of a practical box in Radel with a surgical tray inside that is set-up to hold the instruments according to a guided procedure. The sequences of use of the instruments are indicated by coloured marks.

IMPORTANT WARNING

The surgical kit also contains a test implant (non sterile) which is not to be clinically used, it can be distinguished from the others as it is entirely anodised in blue; it is recommended to use this implant for making trials on the model before starting to use the implants for clinical use, in order to get to know the implant system and its instruments.

code	description
 ZSHELTA-INT	Complete surgical kit of the instruments necessary for Shelta and Shelta SL implants
 SH-TRAY-INT	Radel instrument tray for Shelta and Shelta SL instruments
 GROMMET-CA-1	Kit with 5 spare silicon supports for surgical trays, for drills or instruments with right angle shanks
 GROMMET-CA-2	Kit with 5 spare silicon supports for surgical trays, for instruments fitted with connection hexagon

Table of colour codes

A colour code system has been defined in the Shelta implant system for identifying the intraosseous diameter of the implant.
The final drills and the sequence on the surgical tray are also identified with the colour code.

	ø 3.80	ø 4.25	ø 5.00
Colour code on the pack			

Surgical kit

PILOT DRILL
FPT3-200-LXS

INTERMEDIATE DRILL
FG-200/280XS

STOP FOR PILOT DRILL
STOP3-200-085
STOP3-200-100
STOP3-200-115
STOP3-200-130
STOP3-200-150

STOP FOR CONICAL DRILLS
- SH-STOP-FK380
- SH-STOP-FK425
- SH-STOP-FK500

PRECISION DRILL
FS-230

PARALLELISM PINS
PP-2/28

EXTENSIONS

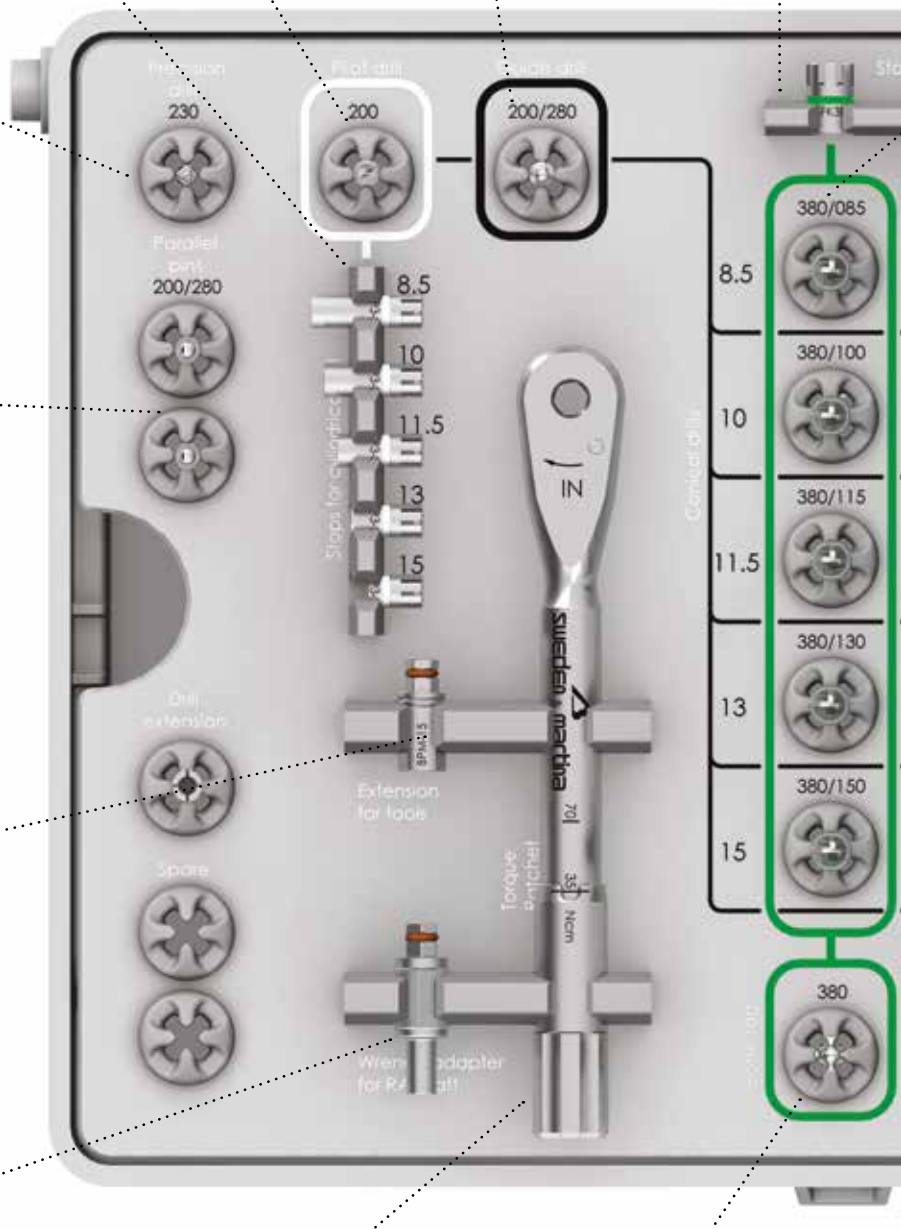
PROF-CAL3

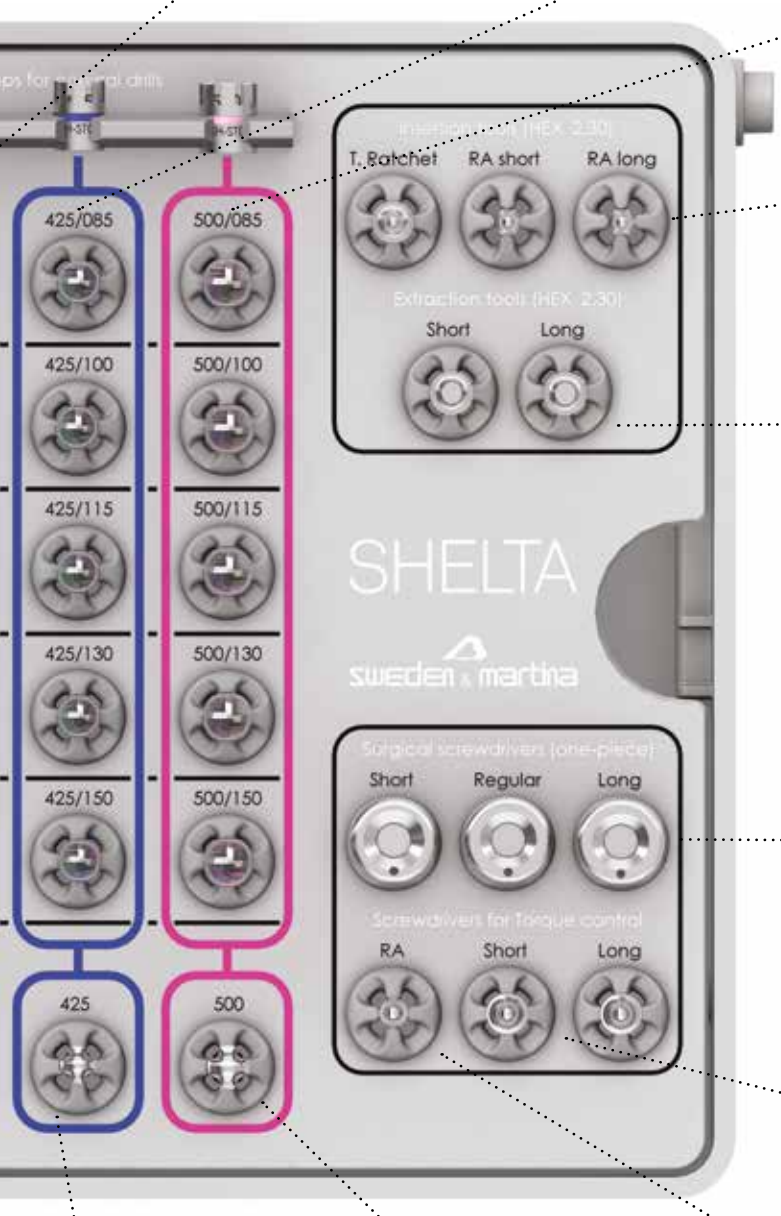
BPM-15

ADAPTER
AVV-CA-DG-EX

TORQUE-CONTROL RATCHET
CRI5

BONE TAPS
SH-MS-380-CA





● CONICAL DRILLS
SH-FK380-085
SH-FK380-100
SH-FK380-115
SH-FK380-130
SH-FK380-150

● CONICAL DRILLS
SH-FK425-085
SH-FK425-100
SH-FK425-115
SH-FK425-130
SH-FK425-150

● CONICAL DRILLS
SH-FK500-085
SH-FK500-100
SH-FK500-115
SH-FK500-130
SH-FK500-150

EASY INSERT
EASY2-EX230-EX
EASYC2-EX230-CA
EASYL2-EX230-CA

DRIVERS
BC-EX230 BL-EX230

HAND DRIVERS FOR CONNECTING SCREWS
HSMXS-20-DG HSM-20-DG HSML-20-DG

DRIVERS FOR RATCHET
HSML-20-EX HSM-20-EX

● BONE TAPS
SH-MS-425-CA

● BONE TAPS
SH-MS-500-CA

RIGHT ANGLE DRIVER
HSM-20-CA

General indications

For the purposes of the European Medical Device Directive 93/42, the surgical instruments designed for use with the implant systems manufactured by Sweden & Martina are reusable medical devices intended for transient use in the oral cavity.
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 (cover screws, transgingival healing screws, screws for posts, abutments, prosthetic 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 implant work other 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 sterilised according to the instructions reported below. Failure to follow these warnings may expose the patient to infection.
The materials used for manufacturing the surgical instruments manufactured by Sweden & Martina 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.
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 sterilisation, 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

The implant codes are so-called "mnemonic" codes, i.e. they allow easy identification of the piece. Below is a table showing how the mnemonic codes work using different types of instruments as an example.

examples	type of component and type of implant	diameter	length
The range of instruments is vast, we indicate some examples of the main families of instruments	The letters "SH" indicate the Shelta system. The other letters indicate the product family	Normally it is the ø of the implant for the insertion of which the instrument is to 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 letter which defines whether a post is repositionable or not
SH-FK380-115	**SH**: Shelta Implant **FK**: Conical drill	380: 3.80 mm	115: 11.50 mm
SH-STOP-FK380	**SH**: Shelta Implant **STOP-FK**: Stop for conical drill	380: 3.80 mm	-
SH-MS-380-CA	**SH-MS**: Bone tap for Shelta implant	380: 3.80 mm	-
PP-2/28	**PP**: Parallelism pin	2/28: from 2.00 mm to 2.80 mm	-

Drills

All Sweden & Martina drills are made of **stainless 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 44 to prevent the development of bone necrosis. Lever movements increase the risk of instrument breakage and should therefore be avoided. Changes in speed should be avoided in general. Never apply pressure such as to force the instrument to stop rotating. This could lead to an excessive increase in heat in the tissues being drilled, with consequent bone necrosis, and damage both the instrument and the appliance (micromotor) used. This could also lead to breakage of the instrument. Using an intermittent approach, with a back and forth movement in a vertical direction, prevents overheating and wear of the working part and an undesirable increase in the temperature in the tissues being cut. Suitable coolant should be used. Inadequate irrigation can lead to bone necrosis.

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

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 depth to which the drill should always be inserted to obtain a suitable guiding hole for the next drills.

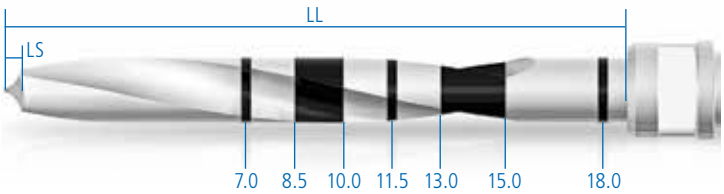
IMPORTANT WARNING

The precision drill comes with a protective silicone sheath The sole purpose of this protective sheath is to protect the instrument during transportation and it must be removed before first use. Since this drill is extremely sharp, special caution is required during handling.

Pilot drill FPT3-200-LXS

The pilot drill ø 2.00 is used to prepare the initial hole for preparing the site. The drill is easy to identify, thanks to the presence of a white ring and to the code laser-etched on the drill shank. It has laser-etched depth marks, a cylindrical shape and a spiral with two cutting edges. It must be used with abundant external irrigation.

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.

code	ø	LS	LL
FPT3-200-LXS	2.00	0.58	19.3

Pilot drill stops

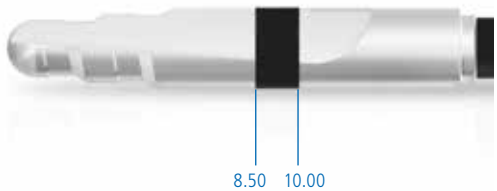
Stops are devices to be fitted in tip → shank direction on drills suited to receive them. They make it possible to restrict the working length of a drill to a pre-set height.

height	8.50 mm	10.00 mm	11.50 mm	13.00 mm	15.00 mm
stops					
	STOP3-200-085	STOP3-200-100	STOP3-200-115	STOP3-200-130	STOP3-200-150

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 drill FG-200/280XS

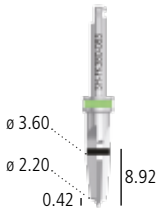
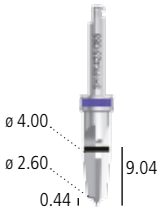
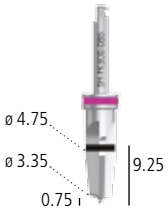
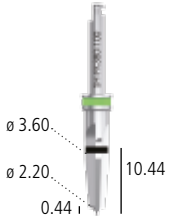
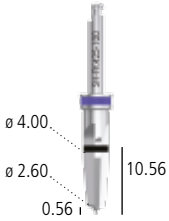
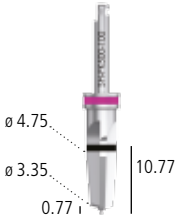
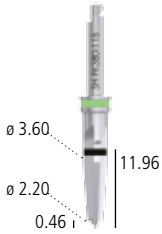
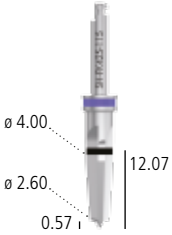
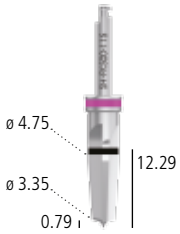
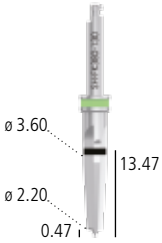
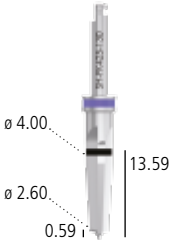
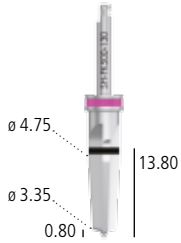
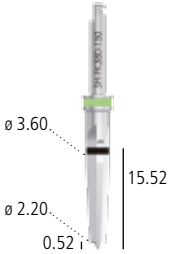
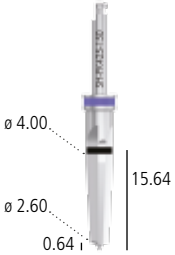
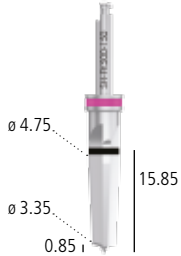
It is a drill with two cutting edges suitable for progressively widening the preparations in relation to the diameter of the drills to be used in succession. It is extremely useful on highly compact bone so as to damage it as little as possible. It has two small steps with an initial guide with a progressive diameter and final diameter of 2.80 mm. It has reference laser markings that range from a height of 8.50 to 10.00 mm.



code	description
 FG-200/280XS	Intermediate drill, for widening the hole to 2.00 mm, 2.40 mm and 2.80 mm

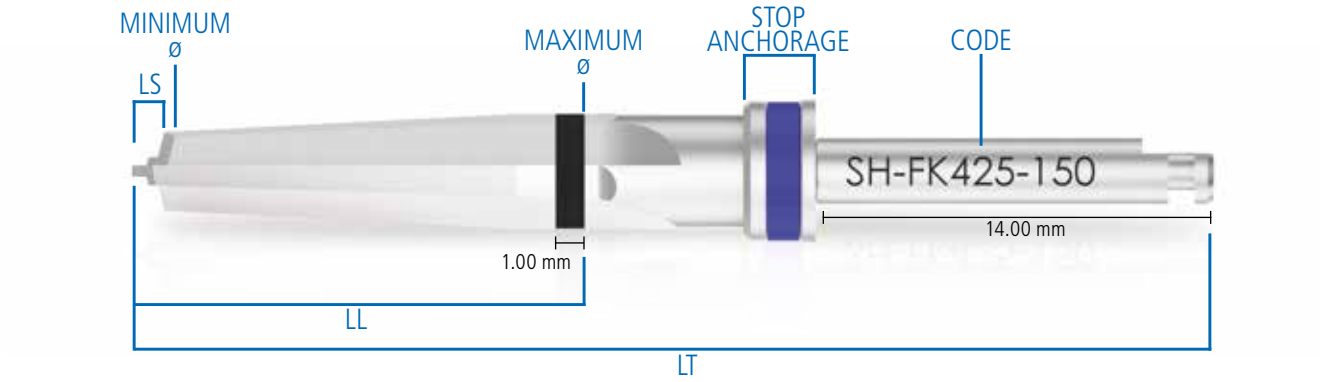
Conical drills

The conical drills are also made of stainless steel with high resistance to corrosion and wear. They 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 results in very precise implant preparations, which are the key to success of conical implants. They have a standard right angle shank 14.00 mm long. The kit contains 15 conical drills, each one of which forms the final hole for the implant with diameter and height referred to by the instrument code. The drills are the following:

implant diameter	ø 3.80 mm	ø 4.25 mm	ø 5.00 mm
8.50	 SH-FK380-085	 SH-FK425-085	 SH-FK500-085
10.00	 SH-FK380-100	 SH-FK425-100	 SH-FK500-100
11.50	 SH-FK380-115	 SH-FK425-115	 SH-FK500-115
13.00	 SH-FK380-130	 SH-FK425-130	 SH-FK500-130
15.00	 SH-FK380-150	 SH-FK425-150	 SH-FK500-150

The conical drills are distinguished by a coloured ring that makes it easy to recognise the instruments intended for each diameter.

LT: Total length of the drill, shank included.
LS: Length of the tip. This measurement must be calculated in addition to the length of the preparation hole.
LL: Working lenght of the drill.



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.
For details of the sizes of the different drills, refer to the table below:

IMPORTANT WARNING

The notch laser-etched on conical drills has a height of 1.00 mm, corresponding to the height of the smooth neck of the implant. This indication is particularly useful to allow the dentist to choose supra-crestal or sub-crestal insertion of the implant.

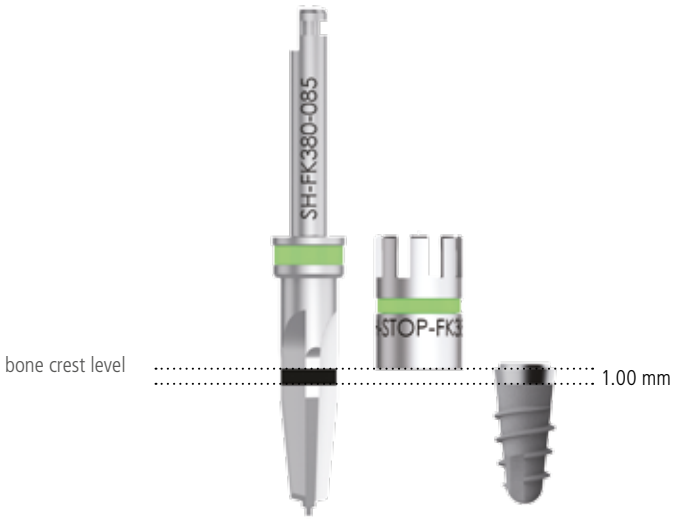
drill code	corresponding implant	nominal ø	minimum ø	maximum ø	LT	LL	LS	colour code
SH-FK380-085	SH-380-085 SH-380SL-085	3.80	2.20	3.60	30.92	8.92	0.42	GREEN
SH-FK380-100	SH-380-100 SH-380SL-100	3.80	2.20	3.60	32.44	10.44	0.44	GREEN
SH-FK380-115	SH-380-115 SH-380SL-115	3.80	2.20	3.60	33.96	11.96	0.46	GREEN
SH-FK380-130	SH-380-130 SH-380SL-130	3.80	2.20	3.60	35.47	13.47	0.47	GREEN
SH-FK380-150	SH-380-150 SH-380SL-150	3.80	2.20	3.60	37.52	15.52	0.52	GREEN
SH-FK425-085	SH-425-085 SH-425SL-085	4.25	2.60	4.00	31.04	9.04	0.44	BLUE
SH-FK425100	SH-425-100 SH-425SL-100	4.25	2.60	4.00	32.56	10.56	0.56	BLUE
SH-FK425-115	SH-425-115 SH-425SL-115	4.25	2.60	4.00	34.07	12.07	0.57	BLUE
SH-FK425-130	SH-425-130 SH-425SL-130	4.25	2.60	4.00	35.59	13.59	0.59	BLUE
SH-FK425-150	SH-425-150 SH-425SL-150	4.25	2.60	4.00	37.64	15.64	0.64	BLUE
SH-FK500-085	SH-500-085 SH-500SL-085	5.00	3.35	4.75	31.26	9.25	0.75	MAGENTA
SH-FK500-100	SH-500-100 SH-500SL-100	5.00	3.35	4.75	32.77	10.77	0.77	MAGENTA
SH-FK500-115	SH-500-115 SH-500SL-115	5.00	3.35	4.75	34.29	12.29	0.79	MAGENTA
SH-FK500-130	SH-500-130 SH-500SL-130	5.00	3.35	4.75	35.80	13.80	0.80	MAGENTA
SH-FK500-150	SH-500-150 SH-500SL-150	5.00	3.35	4.75	37.85	15.85	0.85	MAGENTA

Stops for conical drills

The kit contains a stop for each diameter of the final conical drills, for **inserting the drill from the tip**. They are suitable for limiting the working length to predetermined heights. With the same working diameter, the same stop is compatible with all the drill lengths, as explained in the following table:

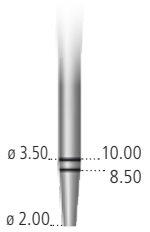
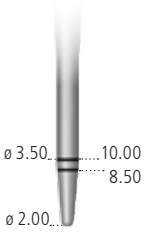
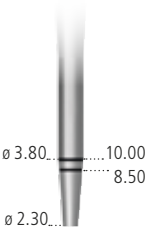
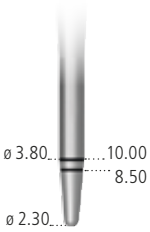
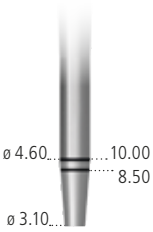
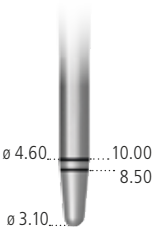
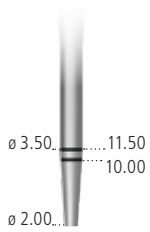
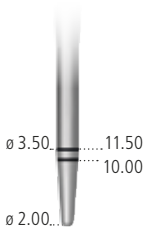
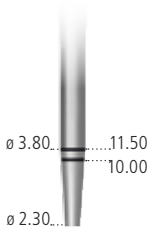
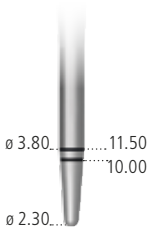
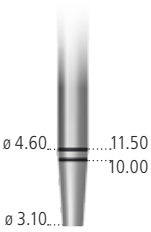
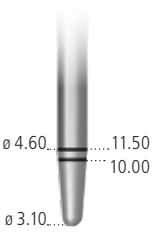
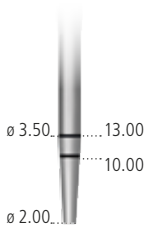
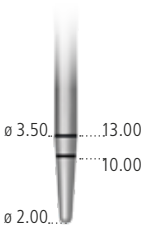
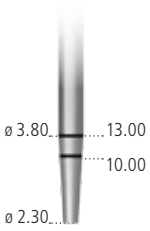
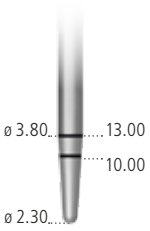
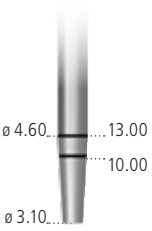
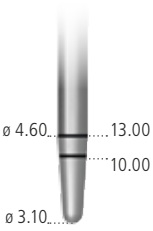
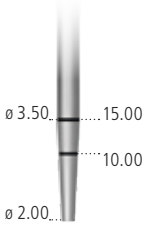
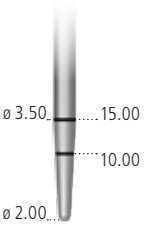
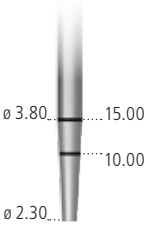
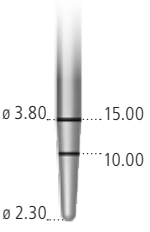
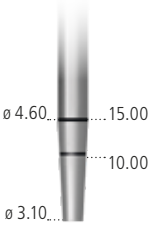
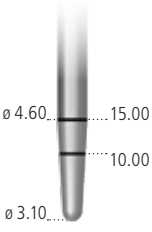
	 SH-STOP-FK380	 SH-STOP-FK425	 SH-STOP-FK500
COLOUR CODES	GREEN	BLUE	MAGENTA
NOMINAL ø corresponds to the implant diameter	3.80	4.25	5.00
DRILL FOR IMPLANT L.8.50 mm	SH-FK380-085	SH-FK425-085	SH-FK500-085
DRILL FOR IMPLANT L.10.00 mm	SH-FK380-100	SH-FK425-100	SH-FK500-100
DRILL FOR IMPLANT L.11.50 mm	SH-FK380-115	SH-FK425-115	SH-FK500-115
DRILL FOR IMPLANT L.13.00 mm	SH-FK380-130	SH-FK425-130	SH-FK500-130
DRILL FOR IMPLANT L.15.00 mm	SH-FK380-150	SH-FK425-150	SH-FK500-150

As already indicated with regard to the pilot drill stops, in this case too it is recommended always to 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.
As specified in the surgical procedures on page 44, the conical drill stops define the working height corresponding to the total nominal length of the implant, determining a working depth such that the fixture is completely submerged. If you want to leave the shiny crown part in a supracrestal position, you must stop at the start of the laser-etched notch on the drill (see page 27).



Osteotomes

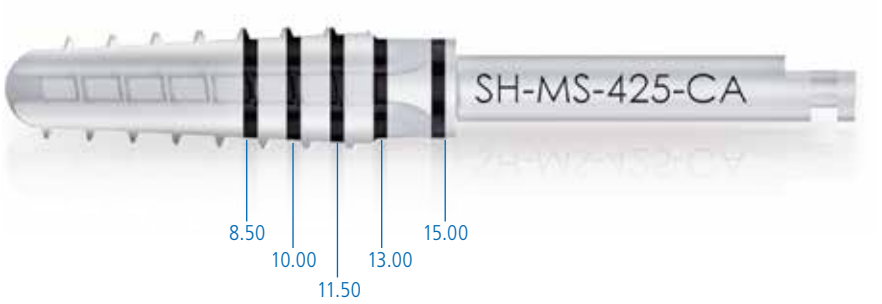
A complete set of osteotomes has been designed for the expansion of thin crests, for mini-crest lifts and for the compaction of poorly mineralised bone, to be used as an alternative to the final drills. The osteotomes are invasive surgical instruments, manual, intended for creating holes in bone, especially in the presence of poor quality bone, and for compacting by the progressive widening of the preparations, compressing the bone against the walls. They can have a flat or rounded tip depending on whether they have to push the bone or cut it, and are tapered in relation to what shape is required for the site to receive implants in a pre-ordered shape. The sequence of use must be determined according to the degree of bone density and the preparation that is to be obtained.

implant diameter	ø 3.80 mm		ø 4.25 mm		ø 5.00 mm	
for implants h. 8.50 and 10.00 mm						
	SH-OS-380-100-PP	SH-OS-380-100-PR	SH-OS-425-100-PP	SH-OS-425-100-PR	SH-OS-500-100-PP	SH-OS-500-100-PR
for implants h. 11.50 mm						
	SH-OS-380-115-PP	SH-OS-380-115-PR	SH-OS-425-115-PP	SH-OS-425-115-PR	SH-OS-500-115-PP	SH-OS-500-115-PR
for implants h. 13.00 mm						
	SH-OS-380-130-PP	SH-OS-380-130-PR	SH-OS-425-130-PP	SH-OS-425-130-PR	SH-OS-500-130-PP	SH-OS-500-130-PR
for implants h. 15.00 mm						
	SH-OS-380-150-PP	SH-OS-380-150-PR	SH-OS-425-150-PP	SH-OS-425-150-PR	SH-OS-500-150-PP	SH-OS-500-150-PR
tip	**flat**	**rounded**	**flat**	**rounded**	**flat**	**rounded**

code	description
 OS-TRAY-INT	Randel cotainer for osteotomes, can hold up to 12 instruments

Bone taps

These are sharp instruments, made of stainless steel, used to prepare the bone to accommodate the threads of the implants, especially in situations where the bone is very compact or cortical, to alleviate compression and insertion torque.



SH-MS-380-CA
Bone tap ø 3.80

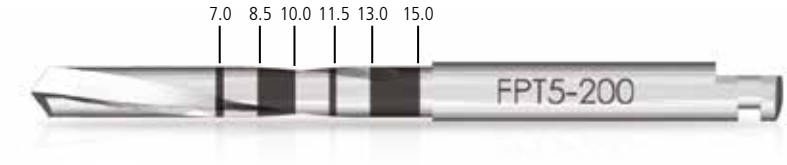
SH-MS-425-CA
Bone tap ø 4.25

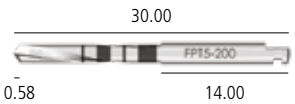
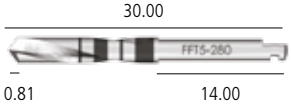
SH-MS-500-CA
Bone tap ø 5.00

The bone taps for Shelta implants have only the right angle attachment. If you want to use them by hand, this can be done with the hand knob AVV-CA-DG-EX.

Drills for distal sectors

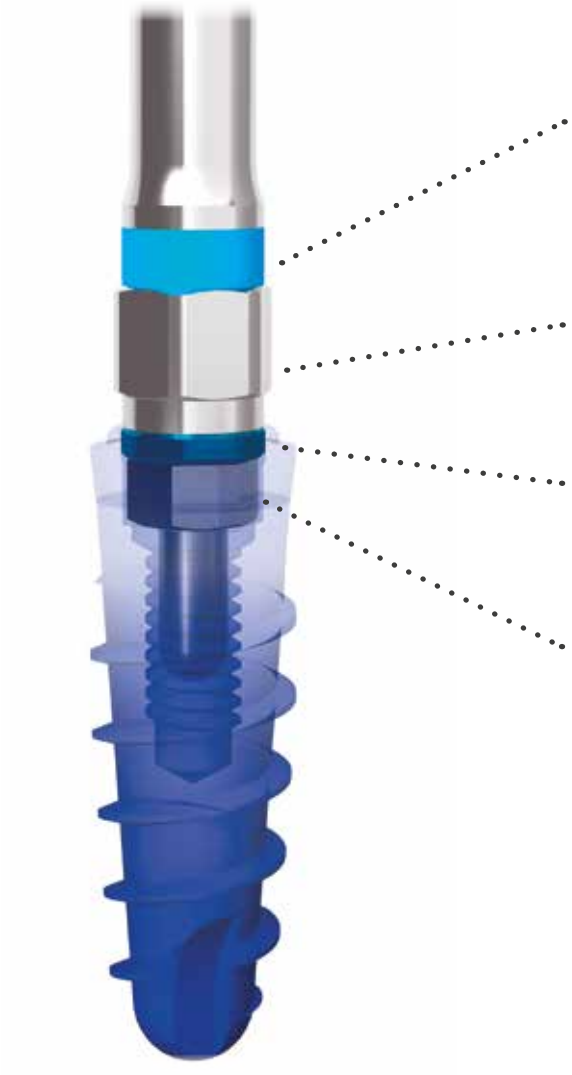
Short drills with a 14.00 mm long shank and total length of 30.00 mm are optionally available; to be used without stops, they are dedicated to distal sectors and do not have the colour code on the shank. They also have a depth marking at 7.00 mm, as they are common to other Sweden & Martina implant systems.



code	description
 FPT5-200-LXS	Cylindrical pilot drill, ø 2.00 mm, not included in the surgical kit.
 FFT5-280-LXS	Universal final cylindrical drill, ø 2.80 mm, not included in the surgical kit.

Easy Insert drivers

The Shelta implant does not require a mounter for inserting into the implant site because 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 wells. The use of these drivers makes the surgical procedure of insertion extremely easy.



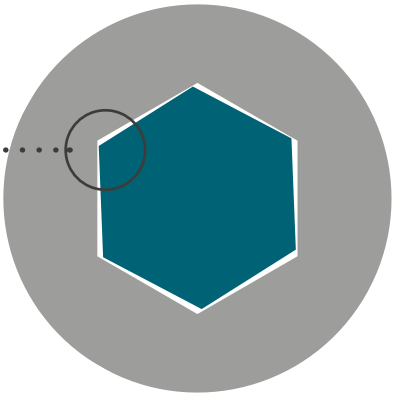
A single instrument that allows the insertion of all Shelta implant diameters.

The Easy Insert drivers aid **visibility of the operating field**, do not occupy much space, and allow adjusting the connection hexagon properly because their hexagonal visual index is the same as the prosthetic index.

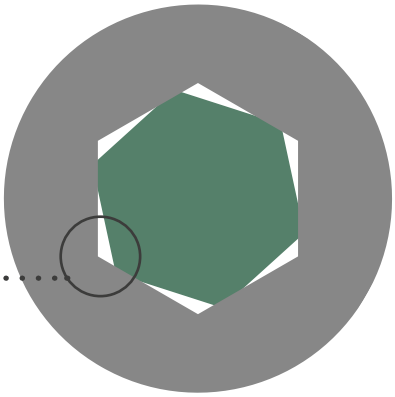
The whole is extremely safe and reliable with the use of a special **titanium o-ring** that engages inside the connection.

The presence of a wide hexagon allows **engaging the patented Easy Insert drivers easily and safely** for easy and safe insertion of the implants into the relative sites.

The picture on the left shows how a traditional instrument (in blue) edges inside the connection (in grey). This geometry inevitably determines the grip and deformation of the actual session.



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



The special design of the Easy Insert drivers (in green 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.

SURGICAL INSTRUMENTS

When using the Easy Insert with 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. 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.

code	description
 EASYC2-EX230-CA	Short driver with right angle shank
 EASYL2-EX230-CA	Long driver with right angle shank
 EASY2-EX230-EX	Driver with connector for torque-control ratchet

Maintenance and care of the Easy Insert drivers

The Easy Insert drivers are supplied pre-mounted with the special titanium o-rings. Since they are mechanical components, the retainer rings are subject to wear over time and can lose their elasticity and functionality.
The o-rings cannot be replaced, but it is necessary to replace the instrument. The Easy Inserts were tested to be good for 50 uses in the worst conditions of use. These limits can therefore change depending on the conditions of use.
However, it is always a good idea to check its good functionality even during the cleaning and sterilisation operations. For this reason and to allow the doctor to familiarise himself with the Easy Inserts, the surgical kits contain a "test implant" that has not been treated or sterilised; it can be distinguished from the others as it is entirely anodised in blue.

IMPORTANT WARNING

It is recommended to use the Easy Inserts with a torque value included between 50 Ncm and 70 Ncm. According to mechanical tests, from 70 Ncm and 100 Ncm a light friction between the instrument and the implant connection may happen, but it is easily resolvable with a contra-rotation movement (40 Ncm) in order to remove the instrument from the connection. It is also recommended to finish the insertion phase using the torque-control ratchet.

Drivers

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. In fact, 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. The Shelta implants must therefore be screwed in only with the Easy Insert drivers.

code	description
 BC-EX230	Short driver
 BL-EX230	Long driver

Screwdrivers

The surgical kit contains various drivers, useful for screwing and unscrewing mounter connecting screws, transgingival healing screws, screws for transfers, posts and abutments, and more generally all the screws in the Shelta system. They are all made of stainless steel for surgical use. The design of the tip of all the drivers is the same, so the screwdrivers are all interchangeable. They are distinguished one from the other by their total length and by the fact that they are one-piece digital drivers, that is they are all in one with the hand knob which allows them to be gripped, or provided with a hexagonal connector compatible with the ratchet. The one-piece drivers are available in the kits in 3 different heights, as follows:

code	description
 HSMXS-20-DG	Screwdriver for surgical cover screw and fixation screw, digital, extra-short
 HSM-20-DG	Screwdriver for surgical cover screw and fixation screw, digital, short
 HSML-20-DG	Screwdriver for surgical cover screw and fixation screw, digital, long

They are very practical in the intra-operative stage because they are safe, practical, and require no assembly or disassembly.

IMPORTANT WARNING

It is recommended to pass a thread through the hole on the top of the knob to prevent it falling.

SURGICAL INSTRUMENTS

The screw drivers with a hexagonal connector at the top are designed for use with the torque-control ratchet. The kit contains the long and short versions:

code	description
 HSM-20-EX	Screwdriver for fixation screws, with hexagonal connector for torque-control ratchet or hand knob, short
 HSML-20-EX	Screwdriver for fixation screws, with hexagonal connector for torque-control ratchet or hand knob, long

An optional extra-long version is also available, necessary when the length of the hole for the screw to pass inside the posts is greater than 13.50 mm:

code	description
 HSMXL-20-EX	Screwdriver for fixation screws, with hexagonal connector for torque-control ratchet or hand knob, extra-long

The kit also contains a driver with right angle shank, very practical both in the surgical and prosthetic phase, if used with a micromotor with torque control:

code	description
 HSM-20-CA	Screwdriver for fixation screws, with right angle shank

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 replaced when worn or when no longer able to friction properly.

A kit of 5 spare O-rings is available which can be ordered with code **ORING180-088**.

IMPORTANT WARNING

Excessive torques may strip the wells of the connecting screws and pare off the corners of the screwdrivers, causing even serious intraoperative or prosthetic complications. The recommended torques for the various components are summed up in the following table:

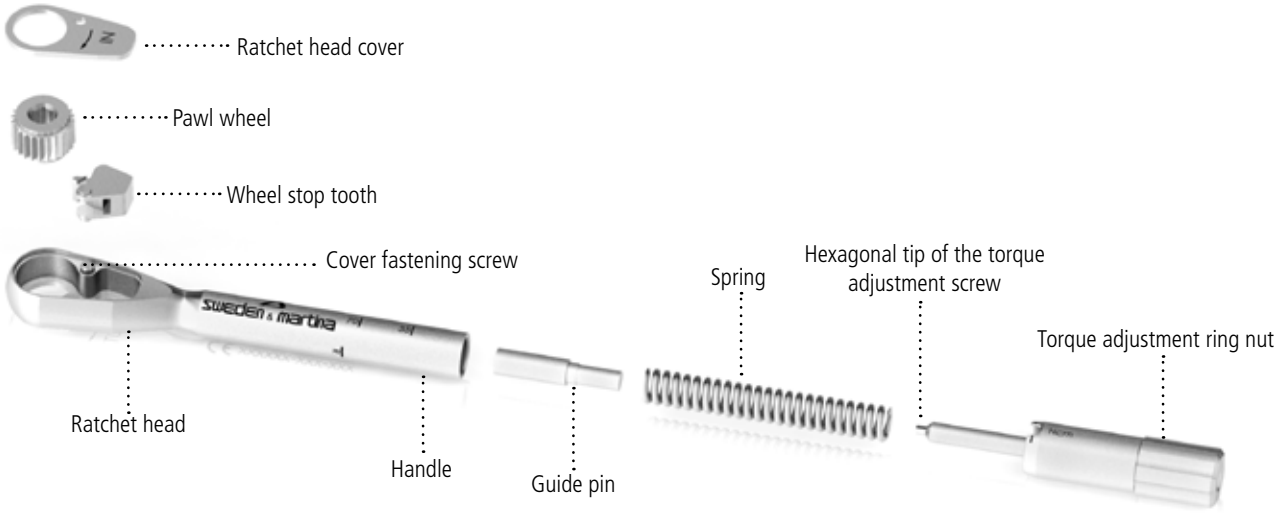
surgical cover screws, healing abutments	8-10 Ncm
all prosthetic screws	20-25 Ncm
all prosthetic components screwed directly onto the implant	25-30 Ncm

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.

Torque-control ratchet CRI5-KIT

The surgical kit of the implant system contains a special ratchet (CRI5), with its own adjustment key, for quickly screwing the torque adjustment ring nut, and with gel lubricant for maintenance. The ratchet may be used with torque adjustment from 10 to 70 Ncm or in a blocked position without torque control. When using as a prosthetic ratchet for fastening the screws, refer to the torque values given in the table on the previous page. The ratchet key CRI5 is a multi-purpose instrument that can be disassembled, and is sold unsterile.



Before each use, this instrument must be cleaned and sterilised according to the instructions on pages 40-41. Adequate maintenance, performed following in detail all the step by step instructions for the disassembly and correct reassembly of the device during cleaning operations, is essential for the correct functioning of the device and for its durability. Personnel who use this tool must be suitably trained, and they must have read the instructions in this manual prior to handling the device.
After sterilisation, the key is ready for use. A test to verify the correct assembly and functioning of the key is necessary before any surgical or prosthetic interventions. 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.

IMPORTANT WARNING

The torque is adjusted by screwing/unscrewing the ring nut located at the bottom of the instrument's handle. The torque must always be adjusted on the rise, starting screwing from a lower value until the desired torque is reached, or unscrewing the ring nut in a clockwise direction. To do this, if it is necessary to set a torque lower than the last one used, you must unscrew the ring nut by two turns below the value of the desired new torque, and work up to that value by rescrewing the ring nut in a clockwise direction.

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.

Extensions and adapters

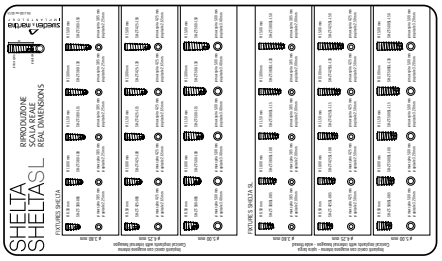
code	description
 BPM-15	Extension for bone taps, mounters, drivers and manual drivers, with hexagonal connector for torque-control ratchet
 PROF-CAL3	Extension for surgical drills
 B-AVV-CA3	Mechanical adapter with right angle shank for instruments with hexagonal connector
 AVV3-MAN-DG	Hand knob for bone taps, mounters, drivers and manual drivers
 AVV-CA-DG-EX	Hand knob for hand use of drivers, bone taps and drivers with right angle shark and with hexagonal connection for torque-control ratchet

Depth gauge PROF3

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

X-Ray templates

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



code	description
SH-L100	X-ray template for Shelta and Shelta SL implants, real dimensions
SH-L120	X-ray template for Shelta and Shelta SL implants, dimensions increased by 20%
SH-L130	X-ray template for Shelta and Shelta SL implants, dimensions increased by 30%

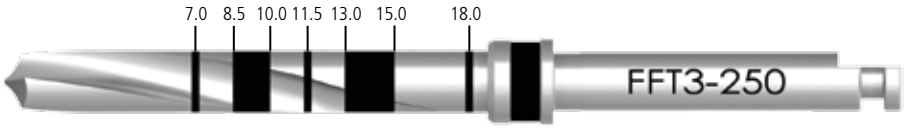
Bone profilers

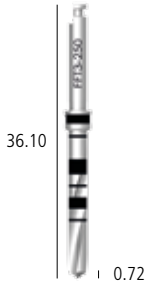
The bone profilers are very useful for levelling a very irregular bone crest at the coronal level, especially in the subsequent use of P.A.D. abutments.

description	code
Wide bone profiler for levelling irregular bone crest for P.A.D. abutment	 A-PAD-PS380-L
Narrow bone profiler for levelling irregular bone crest for P.A.D. abutment	 A-PAD-PS380-S

ø 2.50 mm cylindrical drill

It is available a cylindrical drill with ø 2.50 mm made of surgical steel. Depth stops for this drill are available to proceed with a safe preparation.



	7.00 mm	8.50 mm	10.00 mm	11.50 mm	13.00 mm	15.00 mm
 FFT3-250-LXS	 STOP3-250-070	 STOP3-250-085	 STOP3-250-100	 STOP3-250-115	 STOP3-250-130	 STOP3-250-150

** The drill with ø 2.50 mm and the related depth stops are not included in the surgical kit.*
The complete set of drill and depth stops are to be ordered with the code KIT-INTEGRA-F250. They are available also separately as a spare.

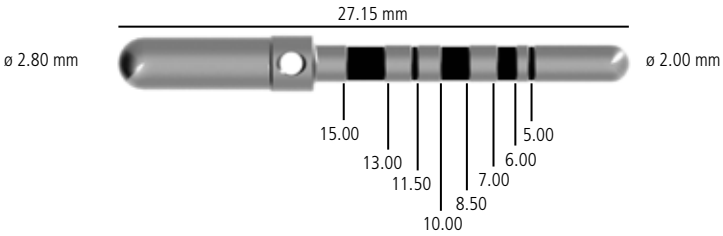
Parallelism pin

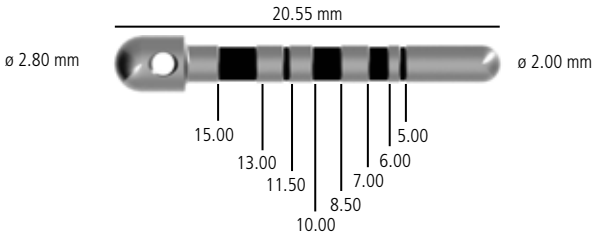
The surgical kit contains two parallelism pins, distinguished by the fact that they have one side with diameter 2.00 mm and the other 2.80 mm, which allow checking of the insertion axis of the implants and the parallelism between several fixtures.

code	description
 PP-2/28	Parallelism pin with one side ø 2.00 and the other ø 2.80 mm

Parallelism pins with depth lines

Parallelism pins with depth lines are available optionally, they allow the control of the preparation depth during the first surgical step, thanks to the presence of dedicated lines in the side with ø 2.00 mm. As the lines have a reduced diameter in comparision with the pin body, it is possible to distinguish them also on the x-ray images. The other side of the instruments has a diameter of ø 2.80 mm and presents a hole for safety thread. The small version of the pin, has a shorter ø 2.80 side.





code	description
 PPTL-2-28	Parallelism pins with depth lines, large version, not included in the surgical kit
 PPTS-2-28	Parallelism pins with depth lines, small version, not included in the surgical kit

IMPORTANT WARNING

It is recommended to pass a thread through the hole in the centre of the pin to prevent it falling.

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

Attention! All the surgical instruments for dental implants are sold NON-STERILE. Before use, they must be cleaned, disinfected and sterilised 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-infection 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 demineralised water to prevent the formation of stains and marks. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually. When cleaning manually: use a suitable 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 sterilisation bags.
Do not exceed 120°C when performing a drying cycle in a washing and disinfection appliance.

b. Sterilisation: in a vacuum autoclave, proceeding as follows:
- autoclave (Gravity-Displacement Cycles) at a temperature of 121°C with a minimum exposure of thirty (30) minutes and a drying of fifteen (15) minutes;
- autoclave (Dynamic-Air-Removal Cycles) at a temperature of 132°C -134°C with a minimum exposure of five (5) minutes and a drying of twenty (20) minutes

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

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

Procedure di smaltimento
If used, dispose of the surgical accessories as biological waste, according to the local regulations.

Cleaning, sterilisation and storage of the torque-control ratchet 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 demineralised 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.

Please note: Blood residues or other deposits reduce the efficacy of the sterilisation 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 sterilisation. Dry the parts, lubricate the functional areas lightly and reassemble the key as shown in the figures below. Too much lubrication may cause the surfaces of the instrument to resurface during sterilisation. Use only the lubricant supplied.

After lubricating the parts shown in the figure, insert the two elements of the ratchet head according 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" side. Tighten the screw with the hexagon tip of the torque adjustment screw.

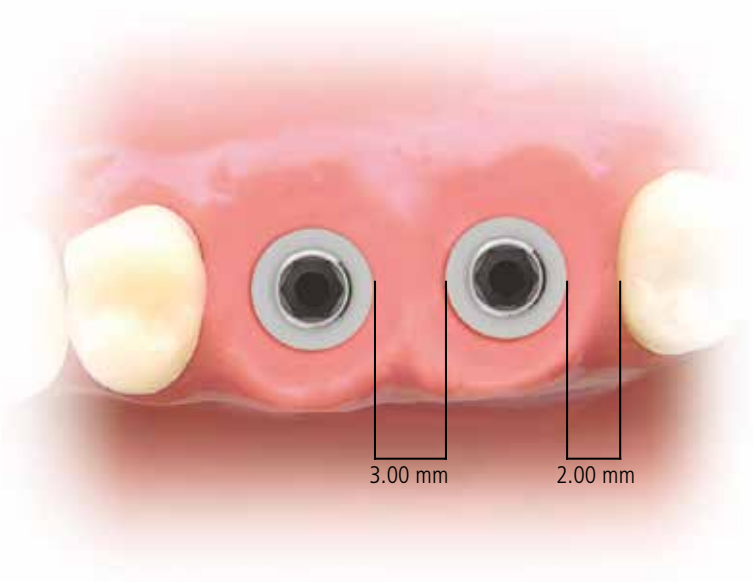
Lubricate the spring inside the ratchet handle as shown in the figure. Assemble the torque adjustment screw, making sure the instrument functions properly. Manually activate the pawl wheel.

Sterilisation: in a vacuum autoclave, proceeding as follows:
Temperature = 121 – 124 °C, with autoclave cycle of at least 20 minutes and drying cycle of 15 minutes.

This procedure is important in order to preserve the precision of the instrument within a tolerance of ± 3.5Ncm. Operate the torque and insertion mechanism to check their proper functioning. Remove any traces of lubricant from the outer surface of the key. Place the device in suitable sterilisation bags. It is recommended to practise the disassembly and reassembly operations, following the instructions.

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 previously, 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 2.20 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. If the thickness is smaller there is a high risk of bone reabsorption failure and exposure of the threads.



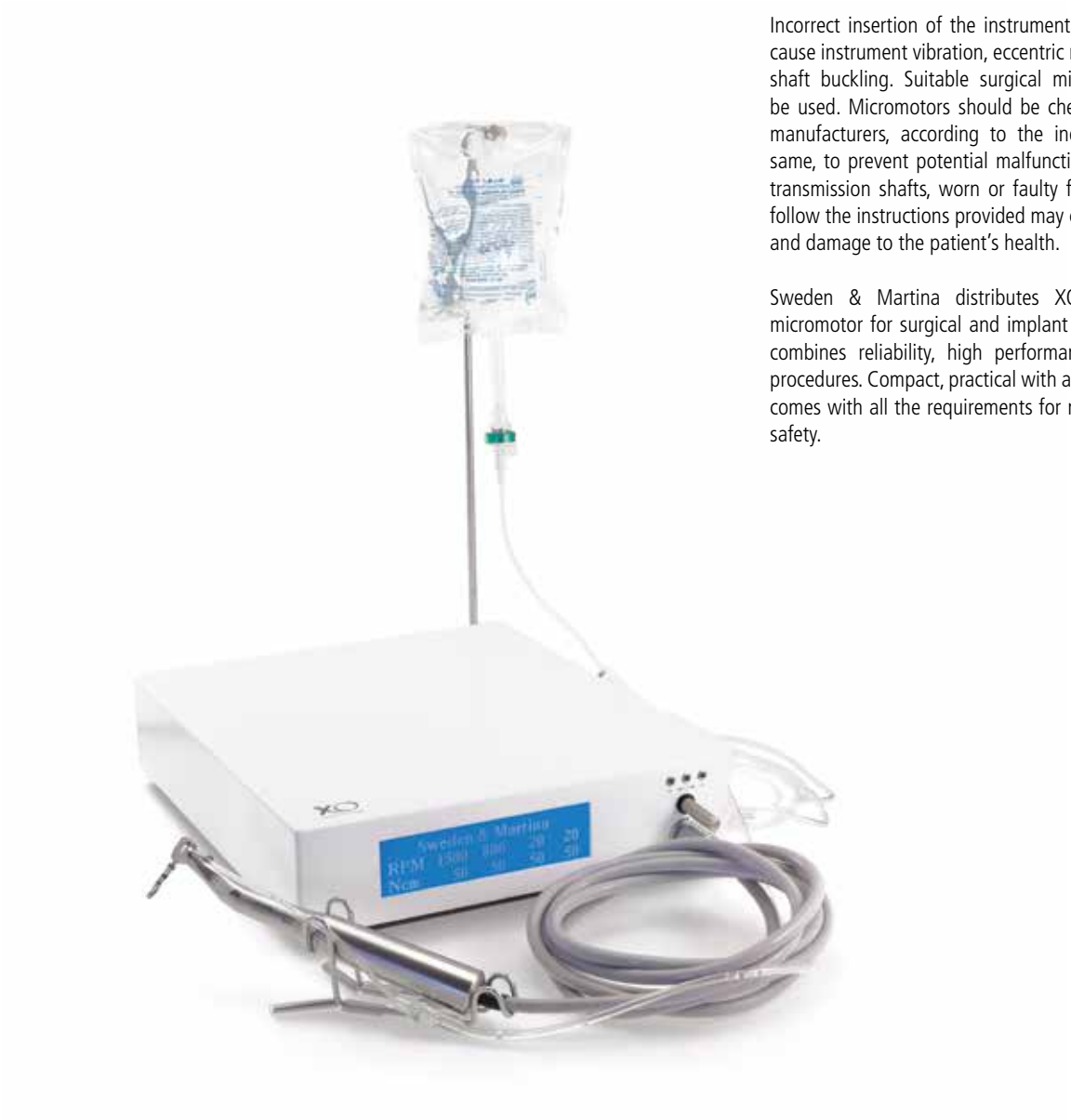
Surgical sequences

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 over-preparation dimensions, refer to page 24 for the cylindrical pilot drill, and to page 27 for the conical drills. 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.

These procedures come from clinical experience and recommendations emerging from numerous studies and clinical protocols for conical implants. It should, however, always 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 the operator to make further considerations. 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.



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.

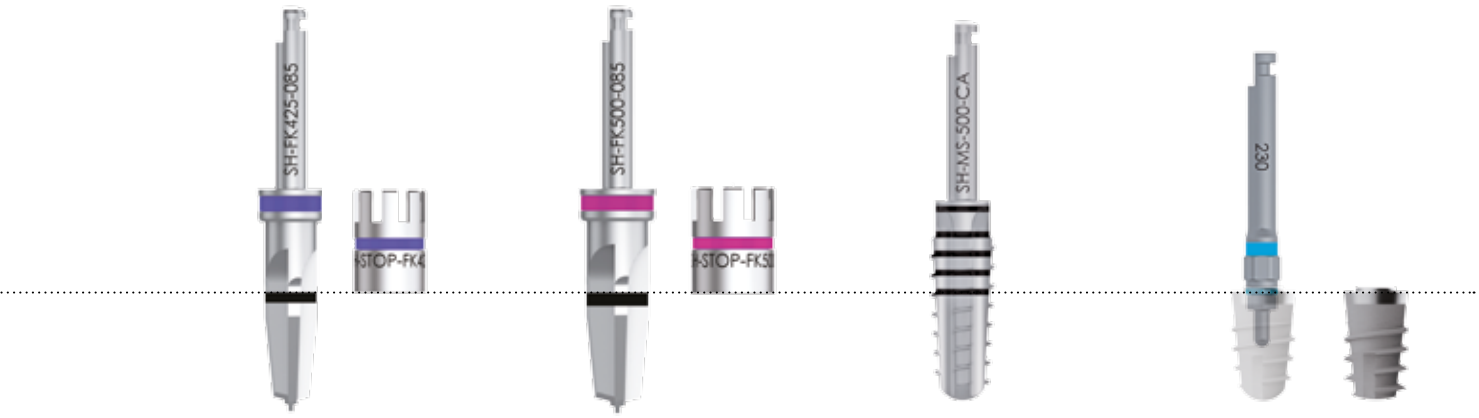
Sweden & Martina distributes XO Osseo, a brushless micromotor for surgical and implant procedures. It perfectly combines reliability, high performances and easy to use procedures. Compact, practical with a basic design, XO Osseo comes with all the requirements for maximum precision and safety.

SURGICAL PROCEDURES

Surgical sequence for implants with lenght 8.50 mm

The sequence illustrates the preparation for the implant with ø 5.00 mm. For the other diameters use only the drills indicated in the individual tables.
The use of the STOP is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility.

		FS-230	FPT3-200-LXS	FG-200/280XS	SH-FK380-085
	SH-380-085 SH-380SL-085		**use up to: marking 8.50 mm**	**use up to: marking 8.50 mm**	
ø 3.80 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-
	SH-425-085 SH-425SL-085		**marking 8.50 mm**	**marking 8.50 mm**	
ø 4.25 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-
	SH-500-085 SH-500SL-085		**marking 8.50 mm**	**marking 8.50 mm**	
ø 5.00 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-



SH-FK425-085	SH-FK500-085	SH-MS-500-CA	EASYC2-EX230-CA
		50 Ncm max	
-	-	SH-MS-380 (20 rpm)	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
900 rpm	-	SH-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	20 rpm
800 rpm	-	-	20 rpm
-	-	-	20 rpm
900 rpm	900 rpm	SH-MS-500 (20 rpm)	20 rpm
900 rpm	900 rpm	-	20 rpm
800 rpm	800 rpm	-	20 rpm
-	-	-	20 rpm

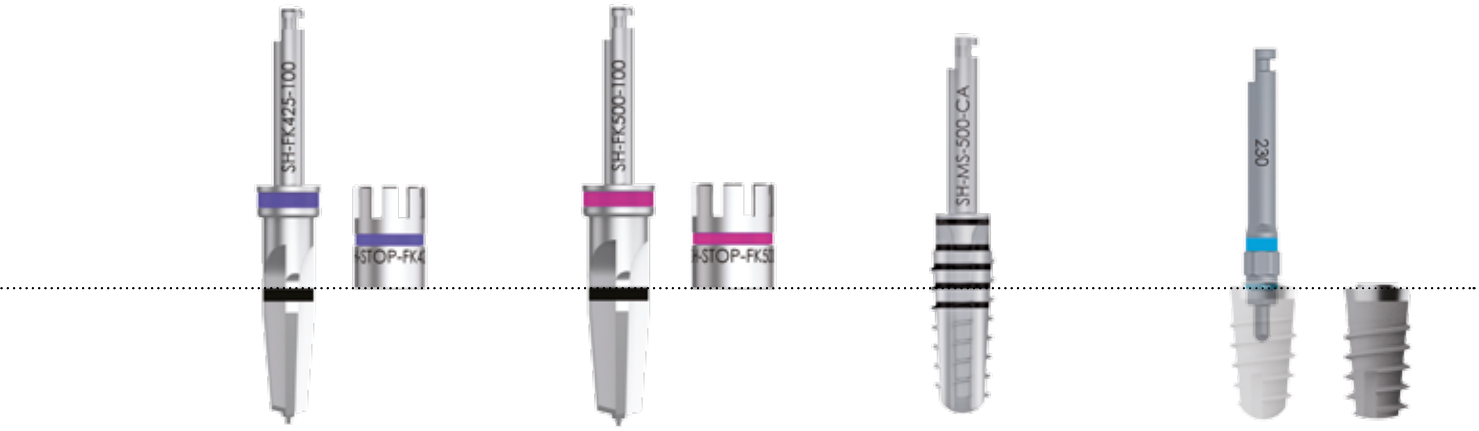
WARNING: The notch laser-etched on conical drills has a height of 1.00 mm, corresponding to the height of the smooth neck of the implant. This indication is particularly useful to allow the dentist to choose supra-crestal or sub-crestal insertion of the implant.

SURGICAL PROCEDURES

Surgical sequence for implants with lenght 10.00 mm

The graphic sequence illustrates the preparation for the implant with ø 5.00 mm. For the other diameters use only the drills indicated in the individual tables.
The use of the STOP is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility.

		FS-230	FPT3-200-LXS	FG-200/280XS	SH-FK380-100
	SH-380-100 SH-380SL-100		**use up to: marking 10.00 mm**	**use up to: marking 10.00 mm**	
ø 3.80 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-
	SH-425-100 SH-425SL-100		**marking 10.00 mm**	**marking 10.00 mm**	
ø 4.25 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-
	SH-500-100 SH-500SL-100		**marking 10.00 mm**	**marking 10.00 mm**	
ø 5.00 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-



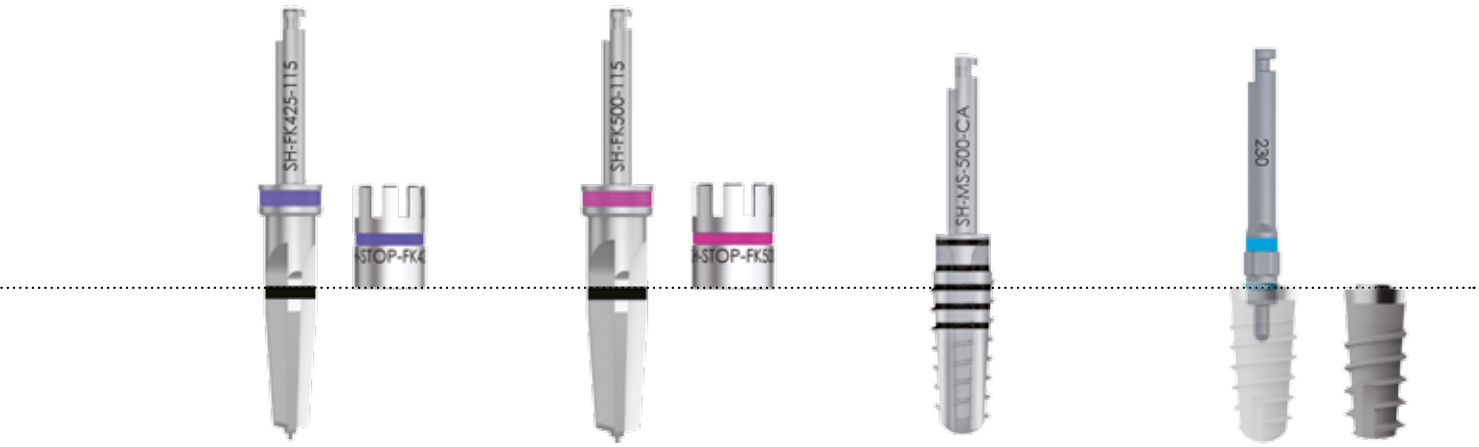
SH-FK425-100	SH-FK500-100	SH-MS-500-CA	EASYC2-EX230-CA
		50 Ncm max	
-	-	SH-MS-380 (20 rpm)	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
900 rpm	-	SH-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	20 rpm
800 rpm	-	-	20 rpm
-	-	-	20 rpm
900 rpm	900 rpm	SH-MS-500 (20 rpm)	20 rpm
900 rpm	900 rpm	-	20 rpm
800 rpm	800 rpm	-	20 rpm
-	-	-	20 rpm

WARNING: The notch laser-etched on conical drills has a height of 1.00 mm, corresponding to the height of the smooth neck of the implant. This indication is particularly useful to allow the dentist to choose supra-crestal or sub-crestal insertion of the implant.

Surgical sequence for implants with lenght 11.50 mm

The graphic sequence illustrates the preparation for the implant with ø 5.00 mm. For the other diameters use only the drills indicated in the individual tables.
The use of the STOP is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility.

		FS-230	FPT3-200-LXS	FG-200/280XS	SH-FK380-115
	SH-380-115 SH-380SL-115		**use up to: marking 11.50 mm**	**use up to: marking 10.00 mm**	
ø 3.80 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-
	SH-425-115 SH-425SL-115		**marking 11.50 mm**	**marking 10.00 mm**	
ø 4.25 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-
	SH-500-115 SH-500SL-115		**marking 11.50 mm**	**marking 10.00 mm**	
ø 5.00 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-

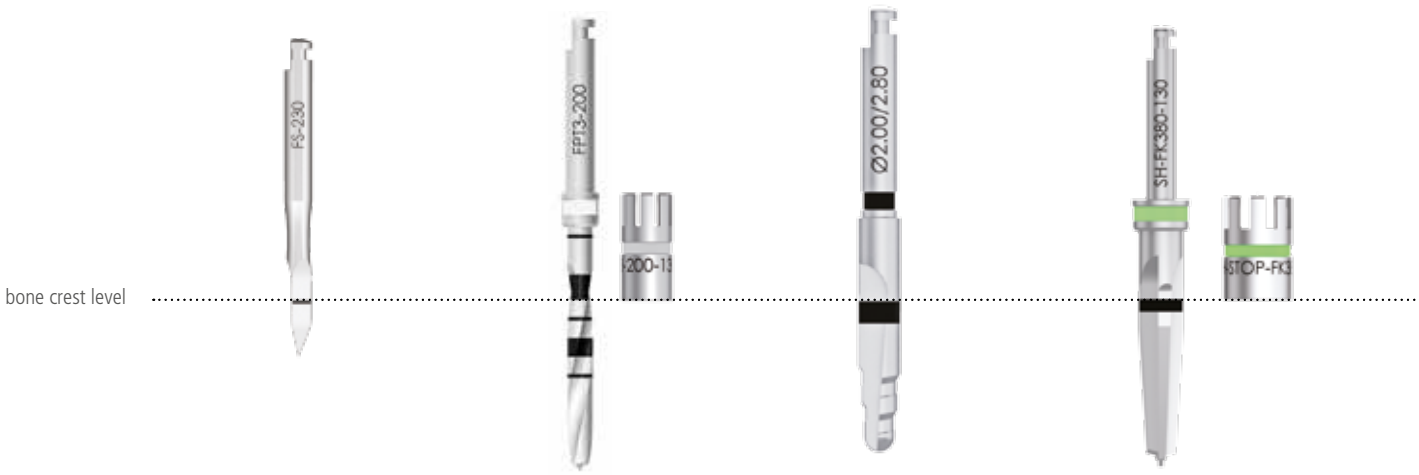


SH-FK425-115	SH-FK500-115	SH-MS-500-CA	EASYC2-EX230-CA
		50 Ncm max	
-	-	SH-MS-380 (20 rpm)	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
900 rpm	-	SH-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	20 rpm
800 rpm	-	-	20 rpm
-	-	-	20 rpm
900 rpm	900 rpm	SH-MS-500 (20 rpm)	20 rpm
900 rpm	900 rpm	-	20 rpm
800 rpm	800 rpm	-	20 rpm
-	-	-	20 rpm

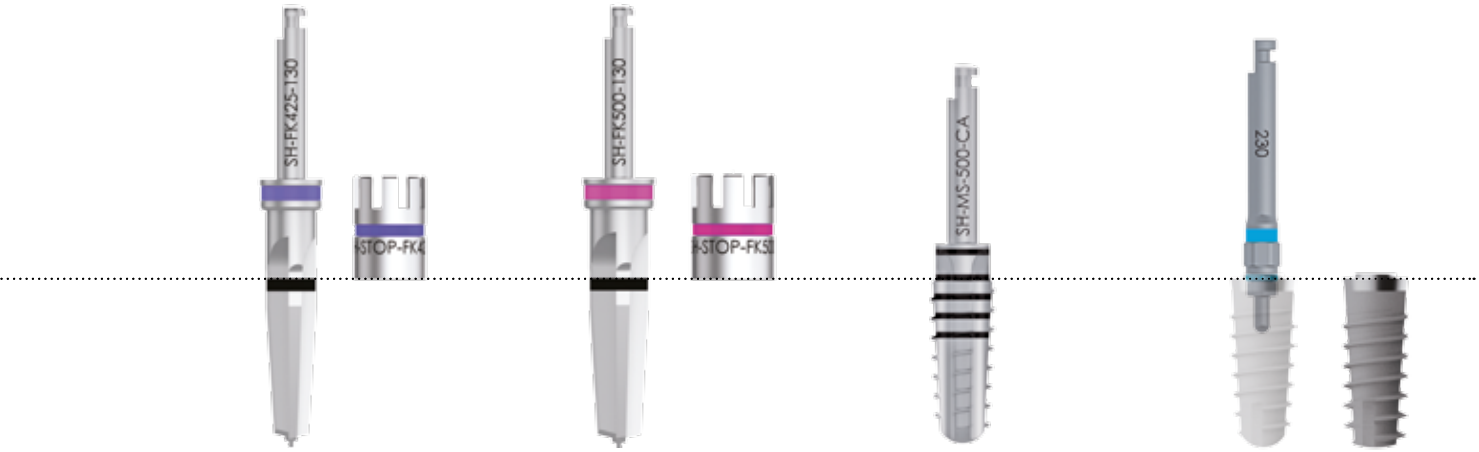
WARNING: The notch laser-etched on conical drills has a lenght of 1.00 mm, corresponding to the height of the smooth neck of the implant. This indication is particularly useful to allow the dentist to choose supra-crestal or sub-crestal insertion of the implant.

Surgical sequence for implants with lenght 13.00 mm

The graphic sequence illustrates the preparation for the implant with ø 5.00 mm. For the other diameters use only the drills indicated in the individual tables.
The use of the STOP is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility.



		FS-230	FPT3-200-LXS	FG-200/280XS	SH-FK380-130
	SH-380-130 SH-380SL-130		**use up to: marking 13.00 mm**	**use up to: marking 10.00 mm**	
ø 3.80 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-
	SH-425-130 SH-425SL-130		**marking 13.00 mm**	**marking 10.00 mm**	
ø 4.25 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-
	SH-500-130 SH-500SL-130		**marking 13.00 mm**	**marking 10.00 mm**	
ø 5.00 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-



SH-FK425-130	SH-FK500-130	SH-MS-500-CA	EASYC2-EX230-CA
		50 Ncm max	
-	-	SH-MS-380 (20 rpm)	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
900 rpm	-	SH-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	20 rpm
800 rpm	-	-	20 rpm
-	-	-	20 rpm
900 rpm	900 rpm	SH-MS-500 (20 rpm)	20 rpm
900 rpm	900 rpm	-	20 rpm
800 rpm	800 rpm	-	20 rpm
-	-	-	20 rpm

WARNING: The notch laser-etched on conical drills has a lenght of 1.00 mm, corresponding to the height of the smooth neck of the implant. This indication is particularly useful to allow the dentist to choose supra-crestal or sub-crestal insertion of the implant.

Surgical sequence for implants with lenght 15.00 mm

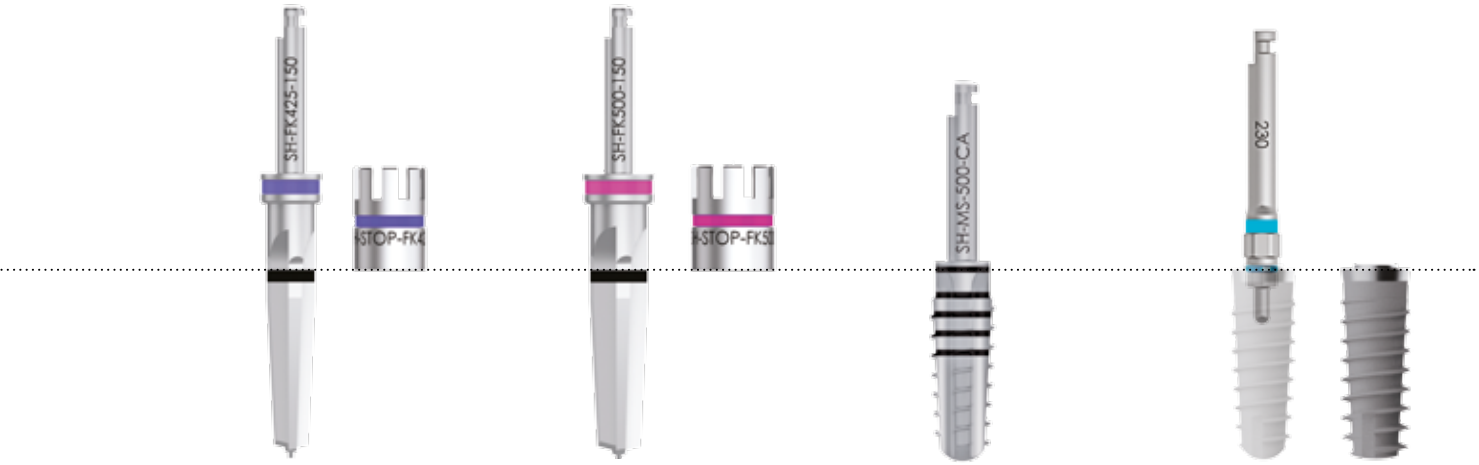
The graphic sequence illustrates the preparation for the implant with ø 5.00 mm. For the other diameters use only the drills indicated in the individual tables. The use of the STOP is at the dentist's discretion. However, its use is recommended, especially in cases of poor intra-operative visibility.

FS-230 | **FPT3-200-LXS** | **FG-200/280XS** | **SH-FK380-150**

	SH-380-150 SH-380SL-150		use up to: marking 15.00 mm	use up to: marking 10.00 mm	
ø 3.80 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-

	SH-425-150 SH-425SL-150		marking 15.00 mm	marking 10.00 mm	
ø 4.25 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-

	SH-500-150 SH-500SL-150		marking 15.00 mm	marking 10.00 mm	
ø 5.00 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	800 rpm
	BONE D4	900 rpm	preparation with osteotomes	-	-



SH-FK425-150	SH-FK500-150	SH-MS-500-CA	EASYC2-EX230-CA
		50 Ncm max	
-	-	SH-MS-380 (20 rpm)	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
-	-	-	20 rpm
900 rpm	-	SH-MS-425 (20 rpm)	20 rpm
900 rpm	-	-	20 rpm
800 rpm	-	-	20 rpm
-	-	-	20 rpm
900 rpm	900 rpm	SH-MS-500 (20 rpm)	20 rpm
900 rpm	900 rpm	-	20 rpm
800 rpm	800 rpm	-	20 rpm
-	-	-	20 rpm

WARNING: The notch laser-etched on conical drills has a lenght of 1.00 mm, corresponding to the height of the smooth neck of the implant. This indication is particularly useful to allow the dentist to choose supra-crestal or sub-crestal insertion of the implant.

Implant insertion

(1) Use the patient label found inside the pack for the patient's medical file and apply it on the Dental Card: this will make it easier to record the patient's treatment plan and will keep a trace of the batch used.

(2) Open the blister and place the vial contained in it on a sterile surface (i.e. on a disposable towel or sterile cloth) next to the operating field.

(3) Immediately before inserting it 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 mounter is presented with the hexagon ready to be engaged. The implant may be picked up using the driver EASYC2-EX230-CA and then screwed mechanically in place with the aid of a suitable surgical micromotor with torque control set at a screwing speed of 20 rpm and max torque 70 Ncm. At the moment this value is the maximum that can be reached by the micromotors on the market. The driver has been tested up to 70 Ncm and has not presented any deformations or failures. Instruments with torque control, both mechanical and normal, are regularly calibrated with a suitable calibrated instrument.

Phase after inserting the implant

HEALING TIMES

It is essential to respect the healing times recommended in implant surgery and to check periodically the state of evolution of osseointegration, even with x-rays. The preliminary healing times at implant loading are influenced by numerous factors:

- the quality of the receiving bone;
- the length of the implant used;
- the number of implants to be splinted together;
- the positioning of the implants in a line or along an arch.

In cases where all or many of the so-called factors are positive, a premature or immediate loading can be assumed (see paragraph on METHOD OF USE on page 7).

SECOND SURGICAL PHASE

In the second surgical phase, therefore, the closing screws of the implants are exposed and any hard tissues in excess are removed, after which the implants are unscrewed. If the right angle driver is used, the surgical micromotor must be set with the following parameters: 20 rpm and torque 10 Ncm. Once the transgingival healing screws have been positioned, the margins of the flaps are secured, the soft tissue is adapted to the profile of the transgingival healing screw and sutured around it. It is recommended to secure the healing screws manually or at any rate with a torque no greater than 10 Ncm.
The soft tissues can be conditioned with an individualised temporary post instead of transgingival healing screws.

In the case of deferred loading, if a submerged double-phase surgical technique is chosen, to minimise discomfort conditioned by the observance of the biological times for osseointegration, temporary mobile prostheses must be used carefully, unloading them amply. Implant protocols with two surgical phases require a healing period to pass for manifesting the biological processes that lead to osseointegration before the second surgical procedure can be performed to replace the surgical cover screws with the transgingival healing screws.

Intra-operative removal of the implants

Should it be necessary to remove an implant that is already inserted, you can proceed by directly holding the hexagonal working connection of the implant. Accurately clean any blood and residue produced during insertion from the well of the implant, take the driver BC-EX230 from the surgical kit, insert the hexagonal part of the driver inside the implant well making sure the instrument is in axis with the implant and that the internal connection is engaged completely and deeply; now block the ratchet head and connect it to the hexagonal part of the driver, making sure the laser-etched arrow on the ratchet head indicates the counter clockwise direction and prise it up while keeping the driver/ratchet assembly in axis with your index finger.

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, good home dental care and regular sessions with a professional hygienist increase the device's service life. Complications such as the pull-out of screws that fasten the restoration to the implants or bone reabsorption causing the loss of the mucosal resting surface in patients with removable restorations can be easily prevented with regular check-ups. If post or prosthetic connecting screws are needed, these operations must be performed by the practitioner using suitable devices with torque tightening control. The calibration of these devices should be checked regularly. In the event of complications of this kind, patients should contact their practitioner as soon as possible, so that the restoration can be repaired and functionality restored. A delay in contacting the doctor may lead to the fracture of the connecting screw or of the prosthesis, in the first case, and to implant failure in the second case, which could impair the rehabilitative result. Practitioners must make this clear to their patients.
Complications can be of a biological nature (loss of integration) or mechanical nature (fracture of a component due to overloading). 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 odontologist in the interests of the success of the same treatment. The patient must, therefore, maintain good hygiene, which should be confirmed during check-up appointments, guaranteed and recorded and the practitioners instructions and orders shall be observed.
The warranty only covers manufacturing defects as long as the faulty piece is identified by the article code and batch number and returned within the validity period of the warranty. The warranty terms are available on the website www.sweden-martina.com.

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 be disposed of as such. If dirty, they must be disposed of as biological waste. In general, the local regulations apply.

Material composition

The materials used for manufacturing the devices 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 and conform to the harmonised 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.

GR. 4 TITANIUM (cold worked)* ASTM F67-13, ISO 5832-2:2012	Maximum allowed values (%)	Tolerance
Chemical composition:		
Nitrogen	0.05	+/- 0.02
Carbon	0.10	+/- 0.02
Hydrogen	0.015	+/- 0.002
Iron	0.25	+/- 0.10 (%<0.25)
		+/- 0.15 (%>0.25)
Oxygen	0.20	+/- 0.02 (%<0.20)
		+/- 0.03 (%>0.20)
Titanium	remainder	-

* *This technical information complies with the express specifications of the regulations in force for the use of Gr. 4 titanium in implantology:*
- *ASTM F67-13: Standard Specification for unalloyed titanium, for surgical implant applications.*
- *ISO 5832-2:2012: Implant for surgery . Metallic materials . Part 2: Unalloyed titanium.*

PLEASE NOTE: the use of bars obtained from cold processing, for the production of Sweden & Martina Spa implants, allows the exploitation of the mechanical characteristics of tensile strength and yield strength about 15% higher than those that can be obtained with a hot process (respectively 550 MPa and 483 MPa).

Surgical instruments

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

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

Remember to ask patients whether they are allergic to any of the raw materials.

Identification of the manufacturer

The manufacturer of Shelta implants and of the respective surgical instruments is:

Sweden & Martina
Via Veneto 10
35020 Due Carrare (Padova) – Italia
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 shown in table 01. Even though the dental implants and respective surgical instruments can be used in all patients who have the suitable therapeutic indications, they must only be used by professional dentists or surgeons with the necessary qualifications and training.

Table 01- Risk classes

device	pack	directive 93/42	rule	risk class
Implant fixtures for dental use, belonging to the Shelta implant system	Single-use and sterile package, fixture complete with surgical cover screw	Implantable devices intended for long-term use (over 30 days)	8	IIb
Surgical cover screws	Sold in packages complete with the respective fixtures or sold individually (single-use and sterile packages)	Implantable devices intended for long-term use (over 30 days)	8	IIb
Complete surgical kits	Sold in NON sterile packages	Reusable surgical instruments	6	IIa
Radel instrument trays and x-ray templates	Sold in NON sterile packages	Non invasive medical devices	1	I
Surgical drills (precision, conical, cylindrical, for distal use, countersinks, bone profilers) and Drill extensions, Drill stops, Bone taps, Drivers and Drivers/Screwdrivers	Sold in NON sterile packages	Reusable invasive surgical instruments for temporary use (for less than 60 minutes at a time)	6	IIa
Osteotomes/Bone Expanders, Drivers/ Screwdrivers, Bone taps, Drivers, Hex drivers, Hand knobs, Depth gauges, Parallelism pins and Stents	Sold in NON sterile packages	Reusable surgical instruments for temporary use (for less than 60 minutes at a time), not intended to be connected to an active medical device	6	I

GENERAL

Key to symbols used on the implant packs:

symbol	description
	Caution! See instruction for use
	Batch number
	Code
	Manufacturer
	Consult instructions for use
	CE conformity mark for class IIa/IIb products
	American federal law restricts this device to sale by or by order of a professional practitioner
	Do not resterilize
	Single use product, do not reuse
	Do not use if packaging is damaged
	Sterile device, sterilisation by radiation.
	Expiry date

Key to symbols used on the surgical instrument packs:

symbol	description
	Caution! See instruction for use
	Batch number
	Code
	Manufacturer
	Consult instructions for use
	CE conformity mark for class IIa/IIb products
	CE conformity mark for class I products
	American federal law restricts this device to sale by or by order of a professional practitioner
	No sterile device

Key to symbols used on the prosthesis packs:

symbol	description
	Caution! See instruction for use
	Batch number
	Code
	Manufacturer
	Consult instructions for use
	CE conformity mark for class IIa/IIb products
	CE conformity mark for class I products
	American federal law restricts this device to sale by or by order of a professional practitioner
	Single use product, do not reuse
	No sterile device

THE LATEST REVISION DATE OF THIS MANUAL IS MARCH 2016

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