# Surgical manual

# SHELTA


sweden & martina

# 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.

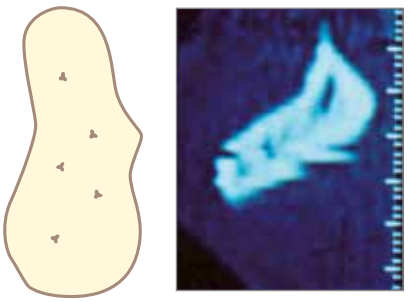
It is contraindicated to fit implants and implant restorations in patients with poor general or oral health, those who are unable to monitor their general conditions properly or those who have had organ transplants. Psychologically unstable patients, alcohol or drug abusers, and poorly motivated or uncooperative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

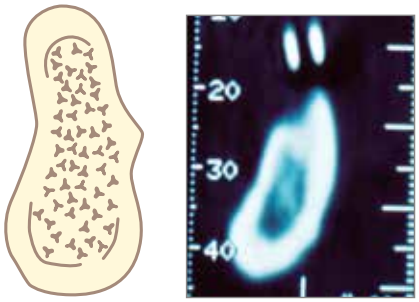
Situations that may occur after surgical procedures include temporary local swelling, oedema, haematoma, temporary sensitivity alterations, temporary masticatory limitations, post-surgical micro-haemorrhages in the following 12-24 hours. The patient may also experience pain, speech problems, gingivitis,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

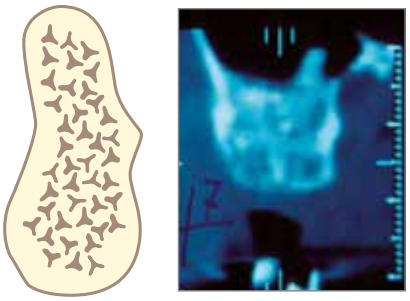
In addition to an oral examination, both clinical and with x-rays, it is recommended to take a Completed Tomography (C.T.) scan of the interested area; once the x-rays and scans have been obtained, the specialist can identify the most suitable implant with the help of convenient transparent radiographic 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:



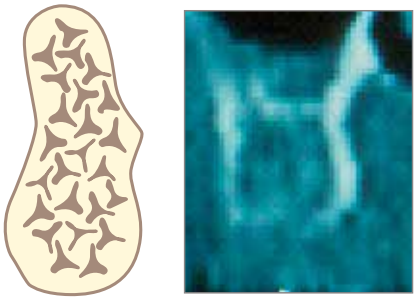
BONE D1: dense cortical bone




BONE D2: thick dense to porous cortical bone on crest and coarse trabecular bone within.



BONE D3: thin porous cortical bone on crest and fine trabecular bone within.



BONE D4: fine trabecular bone.

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

# General indications

Shelta fixtures 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. 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 implants 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.

## Key to the implant codes

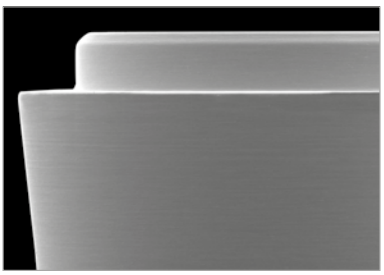
The implant codes are so-called "mnemonic" codes, i.e. they allow easy identification of the piece. Below is a table showing how the mnemonic codes work using SH-ZT-380SL-115 as an example:

| Type of implant<br>SH- | Surface<br>ZT- | Diameter<br>380 | Thread<br>SL- | Length<br>115 |
|---|---|---|---|---|
| SH: Shelta Implant | ZT: ZirTi surface | 380: 3.80 mm<br>425: 4.25 mm<br>500: 5.00 mm | SL: Wide Thread | 085: 8.50 mm<br>100: 10.00 mm<br>115: 11.50 mm<br>130: 13.00 mm<br>150: 15.00 mm |
| | | *it's the size of the platform 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* |

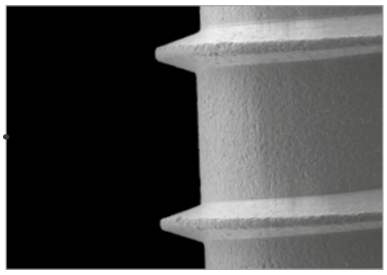
***All measures in the catalogue are given in mm, unless indicated otherwise.***

# Shelta implants

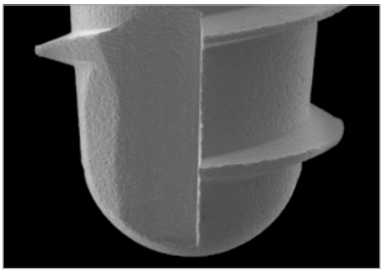
Shelta implants have a collar for the prosthetic support and a machined neck.

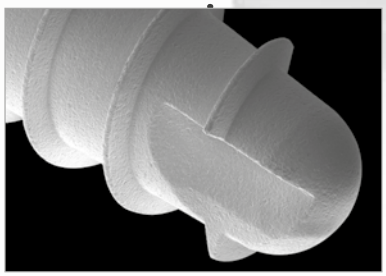


The thread of Shelta implants is characterised by a triangular profile.



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



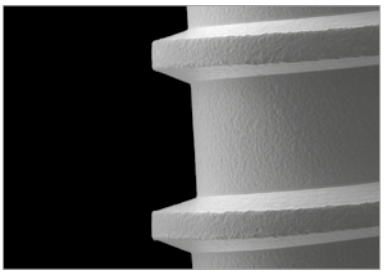


The apex of Shelta implants has two cut-outs that increase its penetration capacity and non-rotational property.

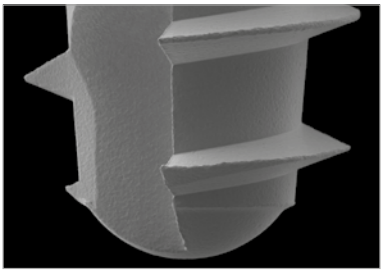
# Shelta SL implants (Wide Thread)

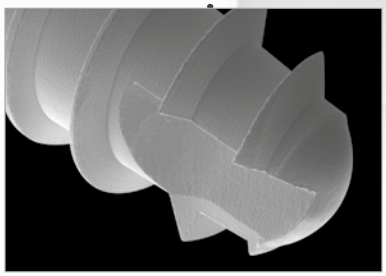
Shelta SL implants have the same prosthetic support collar and the same machined neck as Shelta implants.

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



The thread of the Shelta SL implants maintains a costant outer thread diameter with a tapered inner body diameter. This results in pronounced and sharp apical threads.



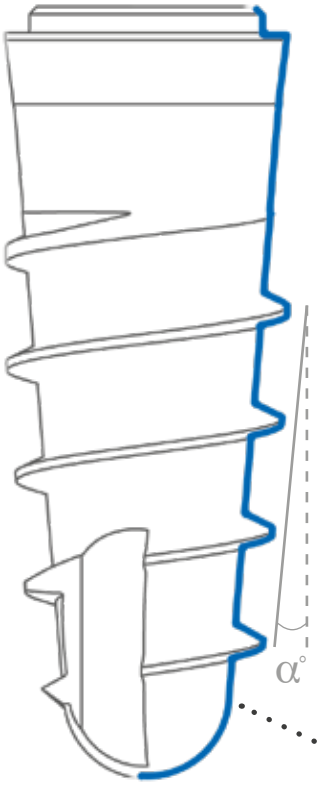


Shelta SL implants have a rounded apex, but the dimensions is reduced due to the more pronounced threading.

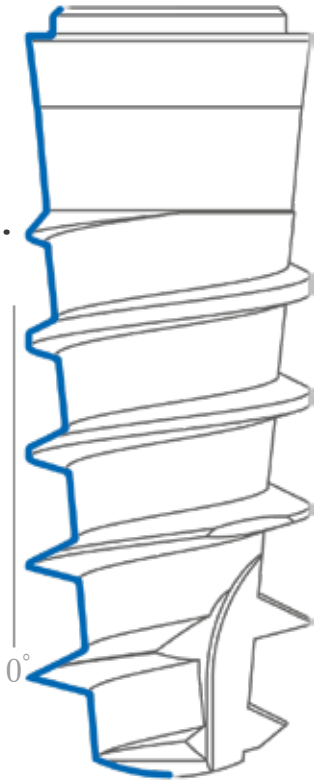
# Choosing the thread

Shelta and Shelta SL implants differ in the morphology of the apical part.

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.

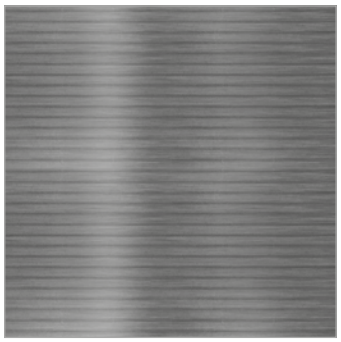
In **Shelta** implants both the core of the implant and the threading have a conical morphology.
Furthermore, unlike Shelta SL implants, the apex is a complete hemisphere with the presence of a less aggressive thread.

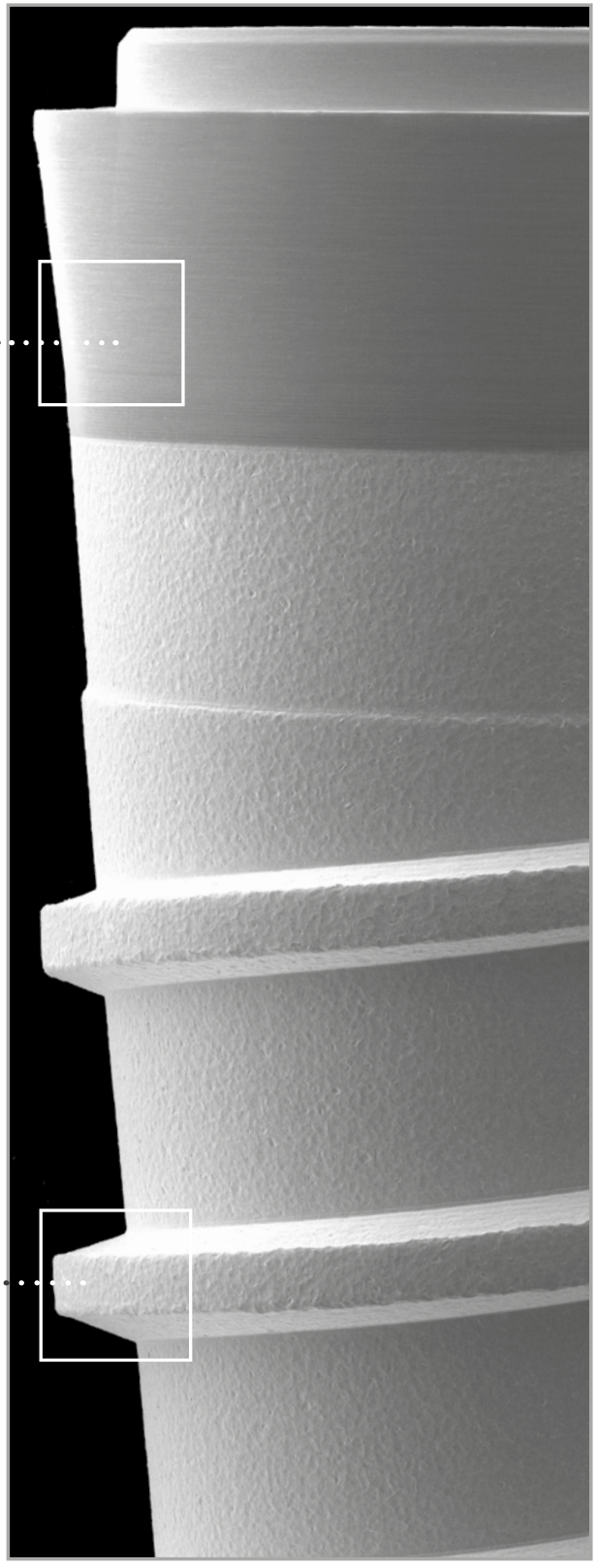
The crest of the thread of **Shelta SL** implants increases gradually in the coronal direction. So in addition to the high cutting capacity of the most apical threads.

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

# ZirTi Surface

The **machined neck** prevents the accumulation of plaque in the area where the post joins the implant.

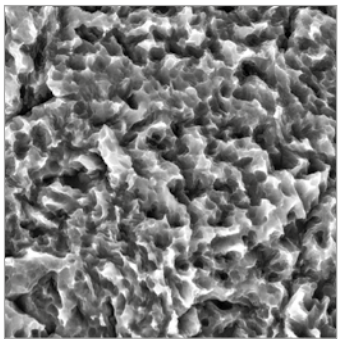


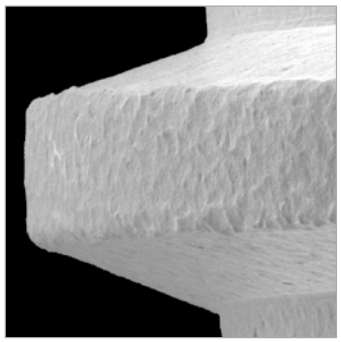


## ZirTi Surface

(Zirconium Sand-Blasted Acid Etched Titanium)

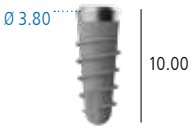
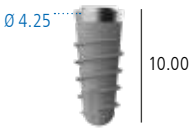
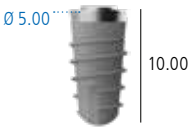
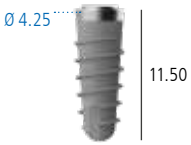
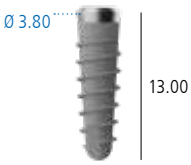
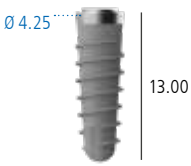
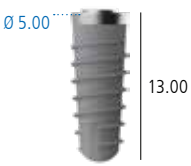
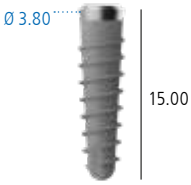
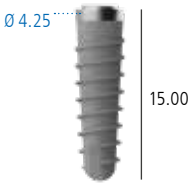
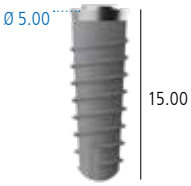
Shelta and Shelta SL implants are available in ZirTi surface. The implant body is treated with appropriate subtraction techniques that give the surface the characteristic ZirTi morphology.





# Shelta implants: the range

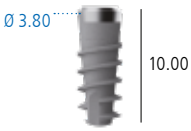
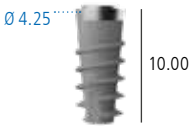
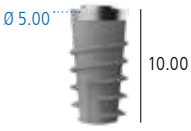
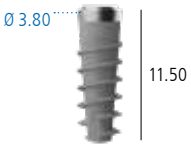
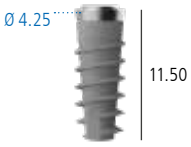
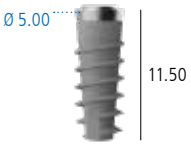
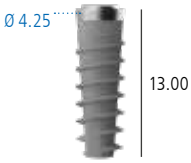
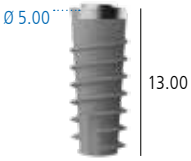
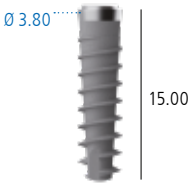
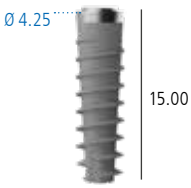
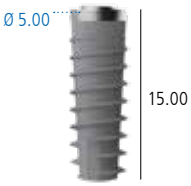
Shelta implants are characterised by tapering the gradually decreases as the length of the implants increases. The angle remains unchanged between implants of different diameters, but of the same length.

| 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 |  SH-ZT-380-115 |  SH-ZT-425-115 |  SH-ZT-500-115 |
| 13.00 |  SH-ZT-380-130 |  SH-ZT-425-130 |  SH-ZT-500-130 |
| 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 8-10 Ncm.*

# Shelta SL implants: the range

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

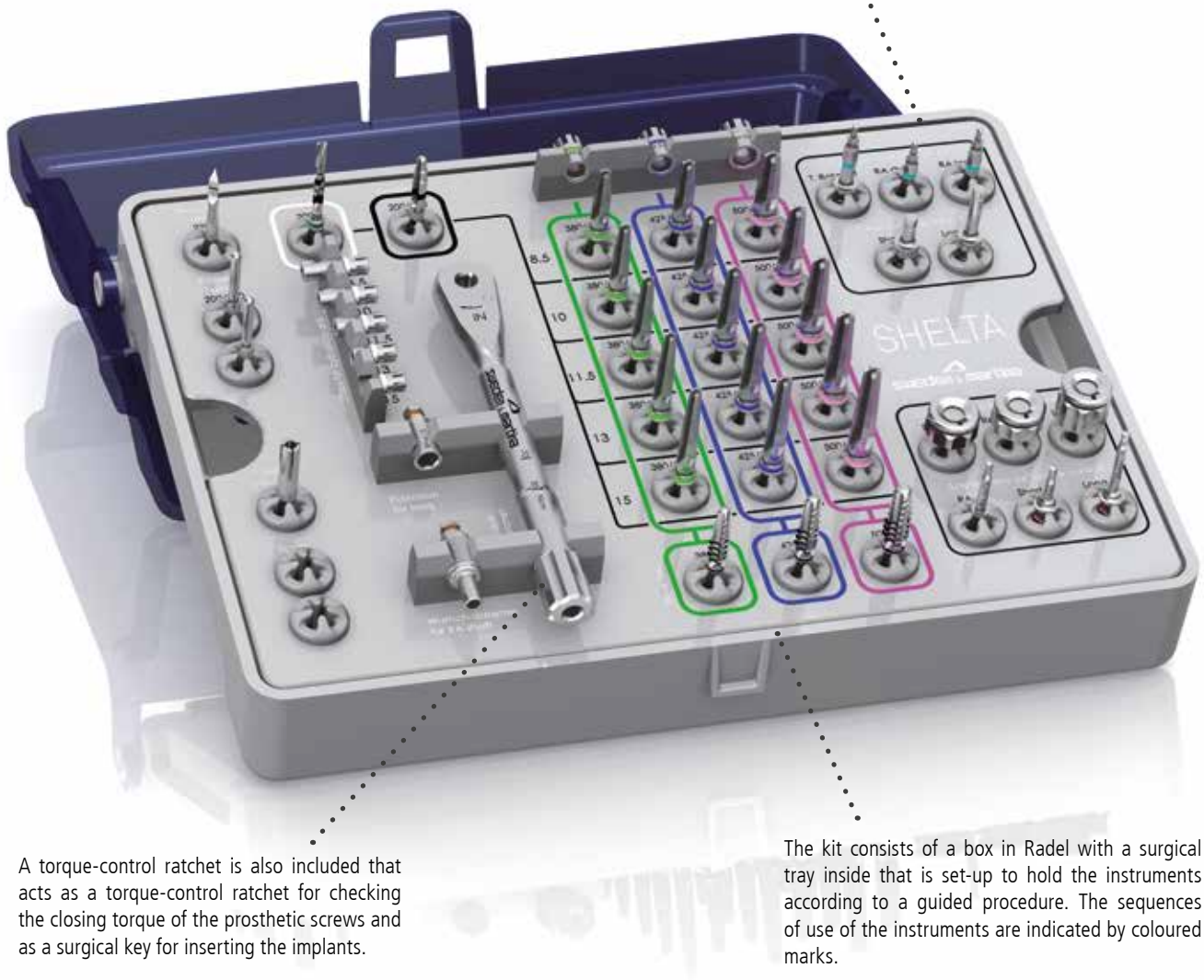
| implant diameter | Ø 3.80 mm | Ø 4.25 mm | Ø 5.00 mm |
|---|---|---|---|
| 8.50 |  SH-ZT-380SL-085 |  SH-ZT-425SL-085 |  SH-ZT-500SL-085 |
| 10.00 |  SH-ZT-380SL-100 |  SH-ZT-425SL-100 |  SH-ZT-500SL-100 |
| 11.50 |  SH-ZT-380SL-115 |  SH-ZT-425SL-115 |  SH-ZT-500SL-115 |
| 13.00 |  SH-ZT-380SL-130 |  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 8-10 Ncm.*

# Surgical kit

The instruments included in the Shelta surgical kit are in steel, have their descriptions screen-printed on the tray to allow the user to identify each instrument more easily and to put it back, with the aid of a colour code system that traces the suitable surgical procedures for the various implant diameters.
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 surgical kit has compact dimensions.




A torque-control ratchet is also included that acts as a torque-control ratchet for checking the closing torque of the prosthetic screws and as a surgical key for inserting the implants.

The kit consists of a 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.

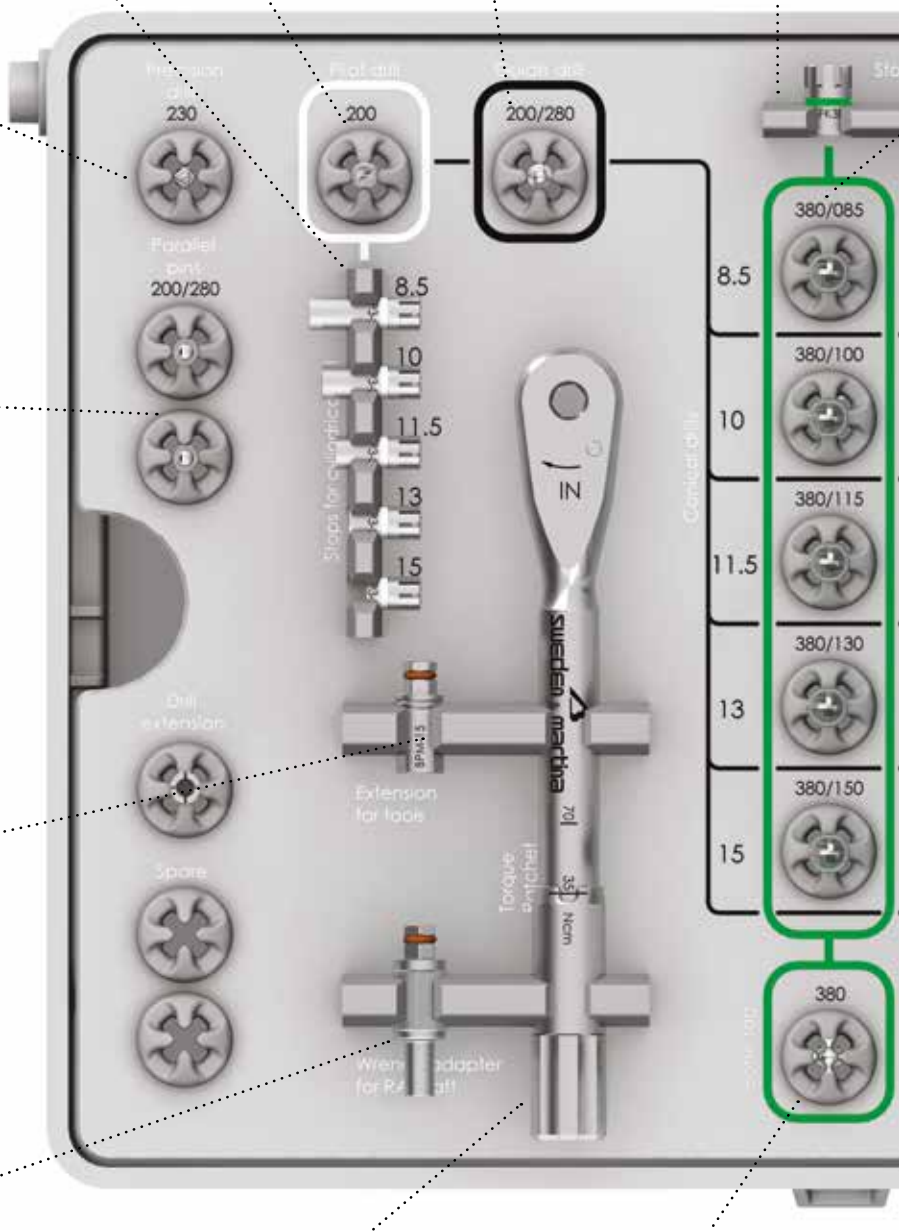
| code | description |
|---|---|
|  ZSHELTA-INT | Complete surgical kit of the instruments necessary for Shelta and Shelta SL implants |
|  SH-TRAY-INT | Radel instrument tray for Shelta and Shelta SL instruments |
|  GROMMET-CA-1 | Kit with 5 spare silicon supports for surgical trays, for drills or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

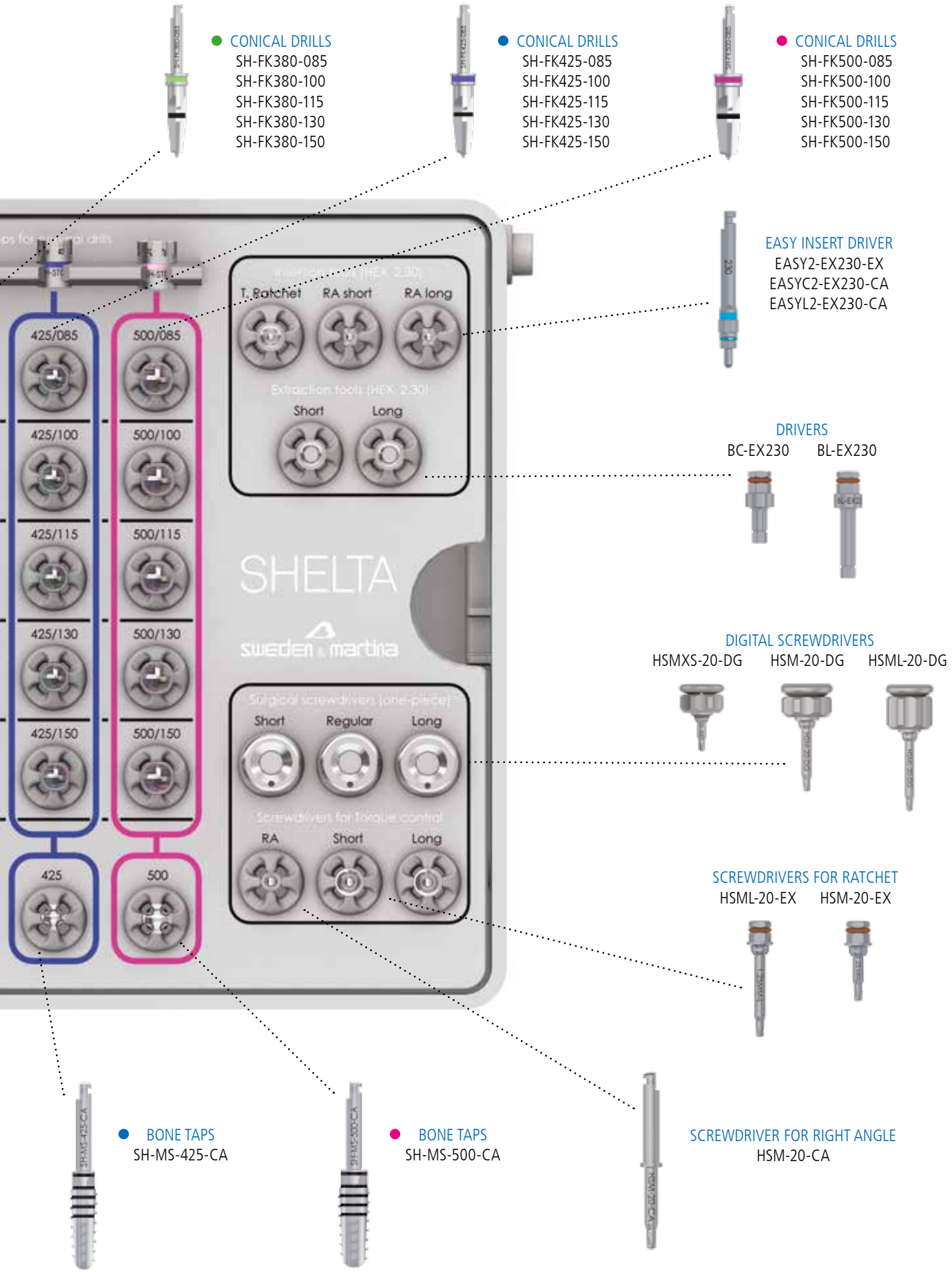
PROF-CAL3

BPM-15

ADAPTER
AVV-CA-DG-EX

TORQUE-CONTROL RATCHET
CRI5-KIT

- 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 DRIVER
EASY2-EX230-EX
EASYC2-EX230-CA
EASYL2-EX230-CA
DRIVERS
BC-EX230
BL-EX230
DIGITAL SCREWDRIVERS
HSMXS-20-DG
HSM-20-DG
HSML-20-DG
SCREWDRIVERS FOR RATCHET
HSML-20-EX
HSM-20-EX
BONE TAPS
SH-MS-425-CA
BONE TAPS
SH-MS-500-CA
SCREWDRIVER FOR RIGHT ANGLE
HSM-20-CA
T. Ratchet
RA short
RA long
Short
Long
Short
Regular
Long
RA
Short
Long
425/085
425/100
425/115
425/130
425/150
425
500/085
500/100
500/115
500/130
500/150
500
SHELTA
sweden martina

# General indications

The surgical instruments designed for use with the implant systems manufactured by Sweden & Martina are reusable medical devices intended for temporary use in the oral cavity.
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 and sterilised according to the instructions reported below. Failure to follow these warnings may potentially 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 and according the related standard.
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<br>**FK**: Conical drill | 380: 3.80 mm | 115: 11.50 mm |
| SH-STOP-FK380 | **SH**: Shelta Implant<br>**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 **steel** specifically for surgical use 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 **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 40 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 steel for surgical use. 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.

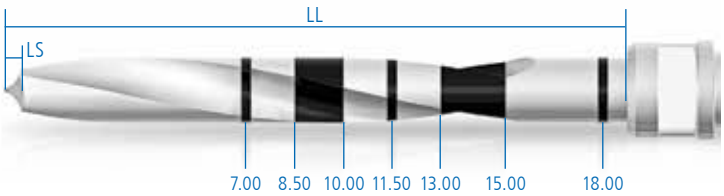

### IMPORTANT WARNING

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 | 19.30 |

## 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.

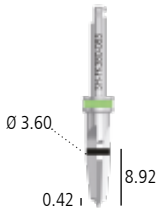
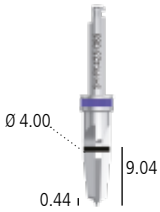
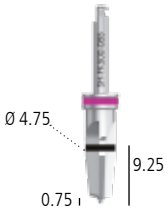
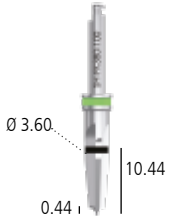
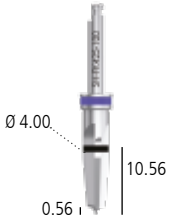
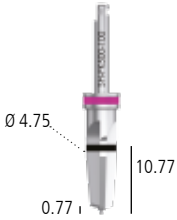
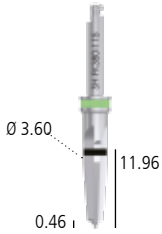
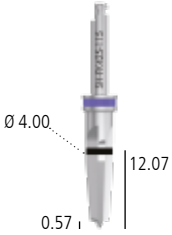
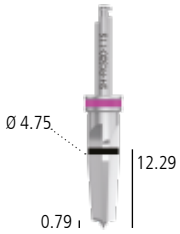
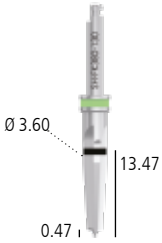
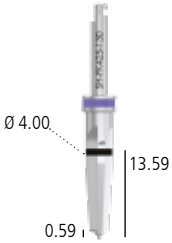
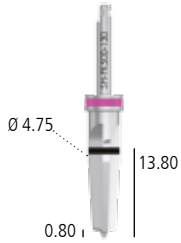
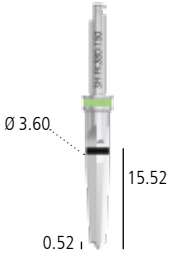
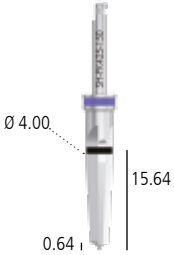
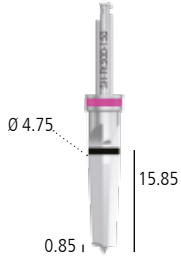
# Intermediate drill FG-200/280XS

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 useful on compact bone. 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 |

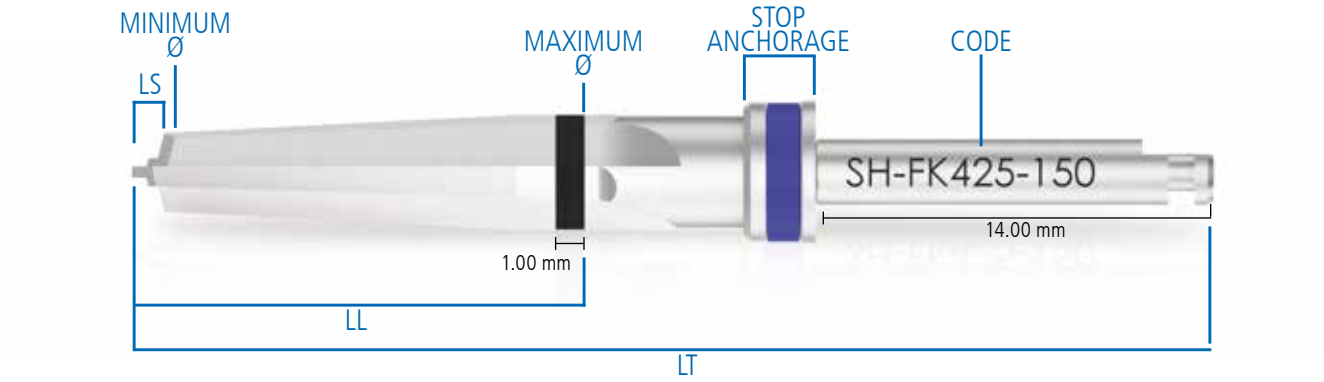
# Conical drills

The conical drills are also made of 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 |  FH-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.

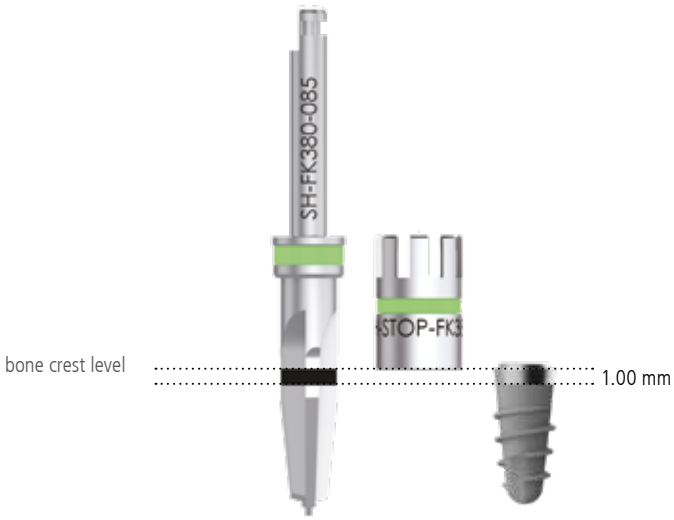
| drill code | corresponding implant | nominal Ø | maximum Ø | LL | LS | colour code |
|---|---|---|---|---|---|---|
| SH-FK380-085 | SH-380-085<br>SH-380SL-085 | 3.80 | 3.60 | 8.92 | 0.42 | GREEN |
| SH-FK380-100 | SH-380-100<br>SH-380SL-100 | 3.80 | 3.60 | 10.44 | 0.44 | GREEN |
| SH-FK380-115 | SH-380-115<br>SH-380SL-115 | 3.80 | 3.60 | 11.96 | 0.46 | GREEN |
| SH-FK380-130 | SH-380-130<br>SH-380SL-130 | 3.80 | 3.60 | 13.47 | 0.47 | GREEN |
| SH-FK380-150 | SH-380-150<br>SH-380SL-150 | 3.80 | 3.60 | 15.52 | 0.52 | GREEN |
| SH-FK425-085 | SH-425-085<br>SH-425SL-085 | 4.25 | 4.00 | 9.04 | 0.44 | BLUE |
| SH-FK425-100 | SH-425-100<br>SH-425SL-100 | 4.25 | 4.00 | 10.56 | 0.56 | BLUE |
| SH-FK425-115 | SH-425-115<br>SH-425SL-115 | 4.25 | 4.00 | 12.07 | 0.57 | BLUE |
| SH-FK425-130 | SH-425-130<br>SH-425SL-130 | 4.25 | 4.00 | 13.59 | 0.59 | BLUE |
| SH-FK425-150 | SH-425-150<br>SH-425SL-150 | 4.25 | 4.00 | 15.64 | 0.64 | BLUE |
| SH-FK500-085 | SH-500-085<br>SH-500SL-085 | 5.00 | 4.75 | 9.25 | 0.75 | MAGENTA |
| SH-FK500-100 | SH-500-100<br>SH-500SL-100 | 5.00 | 4.75 | 10.77 | 0.77 | MAGENTA |
| SH-FK500-115 | SH-500-115<br>SH-500SL-115 | 5.00 | 4.75 | 12.29 | 0.79 | MAGENTA |
| SH-FK500-130 | SH-500-130<br>SH-500SL-130 | 5.00 | 4.75 | 13.80 | 0.80 | MAGENTA |
| SH-FK500-150 | SH-500-150<br>SH-500SL-150 | 5.00 | 4.75 | 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:

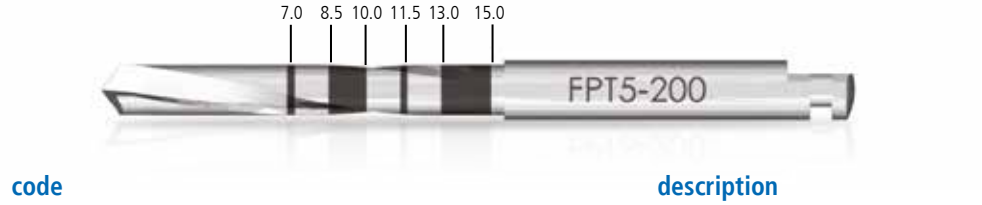
| |  SH-STOP-FK380 |  SH-STOP-FK425 |  SH-STOP-FK500 |
|---|---|---|---|
| **COLOUR CODES** | GREEN | BLUE | MAGENTA |
| **NOMINAL Ø** corresponds to the implant diameter | 3.80 | 4.25 | 5.00 |
| **DRILL FOR IMPLANT Length 8.50 mm** | SH-FK380-085 | SH-FK425-085 | SH-FK500-085 |
| **DRILL FOR IMPLANT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

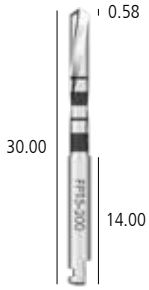
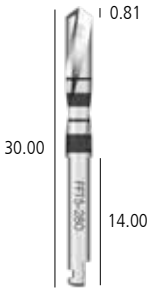
As already indicated with regard to the pilot drill stops, in this case too it is recommended always to check that the stop is inserted at the desired height. Incomplete insertion may reduce the preparation height. Any insertion difficulties can be resolved by loosening the stop tabs slightly, using 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 40, 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 25).



# Drills for distal sectors

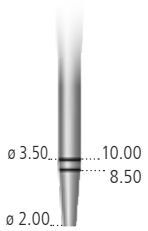
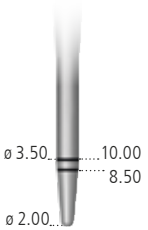
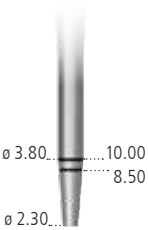
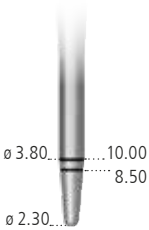
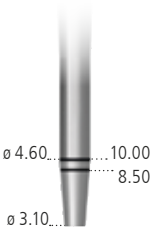
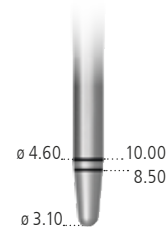
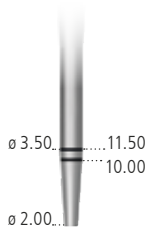
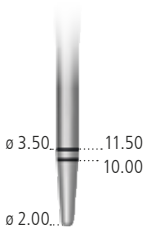
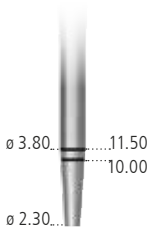
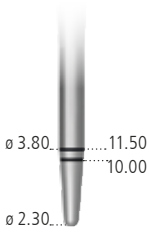
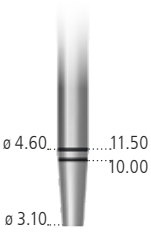
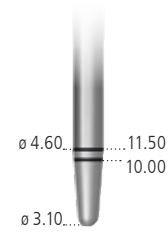
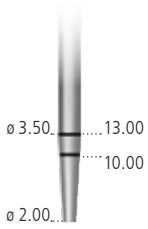
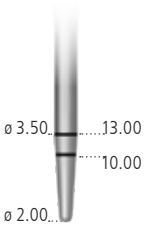
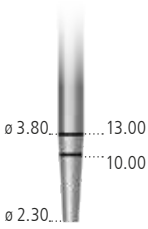
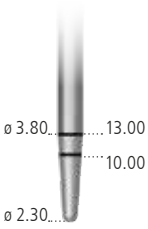
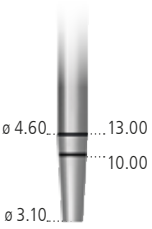
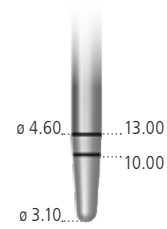
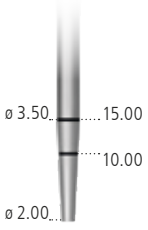
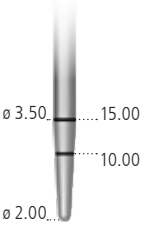
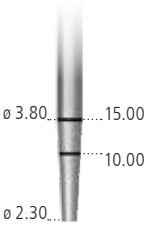
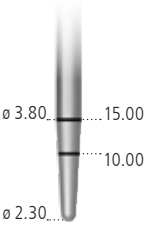
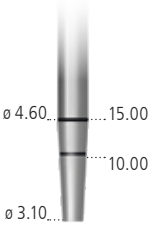
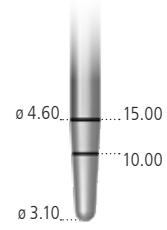
Short drills with a 14.00 mm long shank and total length of 30.00 mm are optionally available; to be used without stops, they are dedicated to distal sectors and do not have the colour code on the shank.




| code | description |
|---|---|
|  FPT5-200-LXS | Cylindrical pilot drill, Ø 2.00 mm, without irrigation, not included in the surgical kit |
|  FFT5-280-LXS | Universal final cylindrical drill, Ø 2.80 mm, without irrigation, not included in the surgical kit |

# Osteotomes

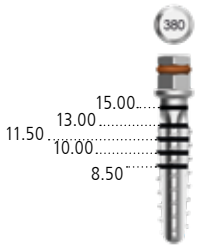
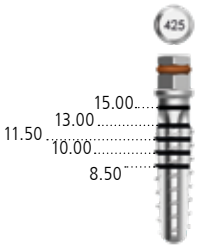
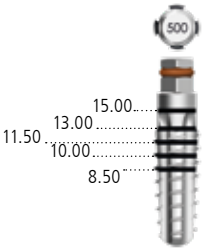
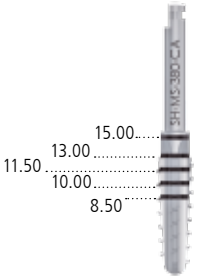
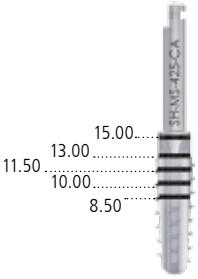
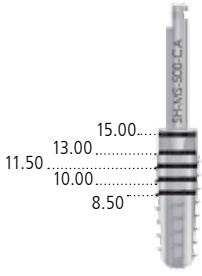
A complete set of osteotomes has been designed for the expansion of thin crests, for mini-crest lifts and for the compaction of poorly mineralised bone, to be used as an alternative to the final drills. The osteotomes are invasive surgical instruments, manual, intended for creating holes in bone, especially 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 steel for surgical use, 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.


| implant diameter | Ø 3.80 mm | Ø 4.25 mm | Ø 5.00 mm |
|---|---|---|---|
| Bone taps with hexagonal attachment |  SH-MS-380 |  SH-MS-425 |  SH-MS-500 |
| Bone taps with right angle attachment |  SH-MS-380-CA |  SH-MS-425-CA |  SH-MS-500-CA |

# Easy Insert drivers

The 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.

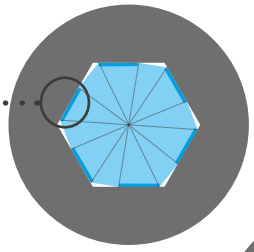
A single instrument that allows the insertion of all Shelta implant diameters.

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 a prosthetic index.

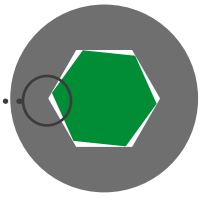
Engagement is obtained with a **titanium O-ring** that engages inside the connection.

# SURGICAL INSTRUMENTS

The **design** of the drivers prevents deformations to the implant connection. The special design of the Easy Insert drivers (in green) enables to interact on a portion of the surface in the centre of the connection hexagon.



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



When using the Easy Insert drivers with the dynamometric ratchet, as if using any other instrument of implant insertion with dynamometric key, it is recommended to be careful in maintaining the working axis as vertical as possible. Moreover, it is fundamental that the ratchet movement during the screwing phase is slow and uniform, avoiding sudden strokes. It is recommended to hold the ratchet in the nearest part to the connection and to maintain a constant and light pressure on it with a finger, in order to allow greater stability during the screwing.

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 and sterilised: it can be distinguished from the others as it is entirely anodised in blue colour.

## 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 dynamometric ratchet.

# Drivers

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

| code | description |
|---|---|
|  BC-EX230 | Short driver (hex 2.30 mm) |
|  BL-EX230 | Long driver (hex 2.30 mm) |

**IMPORTANT WARNING**

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

# Screwdrivers

The surgical kit contains various screw 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 screw 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 connecting screws, digital, extra-short |
|  HSM-20-DG | Screwdriver for surgical cover screw and connecting screws, digital, short |
|  HSML-20-DG | Screwdriver for surgical cover screw and connecting screws, digital, long |

They are practical in the intra-operative stage because they are safe 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 connecting screws, with hexagonal connector for torque-control ratchet or hand knob, short |
|  HSML-20-EX | Screwdriver for connecting 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 connecting 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 connecting 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:

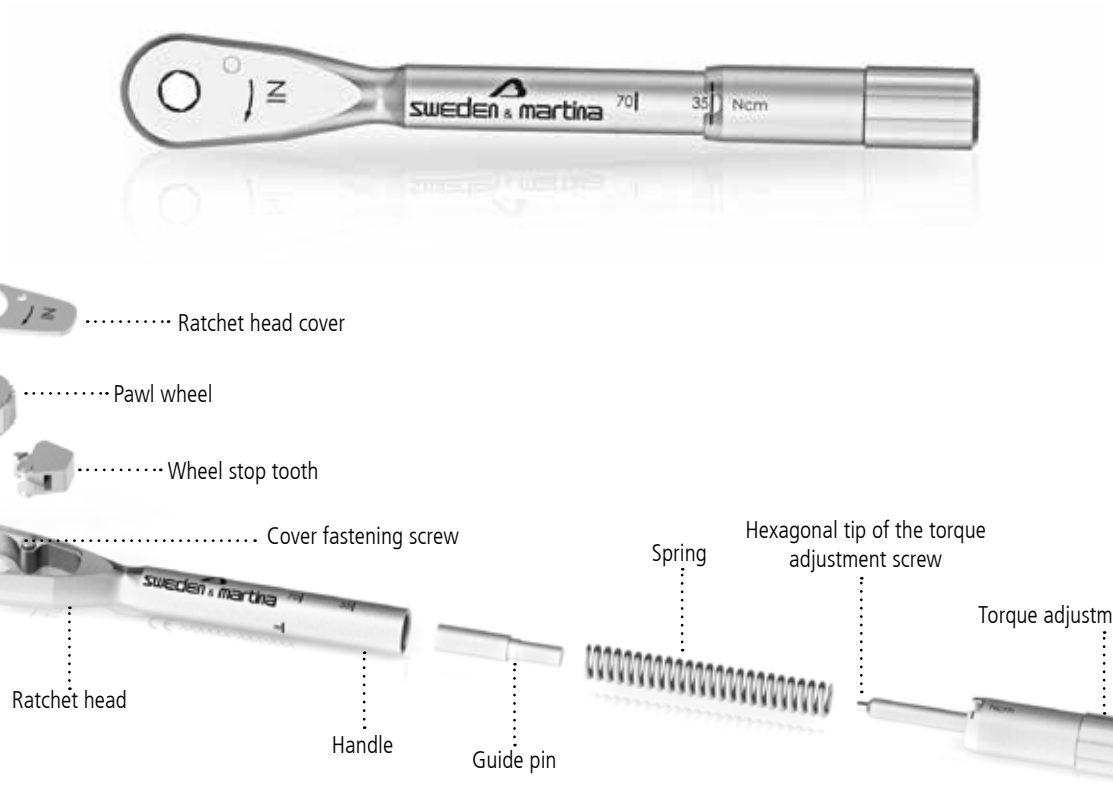
| | |
|---|---|
| surgical cover screws, healing abutments | 8-10 Ncm |
| all prosthetic screws | 20-25 Ncm |
| all prosthetic components screwed directly onto the implant | 25-30 Ncm |

## 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, with its own adjustment key, for quickly screwing the torque adjustment ring nut. 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 torque-control ratchet CRI5-KIT 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 36-37. 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 ratchet 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.

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

### IMPORTANT WARNING

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.

*For setting an increase torque value, just turn the ring nut in a clockwise direction.*

*For decreasing the torque value, just turn the ring nut in an anticlockwise direction, until a value lower than the wanted one; then proceed with the screwing in a clockwise direction until the wanted torque value is reached.*

# Extensions and adapters

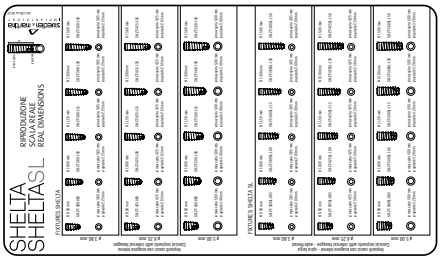
| code | description |
|---|---|
|  BPM-15 | Extension for bone taps, mounters, drivers and manual drivers, with hexagonal connector for torque-control ratched |
|  PROF-CAL3 | Extension for surgical drills |
|  B-AVV-CA3 | Mechanical adapter with right angle shank for instruments with hexagonal connector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

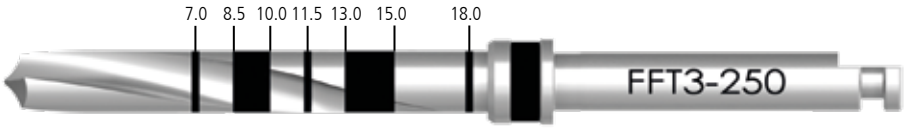
# Bone profilers

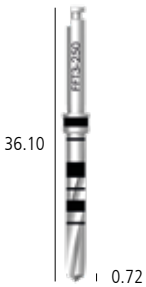
The bone profilers are very useful for levelling a very irregular bone crest at the coronal level, especially in the subsequent use of P.A.D. abutments.

| 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 | 15.00 mm | 18.00 mm |
|---|---|---|---|---|---|---|
|   FFT3-250-LXS |  STOP3-250-070 |  STOP3-250-085 |  STOP3-250-100 |  STOP3-250-115 |  STOP3-250-150 |  STOP3-250-180 |

** 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.*

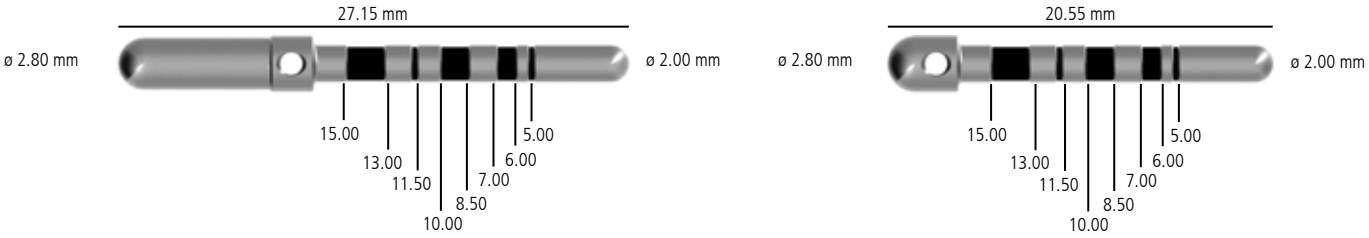
# Parallelism pin PP-2/28

The surgical kit contains six pins that can be used to check the insertion axis of the implants and the parallelism between several fixtures. One side of the pin has a diameter of 2.00 mm and the other 2.80 mm, so that it can be used after drills with these same diameters have been passed.


| 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 and prosthetic components

Attention! The Surgical Instruments and the Prosthetic Components for dental implants are sold NON-STERILE. Before use, they must be cleaned 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 intraoperative complications.

**a. Cleaning**
Containers to be used for washing and transport: there are no special requirements.
In case of automatic cleaning, use an ultrasound bath with a suitable detergent solution (as DURR ID212, DC1 or equivalent). 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 detergent solution (as DURR ID212, DC1 or equivalent) 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.
Do not exceed 120°C when performing a drying cycle.

**b. Steam 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.

**Disposal procedures**
If used, dispose of the surgical accessories as biological waste, according to the local regulations.

## Cleaning, sterilisation and storage of the dynamometric 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 cleaning 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 a lubricant approved.


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.

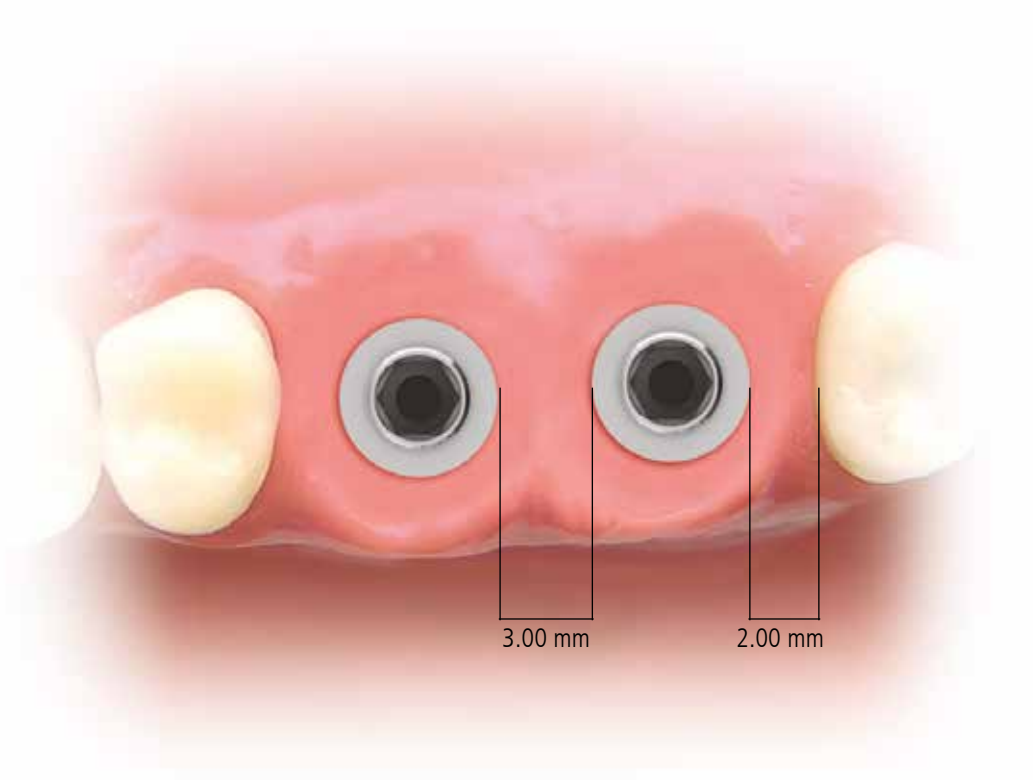
Lubricate the spring inside the ratchet handle as shown in the figure. Assemble the torque adjustment screw, making sure the instrument functions properly. Manually activate the pawl wheel.

**Sterilisation:** in a vacuum autoclave, proceeding as follows:
Temperature = 121 – 124 °C, with autoclave cycle of at least 30 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 22 for the cylindrical pilot drill, and to page 24 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.

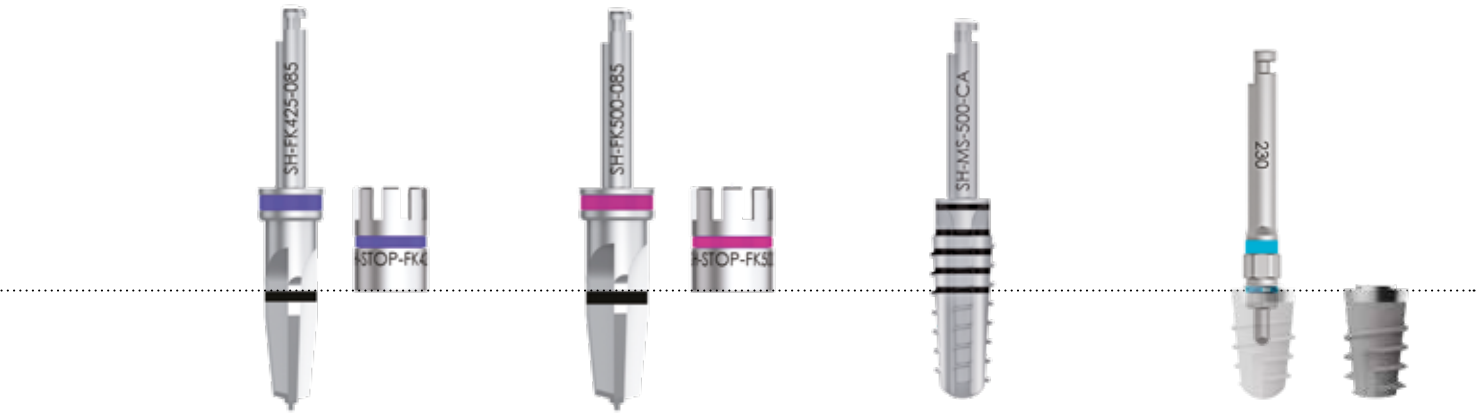
These procedures come from clinical experience and recommendations emerging from numerous studies and clinical protocols for conical implants. It should, however, always be remembered that bone types with different densities require different surgical approaches, and the indications below cannot replace 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.

# SURGICAL PROCEDURES

## Surgical sequence for implants with length 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<br>SH-380SL-085** | | **use up to:<br>marking 8.50 mm** | **use up to:<br>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<br>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<br>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 | - | - |



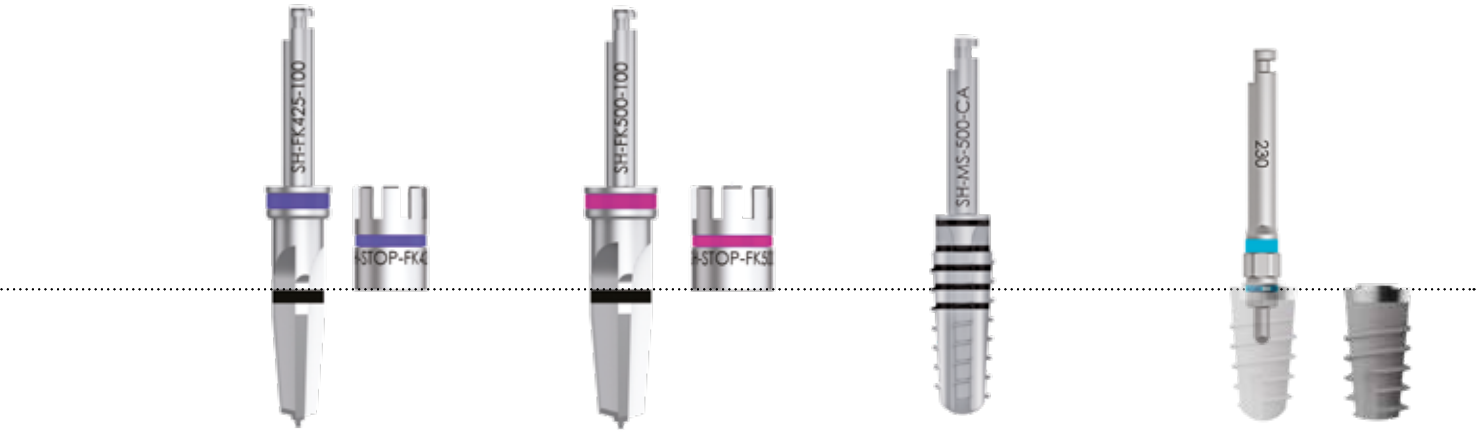

| SH-FK425-085 | SH-FK500-085 | SH-MS-500-CA | EASYC2-EX230-CA |
|---|---|---|---|
| | | **50 Ncm max** | |
| - | - | SH-MS-380 (20 rpm) | 20 rpm |
| - | - | - | 20 rpm |
| - | - | - | 20 rpm |
| - | - | - | 20 rpm |
| | | | |
| 900 rpm | - | SH-MS-425 (20 rpm) | 20 rpm |
| 900 rpm | - | - | 20 rpm |
| 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 length 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 length 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.
N.B. The depth of use of cylindrical drills depends on the implant diameter. See the table below.


| | | 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 | - | - |



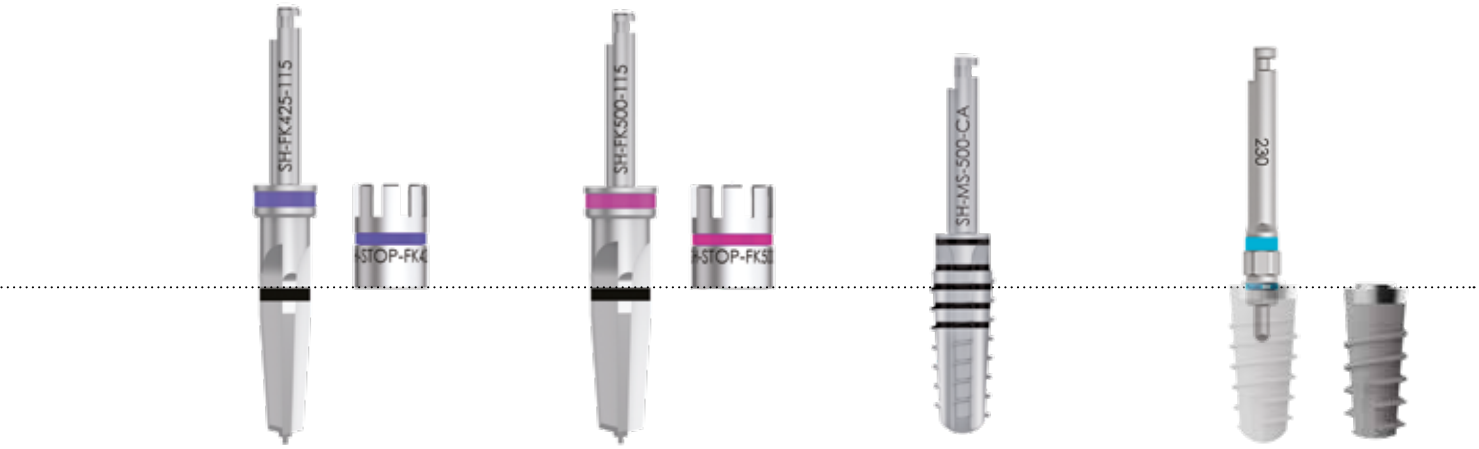

| SH-FK425-100 | SH-FK500-100 | SH-MS-500-CA | EASYC2-EX230-CA |
|---|---|---|---|
| | | **50 Ncm max** | |
| - | - | SH-MS-380 (20 rpm) | 20 rpm |
| - | - | - | 20 rpm |
| - | - | - | 20 rpm |
| - | - | - | 20 rpm |
| | | | |
| 900 rpm | - | SH-MS-425 (20 rpm) | 20 rpm |
| 900 rpm | - | - | 20 rpm |
| 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 length 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 length 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.
N.B. The depth of use of cylindrical drills depends on the implant diameter. See the table below.


| | | 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 length 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 length 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.
N.B. The depth of use of cylindrical drills depends on the implant diameter. See the table below.


| | | 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 length 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 length 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.
N.B. The depth of use of cylindrical drills depends on the implant diameter. See the table below.


| | | 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 length 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

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.

Then 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.

Immediately before inserting it into the oral cavity, remove the 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 tested and 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 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.*

*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)
- 1.4112 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 S.p.A.**
Via Veneto 10
35020 Due Carrare (Pd) Italy
Tel. +39 049 9124300
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www.sweden-martina.com

## 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**

# NOTES

MC-IMP-SHELTA-USA

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The implants, standard prosthetic components and surgical instruments contained in this manual are Medical Devices and are manufactured by Sweden & Martina S.p.A. They conform to the ISO 9001 and ISO 13485 standards and are certified with the CE Mark (Class I) and CE 0476 mark (Class IIA and class IIB) in compliance with European Medical Device Directive No. 93/42 and European Directive No. 2007/47/CE.

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