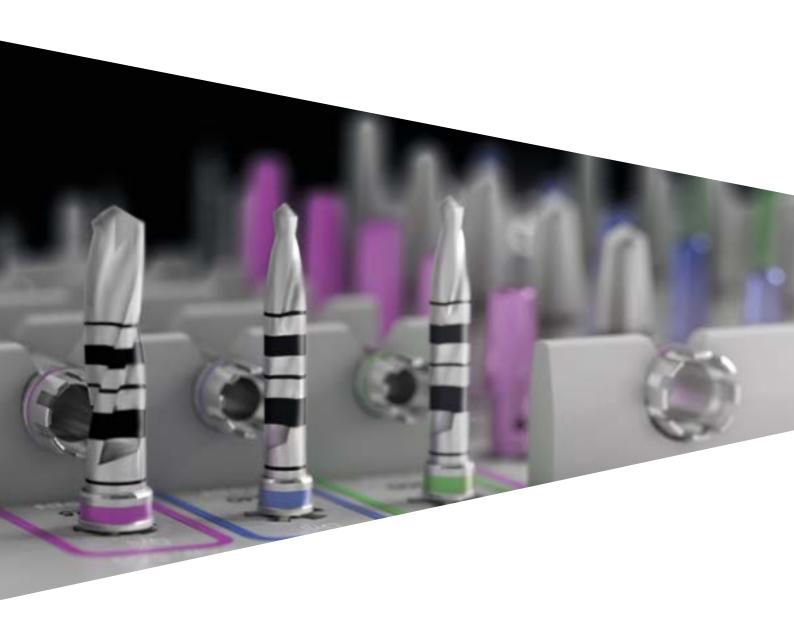
PRAMA Surgical Manual





Prama



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



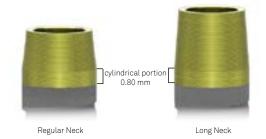
Disposal

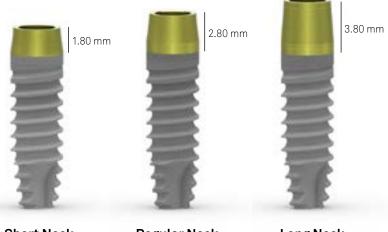
Preparation of the implant site Surgical sequences for Prama implants Surgical sequences for Prama RF and Prama RF SL implants Indications for a deeper positioning Implant insertion Intraoperative removal of the implants if necessary Maintenance of the prosthesis Responsibilitty for detective products and warranty terms

Prama, the one and only intramucosal implant

Prama implant was designed with a converging neck to maximize the thickness of soft tissues. To answer all clinical situations, Prama implants are available in three different heights of the intramucosal neck: Short Neck 1.80 mm, Regular Neck 2.80 mm and Long Neck 3.80 mm.

Regular Neck and Long Neck have a cylindrical portion of h 0.80 mm between the converging portion and the endosseous body, thanks to which it is easier to manage the irregularities of post-extraction sockets or asymmetric crests.





Short Neck

Regular Neck

Long Neck

Prama Slim was specifically developed for those areas with limited horizontal dimensions, with a straight intramucosal neck 1.80 mm or 2.80 mm high.

With the same endosseous morphology, the implant site preparation is the same regardless of the height of the neck.



ø 3.30 Short Neck

ø 3.30 Regular Neck

Prama is available with different endosseous and threads morphologies.



Prama Slim: cylindrical implant with triangular thread, only 3.30 mm diameter Insertion indications page 29





Prama Short: tronco-conical implant h 6.00 mm Insertion indications pages 29-30



Prama: cylindrical implant with tapered apex and reverse buttress thread Insertion indications page 29



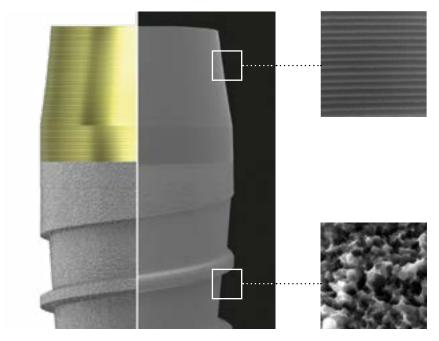
Prama RF: tapered implant with rounded apex and depth thread constant along the whole lenght of the implant

PRAMA RF SL: tapered implant with flat apex and depth thread progressively greater in corono-apical direction

Insertion indications page 30

Positioning options

Prama implants have two surface treatments:



Neck > UTM - anodised microthreaded surface, ideal for the organisation of soft tissues. The traditional insertion of the implant contemplates the UTM surface positioned inside the mucosal path, but it has shown to osseointegrate in contact with hard tissues, thus making easier the management of post-extraction sockets and irregular crests. Moreover, it offers the option of a deeper insertion of the implant, when needed.

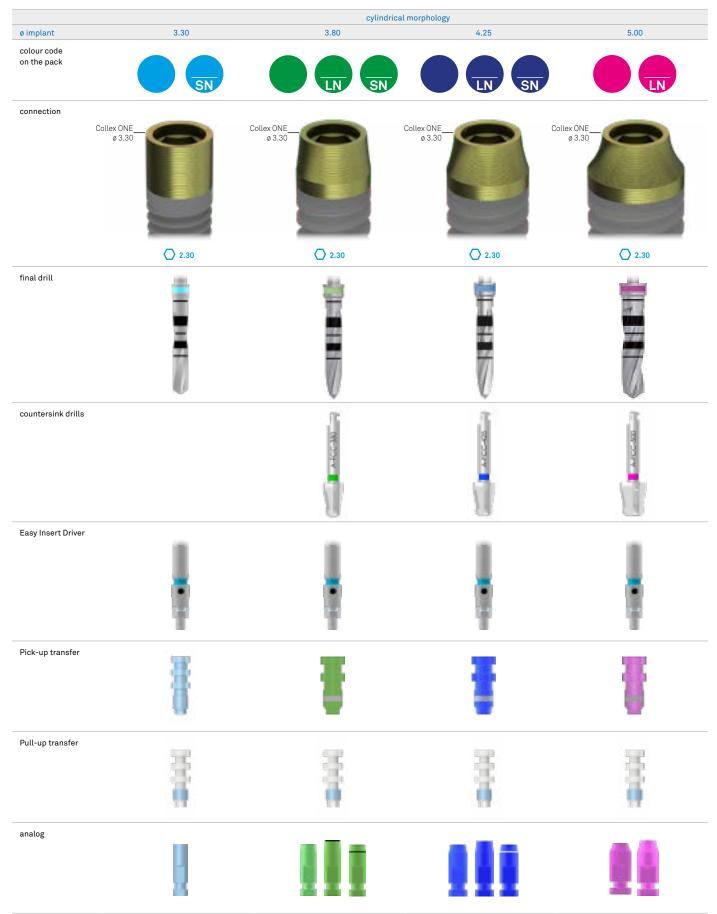
Endosseous body > ZirTi - sandblasted and acid-etched surface, ideal for osteointegration. The whole ZirTi surface portion of Prama implants must be inserted in the bone.

Soft tissues height guides the choice of the neck among Short, Regular and Long: for instance, in case of a 2.00 mm high mucosal path it is possible to choose a Short Neck implant. Alternatively, it is possible to insert a Regular Neck implant, partially submerging the neck into the bone.

type of implant	endosseous mor- phology	neck	surface	diameter	thread (only for RF morphology)	length
L	S	L	ZT	425	SL	115
L: Prama implant	A: cylindrical body S: RF tapered body	S: neck 1.80 mm (no letter): neck 2.80 mm L: neck 3.80 mm	ZT: ZirTi surface and UTM neck	330: 3.30 mm 380: 3.80 mm 425: 4.25 mm 500: 5.00 mm	(no letter): regular thread SL: large thread	060: 6.00 mm 085: 8.50 mm 100: 10.00 mm 115: 11.50 mm 130: 13.00 mm 150: 15.00 mm
				it is the diameter of the implant in its wider point		Nominal length which expresses the legth of ZirTi treatment

Colour codes guide chart



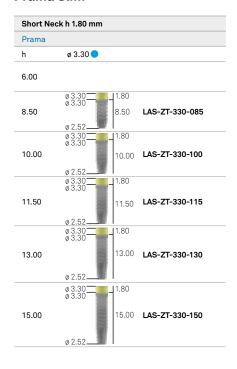


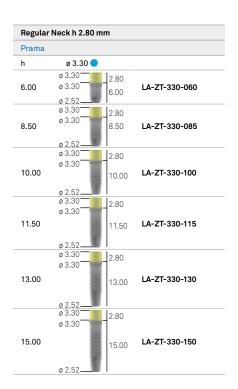




Prama implants

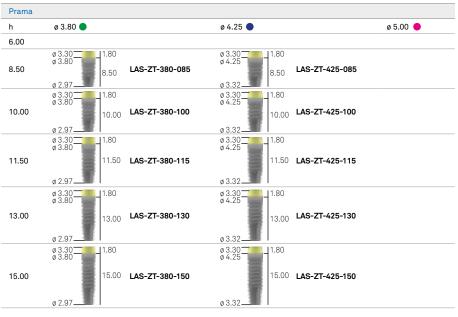
Prama Slim

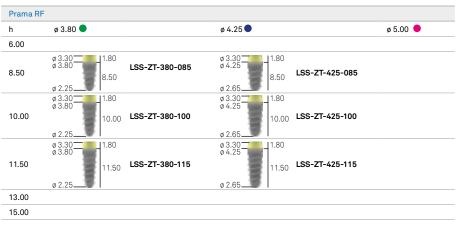




Surgical cover screw included in each pack

Short Neck h 1.80 mm

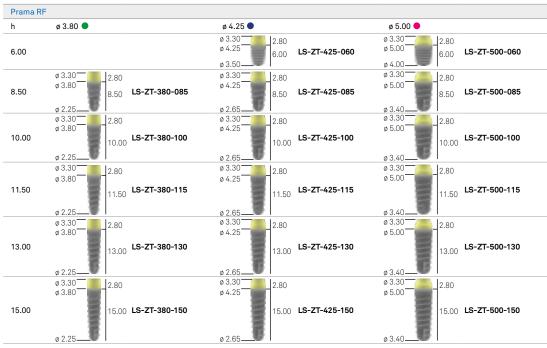


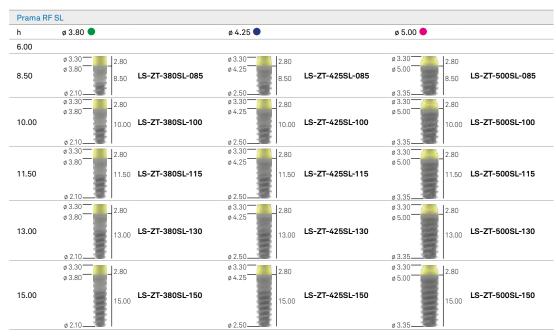


Regular Neck h 2.80 mm

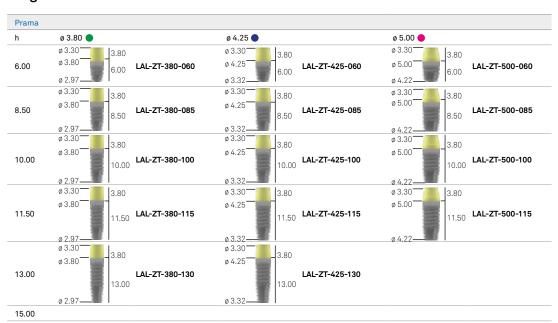




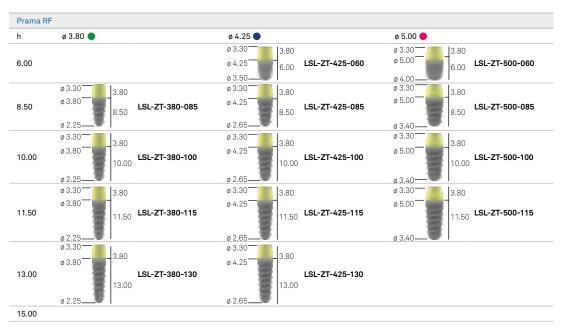


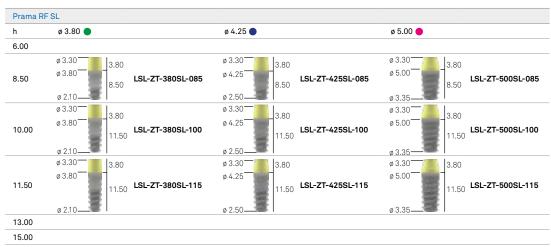


Long Neck h ø 3.80 mm









Surgical kit

The Prama surgical kit includes all the instruments needed to insert both Prama implants with cylindrical endosseous morphology and Prama RF implants with tapered morphology in the sizes 3.80, 4.25 and 5.00 mm. Each type of preparation has the related dedicated drills, whose use sequence is given by coloured marks for the various implant diameters. The kit also contains the replies for Prama RF implants, which allow to evaluate the congruity of the receiving site compared to the implant. Together with the kit also templates are supplied, with the graphical representation of the implants, both in real dimension and enlarged of 20% and 30% in order to allow the choice of the implants in their most appropriate dimensions by means of radiographic or tomographic analysis. For Prama implants 6.00 mm high both with cylindrical and tapered morphology a supplementary set (code L-INTEGRA-060) is available, to be used together with the surgical kit.

For Prama Slim implants a supplementary set (code L-INTEGRA) is available, including the parallelism pins with the indications of the different necks Short Neck, Regular Neck and Long Neck, together with the countersink drills. This supplementary set do not replace the surgical kit, but must be used together with it.



ZPRAMA-INT

complete surgical grommetless kit of the instruments necessary for Prama and Prama RF implants

L-TRAY-INT

radel instrument grommetless tray

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.



Supplementary sets



L-INTEGRA

supplementary set of instruments for Prama Slim ø 3.30 insertion, countersink drills and parallelism pins with neck indications



L-INTEGRA-060

supplementary set of instruments for Prama and Prama RF h 6.00 mm insertion



23

- Pilot drill FPT3-200-LXS o
- Intermediate drills FG-200/280XS • FG-330/425XS •
- Stops for conical drills SH-STOP4-FK380 • SH-STOP4-FK425 • SH-STOP4-FK500 •
- Conical final drills SH-FK380-085 •
 - SH-FK380-100 SH-FK380-115 •
 - SH-FK380-130 SH-FK380-150 •
- Replies SH-380-085-RP • SH-380-100-RP •
 - SH-380-115-RP SH-380-130-RP • SH-380-150-RP •
- Stops for conical drills
 - SH-FK425-085 SH-FK425-100 •
 - SH-FK425-115 SH-FK425-130 •
 - SH-FK425-150 •
- Replies SH-425-085-RP • SH-425-100-RP •
 - SH-425-115-RP SH-425-130-RP • SH-425-150-RP •

- Conical final drills
 - SH-FK500-085 SH-FK500-100 .
 - SH-FK500-115 SH-FK500-130 • SH-FK500-150 •
- Replies SH-500-085-RP •
 - SH-500-100-RP SH-500-115-RP •
 - SH-500-130-RP SH-500-150-RP •
- Cylindrical final drills
 - FFT3-300-LXS FFT3-340-LXS • FFT3-425-LXS •
- Stops for cylindrical drills STOP4-300-085 .
 - STOP4-300-100 STOP4-300-115 • STOP4-300-130 • STOP4-300-150 •
- Stops for cylindrical drills STOP4-340-085 • STOP4-340-100 •
 - STOP4-340-115 STOP4-340-130 • STOP4-340-150 •
- Stops for cylindrical drills STOP4-425-085 • STOP4-425-100 •
 - STOP4-425-115 STOP4-425-130 • STOP4-425-150 •

Drivers BC-EX230 BL-EX230

19 Prost

ic - standard Long

- Bone taps A-MS-380-CA • A-MS-425-CA •

A-MS-500-CA •

- **Easy Insert Driver** EASY4-EX230-EX EASYC4-EX230-CA EASYL4-EX230-CA
- Prosthetic screwdrivers for 18 Full Head screws

I-HSM-FX I-HSMI-FX I-HSMXI-FX I-HSM-CA

Prosthetic screwdrivers for standard screws

HSM-20-FX HSML-20-EX HSM-20-CA

Surgical screwdrivers HSMXS-20-DG HSM-20-DG HSML-20-DG

Bone taps SH-MS-380-CA • SH-MS-425-CA •

18

SH-MS-500-CA •

Long

- Dynamometric ratchet CRI5-KIT
- Adapter 23 AVV-CA-DG-EX
- Extension 24 BPM-15
- Parallelism pins 25 PP-2/28
- Extension PROF-CAL 3
- Stops for pilot drill STOP4-200-085 o

STOP4-200-100 o STOP4-200-115 o

STOP4-200-130 o STOP4-200-150 o

Instruments included in Prama surgical kit



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

LT: Total length of the instrument.

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.

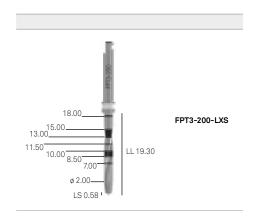
Precision drill FS-230



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

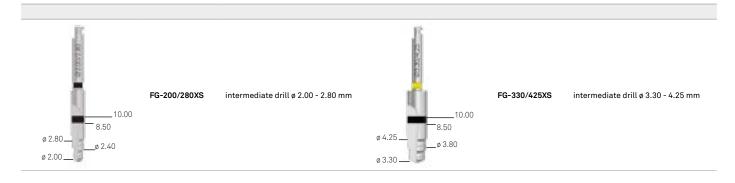


Important warning on the use of the stops

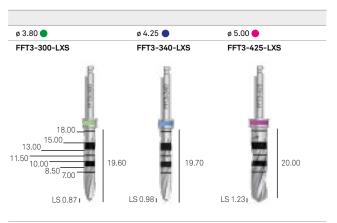
Always check that the stop is inserted at the desired height. Incomplete insertion may reduce the preparation height. Any insertion difficulties can be resolved by loosening the stop tabs slightly, using forceps. It is also recommended to check the retention exerted by the stop, as if retention is too 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.

Stops for pilot drill				
h 8.50	10.00	11.50	13.00	15.00
STOP4-200-085	STOP4-200-100	ST0P4-200-115	ST0P4-200-130	STOP4-200-150
310	100	9.3		
m	2.0	25	AL.	101
111	- 11	- 111	18	1.0

Intermediate drills



Cylindrical final drills and related stops



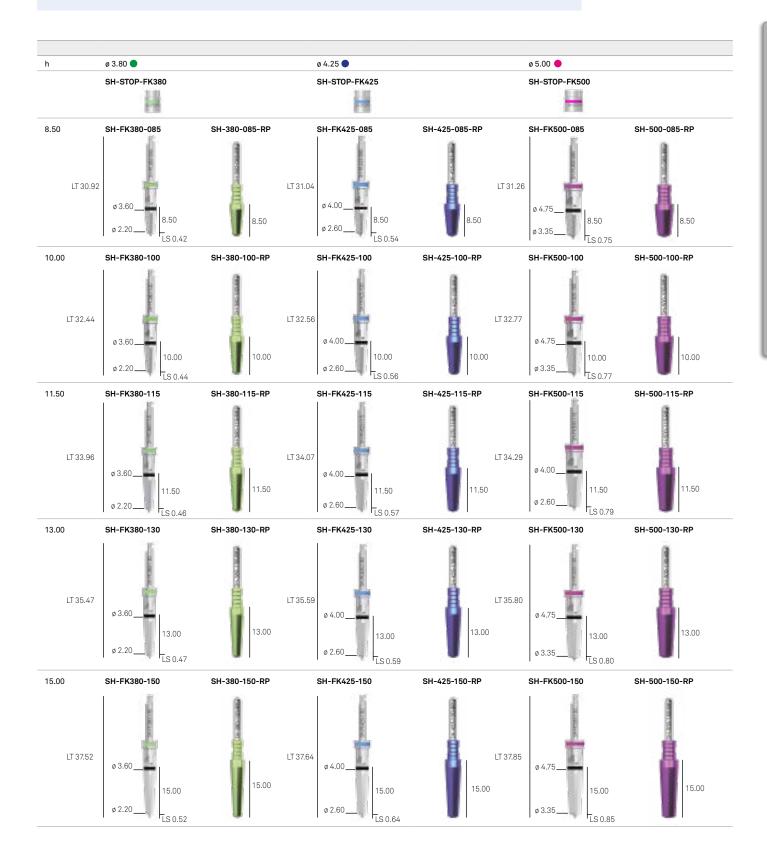


Conical final drills and related stops Reply: replies for Prama RF implants



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.



Bone taps





Important warning

The preparation of Prama 6.00 mm high implant site contemplates the use of bone taps up to 1.00 mm below the first notch. In case of Prama RF implants h 6.00 mm bone taps must not be used.

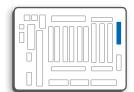
Easy Insert driver

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. If these recommendations are not respected and the insertion torque is exceeded, the instrument should get broken: for this reason a preferential failure point is present above the black laser marks, to help the operator to easily remove the driver.

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.





Maintenance and care of the Easy Insert drivers

The Easy Insert drivers are supplied pre-mounted with the special titanium 0-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 40 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 kit contains a "test implant" that has not been treated or sterilised; it can be distinguished from the others as it is in blue.

important warning

It is recommended to use the Easy Insert with a torque between 50 Ncm and 70 Ncm. Thanks to tests performed on models, it has been observed that from 70 Ncm to 100 Ncm slight frictions between the instrument and the implant connection are possible, they can be avoided with a slight shaking movement of the Easy Insert in the connection. From 100 Ncm to 200 Ncm higher frictions are possible, they can be solved with a simple counter-rotation movement (at 40 Ncm) in order to remove the instrument from the connection. It is moreover recommended to end the bone tapping phase using the dynamometric ratchet CRI5-KIT.

Screwdrivers

important warning

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

recommended torque	dscription
8-10 Ncm	surgical cover screws, healing abutments
20-25 Ncm	all the prosthetic screws
25-30 Ncm	all the prosthetic components with direct screwing on the implant
8-10 Ncm	transfer fixation screws



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

important warning

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

Surgical screwdrivers





Prosthetic screwdrivers for standard screws (surgical cover screws, healing abutments, standard prosthetic screws)

HSM-20-EX screwdriver for fixation screws, with connector, short 15.00 21.00 HSM-20-EX screwdriver for fixation screws, with connector, short screwdriver for fixation screws, with connector for dynamometric ratchet or digital connector, long HSM-20-CA screwdriver for fixation screws, with right angle shank

Prosthetic screwdrivers (for Full Head screws)

7.90 13.90		L-HSM-EX	screwdriver for Full Head screws, digital with connector for dynamometric ratchet, extra- short
15.00 21.00		L-HSML-EX	screwdriver for Full Head screws, digital with connector for dynamometric ratchet, short
31.	25.00 00	- L-HSMXL-EX	screwdriver for Full Head screws, digital with connector for dynamometric ratchet, long
27.00	12.60	L-HSM-CA	screwdriver for Full Head screws, with right angle shank

important warning

All the ratchet drivers have a red polymer O-ring in the connecting hexagon that guarantees friction between the instruments and therefore a correct grip of the components.

Drivers for intraoperative removal of implants

BC-EX230	short driver
BL-EX230	long driver

Parallelism pins

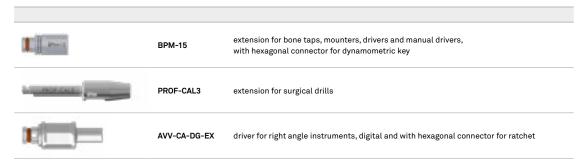




Important warning

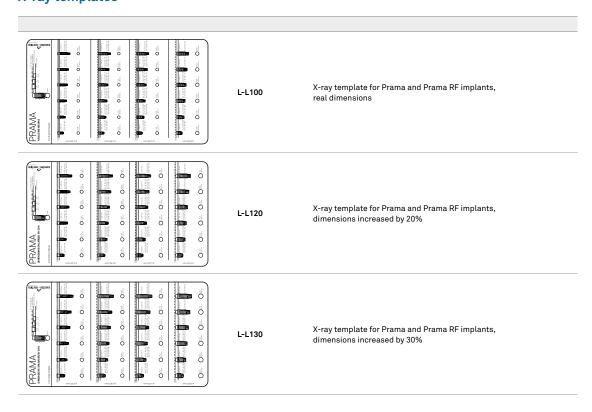
It is recommended to pass a thread through the hole in the centre of the pin to prevent it falling.

Extensions and adapters

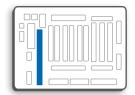




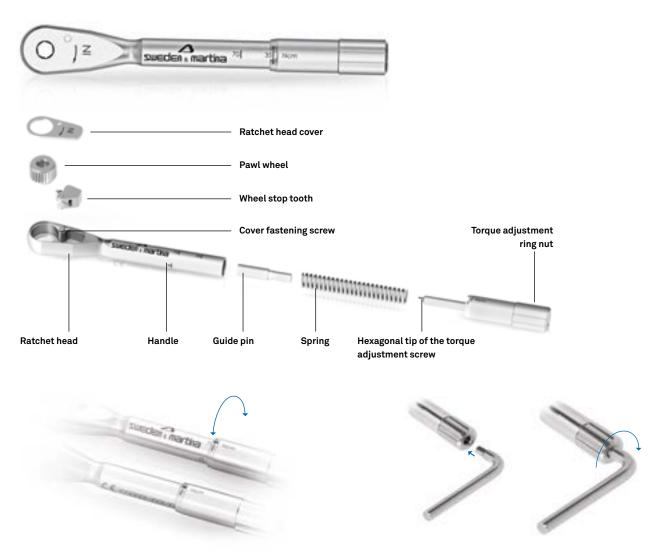
X-ray templates



Dynamometric ratchet CRI5-KIT



The ratchet, included in the surgical kit, 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 page



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 or using the driver.



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.

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

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

more effective. Completely disassemble the key as shown below:



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



Use the hexagon tip at the bottom of the torque adjustment screw to unscrew and completely remove the connecting screw of the cover from the side marked "OUT". Exert a light pressure in order to avoid damaging the hexagon tip.



After removing the cover, pull out the two components contained inside the ratchet head: the toothed pawl wheel and wheel stop tooth.

In case of manual cleaning, clean the outer and inner surfaces of the instrument mechanically under hot water with a soft bristled brush. Inject hot water using a needleless syringe to wash the hard-toaccess holes of the head and the area around the pawl wheel and wheel stop. If necessary, proceed in the same way for the inside of the handle and of the torque adjustment device. Use a suitable neutral detergent and follow the manufacturer's user instructions. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure the running water passes abundantly through the passages. In case of automated ultrasound cleaning: use an ultrasound bath with a suitable detergent solution. Use neutral detergents only.

Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralised water to prevent the formation of stains and marks. During this cycle, avoid contact between the pieces because this causes the machined surfaces to deteriorate, and consequently, loss of precision of the torque measurement. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.

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

The pieces must be reassembled prior to sterilisation. Dry the parts, lubricate the functional areas lightly and reassemble the key as shown in the figures below. Too much lubrication may cause the surfaces of the instrument to resurface during sterilisation. Use only the lubricant supplied.



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



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



Once parts 2 and 3 have been lubricated and inserted in the head of the ratchet body, position the cover and turn the ratchet body from the "OUT" side.

Tighten the screw with the hexagon tip of the torque adjustment screw.



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

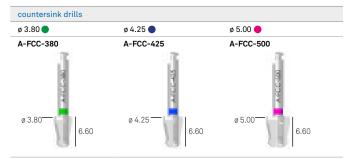
${\bf Sterilisation: in\ a\ vacuum\ autoclave, proceeding\ as\ follows:}$

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

This procedure is important in order to preserve the precision of the instrument within a tolerance of ± 3.5 Ncm. 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 practice the disassembly and reassembly operations, following the instructions.

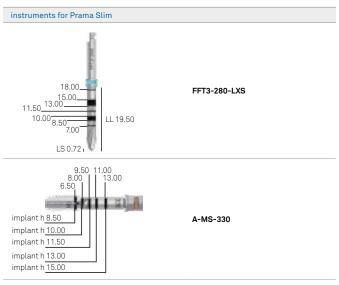
Optional instruments, not included in Prama surgical kit

L-INTEGRA set



Important warning

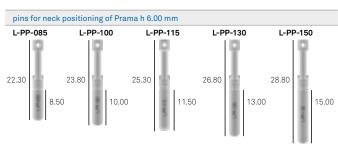
Maximum recommended speed is 1000 rpm. Each drill has to be used only for the implant of equal diameter.

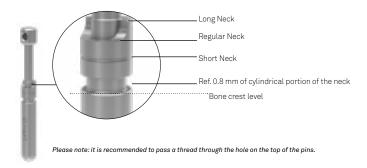




Important warning

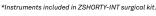
Bone taps ø 3.30 mm must be inserted in the bone to a depth calculated subtracting two millimiters to the length of the implant. For example, in case of a 10.00 mm h implant, the bone tap must be used up to the notch 8.00 mm. The notches on the bone taps have been inserted already calculating the 2.00 mm less (see the image).

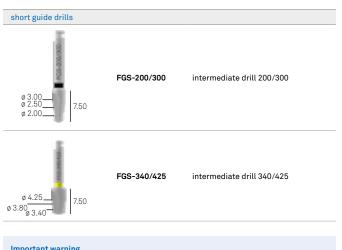




L-INTEGRA-060 set for Prama and Prama RF implants h 6.00 mm



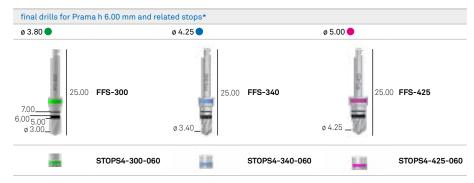




Important warning

When using short guide drills only the working part must be used, not deeper.



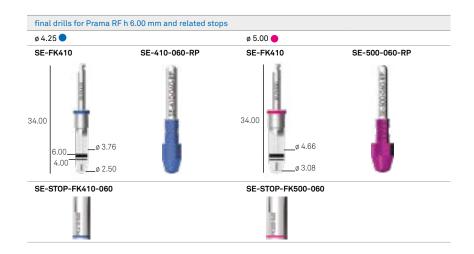


^{*} Instruments included in ZSHORTY-INT surgical kit.

LL: Total length of the working part, including the tip.

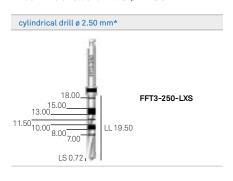
LS: Length of the tip. This measurement must be calculated in addition to the length of the preparation hole.

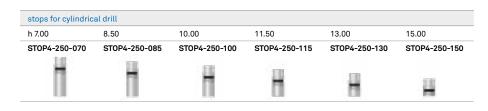
Please note: remember that the drills in the Shorty Drilling Kit for the insertion of implants h 6.00 mm do not over-prepare the surgical site. The working lengths include the portion related to the conical tip of the drill.

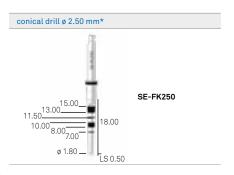


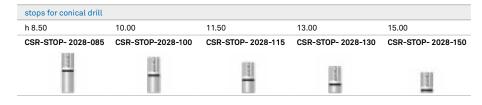
Other instruments not included in the surgical kit

Intermediate drills ø 2.50 mm

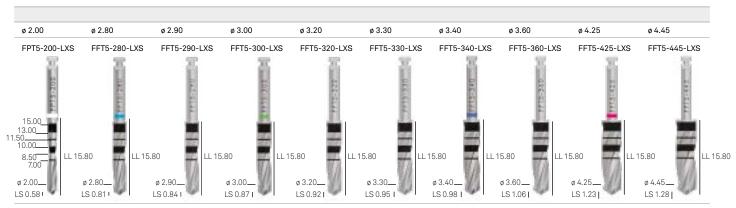






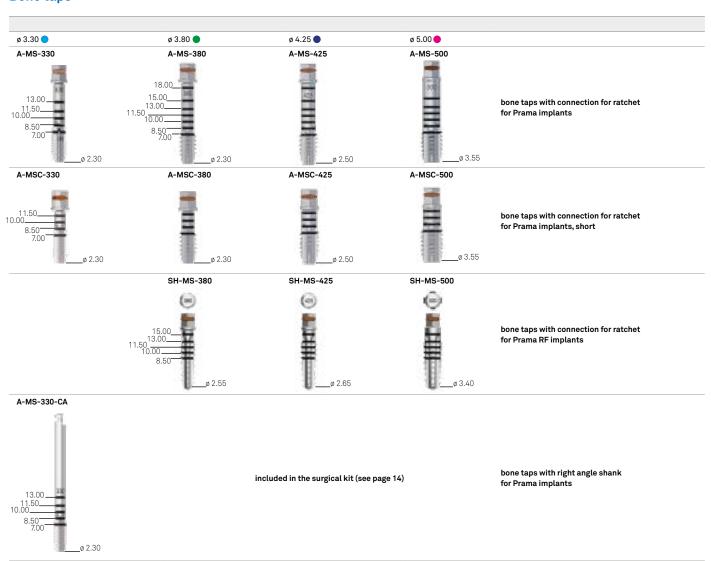


Drills for distal sectors



The drills for distal sectors are not included in the surgical kit, they can be purchased separately and singularly. They cannot be used with depth stops.

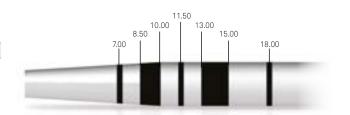
Bone taps



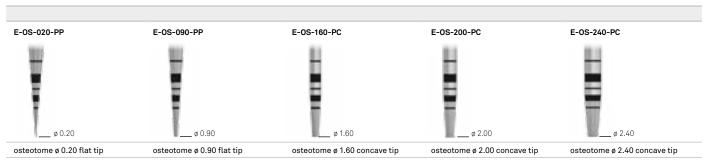
Please note: the sequence for Prama h 6.00 mm implants contemplates the use of the bone taps up to 1.00 mm below the first notch. In case of Prama RF h 6.00 mm bone taps must not be used.

Osteotomes





Prama osteotomes

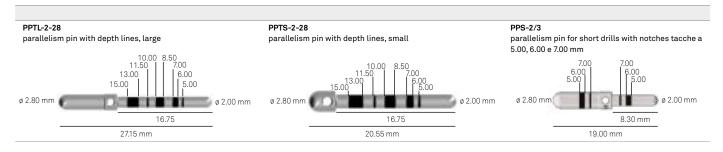


Osteotomes are optional instruments that are not included in the surgical kit. They can be purchased separately and singularly.

Prama RF osteotomes



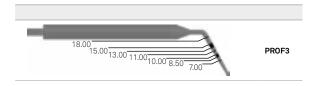
Parallelism pins with depth lines



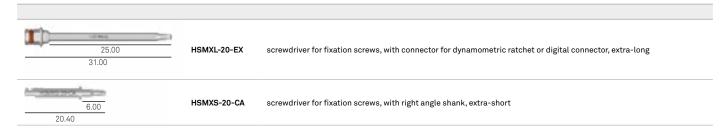
Important warning

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

Depth gauge PROF3



Prosthetic screwdrivers for standard screws (surgical cover screws, healing abutments, standard prosthetic screws)



important warning

All the ratchet drivers have a red polymer O-ring in the connecting hexagon that guarantees friction between the instruments and therefore a correct grip of the components.

Other instruments

	B-AVV-CA3	mechanical adapter with right angle shank for instruments with
- SAWCA)	B-AVV-CA3	hexagonal connector
WHO MARK DO	AVV3-MAN-DG	digital knob for bone taps, mounters, screwdrivers and drivers

Spare O-ring

0	0	0	0	0	ORING180-088	box with 5 spare o-rings for all accessories with hexagonal connector for dynamometric key

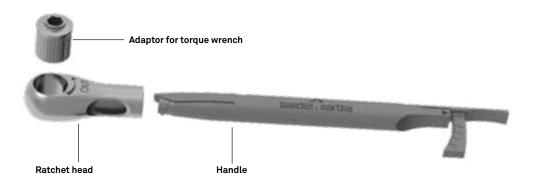
Mounter

	MOU-EX230	mounter
1000	CM2	mounter stop key

Torque wrench with control lever TWL

Separately, a torque wrench with control lever (TWL) can be purchased. The torque wrench can be used to indicate the value of the torque applied during the surgical phases of screwing and unscrewing, showing values from 10 to 90 Ncm. It is supplied complete with a specific adaptor that allows it to be used with surgical instruments with a hexagonal connection.

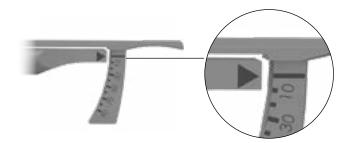
The torque wrench with control lever TWL is a multipurpose instrument that can be dismantled, and it is sold as non-sterile. Every time this instrument is used, it must first be cleaned and sterilised following the instructions.



Important warning

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

The torque wrench can also be used as a fixed key, without using the scale, by using the entire handle as a lever. In this case, it must not exceed the torque value of 150 Ncm.



Cleaning, disinfection, sterilisation and storage of torque wrench with control lever TWL

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

a. Cleaning

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

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

Completely disassemble the key as shown below:



Press the driver and remove it from the head of the torque wrench, then remove the

head by pressing inside the hollow, and delicately pull it out. The three separate components are now ready for cleaning.

In case of manual cleaning, clean the outer and inner surfaces of the instrument mechanically under hot water with a soft bristled brush. Use a suitable neutral detergent and follow the manufacturer's user instructions. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure the running water passes abundantly through the passages. In case of automated ultrasound cleaning: use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times. Use 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.

Observation: 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.

Components must be reassembled before sterilization.

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

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





After cleaning, connect the torque wrench head to the body, pushing the components together and rotating them in opposite directions until a click is heard.

Press the driver into the torque wrench until a click is heard. The arrow on the torque wrench head indicates the direction of operation.

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

b. Sterilisation

In a vacuum autoclave, proceeding as follows:

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

c. Storage

After 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.

 $\label{thm:condition} \textbf{The product must be stored in a cool dry place, away from sunlight, water and sources of heat.}$

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

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

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

a. Cleaning

Containers and transport to be used for washing: there are no special requirements. In case of automatic cleaning, use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralised water to prevent the formation of stains and marks. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.

When cleaning manually: use a suitable neutral detergent and follow the manufacturer's user instructions. Brush the products with a soft-bristled brush under plenty of running water. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure plenty of running water passes through any holes. For drills with internal irrigation, use the special pins provided with the handpieces to ensure that the irrigation holes are completely clean and free of bone fragments or biological tissues. After rinsing, dry the devices thoroughly and place them inside suitable sterilisation bags. Do not exceed 120 °C when performing a drying cycle in a washing and disinfection appliance.

b. Sterilisation

In a vacuum autoclave, sterilizing as follows:

- autoclave (gravity displacement cycle) at a temperature of 121°C with minimum exposure of 30 minutes and drying cycle of 15 minutes;
- autoclave (dynamic air removal cycle) at the temperature of 132°C with minimum exposure of 4 minutes and drying cycle of 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.

Preparation of the implant site

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. It is also essential to check that the thickness of the residual bone wall at buccal level is not less than 1.00 mm. The best aesthetic results can be obtained with buccal plates not less than 2.00 mm. If the thickness is smaller there is a high risk of bone reabsorption failure and exposure of the spires. The following indications cannot replace the necessary training and knowledge of the doctors, nor their personal experience, which can at times lead to different solutions. The sequences that follow refer to specific bone types. In expansion techniques or in case of regenerative surgery, or when you want to increase the compaction in poor quality bone, the use of drills can be replaced with the relative osteotomes.

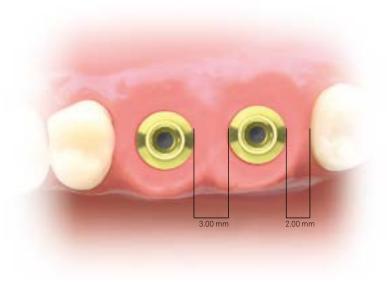
Remember to always use drills with stops correctly inserted. Remember that the drills always prepare a hole that is longer than the implant. For the overpreparation dimensions, refer to page 12 for the pilot drill and the cylindrical drills, and to page 13 for the conical drills.

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

Incorrect insertion of the instruments in the handpiece will cause instrument vibration, eccentric rotation, early wear and shaft buckling. Suitable surgical micromotors only should be used. Micromotors should be checked regularly by their manufacturers, according to the indications given by the same, to prevent potential malfunctions (e.g. axle shifts for transmission shafts, worn or faulty forceps, etc.). Failure to follow the instructions provided may cause surgical problems and damage to the patient's health.



Surgical sequences for Prama implants

The following surgical sequences for each diameter refer to D1 bone using the drills with adequate irrigation. The recommended speed is: 900-1.100 rpm for cylindrical drills, 800-900 rpm for conical drills, 200-400 rpm for countersink drills, 20 rpm for bone taps. The state of wear of the drills must be regularly checked so as to replace them when they lost their cutting capacity, in any case after 20 work cycles.

In case of less density bone it is demanded to the experience of the clinician the choice of use or not the indicated instruments, at low speed, up to the use of osteotomes to replace the drills in case of D4 bone. It is always recommended the use of the stops included in the surgical kit, according to the desired height. For a deeper implant insertion, submerging part of the neck in the bone, see the indications on page 30.

Please remember that the drills over-prepare the surgical site. See pages 12 and 13 for the measures of the tips. The graphic sequence is referred to the \emptyset 5.00 mm implant.



	FS-230	FPT3-200-LXS	FG-200/280XS	FFT3-280-LXS*	FFT3-300-LXS	FFT3-340-LXS	FG-330/425XS	FFT3-425-LXS	countersink drill*	bone tap	EASYC4-EX230-CA
3.30	х	х	х	х						A-MS-330*	x
3.80	х	x	х	(x)	х				A-FCC-380	A-MS-380-CA	x
4.25	х	х	х	(x)	х	х			A-FCC-425	A-MS-425-CA	x
5.00	х	х	x	(x)	x	х	х	x	A-FCC-500	A-MS-500-CA	х
									According to the r use or not of these demended to the clinician	e instruments is	

^{*}Included in the L-INTEGRA set, can be purchased also singularly
**Included in the L-INTEGRA-060 set, can be purchased also singularly

included in the E-INTEGRA-000 Set, can be purchased also singularly



	FS-230	FPS-200**	FGS-200/300**	FFS-300	FFS-340**	FGS-340/425**	FFS-425	countersink drill*	bone tap	EASYC4-EX230-CA
3.30		х	x						A-MS-330*	х
3.80	х	x	х	х				A-FCC-380	A-MS-380-CA	х
4.25	х	х	х	х	х			A-FCC-425	A-MS-425-CA	х
5.00	х	x	х	х	х	х	х	A-FCC-500	A-MS-500-CA	х
								According to the receiving bone, the use or not of these instruments is demended to the experience of the clinician		

mportant warning

 $The preparation of Prama \, 6.00 \, mm \, high \, implant \, site \, contemplates \, the \, use \, of \, bone \, taps \, up \, to \, 1.00 \, mm \, below \, the \, first \, notch.$

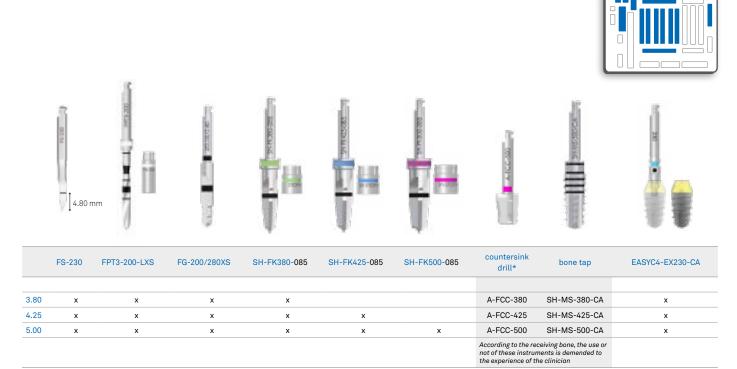
Surgical sequences for Prama RF and Prama RF SL

The following surgical sequences for each diameter refer to D1 bone using the drills with adequate irrigation. The recommended speed is: 900-1.100 rpm for cylindrical drills, 800-900 rpm for conical drills, 200-400 rpm for countersink drills, 20 rpm for bone taps. The state of wear of the drills must be regularly checked so as to replace them when they lost their cutting capacity, in any case after 20 work cycles.

In case of less density bone it is demanded to the experience of the clinician the choice of use or not the indicated instruments, at low speed, up to the use of osteotomes to replace the drills in case of D4 bone. It is always recommended the use of the stops included in the surgical kit, according to the desired height. For a deeper implant insertion, submerging part of the neck in the bone, see the indications on page 30.

 $Please\ remember\ that\ the\ drills\ over-prepare\ the\ surgical\ site.\ See\ pages\ 12\ and\ 13\ for\ the\ measures\ of\ the\ tips.$

The graphic sequence is referred to the ø 5.00 mm implant and height 8.50 mm: in case of longer lengths final drills with the corresponding ending, that is SH-FK425-100 for height 10 mm, SH-FK425-115 for height 11.50 mm, etc. It is also recommended the use of stops related to the desired height, included in the



^{*}Included in the L-INTEGRA set, can be purchased also singularly
**Included in the L-INTEGRA-060 set, can be purchased also singularly

Surgical sequences for Prama RF h 6.00 mm



	FS-230	FPS-200**	SE-FK410** with SE-STOP-FK410-060	SE-FK500** with SE-STOP-FK500-060	countersink drill*	EASYC4-EX230-CA
4.25	x	x	x		A-FCC-425	x
5.00	х	х	х	х	A-FCC-500	х
					According to the receiving bone, the use or not of these instruments is demended to the experience of the clinician	

The use of short conical implants must be limited to anatomical situations where the clinician does not consider possible the use of standard length implants. Given the dimension of these implants the preparation must be carried

Indications for a deeper positioning

The preparation of the implant site is not affected from the length of the chosen neck, because it is based on the length of the ZirTi portion.

With the same endosseous length, then, there will be no difference in the preparation of the implant site of Short or Long Neck implants compared to Regular Neck implants.

According to the different clinical needs, the neck can be partially submerged into the bone. In this case, the drill can be inserted deeper by simply using it with the stop meant for an implant of higher length: for instance, to insert a 11.50 mm h implant the stop for 13.00 mm h implant must be used, inserting the neck deeper as desired.

In case of deeper positioning of the implant planning, please consider the over-preparation carried out from the tip of the drills, shown on pages 12-13.

Indications for a deeper positioning of Prama implants



Indications for a deeper positioning of Prama RF and Prama RF SL implants



Implant insertion

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



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



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



Standard procedure

When the vial is opened the mounter is presented with the hexagon ready to be engaged. The implant may be picked up using the dedicated driver 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. 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.







Intraoperative removal of the implants if necessary

If a previously inserted implant needs to be removed, this can be done by directly engaging the hexagonal driver BC-EX230 or BL-EX230 directly in the hexagonal driver connection of the implant, being very careful that the instrument is on-axis with the implant and that it completely and closely engages the internal hexagon.

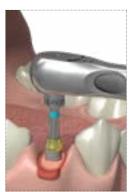




Block the head of the CRI5-KIT ratchet or of the TWL key and connect it with the hexagonal tip of the driver making sure that the laser-etched arrow on the ratchet head indicates an anticlockwise direction, and move it in this direction while keeping the driver/ratchet assembly on-axis with the index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

It is recommended to apply a higher torque than the one applied during the insertion phase. Once it has been unscrewed pick up the removed implant using sterile forceps.





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. Sweden & Martina offers unlimited lifetime warranty for 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.

Key to symbols used on implant packs:

		implant pack	surgical instruments pack	prosthetis pack
\triangle	Caution! See instructions for use	✓	✓	✓
LOT	Batch number	✓	✓	✓
REF	Code	✓	✓	✓
***	Manufacturer	✓	✓	✓
[]i	Consult instruction for use	✓	✓	✓
C € 0476	CE conformity mark for class IIa and IIb products	✓	✓	✓
C€	CE conformity mark for class I		✓	
Rx Only	American federal law restricts this device to sale by or by order of a professional practitioner	✓	✓	✓
STERNIZE	Do not resterilise	✓		
2	Disposable product, do not reuse	✓		✓
	Do not use if the packaging is damaged	✓		
NON STERILE	Nonsterile product		✓	✓
STERILE R	Sterilized with ionizing radiation	✓		
	Expiry date after which the product must not be used	✓		



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