



Prama



Prama, the one and only intramucosal implant **Positioning options** Guide to reading implant codes Colour codes guide chart



Prama implants Surgical kit Supplementary sets Instruments included in Prama surgical kit Precision drill FS-230 Pilot drill FPT3-200-LXS Intermediate drills ø 2.50 mm Cylindrical final drills and related stops Conical final drills and related stops and Reply: replies for Prama RF implants Countersink drills Bone taps Easy Insert driver Maintenance and care of the Easy Insert drivers Screwdrivers Surgical and prosthetic screwdrivers for standard screws Parallelism pins with depth marks Pins for positioning Prama neck Extensions and adapters

X-ray templates for Prama X-ray templates for Prama RF Dynamometric ratchet CRI5-KIT

Optional instruments, not included in Prama surgical kit L-INTEGRA-060 Set L-INTEGRA Set



Instruments not included in the KIt Torque wrench with control lever TWL Cleaning, disinfection, sterilisation and storage of the kit and of the surgical instruments

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 Disposal

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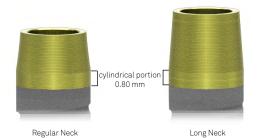
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Prama, the one and only intramucosal implant

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.



1.80 mm

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 sitepreparation 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

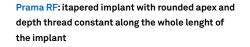


Prama: cylindrical implant with tapered apex and reverse buttress thread Insertion indications page 29



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

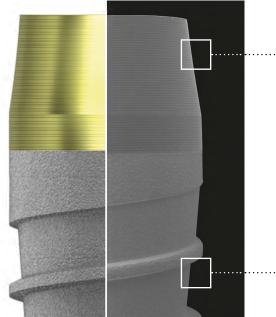




Prama RF SL: tapered implant with flat apex and depth thread progressively greater in corono-apical direction Insertion indications page 30

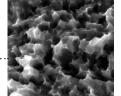
Positioning options

Prama implants have two surface treatments:





Neck > UTM - Sanodised 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.

Guide to reading implant codes

Prama with cylindrical morphology

morphology and neck	surface	diameter	length	
LAS: 1.80 mm - Short Neck	ZT : ZirTi surface and	330 : 3.30 mm - Prama Slim	060 : 6.00 mm	
LA: 2.80 mm - Regular Neck	UTM neck	380 : 3.80 mm	085 : 8.50 mm	
LAL: 3.80 mm - Long Neck		425 : 4.25 mm	100 : 10.00 mm	
-		500 : 5.00 mm	115: 11.50 mm	
			130 : 13.00 mm	
			150 : 15.00 mm	
example: LAS-ZT-380-100				
LAS-	ZT-	380-	100	

Prama with conical morphology

surface	diameter	thread		length	
		regular	wide		
ZT : ZirTi surface and	380 : 3.80 mm	-	SL	060 : 6.00 mm	
UTM neck	425 : 4.25 mm			085 : 8.50 mm	
	500 : 5.00 mm			100 : 10.00 mm	
				115: 11.50 mm	
				130 : 13.00 mm	
				150 : 15.00 mm	
ZT-	380		SL-	100	
	ZT : ZirTi surface and UTM neck	ZT: ZirTi surface and 380: 3.80 mm UTM neck 425: 4.25 mm 500: 5.00 mm	ZT: ZirTi surface and 380: 3.80 mm - UTM neck 425: 4.25 mm - 500: 5.00 mm - -	ZT: ZirTi surface and UTM neck380: 3.80 mm 425: 4.25 mm 500: 5.00 mm-SL	regular wide ZT: ZirTi surface and UTM neck 380: 3.80 mm 425: 4.25 mm 500: 5.00 mm - SL 060: 6.00 mm 085: 8.50 mm 100: 10.00 mm 115: 11.50 mm 130: 13.00 mm 150: 15.00 mm

Colour codes guide chart

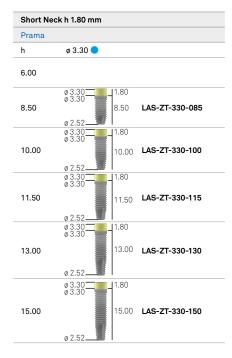
SN Short Neck Regular Neck SN Short Neck

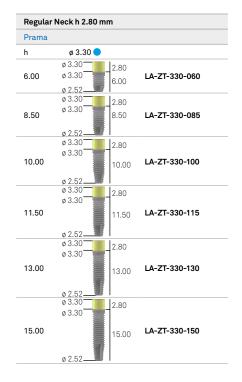
		cylindrical		
ø implant	3.30	3.80	4.25	5.00
colour code on the pack	SN O	SN LN	SN LN	
connection				
	Collex ONE @ 3.30	Collex ONE ø 3.30	Collex ONE Ø 3.30 2.30 2.30	Collex ONE ø 3.30
final drill	_			
countersink drills		3	T	3
		A-FCC-380	A-FCC-425	A-FCC-500
Driver Easy Insert	0	ä	0	0
Pick-up transfer				
Pull-up transfer				
analog		=	=	
	-			



Prama Implant

Prama Slim





Surgical cov	
	L-VT-340

Short Neck h 1.80 mm

	ø 3.80 🔵		ø 4.25 🔵		ø 5.00 🌘
.00					
	ø 3.30		ø 3.30 ø 4.25		
50	8.50	LAS-ZT-380-085	8.50	LAS-ZT-425-085	
	ø 2.97		ø 3.32		
	ø 3.30 ø 3.80		ø 3.30 ø 4.25		
0.00	10.00	LAS-ZT-380-100	10.00	LAS-ZT-425-100	
	ø 2.97		ø 3.32		
	ø 3.30 ø 3.80		ø 3.30 ø 4.25		
1.50	11.50	LAS-ZT-380-115	2000	LAS-ZT-425-115	
	ø 2.97		ø 3.32		
	Ø 3.80		ø 4.25		
3.00	13.00	LAS-ZT-380-130	13.00	LAS-ZT-425-130	
	a 2 07		a 2 2 2		
	ø 2.97 1.80		ø 3.32		
	ø 3.80		ø 4.25		
5.00	15.00	LAS-ZT-380-150	15.00	LAS-ZT-425-150	
	T		T		
	ø 2.97		ø 3.32		
rama RF					
	ø 3.80 🔍		ø 4.25 🔵		ø 5.00 🤇
.00					
	ø 3.30 ø 3.80	LSS-ZT-380-085	ø 3.30 ø 4.25		
.50	8.50		8.50	LSS-ZT-425-085	
	ø 2.25 I1.80		ø 2.65 1.80		
0.00	ø 3.80	100 77 000 100	ø 4.25	100 37 (05 400	
0.00	10.00	LSS-ZT-380-100	10.00	LSS-ZT-425-100	
	ø 2.25		ø 2.65 ø 3.30 1.80		
	ø 3.30 ø 3.80		ø 3.30 ø 4.25		
1.50	11.50	LSS-ZT-380-115	11.50	LSS-ZT-425-115	
	ø 2.25_		ø 2.65		
3.00					



LS-ZT-425SL-115

LS-ZT-425SL-130

LS-ZT-425SL-150

ø3.35_

ø3.30

ø 5.00

ø3.35-

ø3.30-

ø 5.00

ø3.35-

11.50

2.80

13.00

2.80

15.00

ø 2.50_

ø 4.25

ø2.50_

ø 4.25

ø 2.50-

ø 3.30

ø 3.30-

11.50 LS-ZT-500SL-115

13.00 LS-ZT-500SL-130

LS-ZT-500SL-150

2.80

2.80

15.00

Regular Neck h 2.80 mm

Surgical cover screw included in each pack

8

11.50

13.00

15.00

ø 2.10_

ø 3.30-

ø 3.80

ø2.10_

ø3.30-

ø 3.80

ø 2.10-

2.80

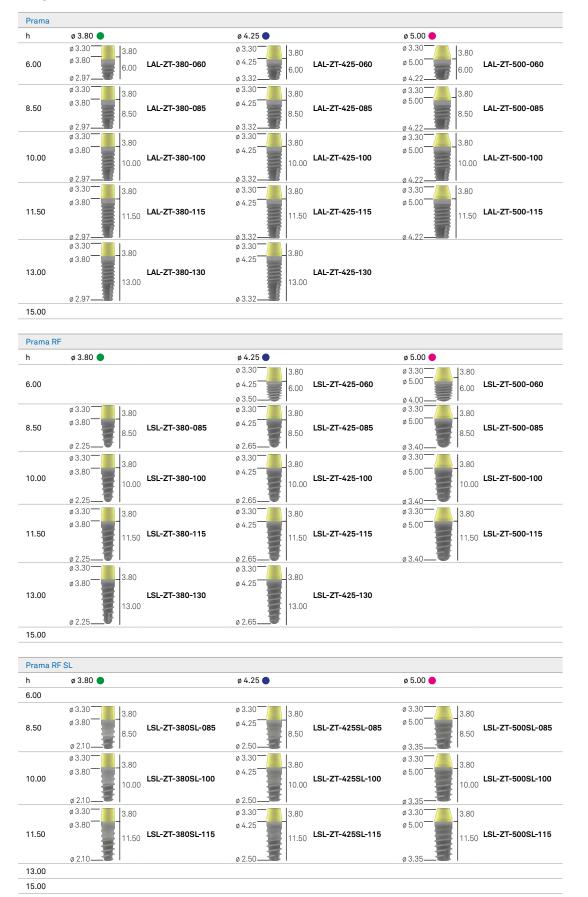
2.80

15.00

11.50 LS-ZT-380SL-115

13.00 LS-ZT-380SL-130

LS-ZT-380SL-150



Long Neck h 3.80 mm

Surgical cover screw included in each pack

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

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.



ZPRAMA-INT	complete surgical grommetless kit of the instruments necessary for Prama and Prama RF implants
L-TRAYL-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-060 Set

The L-INTEGRA-060 set of drills includes the components necessary for the insertion of the Prama and Prama RF implants h 6.00 mm, whose housings are provided within the Prama kit.

L-INTEGRA Set

The L-INTEGRA drill set includes the components necessary for inserting the Prama Slim Ø 3.30 mm, the countersink drills and the pins for positioning the neck. These components are included within the manual version of the Prama surgical kit, but not in the previous version of the kit, so they remain available for those who have the previous version.



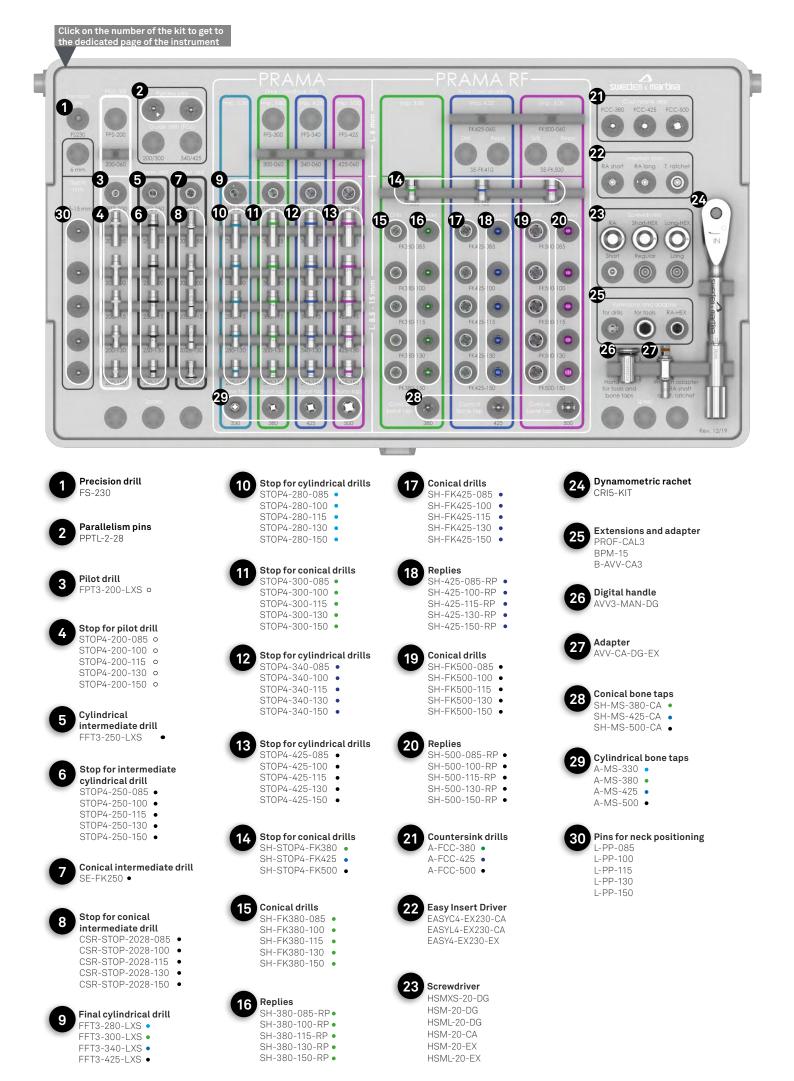
L-INTEGRA-060

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



L-INTEGRA

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



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.

Precision drill FS-230



Important warning

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,

The drills always make a hole that is longer than the implant to be inserted. The oversizing (LS) is equal to the

Pilot drill FPT3-200-LXS

18.00______ 13.00______ 11.50______ 10.00______ 0.00______ 0.00______ LS 0.58______ ES 0.58______ ES 0.58______ ES 0.58______ ES 0.58______ ES 0.58_____ ES 0.58______ ES 0.58__

Important warning on the use of all the stops

special caution is required during handling.

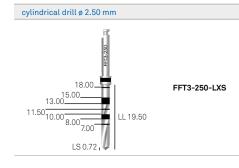
height of the tip of the drill that is being used.

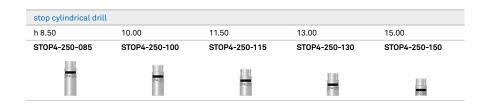
Always check that the stop is inserted at the desired height. Incomplete insertion may reduce the preparation height. Any insertion difficulties can be resolved by loosening the stop tabs slightly, using forceps. It is also recommended to check the retention exerted by the stop, as if retention is too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

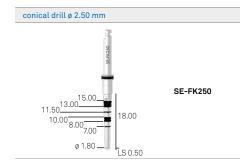


stop for pilot drill				
h 8.50	10.00	11.50	13.00	15.00
STOP4-200-085	STOP4-200-100	STOP4-200-115	STOP4-200-130	STOP4-200-150
1011	1EM			
P4-200	24-200	84-200		1911
			i≥4-200	P4-200

Intermediate drills ø 2.50 mm







stop conical drill				
h 8.50	10.00	11.50	13.00	15.00
CSR-STOP- 2028-085	CSR-STOP-2028-100	CSR-STOP- 2028-115	CSR-STOP- 2028-130	CSR-STOP- 2028-150
CREATOR	CIRAIDO	CHASTOP	CSR4TOP	CRATOP

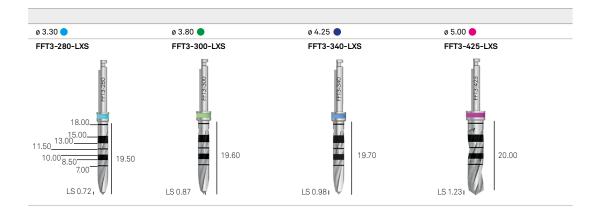
Cylindrical final drills and related stops

Clic on the image to go



Important warning

The drills always make a hole longer than the implant you want to insert. 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 the details of the measures of the different cutters please see refer to the table below.



h	ø 3.30 🔵	ø 3.80 🔵	ø 4.25 🔵	ø 5.00 🔴	
	STOP4-280-085	STOP4-300-085	STOP4-340-085	STOP4-425-085	
8.50) 30-065	11 06490	109432	HOP442	
	STOP4-280-100	STOP4-300-100	STOP4-340-100	STOP4-425-100	
10.00	8710	02436	707454	1(5)443	
	STOP4-280-115	STOP4-300-115	STOP4-340-115	STOP4-425-115	
11.50	304113	1 	TOPA 34	a Grad	
	STOP4-280-130	STOP4-300-130	STOP4-340-130	STOP4-425-130	
13.00	30-13)	094-33	TOP4 SK	30944	
	STOP4-280-150	STOP4-300-150	STOP4-340-150	STOP4-425-150	
15.00	50-180	09430	109435	1 1	

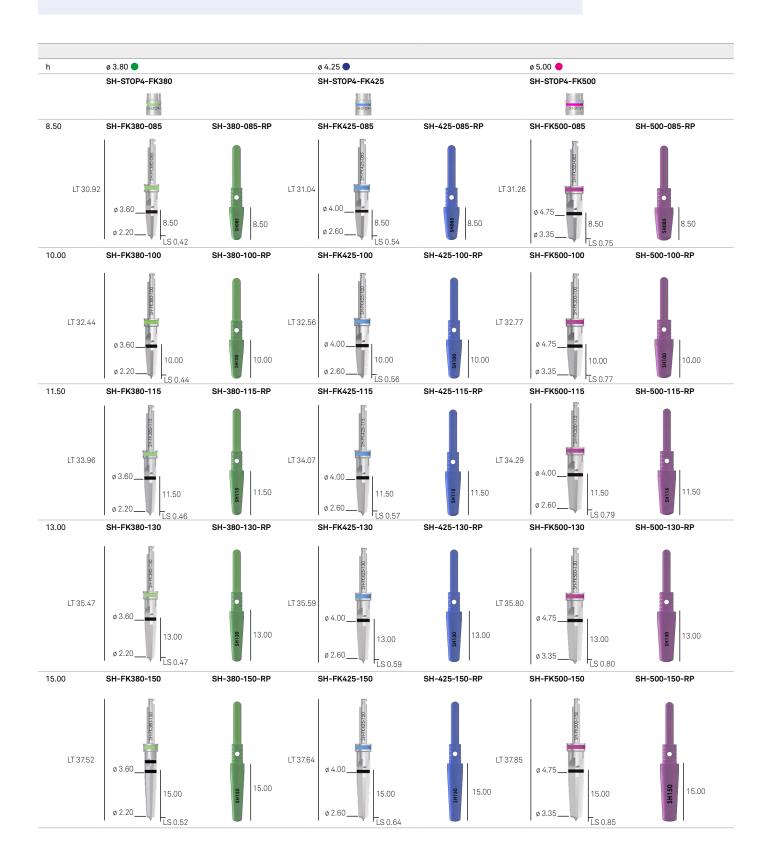
Conical final drills and related stops Reply: replies for Prama RF implants

Clic on the image to go



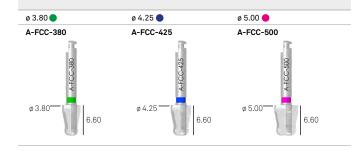
Important warning

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.





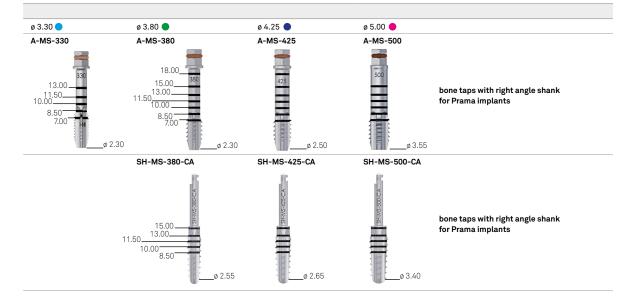
Countersink drills



Important warning

Maximum recommended speed is 200/300 rpm. Each drill has to be used only for the implant of equal diameter.

Bone taps



Important warning

The ø 3.30 mm bone taps are inserted into the bone for a depth calculated by deducting two millimeters from the length of the implant. For example, having to insert a 10.00 mm implant, the male must be inserted for 8.00 mm. The marks on the taps are already calculated by deducting the 2.00 mm (see image on page 21).

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.

Driver Easy Insert

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.

230	EASYC4-EX230-CA	short driver with right angle shank
230	EASYL4-EX230-CA	long driver with right angle shank
	EASY4-EX230-EX	driver with connector for dynamometric key

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 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:

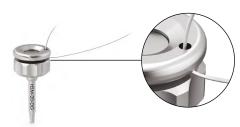
torque raccomandati	descrizione
8-10 Ncm	surgical cover screws, healing abutments
20-25 Ncm	all the prosthetic screws
25-30 Ncm	all the prosthetic components with direct screwing on the implant
8-10 Ncm	transfer fixation screws

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

6.30 15.00	HSMXS-20-DG	screwdriver for surgical cover screws and fixations screws, digital, extra-short
HSM-20-DG 12.30 21.00	HSM-20-DG	screwdriver for surgical cover screws and fixations screws, digital, short
HSML-20-DG 14.80 26.90	HSML-20-DG	screwdriver for surgical cover screws and fixations screws, digital, long

Prosthetic screwdrivers for standard screws

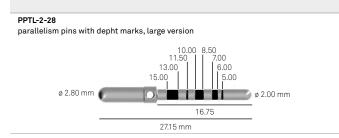
13.90	HSM-20-EX	screwdriver for fixation screws, with connector for dynamometric ratchet or digital connector, short
125MMA-L 15.00 21.00	HSML-20-EX	screwdriver for fixation screws, with connector for dynamometric ratchet or digital connector, long
+HSM-20-CA 12.60 27.00	HSM-20-CA	screwdriver for fixation screws, with right angle shank

Important warning

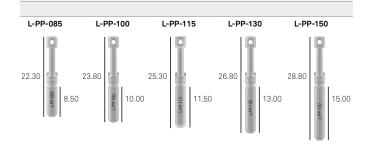
All ratchet screwdrivers have a red polymer 0-ring in the connection hexagon which guarantees the friction between the tools and therefore a correct seal of the components. This 0-ring must be checked periodically and replaced when worn and no longer able to exert the correct friction.

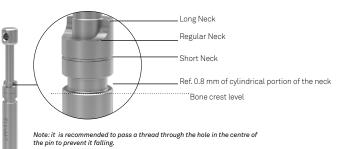
Parallelism pins with depht marks





Pins for positioning Prama neck





Important warning

centre of the pin to prevent it falling.

It is recommended to pass a thread through the hole in the

Extensions and adapters

BPM-15	BPM-15	extension for bone taps, mounters, drivers and manual drivers, with hexagonal connector for dynamometric key
PROF-CAL3	PROF-CAL3	extension for surgical drills
	AVV-CA-DG-EX	driver for right angle instruments, digital and with hexagonal connector for ratchet
B-AVV-CA3	B-AVV-CA3	driver for mounter and mechanical adapter with shank for contra-angle for instruments with hexagonal connector
AW3-MAN-DG	AVV3-MAN-DG	digital knob for bone taps, mounters, screwdrivers and drivers

X-ray templates for Prama

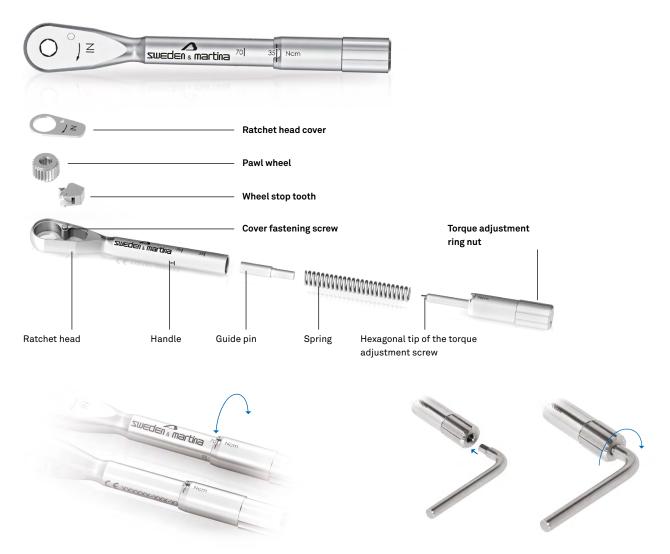
FERMAN (1990)<	LA-L100	real dimension
$\left\ \begin{array}{c} \displaystyle \sum_{i=1}^{n} \sum_{j=1}^{n} \sum_{i=1}^{n} \sum_{j=1$	LA-L120	dimensions increased by 20%
$\begin{array}{c} \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array}{c} \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array} \\ \displaystyle \end{array} \end{array} \\ \displaystyle \begin{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array} \\ \displaystyle \end{array} \end{array} \\ \displaystyle \begin{array} \\ \displaystyle \end{array} \end{array} \\ \displaystyle \begin{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \begin{array} \\ \displaystyle \end{array} \end{array} \\ \displaystyle \begin{array} \\ \displaystyle \end{array} \\ \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \\ \displaystyle \end{array} \\ \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \displaystyle \end{array} \\ \\ \\ \displaystyle \end{array} \\ \\ \\ \\$	LA-L130	dimensions increased by 30%

X-ray templates for Prama RF



Dynamometric ratchet CRI5-KIT

The dynamometric ratchet, supplied within the surgical kit, can be used with torque adjustment from 10 to 70 Ncm or in locked position without torque control. When used as a prosthetic ratchet for tightening the screws, refer to the torque values shown in the table on page 16.



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 mars offective.

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.

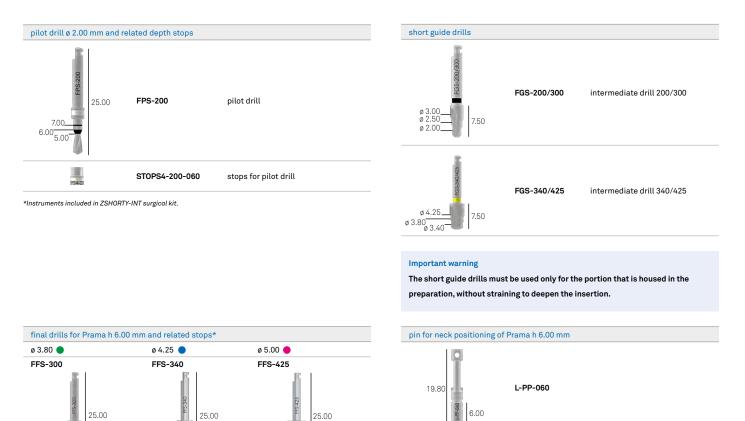
Sterilisation: in a vacuum autoclave, proceeding as follows:

• 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-060 Set



*Instruments included in ZSHORTY-INT surgical kit.

7.00_____ 6.00_5.00 ø.3.00

STOPS4-300-060

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

ø 3.40

STOPS4-340-060

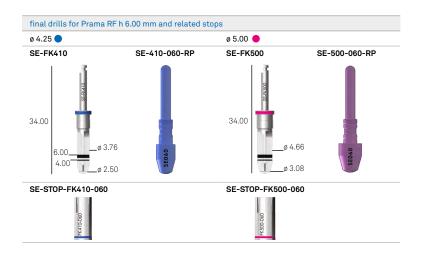
109545

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

ø 4.25 _

SIOPSer

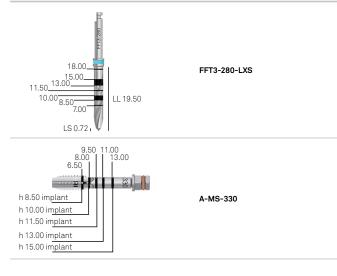
Please note: remember that the drills in the Shorty Drilling Kit for the insertion of implants h 6.00 mm do not over-prepare the surgical site. The working lengths include the portion related to the conical tip of the drill



L-INTEGRA Set



instruments for Prama Slim



Important warning

Maximum recommended speed is 200/300 rpm. Each drill has to be used only for the implant of equal diameter.

stops for pilot dr	ills			
h 8.50	10.00	11.50	13.00	15.00
STOP4-280-085	STOP4-280-100	STOP4-280-115	STOP4-280-130	STOP4-280-150
)]] 20-085	30-100	30-115	30-13)	NO BY

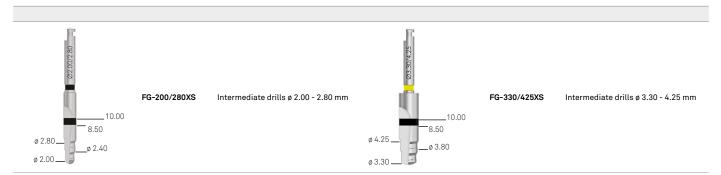
Important warning

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).

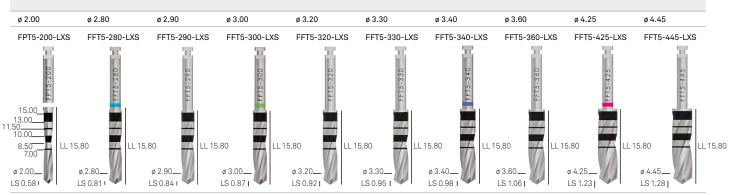
L-PP-085	L-PP-100	L-PP-115	L-PP-130	L-PP-150
22.30	23.80	25.30	26.80 3 8 5 13.00	28.80 <u>R</u> 15.00

Other instruments not included in the surgical kit

Intermediate drills

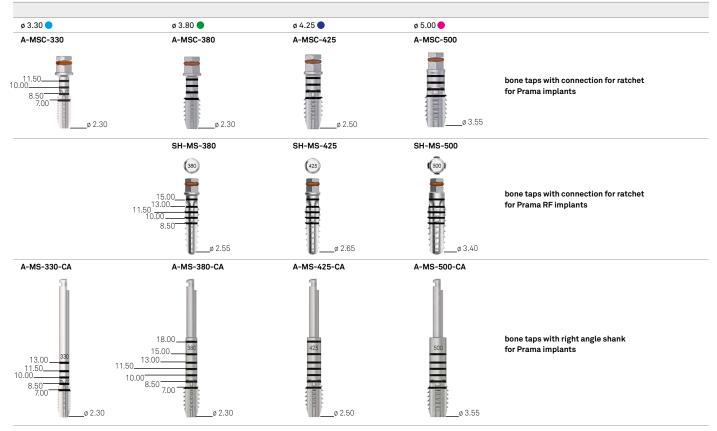


Drills for distal sectors



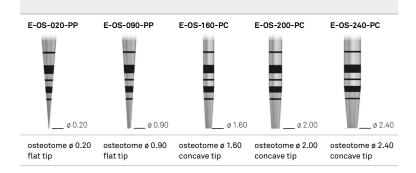
The drills for distal sectors are not included in the surgical kit, they can be purchased separately and singularly. They cannot be used with depth stops

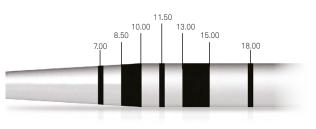
Bone taps



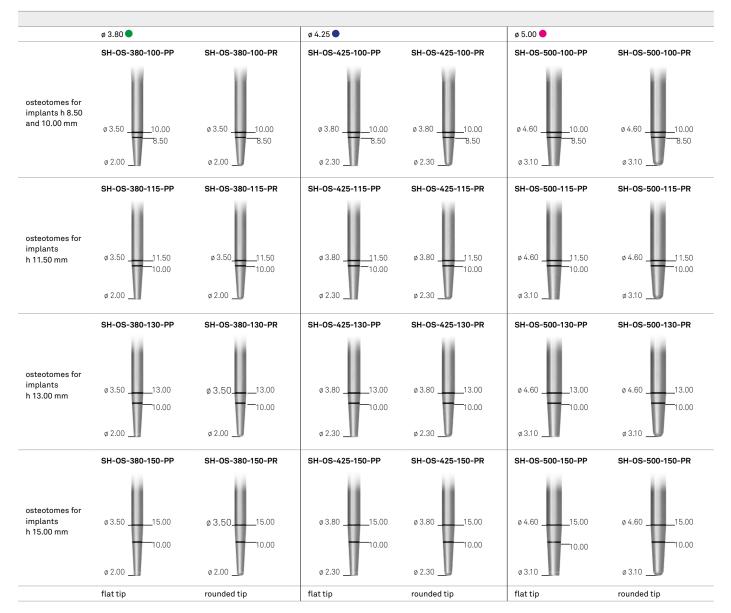
Please note: the sequence for Prama h 6.00 mm implants contemplates the use of the bone taps up to 1.00 mm below the first notch. In case of Prama RF h 6.00 mm bone taps must not be used.

Prama Osteotomes





Prama RF Osteotomes



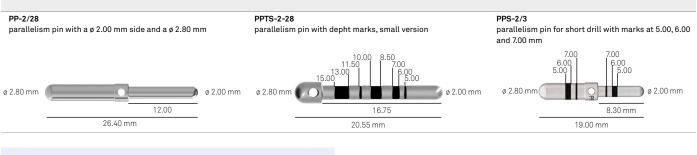
Osteotomes



OS-TRAY

universal case in Radel for osteotomes can hold up to 12 instruments

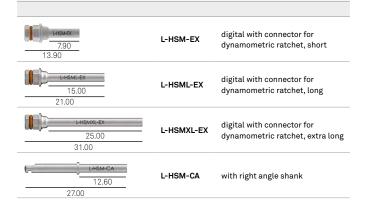
Parallelism pins



Avvertenza importante

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

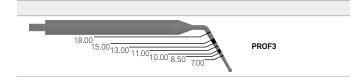
Prosthetic screwdrivers (for Full Head screws)



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. This O-ring must be checked and replaced when worn out.

Depth gauge PROF3



Spare O-ring



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

Drivers for intraoperative removal of implants

BC-EX230	short driver
BL-EX230	long driver

Mounter

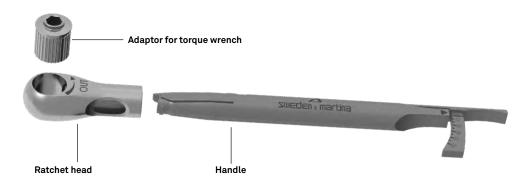
	MOU-EX230	mounter
Successful to	CM2	mounter stop key

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.

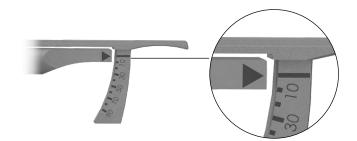
Every time this instrument is used, it must first be cleaned and sterilised following the instructions.



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.

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

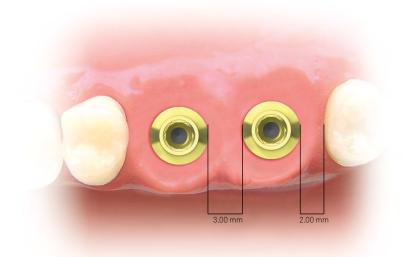
As a rule a distance of 3.00 mm should be maintained between the perimeter of the implants, and at least 2.00 mm between implants and adjacent natural teeth. It is also essential to check that the thickness of the residual bone wall at buccal level is not less than 1.00 mm. The best aesthetic results 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.

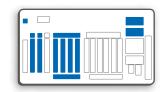


Surgical sequences for Prama implants

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 Ø 5.00 mm implant.





	FS-230	FPT3-200-LXS	FFT3-250-LXS	FFT3-280-LXS	FFT3-300-LXS	FFT3-340-LXS	FFT3-425-LXS	countersink drill	bone tap	EASYC4-EX230-CA
3.30	х	x	x	x					A-MS-330	x
3.80	х	x	x	x	x			A-FCC-380	A-MS-380	x
4.25	х	x	x	x	x	x		A-FCC-425	A-MS-425	x
5.00	х	x	x	x	x	x	x	A-FCC-500	A-MS-500	x

According to the receiving bone, the use or not of these instruments is demended to the experience of the clinician



	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		x	x						A-MS-330	x
3.80	х	x	x	х				A-FCC-380	A-MS-380	x
4.25	x	x	x	x	x			A-FCC-425	A-MS-425	x
5.00	x	x	x	x	x	x	х	A-FCC-500	A-MS-500	x
								According to the receiving not of these instruments experience of the clinician	is demended to the	

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.

Surgical sequences for Prama h 6.00 mm

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

Surgical sequences for Prama RF and Prama RF SL 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 31.

Please remember that the drills over-prepare the surgical site. See pages 12 and 14 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 surgical kit. P4-200 4.80 mm FS-230 FPT3-200-LXS SE-FK250 SH-FK380-085 SH-FK425-085 SH-FK500-085 EASYC4-EX230-CA countersink drill bone tap 3.80 A-FCC-380 SH-MS-380-CA х х х х х 4.25 A-FCC-425 SH-MS-425-CA х х х х х х

х

Surgical sequences for Prama RF h 6.00 mm

х

х

х

5.00

х



х

A-FCC-500

х

SH-MS-500-CA

According to the receiving bone, the use or not of these instruments is demended to the experience of the clinician



	FS-230	FPS-200*	con SE-STOP-FK410-060*	con SE-STOP-FK500-060*	countersink drill	EASYC4-EX230-CA
4.25	x	x	x		A-FCC-425	x
5.00	x	x	х	x	A-FCC-500	x
					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 out carefully in order to obtain a good primary stability.

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

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 12-14.

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.

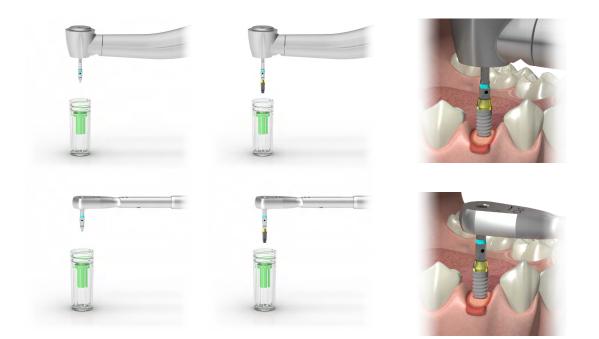


3 Immediately before inserting it into the oral cavity, remove the blue cap of the vial, making sure not to remove the transparent cap containing the surgical cover screw. The implant holding cylinder inside the vial and the surgical cover screw are coloured according to a colour code that allows the 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	\checkmark	\checkmark	\checkmark
LOT	Batch number	\checkmark	\checkmark	\checkmark
REF	Code	\checkmark	\checkmark	\checkmark
** *	Manufacturer	\checkmark	\checkmark	\checkmark
Ĩ	Consult instruction for use	 Image: A start of the start of	✓	✓
С С 0476	CE conformity mark for class IIa and IIb products	\checkmark	\checkmark	\checkmark
CE	CE conformity mark for class I		 ✓ 	
Rx Only	American federal law restricts this device to sale by or by order of a professional practitioner	a 🗸	✓	\checkmark
STEPRIZE	Do not resterilise	\checkmark		
(Disposable product, do not reuse	 Image: A start of the start of		✓
	Do not use if the packaging is damaged	✓		
NON	Nonsterile product		 ✓ 	✓
sterile r	Sterilized with ionizing radiation	✓		
\sum	Expiry date after which the product must not be used	 Image: A start of the start of		

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