





## SURGICAL MANUAL INDEX



When performing prosthetic rehabilitation procedures with Global implants, original Sweden & Martina prosthetic components only may be used. The use of non-original components limits Sweden & Martina's responsibility and invalidates the product warranty. Suitable surgical instruments must be used for the surgical placement of the fixtures. These instruments are sold individually or in kits. Always use original surgical accessories manufactured by Sweden & Martina. Sweden & Martina declines all responsibility for use of any non-original instruments.





Global dental implants are implantable devices developed for the restoration of patients with **total or partial edentulism**. They are destined to be surgically inserted into the upper or lower jaw bone. They can be inserted into different sites in the mouth using various techniques and subsequently connected to the prosthesis at different time points. Depending on the surgical procedure used, they can be implanted using a **subcrestal or transgingival protocol** and depending on the approach chosen, they are suitable for both **immediate and deferred loading**. Global implants can be inserted into **previously edentulous sites or post-extraction sites**, following either immediate or deferred protocols.

## Morphology

The morphology of Global implants has many distinctive features that make it a particularly versatile and safe implant system.

The **variable tapering**, which is lighter in the neck and in the first middle section and heavier in the apical section, creates a characteristic profile that makes the Global implant particularly versatile and suitable for use with different surgical techniques.



**An invitation** that facilitates the insertion of the prosthesis.



The two long, deep, **helical incisions** on the tip allow adequate tapping of the bone, offering two decompression and release areas for clotting, and improve primary stability by increasing the implant's antirotational aspect during the screwing and unscrewing of the components connected to it. However, preventive bone tapping is always required in the presence of very compact bone.



The implant's **rounded tip** makes it ideal for minisinus floor augmentation and maxillary sinus floor augmentation.





The **coronal microthreading**, has the same shape as the effective spire, but with a halved pitch. The microthreaded portion of the implant neck and the continuity of the main thread provide better primary stability.



The **conical-profile thread** has a pitch of 0.6 mm and maximum depth 0.4 mm, to provide a greater contact surface where it meets more spongy bone. The external progressive profile spire, with an angle of 60°, continues up to the tip of the implant.

### Multi-function mounter

The implant is sold with the mounter ready assembled. The mounter's particular sizes and design make it a practical, functional and versatile instrument. The mounter works in the implant well with a special geometry, characterised by rounded corners and blunt edges, specifically designed to avoid deformations of the connection and to facilitate removal of the mounter at the end of implant insertion.

In addition to the usual carrier function, for in situ implant placement, the shape of the mounter makes it suitable for use also for precision impression-taking, thanks to use of a dedicated PEEK\* cap with retentive tabs for stable anchorage in the impression material.



## Surface

It has been repeatedly demonstrated that the closer the roughness to fibroblast size, the greater the impact on cell behaviour. A rough surface generates greater platelet activation than a smooth one, thus accelerating the repair and osseointegration processes: the roughness guides the arrangement of the cells, alters their metabolism and proliferation, differentiates the osteoblasts and modulates production of extra-cellular matrix.





The neck has a 0.3 mm polished portion to allow perfect control of the connection diameter and prevent the accumulation of plaque at the point in which it joins the post.

It has a roughness of Ra 0.2.

#### ZirTi Surface (Zirconium Sand-Blasted Acid Etched Titanium)

The implant body undergoes a ZirTi treatment that significantly increases the bone-implant contact surface and guarantees excellent primary stability. This new generation nanostructured surface is obtained by means of a patented process consisting of a sequence of steps that range from sand-blasting with zirconium oxide to etching with mineral acids. The roughness and condition of the surface promote osteoblastic proliferation and differentiation and the formation and growth of bone tissue and significantly increase the bone-implant contact surface. The ZirTi surface has shown to have a sub-layer that promotes cell regrowth such as to adequately boost differentiation.

It has a roughness of Ra (1.2 - 1.3).



ZirTi surface magnified 4,000 xs and 10,000x using a scanning electron microscope: the roughness obtained with the various steps of the surface treatment is visible.

The materials used to manufacture Global dental implants were selected according to the properties indicated for their intended use, according to directive 93/42, implemented in Italy with law 46/97, Annex I – Essential Requirements, point 7.1.

They are made of commercially pure Grade 4 titanium, in compliance with harmonised standards.

Allergy to titanium is very rare but possible. Always ask patients whether they are allergic to titanium before treatment.

## Cold plasma surface decontamination

At the end of the surface treatments, the implants undergo thorough surface decontaminated using cold argon plasma having been cleaned of any major contaminants with numerous washing cycles using suitable solvents. During the argon treatment, the gas atoms are partially ionised, they acquire energy and "bombard" the surface of the fixture violently. This kind of "atomic sand-blasting" removes organic contaminants without leaving any traces or additional residues. As is known, argon is an inert gas that does not react with the titanium surface. Superficial decontamination status is duly controlled by randomised residual bioburden analysis and SEM inspection on all production batches. This process activates the ionisation of the atoms on the surface of the titanium oxide, which in turn increases the wettability of the fixture.



Implant before the decontamination process



Working plasma reactor during surface decontamination of the implants



Implant after the decontamination process

#### Superficial composition of the implants

The better the processes of passivation, cleaning and decontamination of an implant surface, the greater the presence of pure titanium on its surface, which proportionally increases the possibilities of osseointegration.

With its stringent surface treatments and cold plasma decontamination processes, Sweden & Martina has succeeded in obtaining an **extremely high titanium value in terms of atomic percentage**, as proven by ESCA tests carried out on random production batches. Only implants that undergo these types of accurate treatments guarantee excellent results, offering the best likelihood of success and duration.



## Implant packaging

The implants are packaged in PMMA vials, sealed inside a titanium basket, which protects the surface of the fixture against potential contact-induced recontamination. All packaging materials have been suitably tested to verify their suitability for sterilisation, preservation and medical use.



A surgical cover screw is provided with each implant and is lodged in a special compartment in the upper part of the dark blue LDPE cap that closes the vial. A small, transparent cover in PMMA then seals the blue cap.

The vials are packaged in a special PETG blister pack sealed with Tyvek film, which guarantees product sterility for 5 years.

## Sterilisation

Sterilisation is carried out **using beta rays**. The sterilisation procedures are carried out in accordance with UNI EN ISO 13485 and UNI EN ISO 9001 quality standards. A beta ray sterilisation process was chosen because it has a number of different advantages:

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

The sterilisation process was validated according to law. Validation was conducted in accordance with the methods indicated and described in standards ISO 11137-(1-3):2006, ISO 11137-2:2012, UNI EN 552:2002 and ISO/ TS 13409:2002. Implant samples then undergo regular microbiological and biological tests to ensure that the parameters validated for sterilisation do not change over time.

#### **IMPORTANT WARNING**

The expiry date is indicated on the pack. The sterile blister should be opened during the procedure. Before opening, check that the pack is perfectly intact. Any damage could compromise the implant's sterility and consequently the success of the operation. Previously used or non-sterile implants must not be used.

It is a single-use device. Reuse is not permitted and may lead to loss of the implant and cross-infection.

## Colour coding: implants

The implant codes are "mnemonic" codes, i.e. they allow easy identification of the piece. Below is a table showing how the mnemonic codes work using U-ZT-550-115 as an example:

Type of implant	Surface	Diameter	Length
U-	ZT-	550	115
U: Global Implant	ZT: ZirTi surface	380: 3.80 mm 430: 4.30 mm 480: 4.80 mm 550: 5.50 mm implant connection ø size	085: 8.5 mm 100: 10 mm 115: 11.5 mm 130: 13 mm 150: 15 mm refers to the length of the implant

## Global implants

The root form morphology that characterises Global implants features an initial 6 mm portion with a 1° taper, which is useful for stabilising the implant in the more cortical area of the receiving bone and a tip with a 6° taper, but with variable lengths, so that it can adapt better to the shape of the bone crests, thanks to the gradual reduction of the apical diameter.



Material used for implants and surgical cap screws: grade 4 titanium.

- Materials used for standard mounters and fixing screws: grade 5 titanium.
- \* Mounters are only sold pre-assembled on the implants of the corresponding diameter and they are not available for individual sale. The mounter screw (code U-VMOU-180) that fastens the mounter to the implant, however, is also available as a spare.
  \*\* Each implant is sold with its corresponding surgical can screw. The starily packed surgical screws are also available.
- \*\* Each implant is sold with its corresponding surgical cap screw. The sterile-packed surgical screws are also available for individual sale.

For full information on implants, see the instructions for use contained in each pack.





All sizes are expressed in mm, unless indicated otherwise.

## Surgical Kit

The surgical kit for the Global implant system was designed for maximum simplicity and ergonomics. The instrument descriptions are printed on the tray to facilitate assistants when repositioning them after cleansing and cleaning. The kits contain the stops for a safe use of the drills (does not include countersinks and bone profilers). These stops are extremely practical because they allow manual drill insertion and removal in a tip  $\rightarrow$  stem direction. All the instruments contained in the kit are made of surgical grade stainless steel. To guarantee maximum duration of the pieces, follow the recommended cleaning and sterilisation procedures. The surgical kits also contain x-ray templates for the graphic representation of the implant sizes to make it possible to choose the most suitable implant diameters and lengths using imaging methods. The kit comes with a mock-up implant for practical trials (it is not suitable for use in patients because it is anodised and non-sterile), a mounter with corresponding mounter screw and the surgical manual for Global implants. A hand driver for fast adjustment of the dynamometric ratchet value and a tube of lubricant gel for maintenance are also provided.

A practical torque control ratchet is also included that acts as a dynamometric key for checking the closing torque of the prosthetic screws and as a surgical key during implant insertion. The ratchet has a very small head, whose compact design makes it easy to use even in distal sectors.



The kit is constituted by a practical Radel box containing a surgical tray designed to hold the instruments according to a guided procedure. The sequences for use of the instruments are indicated by coloured marks.



code	description
ZGLOBAL2*	Surgical kit complete with all the instruments necessary for Global implants
GLO2-KIT*	Radel instrument box for Global implants
GROMMET-3	Kit with 5 spare silicone supports for surgical trays, for drills or instruments with right angle shanks
GROMMET-4	Kit with 5 spare silicone surgical trays, for instruments fitted with a hex connection
GROMMET-5	Kit with 5 spare silicone surgical trays, for digital or manual handheld instruments

\* The abbreviations ZGLOBAL2\* and GLO2-KIT\* are followed by a letter and a number that indicate the edition of the surgical kit.

### Colour code

A colour coding system has been developed for the Global implant system to identify the diameter and connection of the components.

In the surgical kit, colour coding is used to identify the surgical drills and drill stops (coloured ring on the piece):

Ø 2.20 WHITE Ø 2.80 BLACK Ø 3.80 GREEN Ø 4.30 DARK BLUE Ø 4.80 MAGENTA Ø 5.50 LIGHT BLUE

The surgical cap screws, impression transfers and laboratory analogues follow the same colour coding scheme to allow easy recognition of the platforms, during the second surgical phase and creation of the prosthesis.

### SURGICAL INSTRUMENTS







## General instructions

The surgical instruments designed for use with the implant systems manufactured by Sweden & Martina are reusable medical devices intended for transient use in the oral cavity (no more than 60 minutes at a time).

The surgical instruments have been designed for the preparation of sites for Sweden & Martina implants, insertion of the implants in the sites and the tightening and loosening of all connection screws (surgical cover screws, transgingival healing caps, post screws, abutments, prosthetic screws, transfer screws, etc.).

The surgical instruments manufactured by Sweden & Martina are destined for use with dental implants manufactured by Sweden & Martina. Use of surgical instruments for implant work other than those manufactured by Sweden & Martina limits its responsibility and renders the product warranty void. Sweden & Martina declines all responsibility for use of any non-original instruments.

Sweden & Martina surgical instruments are sold in NON-STERILE packs. Before use, they must be cleaned, disinfected and sterilised according to the instructions reported below. Failure to follow this warning may expose the patient to infection. The materials used to manufacture the surgical instruments for Sweden & Martina dental implants were selected according to the properties indicated for their intended use, in compliance with directive 93/42, implemented in Italy with Law 46/97, Annex I – Essential Requirements, point 7.1.

Each pack indicates the code, description of the contents and batch number. These details are also indicated on the patient labels inside the pack and must always be cited by the practitioner in any relevant correspondence.

## Code key: surgical instruments

The implant codes are "mnemonic" codes, i.e. they allow easy identification of the piece. Below is a table showing how the mnemonic codes work using different instrument types as examples:

Example	Type of component and type of implant	Edition/Size	Diameter	Length
As the instrument range is vast, here just a few examples for the main instrument families are provided	The letter "U" indicates the Global system. The other letters indicate the product family.	Identifies the length of the shank for the drills, or the edition number for accessories.	Usually, the ø size of the implant the instrument is designed for.	This size usually relates to the height of the component or other pertinent distinguishing measurements, otherwise it is a code that indicates whether or not a post is repositionable.
FU3-380-150	FU: Global implant drill	3: Edition 3 (for drills, it indicates a 14 mm shank)	380: 3.80 mm	150: 15 mm
STOP3-220/280-150	STOP: Cylindrical drill stop	3: Edition 3	220: 2.20 mm 280: 2.80 mm	150: 15 mm
U-STOP3-550	U-STOP: Conical drill stop for Global implants	3: Edition 3	550: 5.50 mm	-
U-MS-430	U-MS: Global implant bone tap	-	430: 4.30 mm	-
U-PP-280	U-PP: Parallelism pin for Global implant	-	280: 2.80 mm	-
U-BLP-OT275	U-BLP: Non retentive long driver for Global implant	OT: Octagonal	-	275: 2.75 mm

### SURGICAL INSTRUMENTS

## Drills

All Sweden & Martin drills are made from **high wear- and corrosion resistant stainless steel**. They are intended for mechanical use, i.e. they have a shank with a right angle connection and must be used with an appropriate micromotor. Extreme design and manufacture accuracy allow use in the **total absence of vibrations and oscillations**. Incorrect insertion of the instruments in the handpiece, however, will cause instrument vibration, eccentric rotation, early wear and shank 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. transmission shaft axle shifts, worn or faulty forceps, etc.). Failure to follow the instructions provided may cause surgical problems and damage to the patient's health.

Use the rotation speed indicated in the procedures on page 42 to prevent the development of bone necrosis. Lever movements increase the risks of instrument breakage and should therefore be avoided. Changes in speed should be avoided as far as possible. Never apply so much pressure that the instrument is prevented from rotating. This could lead to an excessive increase in heat in the tissues being drilled, with consequent bone necrosis, and damage both the instrument and the appliance (micromotor) used. This could also lead to breakage of the instrument. Using an intermittent approach prevents the overheating and wear of the instrument used and an undesirable increase in the temperature in the tissues being drilled. Suitable coolant should be used. Inadequate irrigation can lead to bone necrosis.

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





### Precision drill FS230

The precision drill is made of surgical-grade stainless steel. It is used to cut cortical bone and is consequently very pointed and sharp. The design of the blades guarantees efficacious cutting when using both the tip and the side. It has a maximum diameter of 2.30 mm. The 4.80 mm laser marking indicates the depth that the drill should always be inserted to in order to obtain a suitable guide hole for subsequent drills.



### Cylindrical drills FI3-220-LXS FI3-280-LXS

The intermediate drills for Global implants are cylindrical and have a two-bladed helical design. They are equipped with laser-etched lines to indicate the working depth. They must be used with plentiful external irrigation.

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

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



#### **IMPORTANT WARNING**

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

Code	Ø	Lp	Lt
FI3-220-LXS	2.20	0.64	18.20
FI3-280-LXS	2.80	0.81	18.35

#### SURGICAL INSTRUMENTS

### Cylindrical drill stops

The kit contains two full series of cylindrical drill stops. The two series are identical and interchangeable, to allow the clinician to lay out all the instruments, pre-assembled, required for the entire surgical procedure on the sterile table.



Stops are devices to be inserted in a tip  $\rightarrow$  shank direction on drills designed specifically for use with them. They make it possible to restrict the working length of a drill to a pre-set height.

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

The two series of cylindrical drill stops are identical and can be fitted on drills with diameters of 2.20 mm and 2.80 mm. In the interests of convenience and completeness, the kit contains two series.



## Conical drills

Conical drills are made from high wear- and corrosion-resistant stainless steel. They include a number of cutting instruments calibrated according to the diameter of the hole, to allow a continuous and homogeneous cutting movement and greater instrument stability during the various phases of the procedure. This translates into high precision implant preparations, the key to the success of all conical implants.

They have a 14.5 mm standard right angle shank. The kit contains 20 conical drills, each of which shapes the final hole for the implant with the diameter and height indicated by the instrument code. The drills available are:



All sizes are expressed in mm, unless indicated otherwise.

#### **SURGICAL INSTRUMENTS**

Conical drills have a colour-coded ring that facilitates recognition of the instruments dedicated to each diameter.

- LS: over-preparation size.
- **LL:** working length, including tip over-preparation.

LT: total length of the part remaining outside the contra-angle.



#### **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 implant height.

For details concerning the sizes of the different drills, see the table below.

Drill code	Corresponding implant	Nominal ø	ø Minimum	ø Maximum	LΤ	LL	LS	COLOUR CODE
FU3-380-085	U-ZT-380-085	3.80	3.00	3.25	15.70	8.90	0.40	GREEN
FU3-380-100	U-ZT-380-100	3.80	2.80	3.25	17.15	10.35	0.35	GREEN
FU3-380-115	U-ZT-380-115	3.80	2.40	3.25	18.60	11.80	0.30	GREEN
FU3-380-130	U-ZT-380-130	3.80	2.10	3.25	20.05	13.25	0.25	GREEN
FU3-380-150	U-ZT-380-150	3.80	1.70	3.25	22.00	15.20	0.20	GREEN
FU3-430-085	U-ZT-430-085	4.30	3.40	3.70	15.75	8.95	0.45	DARK BLUE
FU3-430-100	U-ZT-430-100	4.30	3.20	3.70	17.20	10.40	0.40	DARK BLUE
FU3-430-115	U-ZT-430-115	4.30	2.80	3.70	18.65	11.85	0.35	DARK BLUE
FU3-430-130	U-ZT-430-130	4.30	2.50	3.70	20.10	13.30	0.30	DARK BLUE
FU3-430-150	U-ZT-430-150	4.30	2.10	3.70	22.05	15.25	0.25	DARK BLUE
FU3-480-085	U-ZT-480-085	4.80	4.00	4.25	15.80	9.00	0.50	MAGENTA
FU3-480-100	U-ZT-480-100	4.80	3.70	4.25	17.25	10.45	0.45	MAGENTA
FU3-480-115	U-ZT-480-115	4.80	3.40	4.25	18.70	11.90	0.40	MAGENTA
FU3-480-130	U-ZT-480-130	4.80	3.00	4.25	18.15	13.35	0.35	MAGENTA
FU3-480-150	U-ZT-480-150	4.80	2.60	4.25	22.10	15.35	0.35	MAGENTA
FU3-550-085	U-ZT-550-085	5.50	4.80	5.05	15.90	9.10	0.60	LIGHT BLUE
FU3-550-100	U-ZT-550-100	5.50	4.40	5.05	17.35	10.55	0.55	LIGHT BLUE
FU3-550-115	U-ZT-550-115	5.50	4.10	5.05	18.80	12.00	0.50	LIGHT BLUE
FU3-550-130	U-ZT-550-130	5.50	3.80	5.05	20.25	13.45	0.45	LIGHT BLUE
FU3-550-150	U-ZT-550-150	5.50	3.30	5.05	22.20	15.40	0.40	LIGHT BLUE

## Conical drill stops

The kit contains one stop for each final conical drill diameter, designed for **insertion from the drill tip**. They restrict the working length to pre-set heights. At equal working diameters, the same stop is compatible with all drill lengths, as indicated in the table below:

	U-STOP3-380	U-STOP3-430	U-STOP3-480	U-STOP3-550
COLOUR CODE	GREEN	DARK BLUE	MAGENTA	LIGHT BUE
NOMINAL Ø corresponding to the diameter of the implant	3.80	4.30	4.80	5.50
DRILL FOR L. 8.50 mm IMPLANT	FU3-380-085	FU3-430-085	FU3-480-085	FU3-550-085
DRILL FOR L.10.00 mm IMPLANT	FU3-380-100	FU3-430-100	FU3-480-100	FU3-550-100
DRILL FOR L.11.50 mm IMPLANT	FU3-380-115	FU3-430-115	FU3-480-115	FU3-550-115
DRILL FOR L.13.00 mm IMPLANT	FU3-380-130	FU3-430-130	FU3-480-130	FU3-550-130
DRILL FOR L.15.00 mm IMPLANT	FU3-380-150	FU3-430-150	FU3-480-150	FU3-550-150

As previously indicated in relation to the cylindrical drill stops, once again in this case we recommend always checking that the stop is inserted to the desired height. Incomplete insertion may reduce the height of the preparation. Any insertion difficulties can be resolved by loosening the stop tabs slightly, using forceps.

It is also advisable to check the retention exerted by the stop, since excessively weak retention can cause the instrument to fall off the drill during the procedure. In the event of reduced stop retention capacity, simply tighten the tabs by hand or using forceps.

## Bone taps

These are cutting instruments used to prepare a recess in the bone for the implant spires, especially in those situations in which the bone is very compact or cortical, to alleviate compression and reduce insertion torque.



#### **IMPORTANT WARNING**

Since the portion of the implant in contact with the most cortical bone is that with a cylindrical profile, there is just one bone tap per platform, with a laser-etched marking 8.00 mm from the tip of the instrument, which helps to identify with precision the part common to all heights of the same implant diameter.



Bone taps are used manually with AVV3-MAN-DG digital handpieces or torque control ratchet CRI5. For indications on how to use the dynamometric ratchet and digital handpiece, see pages 31 and 29, respectively.

If they are used with the ratchet, set torque to 40-50 Ncm and gradually increase to the maximum value (without torque adjustment) only when absolutely necessary. High torque values exert compression on the bone, with the risk of ischaemia and a reduction in the tissues' vascularisation capacity. When instrument penetration is difficult, to reduce compression, it is advisable to proceed by rotating through 2-3 turns then reverse-rotating through 1-2 turns, thereby continuously alternating penetration and unscrewing.

Bone taps are manufactured using stainless steel. They have a hex connection that makes them compatible with the instruments in the kit. The hex connection contains an o-ring that guarantees a grip on the components.

This o-ring must be checked regularly and replaced when worn and no longer able to exert the correct friction.



A 5-piece kit of spare o-rings can be ordered with the code ORING180-088.

## Mounter driver

Drivers are devices used to transfer implants and screw them into surgical sites. They are products made of surgical stainless steel. Global implants are supplied with the pre-assembled mounter, which is supplied in the pack ready to be engaged using the appropriate driver.

The surgical kit drivers intended for this purpose are described below.



Mounter drivers can be used to transport the implant to the oral cavity, since they exert friction inside the mounter. Friction depends on the mechanical design of the two components. These drivers have been tested with torques of up to 70 Ncm. Higher insertion torques can cause critical mechanical conditions. If the insertion torque exceeds this value, it is advisable to remove the mounter and continue tightening using solid driver U-BLP-OT275. See page 53 for the full insertion procedure.



## Implant drivers

The surgical kit also contains 3 retentive drivers to be used to transport and screw in the implant whenever it is necessary or preferable to remove the mounter prior to surgery.



These drivers, of which two are for hand use (one short and one long) and one is mechanical for use with a micromotor, have a metal o-ring in the part that is introduced inside the implants that clicks into the connection and makes it possible to transport the implant to the patient's mouth once the mounter has been removed. These drivers are tested for torques of up to 70 Ncm. Higher insertion torques can cause critical mechanical conditions. If the insertion torque exceeds this value, it is advisable to remove the driver and continue tightening with solid driver U-BLP-OT275.

### Non-retentive

The driver intended for hand use only does not have a retention device inside the connection, as is the case for the three drivers described above. It is a non-retentive driver that can be useful when working on particularly dense bone, in order to complete insertion of the implant when the torque required for insertion is very high, however it cannot be used as a carrier.



See page 53 for the full insertion procedure.

Drivers for hand use must be used with the AVV3-MAN-DG hand knob or CRI5 torque control ratchet and they have a red polymer o-ring in the hex, used to connect with these instruments. For indications on how to use the hand knob and torque control ratchet, see pages 31 and 29, respectively.

For the maintenance of red polymer o-rings, see the details contained in the "bone tap" section on page 24.

#### **IMPORTANT WARNING**

Lever movements can break or warp the driver, with potential intraoperative complications.

## Screwdrivers for connecting screws

The surgical kit contains a number of screwdrivers that can be used to tighten and unscrew mounter connection screws, transgingival healing caps and transfer, post and abutment screws and Global system connecting screws in general. They are made of surgical-grade stainless steel.

All driver tips share the same design and the screwdrivers are therefore interchangeable. They differ from one another in their overall length and the fact that they can be either digital and single-pieced, i.e. joined to the handle used to grasp them, or fitted with a hex connection compatible with the torque control ratchet.

Screwdrivers come in kits featuring 3 different heights, as indicated below.



They are very handy during the intraoperative phase because they are safe, practical devices that do not need to be assembled and dismantled.

#### **IMPORTANT WARNING**

It is advisable to tie a safety thread through the loop on the end of the handpiece.



The drivers with an upper hex connection, on the other hand, have been designed for use with the torque control ratchet, in order to control the torque used. The kit contains long and short versions:



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



Digital screwdriver, for connecting screws, to be used with torque control ratchet, extra long (Not included in the surgical kit, to be purchased separately).

The kit also contains a driver with a contra-angle shank, which is very practical during both the surgical and the prosthetic phases, when used with a torque-control micromotor.

HSM-20-CA HSM-20-CA

Screw driver for connection screws, for right angle.

All ratchet drivers have a red polymer o-ring in the hexagon connection for this instrument that guarantees friction between the instruments. For the maintenance and replacement of these o-rings, see the details contained in the "bone tap" section on page 24.

#### **IMPORTANT WARNING**

Excessive torque can pare down the connection screw wells and blunt the corners of the screwdrivers, thereby causing intraoperative and prosthetic complications that can, in some cases, be severe. The torques recommended for the various components are summarised in the table below:

surgical cap screws, transgingival healing screws	10 Ncm
all prosthetic screws	20-25 Ncm
all prosthetic components that are screwed directly on to the implant	25-30 Ncm

sueden , martha

## Torque control ratchet CRI5

The implant system surgical kit contains a special ratchet (CRI5), together with corresponding regulation key, for rapid tightening of the torque adjustment ring and gel lubricant for maintenance. The ratchet can be used with torque adjustment from 10 to 70 Ncm, or in a locked, no torque-control position.

When using as a prosthetic ratchet for fastening the screws, follow the torque values in the table overleaf.

The CRI5 ratchet key is a multi-purpose instrument that can be disassembled, and is sold non-sterile.



Before each use, the instrument must be cleaned and sterilised following the indications on page 36. Adequate maintenance, performed following all the step-by-step phases for the dismantling and correct re-assembly of the device during cleaning operations, is fundamental for the correct operation of the device and to preserve its duration. Persons who use this tool must be suitably trained, and they must have read the instructions provided in this manual before handling the device.

Once the key has been sterilised, the key is ready for use. Before performing any surgical or restoration procedure, test the key to make sure that it is correctly assembled and in perfect working order.

#### SURGICAL INSTRUMENTS

Once it has been sterilised, the key is ready for use. Before performing any surgical or restoration procedure, test the key to make sure that it is correctly assembled and in perfect working order. Torque can be adjusted by aligning the desired torque marking with the circular opening on the handle. The "IN" arrow on the head seen from above indicates the key position that permits tightening. The "OUT" arrow legible on the top of the head indicates the loosening position. An unlimited torque position is obtained by positioning the torque adjustment device up to the line marked "R" on the handle of the ratchet body.



#### **IMPORTANT WARNING**

Once again, torque can be adjusted by screwing/unscrewing the ring nut located at the bottom of the instrument's handle. Torque must always be up-regulated, starting tightening at a lower value and working up to the torque desired, i.e. by turning the ring nut in a clockwise direction. To do so, if the torque required is lower than that last used, unscrew by two turns below the new desired torque value and work back up to this value by turning the ring nut again clockwise.

The ring nut can be tightened or loosened manually, however, in order to speed up such operations, the kit also contains a driver that makes it possible to turn it rapidly.

Any deterioration of the screwing, insertion and torque mechanisms must be checked by personnel responsible for the control and maintenance of this dental instrument. The pieces of this mechanism are not interchangeable; one piece from one key cannot be replaced with a piece from another key as each ratchet is INDIVIDUALLY calibrated. If a piece is lost, please return the instrument to Sweden & Martina for the necessary repair work. No ratchet assembly components are sold individually.

Failure to comply with the indications provided can cause problems in relation to the maintenance and stability of the restoration.





## Mounter stop key

This key is intended for holding the implant mounter still during connection screw loosening operations. It is manufactured using surgical-grade stainless steel. See page 55 for the mounter removal procedure.





## Adaptors and extensions



## Parallelism pins

The surgical kit contains two series of parallelism pins, one with a diameter of 2.20 mm, characterised by 8.5, 10, 11.5, 13 and 15 mm depth markings that also make it possible to verify the depth of holes prepared using the cylindrical drills.



#### **IMPORTANT WARNING**

It is advisable to tie a safety thread through the loop on the end of the handpiece.

## X-Ray templates

The surgical kits also contain templates for the **graphic representation** of the implant sizes, to make it possible to choose the most suitable implant diameters and lengths using imaging methods. The templates come in three versions: real size, 20% increased and 30% increased size.



U2-L100





U2-L130

## Drills for distal sectors

Optional short drills with a 14 mm-long shank and total length of 30 mm are also available, for use without STOPS, they are dedicated to distal sectors and do not have a colour-coded shank. They have a depth marking at 7 mm, as they are common to a number of different Sweden & Martina implant systems.





### Osteotomes

A complete set of osteotomes has been designed for the expansion of thin crests, for mini-crest lifts and for the compaction of poorly mineralised bone, to be used as an alternative to the final drills. The sequence of use must be determined according to the degree of bone density and the preparation desired.

code	description
OS-U-KIT*	OS-U-KIT* Osteotome kit for Global implants including: - Radel container - osteotomes: OS-U-380-85-PT, OS-U-380-10-PT, OS-U-380-115-PT, OS-U-380-13-PT, OS-U-430-85-PT, OS-U-430-10-PT, OS-U-430-115-PT, OS-U-430-13-PT OS-U-480-85-PT, OS-U-480-10-PT, OS-U-480-115-PT, OS-U-480-13-PT
OS-U-TRAY	Radel-R container for Global implant osteotomes. Can hold up to 12 instruments.

\* The OS-U-KIT code is followed by a letter indicating the edition of the surgical kit.

#### osteotome sizes



\* Not all osteotomes are contained in the kit. See details on page 33. Codes marked with an asterisk must be ordered separately.

# Cleaning, disinfecting, sterilising and storing the kits and surgical instruments

Caution! All 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 a minimal effect on these devices in terms of wear. 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 connection 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 instructions for use. Brush the products with a soft 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, using the following procedure:

- Temperature = 121 - 124 °C, with autoclave cycle of at least 20 minutes and drying cycle of 15 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 re-sterilise in new bags before using them again. The storage time for products sterilised inside the bags should not exceed that recommended by the manufacturer of the bags.

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

#### **Reference standards**

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

#### Disposal procedures

If used, dispose of the surgical instruments as biological waste, according to applicable local regulations.

### SURGICAL INSTRUMENTS

### Cleaning, disinfecting, sterilising and storing torque ratchet CRI5

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

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/detergent solution and covered with a cloth. This prevents biological contaminants from the patient drying out and dissolves them, thereby making cleaning easier and more effective.

Completely dismantle 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 acting as a stop.

With the hexagon tip at the bottom of the torque adjustment screw, unscrew and completely remove the connecting screw of the cover from the side labelled "OUT". Exert 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.

When cleaning manually, clean the outer and inner surfaces of the instrument mechanically under hot water with a soft brush. Using a needleless syringe, inject hot water to wash the hard-to-access holes of the head and the area around the pawl wheel and wheel stop tooth. If necessary, proceed in the same way for the inside of the handle and the torque adjustment device. Use a suitable neutral detergent and follow the manufacturer's instructions for use. 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 the holes.



For 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, as it would cause a deterioration in the machined surfaces and, consequently, loss of precision of the torque measurement.

When unloading, 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 thorough cleaning is important. During cleaning, avoid sprays or jets of liquid and use adequate protective equipment. Avoid contact between this instrument and other nickel-plated instruments.

The pieces must be reassembled before sterilisation. Dry the pieces and moderately lubricate the functional areas, then reassemble the key as indicated in the figures below. If too much lubricant is applied, it will appear on the surface of the instrument during sterilisation. Use the lubricant supplied only.



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



Once parts 2 and 3 have been lubricated and inserted into 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 contact areas between the tooth of the pawl wheel and the pin of the wheel stop tooth.



Lubricate the spring inside the ratchet handle as shown in the figure. Assemble the torque adjustment screw, making sure the instrument works properly. Activate the pawl wheel manually.

**Sterilisation:** in a vacuum autoclave, using the following procedure: Temperature =  $121 \div 124$  °C, with autoclave cycle of at least 20 minutes and drying cycle of 15 minutes.

This procedure is important in order to preserve the precision of the instrument within a tolerance of  $\pm$  3,5Ncm. Operate the torque and insertion mechanism to check they work properly. Remove any traces of lubricant from the outer surface of the key. Place the device in suitable sterilisation bags.

It is advisable to practice the assembly and dismantling operations following the indications.

### **CLINICAL INDICATIONS**

## Patient's medical history and treatment plan

When assessing the patient, in addition to his/her eligibility as regards implant-restoration rehabilitation, it is usually necessary to consider the contraindications that apply to oral surgery procedures in general.

These include:

- Clotting disorders, anticoagulant therapy.
- Healing or bone regeneration disorders such as, for example:
  - Decompensated diabetes mellitus.
  - Metabolic or systemic diseases that compromise tissue regeneration with particular pertinence for healing and bone regeneration.
  - Alcohol abuse, smoking and use of drugs.
- Immunosuppressive therapy, such as: chemotherapy and radiotherapy.
- Infections and inflammations, such as: periodontitis, gingivitis.
- Poor oral hygiene.
- Inadequate motivation.
- Occlusion and/or articulation disorders as well as an inadequate interocclusal space.
- Inadequate alveolar process.

#### **IMPORTANT WARNING**

Drills must be used with caution in cases of low bone density and implant sites must be adequately prepared in advance. Use osteotomes whenever possible.

It is contraindicated to fit implants and implant restorations in patients with poor general or oral health, those who are unable to monitor their general conditions properly or those who have had organ transplants. Psychologically unstable patients, alcohol or drug abusers, and poorly motivated or uncooperative patients should also be considered unsuitable for this kind of treatment. Patients with poor periodontal health should first be treated and allowed to recover. In the presence of a lack of bone substance or poor quality of the receiving bone, such as to compromise the stability of the implant, suitable guided tissue regeneration must be performed prior to implant treatment. Contraindications also include: allergy to titanium, acute or chronic infectious diseases, sub-acute chronic maxillary osteitis, systemic diseases, endocrine disorders, diseases resulting in disorders of the lesser circulation, pregnancy, breastfeeding, previous exposure to radiation, haemophilia, neutropenia, steroid use, diabetes mellitus, kidney failure and fibrous dysplasia and treatment with bisphosphonates.

Implants designed to support restorations are medical devices that are introduced into the mouth during surgical procedures and as such they involve further restrictions to use, details of which can be found in the instructions for use for the implant fixtures.

#### Side effects

The following may present after surgical procedures:

- Temporary local swelling, oedema and haematoma.
- Temporary sensitivity alterations.
- Temporary masticatory limitations.
- Post-surgical micro-haemorrhages in the following 12-24 hours.



It is important to perform a careful pre-operative analysis of the patient's medical history to verify their suitability to the implant treatment. It is recommended to collect and file all the clinical, radiological and radiographic records.

After making models of both arches, the best position and orientation of the chosen implants will be evaluated, based on the occlusal plane and on a correct distribution of the forces. In this phase, a surgical stent may be created to guide the specialist, to favour correct positioning of the Global implants during the operation.

Having evaluated the specific case, the practitioner will decide to use a one- or two-step surgical phase to produce a radiological/surgical stent using titanium cylinders (code DIM).



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

In addition to an oral examination, both clinical and with x-rays, it is advisable to perform a CAT scan of the interested area; once the x-rays and CAT scans have been obtained, the specialist can identify the best suited implant, with the help of convenient transparent radiographic guides.

The pre-operative study of the Dentalscan CT scan makes it possible to identify the type of bone present at the planned implant insertion point.

The choice of the surgical procedure must take into consideration the type of bone present.

Bone is normally classified into 4 types according to density. The classification (according to Karl Misch) is the following:



D1 BONE: all cortical bone.



D3BONE: all medullary bone without cortical crestal bone.



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



D4 BONE: all medullary bone with very low mineralisation.

## Preparation of the implant site

To obtain a three-dimensional view of the bone available, it is advisable to lift a mucoperiosteal flap.

As mentioned previously, pre-operative clinical and radiographic analysis plays an important role in determining the position and direction to be used for implant placement. During this stage, a surgical stent would be helpful, to act as a guide during the marking of the cortical bone with the precision drill and in the drilling phase using the 2.20 mm pilot drill.

Generally speaking, a distance of 3 mm should be maintained between the edges of the implants.



The following pages contain information on the drilling sequences to be used for optimal preparation of all implant types. Remember to always use drills with stops correctly inserted.

Remember that the drills always prepare a hole that is longer than the implant. For overpreparation sizes, see page 19 for cylindrical drills, and page 22 for conical drills. The preparations must be non-traumatic and as gradual as possible, and must be made 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 procedure to be performed. In particular:

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





Sweden & Martina distributes XO Osseo, a brushless micromotor for surgical and implant procedures. This device perfectly combines reliability, high performance and simple procedures.

Compact and practical with a basic design, XO Osseo has all the requisites for maximum precision and safety.

### Surgical sequences

The following pages describe the surgical procedures and the sequences for use of the site preparation instruments for Global implants.

These procedures are based on clinical experience and the recommendations of numerous studies and clinical protocols for implants of this type. However, it should be remembered that bone types with different densities require different surgical approaches, and the indications below cannot replace adequate training and knowledge of the doctors, nor their personal experience, which may at times guide them towards alternative solutions and indications. The sequences that follow refer to specific bone types. In expansion techniques, either in the case of regenerative surgery, or when it is necessary to increase compaction in poor quality bone, the use of drills can be replaced by their corresponding osteotomes.

#### SURGICAL SEQUENCE FOR 8.50 mm HEIGHT IMPLANTS

The sequence illustrates the preparation for the ø 5.50 mm implant. For the other diameters, the drills indicated in the individual tables should be used.

The STOP can be used at the clinician's discretion. However, it is strongly recommended, particularly in cases of poor intraoperative visibility.



	BONE D1	1.100 rpm	1.100 rpm	1.100 rpm	1.100 rpm
m m 0	D2 BONE	1.100 rpm	1.100 rpm	1.100 rpm	1.100 rpm
ø 5.5	D3 BONE	900 rpm	900 rpm	900 rpm	900 rpm
	D4 BONE	900 rpm	preparation with osteotomes	-	-





			50 Ncm max	50 Ncm max
-	-	-	U-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
900 rpm	-	-	U-MS-430 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	900 rpm	-	U-MS-480 (20 rpm)	20 rpm
1.100 rpm	900 rpm	-	-	20 rpm
900 rpm	900 rpm	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	1.100 rpm	900 rpm	U-MS-550 (20 rpm)	20 rpm
1.100 rpm	1.100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
-	-	-	-	20 rpm

#### SURGICAL SEQUENCE FOR 10.00 mm HEIGHT IMPLANTS

The sequence illustrates the preparation for the  $\emptyset$  5.50 mm implant. For the other diameters, the drills indicated in the individual tables should be used. The STOP can be used at the clinician's discretion. However, it is strongly recommended, particularly in cases of poor intraoperative visibility. **N.B.** The depth of use for the cylindrical drills depends on the diameter of the implant. See the table below.



	D2 BONE	1.100 rpm	1.100 rpm	1.100 rpm	1.100 rpm
<b>0 4.8</b>	D3 BONE	900 rpm	900 rpm	900 rpm	900 rpm
	D4 BONE	900 rpm	preparation with osteotomes	-	-

U-ZT-550-100 10.00 mm marking 10.00 mm marking D1 BONE 1.100 rpm 1.100 rpm 1.100 rpm 1.100 rpm a 5.50 mm D2 BONE 1.100 rpm 1.100 rpm 1.100 rpm 1.100 rpm D3 BONE 900 rpm 900 rpm 900 rpm 900 rpm D4 BONE preparation with osteotomes 900 rpm





			50 Ncm max	50 Ncm max
-	-	-	U-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
900 rpm	-	-	U-MS-430 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	900 rpm	-	U-MS-480 (20 rpm)	20 rpm
1.100 rpm	900 rpm	-	-	20 rpm
900 rpm	900 rpm	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	1.100 rpm	900 rpm	U-MS-550 (20 rpm)	20 rpm
1.100 rpm	1.100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
-	-	-	-	20 rpm

#### SURGICAL SEQUENCE FOR 11.50 mm HEIGHT IMPLANTS

The sequence illustrates the preparation for the ø 5.50 mm implant. For the other diameters, the drills indicated in the individual tables should be used. The STOP can be used at the clinician's discretion. However, it is strongly recommended, particularly in cases of poor intraoperative visibility. **N.B.** The depth of use for the cylindrical drills depends on the diameter of the implant. See the table below.



	0-21-550-115		11.50 min marking	11.50 mini marking	
	D1 BONE	1.100 rpm	1.100 rpm	1.100 rpm	1.100 rpm
	D2 BONE	1.100 rpm	1.100 rpm	1.100 rpm	1.100 rpm
ø 5.5	D3 BONE	900 rpm	900 rpm	900 rpm	900 rpm
	D4 BONE	900 rpm	preparation with osteotomes	-	-





			50 Ncm max	50 Ncm max
-	-	-	U-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
900 rpm	-	-	U-MS-430 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	900 rpm	-	U-MS-480 (20 rpm)	20 rpm
1.100 rpm	900 rpm	-	-	20 rpm
900 rpm	900 rpm	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	1.100 rpm	900 rpm	U-MS-550 (20 rpm)	20 rpm
1.100 rpm	1.100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
-	-	-	-	20 rpm

#### SURGICAL SEQUENCE FOR 13.00 mm HEIGHT IMPLANTS

The sequence illustrates the preparation for the ø 5.50 mm implant. For the other diameters, the drills indicated in the individual tables should be used. The STOP can be used at the clinician's discretion. However, it is strongly recommended, particularly in cases of poor intraoperative visibility. **N.B.** The depth of use for the cylindrical drills depends on the diameter of the implant. See the table below.



preparation with osteotomes

D4 BONE

900 rpm





			50 Ncm max	50 Ncm max
-	-	-	U-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
900 rpm	-	-	U-MS-430 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	900 rpm	-	U-MS-480 (20 rpm)	20 rpm
1.100 rpm	900 rpm	-	-	20 rpm
900 rpm	900 rpm	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	1.100 rpm	900 rpm	U-MS-550 (20 rpm)	20 rpm
1.100 rpm	1.100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
-	-	-	-	20 rpm

#### SURGICAL SEQUENCE FOR 15.00 mm HEIGHT IMPLANTS

The sequence illustrates the preparation for the ø 5.50 mm implant. For the other diameters, the drills indicated in the individual tables should be used. The STOP can be used at the clinician's discretion. However, it is strongly recommended, particularly in cases of poor intraoperative visibility. **N.B.** The depth of use for the cylindrical drills depends on the diameter of the implant. See the table below.

![](_page_49_Figure_2.jpeg)

preparation with osteotomes

D4 BONE

900 rpm

![](_page_50_Picture_0.jpeg)

![](_page_50_Figure_1.jpeg)

			50 Ncm max	50 Ncm max
-	-	-	U-MS-380 (20 rpm)	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
900 rpm	-	-	U-MS-430 (20 rpm)	20 rpm
900 rpm	-	-	-	20 rpm
900 rpm	-	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	900 rpm	-	U-MS-480 (20 rpm)	20 rpm
1.100 rpm	900 rpm	-	-	20 rpm
900 rpm	900 rpm	-	-	20 rpm
-	-	-	-	20 rpm

			50 Ncm max	50 Ncm max
1.100 rpm	1.100 rpm	900 rpm	U-MS-550 (20 rpm)	20 rpm
1.100 rpm	1.100 rpm	900 rpm	-	20 rpm
900 rpm	900 rpm	900 rpm	-	20 rpm
-	-	-	-	20 rpm

### **CLINICAL INDICATIONS**

## Operative phase of implant positioning

![](_page_51_Picture_2.jpeg)

(1) Use the patient label inside the pack for the patient's medical file and apply to the Dental Card: This will make it easier to record the patient's treatment plan and the batch used.

![](_page_51_Picture_4.jpeg)

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

![](_page_51_Figure_6.jpeg)

![](_page_51_Figure_7.jpeg)

![](_page_52_Picture_0.jpeg)

![](_page_52_Picture_1.jpeg)

(3) Immediately before introduction into the oral cavity, remove the dark blue stopper from the vial, making sure to not remove the transparent cap containing the surgical cover screw on top of it. The fixture-holder disk inside the vial and the surgical cover screw are colour-coded, to allow easy identification of the implant diameter.

The Global mounter makes it possible to pull the fixture out of the vial using the instrument provided, without having to touch the surface. This prevents the possibility of contaminating the surface of the fixture, which is very important for the osseointegration process. The Global mounter pre-assembled on all the fixtures in the system can be used for insertion with a contra-angle and can also be used for impression-taking and, subsequently, to create the provisional prosthesis.

### Standard procedure

When the vial is opened, the fixture is arranged with the octagon exposed, ready to be engaged.

The fixture can be picked up using the U-AVV3-MOU-CA driver and then screwed mechanically into the site using a torquecontrol surgical micromotor set to a screwing speed of 20 rpm and max torque of 70 Ncm. At the current state, this is the highest value that can be achieved using the micromotors on the market.

The driver has been tested up to 70 Ncm and did not present any deformity or collapse. Mechanical and normal instruments with torque control features are regularly calibrated with a suitable calibrated instrument.

![](_page_52_Picture_8.jpeg)

As an alternative to the use of the contra-angle driver, the implant can be picked up using digital driver U-AVV-MOUC. If necessary, the special extension BPM-15 can be used. Digital handpiece AVV3-MAN-DG or ratchet CRI5 can be used for tightening.

U-AVV-MOUC has four facets arranged symmetrically along the outside edge.

The facets are aligned with four alternate sides of the implant's internal octagon. This makes it possible to position the implant with the octagon facing in the desired direction. If necessary, these instruments can also be used to remove the implant easily.

![](_page_53_Picture_4.jpeg)

#### **IMPORTANT WARNING**

The implant - mounter - manual driver U-AVV-MOUC complex was tested without any reported damage up to a torque of 140-150 Ncm. If, nevertheless, it is difficult to insert the implant in the surgical site, it is advisable to:

- unscrew it and screw it back again by 2 turns, a few times;
- tap or re-tap;
- slightly oversize the coronal part of the preparation.

![](_page_54_Picture_0.jpeg)

In the presence of very compact bone, it is advisable to remove the mounter before completely inserting the implant and, if necessary, to perform final tightening of the implant using solid driver U-BLP-OT275, whose resistance has been tested up to a torque of 150 Ncm and which is joined to the internal working octagon of the implant, taking care to insert the octagonal part of the driver inside the implant well straight in relation to the implant itself by completely and deeply engaging the entire internal connection. The hex connection can be connected to the dedicated digital driver AVV3-MAN-DG or torque ratchet CRI5.

Intraoperative mounter removal phase.

![](_page_54_Picture_3.jpeg)

Full driver tightening phase U-BLP-OT275.

### Procedure to be used for pre-surgical mounter removal

For all those cases in which it is necessary or preferable to remove the mounter before inserting the implant (patient unable to open his/her mouth properly, distal positions in which it is more difficult to unscrew in the mouth, immediate loading with temporary posts other than the mounter), a procedure has been devised using a titanium support (code U-SUP, not included in the surgical kit and to be ordered separately), that can be sterilised and reused, and houses the implant while loosening the mounter connection screws without the risk of contaminating the surface of the implant.

![](_page_55_Picture_3.jpeg)

![](_page_56_Picture_1.jpeg)

4) The retentive drivers are tested to resist torques of up to 70 Ncm safely during tightening. In the event of higher torques, it is advisable to proceed with the implant's final tightening using the U-BLP-OT275 solid driver, whose resistance has been tested at torques of up to 150 Ncm.

If, nevertheless, it is difficult to insert the implant in the surgical site, it is advisable to:

- unscrew it and screw it back in again by 2 turns, a few times;
- tap or re-tap;
- slightly oversize the coronal part of the preparation.

### Phase following implant insertion

Having completed implant insertion, depending on the treatment plan:

- for immediate loading, impressions can be taken and a temporary prosthesis made directly on the mounter.
- for deferred loading, the mounter can be removed by unscrewing the screw that secures it to the fixture (when it has
  not already been removed before completing the tightening of the implant). To remove the mounter, use the dedicated
  right angle screwdriver (HSM-20-CA) and keep the mounter locked with the U-CM key to prevent the implant itself from
  moving.

The mounter is very precise in its connection with the "working" octagon of the implant, so much so that it is securely fastened to it during the insertion phase. As a result of this extreme precision, a slight anti-clockwise movement may be needed to remove the mounter, using the U-CM mounter wrench for easy dismantling. Take the cap screw from its position in the blue vial stopper and screw it to the implant, either manually or in any case with a torque of no more than 10 Ncm. Suture flaps as usual.

#### **HEALING TIMES**

The preliminary healing times to implant loading are influenced by numerous factors:

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

In cases where all or many of the above factors are positive, premature or immediate loading can be considered.

#### SECOND SURGICAL PHASE

In the second surgical phase, therefore, the implant cover screws are exposed and any excess hard tissue is removed, before the implants are unscrewed. If the right angle driver is used, the surgical micromotor must be chosen with the following parameters: 20 rpm and a torque of 10 Ncm.

Once the transgingival healing caps have been positioned, the margins of the flaps are secured and the soft tissue is contoured to fit the profile of the transgingival healing cap and stitched around it. The healing caps should be tightened manually using torques no higher than 10 Ncm.

The soft tissues can be conditioned with a provisional fixture customised with transgingival healing caps.

#### **CLINICAL INDICATIONS**

In the case of a subcrestal technique with two surgical phases, to minimise the discomfort caused by the observance of the biological times required for osseointegration, a temporary removable prosthesis should be used with caution and adequately unloaded. In implant protocols with two surgical phases, a healing period is required for the biological processes that lead to osseointegration, before the second surgical procedure can be performed to replace the cover screws with transgingival healing screws.

## Intra-operative removal of the implants

Should it be necessary to remove a previously inserted implant, this can be done using a mounter or by directly grasping the octagonal working connection of the implant.

### Removal using a mounter

If the mounter has already been removed, accurately clean the implant well of any blood and residues produced during the insertion phase, and reposition the mounter by securing it to the implant with the corresponding screw. During the tightening phase, use the right angle screwdriver (HSM-20-CA), setting the surgical micromotor with the following parameters: 20 rpm and a torque of 10 Ncm; as an alternative, one-piece digital screwdrivers can be used. During this phase, remember to keep the mounter locked with the dedicated U-CM wrench to prevent the implant being screwed further into the bone, making it even more difficult to remove.

When the mounter is correctly connected to the implant, the upper internal octagon is ready to be engaged using the appropriate right angle instrument (U-AVV3-MOU-CA). The implant can be unscrewed (the instrument must be turned in an anti-clockwise direction) and removed from the site using a suitable surgical micromotor with torque control set to an unscrewing speed of 20 rpm and maximum torque. Alternatively, the implant can be unscrewed and removed using the manual driver (U-AVV-MOUC) fitted to the digital driver (AVV3-MAN-DG) or with the ratchet (CRI3) used in the torque control position or in the locked position, making sure that the laser-etched arrow on the head of the ratchet indicates an anti-clockwise direction.

Lift the removed implant using sterile forceps.

### Removal without using a mounter

If the mounter has already been removed and the practitioner wishes to remove the implant without using a mounter, carefully clean the implant well of any blood and any residues produced during the insertion phase, take solid driver U-BLP-OT275 from the surgical kit and fit the octagonal part of the driver inside the implant well, making sure the instrument is straight in relation to the implant and that the internal connection is engaged completely and deeply. Lock the head of the ratchet, connect it to the hexagonal part of the driver, making sure the laser-etched arrow on the head of the ratchet indicates the anti-clockwise direction and prise it in this direction, while holding the driver/ratchet system straight with the index finger.

#### **IMPORTANT WARNING**

Solid driver U-BLP-OT275 does not grip the connection inside and the implant is therefore picked up using forceps, taking care not to drop it in the mouth. It is important to use retentive drivers, as the torques required to remove the implants are usually very high.

## Manufacturer's details

The manufacturer of the Global implant system, comprising implants, surgical instruments and prosthetic components, is:

#### Sweden & Martina

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

### Key for the symbols that appear on the packaging of implants, and/ or surgical instruments and/or prosthetic components:

symbol	description		
	Caution! See instructions for use		
LOT	Batch number		
REF	Code		
STERILE R	Sterilised using ionising radiation (spare surgical cover screws and implants only)		
	Non-sterile product (prosthetic components and surgical instruments only)		
$\Sigma$	Expiry date after which the product must not be used (implants only)		
$\otimes$	Single-use product, do not reuse		
	Manufacturer		
ĺ	See the instructions for use		
	Do not use the product if the packaging is damaged		
CE	CE conformity marking for class 1 products		
<b>C €</b> <sub>0476</sub>	CE conformity marking for class 2a and 2b products		
Rx Only	Restricts this device to sale by or on the order of licensed practitioner.		

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