SURGICAL PROCEDURE

GALAXY

Conical connection implants

Ziacom®

GALAXY

Surgical procedure manual

Ziacom®

Important information

Please read carefully before using Ziacom® products

General information

This document contains basic information on the use of original Ziacom® dental implant systems, hereafter referred to as Ziacom® dental implants or simply Ziacom® products. This document has been created as quick guide for clinicians responsible for treatment, hereafter the "user", and, therefore, is neither an alternative nor a substitute for specialized training or professional clinical experience.

Ziacom® products must be used according to a suitable treatment plan and adhering strictly to the surgical and prosthetic protocols established by the manufacturer. Read the product-specific surgical and prosthetic protocols as well as the instructions for use and maintenance before using each Ziacom® product. You can find this information on our website, www.ziacom.com, or request it from your nearest authorised Ziacom® distributor.

Liability, safety and guarantee.

The instructions for the use and handling of Ziacom® products are based on internationally published literature, current clinical standards and our clinical experience, so they should be understood as general guiding information. The handling and use of Ziacom® products is the sole responsibility of the user as it is outside the control of Ziacom Medical SL. Ziacom Medical SL, their affiliates and/or their authorised distributors disclaim all responsibility, whether explicit or implicit, total or partial, for possible damage or injury caused by poor handling of the product or any other situation not considered in their protocols and manuals for the correct use of their products.

The user must ensure that the Ziacom® product is appropriate for the intended procedure and end purpose. Neither these instructions for use nor the work or handling protocols for the products release the user from this obligation. Ziacom® products must be used, handled and applied by professionals with the appropriate training and qualifications required according to current legislation in each country.

The total or partial use, handling and/or application of Ziacom® products at any stage of their implementation by personnel who are unqualified or lack the necessary training will automatically void any type of warranty and may cause severe damage to the patient's health.

Ziacom® products are part of their own system, with their own design characteristics and work protocols, including dental implants, abutments or prosthetic components and surgical or prosthetic instruments. The use of Ziacom® products in combination with elements or components from other manufacturers could result in treatment failure, damage to tissues or bone structures, inadequate aesthetic outcomes and severe damage to the patient's health. Therefore, only original Ziacom® products should be used.

The clinician in charge of the treatment is solely responsible for ensuring the use of original Ziacom® products and that they are used according to the corresponding instructions for use and handling protocols throughout the implant procedure. The use of any other non-original Ziacom® components, instruments or products, whether alone or in combination with any original Ziacom® products, will immediately void the warranty of the original Ziacom® products.

See the Ziacom Medical SL Warranty Programme (available on the website or by contacting Ziacom Medical SL, their affiliates or authorised distributors).

Warning. Not all Ziacom® products are available in all counties. Check availability in your country.

Together for **health**

Index

Characteristics

CONNECTION

- 11° conical connection with double internal hex.
- Single platform for all diameters.
- Platform switch.

CORTICAL ZONE

- Microrings.
- Inverted cone cortical macro-design.

CONICAL BODY

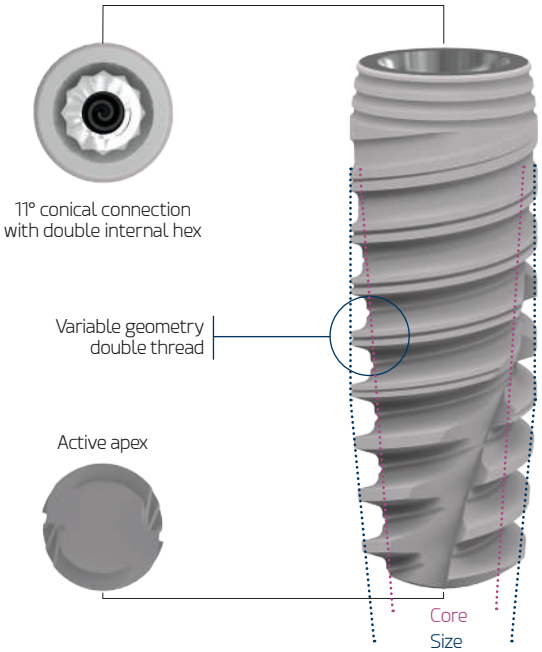
- Double threaded.
- Variable geometry:
  - » Coronal - thick trapezoidal thread.
  - » Middle - thinner trapezoidal thread.
  - » Apex - V-shaped thread.

APEX

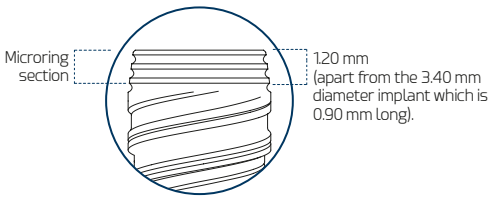
- Oblique apical windows.
- Self-tapping active apex.
- Atraumatic rounded apex.

INDICATIONS

- Bones of very poor quality.
- Immediate loading.
- Immediate postextraction implant placement.
- Aesthetic anterior segment.



Dimensions of the implant's coronal section



Advantages

1. The conical connection prevents micromovement and microfiltration at the implant–abutment interface.
2. The single platform provides a significant simplification of prosthetic procedures.
3. The reverse taper neck mitigates cortical stress during surgery.
4. The thread design confers a very high primary stability even in poor quality bone.
5. The active apex facilitates insertion axis correction in postextraction alveoli.

Diameters and lengths

		LENGTH (L)						
Ø DIAMETER	Ø PLATFORM	6	7	8.5	10	11.5	13	14.5
RP 3.40	2.85							
RP 3.70								
RP 4.00		N 	N 					
RP 4.30		N 	N 					
RP 4.80		N 	N 	N 	N 	N 	N 	

Dimensions in mm.

N New product. Check availability.

Surface treatments

Titansure surface

Implants inserted following surface treatment are known to benefit from improved osseointegration by increasing the bone-to-implant contact area. This is partly due to the implant's chemical composition and topographical characteristics.

With our **Titansure** surface treatment, at Ziacom Medical we have obtained a contaminant-free surface topography and optimal average macro- and microporosity values, which are key specifications for achieving prompt and proper osseointegration and, in turn, extremely reliable and predictable implants.

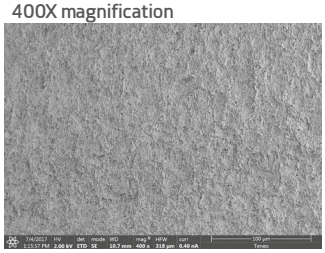
TITANSURE SURFACE ANALYSIS

Titansure is an SLA surface treatment created through a subtraction process involving sandblasting with white aluminium oxide and double acid etching with hydrofluoric acid and a sulphuric/phosphoric acid mix.

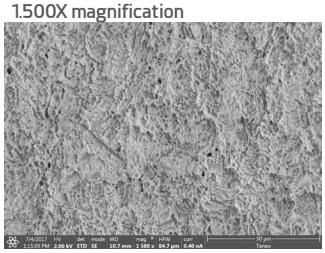
Surface morphology analysis

With the aid of a scanning electron microscope (FEI TENEO, Thermo Fisher Scientific Inc., Waltham, MA, USA), we can see the rough, porous surface creating numerous cavities with thin, sharp edges.

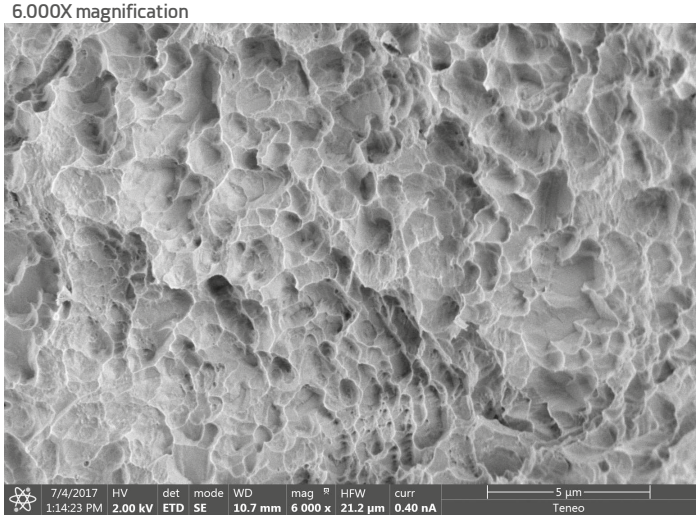
400X magnification



1.500X magnification

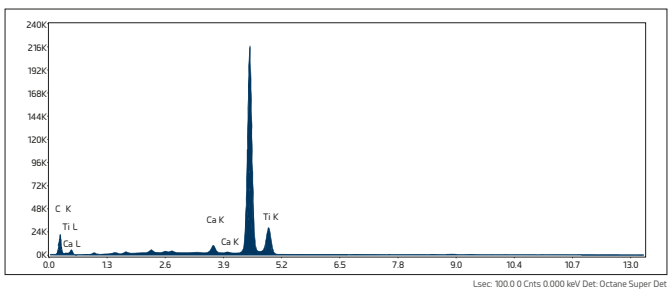


6.000X magnification



Surface elemental analysis

We used an energy-dispersive X-ray spectrometer (Octane Super, Edax-Ametek, Mahwah, NJ, USA) to analyse the chemical composition at the surface.



Compositional analysis of implant surface

ELEMENT	WEIGHT (%)
C K	9.32 (10.23)
Al K	-
Ti K	89.53 (11.77)

No aluminum was detected

Results are expressed as the mean and standard deviation of the mass percentage (WEIGHT (%)).

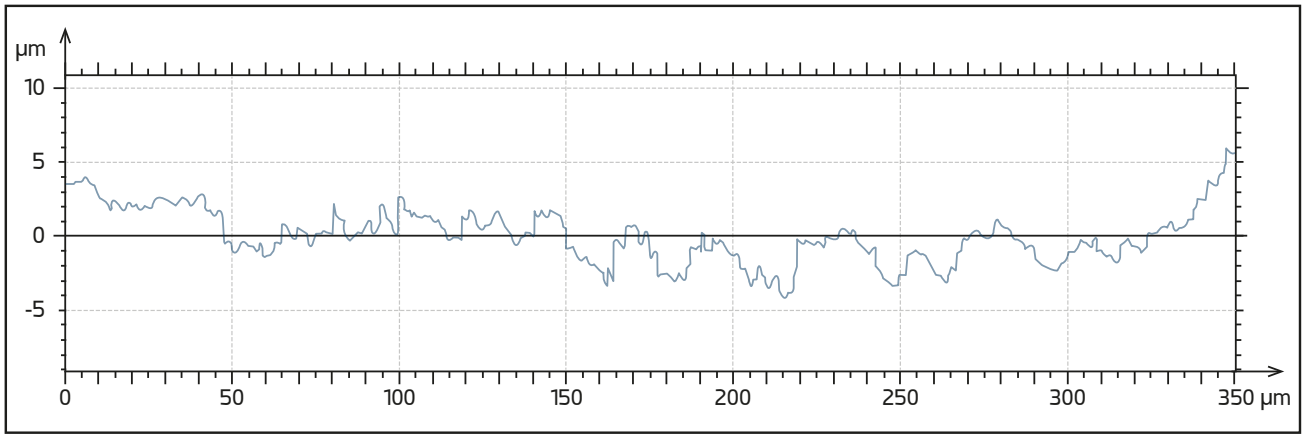
Surface roughness analysis

The roughness study was conducted with a Sensofar S NEOX interferometric-confocal microscope (Sensofar Medical, Terrasa, Spain) and SensoMAP Premium 7.4 software. The quantitative roughness profile parameters applied were: average roughness (Ra), root-mean-square roughness (Rq), maximum profile peak height roughness (Rp) and maximum profile valley depth roughness (Rv).

Ra (µm) (SD)	Rq (µm) (SD)	Rp (µm) (SD)	Rv (µm) (SD)
0.82 (0.10)	0.97 (0.08)	1.84 (0.04)	2.21 (0.01)

The 3D surface roughness (Sa), 3D root mean square height (Sq), maximum 3D peak height (Sp) and maximum 3D pit depth of the selected area (Sv) were also recorded.

Sa (µm) (SD)	Sq (µm) (SD)	Sp (µm) (SD)	Sv (µm) (SD)
0.76 (0.01)	0.97 (0.01)	4.20 (0.12)	4.62 (0.20)



The data were extracted from:

Rizo-Gorrita, M.; Fernandez-Asian, I.; Garcia-de-Frenza, A.; Vazquez-Pachon, C.; Serrera-Figallo, M.; Torres-Lagares, D.; Gutierrez-Perez, J. Influence of Three Dental Implant Surfaces on Cell Viability and Bone Behavior. An In Vitro and a Histometric Study in a Rabbit Model. Appl. Sci. 2020. 10(14), 4790

OPTIMAL OSSEOINTEGRATION

The **Titansure** surface has a three-dimensional surface structure with high peaks and broad troughs, which is known to be highly effective at promoting the coagulation cascade and the release of growth factors through platelet activation [Kim, H.; Choi, S.H.; Ryu, J.J.; Koh, S.Y.; Park, J.H.; Lee, I.S. The biocompatibility of SLA-treated titanium implants. Biomed. Mater. 2008. 3. 025011.].

This type of surface may have an osteogenic effect thanks to its different topographical features at a micrometer and nanometer level, which has a very similar morphology to the osteoclastic bone resorption cavities [Le Guehennec, L.; Goyenvalle, E.; Lopez-Heredia, M.A.; Weiss, P.; Amouriq, Y.; Layrolle, P. Histomorphometric analysis of the osseointegration of four different implant surfaces in the femoral epiphyses of rabbits. Clin. Oral Implants Res. 2008. 19. 1103–1110].

For more information on the surface treatment see the literature available at **www.ziacom.com/biblioteca**

Surface treatments

Titansure Active surface treatment

Ziacom® presents the **Titansure Active** surface treatment with bone bioactive liquid (BBL) as the latest innovation for the presentation of our dental implants. The **Titansure Active** surface treatment is a combination of **Titansure** with BBL technology (Bone Bioactive Liquid), a patent acquired by Ziacom® and developed by the Biointelligence Systems research group led by Professor Maher Al-Atari Abou-Asi.

"BBL technology consists of a saline solution containing calcium chloride (CaCl2) and magnesium chloride (MgCl2.6H20) with a net negative charge and creates the ideal conditions for post-implant cell adhesion in the region with bone damage. What is more, surface treatment with BBL provides a significant increase in the density of hydroxyl groups on the surface of implants, thus improving their hydration considerably compared with other surfaces. This hydrophilic implant surface is precisely what enables active ion interaction with blood plasma and bone-forming cells long before the first steam cells can attach to the surface. Finally, this yields improved intercellular communication and a greater final bone-to-implant contact area in a significantly shorter time, thereby markedly reducing the postoperative inflammatory process."

Dr. Prof. Maher Al Atari

SURFACE STUDIES OF BBL-TREATED IMPLANTS

In vitro research

Dental pulp pluripotent-like stem cell (DPPSC) and dental pulp mesenchymal stem cell (DPMSC) cultures were prepared on titanium discs sandblasted with aluminium oxide and acid etched in an osteoblast differentiation medium.

The samples were divided into two treatment groups:

- **Group A.** Titanium discs - Traditional, untreated surface.
- **Group B.** Titanium discs - BBL-treated surface.

The surfaces were examined using energy-dispersive X-ray microanalysis (EDXMA) to determine the composition of surface elements.

Comparison of different elements in the two groups		
	Untreated surface	Treated surface **Titansure Active**
Carbon	32.22 ± 5.89	32.89 ± 1.76
Oxygen	14.34 ± 1.23	13.97 ± 1.45
Phosphorus	3.96 ± 2.8	3.89 ± 1.87
Calcium	5.86 ± 3.8	9.53 ± 4.04
Titanium	39.76 ± 1.65	41.34 ± 1.89
Ca/P	1.678	2.347

In vivo research

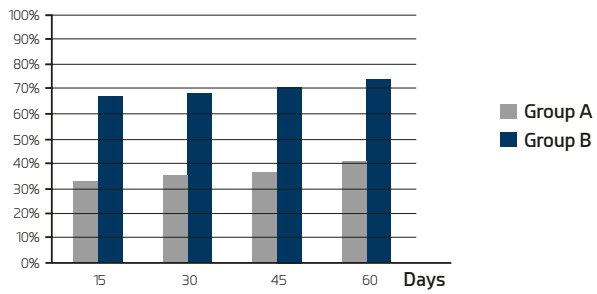
A study was conducted in the tibiae of 10 adult New Zealand rabbits after inserting four implants per rabbit (two in each tibia).

The subjects were assigned to two treatment groups with implants:

- **Group A.** Implants with a traditional, untreated surface.
- **Group B.** Implants with a traditional, BBL-treated surface.

In general, group B had higher BIC (bone-to-implant contact) values than group A.

Histomorphometric analysis - Bone-to-implant contact (BIC)		
Time of measurement	Group A Untreated surface (Control) mean + SD	Group B Treated surface **Titansure Active** mean + SD
15 days	33.7 ± 2.3%	68.92 ± 0.3%
30 days	35.8 ± 1.8%	69.35 ± 2.2%
45 days	37.9 ± 1.2%	70.34 ± 1.1%
60 days	41.2 ± 0.8%	73.89 ± 1.9%



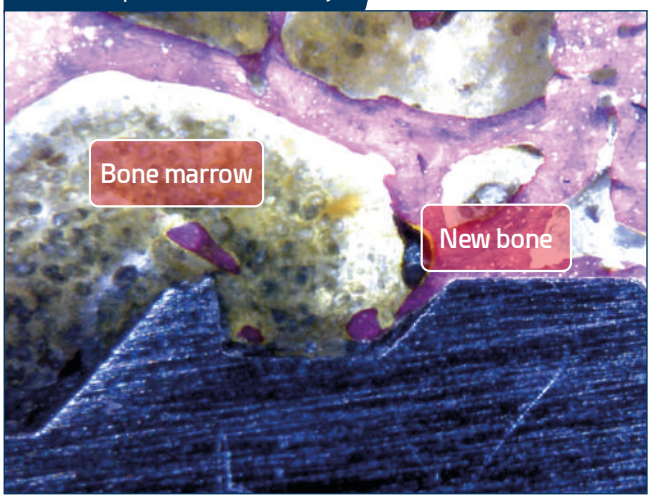
Conclusions

Within the scope of this study, the histomorphometric analysis demonstrated that the group B implants achieved quicker and more effective osseointegration than control group A. Nevertheless, an assessment of bone growth in the medullary portion of the subjects' tibiae revealed the new surface's potential for osteoinduction.

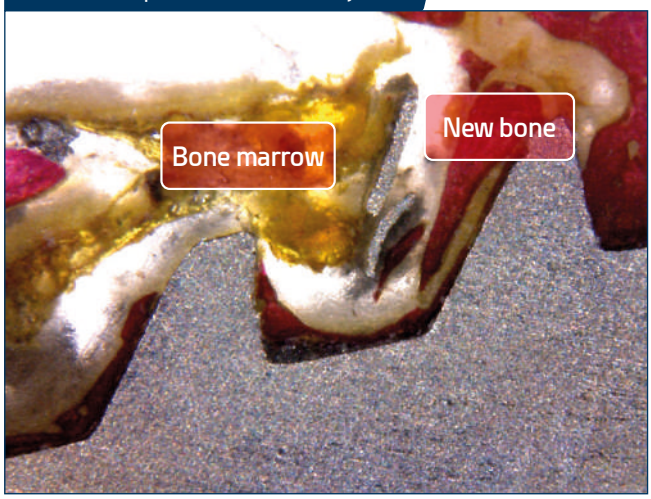
As explained by Dr. Sérgio Alexandre Gehrke, the histologist in charge of the study: "Within the study's limits, data from the histomorphometric analysis of the implants with a BBL-treated surface (78.92 + 0.3%) highlighted a much quicker and more effective osseointegration compared to the control group (53.8 + 2.3% of BIC). Assessment of bone growth in the medullary portion of the rabbits' tibiae showed the new test surface's potential for osteoinduction."

EVOLUTION OF OSSEOINTEGRATION

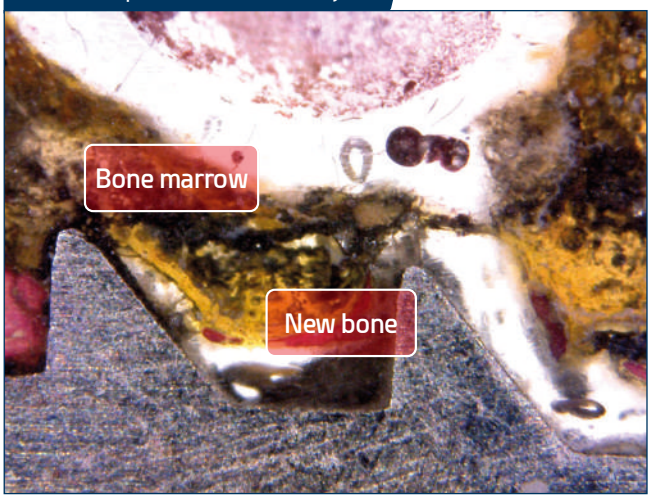
Untreated implant - Evolution at 15 days



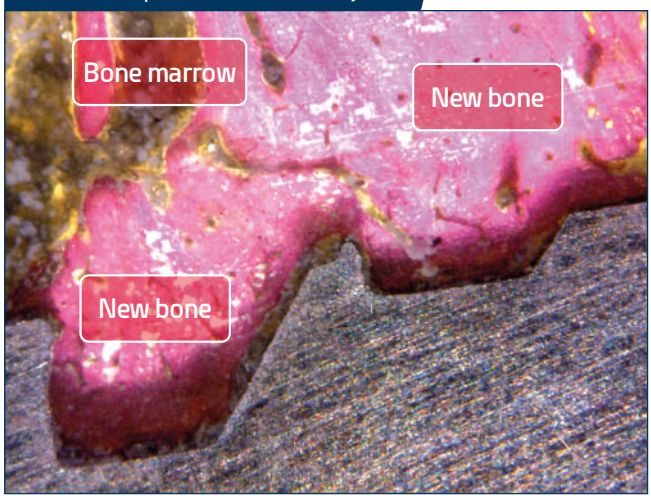
BBL-treated implant - Evolution at 15 days



Untreated implant - Evolution at 60 days



BBL-treated implant - Evolution at 60 days



NOTE
The images are of Ziacom® implants manufactured specifically for use in the study of BBL-treated implants.

Product presentation

Packaging tailored to the type of surface

Ziacom® offers two different types of product packaging depending on the type of implant surface:

Blister packaging
Available for implants with **Titansure** surface treatment. The blisters are heat-sealed and include identification labels for product traceability and a flap for easy opening in the clinic but while preventing accidental opening.

Bottle packaging
Available for implants with **Titansure Active** surface treatment. The sealed bottle contains bone bioactive liquid (BBL) to ensure the perfect preservation of the implant's properties. The bottles include identification labels for product traceability.

Titansure

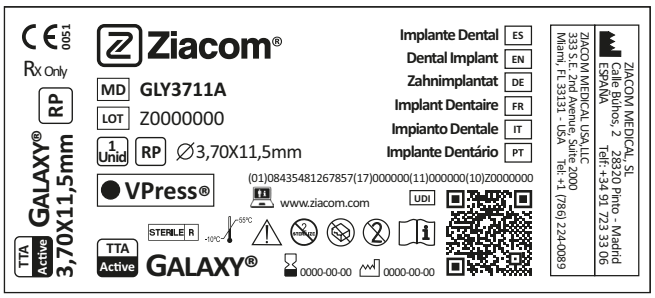
Titansure Active N

IMPORTANT
Do not open the sterile container until just before inserting the implant.

N New product. Check availability.

Outer identification label

Ziacom® implants are supplied in a sealed cardboard box that includes a product identification label with a description of their main characteristics.



Description of the symbology used

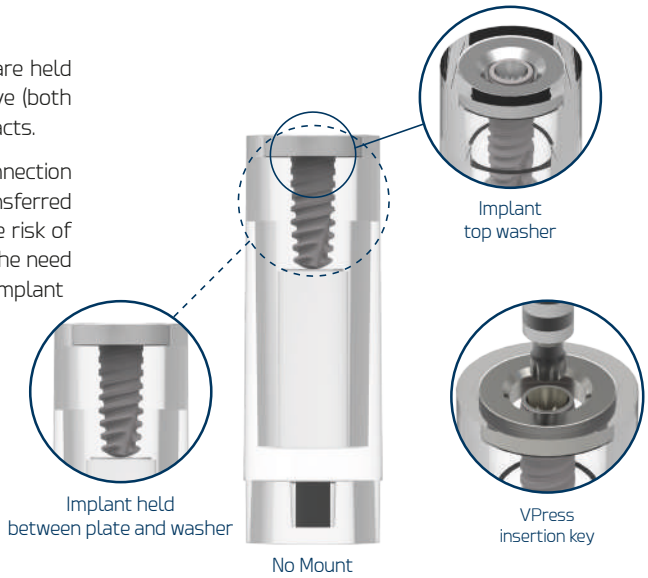
- MDD CE certification and notified body
- MD Name of the medical device
- LOT Number of product batch
- Patient information website
- UDI Unique device identification
- STERILE R Sterilised using radiation
- Temperature restriction
- Caution, consult accompanying documents
- Do not resterilise
- Do not use if the packaging is damaged
- Non-reusable product
- Consult the instructions for use
- Expiry date of the product
- Date of manufacture
- Product manufacturer
- TT Titansure surface treatment
- TTA Active Titansure Active surface treatment
- Rx Only Caution: federal law prohibits dispensing without prescription

For full details on the product presentation and instructions for use (IFU) see **www.ziacom.com/ifus** or scan the QR code on the box.

Ziacom® No Mount

Galaxy implants are supplied in Ziacom® No Mount vials; the implants are held vertically inside a plastic vial between a plate below and a washer above (both made from titanium), thus preventing any movements or unwanted contacts.

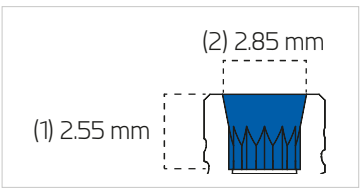
This packaging means that the pressure is applied directly to the connection so the implant can be safely and easily withdrawn from the vial and transferred to the surgical site. Therefore, Ziacom® No Mount implants eliminate the risk of reducing the primary stability caused by over instrumentation, squash the need to handle the implant when removing it from the mount, and simplify implant insertion in posterior areas with limited access.



Galaxy references

	IMPLANT					
	Ø (mm)	Ø Core (mm)	Length (mm)	Ref. Titansure	Ref. Titansure Active	
GALAXY	3.40	2.00/3.15	8.5	GLY3485	GLY3485A	
			10.0	GLY3410	GLY3410A	
			11.5	GLY3411	GLY3411A	
			13.0	GLY3413	GLY3413A	
			14.5	GLY3414	GLY3414A	
	3.70	2.20/3.70	8.5	GLY3785	GLY3785A	
			10.0	GLY3710	GLY3710A	
			11.5	GLY3711	GLY3711A	
			13.0	GLY3713	GLY3713A	
			14.5	GLY3714	GLY3714A	
	4.00	2.40/3.90	6.0	GLY4006	GLY4006A	
			7.0	GLY4007	GLY4007A	
			8.5	GLY4085	GLY4085A	
			10.0	GLY4010	GLY4010A	
			11.5	GLY4011	GLY4011A	
			13.0	GLY4013	GLY4013A	
			14.5	GLY4014	GLY4014A	
	4.30	2.60/4.05	6.0	GLY4306	GLY4306A	
			7.0	GLY4307	GLY4307A	
			8.5	GLY4385	GLY4385A	
			10.0	GLY4310	GLY4310A	
			11.5	GLY4311	GLY4311A	
			13.0	GLY4313	GLY4313A	
			14.5	GLY4314	GLY4314A	
	4.80	2.90/4.40	6.0	GLY4806	GLY4806A	
			7.0	GLY4807	GLY4807A	
			8.5	GLY4885	GLY4885A	
			10.0	GLY4810	GLY4810A	
			11.5	GLY4811	GLY4811A	
			13.0	GLY4813	GLY4813A	

Platform



Single platform for all implants: (1) Height of inner cone (2) Diameter of the working platform

Metric

Unique metric of 1.60

Cover screw*

Platf.	Length (L)	Reference
	5.10	GLYRT

Anodised RP

* Screw included with each implant.

Recommendations for use

All implant treatments must respect the natural biomechanical stability of the oral cavity and allow the natural emergence of the dental crown through the soft tissue. The implantologist must assess the quantity and quality of bone currently in the implant area and consider the need for prior or simultaneous bone regeneration, as appropriate.

Ziacom® has a wide range of implants available to cover every reconstruction possibility. The inverted trapeziums on the periodontal chart represent the implant diameters and platforms recommended for each tooth position.

These recommendations are valid for the replacement of teeth with single restorations, bridges, hybrid work or overdentures.

Remember to maintain minimum distances between adjacent implants and between implants and teeth in order to preserve interdental papilla, bone vascularisation and natural emergence profiles.

Selection of the appropriate implant for each case is the sole responsibility of the implantologist. Ziacom® advises all clinicians to take into account the warnings based on scientific evidence which can be found in the product catalogues and our website.

CLARIFICATIONS ON DRILLING MEASUREMENTS AND TECHNIQUES

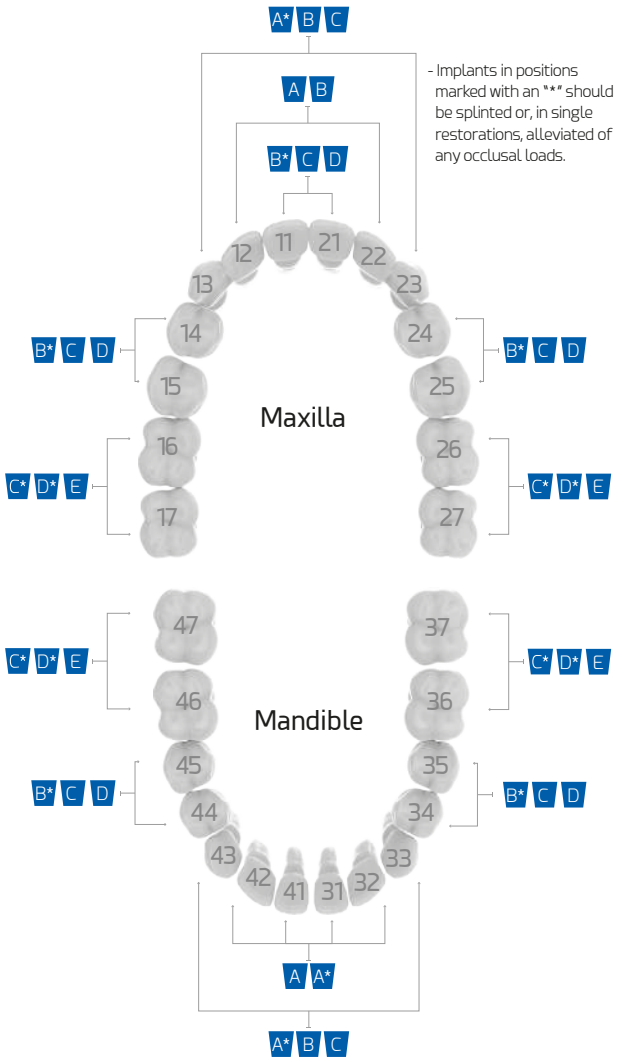
- **IMPLANT SIZE:** identifies the diameter and length of the implant.
- **IMPLANT BODY:** diameter of the implant core.
- **DRILL SIZE:** drill bit diameter.
- **DRILLING TECHNIQUE:** we have developed various drilling protocols to enable you to deal with different situations that arise in a schematic way when performing implant surgery.

Periodontal chart

GALAXY

Implant diameter

A RP	B RP	C RP	D RP	E RP
Ø3.40 mm	Ø3.70 mm	Ø4.00 mm	Ø4.30 mm	Ø4.80 mm



IMPORTANT
Short, 6.00 and 7.00 mm implants are ONLY recommended for splinted use in combination with normal length implants (≥ 10.00 mm).

For more information on implant size selection see the literature available at **www.ziacom.com/biblioteca**

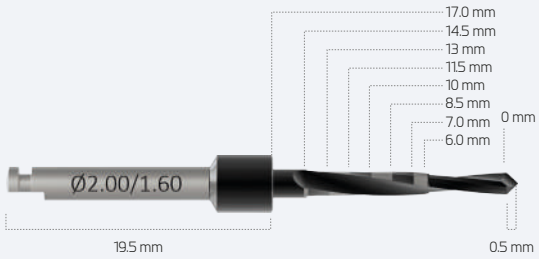
Surgical protocol

Surgical protocol

General considerations

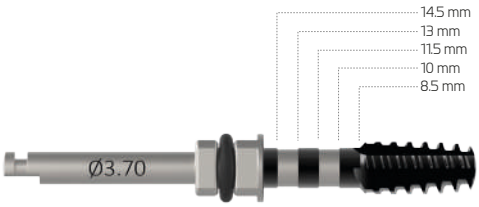
Ziacom® drill system - DLC surface

The drills for the Ziacom® implant systems are made from stainless steel coated with a diamond-like carbon (DLC) surface treatment which bestows them greater corrosion resistance during sterilisation, a low friction coefficient and increased wear resistance, thus increasing the service life of their cutting edge. Furthermore, they have a matte finish and therefore anti-reflective properties. A laser marking on the drill's shank identifies its inner and outer diameters and its length, while the horizontal laser marked bands on the active section corresponds to the different lengths of the implants (milimeter drills). The drill tip is 0.5 mm long and is not included in the laser marked measurements.



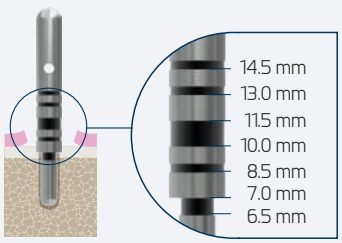
Ziacom® taps - DLC surface

Taps are available for contra-angle handpieces. The laser marking on the tap's shank identifies its diameter, while the horizontal laser marked bands on the active section corresponds to the different lengths.



Depth gauge

Check the depth of the surgical site, especially when not using drill stops. To check the surgical site axis, the paralleling pins are available in different diameters according to the drilling sequence.

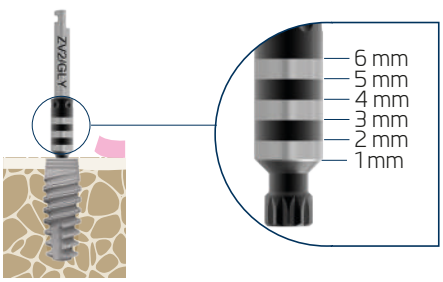


VPress insertion keys

The VPress insertion key for contra-angle handpieces or ratchets has been especially designed for transporting Galaxy implants from their No-Mount vial to the surgical site ready for insertion.

Short and long insertion keys for ratchets and contra-angle handpieces

Depth within the implant platform marked on the insertion keys



DETAILS INSIDE THE GALAXY SURGICAL BOX

Recommendations on the maximum insertion torque

50 Ncm

The recommended insertion torque ranges between **35** and **50 Ncm** on a case-by-case basis.

To avoid deforming the key and/or implant connection, insertions performed with a contra-angle handpiece (CA) must respect the recommended maximum rpm (25 rpm) and maximum torque (50 Ncm).

If the implant cannot be fully inserted using the recommended maximum torque, withdraw the implant, repeat the drilling and then re-insert it.

Control the final insertion torque with the adjustable dynamometric ratchet Ref. TORK50 or a contra-angle handpiece.

Exceeding the maximum torque (50 Ncm) when inserting the implant can cause:

- Irreversible deformations in the implant's internal connection.
- Irreversible deformations in the implant insertion instruments.
- Difficulty or impossibility in dismounting the instrument/implant assembly.

Surgical protocol

Galaxy implant

It should be noted that the drilling protocol for Galaxy implants varies significantly depending on the diameter of the implant and the type of bone in the surgical site, so special attention should be paid to these two aspects.

GALAXY

- EXAMPLE:

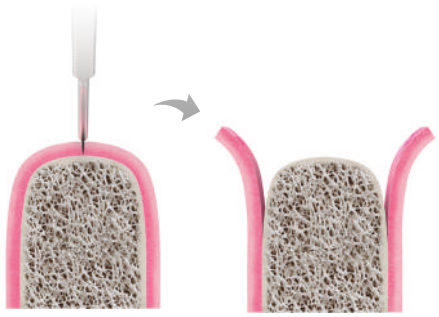
Galaxy implant
Ø4.30x11.50mm

RP (Ø4.30mm)
Ø platform 2.85mm

Steps for drilling protocol in soft bone (IV)

PRELIMINARY STEP | Gingiva opening

Make an incision and flap reflection.



STEP 1 | Lance drill

Start the surgical site drilling sequence using millimeter lance drill Ref. SID010 with stop Ref. GTPD115. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 2 | Pilot drill Ø1.60/2.00

Continue the drilling sequence using Galaxy pilot drill Ref. OSPD20G until the total length corresponding to the selected implant is reached. Note the laser mark on the drill indicating the length or use the drill stop Ref. GTPD115. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 3 | Probe/Paralleling pin Ø2.00/1.60

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR100G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

STEP 4 | Galaxy stepped surgical drill Ø1.80/2.50

Continue the drilling sequence using surgical drill Ø1.80/2.50 Ref. OSTD25G until the total length corresponding to the selected implant is reached. Note the laser mark on the drill indicating the length or use the drill stop Ref. GTPD115. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 5 | Probe/Paralleling pin Ø2.50/1.80

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR200G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

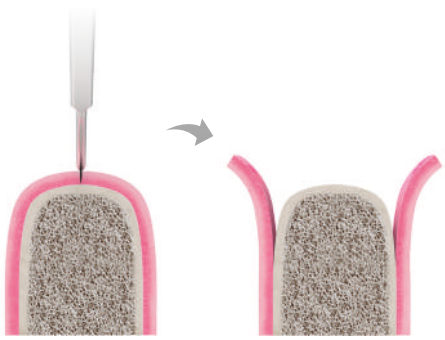
STEP 6 | Galaxy stepped surgical drill Ø2.15/3.30

Continue the drilling sequence using surgical drill Ø2,15/3.30mm, Ref. OSTD33G to the length corresponding to the thickness of the *cortical bone (see "Cortical area of Galaxy drills" section on page 28), according to each case. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to apply too much pressure to the bone. If necessary, use the drill extender Ref. DEXT10.

Steps for drilling protocol in medium bone (II & III)

PRELIMINARY STEP | Gingiva opening

Make an incision and flap reflection.



STEP 1 | Lance drill

Start the surgical site drilling sequence using millimeter lance drill Ref. SID010 with stop Ref. GTPD115. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

Surgical protocol

STEP 2 | Pilot drill Ø1.60/2.00

Continue the drilling sequence using pilot drill Ref. OSPD20G until the total length corresponding to the selected implant is reached. Pay attention to the laser mark on the drill that indicates the length or use the drill stop Ref. GTPD115. Control the direction and lean of the drilling, always performing intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 3 | Probe/Paralleling pin Ø2.00/1.60

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR100G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

STEP 4 | Stepped surgical drill Ø1.80/2.50

Continue the drilling sequence using surgical drill Ø1.80/2.50 Ref. OSTD25G, until the total length corresponding to the selected implant is reached. Note the laser mark on the drill indicating the length or use the drill stop Ref. GTPD115. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 5 | Probe/Paralleling pin Ø2.50/1.80

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR200G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

STEP 6 | Stepped surgical drill Ø2.15/3.30

Continue the drilling sequence using surgical drill Ø2.15/3.30mm Ref. OSTD33G, until the total length corresponding to the selected implant is reached. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 7 | Probe/Paralleling pin Ø3.30/2.10

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR300G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

STEP 8 | Stepped surgical drill Ø2.50/3.70

Continue the drilling sequence using surgical drill Ø2.50/3.70mm Ref. OSTD37G, until the total length corresponding to the selected implant is reached. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 9 | Probe/Paralleling pin Ø3.70/2.50

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR400G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

STEP 10 | Stepped surgical drill Ø2.90/4.10

Continue the drilling sequence using surgical drill Ø2.90/4.10mm, Ref. OSTD41G to the length corresponding to the thickness of the *cortical bone (see "Cortical area of Galaxy drills" section on page 28), according to each case. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to apply too much pressure to the bone. If necessary, use the drill extender Ref. DEXT10.

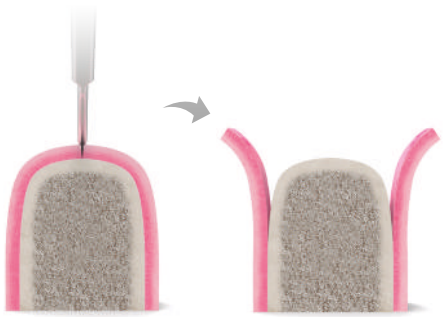
STEP 11 | Tap Ø4.30

Place the surgical tap Ø4.30mm Ref. GTAP43M in the surgical site. Press firmly and start turning slowly, then let the tap advance without pressure to the planned depth. If you encounter excessive resistance, make a 90° counter-rotation movement for each complete turn. To remove the tap, turn it in the opposite direction to the insertion one. The use of the tap will depend on the type of bone and the diameter of implant selected.

Steps for drilling protocol in hard bone (I)

PRELIMINARY STEP | Gingiva opening

Make an incision and flap reflection.



STEP 1 | Lance drill

Start the surgical site drilling sequence using millimeter lance drill Ref. SID010 with stop Ref. GTPD115. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

Surgical protocol

STEP 2 | Pilot drill Ø1.60/2.00

Continue the drilling sequence using pilot drill Ref. OSPD20G until the total length corresponding to the selected implant is reached. Pay attention to the laser mark on the drill that indicates the length or use the drill stop Ref. GTPD115. Control the direction and inclination of the drilling, always performing intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 3 | Probe/Paralleling pin Ø2.00/1.60

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR100G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

STEP 4 | Stepped surgical drill Ø1.80/2.50

Continue the drilling sequence using surgical drill Ø1.80/2.50 Ref. OSTD25G until the total length corresponding to the selected implant is reached. Note the laser mark on the drill indicating the length or use the drill stop Ref. GTPD115. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 5 | Probe/Paralleling pin Ø2.50/1.80

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR200G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

STEP 6 | Stepped surgical drill Ø2.15/3.30

Continue the drilling sequence using surgical drill Ø2.15/3.30mm Ref. OSTD33G until the total length corresponding to the selected implant is reached. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 7 | Probe/Paralleling pin Ø3.30/2.10

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR300G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

STEP 8 | Stepped surgical drill Ø2.50/3.70

Continue the drilling sequence using surgical drill Ø2.50/3.70mm Ref. OSTD37G until the total length corresponding to the selected implant is reached. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 9 | Probe/Paralleling pin Ø3.70/2.50

Check the surgical site depth and the insertion axis by inserting the probe/paralleling pin Ref. MUR400G2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

STEP 10 | Stepped surgical drill Ø2.90/4.10

Continue the drilling sequence using surgical drill Ø2.90/4.10mm, Ref. OSTD41G to the length corresponding to the thickness of the *cortical bone (see "Cortical area of Galaxy drills" section on page 28), according to each case. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to apply too much pressure to the bone. If necessary, use the drill extender Ref. DEXT10.

STEP 11 | Tap Ø4.00

Place the surgical tap Ø4.00mm Ref. GTAP40M in the surgical site. Press firmly and start turning slowly, then let the tap advance without pressure to the planned depth. If you encounter excessive resistance, make a 90° counter-rotation movement for each complete turn. To remove the tap, turn it in the opposite direction to the insertion one. The use of the tap will depend on the type of bone and the diameter of implant selected.

Surgical protocol

Implant insertion using Ziacom® No Mount | **Titansure**

Ziacom® No Mount

Surface treatment

Titansure

STEP 1 | Implant unpacking

1.1 Press the word "PRESS" and tear open the carton.

1.2 Remove the flap from the carton and pull out the blister.

1.3 Carefully remove the blister seal.

1.4 Drop the implant vial onto a sterile cloth in the surgical area.

1.5 Hold the vial with one hand in a vertical position. Remove the cap by turning it vertically.

1.6 Remember to remove the implant label in order to adhere it to the patient's implant card and medical record to allow the product to be traced.

STEP 2 | Choice of insertion instrument

Depending on the clinical situation and access to the area, three different instruments can be chosen to insert the implant:

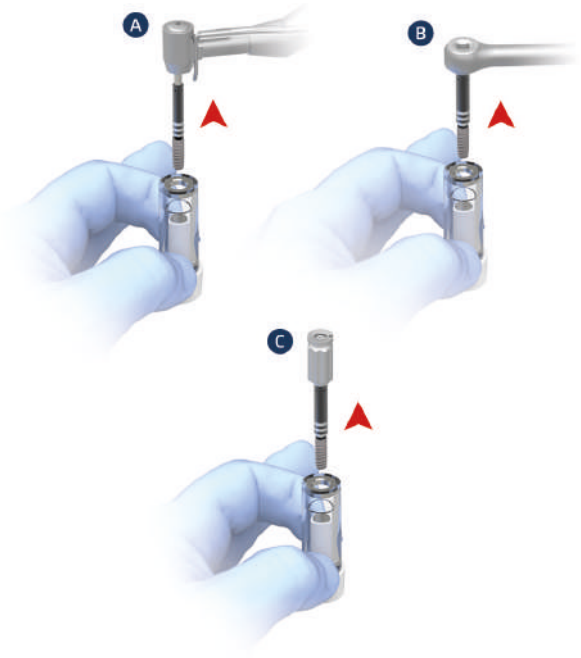
A **Contra-angle.** Use VPress insertion key. CA of the length of your choice (Ref. SMRGV1 or LMRGV1) and insert it into the contra-angle.

B **Ratchet Ref. TORK50.** Use VPress insertion key. Ratchet/Manual of the length of your choice (Ref. SMRGV or LMRGV) and insert it into the ratchet in function "IN".

C **Screwdriver handle 4x4 Ref. MADW10.** Use VPress insertion key. Ratchet/Manual of the length of your choice (Ref. SMRGV or LMRGV) and insert it into the screwdriver handle.

STEP 3 | Remove the implant from the vial

Hold the implant carrier vial in one hand and insert the selected insertion key into the implant with the other hand. Remove the implant by pulling up the vial vertically.

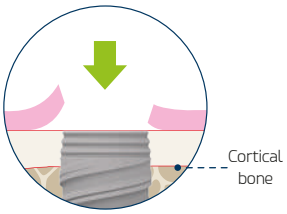


STEP 4 | Implant insertion

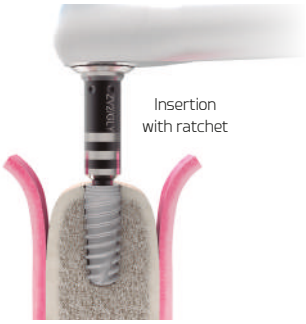
When inserting with contra-angle, use a maximum speed of 25 Rpm.

The recommended insertion torque is between 35 and 50 Ncm.

If there is resistance during insertion, it is recommended that the implant be rotated in the opposite direction to the insertion direction and after seconds of pause continue with insertion. Repeat this process as many times as necessary.

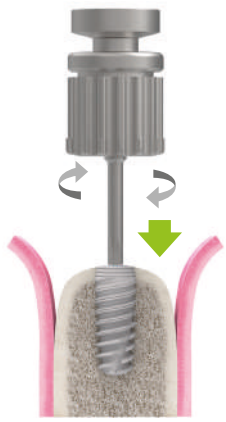


The Ziacom® surgical protocol establishes crestal position of the implant platform.



Soft tissue conditioning

STEP 1 | Cover screw placement



Insert manual surgical screwdriver Ref. SMSD or LMSD into the cover screw. Approach it to the implant avoiding the fall and accidental screw swallowing. Insert it into the implant until it locks, with manual torque and clockwise.

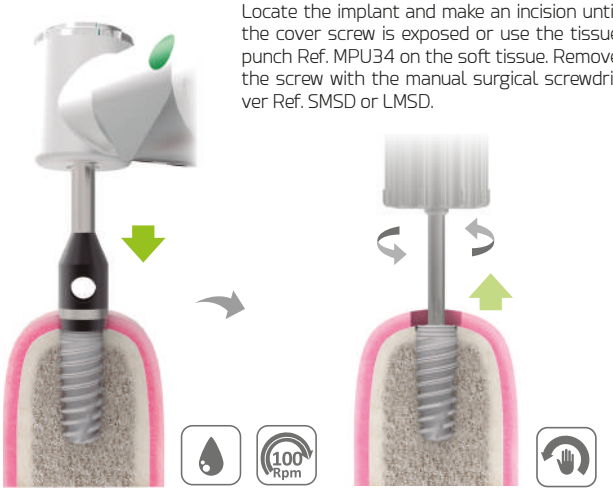
A second surgery is required to place a cover screw in order to uncover the implant and fit the required abutment.

Depending on the individual case, the professional may decide not to fit a cover screw but to directly fit a healing abutment.

STEP 2 | Soft tissue closure

Close and suture the soft tissue, fitting the flaps carefully.

STEP 3 | Uncovering and removing the cover screw



Locate the implant and make an incision until the cover screw is exposed or use the tissue punch Ref. MPU34 on the soft tissue. Remove the screw with the manual surgical screwdriver Ref. SMSD or LMSD.

STEP 4 | Healing abutment placement

Insert selected healing abutment with manual surgical screwdriver Ref. SMSD or LMSD.

The choice of the healing abutment will depend on each case. It must match the implant platform and be in accordance with the gingival tissue height to avoid abutment occlusion. Excessive height could subject the implant to premature loading, compromising the osseointegration process.

Surgical protocol

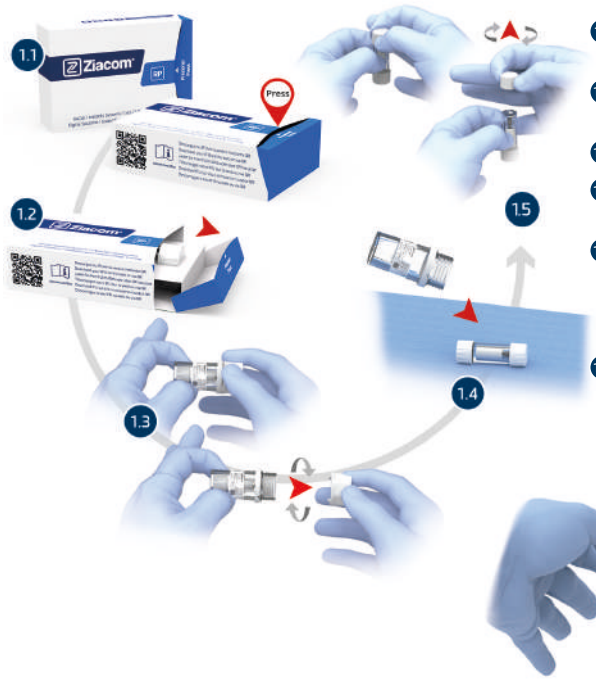
Implant insertion using Ziacom® No Mount | **Titansure Active**

Ziacom® No Mount

Surface treatment

Titansure Active

STEP 1 | Implant unpacking



1.1 Press the word "PRESS" and tear open the carton.

1.2 Remove the container holding the vial containing the implant and the BBL.

1.3 Carefully remove the blister seal.

1.4 Drop the implant holder vial onto a sterile cloth in the surgical area.

1.5 Hold the vial with one hand in a vertical position. Remove the cap by turning and lifting it.

Note: Take care when opening the vial as the implant is submerged in a bioactive liquid.

1.6 Remember to remove the implant labels in order to adhere them to the patient's implant card and medical record to allow the implant reference number and lot number to be traced.

Note: Do not reuse any remaining liquid.

STEP 2 | Choice of insertion instrument

Depending on the clinical situation and access to the area, three different instruments can be chosen to insert the implant:

A **Contra-angle.** Use VPress insertion key. CA of the length of your choice (Ref. SMRGV1 or LMRGV1) and insert it into the contra-angle.

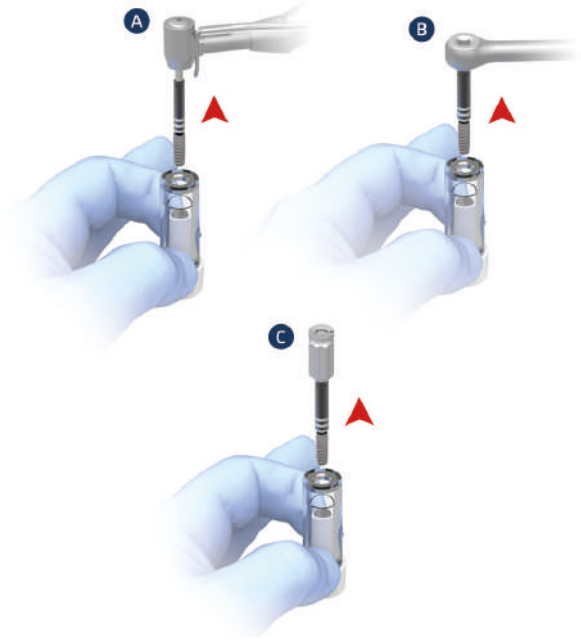
B **Ratchet Ref. TORK50.** Use VPress insertion key. Ratchet/Manual of the length of your choice (Ref. SMRGV or LMRGV) and insert it into the ratchet in function "IN".

C **Screwdriver handle 4x4 Ref. MADW10.** Use VPress insertion key. Ratchet/Manual of the length of your choice (Ref. SMRGV or LMRGV) and insert it into the screwdriver handle.

STEP 3 | Remove the implant from the vial

Hold the implant carrier vial in one hand and insert the selected insertion key into the implant with the other hand. Remove the implant by pulling up the vial vertically.

Note:
Take care when opening the vial. The Bioactive Liquid may spill. Any remaining Bioactive Liquid cannot be reused.

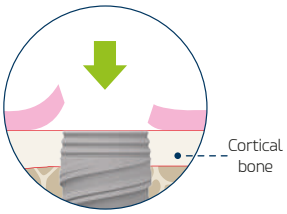


STEP 4 | Implant insertion

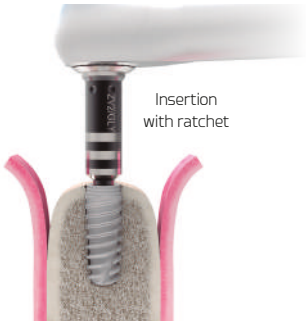
When inserting with contra-angle, use a maximum speed of 25 Rpm.

The recommended insertion torque is between 35 and 50 Ncm.

If there is resistance during insertion, it is recommended that the implant be rotated in the opposite direction to the insertion direction and after seconds of pause continue with insertion. Repeat this process as many times as necessary.

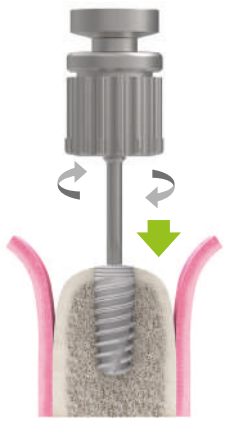


The Ziacom® surgical protocol establishes crestal position of the implant platform.



Soft tissue conditioning

STEP 1 | Cover screw placement



Insert manual surgical screwdriver Ref. SMSD or LMSD into the cover screw. Approach it to the implant avoiding the fall and accidental screw swallowing. Insert it into the implant until it locks, with manual torque and clockwise.

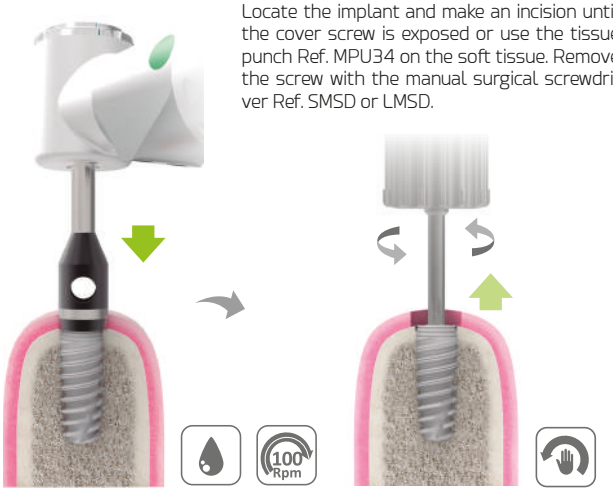
A second surgery is required to place a cover screw in order to uncover the implant and fit the required abutment.

Depending on the individual case, the professional may decide not to fit a cover screw but to directly fit a healing abutment.

STEP 2 | Soft tissue closure

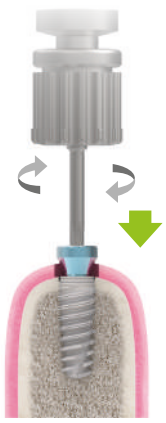
Close and suture the soft tissue, fitting the flaps carefully.

STEP 3 | Uncovering and removing the cover screw



Locate the implant and make an incision until the cover screw is exposed or use the tissue punch Ref. MPU34 on the soft tissue. Remove the screw with the manual surgical screwdriver Ref. SMSD or LMSD.

STEP 4 | Healing abutment placement



Insert selected healing abutment with manual surgical screwdriver Ref. SMSD or LMSD.

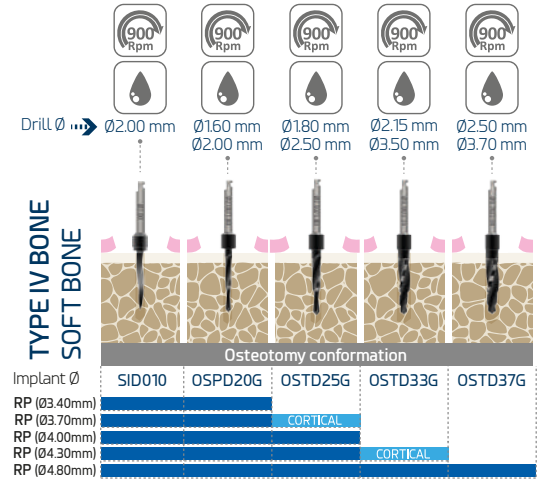
The choice of the healing abutment will depend on each case. It must match the implant platform and be in accordance with the gingival tissue height to avoid abutment occlusion. Excessive height could subject the implant to premature loading, compromising the osseointegration process.

Simplified surgical protocol

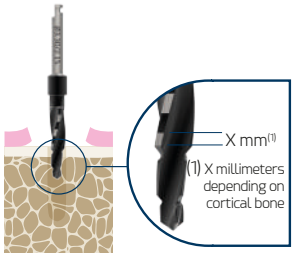
Drilling protocol - Ziacom® No Mount

Rotation | Irrigation required | Ø Drill diameter | Torque

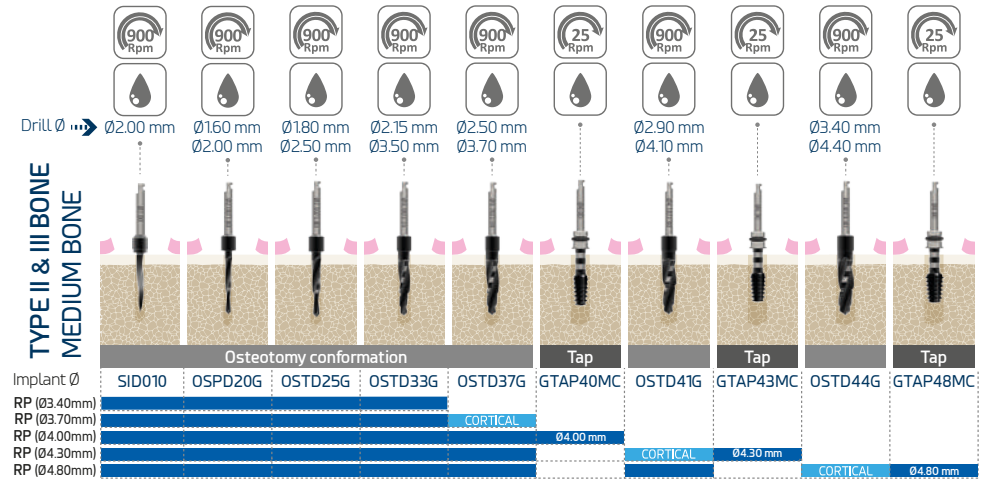
Detailed speeds are the recommended

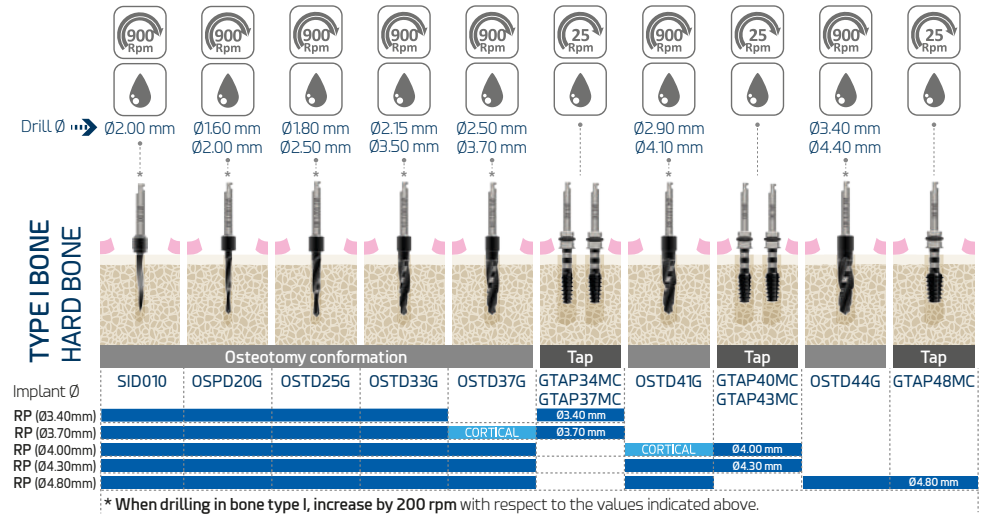


Cortical section of Galaxy drills



When the protocol indicates, CORTICAL we recommend drilling to a length that corresponds to the thickness of the cortical bone on a case-by-case basis.

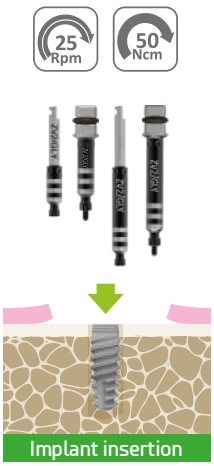




*** When drilling in bone type I, increase by 200 rpm** with respect to the values indicated above.

Galaxy implant insertion

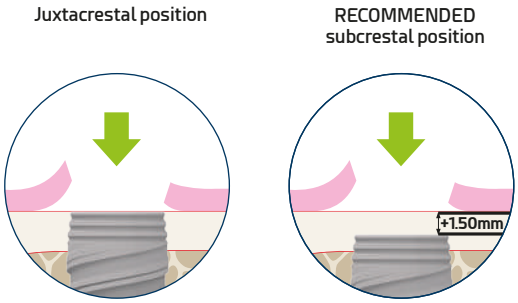
Implant insertion



SMRGV / LMRGV
SMRGV1 / LMRGV1

Crestal placement of implant

The drilling protocols are described so that the platform for the Galaxy implants is juxtacrestal. Nevertheless, recommendations are to leave the platform slightly subcrestal.



Bone types

Lekholm and Zarb classification (1985)

TYPE IV BONE - SOFT BONE

- Thin cortical layer surrounding a low-density trabecular bone.

TYPE II & III BONE - MEDIUM BONE

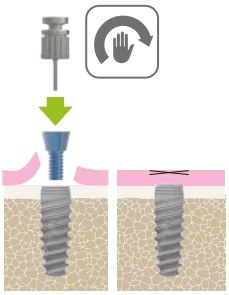
- Type II: thick layer of compact bone surrounding a dense trabecular bone.
- Type III: thin cortical layer surrounding a dense trabecular bone.

TYPE I BONE - HARD BONE

- Composed almost entirely of homogeneous compact bone.

Handling cover screw

Place the cover screw in the screwdriver. Move it towards the implant while taking care that it does not fall and become accidentally ingested. Place the screw in the implant applying manual torque in a clockwise direction.



Simplified surgical protocol

General recommendations

To consider during the intervention

1. The surgical drills must be inserted in the contra-angle handpieces when the motor is stopped and ensure they are attached and rotate correctly before starting to drill. Treat the drills with the utmost care; the slightest damage to the tips could compromise their effective operation.
2. Damaged instruments must be disposed of according to local regulations.
3. Implantologists should keep one of the identification labels supplied with the product in the patient's file so that it may be traced correctly.
4. Each instrument must only be used for the specific use recommended by the manufacturer.

Always consult the surgical and prosthetic protocols published in this catalogue, as well as the other documents available in the "Reference literature" section of our website www.ziacom.com/biblioteca which explained the procedures, protocols and instructions for use before using the Galaxy system by Ziacom®.

Cleaning, disinfection and sterilisation

Cleaning, disinfection and sterilisation

The protocols described in this section must only be carried out by personnel qualified to clean, disinfect and sterilise the dental materials specified here in.

Cleaning and disinfection instructions

Applicable for instruments, surgical and prosthetic boxes and plastic retainer caps.

Disassembly

1. Dismount* the appropriate instruments, for example manual ratchets, drills or drill stops.
2. Remove the various components from the surgical or prosthetic box for correct cleaning.

Cleaning and disinfection

For disinfecting instruments and surgical boxes:

1. Submerge the instruments in a detergent/disinfectant solution** suitable for dental instruments to help eliminate any adhered biological residues. If an ultrasound bath is available***, confirm that the detergent/disinfectant solution is indicated for use with this type of equipment.
2. Manually remove any biological residues with a non-metallic brush and pH-neutral detergent.
3. Rinse with copious water.
4. When cleaning the surgical and prosthetic boxes, always use a pH-neutral detergent and non-abrasive utensils to avoid damaging the surface of the boxes.
5. Dry the materials with disposable cellulose, lint-free clothes or compressed air.

For disinfecting plastic caps and spacers:

1. Submerge in a neat benzalkonium chloride solution for 10 minutes.
2. Rinse with distilled water.
3. Dry the caps and spacer before use.

Inspection

1. Check that the instruments are perfectly clean; if not, repeat the cleaning and disinfection steps.
2. Discard any instruments with imperfections and replace them before the next procedure.
3. Check that the instruments and the surgical and prosthetic boxes are perfectly dry before reassembling the parts and proceeding to their sterilisation.

* See the assembly disassembly manuals at **www.ziacom.com/biblioteca**

** Follow the instructions from the disinfectant's manufacturer to determine the correct concentrations and times.

*** Follow the instructions from the ultrasound bath's manufacturer to determine the correct temperature, concentration and times.

Sterilisation instructions for steam autoclave

Applicable to orthodontic implants, abutments, and surgical and prosthetic instruments and boxes.

1. Introduce each material separately in individual sterilisation bags, then seal the bags. For joint sterilisation, place the instruments in their surgical box, introduce the box into a sterilisation bag and seal the bag.
2. Place the bags to be sterilised in the autoclave.
3. Sterilise in a steam autoclave at 134°C/273°F (max. 137°C/276°F) for 4 min (minimum) and at 2 atm. Torque wrenches must be sterilised in 3 vacuum cycles at 132°C/270°F for a minimum of 1.5 minutes and vacuum-dried for a minimum of 20 minutes.

For the United States only: The validated and recommended sterilisation cycle for the US must be performed in a steam autoclave at 132°C/270°F for at least 15 min and with the drying time of at least 15 - 30 min.

IMPORTANT
Make sure the drying stage is allowed to run to completion, otherwise the products may be damp.
Check the sterilisation equipment if the materials or sterilisation bags are damp at the end of the sterilisation cycle.
Perform the necessary maintenance actions on the autoclave according to the established periodicity and following the manufacturer's instructions.

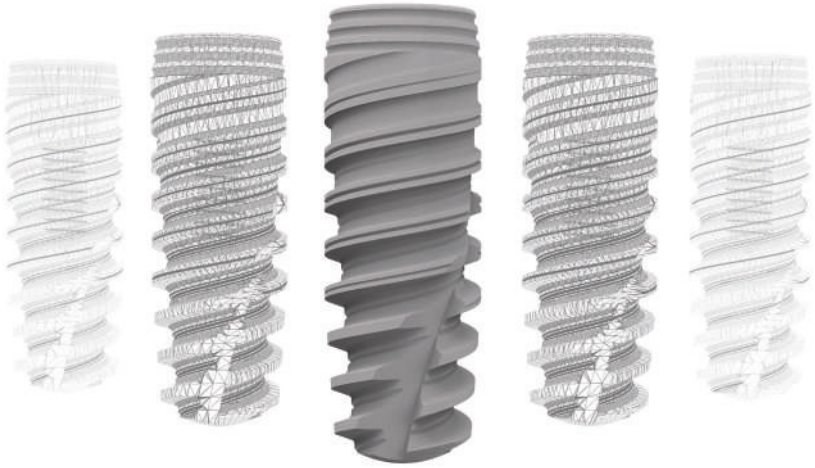
Storage of Ziacom® products

- Store the products in their original packaging and in a clean, dry location until they are used.
- After sterilisation, keep the products in the sealed sterilisation bags and in a clean, dry location.
- Never exceed the use by date indicated by the manufacturer of the sterilisation bags.
- Always follow the indications of the manufacturer of the sterilisation bags.

General recommendations

- Never use damaged or dirty material; never reuse single-use products. The user is responsible for following the instructions described in this document correctly.
- The attention to piercing or sharp elements. Gloves should be worn when cleaning the materials to avoid accidents during handling.
- Follow the safety instructions indicated by the manufacturer of the disinfectant agent.
- The product's sterility cannot be guaranteed if the sterilisation bag is open, damaged or damp.
- Respect all stages of the sterilisation process. If the materials or sterilisation bags contain traces of water or moisture, check the autoclave and repeat the sterilisation.
- Orthodontic abutments and implants are supplied UNSTERILISED and must always be sterilised before use.
- Instruments and surgical and prosthetic boxes are supplied UNSTERILISED and must always be sterilised before use and cleaned and disinfected after use.
- The sterilisation, cleaning and disinfection processes gradually deteriorate the instruments. Inspect the instruments thoroughly to detect any signs of deterioration.
- Avoid contact between products made from different materials (steel, titanium, etc.) during the cleaning, disinfection and sterilisation processes.
- Ziacom Medical SL recommends these instructions are implemented for the correct maintenance and safety of their products; accordingly, the company refuses any liability for any damage to the products that could arise if the user applies alternative cleaning, disinfection and sterilisation procedures.

See **www.ziacom.com/biblioteca** for the latest version of the cleaning, disinfection and sterilisation instructions.



Ziacom®

See the latest version of the general conditions of sale on our website **www.ziacom.com**.

Check the availability of each product in your country.

See the latest version of the catalogues available at **www.ziacom.com**.

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