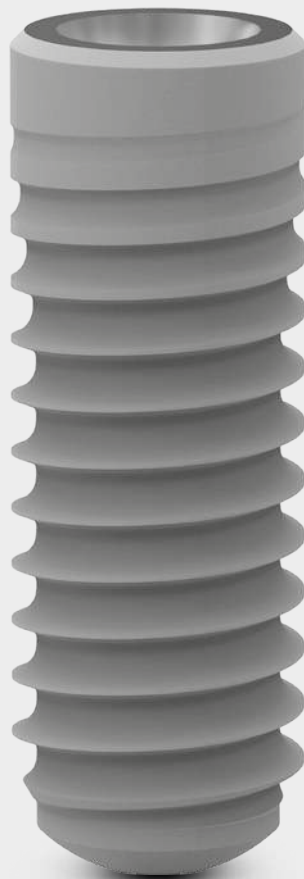


Surgical procedure manual

ZV2[®]

Conical connection implants



ZV2[®]

Surgical procedure manual

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

Warning. Not all ZIACOM® products are available in all countries. Check availability in your country.

ZIACOM®, Zinic®, Zinic®MT, ZMK®, ZMR®, ZM1®, ZM1®MT, ZM4®, ZM4®MT, ZM8®, ZM8®N, ZM8®S, Galaxy®, ZV2®, Ziacom®3D, Kiran®, Kirator®, ZM-Equator®, Basic®, XDrive®, ZiaCam®, ZIACOR®, Tx30®, Zellplex®, DSQ®, Titansure® and Ziasure® are some of the trademarks registered of Ziacom Medical SLU. Consult the website for the full list and their corresponding logos.

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Characteristics

CONNECTION

- Conical connection: 11° morse taper with double internal hexagon.
- Conical sealing: no infiltration.
- Friction fit: no microfiltrations.
- RP and WP platforms.
- Platform switch: soft tissue formation and emergence profile shaping.

CORTICAL AREA

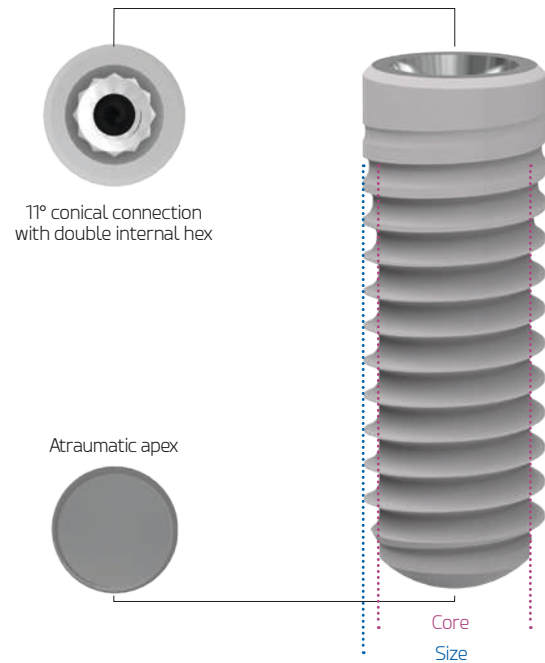
- Shoulder implant design for crestal bone placement.
- Slightly tapered core in coronal area: high cortical compression.
- Thread in reduction up to platform.
- 0.2 mm bevel (except for 3.40mm diameter implant whose bevel is 0.15 mm).

BODY

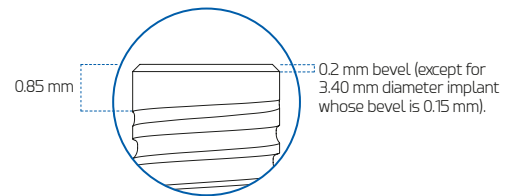
- Lead threads: provide stability during insertion with 0.8 mm thread pitch.
- Optimised cylindrical morphology: high primary stability.
- Atraumatic apex: protects anatomical structures.

CYLINDRICAL DESIGN

- Versatile, suitable for all positions.
- Available in narrow 3.40mm diameter.
- Morphology allows surgical compatibility.



Dimensions of the implant's coronal section



Diameters and lengths available

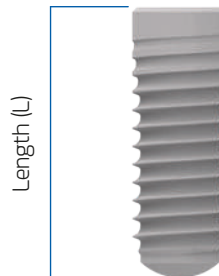
Ø DIAMETER	Ø PLATFORM	LENGTH (L)				
		6	8	10	12	14
RP 3.40	2.85					
RP 4.10						
WP 4.80	3.85					

When choosing the correct implant length, consider the overdrill due to the length of the drill tip:

Length of drill tip



Total implant dimensions



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.

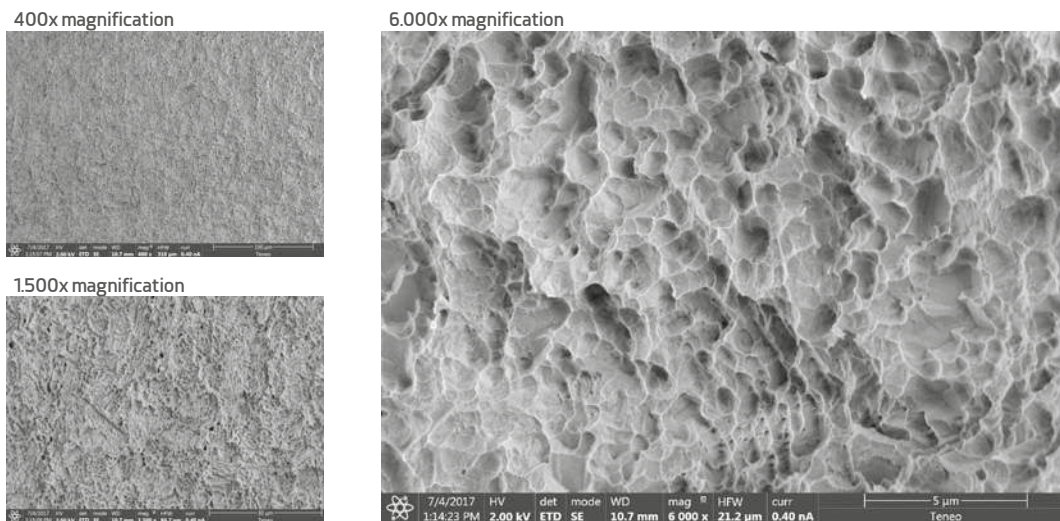
With our Titansure® surface treatment, at Ziacom Medical we have obtained a contaminant-free surface topography and optimal average macro- and microporosity values, which are key specifications for achieving prompt and proper osseointegration and, in turn, extremely reliable and predictable implants.

CHARACTERISATION OF THE TITANSURE® SURFACE TREATMENT

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.

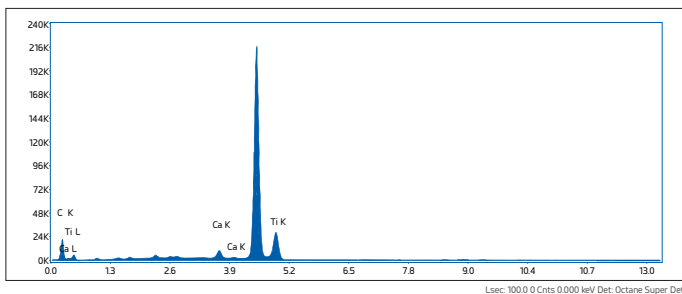
Surface morphology analysis

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.



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

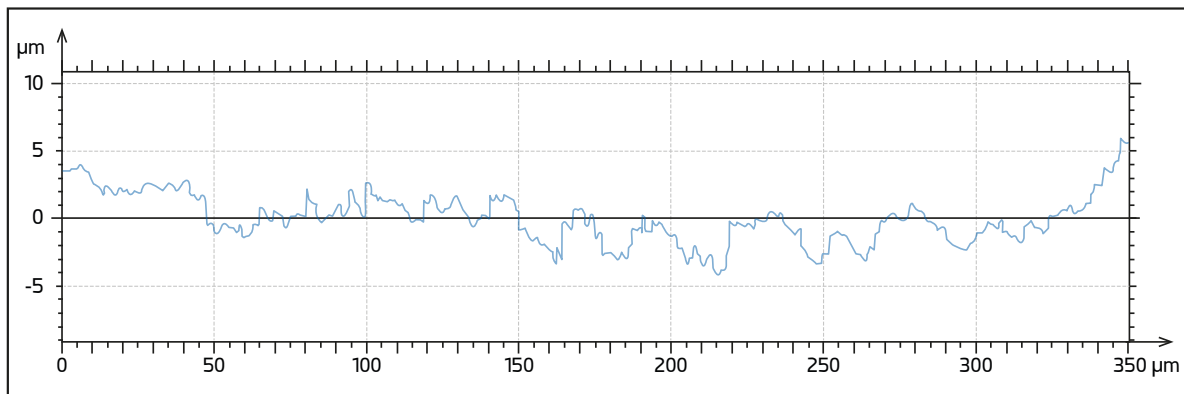
The roughness study was conducted with a Sensofar S NEOX interferometric-confocal microscope (Sensofar Medical, Terrasa, Spain) and SensoMAP Premium 7.4 software. The quantitative roughness profile parameters applied were: average roughness (Ra), root-mean-square roughness (Rq), maximum profile peak 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 (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 roughness profile featured peaks and valleys in the range of 3–4 µm.



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].



Surface treatments

Superficie Titansure® Active

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 (MgCl₂·6H₂O) 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 stem 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.

	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

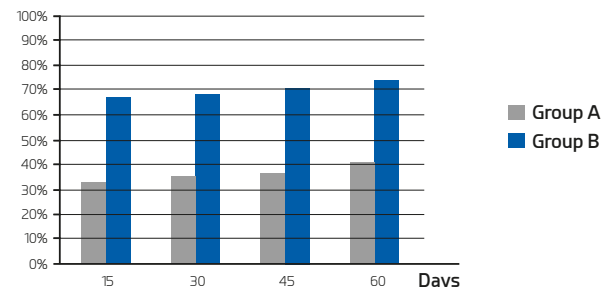
A study was conducted in the tibiae of 10 adult New Zealand rabbits after inserting four implants per rabbit (two in each tibia).

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.

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%



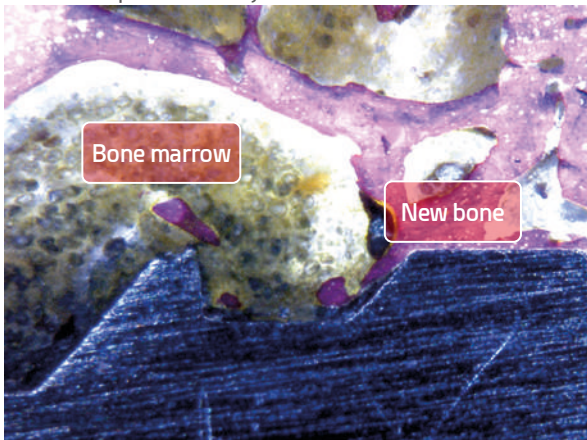
Conclusions

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.

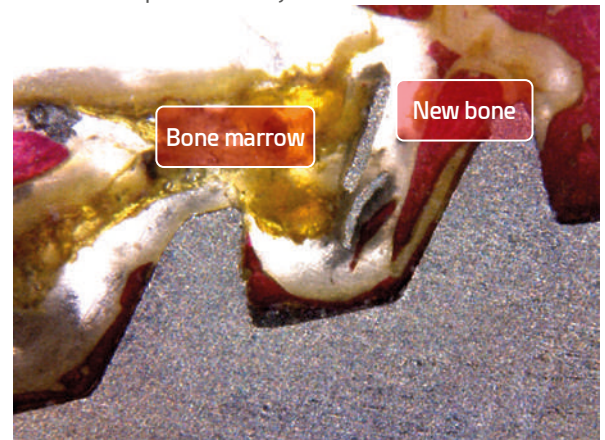
As explained by Dr. Sérgio Alexandre Gehrke, the histologist in charge of the study: *"Within the study's limits, data from the histomorphometric analysis of the implants with a BBL-treated surface (78.92 + 0.3%) highlighted a much quicker and more effective osseointegration compared to the control group (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

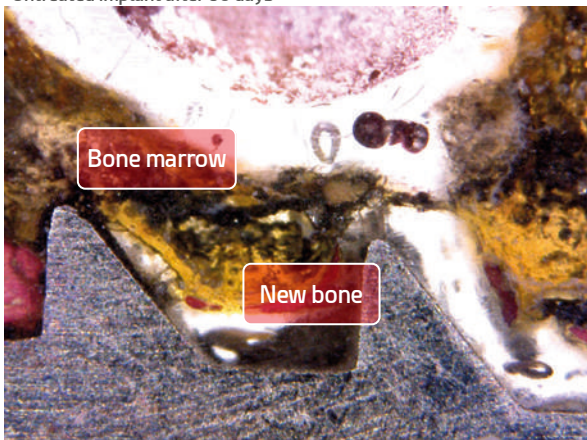
Untreated implant after 15 days



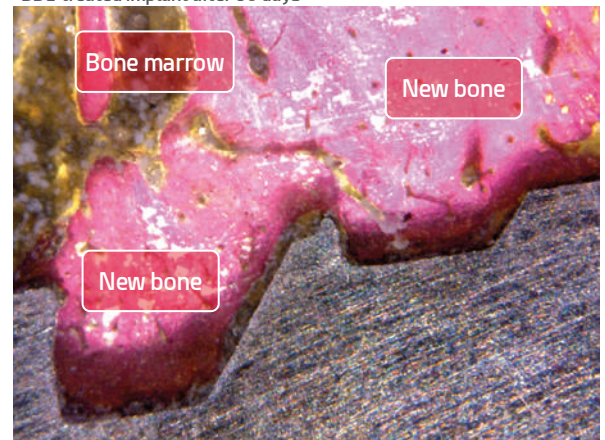
BBL-treated implant after 15 days



Untreated implant after 60 days



BBL-treated implant after 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.



IMPORTANT

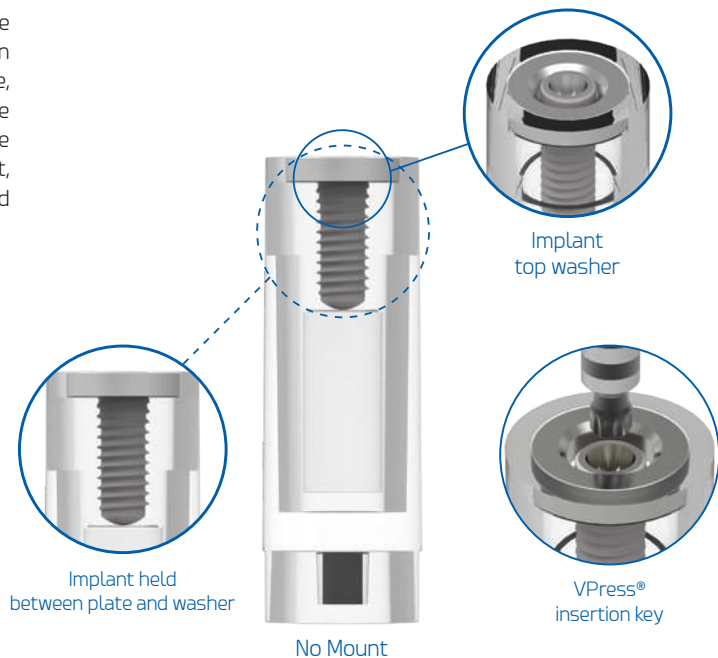
Do not open the sterile container until just before inserting the implant.

N New product. Check availability.

ZIACOM® No Mount

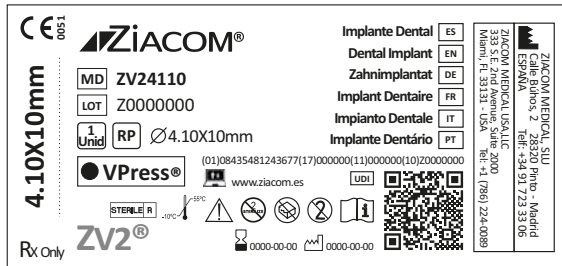
ZV2® implants are supplied in ZIACOM® No-Mount vials; the implants are held vertically inside a plastic vial between a plate below and a washer above (both made from titanium), thus preventing any movements or unwanted contacts.

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.



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 | Do not resterilise |
| Name of the medical device | Do not use if the packaging is damaged |
| Number of product batch | Non-reusable product |
| Patient information website | Consult the instructions for use |
| Unique device identification | Expiry date of the product |
| Sterilised using radiation | Date of manufacture |
| Temperature restriction | Product manufacturer |
| Caution, consult accompanying documents | Caution: federal law prohibits dispensing without prescription |

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

References: ZV2® with ZIACOM® No Mount - Titansure®/Titansure® Active

		IMPLANT				
	Ø (mm)	Ø Core (mm)	Length (mm)	Titansure® ref.	Titansure® Active ref.	
ZV2®	3.40	2.80	8.0	ZV23408	ZV23408A	
			10.0	ZV23410	ZV23410A	
			12.0	ZV23412	ZV23412A	
			14.0	ZV23414	ZV23414A	
4.10	3.40	6.0	ZV24106	ZV24106A		
		8.0	ZV24108	ZV24108A		
		10.0	ZV24110	ZV24110A		
		12.0	ZV24112	ZV24112A		
4.80	4.10	10.0	ZV24810	ZV24810A		
		12.0	ZV24812	ZV24812A		
		14.0	ZV24814	ZV24814A		

Metric



Metrics of 1.60 (RP) and 2.00 (WP)

Cover screw*

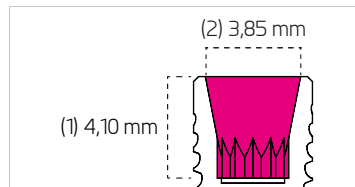
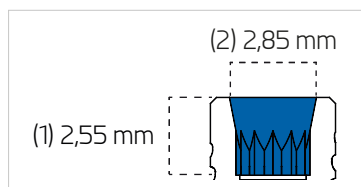
Platf.	Length (L)	Reference
	5.10	GLYRT
	6.10	GLYWT

Anodised RP WP



* Screw included with each implant.

Platform



(1) Height of inner cone (2) Diameter of the working platform

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.
- **UNDERDRILLING TECHNIQUE:** comprises the preparation of the implant bed using a final drill bit with a smaller diameter than the implant core. Technique associated with a high insertion torque and an increase in primary stability.

IMPORTANT

Possible increased risk of bone necrosis due to pressure.

- **SIMPLIFIED DRILLING TECHNIQUE:** technique proposed by Coelho and Cols in 2013 (1). It consists of the use of pilot drill and final drill corresponding to the size of the implant. It reduces drilling sequence but with risk of bone necrosis due to thermal increase.

Periodontal chart

ZV2®

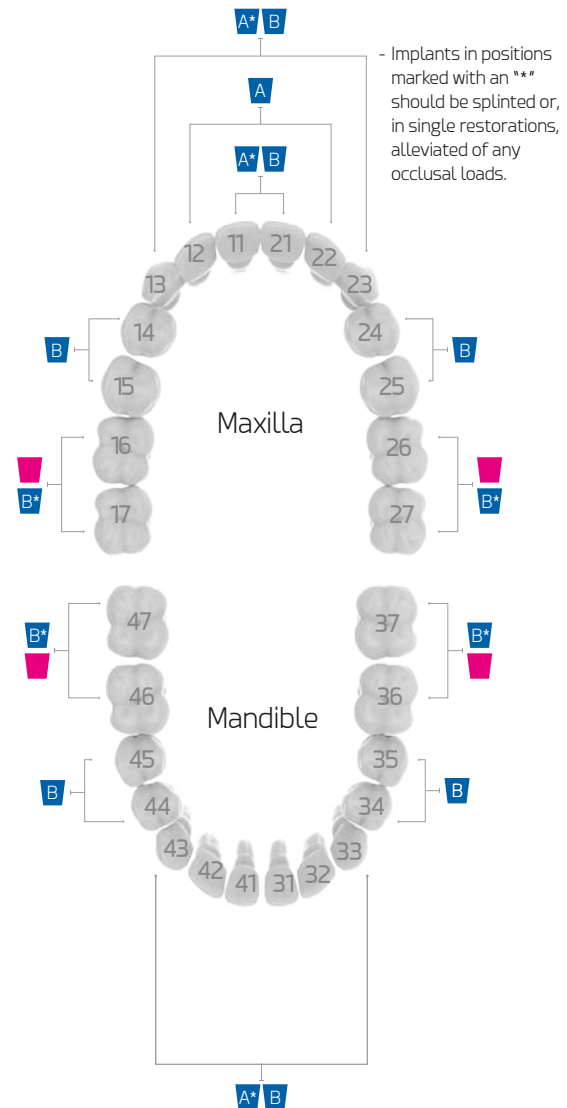
Implant diameter ⁽¹⁾

A RP **B** RP **W** P
 Ø3.40 mm Ø4.10 mm Ø4,80 mm

(1) Diameters are available for analog platforms.

Coronal implant diameter

B RP **W** P
 Ø2.85 mm Ø3.85 mm



ZV2[®]

Surgical
protocols |



Steps for placing ZV2® implants		Instruments required	Implant insertion
ZIACOM® No Mount	Soft tissue conditioning		

Steps for placing ZV2® implants

Instruments required



ZV2®

• **EXAMPLE:**
ZV2® implant
Ø4.10x12.00mm

● **RP (Ø4.10mm)**
Ø plataforma 2.85mm

12.00

Step 02

Pilot drill Ø2.20



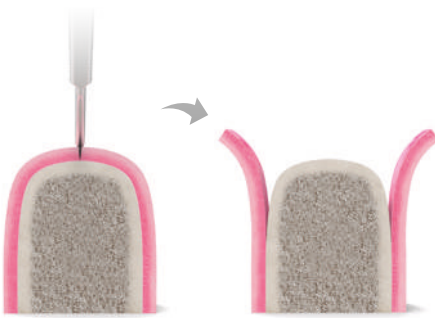
Continue the drilling sequence using the pilot drill Ref. OSPD22Z until the total length corresponding to the selected implant is reached. Note the laser mark on the drill indicating the length or use the drill stop Ref. VTPD112. Check the direction and lean of the drill, always making intermittent pressure in a vertical direction, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.



Preliminary step

Gingiva opening

Make an incision and flap reflection.



Step 03

Depth gauge/paralleling pin Ø2.20



Check the surgical site depth and the insertion axis by inserting the depth gauge/paralleling pin Ref. MUR100V2. You can repeat this step as many times as you consider necessary throughout the surgical procedure.

Step 01

Lance drill



Start surgical site drilling sequence using lance drill Ref. SID010. Note the laser mark on the drill indicating the length or use the drill stop Ref. VTPD112. 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 04

Surgical drill Ø2,80



Continue the drilling sequence using surgical drill Ø2,8 Ref. OSTD28Z 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. VTPD112. 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.



Steps for placing ZV2® implants	Instruments required	Implant insertion
	ZIACOM® No Mount	Soft tissue conditioning

Step 05
Cortical drill



Use the cortical drill Ref. OTDZ2CA to shape the coronal area of the surgical site. Insert the drill up to its laser mark. Check drilling direction and lean, always making intermittent pressures in the vertical plane, taking care not to generate excessive pressure on the bone. If necessary, use the drill extender Ref. DEXT10.

The use of the cortical drill will depend on the type of bone:



Bone type	Implant diameter (mm)		
	Ø3,30	Ø4,10	Ø4,80
Type I	Mandatory*		
Type II	Mandatory*		
Type III-IV	Mandatory*		

* Use of the cortical drill for maxillary sinus lifts is not recommended.

Step 06
Depth gauge/paralleling pin Ø2,80



Check the surgical site depth and the insertion axis by inserting the depth gauge/paralleling pin Ref. MUR200V2.

You can repeat this step as many times as you consider necessary throughout the surgical procedure.

Step 07
Final drill Ø3,50



Continue the drilling sequence using surgical drill Ø3,50 Ref. OSTD35Z, 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. VTPD112. 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 08
Depth gauge/paralleling pin Ø3,50



Check the current depth of the surgical site and the insertion axis by inserting the depth gauge/paralleling pin Ref. MUR300V2.

You can repeat this step as many times as you consider necessary throughout the surgical procedure.

Step 09
Tap



Place the surgical tap Ø 4.0 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 tap Ref. VTAP41M should be used with contra-angle.

Depending on the diameter of the implant and the type of bone:

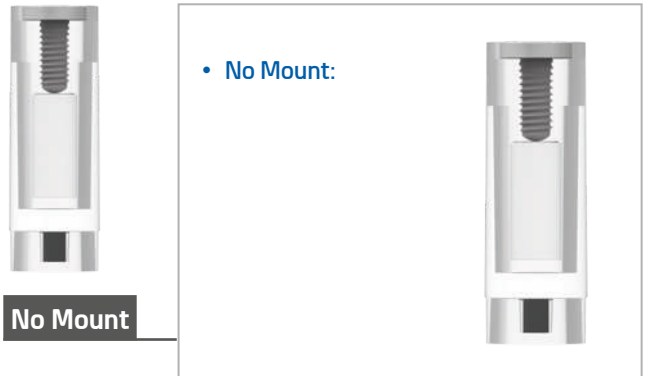


Bone type	Implant diameter (mm)		
	Ø3,30	Ø4,10	Ø4,80
Type I	Total		
Type II	Total		
Type III-IV	Not necessary		Total

Steps for placing ZV2® implants		Instruments required	Implant insertion
ZIACOM® No Mount	Soft tissue conditioning		

Implant insertion

ZIACOM® No Mount



Step 01

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 02

Choice of insertion instrument

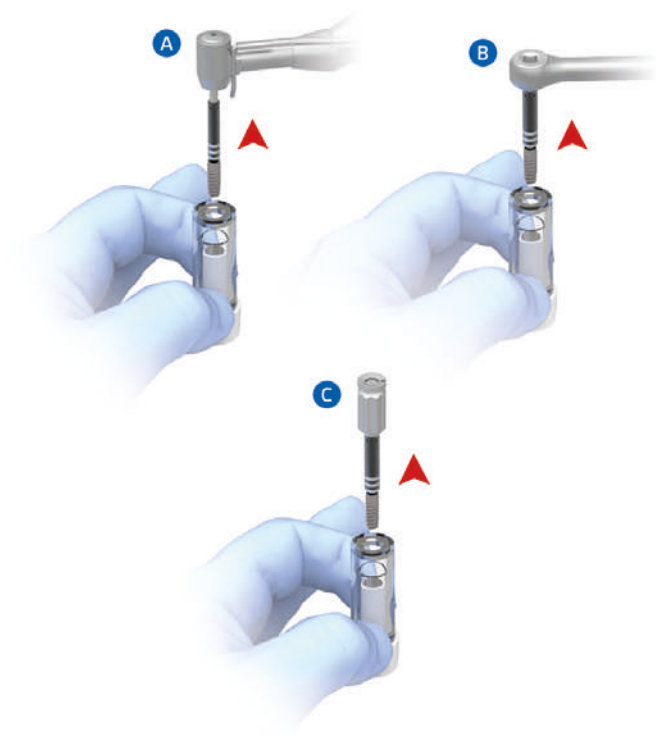
Depending on the clinical situation and access to the area, three different instruments can be chosen to insert the implant:

- 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. TORK70.** 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 03

Remove the implant from the vial

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



Steps for placing ZV2® implants	Instruments required	Implant insertion
	ZIACOM® No Mount	Soft tissue conditioning

Step 04
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.

Insertion with contra-angle

Insertion with ratchet

Cortical bone

The ZV2® implant platform should be placed at bone crestal level.

Soft tissue conditioning

Step 01
Cover screw placement

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

In ZIACOM® No Mount option, the cover screws are supplied separately.

The placement of a cover screw requires a second surgery for the discovery of the implant and the placement of the desired abutment.

Depending on the case, you can choose not to place a cover screw but to place a healing abutment directly.

Step 02
Soft tissue closure

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

Step 03
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.

100 Rpm

Step 04
Healing abutment placement

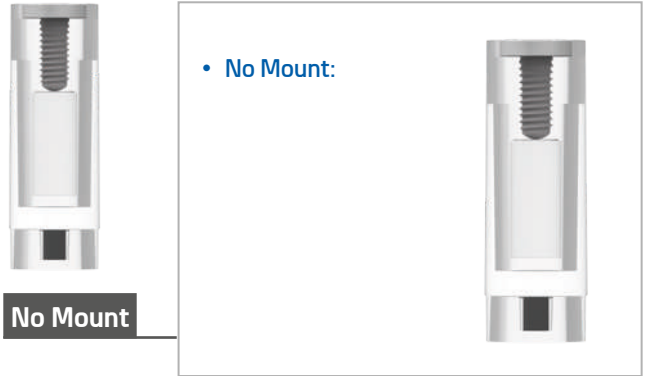
Insert the selected healing abutment using manual surgical screwdriver Ref. SMSD or LMSD.

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.

Steps for placing ZV2® implants		Instruments required	Implant insertion
ZIACOM® No Mount	Soft tissue conditioning		

Implant insertion

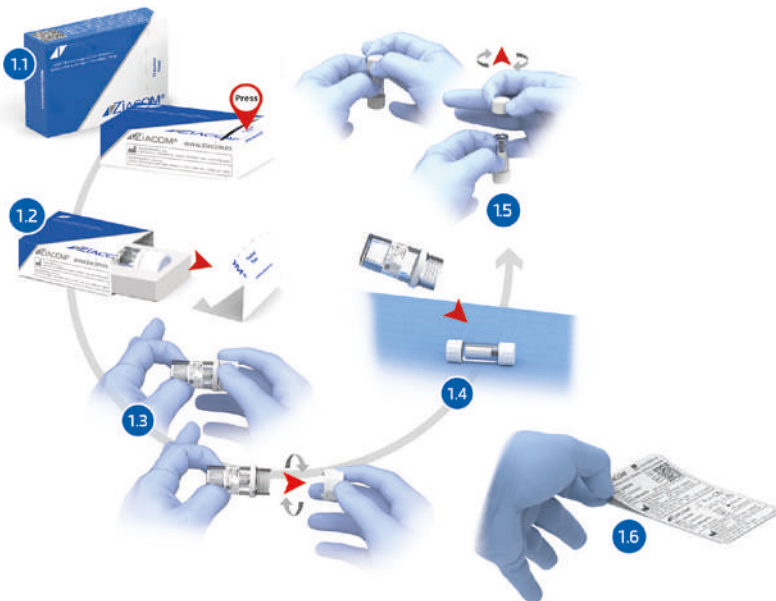
ZIACOM® No Mount



Step 01

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 Hold the container in a horizontal position and remove the cap by turning it counter-clockwise.
- 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 02

Choice of insertion instrument

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

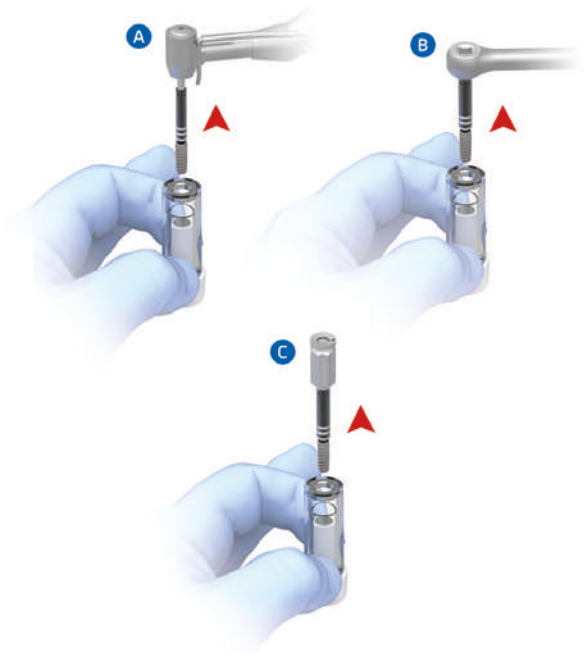
- A Contra-angle.** Use VPress® insertion key, CA of the length of your choice (Ref. SMRGV1 or LMRGV1) and insert it into the contra-angle.
- B Ratchet Ref. TORK70:** Use VPress® insertion key, Ratchet/Manual of the length of your choice (Ref. SMRGV or LMRGV) and insert it into the ratchet in function "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 03

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.



Steps for placing ZV2® implants	Instruments required	Implant insertion
	ZIACOM® No Mount	Soft tissue conditioning

Step 04
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 to turn the implant in the opposite direction to the insertion one and after seconds of pause continue insertion. Repeat this process as many times as necessary.

Insertion with contra-angle

Insertion with ratchet

Cortical bone

The ZV2® implant platform should be placed at bone crestal level.

Soft tissue conditioning

Step 01
Cover screw placement

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

In ZIACOM® No Mount option, the cover screws are supplied separately.

The placement of a cover screw requires a second surgery for the discovery of the implant and the placement of the desired abutment.

Depending on the case, you can choose not to place a cover screw but to place a healing abutment directly.

Step 02
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Close and suture the soft tissue, fitting the flaps carefully.

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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.

100 Rpm

Step 04
Healing abutment placement

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

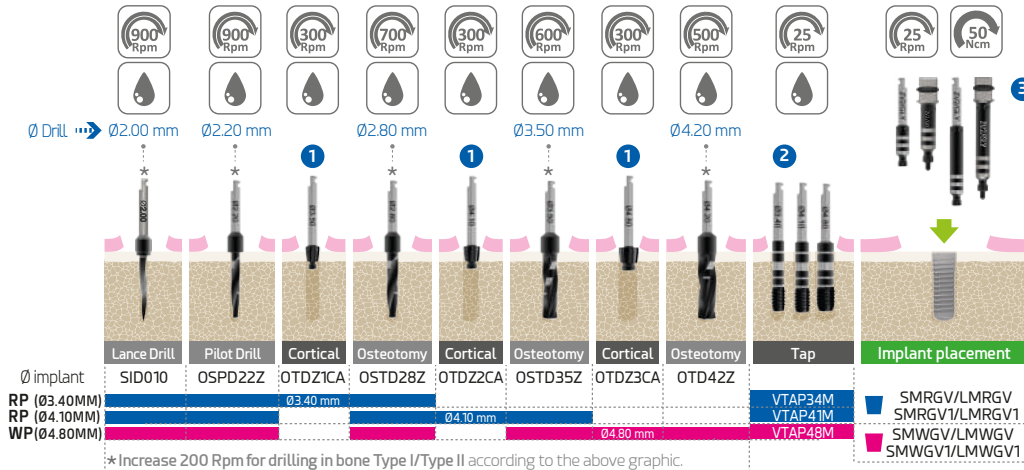
The choice of the healing abutment will depend on each case. It must match the implant platform and be in accordance with the gingival tissue height to avoid abutment occlusion. Excessive height could subject the implant to premature loading, compromising the osseointegration process.

Surgical protocol

Drilling protocol - ZIACOM® No-Mount

Rotation Irrigation required Drill diameter See instructions Torque

Detailed speeds are the recommended



About ZIACOM® No Mount for ZV2®

This blister format allows implantologists to conveniently remove the implant from the vial and place it in the surgical site with a direct instrument in one step, reducing surgical time.

The No Mount implant facilitates instrumentation in confined spaces and allows better visibility of the working field. (Consult the ZV2® instructions for use (IFU)).



ZV2®



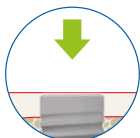
Step 1: VPress® insertion key connection



Step 2A: implant final position with CA



Step 2B: implant final position with ratchet



Implant placement at crestal level

ZV2® implant platforms should be placed at bone crest level.

1 Cortical drill usage

Depending on implant diameter and bone type:



Bone type	Implant diameter		
	Ø3.30 mm	Ø4.10 mm	Ø4.80 mm
Type I	Mandatory*	Mandatory*	Mandatory*
Type II		Mandatory*	Mandatory*
Type III-IV			Mandatory*

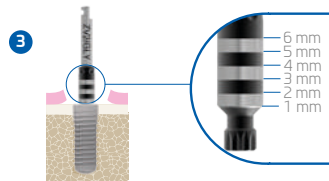
* Use of the cortical drill for maxillary sinus lifts is not recommended.

2 Tap usage

Depending on implant diameter and bone type:



Bone type	Implant diameter		
	Ø3.30 mm	Ø4.10 mm	Ø4.80 mm
Type I	Total	Total	Total
Type II		Total	Total
Type III-IV	Not necessary		Total

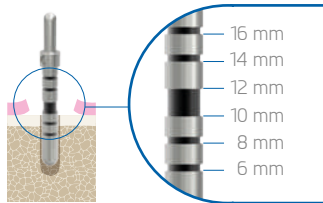


VPress® depth measurements

VPress® insertion keys for RP and WP have horizontal marks to guide the depth of the implant placement, according to each clinical case.

General recommendations

Supplementary instrument



Depth gauge/Paralleling pin

Check the surgical site depth, especially if stoppers were not used.

To check the surgical site axis, the paralleling pins have different diameters according to the drilling sequence.

Consider during intervention



Surgical drills should be inserted in the contra-angle with the surgical motor stopped, ensuring correct anchoring and rotation before starting drilling. Treat the drills with great care: the slightest damage to the tips can compromise their effectiveness.



Each instrument must be used only for the specific use recommended by the manufacturer.

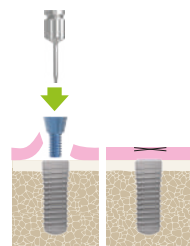


Damaged instruments must be disposed of according to local regulations.



The clinician must keep in the patient's file the identification label supplied with the product, for proper traceability.

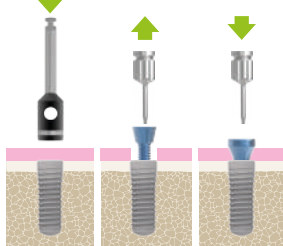
Cover screw handling



Position the cover screw on the screwdriver. Approach the implant by avoiding accidental dropping and ingestion of the screw. Insert it into the implant with manual torque and clockwise.

Second phase surgical procedure

Healing abutment placement



The healing abutment should correspond to the implant platform, considering the option of applying the platform switch technique with anatomical abutments and be in accordance with the height of the gingival tissue to avoid abutment occlusion. Excessive height could expose the implant to premature loading, compromising the osseointegration process.

IMPORTANT WARNINGS

About implant placement

Excessive compression to the bone can lead a non-osseointegration of the implant.

Failure to follow the steps described in the surgical sequence may result in:

- Lack of primary stability due to loss of support bone.
- Difficulties during the implant placement.

Exceeding the torque (50 Ncm) at the implant insertion can produce:

- Irreversible distortions in the internal/external connection.
- Irreversible deformations in the instruments indicated for insertion of the implant.
- Difficulty of disassembling the instrument/implant assembly

Maximum insertion torque and speed

The recommended insertion torque is between **35 and 50 Ncm** according to each case without being limited to a single torque



The Implant placement should be performed with controlled torque and according to the density and bone.

Insertion instruments or contra-angle (CA) screwdrivers use maximum speed of:



ZV2® implants

ZIACOM® surgical protocol establishes a crestal position of the implant platform.

To avoid cortical stress and deformation of the key and/or connection of the implant, insertion with contra-angle (CA) must respect the maximum recommended rpm (**25 Rpm**) and the maximum indicated torque (**50 Ncm**).

If resistance is encountered during insertion, it is recommended to turn the insertion anticlockwise and after seconds of pause continue with the insertion. Repeat this process as many times as necessary.

Check the final insertion torque with the regulable torque wrench Ref. TORK 70 or with CA

Make sure that the entire implant with **Titansure® / Titansure® Active** surface treatment is completely covered with bone.

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.es/en/download-eng which explained the procedures, protocols and instructions for use before using the ZV2® system by ZIACOM®.





ZV2[®]

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 herein.

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.es/en/download-eng

** 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 autoclaves

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 15 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.

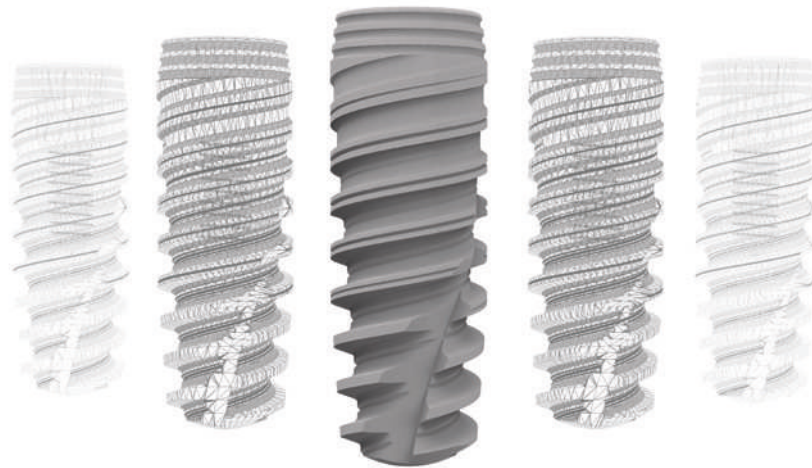
Storage of ZIACOM® products

- 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 SLU 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 the latest version of the general conditions of sale on our website www.ziacom.es

Check the availability of each product in your country.

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