Z_M1

Conical implants with external hex connection





ZM1Surgical 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.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).

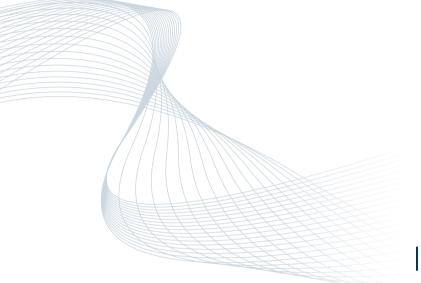
Warning. Not all Ziacom® products are available in all counties. Check availability in your country.

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Together for health



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ZM1 implants

Characteristics

CONNECTION

- External hexagonal connection: simplicity and versatility.
- Upper screw canal: facilitates the insertion of the screws.

CORTICAL AREA

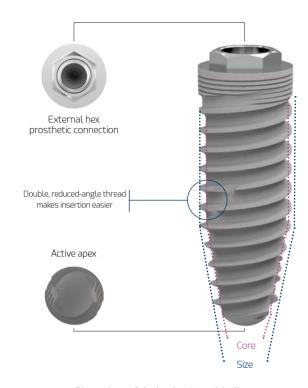
- Micro-thread design: preserves marginal bone.
- Micro-thread extension: improves load distribution.
- Macro-design: excellent cortical compression.

BODY

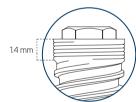
- Reduced angle lead threads: provide stability during insertion and increase BIC (bone-implant contact).
- Double lead thread: quick insertion and reduction of surgical time.
- Self-tapping active apex: facilitates insertion with undersized drilling technique.
- Transverse apical windows: collect remnants of bone during insertion.
- · Optimised morphology: high primary stability.
- · Atraumatic apex: no damage to anatomical structures.

CONICAL DESIGN

- · Facilitates shaping in low density bone.
- · Indicated for immediate loading.
- Indicated for cases of apical convergence and/or collapse.



Dimensions of the implant's neck/collar





Diameters and lengths

| | | | | | LENGTH (L) | | | |
|------------|------------|---|---|-----|------------|------|----|------|
| Ø DIAMETER | Ø PLATFORM | 6 | 7 | 8.5 | 10 | 11.5 | 13 | 14.5 |
| NP 3.30 | 3.30 | | | | | | | |
| RP 3.60 | | | | | | | | |
| RP 4.00 | 4.10 | N | N | | | | | N |
| RP 4.40 | | | N | | | | | N |
| WP 4.80 | 5.00 | N | | | | | | |

Dimensions in mm.

New product. Check availability.

ZM1 implants

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.

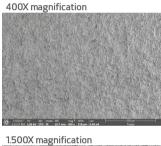
With our **Titansure** surface treatment, at Ziacom Medical we have obtained a contaminant-free surface topography and optimal average macroand microporosity values, which are key specifications for achieving prompt and proper osseointegration and, in turn, extremely reliable and predictable implants.

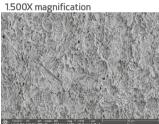
■ TITANSURE SURFACE ANALYSIS

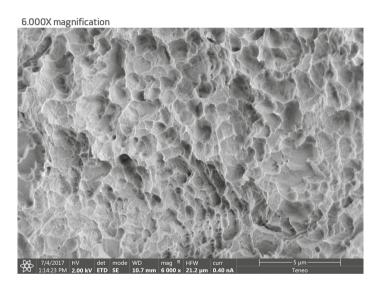
Titansure is an SLA surface treatment created through a subtraction process involving sandblasting with white aluminium oxide and double acid etching with hydrofluoric acid and a sulphuric/phosphoric acid mix.

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.

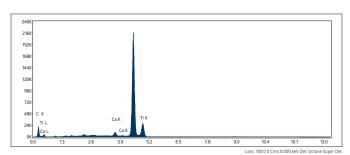






Surface elemental analysis

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 (%) |
|---------|---------------|
| CK | 9.32 (10.23) |
| AI 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 (%)).



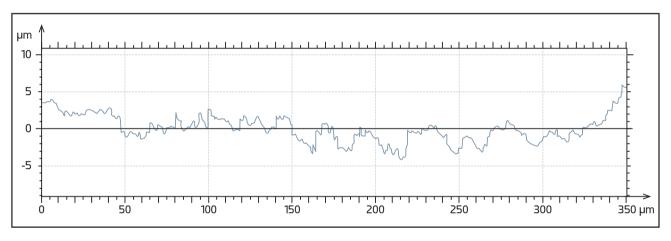
Surface roughness analysis

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



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ZM1 implants

Surface treatments

■ Titansure Active surface treatment

Ziacom® presents the **Tibansure Active** surface treatment with bone bioactive liquid (BBL) as the latest innovation for the presentation of our dental implants. The **Tibansure Active** surface treatment is a combination of **Tibansure** 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 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

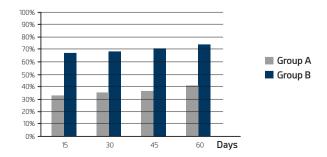
A study was conducted in the tibiae of 10 adult New Zealand rabbits after inserting four implants per rabbit (two in each tibia).

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 $\ensuremath{\mathrm{A}}\xspace.$

| 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% | |



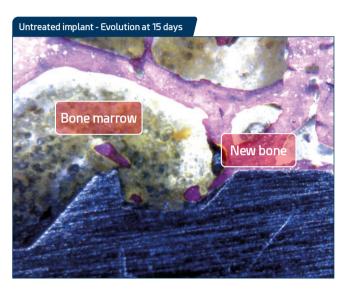


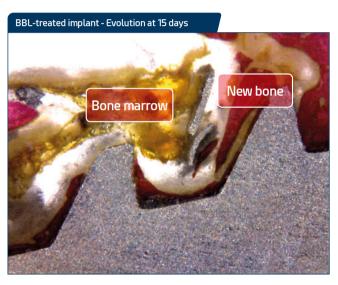
Conclusions

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.

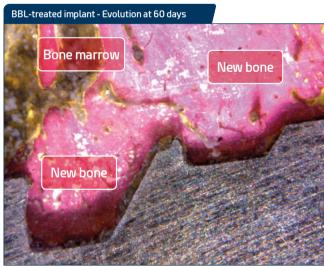
As explained by Dr. Sérgio Alexandre Gehrke, the histologist in charge of the study: "Within the study's limits, data from the histomorphometric analysis of the implants with a BBL-treated surface (78.92 + 0.3%) highlighted a much quicker and more effective osseointegration compared to the control group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









NOTE

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

ZM1 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



IMPORTANT

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



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

C€ MDD CE certification and notified body

MD Name of the medical device

Number of product batch

Patient information website

UDI Unique device identification

Sterilised using radiation

As

_____ 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

RxOnly 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.



7 12 Ziacom®



■ ZPlus Mount

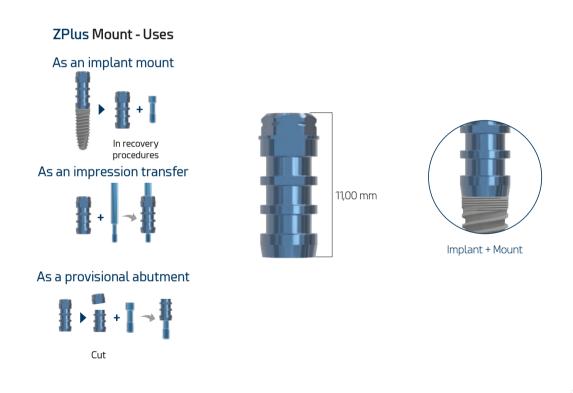
ZM1 implants are supplied with the **ZPlus** Mount, a multi-functional abutment made in grade 5 ELI titanium (sanitary grade), which allows easy handling of the implant during the procedure. Additionally, the **ZPlus** mount concept is based on reducing treatment costs, as it works equally well as an implant mount, impression abutment, or provisional abutment for cement-screwed.

The ZPlus mount is available for the following implant ranges Zinic® MT, ZM4. ZM4 MT and ZM1.

As we said, the ZPlus mount may be used as a provisional abutment, in which case it should be sculpted extra-orally and adjusted on an analogue, preferably a lab model or clamp. Check also the structural integrity of the mount and screw, to ensure that they have not suffered any deformation or damage due to excessive insertion torque or forced removal manoeuvre. Additionally, verify on an analogue that the ZPlus fixing screw is well fitted and that the connection is secure.

IMPORTANT

Always follow the surgical protocol when inserting the implant. This will protect the mount and screw from possible damage which could prevent it being used later as an impression abutment and/or provisional abutment. Use each **ZPlus** only with the implant to which it belongs. To avoid mix-ups, keep the **ZPlus** and screw with the patient's ID, detailing the corresponding reference and batch number. The **ZPlus** has 3 flat sides. After finishing the implant procedure, ensure that one of the flat sides faces into the vestibular cavity.



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ZM1 implants

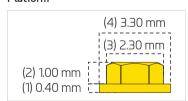
7M1 references

■ ZM1 with ZPlus - Titansure / Titansure Active references

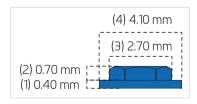
IMPLANT Ø (mm) Ø Core (mm) Length (mm) Ref. Titansure Ref. Titansure Active 8.5 ZM13385 ZM13385A 10.0 ZM13310 ZM13310A 3.30 2.80/1.70 11.5 ZM13311 ZM13311A 13.0 ZM13313 ZM13313A 14.5 ZM13314 ZM13314A 8.5 ZM13685 ZM13685A 10.0 ZM13610 ZM13610A 3.10/1.80 3.60 11.5 ZM13611 ZM13611A 13.0 ZM13613 ZM13613A 14.5 ZM13614 ZM13614A 6.0 ZM14006 ZM14006A 7.0 ZM14007 ZM14007A 8.5 ZM14085 ZM14085A 4.00 3.40/2.10 10.0 ZM14010A ZM14010 11.5 ZM14011 ZM14011A 13.0 ZM14013 ZM14013A 14.5 ZM14014 ZM14014A 6.0 ZM14406 ZM14406A 7.0 ZM14407 ZM14407A 8.5 ZM14485 ZM14485A 4.40 3.80/2.30 10.0 ZM14410 ZM14410A 11.5 ZM14411 ZM14411A 13.0 ZM14413 7M14413A 14.5 ZM14414 ZM14414A 6.0 ZM14806 ZM14806A 7.0 ZM14807 ZM14807A 8.5 ZM14885 ZM14885A 4.80 4.10/2.40 10.0 ZM14810 ZM14810A 11.5 ZM14811 ZM14811A



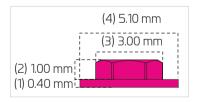
Platform



13.0



ZM14813A



(1) Untreated mechanised zone. (2) Height of external hexagon (3) Distance between internal hex faces. (4) Platform work diameter.

ZM14813



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 squares 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: diameter and length of the drill bit.
- **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

Z_M1

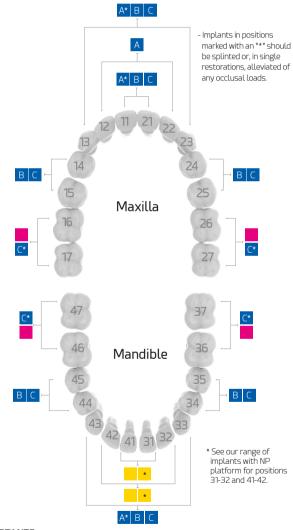
Implant diameter (1)

NP A RP B RP C RP WP Ø3.30 mm Ø3.60 mm Ø4.00 mm Ø4.40 mm Ø4.80 mm

(1) Diameters available for analogue platforms.

Implant crown diameter

NP RP WP Ø3.30 mm Ø4.10 mm Ø5.00 mm



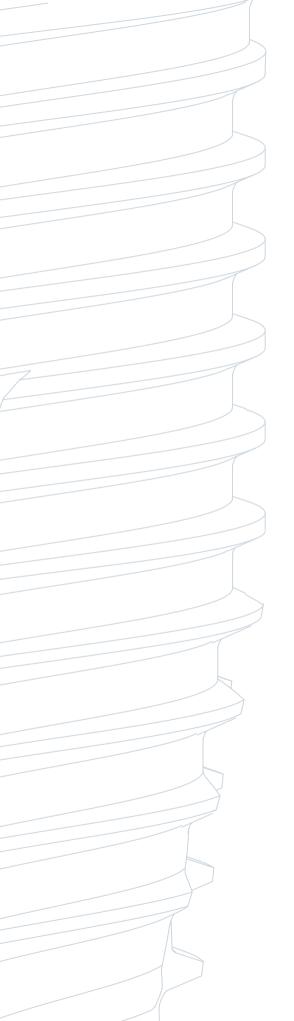
IMPORTANTE

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

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



15 2



ZM1



General considerations

■ Ziacom® drill system

Ziacom® implant system drills are made from stainless steel. The drills should be handled carefully to avoid any damage that could compromise their effectiveness. It is important to make sure the drills are in good condition. If you are unsure about the condition of any instrument, do not use it.

DRILLING SEQUENCE INDICATIONS

- · Drills must be inserted into the contra-angle handpiece with the motor stopped, ensuring that they are seated and rotate properly before starting drilling.
- Drills should be used with external irrigation.
- The speed and torque recommended for each drill should be respected. (See surgical protocol).
- · Position the drill at the chosen implant insertion site before starting drilling.
- · Perform controlled tapping movements, drilling the bone to the desired depth, guided by the reference depth laser marking.
- · Remove the drill from the surgical site with the motor running.

NOTES

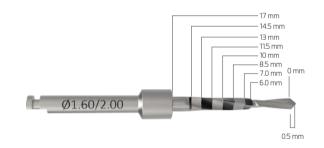
- · Do not continue drilling without irrigation.
- · If using a drill extender, supplement irrigation manually.
- For surgical and cortical drills, a maximum of 45 uses is recommended per drill. Exceeding the recommended number of uses puts the implant osseointegration process at risk.
- If any damage to the drill is observed, do not use it and replace with a new drill.
- Sterilise the instruments after each use in accordance with the cleaning and sterilisation instructions (page 38). The drills should be handled carefully to avoid any damage that could compromise their effectiveness. It is important to make sure the drills are in good condition. If you are unsure about the condition of any instrument, do not use it.

Surgical drills

The Ziacom® surgical drill length measurement system is simple and guides you during the surgical site drilling process.

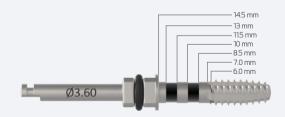
The laser marking on the drill shank identifies its diameter, while the horizontal laser-marked band on the active section corresponds to the length of the different implants (mm-graduated drills).

The drill tip is 0.5 mm long and this is not included in the different laser-marked lengths. When placing the implant using a flapless procedure, measure the thickness of the soft tissue with a periodontal probe and add this measurement to the drilling depth.



Surgical taps

Use of the surgical tap to make each implant's thread is dependent on the type of bone. Taps for use with contra-angle handpieces and manual tools are available. The choice of tap will depend on the individual case and the professional's preference. The laser marking on the tap shank identifies its diameter, while the horizontal laser-marked band on the active section corresponds to the length of the different implants.



Ziacom®



■ Drill stops

The Ziacom® drill stop system has been created to simplify the drilling sequence, ensuring osteotomy depth control..

The stops have two laser markings. The first represents the length of the implant to be inserted, and therefore the drilling depth, and the second indicates which drill is to be used.

WARNING

When using a drill with a stop, the length of the drill tip should be taken into consideration as the stops are calibrated to the actual length of the laser markings, not including the length of the drill tip.

The drill stops use a friction locking system. To assemble, place the grooved area of the stop over the drill tip and push it up until it is seated against the drill and locks with friction, as shown in the drawing below. The laser-marked line on the drill and the stop should line up with the selected length.





■ Probe

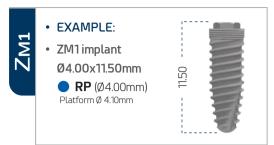
Check the depth of the surgical site, especially when not using drill stops. To check the surgical bed axis, the paralleling pins are available in different diameters according to the drilling sequence.



ZM1 19 **Z**

■ ZM1 implant

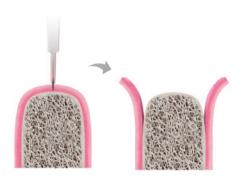
It is important to note that the drilling protocol for ZM1 implants using stepped drills varies significantly based on the implant diameter and the type of bone at the surgical site and therefore it is important to pay special attention to these two aspects.



Steps for drilling protocol in soft bone (IV)

PRELIMINARY STEP | Opening the gum

Make an incision and raise the flap.



STEP 1 | Crestal drill



STEP 2 | Lance drill



Start the implant site drilling sequence using mm-graduated lance drill Ref. SID001M with stop Ref. ZMPD115. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 3 | Pilot drill Ø1.60/2.00



Continue the drilling sequence using pilot drill Ref. OSPD20M until the length of the chosen implant is reached. Use the length-indicating laser mark on the drill or use stop Ref. ZMPD115. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.







STEP 4 | Probe/Paralleling pin Ø2.00/1.60

Check the depth of the surgical site and the insertion axis by inserting probe/paralleling pin Ref. MUR10MT.



○ 2.80/2.00

STEP 5 | Stepped surgical drill Ø2.00/2.80

Continue the drilling sequence using stepped surgical drill Ref. OSTD28M until the length of the chosen implant is reached. Use the length-indicating laser mark on the drill or use stop Ref. ZMPD115. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 6 | Probe/Paralleling pin Ø1.80/2.50

Check the depth of the surgical site and the insertion axis by inserting probe/paralleling pin Ref. MUR20MT. Repeat this step as many times as necessary during the surgery.



STEP 7 | Stepped surgical drill Ø2.20/3.10



Continue the drilling sequence using stepped surgical drill Ref. OSTD31M until the length of the chosen implant is reached. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





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

PRELIMINARY STEP | Opening the gum

Make an incision and raise the flap.



STEP 1 | Crestal drill



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STEP 2 | Lance drill



Start the implant site drilling sequence using mm-graduated lance drill Ref. SID001M with stop Ref. ZMPD115.

Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 3 | Pilot drill Ø1.60/2.00



Continue the drilling sequence using pilot drill Ref. OSPD20M until the length of the chosen implant is reached.

Use the length-indicating laser mark on the drill or use stop Ref. ZMPD115. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 4 | Stepped surgical drill Ø2.00/2.80



Continue the drilling sequence using stepped surgical drill Ref. OSTD28M until the length of the chosen implant is reached.

Use the length-indicating laser mark on the drill or use stop Ref. ZMPD115. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 5 | Probe/Paralleling pin Ø1.80/2.50

Check the depth of the surgical site and the insertion axis by inserting probe/paralleling pin Ref. MUR20MT. Repeat this step as many times as necessary during the surgery.



STEP 6 | Stepped surgical drill Ø2.20/3.10



Continue the drilling sequence using stepped surgical drill Ref. OSTD31M until the length of the chosen implant is reached.

Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 7 | Probe/Paralleling pin Ø2.20/3.10

Check the depth of the surgical site and the insertion axis by inserting probe/paralleling pin Ref. MUR30MT. Repeat this step as many times as necessary during the surgery.



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STEP 8 | Stepped surgical drill Ø2.40/3.40



Continue the drilling sequence using stepped surgical drill Ref. OSTD34M until the length of the chosen implant is reached.

Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 9 | Stepped surgical drill Ø2.60/3.80



Continue the drilling sequence using surgical drill Ref. OSTD38M until the length of the chosen implant is reached.

Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 10 | Cortical drill



Use cortical drill Ref. OTD01ST to shape the coronal area of the implant site. Insert the drill up to its laser mark, always applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary for this step, use drill extender Ref. DEXT10.

Use of the cortical drill will depend on the type* of bone:





*Based on the Lekholm and Zarb 1985 bone quality classification

Steps for drilling protocol in hard bone (I)

PRELIMINARY STEP | Opening the gum

Make an incision and raise the flap.



STEP 1 | Lance drill



Start the implant site drilling sequence using mm-graduated lance drill Ref. SID001M with stop Ref. ZMPD115.

Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.







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STEP 2 | Pilot drill Ø1.60/2.00



Continue the drilling sequence using pilot drill Ref. OSPD20M until the length of the chosen implant is reached. Use the length-indicating laser mark on the drill or use stop Ref. ZMPD115. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 3 | Probe/Paralleling pin Ø1.60/2.00

Check the depth of the surgical site and the insertion axis by inserting probe/paralleling pin Ref. MUR10MT. Repeat this step as many times as necessary during the surgery.



STEP 4 | Stepped surgical drill Ø2.00/2.80



Continue the drilling sequence using stepped surgical drill Ref. OSTD28M until the length of the chosen implant is reached.

Use the length-indicating laser mark on the drill or use stop Ref. ZMPD115. Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 5 | Probe/Paralleling pin Ø1.80/2.50

Check the depth of the surgical site and the insertion axis by inserting probe/paralleling pin Ref. MUR20MT. Repeat this step as many times as necessary during the surgery.



STEP 6 | Stepped surgical drill Ø2.20/3.10



Continue the drilling sequence using stepped surgical drill Ref. OSTD31M until the length of the chosen implant is reached

Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





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

Check the depth of the surgical site and the insertion axis by inserting probe/paralleling pin Ref. MUR30MT. Repeat this step as many times as necessary during the surgery.





STEP 8 | Stepped surgical drill Ø2.40/3.40



Continue the drilling sequence using stepped surgical drill Ref. OSTD34M until the length of the chosen implant is reached.

Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





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

Check the depth of the surgical site and the insertion axis by inserting probe/paralleling pin Ref. MUR40MT. Repeat this step as many times as necessary during the surgery.



STEP 10 | Stepped surgical drill Ø2.60/3.80



Continue the drilling sequence using stepped surgical drill Ref. OSTD38M until the length of the chosen implant is reached.

Control the direction and angle of drilling by applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary, use drill extender Ref. DEXT10.





STEP 11 | Cortical drill



Use cortical drill Ref. OTD01ST to shape the coronal area of the implant site. Insert the drill up to its laser mark, always applying intermittent pressure vertically, taking care not to exert too much pressure on the bone. If necessary for this step, use drill extender Ref. DEXT10.

Use of the cortical drill will depend on the type* of bone:



| Type I | Mandatory |
|---------------|-------------------------------|
| Type II | Depends on cortical thickness |
| Type III - IV | Not required |
| | |

*Based on the Lekholm and Zarb 1985 bone quality classification

STEP 12 | Surgical tap Ø4.00



Place surgical tap Ø4.00 mm Ref. MTAP-40MC in the prepared surgical site. Apply firm pressure and start to turn slowly. Once threads engage, continue to screw the tap in without pressure to the planned depth. If excessive resistance is met, turn 90° anti-clockwise after each complete turn.

To remove the tap, turn it anti-clockwise. Use of the tap will depend on the type of bone and the chosen implant diameter.



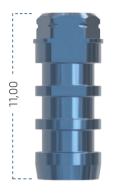
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Implant insertion using ZPlus Mount | Titansure

ZPlus Mount

Surface treatment

Titansure



STEP 1 | Unpacking the implant

- 11 Press the word "PRESS" and open the implant carton.
- Remove the top of the carton and take out the blister pack.
- (13) Carefully remove the seal from the blister pack.
- 14 Turn the vial containing the implant out onto a sterile cloth in the operating area.
- 15 Remember to remove the label from the implant and to adhere it to the patient's implant card and medical record to ensure that the product is traceable.





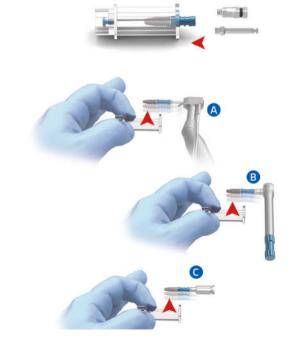
STEP 2 | Choosing the right placement instrument

Based on the specific clinical situation and access to the surgical site, one of three different instruments can be selected to insert the implant:

- (A Contra-angle: select the ZPlus CA driver of the desired length (Ref. 01MMIN / 02MMIN) and insert it into the contra-angle.
- B Ratchet Ref. RATC50: select the ZPlus Ratchet/Manual driver of the desired length (Ref. XSMIN / TSMIN / TLMIN) and insert it into the ratchet set to function "IN", which is identified with an arrow.
- Screwdriver handle 4x4 Ref. MADW10: select the ZPlus Ratchet/Manual driver of the desired length (Ref. XSMIN / TSMIN / TLMIN) and insert it into the screwdriver handle.

STEP 3 | Removing the implant from its vial

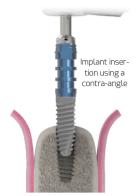
Hold the vial containing the implant in one hand and insert the selected driver into the ZPlus mount with the other hand. Remove the implant-mount assembly by lifting it vertically out of the vial.



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STEP 4 | Inserting the implant

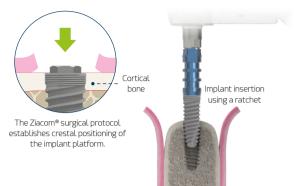


Insert the implant into the surgical site, controlling both the direction and angle of the implant. When inserting the implant with a contra-angle, use a maximum speed of 25 rpm. The recommended insertion torque ranges from 35 to 50 Ncm, according to each case, and is not limited to a single torque.

If resistance is met during insertion, turn the implant slightly anti-clockwise and then continue to insert after waiting a few seconds. Repeat this process as many times as necessary.

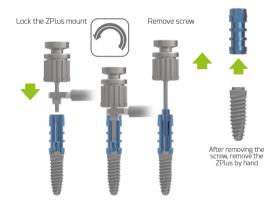
The Ziacom® surgical protocol establishes crestal positioning of the implant platform.

The ZPlus mount has 3 flat sides. After inserting the implant, make sure that one of these flat sides faces the vestibular direction.



STEP 5 | Extracting the ZPlus Mount

Lock the ZPlus mount using locking key Ref. 01M0HW and remove the screw using manual surgical screwdriver Ref. SMSD / LMSD. After removing the screw, remove the ZPlus by hand.



ZM1

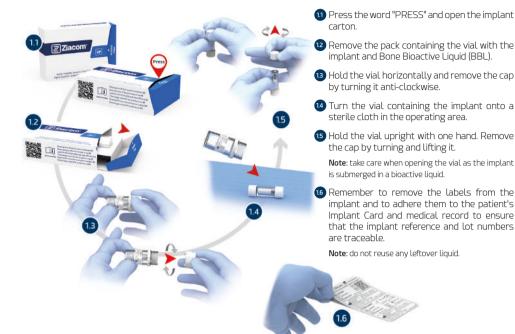
Implant insertion using ZPlus Mount | Titansure Active

ZPlus Mount

Surface treatment



STEP 1 | Unpacking the implant



STEP 3 | Removing the implant from its vial

Based on the specific clinical situation and access to the surgical site, one of three different instruments can be selected to insert the implant:

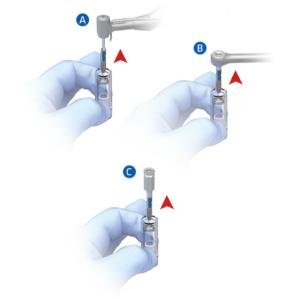
STEP 2 | Choosing the right placement instrument

- (A Contra-angle: select the ZPlus CA driver of the desired length (Ref. 01MMIN / 02MMIN) and insert it into the contra-angle.
- B Ratchet Ref. RATC50: select the ZPlus Ratchet/Manual driver of the desired length (Ref. XSMIN / TSMIN / TLMIN) and insert it into the ratchet set to function "IN", which is identified with an arrow.
- © Screwdriver handle 4x4 Ref. MADW10: select the ZPlus Ratchet/Manual driver of the desired length (Ref. XSMIN / TSMIN / TLMIN) and insert it into the screwdriver handle.

Hold the vial containing the implant in one hand and insert the selected driver into the ZPlus mount with the other hand. Remove the implant-mount assembly by lifting it vertically out of the vial.

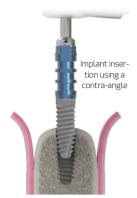
NOTE

Take care when opening the vial so as not to spill the Bioactive Liquid. Leftover Bioactive Liquid cannot be reused.





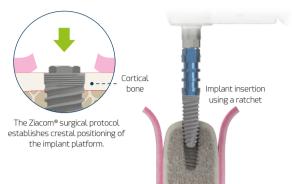
STEP 4 | Inserting the implant



Insert the implant into the surgical site, controlling both the direction and angle of the implant. When inserting the implant with a contra-angle, use a maximum speed of 25 rpm. The recommended insertion torque ranges from 35 to 50 Ncm, according to each case, and is not limited to a single torque.

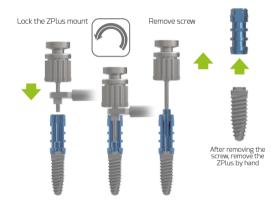
If resistance is met during insertion, turn the implant slightly anti-clockwise and then continue to insert after waiting a few seconds. Repeat this process as many times as necessary.

The Ziacom® surgical protocol establishes crestal positioning of the implant platform. The ZPlus mount has 3 flat sides. After inserting the implant, make sure that one of these flat sides faces the vestibular direction.



STEP 5 | Extracting the ZPlus Mount

Lock the ZPlus mount using locking key Ref. 01M0HW and remove the screw using manual surgical screwdriver Ref. SMSD / LMSD. After removing the screw, remove the ZPlus by hand.



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Implant insertion using ZPlus Mount | Titansure Active

■ Soft tissue conditioning

STEP 1 | Placing the cover screw



Remove the cover screw anti-clockwise using manual surgical screwdriver Ref. SMSD / LMSD.

Move the cover screw towards the implant while taking care not to drop it and cause its accidental ingestion. Insert the screw into the implant until it locks, applying manual torque in a clockwise direction. Placement of the cover screw during the first surgical phase requires that, after the osseointegration period, the second surgical phase should be performed or the implant should be exposed to fit the chosen

Based on each individual case, you can choose not to place a cover screw but instead to directly attach a healing abutment.



STEP 3 | Exposing and extracting the cover screw

Locate the implant and make an incision to expose the cover screw or use tissue punch Ref. MPU34 on the soft tissue. Remove the screw using manual surgical screwdriver Ref. SMSD



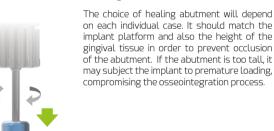
STEP 2 | Closing the soft tissue

Close and suture the soft tissue, carefully lining up the flaps.



STEP 4 | Placing the healing abutment

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

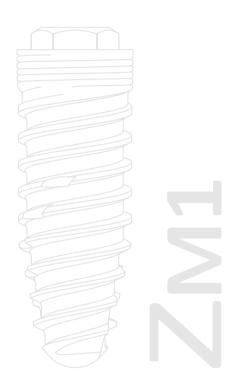






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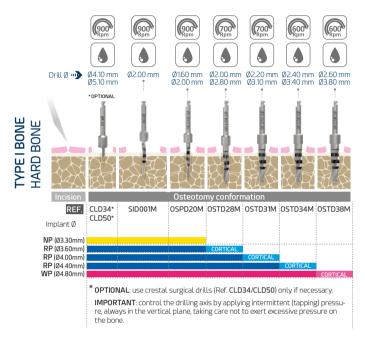
ZM1 31 **Z**

Simplified surgical protocol

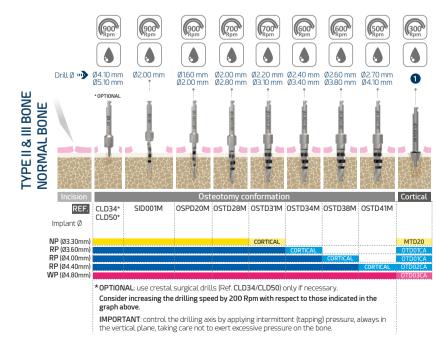
Drilling protocol - ZPlus



The specified speeds are recommended







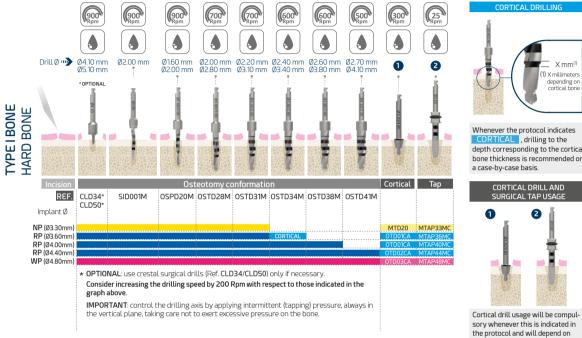




Drilling protocol - ZPlus



The specified speeds are recommended



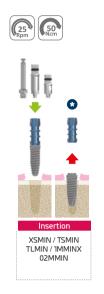


ZM1

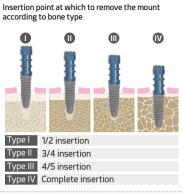
Simplified surgical protocol

Implant insertion - ZPlus

Insertion



■ Removing the mount ②





extractor screw to remove it: with NP platform, use Ref. EDSZ20 and with RP/WP platform, use Ref. EDSZ34

Direct insertion









It has direct insertion keys to the implant ref.: SMEX20/SMEX34/SMEX50. for ratchet/manual and MMEX20/MMEX34/ MMEX50 for CA, to adjust the implant end-position.

■ Crestal placement

The Ziacom® implant platform should be placed at bone crest level.

RECOMMENDED crestal position



Bone types

Lekholm and Zarb classification (1985)



TYPE IV BONE - SOFT BONE

• Thin cortical layer surrounding a lowdensity 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

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General recommendations

Consider during intervention



Surgical drills must be inserted into the contra-angle handniece with the motor stopped, ensuring that they are seated and rotate properly before starting drilling. Treat drills with the utmost care; the slightest damage to the tips could compromise their effective operation.



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



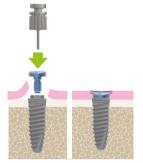
Damaged instruments must be disposed of according to local regulations.



Implantologists should keep one of the identification labels supplied with the product in the patient's file so that it may be traced correctly

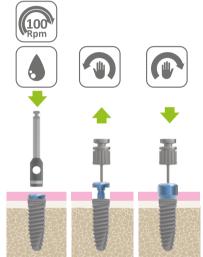
Handling of cover screw





Remove the cover screw from its vial using the hex screwdriver in a counter-clockwise direction. Move the cover screw towards the implant while taking care not to drop it and cause its accidental ingestion. Insert the cover screw into the implant and tighten it using manual torque in a clockwise direction

Preparation for second surgical phase



Placement of healing abutment

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 insertion

Excessive compression of the bone can lead to failure of implant osseointegration.

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

- Lack of primary stability due to loss of supporting bone
- Difficulties during implant insertion.

Exceeding the torque (50 Ncm) when inserting the implant may result in:

- Irreversible deformation of the implant's internal/external connection
- Irreversible deformation of the implant insertion instrument.
- Difficulty disassembling the instrument/ implant assembly.

Maximum insertion torque and speed

The recommended insertion torque ranges from 35 to 50 Ncm, according to each case, and is not limited to a single torque





The implant should be inserted with controlled torque based on the bone density and quality of the implant placement site:

Without partial or complete disassembly of the implant Mount, in type III and IV bone, respectively, with recommended torque of 35 to **50 Ncm** to avoid deformation of the Mount or cold welding between the Mount and the implant.

With partial or complete disassembly of the implant Mount and using a direct-to-implant key, in type I and II bone, respectively, with recommended torque of 35 to 50 Ncm to avoid deformation of the connection and excessive bone compression.

Insertion instrument or CA screwdrivers: use a maximum speed of:



ZM1 implants

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

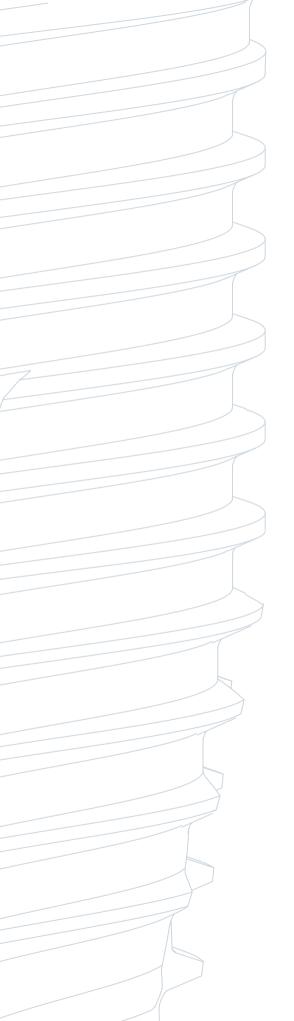
To avoid cortical stress and deformation of the key and/or implant connection, and also to avoid galling between the implant and the Mount, the recommended maximum speed (25 Rpm) and maximum torque (50 Ncm) must be respected when inserting with a contra-angle (CA) handpiece.

When using a ratchet, it is necessary to monitor resistance during insertion. If there is any resistance, the implant should be removed by turning it twice (to release the bone from the tension created and free the thread) and then, after a few seconds, the implant should be inserted again, repeating this process as many times as is necessary.

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 ZM1 system by Ziacom®.



ZM1



ZM1

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.

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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.

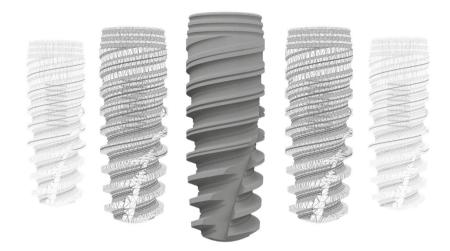
General recommendations

- 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.



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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.

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