SURGICAL PROCEDURE

ZMK · ZMR

Special connection onepiece implants

Ziacom®

ZMK · ZMR

Surgical procedure manual

Ziacom®

Important information

Please read carefully before using Ziacom® products

General information

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

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

Liability, safety and guarantee.

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

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

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

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

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

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

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

Together for **health**

Índice

ZMK® · ZMR® · ZMRs implants

ZMK characteristics

SURGICAL PHASE

- Minimally invasive surgery: simplifies drilling protocol and reduces surgical time.
- Single surgical phase, transmucosal: surgical simplicity and mostly asymptomatic postoperative.
- Non second surgery needed: shorter tissue healing time.
- Reduced diameter: allows implant placement in reduced M-D spaces.

PROSTHETIC SIMPLICITY

- Kirator abutment included.
- No abutment screws: non loosening or deterioration due to micro-movements.
- Overdentures: reduction of costs by including abutment (processing pack not included).

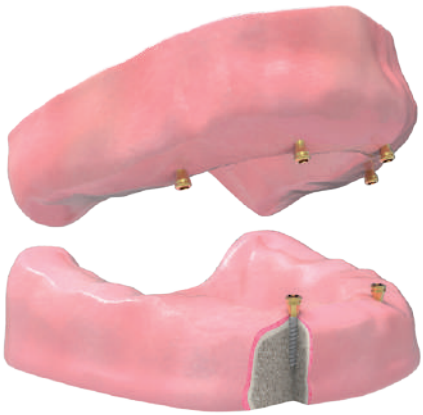
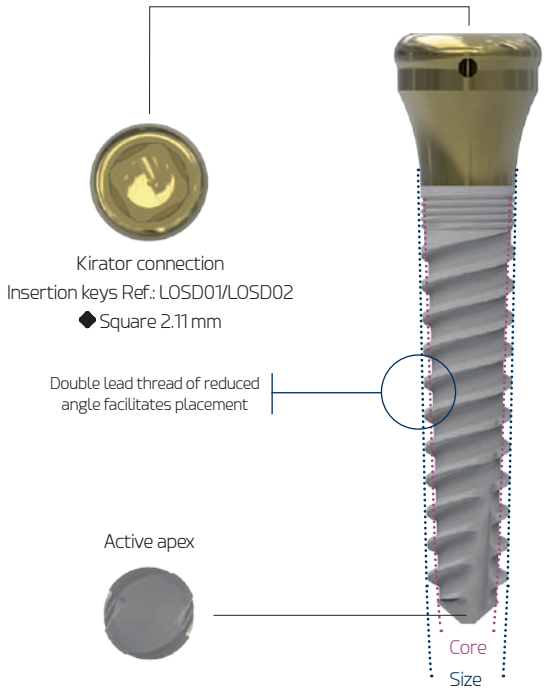
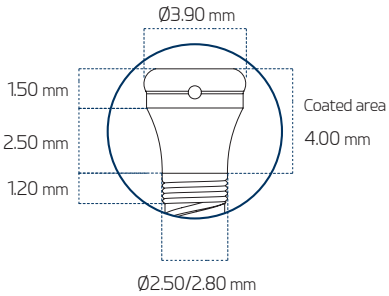


Image of a clinical case for rehabilitation with bimaxillary muco-supported implant-retained overdenture



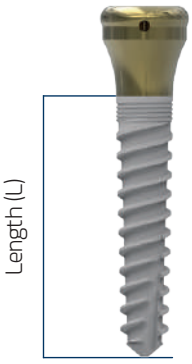
Implant coronal area measurements



ZMK diameters and lengths

Ø DIAMETER	Ø PLATFORM	LENGTH (L) 10	11.5	13
▲ RP 2.50	3.90			
▲ RP 2.80				

Dimensions in mm.



ZMR · ZMRS characteristics

SURGICAL PHASE

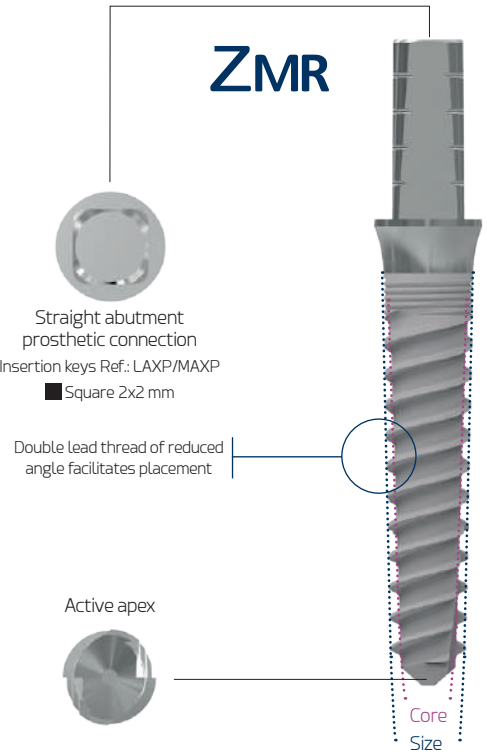
- Minimally invasive surgery: simplifies drilling protocol and reduces surgical time.
- Single surgical phase, transmucosal: surgical simplicity and mostly asymptomatic postoperative.
- Non second surgery needed: shorter tissue healing time .
- Reduced diameter: allows implant placement in reduced M-D spaces.

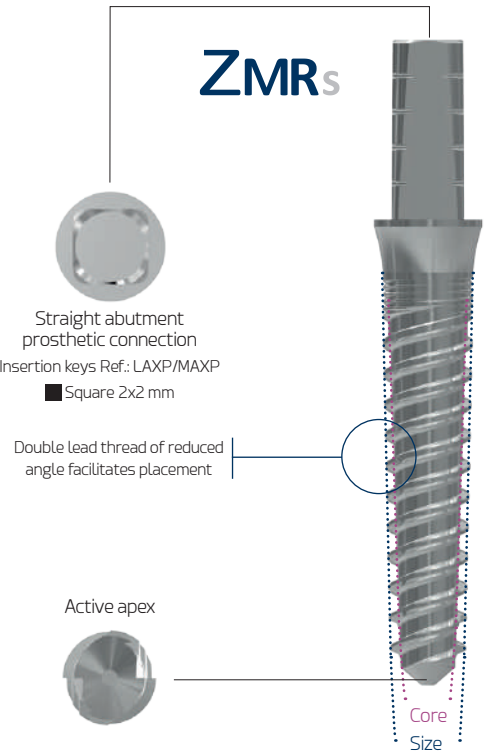
PROSTHETIC SIMPLICITY

- Scuptable straight abutment: makes impression easy. Immediate function.
- No abutment screws: non loosening or deterioration due to micro-movements.

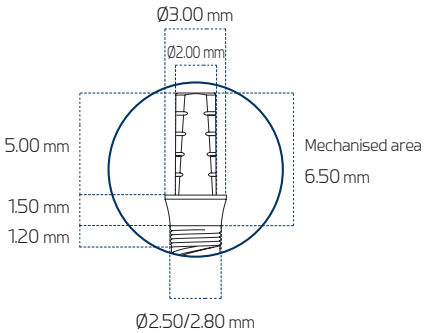
TWO TYPES

- Non surface treatment models as a trasitional implant for provisional immediate loading are available (only in Ø2.5mm)

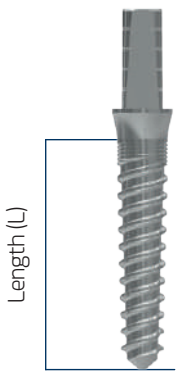




Implant coronal area measurements



ZMR · ZMRS diameters and lengths



Ø DIAMETER	Ø PLATFORM	LENGTH (L) 10	11.5	13
▲ RP 2.50	3.00			
▲ RP 2.80				

Dimensions in mm.

Surface treatments

Titansure surface

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

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

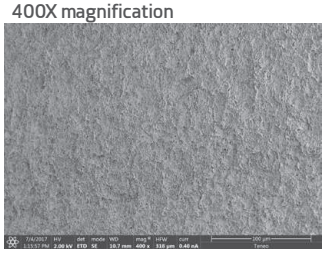
TITANSURE SURFACE ANALYSIS

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

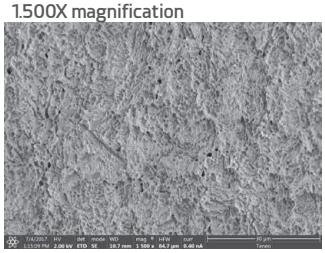
Surface morphology analysis

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

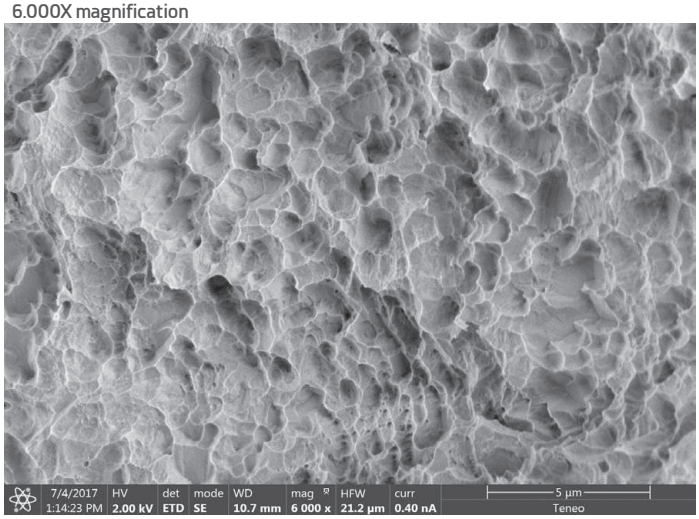
400X magnification



1.500X magnification

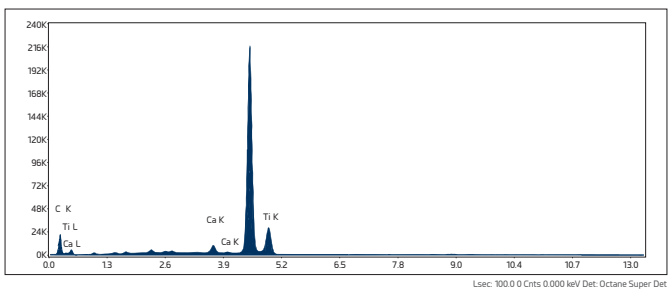


6.000X magnification



Surface elemental analysis

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



Compositional analysis of implant surface

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

No aluminum was detected

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

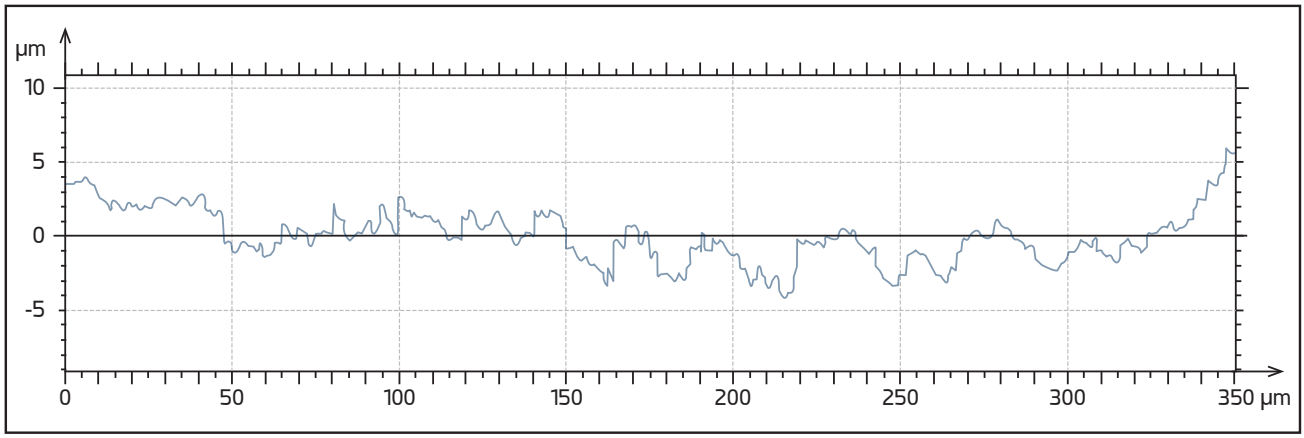
Surface roughness analysis

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

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

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

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



The data were extracted from:

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

OPTIMAL OSSEOINTEGRATION

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

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

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

Product presentation

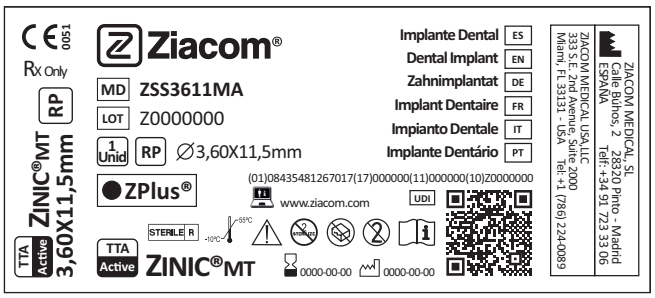
Blister packaging

Available for implants with **Titansure** surface treatment. Blister packs are heat sealed and include product labels in order to be able to trace products correctly and a flap for easy opening in the clinic but while preventing accidental opening.

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

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
- Name of the medical device
- Number of product batch
- Patient information website
- Unique device identification
- Sterilised using radiation
- Temperature restriction
- Caution, consult accompanying documents
- Do not resterilise
- Do not use if the packaging is damaged
- Non-reusable product
- Consult the instructions for use
- Expiry date of the product
- Date of manufacture
- Product manufacturer
- Titansure surface treatment
- Titansure Active surface treatment
- Rx Only Prescription only

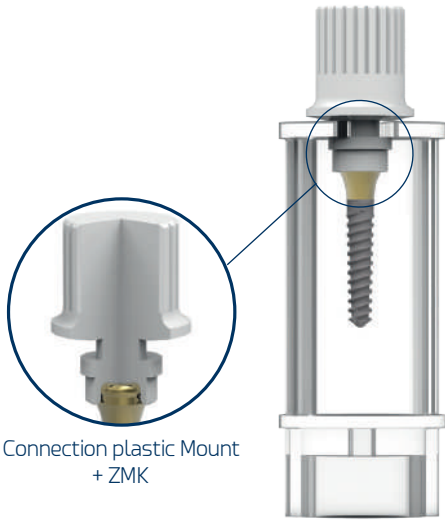
For full details on the product presentation and instructions for use (IFU) see **www.ziacom.com/ifus** or scan the QR code on the box.

Plastic Mount

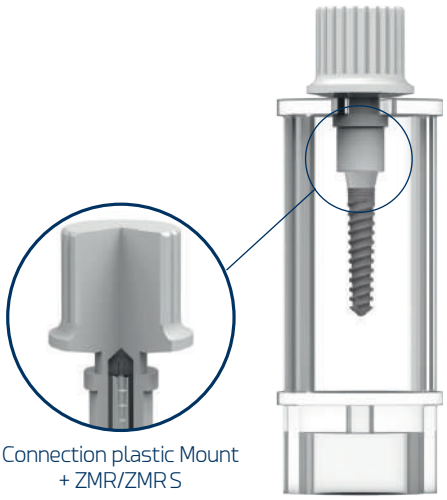
The packaging option of the one-piece implant with a **plastic mount** allows a comfortable and quick manual insertion of the implant in the surgical site.

Its advantages include:

- Convenient initial insertion in the implant site.
- Higher retention area for manual use.
- Higher length: facilitates its use with adjacent teeth.
- Higher resistance to torsion.

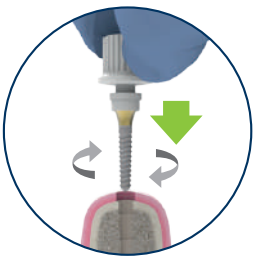


Connection plastic Mount + ZMK

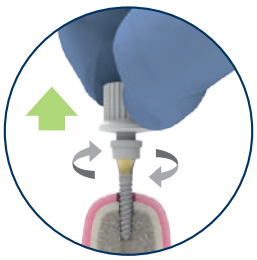


Connection plastic Mount + ZMR/ZMR S

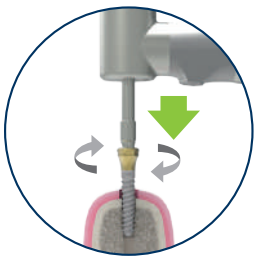
Insert steps



Step 1: insert the implant manually by turning clockwise



Step 2: separate the plastic Mount at the same time as you perform the insertion



Step 3A: final implant position with CA (Ref. LOSD02)

Step 3B: final implant position with ratchet (Ref. LOSD01)

For more information on the use of surgical instruments, see the "Surgical protocol" section on pages of this catalogue.

ZMK · ZMR · ZMR S references

IMPLANT

	Ø (mm)	Ø Core (mm)	Length	Ref. Titansure	
ZMK	2.50	2.10/1.50	10.0 mm	ZMK2510	
			11.5 mm	ZMK2511	
			13.0 mm	ZMK2513	
	2.80	2.40/1.75	10.0 mm	ZMK2810	
			11.5 mm	ZMK2811	
			13.0 mm	ZMK2813	

IMPLANT

	Ø (mm)	Ø Core (mm)	Length	Ref. Titansure	
ZMR	2.50	2.10/1.50	10.0 mm	ZMR2510	
			11.5 mm	ZMR2511	
			13.0 mm	ZMR2513	
	2.80	2.40/1.75	10.0 mm	ZMR2810	
			11.5 mm	ZMR2811	
			13.0 mm	ZMR2813	

IMPLANT

	Ø (mm)	Ø Core (mm)	Length	References	
ZMRs	2.50	2.10/1.50	10.0 mm	ZMR2510S	
			11.5 mm	ZMR2511S	
			13.0 mm	ZMR2513S	

ZMR

Recommendations for use

All implant planning must respect the natural biomechanical stability of the oral cavity and allow natural emergence of the dental crown through the soft tissue by means of an implant with a prosthetic platform that has a diameter that is proportionally smaller than the emergence diameter of the tooth to be restored. 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 triangles identified with letters on the periodontal chart represent the implant diameters and platforms recommended for those tooth positions. These recommendations are valid for replacing teeth with single-unit restorations, bridges or partial or complete implant-retained, tissue-supported dentures.

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 Medical 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 of the drill.
- **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.

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

Periodontal chart

ZMK

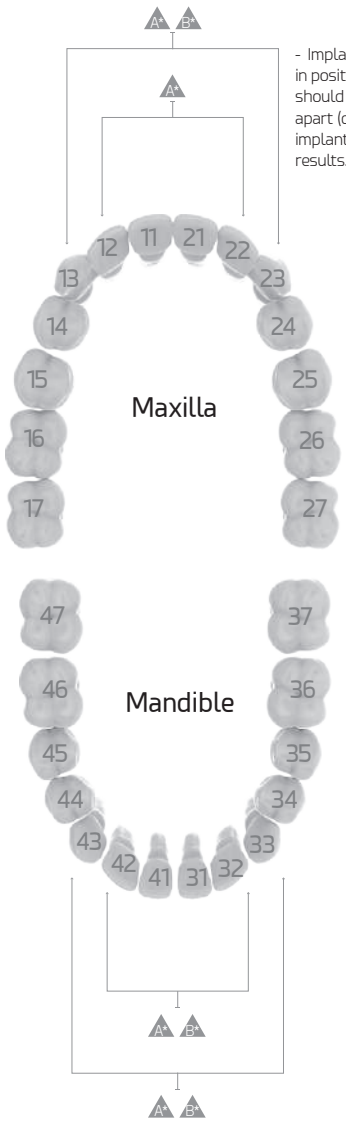
Implant diameter(1)

A RP Ø2.50 mm
B RP Ø2.80 mm

(1) Diameters available for analogue platforms

Implant crown diameter

▲ RP Ø2.50 mm
▲ RP Ø2.80 mm



- Implants with overdenture in positions marked "*" should be placed 22-27 mm apart (distance between implant centres) for optimal results.

Recommendations for use

All implant planning must respect the natural biomechanical stability of the oral cavity and allow natural emergence of the dental crown through the soft tissue by means of an implant with a prosthetic platform that has a diameter that is proportionally smaller than the emergence diameter of the tooth to be restored. 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.

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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.

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Periodontal chart

ZMR · ZMRs

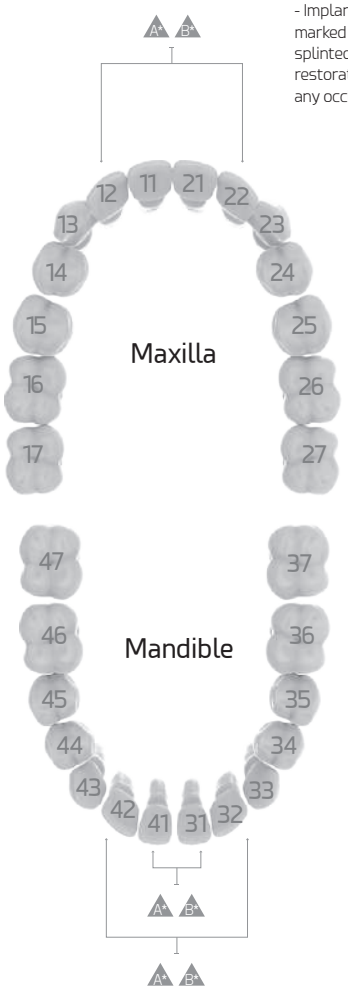
Implant diameter(1)

▲ RP Ø2.50 mm ▲ RP Ø2.80 mm

(1) Diameters available for analogue platforms

Implant crown diameter

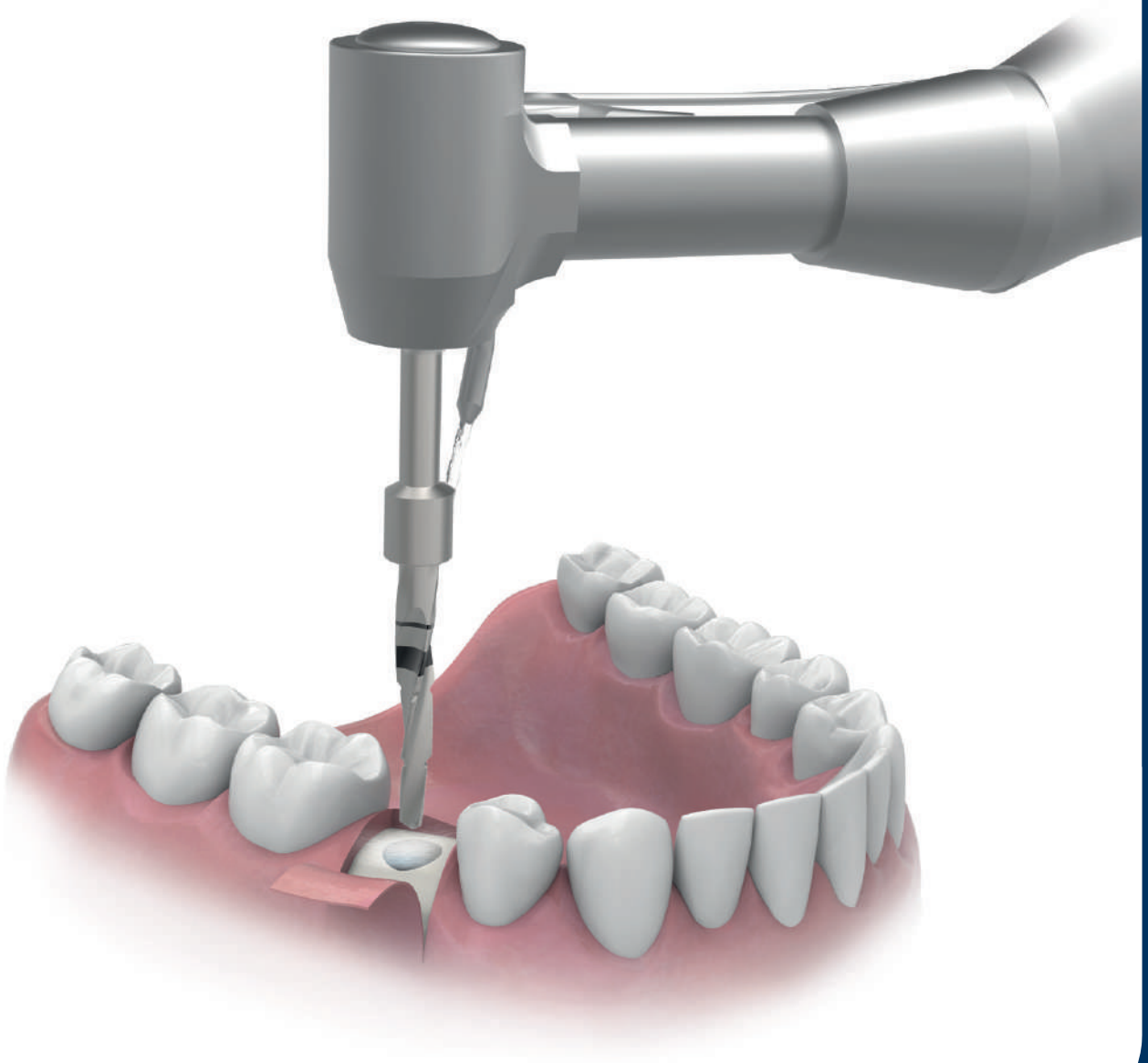
▲ RP Ø2.50 mm ▲ RP Ø2.80 mm



- Implants in positions marked "**" should be splinted or, in single-unit restorations, alleviated of any occlusal loads.

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

Surgical protocol



Surgical protocol

General considerations

Ziacom® drill system

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

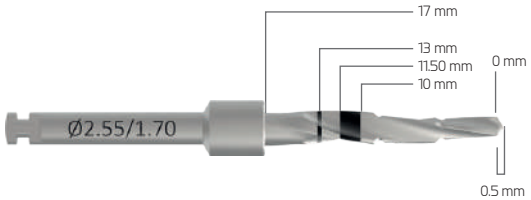
- Do not continue drilling without irrigation.
- If using a drill extender, supplement irrigation manually.
- For surgical and cortical drills, a maximum of 45 uses is recommended per drill. Exceeding the recommended number of uses puts the implant osseointegration process at risk.
- If any damage to 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 28). 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.

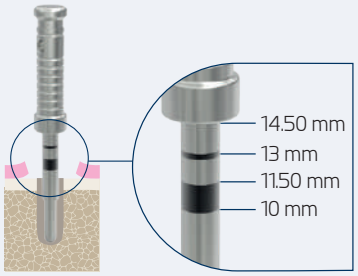
The laser marking on the drill shank identifies its diameter, while the horizontal laser-marked band on the active section corresponds to the length of the different implants (mm-graduated drills).

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.



Probes

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.



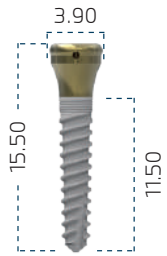
Double paralleling pin

Steps of drilling protocol

ZMK implant

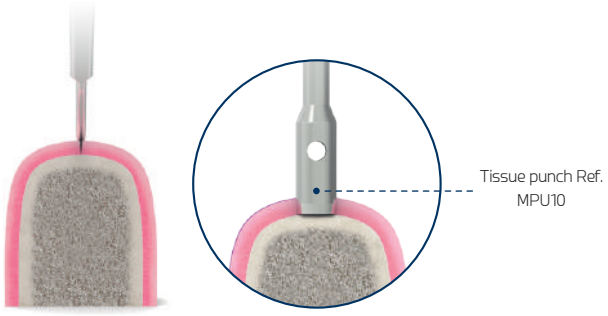
ZMK

- **EXAMPLE:**
  ZMK implant
  Ø2.50x11.50mm
  RP (Ø2.50mm)
  Ø platform 3.90mm



PRELIMINARY STEP | Opening the gum

Make an incision and lift the flap or use tissue punch Ref. MPU10 on the soft tissue.



STEP 1 | Lance drill

Start the implant site drilling sequence using mm-graduated lance drill Ref. MSID02. 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 2 | Stepped surgical drill Ø1.40/2.25

Continue the drilling sequence using stepped surgical drill Ref. OTD18ZM until the length of the chosen implant is reached. Use the length-indicating laser mark on the drill. 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.

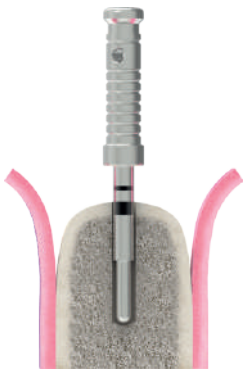
STEP 3 | Double paralleling pin Ø1.85/2.15

Check the parallelism between implants using double paralleling pin Ref. PARA70. Repeat this step as many times as necessary during the surgery.

STEP 4 | Probe

Check the depth of the surgical site by inserting probe Ref. MURE40.

Repeat this step as many times as necessary during the surgery.



Surgical protocol

Implant insertion using plastic mount ZMK | **Titansure**

ZMK plastic mount

Surface treatment

Titansure

STEP 1 | Unpacking the implant

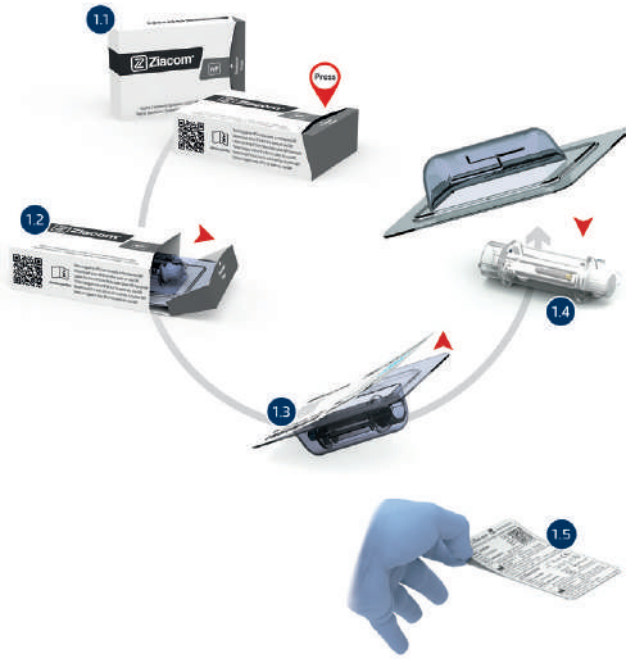
1.1 Press the word "PRESS" and open the carton.

1.2 Remove the top of the carton and take out the blister pack.

1.3 Carefully remove the seal from the blister pack.

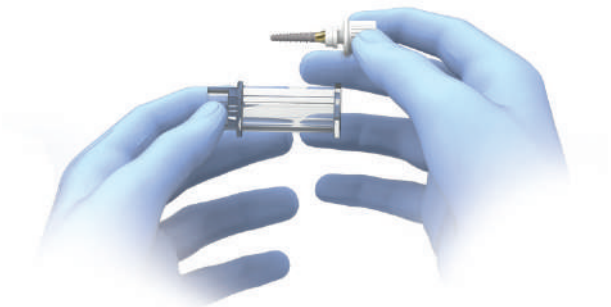
1.4 Turn the vial containing the implant onto a sterile cloth in the operating area.

1.5 Remember to remove the label from the implant and to adhere it to the patient's records to ensure that the product is traceable.



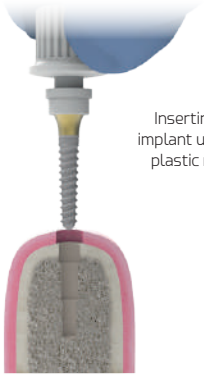
STEP 2 | Removing the implant from its vial

Hold the vial containing the implant in one hand and the ZMK plastic mount in the other. Remove the implant-mount assembly by lifting it vertically out of the vial.

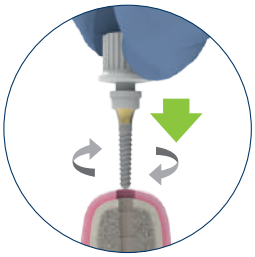


STEP 3 | Inserting the implant - ZMK plastic mount

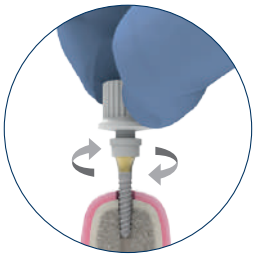
Insert the implant into the surgical site, controlling both the direction and angle of the implant.When inserting the implant with a contra-angle, use a maximum speed of 25 rpm. The recommended insertion torque ranges from 35 to 50 Ncm, according to each case, and is not limited to a single torque. If resistance is met during insertion, turn the implant anti-clockwise and then continue to insert after waiting a few seconds. Repeat this process as many times as necessary.



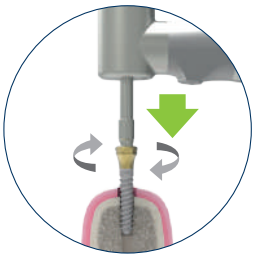
Inserting the implant using the plastic mount



Step 1: inserting the implant by hand by turning it clockwise

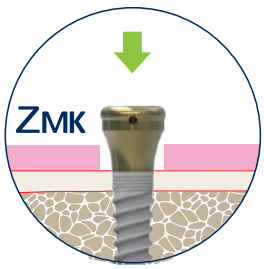


Step 2: disengage the plastic mount while turning it to insert it



Step 3A: final positioning of implant using CA (Ref. LOSD02)

Step 3B: final positioning of implant using ratchet (Ref. LOSD01)



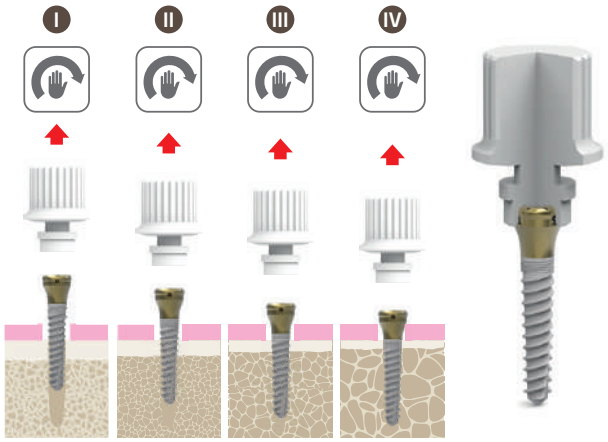
Step 4: crestal placement

STEP 4 | Removing the ZMK plastic mount

Remove the ZMK implants from the vial in the blister pack and insert them into the surgical site by hand using the plastic mount until sufficient mechanical anchorage is achieved for its removal.

Disengage the plastic mount while turning it to insert it. Do not fully insert the implant with the plastic mount. The point of insertion at which the ZMK plastic mount should be removed will depend on the bone type.

After removing the mount, use the ratchet or contra-angle drivers to insert the implant platform to the position indicated in the protocol.



Surgical protocol

Implant insertion using plastic mount ZMR | Titansure

ZMK
plastic mount

Surface treatment

Titansure

STEP 1 | Unpacking the implant

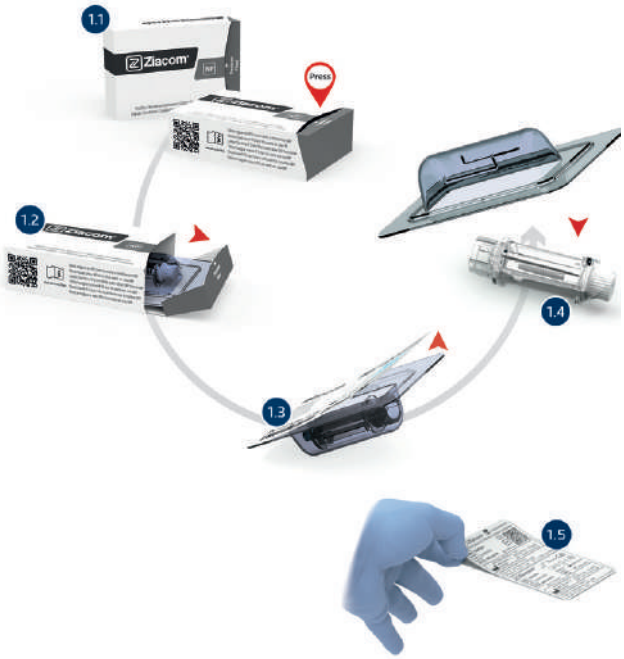
1.1 Press the word "PRESS" and open the carton.

1.2 Remove the top of the carton and take out the blister pack.

1.3 Carefully remove the seal from the blister pack.

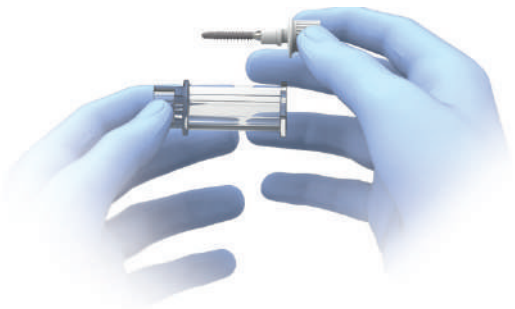
1.4 Turn the vial containing the implant onto a sterile cloth in the operating area.

1.5 Remember to remove the label from the implant and to adhere it to the patient's records to ensure that the product is traceable.



STEP 2 | Removing the implant from its vial

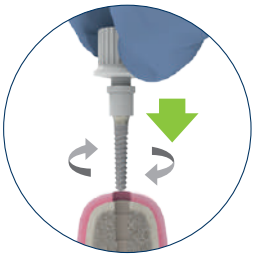
Hold the vial containing the implant in one hand and the ZMR ZMRS plastic mount in the other. Remove the implant–mount assembly by lifting it vertically out of the vial.



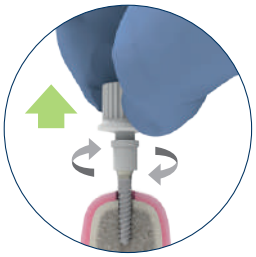
STEP 3 | Inserting the implant - ZMR • ZMRS plastic mount

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 anti-clockwise and then continue to insert after waiting a few seconds. Repeat this process as many times as necessary.

Inserting the implant using the plastic mount



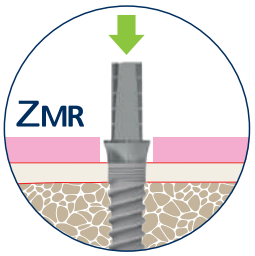
Step 1: inserting the implant by hand by turning it clockwise

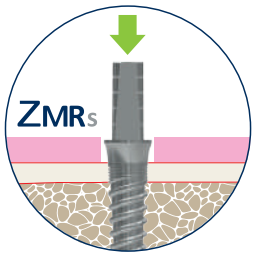


Step 2: disengage the plastic mount while turning it to insert it

Step 3A: final positioning of implant using CA (Ref. MAXP)

Step 3B: final positioning of implant using ratchet (Ref. LAXP)





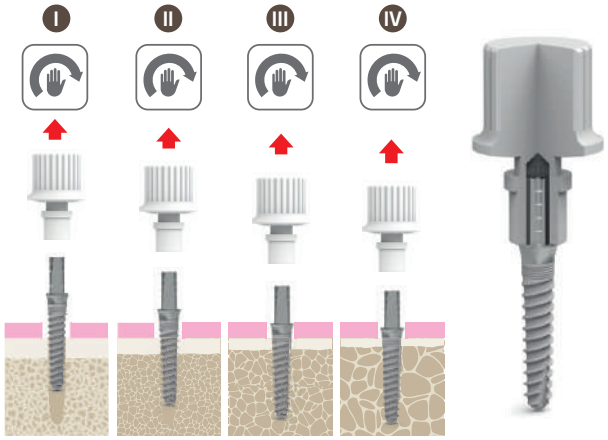
Step 4: crestal placement

STEP 4 | Removing the ZMR • ZMRS plastic mount

Remove the ZMR · ZMRS implants from the vial in the blister pack and insert them into the surgical site by hand using the plastic mount until sufficient mechanical anchorage is achieved for its removal.

Disengage the plastic mount while turning it to insert it. Do not fully insert the implant with the plastic mount. The point of insertion at which the ZMR· ZMRS plastic mount should be removed will depend on the bone type.

After removing the mount, use the ratchet or contra-angle drivers to insert the implant platform to the position indicated in the protocol.



Soft tissue conditioning

STEP 1 | Placing the ZMR • ZMRS healing abutment

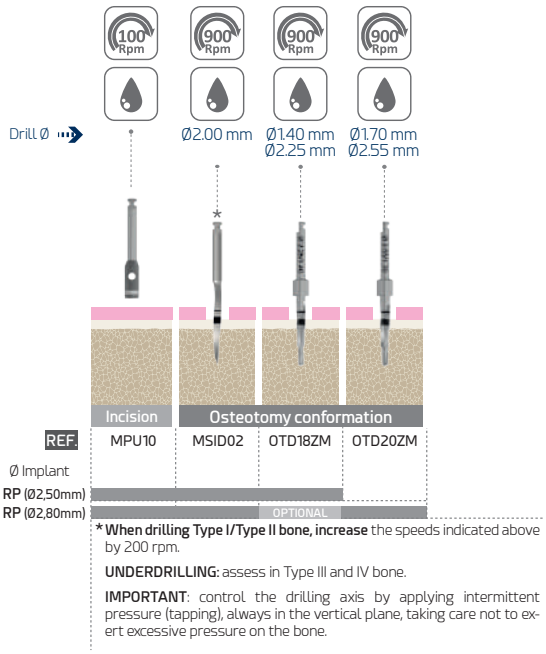
Place healing abutment Ref. HABA05 on the straight abutment of the ZMR · ZMRS implant until it is engaged properly.

Simplified surgical protocol

ZMK drilling protocol

Rotation | Irrigation required | Ø Drill diameter | See instructions | Torque

The specified speeds are recommended



* **When drilling Type I/Type II bone, increase** the speeds indicated above by 200 rpm.

UNDERDRILLING: assess in Type III and IV bone.

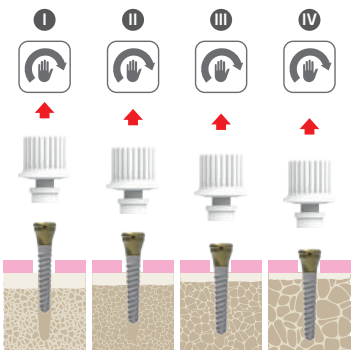
IMPORTANT: control the drilling axis by applying intermittent pressure (tapping), always in the vertical plane, taking care not to exert excessive pressure on the bone.

ZMK implant insertion

Insertion

Removing the ZMK plastic mount

Point of insertion at which to remove the mount according to bone type



Remove the ZMK implants from the vial in the blister pack and insert them into the surgical site by hand using the plastic mount until sufficient mechanical anchorage is achieved for its removal. Disengage the mount while turning it to insert it.

Do not fully insert the implant with the plastic mount.

After removing the mount, use the ratchet or contra-angle insertion keys to insert the implant platform to the position indicated in the protocol.

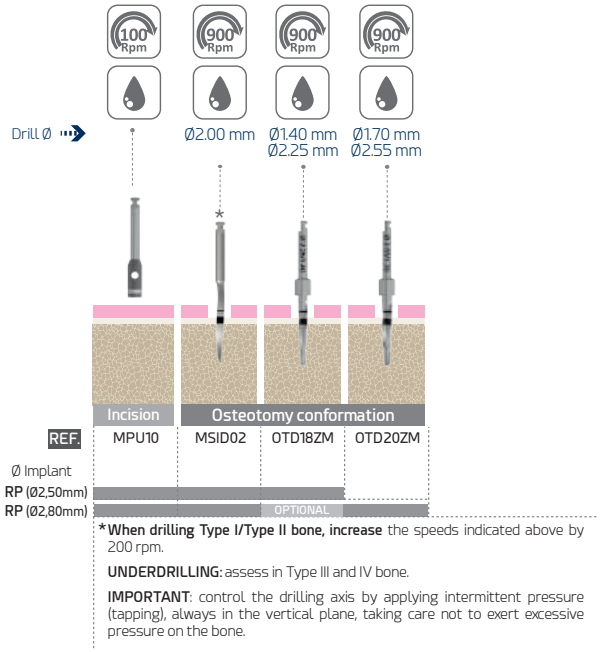
Direct insertion

LOSD01
LOSD02

ZMR · ZMR S drilling protocol

Rotation · Irrigation required · Ø Drill diameter · See instructions · Torque

The specified speeds are recommended



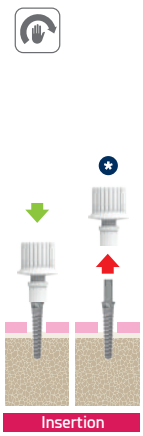
*When drilling Type I/Type II bone, increase the speeds indicated above by 200 rpm.

UNDERDRILLING: assess in Type III and IV bone.

IMPORTANT: control the drilling axis by applying intermittent pressure (tapping), always in the vertical plane, taking care not to exert excessive pressure on the bone.

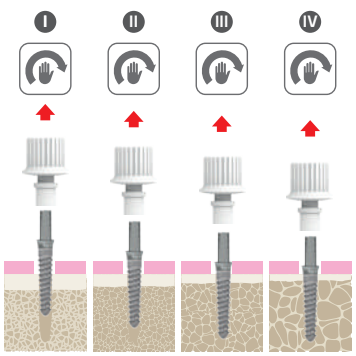
ZMR · ZMR S implant insertion

Insertion



Removing the ZMR · ZMR S plastic mount

Point of insertion at which to remove the mount according to bone type



Remove the ZMR · ZMR S implants from the vial in the blister pack and insert them into the surgical site by hand using the plastic mount until sufficient mechanical anchorage is achieved for its removal. Disengage the mount while turning it to insert it.

Do not fully insert the implant with the plastic mount.

After removing the mount, use the ratchet or contra-angle insertion keys to insert the implant platform to the position indicated in the protocol.

Direct insertion

MAXP
LAXP

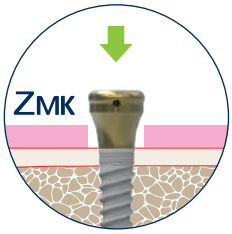
Simplified surgical protocol

Implants insertion ZMK · ZMR · ZMR S

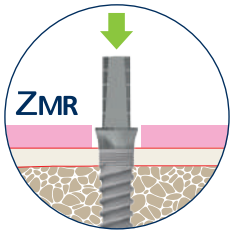
Crestal placement of implants

The Ziacom® implants platform must be placed in a supracrestal position.

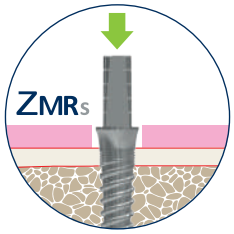
RECOMMENDED supracrestal position



RECOMMENDED supracrestal position



RECOMMENDED supracrestal position



Bone types

Lekholm and Zarb classification (1985)

TYPE IV BONE - SOFT BONE

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

TYPE II & III BONE - MEDIUM BONE

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

TYPE I BONE - HARD BONE

- Composed almost entirely of homogeneous compact bone.

General recommendations

Consider during intervention

Surgical drills must be inserted into the contra-angle handpiece 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.

IMPORTANT WARNINGS

About implant insertion

Respect the recommended maximum rpm. screwdrivers and insertion keys for contra-angle: maximum **25 rpm**.

Maximum insertion torque:

The implant should be inserted with controlled torque according to the density and quality of the bone at the implant site.

The recommended insertion torque based on scientific evidence ranges from **35** to **50 Ncm** according to each case and is not limited to a single torque.

Avoid cortical stress and deformation of the instrument and implant connection:

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

To avoid cortical stress and deformation of the insertion 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.

Ignoring these important warnings could cause:

- Irreversible deformation of the mount.
- Difficulty removing the mount.
- Irreversible deformation of the implant's internal/external connection.
- Difficulty disassembling the instrument/implant assembly.
- Difficulties during implant insertion.
- Lack of primary stability due to loss of supporting bone.
- No osseointegration due to bone necrosis as a result of excessive compaction of the 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.com/biblioteca** which explained the procedures, protocols and instructions for use before using the ZMK · ZMR · ZMR S system by Ziacom®.

ZMK - ZMR

Cleaning, disinfection and sterilisation

Cleaning, disinfection and sterilisation

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

Cleaning and disinfection instructions

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

Disassembly

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

Cleaning and disinfection

For disinfecting instruments and surgical boxes:

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

For disinfecting plastic caps and spacers:

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

Inspection

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

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

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

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

Sterilisation instructions for steam autoclave

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

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

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

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

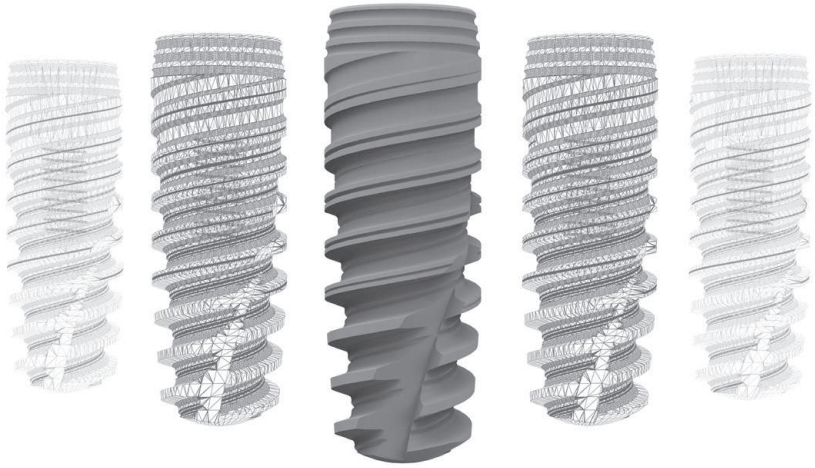
Storage of Ziacom® products

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

General recommendations

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

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



Ziacom®

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

Check the availability of each product in your country.

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

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