ZIBONE

Procedure Manual

Content

1. General information

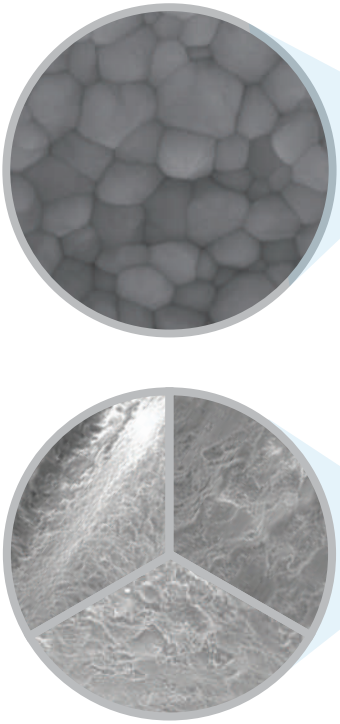
1.1 Material

Zibone applies zirconia material and meets biocompatibility for ISO 10993 and ISO 7405, and monitor strictly product quality with fine manufacturing procedure, not involving any CMR or endocrine-disrupting substances.

Studies show that the titanium may result in hypersensitivity in some patients. Zirconia is a high strength ceramic material which is biocompatible and will eliminate the hypersensitivity on metal. ZiBone implants and surgical instruments are made of zirconia to offer a metal-free treatment to patients.

ZiBone ceramic implants provide a superior esthetics result than the titanium implants. Unlike the greyish appearance on the titanium implants showing apical to the restorations, especially at the junction of restoration and implant, ZiBone ceramic implants show a harmony of shade matching of restoration in the esthetics-demanding zone.

Osseointegration on zirconia implants is comparable to that in titanium implants. Zirconia surfaces show less plaque accumulation; therefore, reduce the risk of peri-implantitis. Without the junction of the abutment, the ZiBone ceramic implants can easily maintain the bone level. Long-term clinical data show the reliable outcomes of zirconia implants.



Conical abutment design
Ensure crown to support firmly

Use of bio-tech grade ceramic
Esthetically natural color

Fixture Surface Roughness Ra4~6μm
Enhance osseointegration

Cylindrical Body design
Increase the contact area with alveolar bone

Cylindrical structural design
Increase initial stability

Conical Tip design
Allow implant to have a smoother embedding into dental alveolus

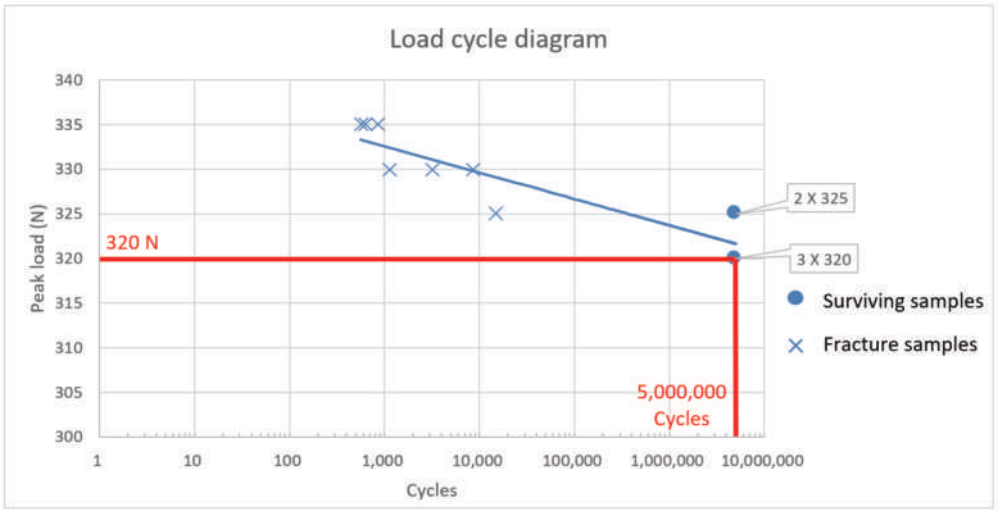
High Bone-Implant Contact

Studies have shown that zirconia integrates with bone tissue similar to titanium.
Early loading is possible due to its one-piece design when bone conditions allow.

Superior Mechanical Properties

ZiBone has been tested to verify its performance under different mechanical conditions. The results show that ZiBone has mechanical properties superior to titanium and aluminum oxide. It means that ZiBone performs well in clinical situations.

5 million cycles fatigue testing



With ISO13356 standard, made with high purity of zirconia oxide.

1	Density	≧ 6.00g/cm3
2	4-point bending flexural strength	≧ 800MPa
3	Fatigue strength (5,000,000 cycles)	≧ 320MPa
4	4-point bending flexural strength after aging treatment	≧ 800MPa
5	Radioactivity	≦0.0043 Bq/g
6	Highly Biocompatible	Satisfied ISO7405 standard

Surgery set

The Zibone surgical kit has a two-layer design. After lifting the lid of the kit, you can see the Contra angle-related instruments, including 12 conventional instruments and 10 expansion slots for preparation. Try to take out the first layer and you can See the torque wrench and the implant adapter.

The conventional instrument set includes a Pilot drill, a depth gauge of 4 specifications, a twist drill of 5 specifications, a torque wrench adapter (length and short) and a contra-angle adapter (long and short), and 10 additional slots corresponding to the contra-angle for expansion.

The outer box is made of PEI, a high-temperature resistant plastic, and can withstand routine high-temperature sterilization. After use, the instrument must be carefully scrubbed and then put back in the protective box for high-temperature sterilization before it can be used again.

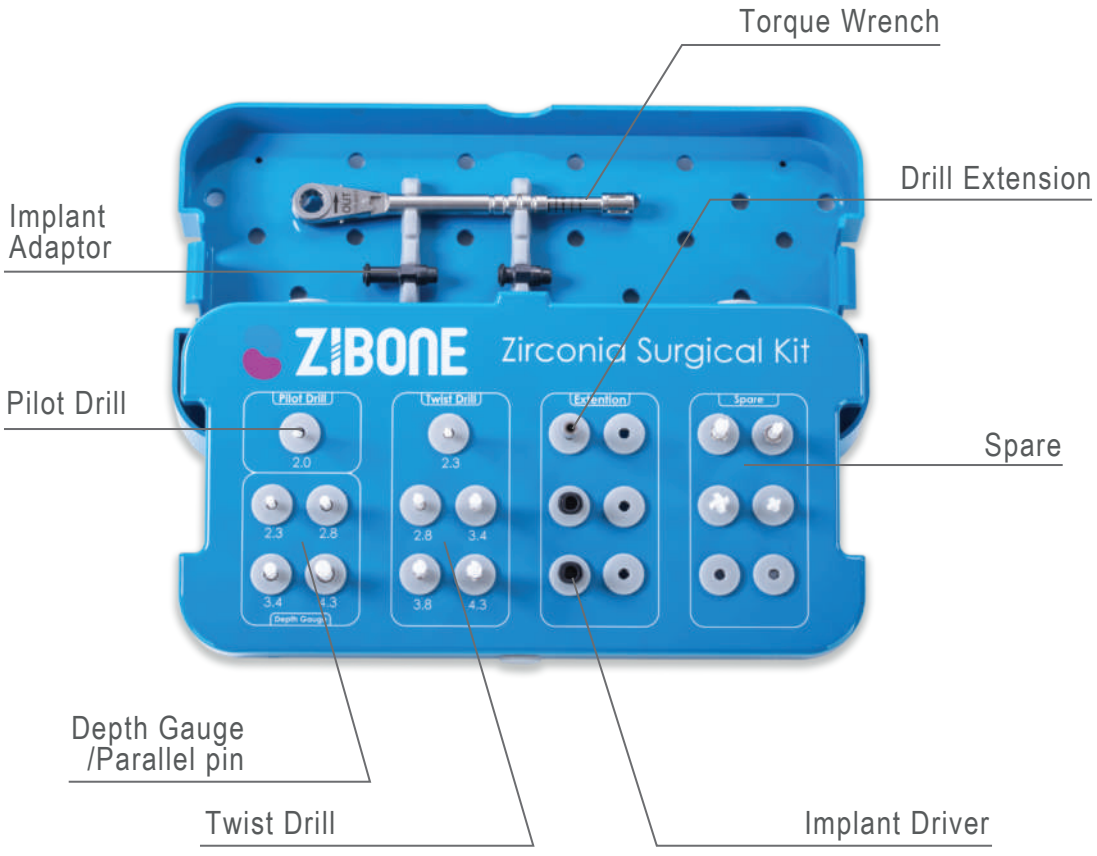
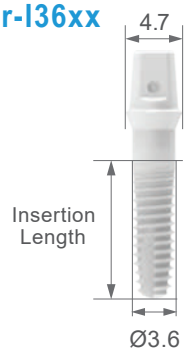
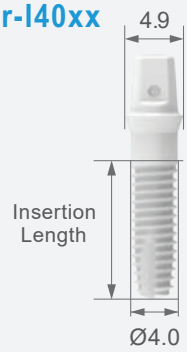
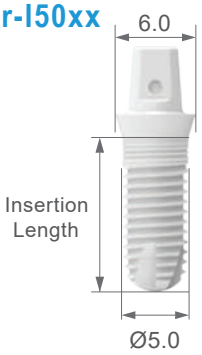


Image	Insertion Length	Final Drill	Artical No.
Zr-I36xx 	8.0	D 2.8	Zr-I3608
	10.0	D 2.8	Zr-I3610
	11.5	D 2.8	Zr-I3611
	13.0	D 2.8	Zr-I3613
	14.5	D 2.8	Zr-I3614
Zr-I40xx 	8.0	D 3.4	Zr-I4008
	10.0	D 3.4	Zr-I4010
	11.5	D 3.4	Zr-I4011
	13.0	D 3.4	Zr-I4013
	14.5	D 3.4	Zr-I4014
Zr-I50xx 	8.0	D 4.3	Zr-I5008
	10.0	D 4.3	Zr-I5010
	11.5	D 4.3	Zr-I5011
	13.0	D 4.3	Zr-I5013
	14.5	D 4.3	Zr-I5014

Unit: mm

Indication：
Zibone ceramic dental implants are indicated for implantation into upper or lower jaw as a supportive pillar for prosthetic devices, such as dental crowns and bridges, or other artificial attachments. The product is metal free and applicable for patients with metallic allergy.

Contraindications：
Surgery with dental implant might be not allowed to patients with poor bone quality, uncontrolled periodontics, or unqualified health state such as diabetes or cardiac disease. Used or damaged dental implants must not be used.

WARNING：
If implants were suffering from affordable pressure, situations such as peri-implantitis or implant fracture might happen. Patient's physical condition is critical to successful implant surgery. Therefore, below condition must be considered before implantation:
1. Poor bone quality
2. Poor oral hygiene
3. Health risk due to blood disease or hormone non-homeostasis
4. Alcohol or drug abuse
5. Implants must be prevented from heavy force after surgery
6. Laser engraving is prohibited to implants.
7. Therapists are obligated to inform relevant information to patients.

Notification：
1. Please do not throw or press it. Please do not use it after throwing it.
2. Because it is a one-piece designed implant, incomplete osseointegration might cause failure easily. Therefore, patients should be tracked for longer period before placing on prosthesis.
3. Post-surgery period until osteointegration, overweight occlusion and direct force must be avoided.

Sterilization and handling：
The product has been processed via moist heat sterilization. Implants must be stored in original packaging, under clean and dry conditions. If moisture is present in inner package, package damaged, or unintentionally opened, implants must not be used. Before use it, specification number must be checked against package's label. After taking it out, the product must be prevented to contact with any non-sterilized products. Re-sterilization must be prohibited.

Image	Article	Spec.	Artical No.
	Pilot Drill	2.0	Zr-P2017
	Twist Drill (6, 8, 10, 12, 14, 16)	D 2.3	Zr-D2316
		D 2.8	Zr-D2816
		D 3.4	Zr-D3416
		D 3.8	Zr-D3816
		D 4.3	Zr-D4316
	Twist Drill (8, 10, 11.5, 13, 14.5)	D 2.3	Zr-D2314
		D 2.8	Zr-D2814
		D 3.4	Zr-D3414
		D 3.8	Zr-D3814
		D 4.3	Zr-D4314
	Depth Gauge	D 2.3	Zr-G2316
		D 2.8	Zr-G2816
		D 3.4	Zr-G3416
		D 4.3	Zr-G4316
	Cortical Bone Drill	D 3.6	Zr-C36
		D 4.0	Zr-C40
		D 5.0	Zr-C50
	Tissue Punch	D 3.5	TP-35
		D 4.0	TP-40
		D 4.5	TP-45
		D 5.0	TP-50
		D 5.5	TP-55

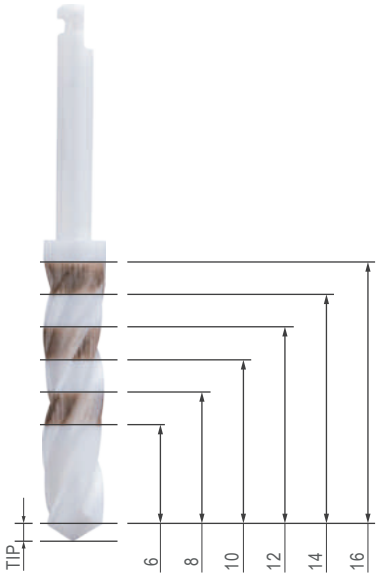
Unit: mm

Clinical sequence of drill

1. Determine the correct size of the twist drill and the drilling depth required.
2. Determine the size and position of the implant with the aid of radiographs.
3. To establish the exact position and the depth of the socket, additional CT scan is recommended.
4. In order to prevent any danger to adjacent structures, inspect carefully the area surrounding the preparation site.
5. Administer a local anesthesia to the operation site.
6. Cut the mucosa and periost to the bone and expose the operation site.
7. Mark the position with the a round bur, Apply the pilot bur at the location.
8. Drilling should be in a discontinuous motion with constant cooling using saline solution to avoid thermal damage to the bone tissue and to guarantee optimal chip removal.
9. Do not allow the drill get jammed or stuck during drilling (risk of fracture). Apply low pressure and drill to the required depth at a speed of 800-1000 rpm. Do not exceed 30 Ncm of torque.
10. The progressively larger drills are used to widen the implant site for the implant size selected.

WARNING

1. The drill is provided in non-sterile condition; therefore it must be cleaned, and sterilized before first time use.
2. After use, please immediately proceed to clean and sterilize. Do not let any blood or tissue to dry on the surface after use.
3. Immerse the drills in disinfecting solution immediately after use.
4. Follow carefully manufacturer's instructions for the use of the cleaning products to prevent any deterioration.
5. For recommendations for use (immersion time, concentration, suitability) of the disinfecting and cleaning agents please refer to the manufacturers' instructions.
6. Only use non-metal brushes for cleaning to avoid scratches. Do not collide and bend it to avoid scratch and crack.
7. Avoid contact with other drills or instruments when cleaning in the ultrasonic bath.



Model Name	Tip Depth
Zr-D2316	0.8 mm
Zr-D2816	0.9 mm
Zr-D3416	1.0 mm
Zr-D3816	1.1 mm
Zr-D4316	1.3 mm

Image	Article	Spec.	Artical No.
	Torque Wrench		ME-TRC50
	Implant Adaptor	4.5	ME-A4815
		10.5	ME-A4821
	Implant Driver	22	ME-D4822
		25	Me-D4825

Unit: mm

Product Description:
This product is an attachment to Zibone zirconia dental implants, which can assist in implantation and increase convenience.

Intended Use:
Torque wrench: connected to the implant adapter for torque limitation when the implant is screwed in.
Implant adaptor: As an adaptor between implant and torque wrench or contra-angle handpiece, it is used to screw the implant into the patient's alveolar bone.

Contraindications:
This product is an accessory to Zibone dental implants. Therefore, only suitable for patients with Zibone dental implants.

Side Effects:
Reports regarding systemic side effects are not yet available. However, incorrect use may cause choke or mouth inflammation.

Store Conditions:
The product is required to be stored in room temperature and in a dry place without direct sunlight exposure.

Clinical Procedures:
Torque wrench: It can be used with an implant adapter to limit the maximum torque of implant installation.
Implant Adaptor: The adapter is mounted on the dental handpiece or toque wrench and then connected to the implant and implanted through the dental handpiece.

Precautions:
1. This product is not for purposes described other than in the Instructions.
2. Any use questions can be sought with the manufacturer for assistance and education.
3. Do not use products that exceed the shelf life.

Item	Specification
	Catalogue number
	Batch code
	Date of manufacture
	Use-by date
	Do not re-use
	Sterilized using steam or dry heat
	Manufacturer
	Communate Europpene
	Authorized representative in the European Community
	Manufacturer

2. Surgery

2.1 Pre-surgery

Patient Evaluations

Patients must be evaluated before surgical procedures. The following criteria are needed for a successful treatment:

- Good oral and general health conditions.
- Normal wound healing capability.
- Sufficient and healthy bone presence.
- Good oral hygiene.

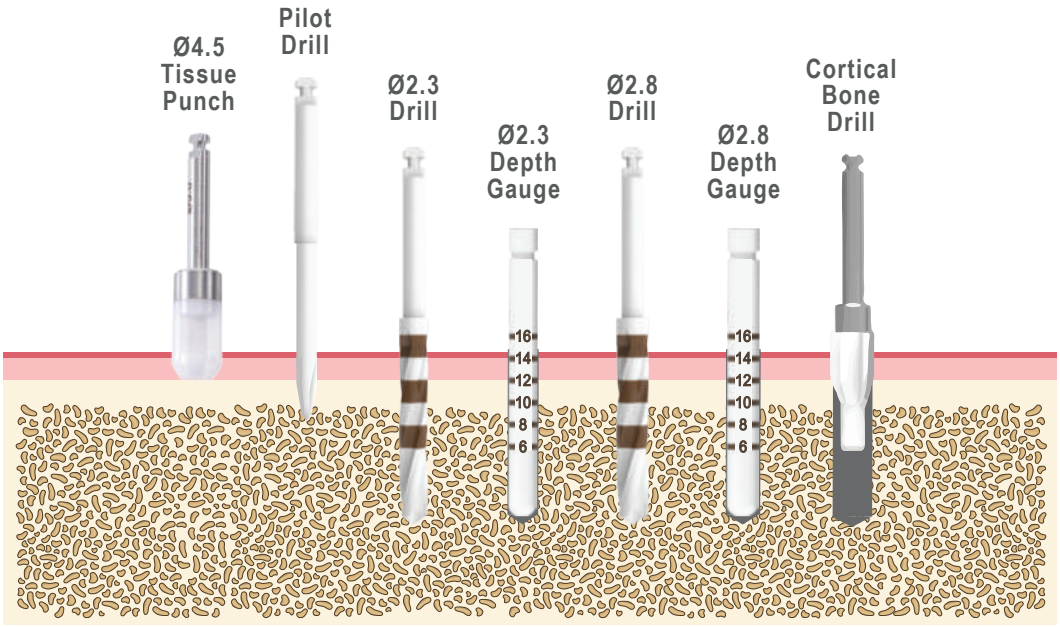
Case Planning

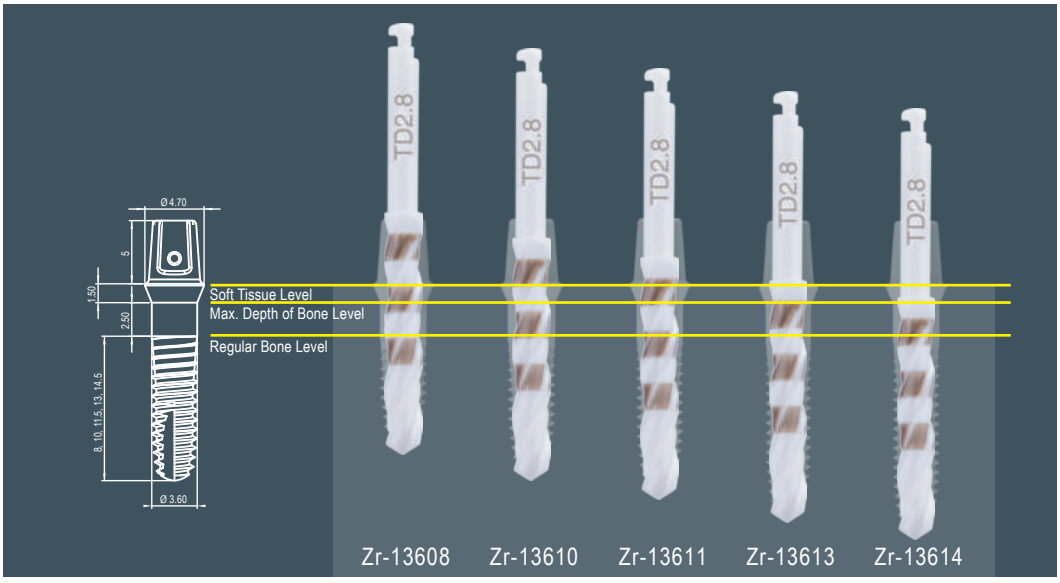
- Meticulous initial examination, with multi-disciplinary approach.
* Anatomy of the alveolar ridge
* Thickness and quality of the gingiva/gum
* Occulsal relationship
- Panoramic x-ray. (Periapical x-rays and CT exams when needed)
* Bone available for implant anchorage both height and width
* Position of the alveolar nerve/maxillary sinus
- Stone models in the articulator, and a wax-up of the intended restorative final objective.
- Take photo records.
- Select Implant model.

***** Optional but recommended *****

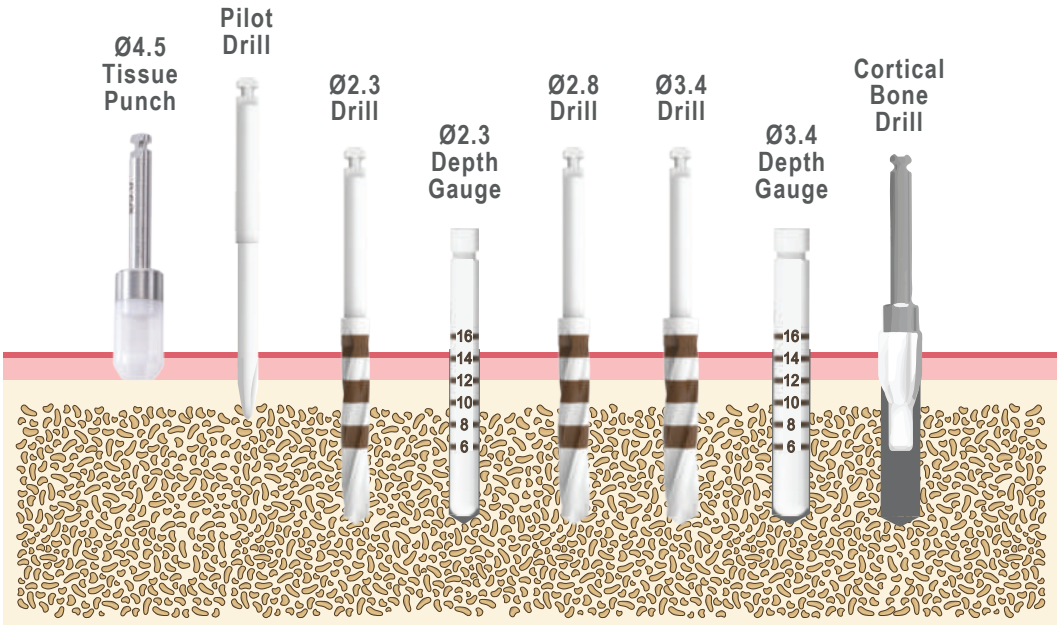
- Prepare a Surgical Guide. (a simple vacuum splint could be enough)
- Use spacer to make an implant protector.

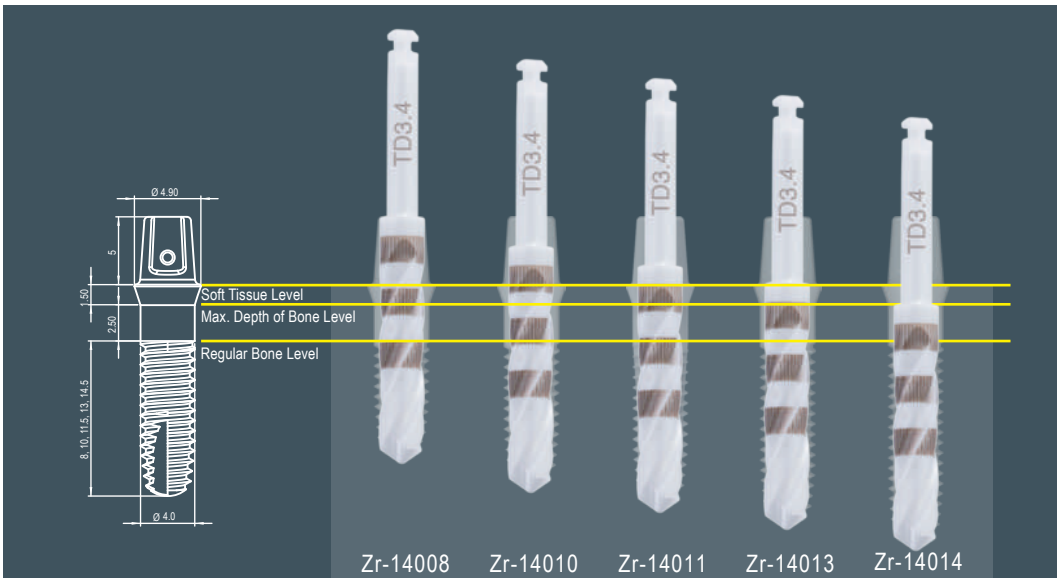
Ø3.6 Implant drilling plan



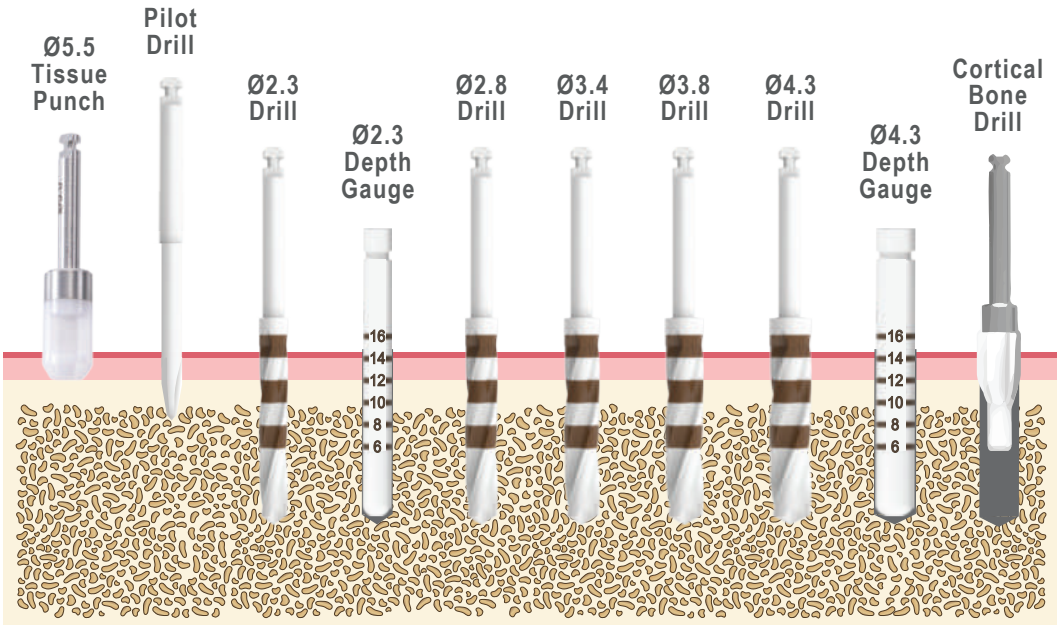


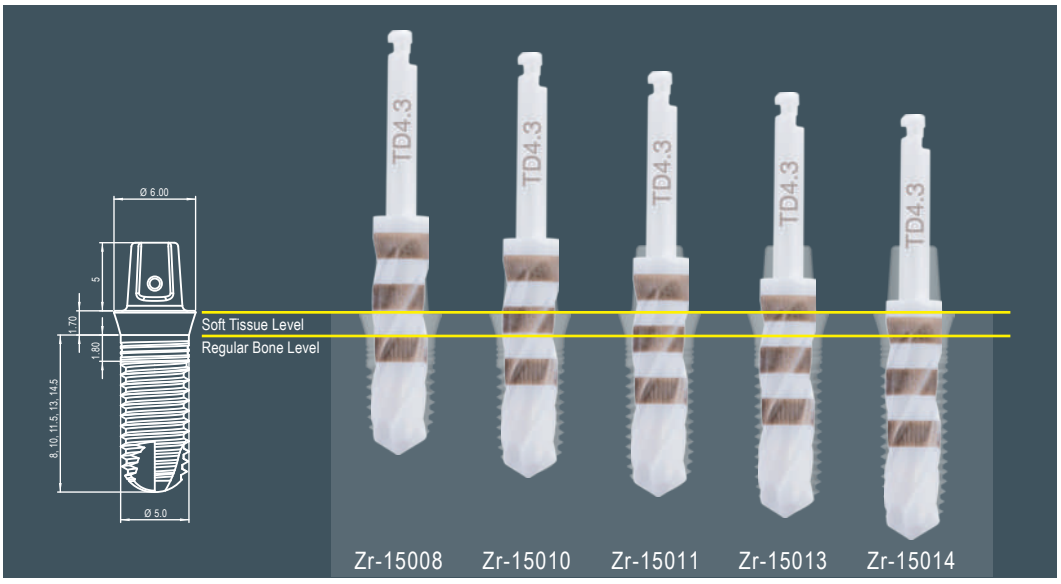
Ø4.0 Implant drilling plan



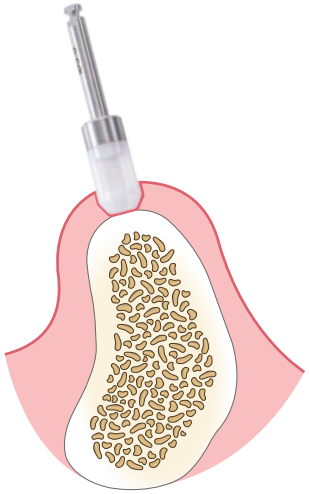


Ø5.0 Implant drilling plan

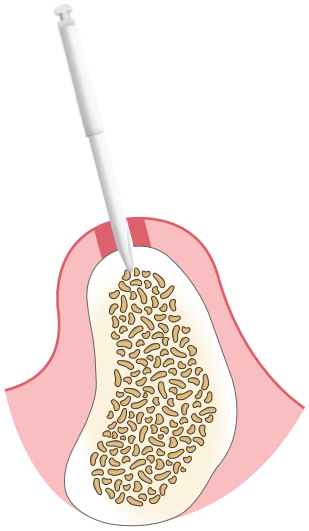




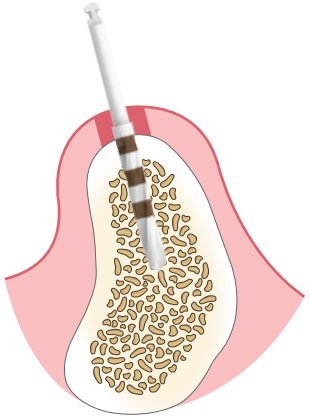
2.2 Surgical procedure



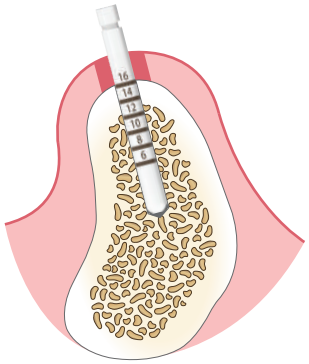
Use tissue punch to punch a hole in the gums for flapless surgery. (Or perform traditional open flap surgery)



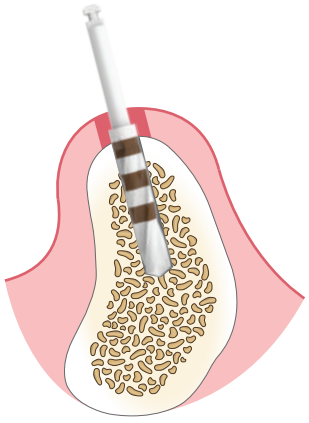
Use Pilot drill to drill and locate the cortical bone. (5mm is enough) And don't forget the cooling water.



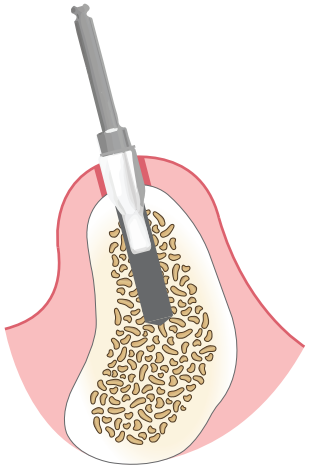
Use a 2.3mm twist drill to drill to the target depth under sufficient cooling.



Insert the depth gauge to confirm the axis and depth of the hole. If necessary, X-ray imaging can be taken with the depth gauge.



Use a twist drill to drill to the target diameter in sequence with sufficient cooling.



(Optional, it can be performed when the alveolar bone of the surgical site is not flat) Use countersink for trimming to prevent interference between the alveolar bone and the shoulder of the implant and affect the implantation.

Take the implant from the packaging

ZiBone ceramic implant is delivered with instruction and product sticker. The implant is placed in a sterilized bag. Don't use if there is any damage on the package.

ZiBone implant is in a container with a carrier for initial insertion to the prepared socket.

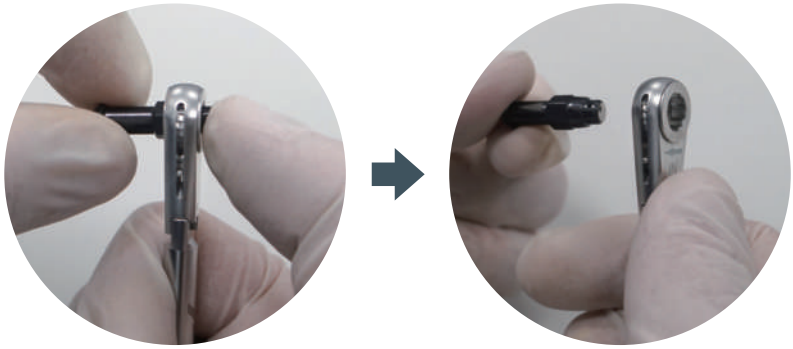
Operating Guide for Torque Wrench

Zibone torque wrench has a ratchet design, so the front and back sides correspond to the functions of screwing in and screwing out respectively. When installing, pay attention to the marking on the top view.

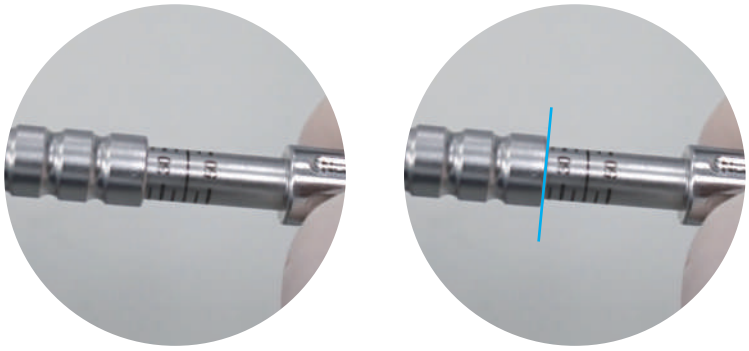
Install the adapter

When the adapter and the wrench are installed, you will hear an obvious "Clip". Incorrect installation may cause unexpected fall off and cause the patient to choke.

Remove the adapter

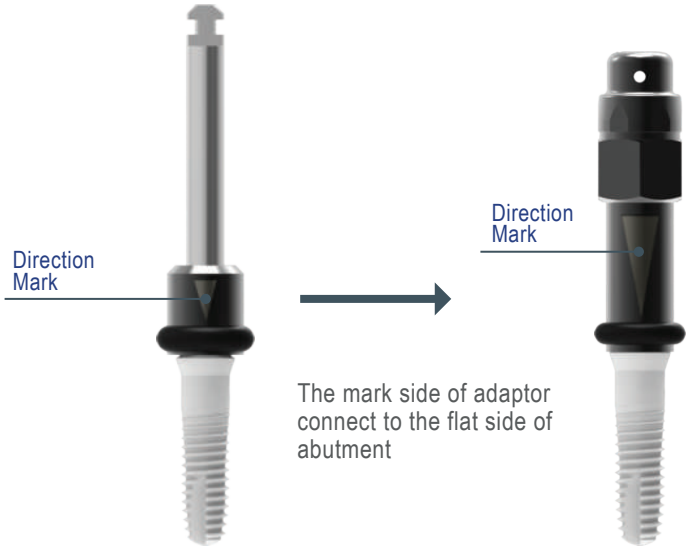


When removing, press the top of the adapter and grasp the bottom of the adapter to remove.

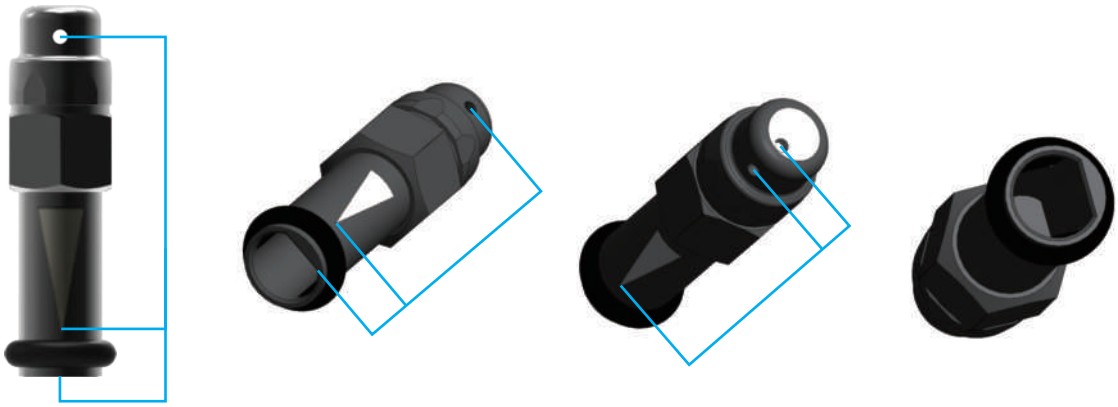


Rotate the knob at the end of the wrench and align the target torque with the edge of the rod. (blue line in the picture)

Directional indication on the adapter



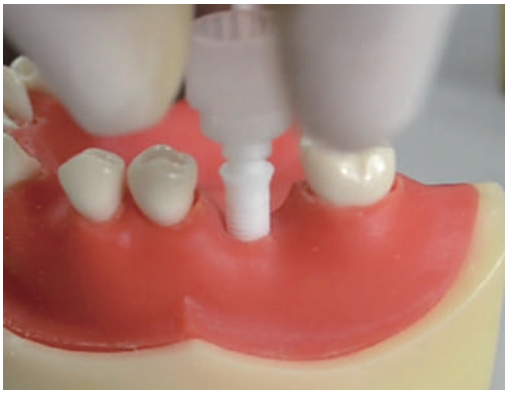
The implant could be inserted manually with torque wrench, or with an implant driver by machine. The triangular mark on the implant adaptor and implant driver should be the same orientation to the flat surface on the abutment.



The markings on the wrench adapter pointing to the flat surface of the abutment:

1. The round hole on the top surface.
2. Through hole on the top side.
3. The light triangle marks on the side.

Implantation

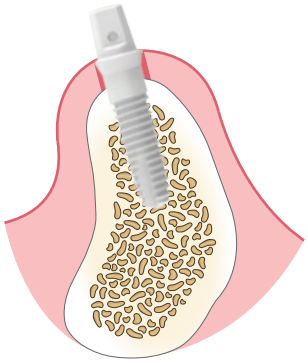


Transfer the implant to the surgical site with the base included in the package. Rotate 3~5 times and remove the base after the implant is roughly fixed.

*Optional*Use the implant driver to install the implant to the approximate position. (20RPM, 40Ncm MAX)

Use the toque wrench and adaptor to install the implant to the final position. (40Ncm MAX)

The torque forces should be remained between 30~40 Ncm in the process. Immediate loading on the ZiBone implant is possible but it depends on the initial stability, systemic condition, and bone quality. It take 3-4 months for osseointegration. A radiograph and thorough clinical evaluation are needed to confirm the osseointegration before the definitive restoration procedures.



The Zibone implant will be screwed in 0.5mm every time it rotates, It is recommended to place the Platform margin 1mm below the gums. And the rotating position of the flat surface can be adjusted if necessary.

3. Post-surgery

3.1 Postoperative follow-up

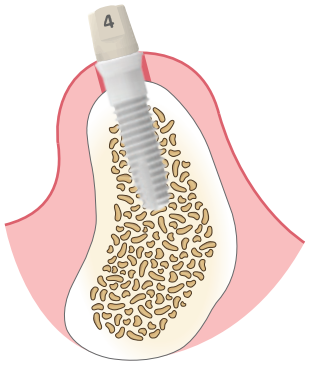
Within 1 week - observe the axis and position of the implant and the health of the gums.

Within 1 month - After the wound is completely healed, confirm the osseointegration status by light impact or Perio-test.

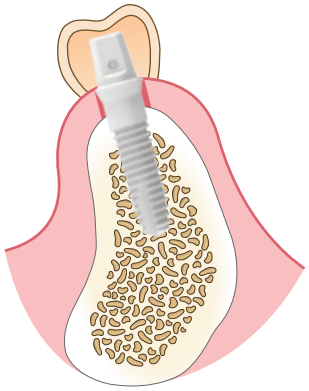
Within 3 months - confirm the osseointegration status and decide whether to perform an impression.

Within 6 months - determine whether to install a permanent crown.

3.2 Temporary prosthesis

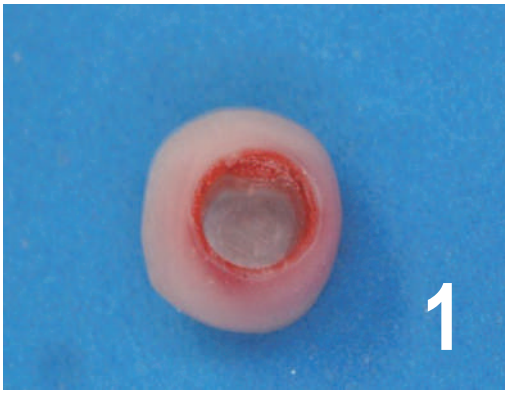


Use temporary coping as the base and coat with PMMA resin to make temporary crown.



Use spacer to make an implant protector and fix it on the adjacent tooth as a temporary restoration.

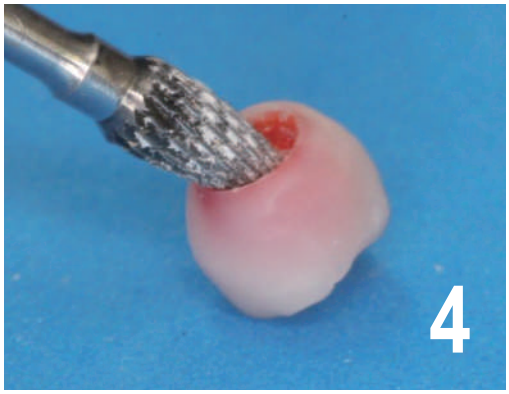
Image	Article	Spec.	Artical No.
	Temporary Coping	3.6 Implant	TM-3605
		4.0 Implant	TM-4005
		5.0 Implant	TM-5005
	Spacer	3.6 Implant	SP-3610
		4.0 Implant	SP-4010
		5.0 Implant	SP-5010



Use spacer as the base and make temporary restorations with PMMA resin.

Place the temporary restoration on the implant and adjust the occlusion to confirm that there is no contact point. Polishing and finishing.

Use silicone putty to make an index covering the occlusal surface and tongue side.

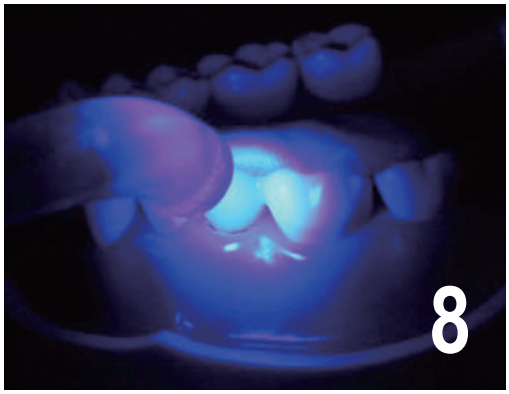


Remove Spacer from the temporary restoration. It's main body of the implant protector.

Apply a small amount of glue to the occlusal surface of the implant protector and fix it on the putty matrix.

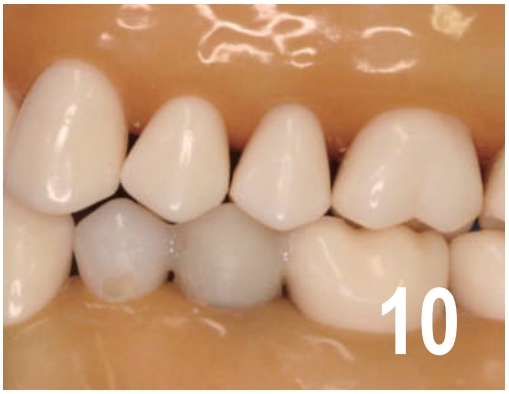
Apply temporary adhesive on the edge of the implant protector. (**Note that only on the edge**)

Etch the adjacent teeth, apply primer and adhesive. Put the implant protector into position through putty matrix and connect the implant protector to the adjacent teeth with resin cement.



After light curing, remove the putty matrix.

Confirm the bonding status, and remove excess adhesive.



Check the bite again and adjust to no contact point.

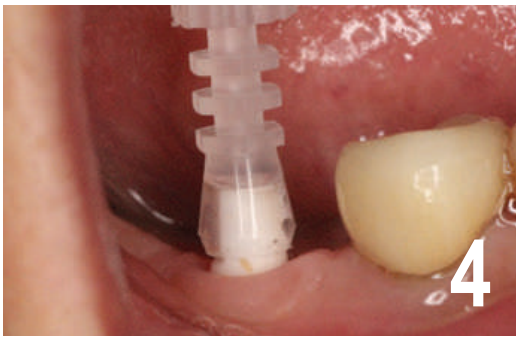
3.3 Impressing technique

3.3.1Conventional Impression Technique

Zibone abutment has a unique flat surface design for anti-rotation of prosthesis and can be used as an orientation reference when making the definitive impression. A preliminary impression with alginate could be used as a verification cast.

After the appropriate healing time, remove the healing cap and remove any debris from the surface of the abutment. Do not use The metal instrument to clean the surface because it will create the greyish scratch marks on the implant. Exam the stability and osseointegration before making the impression.

Make sure the surface is clean and ready for the impression procedure. Do not use metal instrument to clean the surface because it will create greyish marks on the surface.



The plastic impression cap is for single use only. Avoid repeatedly inserting and removing from the abutment as it will cause damage on the impression cap. It is one size for all 3 different diameters Zibone implants. Be careful to keep the flat surface on the impression cap to face the flat surface on the abutment. Insert the impression cap to the abutment and ensure completely seating on the abutment.

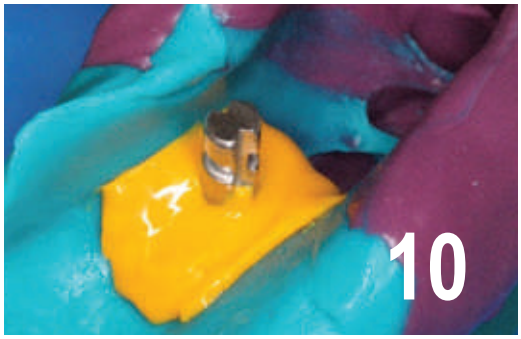
Select an appropriate size of tray. Avoid the contact of tray and impression cap. Shorten the impression cap if necessary. Use a self-curing acrylic resin to create an extension on the impression cap. Make a notch on the flat surface on impression cap as a reference for position. (Option)

Shorten impression cap with an acrylic resin extension, occlusal view. (Option)

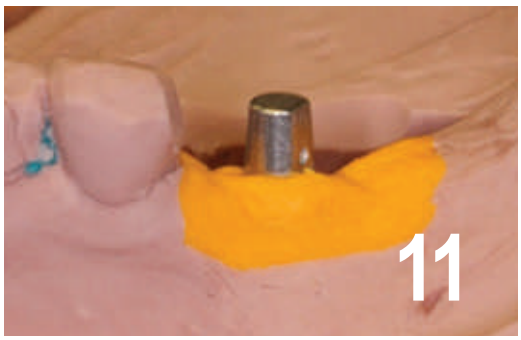
Load the impression material (polyvinyl siloxane, PVS). Inject additional impression material direct onto the impression cap and make an impression as conventional procedure. Additional material may be needed on the tray if there is an additional space above the occlusal plane due to the height of impression cap.

Remove the impression after material polymerizes. Exam any defect on the impression.

Insert the correct size of implant analog into the impression cap inside the impression.

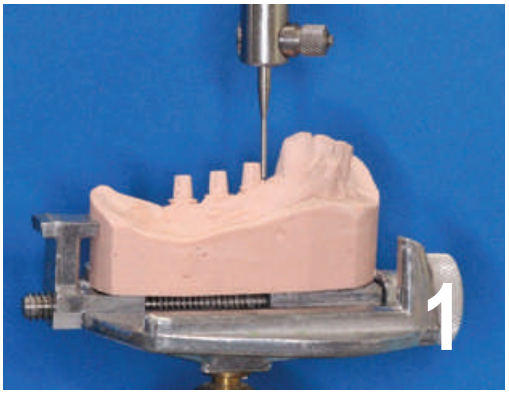


Paint a layer of separating material (Vaseline) on the impression material around the analog. Use a low viscosity PVS impression material to fabricate the soft tissue replica around the implant.



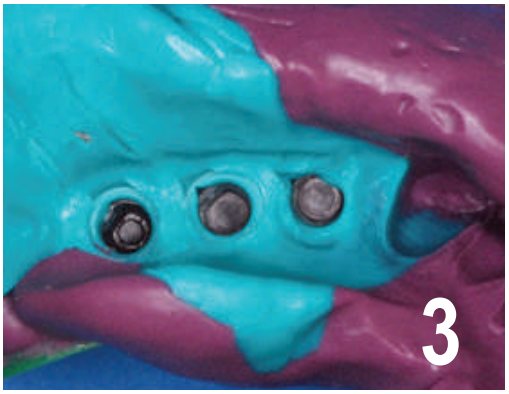
Pour the impression with a type 4 low expansion dental stone (SilkyRock; WhipMix). Mount the opposing cast and make a restoration as conventional technique; however, the all-ceramic material is recommended.

3.3.2 Alternative Impression Technique for Multiple Zibone Implants

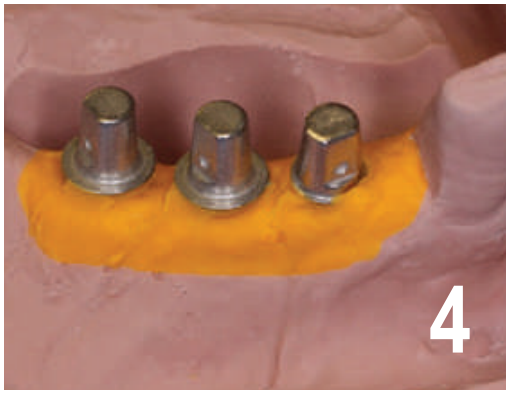


For multiple implants, make an alginate impression as a reference of the implant orientation and place the cast on a surveyor to check the parallelism. If the path of insertion is allowed for one unit restoration, the impression cap may be joined together before impression.

Use a diamond bur as a connecting tool. Create several notches on the flat end of the bur. Use a low expansion acrylic resin (Pattern resin or Duralay) to connect the impression caps before impression.



Make impression soft tissue replica as mentioned above.



Pour up with a Type 4 low expansion dental stone. After stone sets, remove the impression and mount with an opposing cast before sending to the lab for the definitive restoration.

3.4 Follow-up

It is recommended that patients regularly follow up for follow-up visits. Refer to the following table for follow-up records. If you like, you can send the information to the manufacturer for statistics. We will be very grateful for your assistance to make our products sustainable.

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Clinical Follow-up Case Report Form (Page 1/ 2)

Clinical Institution			
Dentist/Surgeon		Patient Age	
Patient ID		Surgery Date	
Patient Gender		Model NO./Lot NO.	
Restoration delivered date		Tooth Position	

Medical History	
Diabetes	☐ No ☐ Yes
Cardiovascular disease	☐ No ☐ Yes
Hypertension	☐ No ☐ Yes
Bone disease	☐ No ☐ Yes
Autoimmune disease	☐ No ☐ Yes
Smoking	☐ Never ☐ Yes, in the past but quit now ☐ Yes, _____ pack per day
Taking medicine that may affect osseointegration (e.g. Bisphosphate)	☐ No ☐ Yes

Dental History	
Edentulous on implant site	☐ Immediate placement ☐ < 3 months ☐ 3-12 months ☐ > 12 months
Periodontal Disease	☐ No ☐ Yes
Bruxism	☐ No ☐ Yes
Ridge augmented on surgical site	☐ No ☐ Yes

Surgery	
Bone graft material used around implant	☐ No ☐ Yes
Sinus perforation	☐ No ☐ Yes
Bone fracture during implant placement	☐ No ☐ Yes
Temporary restoration used	☐ No ☐ Yes, when _____
What type of prostheses was used	☐ N/A ☐ Fixed ☐ Removable
When did you deliver the temporary restoration	☐ Immediately ☐ < 48 hours ☐ 2~7 days ☐ > 1 week
Final insertion Torque	_____ Ncm

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Clinical Follow-up Case Report Form (Page 2/ 2)

	Post-surgery follow up period			
	1~2 Weeks	6 Months	1 Year	> 1Year
Fail to osseo-integrate / implant loosening	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Swollen gum	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Numbness on surgical site	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Sinus perforation	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Implant fracture	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Pain	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Regular follow up	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Exudate around implant	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Radiographic bone loss > 3mm with bleeding on probing	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Please provide X-ray and clinical photographs of each follow up period with the file name nomenclature rule：(Dr. name) - (Patient ID) - (Tooth position) - (Photograph date)				

The last follow up date (YYYY/MM/DD)	
Prosthetics type	☐ Single crown ☐ Splinted crowns ☐ Bridge
Prosthetic material	☐ Zirconia ☐ Lithium Disilicate ☐ Metal ceramic ☐ Metal

Any Other Adverse Effect Description (Post-surgery follow-up schedule depends on the individual clinical case situation)

Signature_____ Date_____

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