DIGITAL VERSION

ZiNova

IMPLANT SYSTEM

ZIRCONIA INNOVATION

Surgical Guide

ONE-PIECE SYSTEM

Ceramic Dental Implants

MABB
BIOMATERIAL

Contents

THE PROCEDURES DESCRIBED IN THIS DOCUMENT PROVIDE ESSENTIAL INFORMATION TO PERFORM THE SURGICAL AND PROSTHETICS TECHNIQUES OF THE ZINOVA BY MABB IMPLANT, “ONE-PIECE” MODEL. THIS GUIDE DOES NOT REPLACE THE USER INSTRUCTIONS. PLEASE ENSURE TO READ THE USER INSTRUCTIONS BEFORE USING THE PRODUCTS.

2023 ZINOVA ONE PIECE SURGICAL GUIDE

Scan to complete product warranty

ZINOVA LLC MABB HOLDING CORP. GROUP 28 Felmley Road, Whitehouse Station, NJ

Characteristics of the One-piece implant family

The micro and macro roughnesses on the ZiNova 3D Native implant surface (3D-N) allow for successful osseointegration following implantation.

Technical Properties of Zirconia

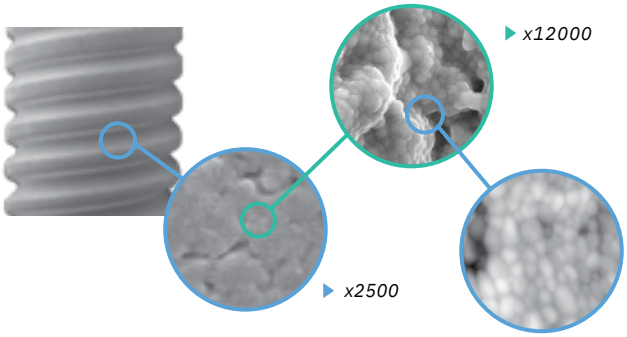
The mechanical efficiency of the ZiNova Zirconia One-piece implants is tested under the ISO 14801:2016 standard. The reported mechanical properties show the implants meet all mechanical requirements necessary for successful implantation.

Y-TZP PROPERTIES TABLE

Density *(g/cm³)*	6 g/cm³
Hardness HV *(Gpa)*	11,9
Elasticity unit *(Gpa)*	229

Implant surface

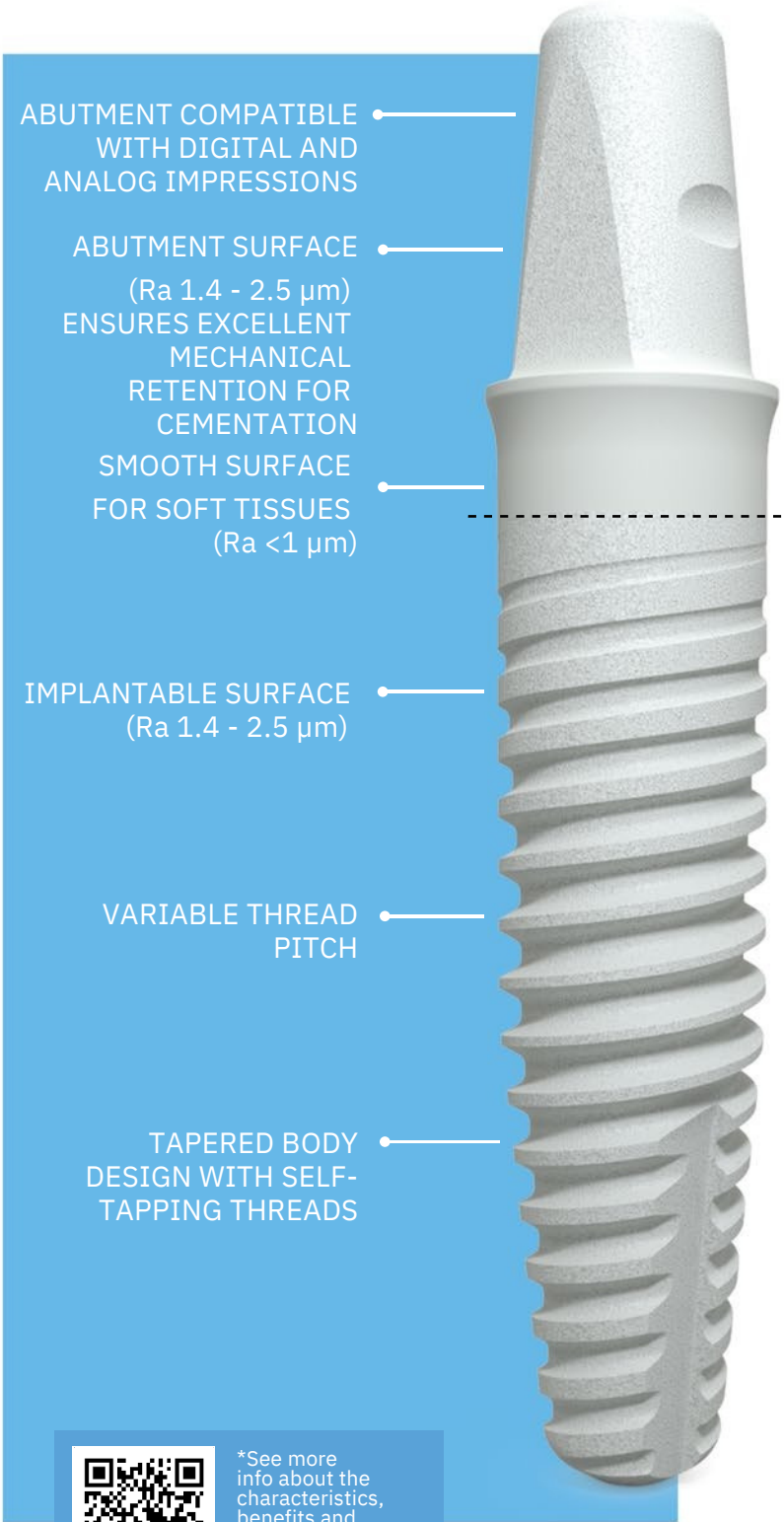
Ceramic Injection Molding (CIM) technology, an ultra-high pressure ceramic Injection process, allows us to design and develop micro and macro surfaces directly structured in the ZiNova implant mold. Compared to conventional milling manufacturing and post-processing steps, CIM technology does not require post-processing, resulting in reduced risk of impurities due to removing the need for these post-processing steps.



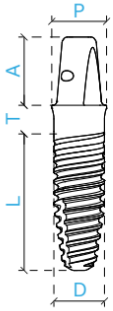
*Scanning electron microscopy (SEM) and atomic force microscopy (AFM) - macro and micro surface characteristics of the ZiNova implants**

ZiNova
IMPLANT SYSTEM
ZIRCONIA INNOVATION

Characteristics of the implant design



*See more info about the characteristics, benefits and scientific medical references in the ZiNova brochure.



Dimensions (mm)

D	L		P	T	A
3.7	10	13	4	1.8	5
4.3	10	13	4.8	1.8	5

D: Intraosseous body diameter;
L: Intraosseous length; P: Neck diameter;
T: Transmucosal height; A: Abutment height.

Surgical Procedure

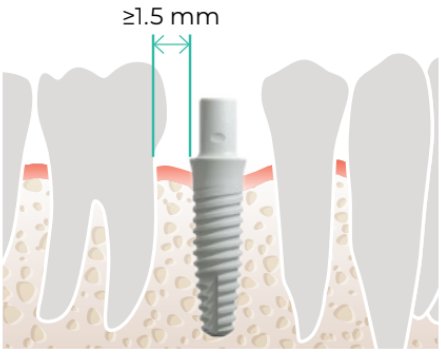
It is highly recommended that when using the ZiNova Ceramic Implant One-piece, the clinician ensures they are familiar with the specific product characteristics and general instructions for use of the system.

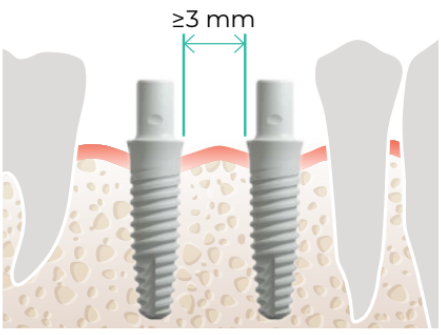
1. Surgical Planning

The diameter, implant type, position and number of implants should be selected individually, taking the anatomy and spatial circumstances into account. A prosthetic-driven planning is recommended.

Implant Positioning

To plan implant positioning, the following three basic rules must be followed





1. Distance to adjacent tooth at bone level: The required minimal distance from the implant shoulder to the adjacent tooth at bone level (mesial and distal) is ≥1.5 mm.
2. Distance to adjacent implants at bone level: the recommended minimal distance between to adjacent implant shoulders (mesiodistal) is ≥3 mm.
3. Special attention should be paid to the ZiNova Implant One-piece in order to achieve an optimal positioning of the implant.

NOTE

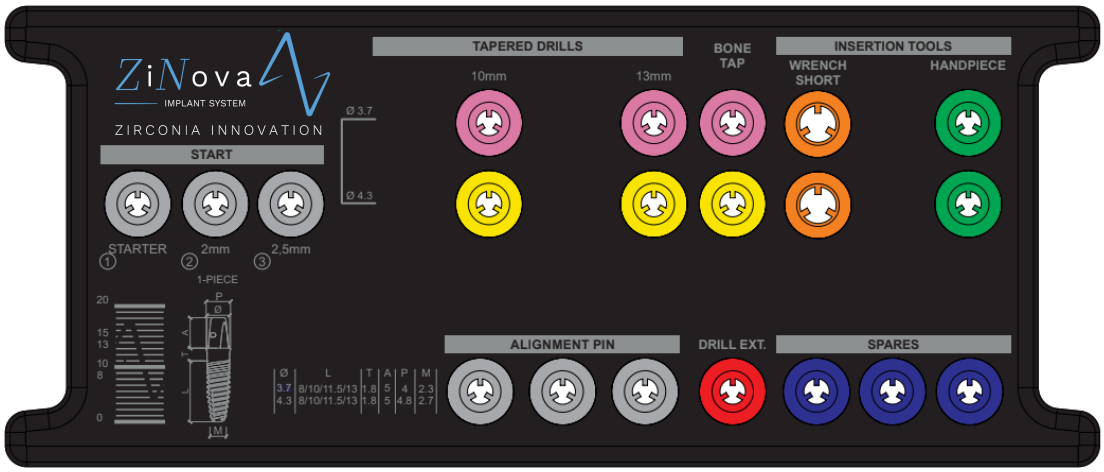
No angular correction of the abutments is allowed nor is placing the implant bodies at an angle (i.e., implants must be used in parallel to the direction of occlusal loading forces).

2. Preparation of the surgical bed

The preparation of the surgical bed is accomplished with the ZiNova Implants Surgical Kit

2.1 Surgical instruments

The Surgical Kit cassette consists of two separate levels for the items to be sterilized. The upper level is used to place the surgical tools and the lower level is destined for the Torque Wrench.



STARTER DRILL,
PRODUCT CODE: FLD

TWIST DRILLS,
PRODUCT CODE: FDR

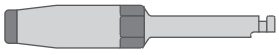
TAPERED DRILL,
PRODUCT CODE: FDA

BONE TAP,
PRODUCT CODE: FRR

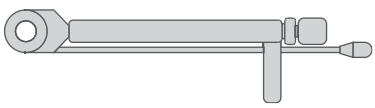
INSERT HANDPIECE
PRODUCT CODE: IMECZ

ALIGNMENT PIN,
PRODUCT CODE: PARZ

INSERT WRENCH,
PRODUCT CODE: ILLZ



DRILL EXTENDER,
PRODUCT CODE: PRF



TORQUE WRENCH,
PRODUCT CODE: TORQ-T

2.2 Alignment Pin

The usage of the Alignment Pin is important to ensure correct positioning of the implant during implant bed preparation. The alignment pin serves as a direction indicator and as a duplicate of the implant's neck and abutment. After the initial osteotomy with the Ø2mm twist drill, place the alignment pin in order to confirm angulation, depth of the implant and position of the restorative margin.

		PRODUCT'S CODE
Platform NP Ø3.7	Ø3.7x2.5 mm	PARZ3725-0
Platform RP Ø4.3	Ø4.3x2.5 mm	PARZ4325-0

3. Osteotomy

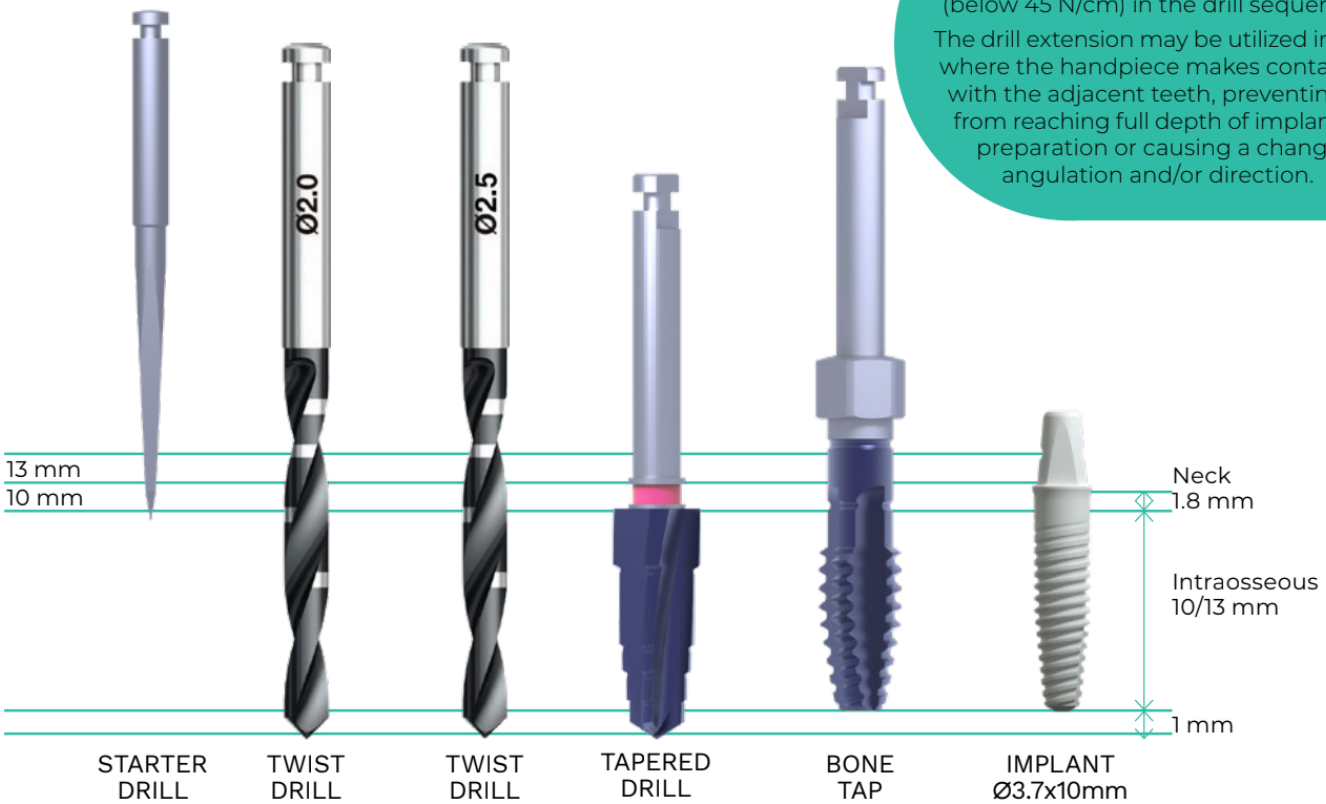
ZiNova One-piece Implant Ø3.7 mm

	Ø (mm)	RPM
Step 1 Starter drill	-	<1200
Step 2 Twist drill	2	<800
Step 3 Twist drill	2.5	<800
Step 4 Tapered drill	3.7	<800
Step 5 Bone tap*	3.7	<20

RECOMMENDATIONS

Follow the recommended sequence, with copious irrigation and torque control (below 45 N/cm) in the drill sequence.

The drill extension may be utilized in cases where the handpiece makes contact with the adjacent teeth, preventing it from reaching full depth of implant bed preparation or causing a change in angulation and/or direction.

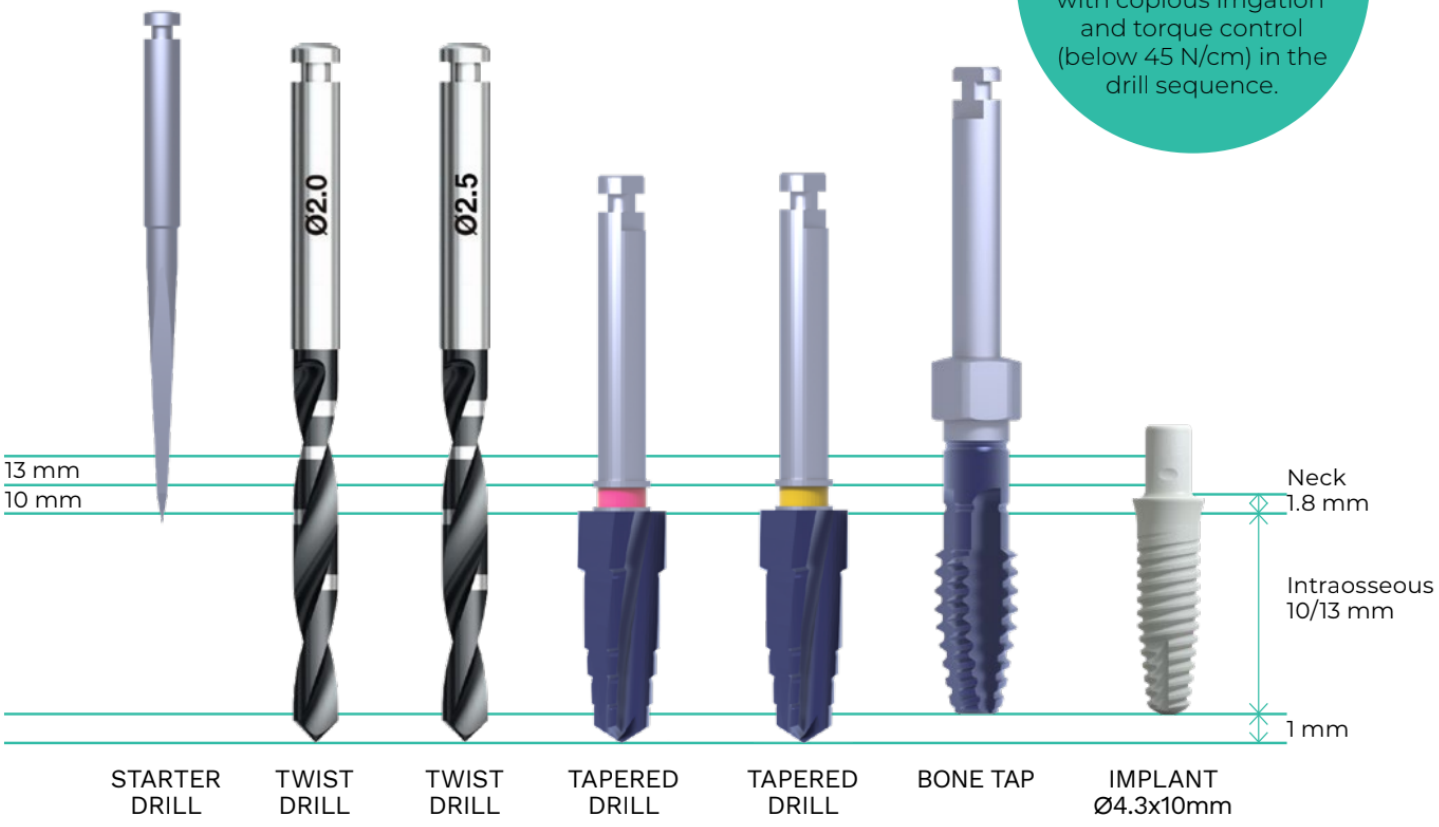


ZiNova One-piece Implant Ø4.3 mm

	Ø (mm)	RPM
Step 1 Starter drill	-	<1200
Step 2 Twist drill	2	<800
Step 3 Twist drill	2.5	<800
Step 4 Tapered drill	3.7	<800
Step 5 Tapered drill	4.3	<800
Step 6 Bone Tap*	4.3	<20

RECOMMENDATIONS

Follow the recommended sequence, with copious irrigation and torque control (below 45 N/cm) in the drill sequence.



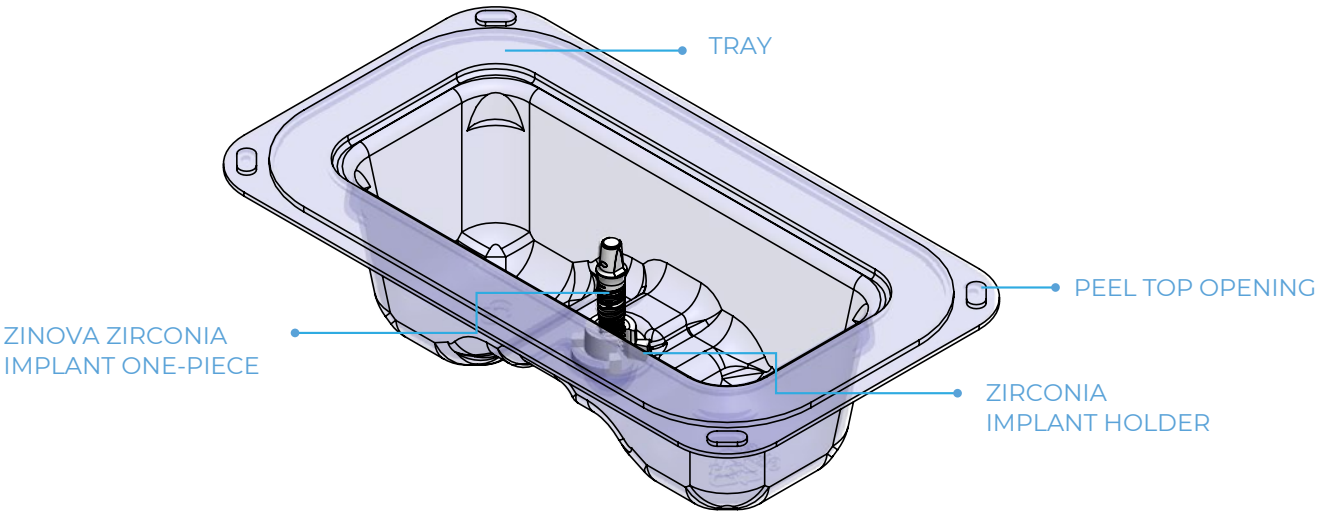
*Appropriate for high density osseous tissue, Eg: Bone type 1 and 2.

4. Implant Insertion

4.1 Container

The container allows for proper product handling and ensures its sterility. It is composed of a sterile tray which contains the ceramic implant holder. The ZiNova Zirconia Implant does not contact the plastic tray packaging.

This implant packaging design differs slightly from other packaging designs where the implant may be provided with a rigid cylinder in a tray with lid or another two-layer system. In this system, the implant is provided in a single sterile barrier packaging system with the implant held upright in a ceramic implant holder.



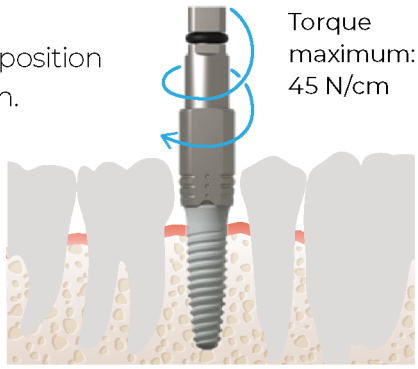
4.2 Aseptic Transfer

Care should be taken to ensure aseptic transfer of the implant into the sterile field. Open the implant as close to the time of use as possible. Have appropriate non-sterile personnel open and hold the opened device at the edge of the sterile field. Scrubbed individuals should use the Insert Handpiece to remove the implant from the implant holder. The Insert Handpiece directly couples with the top of the implant and is the same instrument used for initial positioning of the implant. Once firmly attached to the handpiece, the implant may then be transferred into the sterile field for initial positioning.

4.3 Implant Insertion Instructions

Instruments - Implant placement should be initiated with the insert Handpiece first to allow for better control of angulation/position.

The insert Wrench tool can be utilized to seat the implant to its final position and perform fine adjustments. Torque should not exceed 45N/cm.



Instruments	Implant placement can be performed manually or with a handpiece.
Step 1	Place the implant into position without exceeding the suggested torque of 45 N/cm.

5. Prosthetic Procedure

The recommended healing period to achieve successful osseointegration should be no less than 12 weeks.

In some situations like low bone density, poor primary stability, simultaneous bone grafting or other clinical situations, a longer healing period may be recommended. The clinican should determine, based on their experience and knowledge, what the appropriate healing time should be in these cases.

Once the implant is placed the steps that lead to a successful achievement of the final prosthetic procedures are the following:

1. Protection during the healing phase.
2. Delivery of a provisional prosthesis (if indicated).
3. Final impressions.
4. Delivery of the definitive prosthesis.

5.1 Healing

In clinical situations where a delayed or traditional loading approach is followed, the use of a protective healing cap is recommended.

This prosthetic accessory prevents and softens the unwanted chewing forces and protects the implant, ensuring a successful osseointegration.

In addition, this protective healing cap prevents the mucosa from covering the shoulder of the implant, and aids in the final conformation of the prosthetic emergence profile.

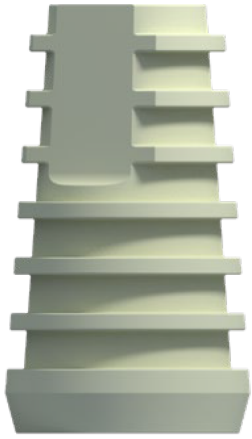
CHARACTERISTICS AND USAGE OF THE PROTECTIVE HEALING CAP

- Manufactured from PEEK.
- Must be cemented with provisional cement.
- Once set, remove excess cement.

	PRODUCT'S CODE
Healing Cap One-piece Ø3,7	TCI371-0
Healing Cap One-piece Ø4,3	TCI431-0

5.2 Provisional prosthesis preparation

In cases where a provisional crown is planned, it is recommended to use the Temporary Abutment, which is specifically designed to fit the implant abutment. This allows for proper retention and seal of the provisional restoration.



	PRODUCT'S CODE
Temporary Abutment One-piece Ø3.7	CZA37-0
Temporary Abutment One-piece Ø4.3	CZA43-0

NOTES AND INSTRUCTIONS

1. Place the Temporary Abutment on the implant's abutment, making sure it is properly seated.
2. If needed, trim the Temporary Abutment to the desired dimension (eg. occlusal adjustment)
3. Reline the provisional crown with the material of choice (acrylic/composite).
4. Trim the excesses and, if needed, repeat the procedure until achieving the appropriate contours.
5. Polish the provisional in order to obtain a smooth surface. This will reduce the bacterial plaque accumulation and minimize irritation of the soft tissues.
6. In cases of immediate provisionalization (immediate loading), ensure that the provisional is out of occlusion
7. Temporary cement should be used. Once cement is set, remove excess.

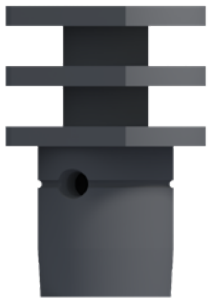
5.3 Taking impressions

For analog impressions, a closed tray impression technique is indicated for the ZiNova One-piece implant. It is recommended to use rigid impression trays.

Alternatively, a digital impression technique using an FDA-cleared intraoral/lab scanner can be used.

The Impression Coping is utilized for analog impressions. Proper seating of the cap should be verified. The use of this accessory allows for an exact reproduction of the intraoral situation.

Implant analogs are also available, providing a replica of the implant design.



IMPRE S SIONS

PRODUCT'S CODE

Ø3.7	Ø4.3
ZiNova-CIMZ37-0	Z 7- CIMZ4 3 - 0

ANALOGUES

PRODUCT'S CODE

Ø3.7	Ø4.3
ZiNova-AIZ37-0	ZiNova-AIZ43-0

NOTES AND INSTRUCTIONS:

1. If a provisional crown or a protective cap/ healing abutment was used, remove it. Remove all traces of temporary cement from the abutment and shoulder of the implant. It must be clean in order for the Impression Coping to fit without distortion.

2. Seat the appropriate Impression Coping over the implant's abutment, verifying that it is properly set and not moving. If any discrepancies are observed in the fit, replace the Impression Coping.

3. Take the impression utilizing conventional impression technique and materials.

4. Once the impression is taken, place the temporary cap or temporary restoration back on to avoid collapse of the soft tissues.

5. We recommend that the implant analog is placed in the impression by the clinician before sending it to the laboratory to ensure correct positioning.

6. Verify that the impression/analog is seated correctly before sending it to the laboratory.

7. Production of the working model in plaster and gingival mask in order to recreate the intraoral appearance.

5.4 Definitive restoration

Definitive restorations should be metal-free (zirconia, lithium disilicate, graphene, etc.) Laboratories may use conventional techniques to manufacture the definitive restorations.

A digital impression workflow may be followed for the ZiNova Zirconia One-piece implant and a digital impression can be taken using an FDA-cleared intraoral/lab scanner.

If a conventional impression (analog) technique was utilized, the laboratory can use a table scanner to import the data and fabricate the definitive prosthesis.

NOTES AND INSTRUCTIONS:

1. Prior to delivery/final cementation, the fit of the definitive restoration should be checked and appropriate adjustments should be made (if necessary).

2. Remove the Healing Cap or Temporary restoration and clean the excess cement from the implant abutment and shoulder.

   To minimize excess cement, cord can be packed and the analog can be used to extrude excess cement.

3. Cement the final restoration. A dual-cure cement is recommended.

4. Once the cement is set (according to the manufacturer's recommendation), remove excess cement.

6. Surgical and prosthetics components

Implants

ONE-PIECE IMPLANT

	PRODUCT'S CODE	
Length	Ø3.7	Ø4.3
10	Z13710	Z14310
13	Z13713	Z14313

Surgical Elements

STARTER DRILL

PRODUCT'S CODE
FLD Starter Drill

DRILL EXTENDER

PRODUCT'S CODE
PRF Drill Extender

TAPERED DRILL

	PRODUCT'S CODE	
Length	Ø3.7	Ø4.3
10	FDA3710	FDA4310
13	FDA3713	FDA4313

TWIST DRILLS

	PRODUCT'S CODE
Ø	
2	FDR2
2.5	FDR25

BONE TAP

PRODUCT'S CODE	
Ø3.7	Ø4.3
FRRZ37	FRRZ43

ALIGNMENT PIN

	PRODUCT'S CODE
Allignment Pin One-piece Ø3.7 x 2.5	PARZ3725-0
Allignment Pin One-piece Ø4.3 x 2.5	PARZ4325-0

INSERT WRENCH

	PRODUCT'S CODE
Insert Wrench One-piece Ø3.7 H2	ILLZ37-0
Insert Wrench One-piece Ø4.3 H2	ILLZ43-0

INSERT HANDPIECE

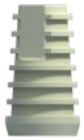
	PRODUCT'S CODE
Insert Handpiece One-piece Ø3.7	IMECZ37-0
Insert Handpiece One-piece Ø4.3	IMECZ43-0

TORQUE WRENCH

PRODUCT'S CODE
TORQ-T

PROTECTIVE/HEALING CAP

	PRODUCT'S CODE
Healing Cap One-piece Ø3.7 H1	TCI371-0
Healing Cap One-piece Ø4.3 H1	TCI431-0



PROVISIONALS

	PRODUCT'S CODE
Temporary Abutment One-piece Ø3.7	CZA37-0
Temporary Abutment One-piece Ø4.3	CZA43-0

IMPRESSION COPING

	PRODUCT'S CODE
Impression Coping One-piece Ø3.7	CIMZ37-0
Impression Coping One-piece Ø4.3	CIMZ43-0

ANALOGOUS

	PRODUCT'S CODE
Implant Analog One-piece Ø3.7	AIZ37-0
Implant Analog One-piece Ø4.3	AIZ43-0

Legal Notes

CLARIFICATION

Clinicians must have knowledge of dental implantology and instruction in the handling of the ZiNova product described herein ("ZiNova Product") to use the ZiNova Product safely and properly in accordance with this guide. The ZiNova Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine whether the device fits the patient's individual situation.

The ZiNova Product is part of an overall concept and must only be used in conjunction with corresponding original components and instruments distributed by ZiNova LLC, its ultimate parent company and all affiliates or subsidiaries of the parent company ("ZiNova"). Use of third-party products not distributed by ZiNova voids any warranty or other obligation, express or implied, of ZiNova.

Any issues that arise in relation to the device should be reported together with the impacted product to the local ZiNova organization. In the event of a serious incident, the user must file a report to the local ZiNova organization and the appropriate competent authority as required by local regulations.

AVAILABILITY

Some items of the ZiNova Dental Implant System are not available in all countries.

PRECAUTIONS

Aside from the precautions noted in this document, our products must be protected against inhalation when used in intraoral procedures.

DOCUMENTATION

In order to obtain detailed instructions of the ZiNova Zirconia Implant System, contact your representative or authorized distributor in your country.

COPYRIGHT AND TRADEMARKS

Warranty

All the ZiNova Zirconia Implants have a life-time warranty. No grinding of any part of the implant is allowed. Grinding can lead to a reduction in structural integrity of the implant material, thus causing implant fracture during normal occlusal loading. There is also the risk of bone necrosis due to excessive heat generated during the grinding of ceramics. Grinding of any part of the implant will void any warranties, express or implied, of ZiNova LLC, its parent company and any of its affiliates.

For more information and to activate the warranty, the clinician must scan the QR code in the packaging.

ZiNova

IMPLANT SYSTEM

ZIRCONIA INNOVATION

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MABB

BIOMATERIAL

BIOENGINEERING | CIM TECHNOLOGY
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ISO 13485

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