ZiNova Zirconia
Implant One Piece

Instructions For Use

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1. Device description

The ZiNova Zirconia Implant System is an integrated system of endosseous dental implants (ZiNova Zirconia Implant One Piece) and PEEK prosthetic parts. The ZiNova Zirconia Implant One Piece are yttria stabilized tetragonal zirconia (Y-TZP) dental implants composed of a One Piece, monotype implant with an integrated abutment. The implant is manufactured via a ceramic injection molding with the macro and micro surface characteristics of the implant directly structured in the mold. The implant body portion is configured to extend into the bone and osseo-integrate with the alveolar bone. The neck should be positioned 1.8mm above the bone. The implants come in corresponding diameters of 3.7 and 4.3 mm.

2. Material

The ZiNova Zirconia Implant One Piece is made of 100% yttria- stabilized zirconia.

Chemical components	Composition % (mass/mass)
$ZrO_2+HfO_2+Y_2O_3$	> 99
Y_2O_3	> 4.5 to ≤ 6.0
HfO_2	≤ 5
Al_2O_3	≤ 0.3
Other oxides	≤ 0.2

The ZiNova Zirconia Implant One Piece Healing Caps and Temporary Abutments are composed of PEEK.

3. Intended Use

The ZiNova Zirconia Implant One Piece is intended for oral implantation to provide a support structure for connected prosthetic devices.

4. Indications for Use

The ZiNova Zirconia Implant System is intended for surgical placement in the patient's upper and lower jaw to provide support for prosthetic devices, such as artificial teeth and in order to restore the patient chewing function. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The ø3.7 mm reduced diameter implants are recommended for central and lateral incisors only.

5. Intended Users and Patient Group

The ZiNova Zirconia Implant One Piece is intended for use in adult (21 years of age or older) subject to dental implant treatment

The ZiNova Zirconia Implant One Piece is to be used by dental healthcare professionals.

6. Contraindications

It is contraindicated to use ZiNova Zirconia Implant One Piece in:

- Patients who are medically unfit for an oral surgical procedure
- Patients with alcohol addiction or psychiatric disorders, blood dyscrasias, uncontrolled diabetes, hyperthyroidism, oral infections, malignancies, or patients who have had myocardial infarction within the last 12 months.
- Patients with systemic diseases that compromise the immune system, such as AIDS, patients on medications that would compromise healing of an implant site, patients with a history of poor or non-compliance to oral hygiene procedures, or patients who cannot maintain oral hygiene procedures if implants are placed.
- Patients in whom adequate sizes, numbers, or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads
- Patients who are allergic or hypersensitive to zirconium dioxide (ZrO_2), yttrium oxide (Y_2O_3), hafnium dioxide (HfO_2), or aluminum oxide (Al_2O_3).
- Tobacco usage increases the occurrence of complications and failures.

7. Warnings

Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.

Take care to avoid the mandibular nerve canal during implant bed preparation and implant insertion. Nerve damage may result in anesthesia, paresthesia, or dysesthesia.

Do not exceed recommended insertion torques (> 45 Ncm). Exceeding recommended insertion torques may cause bone necrosis.

Do not grind or modify the implant. No grinding or modification of any part of the implant is allowed. Grinding or modification can lead to a reduction in structural integrity of the implant material causing implant fracture during normal occlusal loading. Bone necrosis may also result due to excessive heat generated during the grinding of ceramics. Grinding or modification of any part of the implant will void any warranties, express or implied, of ZiNova LLC, its parent company and any of its affiliates.

8. Cautions

The ZiNova Zirconia Implant One Piece should not be placed in bones other than the maxilla or mandible.

Use with adequate bone quality and/or volume that allows primary stability. Inadequate bone volume and/or quality might lead to insufficient primary stability.

Always select the implant with the largest diameter that can be supported by the available bone thickness, bone quality, interdental spacing, and anticipated mastication forces.

Particular care should be taken to ensure proper implant alignment where comparatively high loads are expected.

A careful clinical and radiological examination should be performed prior to surgery to determine the patient's psychological and physical status. Special attention should be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or with the osseointegration process (e.g. bone metabolism disturbances, type 1 diabetes mellitus, anticoagulation therapy/bleeding disorders, bruxism, parafunctional habits, unfavorable anatomic bone conditions, tobacco abuse, untreated periodontal diseases, acute implant site infection, temporomandibular joint disorders, treatable pathologic diseases of the jaw and changes in the oral mucosa, pregnancy, or inadequate oral hygiene).

It is strongly recommended that ZiNova Zirconia Implant System instruments and prosthetic components are used only with ZiNova Zirconia Implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue, or unsatisfactory esthetic results.

Do not use the ZiNova Zirconia Implant One Piece after the expiration date indicated on the packaging.

Do not process or re-sterilize the ZiNova Zirconia Implant One Piece. Cleaning and sterilization may compromise essential material and design characteristics, leading to device failure.

Do not re-use the ZiNova Zirconia Implant One Piece. Re-use of single-use devices creates a potential risk of patient or user infections.

Sterile handling is essential. Never use potentially contaminated components. Contamination may lead to infections.

As with all surgical procedures, the operatory field should be maintained with sterile coverings (light handles, chair controls, bracket tray, and all instruments and components). Barrier technology, sterile solutions and sprays, sterile coverings, and proper autoclaving techniques must be employed as indicated.

Avoid corrections of the vertical position using reverse (counterclockwise) rotation. This may lead to decreased primary stability.

Due to the one piece design of the ZiNova Zirconia Implant One Piece, there is a higher risk of implant removal if the abutment is damaged or fractured. If the implant needs to be explanted, it should be done with a minimally invasive technique. Always secure the implant against aspiration when removing the implant.

Immediately after the insertion of dental implants, activities that demand considerable physical exertion should be avoided.

9. **MRI Safety Information** The ZiNova Zirconia Implant One Piece and its provisional components are MR-SAFE.

10. Residual Risks and Side Effects

The clinical outcome of dental treatment is influenced by multiple variables. The following possible residual risks and side effects relate to the ZiNova Zirconia Implant One Piece and may lead to additional treatment at the dentist's office:

- Bite/mastication/phonetic problems
- Bone damage
- Bone compression
- Hypersensitivity/allergic reactions
- Implant fracture
- Longer recovery/healing time than expected Loss of implant
- Loss of prosthetic components
- Other toxicity reactions
- Poor esthetic outcome
- Risk of surgical implant explantation
- Risk of swallowing/inhaling small parts during the procedure
- Sinus perforation
- Nerve damage possibly resulting in chronic pain
- Paresthesia
- Dysesthesia
- Swelling
- Local inflammation
- Bruising
- Maxillary/mandibular ridge bone resorption
- Systemic or local infection (including peri-implantitis, periodontitis, gingivitis, fistula)
- Minor bleeding

11. Compatibility Information

The ZiNova Zirconia Implant One Piece and its prosthetic components are available in a variety of configurations. Only use ZiNova parts with the corresponding connection for restoring a ZiNova Zirconia Implant One Piece (e.g. for prosthetic platform RP "Regular Platform" only components noted RP can be used. For prosthetic platform NP "Narrow Platform" only components noted NP can be used).

Property	Regular Platform (RP)	Narrow Platform (NP)
Interosseous Diameter	3.7 mm	4.3 mm
Neck Diameter	4 mm	4.8 mm
Implant Part Number(s)	Z14310 (10 mm length) Z14313 (13 mm length)	Z13710 (10 mm length) Z13713 (13 mm length)
PEEK Healing Cap Part Number	TCI431-0	TCI371-0

PEEK Temporary Abutment Part Number	CZA37-0	CZA43-0

12. Cleaning and Disinfection

The ZiNova Zirconia Implant One Piece and prosthetic components are delivered for single use. Do not process or re-sterilize the ZiNova Zirconia Implant One Piece or prosthetic components prior to use. Cleaning and sterilization may compromise essential material and design characteristics, leading to device failure.

Refer to "Z7LLC-ONE-PIECE-IFU-INSTRUMENTS-v1" ZiNova Zirconia Implant One-piece Surgical Kit Instructions For Use

13. Sterilization

The ZiNova Zirconia Implant One Piece is delivered sterile for single use. Do not re-sterilize the implants. The tamper-proof packaging system protects the sterilized device from outside influences and, if the device is stored correctly (see "Storage"), ensures sterility up to the expiration date.

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.

Check the implant packaging for damage prior to use. Devices with a damaged packaging system must not be used. It is recommended to have a replacement on hand. ZiNova LLC does not accept any responsibility for re-sterilized devices initially delivered sterile, regardless of who carries out re-sterilization or by what method. **A previously used or non- sterile implant must not be used under any circumstances.** If the original packaging is damaged, the contents will not be taken back by Z7 LLC.

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**.** Refer to Section 14 for appropriate techniques for implanting the device.

The ZiNova Zirconia Implant healing caps and temporary abutments are delivered non-sterile for single use. **Do not sterilize the PEEK healing caps or temporary abutments in the ZiNova instrument tray.** For sterilization, the healing caps and temporary abutments must be removed from their original packaging, cleaned and placed into individual standard separate steam sterilization pouches. Steam sterilization pouches must be standard, medical grade, steam sterilization pouches that meet all applicable regulatory requirements (e.g., ISO 11607-1, FDA cleared, etc.).

Prior to use, steam sterilize ZiNova Zirconia Implant healing caps and temporary abutments using the following conditions:

- Steam Sterilization Method: Gravity Cycle
- Minimum Temperature: 121°C
- Cycle Time: 30min
- Minimum Dry Time: 30min

14. Procedure

Refer to "SURGICAL GUIDE" Z7LLC-ONE-PIECE-STG-v1 for complete instructions on how to prepare the implant site, implant the ZiNova Zirconia Implant One Piece, and use supporting instruments and temporary prosthetic components.

14.1. Preoperative planning

The implant diameter, implant type, position and number of implants should be selected individually, taking the anatomy and any spatial circumstances into account. The measurements given should be regarded as minimum guidelines and are further specified in the basic information brochures on the surgical procedures.

14.2. Implant bed preparation

The ZiNova Implants Surgical Kit instruments must be used for implant bed preparation. Take care to minimize excessive rises in temperature. Heat damage prevents healing of a dental implant. Follow all specified recommendations for drilling speeds, intermittent drilling techniques and adequate cooling when preparing the implant site for ZiNova Implants.

14.3. Insertion of the implant

The main aim during implant insertion is to achieve a good primary stability of the implant. A ZiNova Zirconia Implant One Piece can be placed either manually with the Insert Wrench or with the aid of the Insert Handpiece. A maximum speed of 15 rpm is recommended. Place the implant using a maximum insertion torque of 45 Ncm.

14.4. Treatment of soft tissue, wound closure

Due to the design of the ZiNova Zirconia Implant One Piece only transmucosal healing is possible.

15. Healing Phase

The healing time required for osseointegration varies considerably and depends on the specific patient and individual treatment. It is the sole responsibility of the clinician to decide when the implant can be loaded. If temporary components are

used during the healing phase, they must not be placed in occlusion.

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 clinician should determine, based on their experience and knowledge, what the appropriate healing time should be in these cases.

The maximum permanence time indicated for a Healing Cap or temporary abutment is 180 days.

Final restorations may be placed in occlusion when the implant is completely osseointegrated.

16. Further Information

Reference documents:

- "Surguical Guide" Z7LLC-ONE-PIECE-STG-v1

- "ZiNova Zirconia Implant One-piece Surgical Kit Instructions For Use"

  Z7LLC-ONE-PIECE-IFU-INSTRUMENTS-v1

Further information regarding different types of ZiNova dental implants and other components of the ZiNova Zirconia Implant System is available online on the ZiNova Implants website or via the local ZiNova organizations.

17. Storage

Store ZiNova Zirconia Implant System components in a dry place in their original packaging at room temperature and protected from direct sunlight. Improper storage may compromise essential material and design characteristics, leading to device failure.

18. Disposal

Disposal should be handled in an environmentally sustainable manner according to local regulations. Hazardous waste from contaminated devices or sharps should be disposed of in appropriate containers which meet specific technical requirements.

19. Information to be Provided to the Patient

Information on contraindications, warnings, precautions, side effects and complications with ZiNova products should be provided to the patient. The patient must be informed about MRI compatibility regarding the ZiNova products used.

20. Please Note

Clinicians must have sufficient education and knowledge of dental implantation techniques and instruction in the handling of the ZiNova Zirconia Implant One Piece described herein ("ZiNova Product") to use the ZiNova Product safely and properly in accordance with these instructions for use.

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 Z7 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.
The ZiNova Lifetime Guarantee and ZiNova Guarantee Questionnaire are available in hardcopy and online on the website of the appropriate local ZiNova organization.

21. Validity

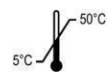
Upon publication of these instructions for use, all previous versions are superseded.

22. Availability

Some items of the ZiNova Zirconia Implant One Piece are not available in all countries.

23. Symbols

The following table describes the symbols that may be printed on the packaging label. Please refer to the packaging label for the applicable symbols related to the product.

Symbol	Description
	Catalog Number
	Lot Number
	Quantity
	Use-by Date
	Single Use Only
	Sterilized using Ethylene Oxide
	Non-sterile
	Do not use if package is damaged and consult instructions for use
	Do not resterilize
	Temperature limits
	Consult instructions for use
	Manufacturer