ZiNova Zirconia Implant
One-piece

Surgical Kit 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 prosthetic components including the healing caps and temporary abutments. The ZiNova Surgical Kit consists of the reusable surgical instruments including surgical drivers and surgical drills used during implantation of ZiNova Zirconia Implants.

2. Material

The healing caps and temporary abutments are made in Polyetheretherketone (PEEK).

The ZiNova Zirconia Surgical Kit instruments are composed of stainless steel and titanium alloys.

3. Cautions of Use

ZiNova Zirconia Implant System instruments are only designed to be compatible with ZiNova Zirconia Implants. Do not use ZiNova Zirconia Implant System instruments with other systems. Combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue, or unsatisfactory esthetic results.

The ZiNova Surgical Kit and prosthetic components are provided non-sterile and must be sterilized before use.

As with all surgical procedures, the sterile 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.

Create a surgical plan before implantation of ZiNova Zirconia Implant One-piece.

ZiNova Surgical Kit instruments must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury. After surgery, surgical instruments should be thoroughly washed, cleaned, and sterilized in accordance with the validated methods.

4. Directions for Use

4.1. Matters to Prepare Before Use

Check instruments for damage prior to use. Instruments should only be used in surgery after checking for any damage or problems with the product.

The user should completely understand the surgical sequence and protocol by using the ZiNova Zirconia implant One-piece surgical instruments prior to performing the dental procedure.

Clean the surgical instruments and the prosthetic components per the specified, validated methodology (See “Manual / Automated Cleaning Steps”). Use of other sterilization cleaning processes have not been validated.

Sterilize the surgical instruments and the prosthetic components per the specified, validated methodology (See “Sterilization Conditions”). Use of other sterilization methods / settings have not been validated.

The surgeon, dentist and dental technician should have a surgical plan in place and discuss the patient’s case prior to surgery

4.2. During Surgery

Refer to “SURGICAL GUIDE” Z7LLC-ONE-PIECE-STG-v1 and “ZiNova Zirconia Implant One- Piece Instructions for Use” Z7LLC-ONE-PIECE-IFU-IMPLANT-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.

Follow all specified recommendations for drilling speeds, intermittent drilling techniques, and adequate cooling when preparing the implant site for ZiNova Implants.

Irrigate with copious amounts of normal saline to prevent overheating of drills during drilling protocol.

5. Manual Cleaning Steps

Completely submerge instruments and the prosthetic components in a diluted solution of enzyme cleaning agent and soak for at least 20 minutes (dilution ratio: 1g/1L). Only FDA cleared cleaning agents recognized for cleaning of instruments should be used.

After the soak, clean the device using soft, non-abrasive brushes (e.g., nylon brush) in the soak solution or fresh cleaning solution. Pay attention to rough services, mated surfaces, crevices, lumens, joints, and other hard-to-clean areas where soil may be trapped. Operate the action of any moving parts and brush the revealed surfaces to remove any soil. The appropriate size and shape brushes should be selected for each lumen or crevice. Brush the entire surface of the device for a minimum of 1 minute.

Rinse each instrument and prosthetic part for 3 minutes with running tap water to remove enzyme cleaning

agent residue.

Rinse each instrument and prosthetic part with distilled water for 1 minute (3 times or more). Dry for 60 minutes at a dryer temperature of 60°C.

6. Automated Cleaning Steps

Prosthetic components must not be cleaned using an automatic washing machine. Only the instruments can be cleaned with an automatic washing machine.

Completely submerge instruments in a diluted solution of enzyme cleaning agent and soak for at least 20 minutes (dilution ratio: 1g/1L). Only FDA cleared cleaning agents recognized for cleaning of instruments should be used.

Prepare an ultrasonic bath large enough to submerge the instrument(s) in a diluted solution of enzyme cleaning agent (dilution ratio: 1g/1L). Only FDA cleared cleaning agents recognized for cleaning of instruments should be used.

Submerge the instrument(s) in the diluted solution of enzyme cleaning agent ultrasonic cleaner and ultrasonically clean for 20 minutes at 40°C.

Refill the ultrasonic cleaner with tap water. Submerge the instrument(s) in the water and ultrasonically clean for 3 minutes at 40°C.

Rinse with distilled water for 1 minute (3 times or more).

Dry for 60 minutes at a dryer temperature of 60°C.

7. Pre-Sterilization Inspection

Prior to sterilization, all instruments must be inspected to ensure they are clean, undamaged, and functional. Inspection may generally be performed without magnification if there is adequate lighting. Inspect for the following:

- Verify that no soil or contaminants are present on the surface of the instrumentation including drills, wrenches, and connecting components.
- Inspect cutting edges to ensure that edges are sharp with no visible damage. Damage includes dents, chips, burrs, nicks, or other visible damage.
- Verify that identifying markings are present and legible.
- If soil is present on the trays, they may be cleaned with lint- free wipes and an alkaline disinfection solution followed by a rinse with clean water.

8. Sterilization Conditions

Wrap instrument tray in two layers of FDA cleared sterilization wraps (1-ply Halyard H300 or equivalent) using sequential wrapping techniques.

Steam Sterilization Method: Gravity Cycle (Wrapped)

- Minimum Temperature: 121°C
- Cycle Time: 30min
- Minimum Dry Time: 30min

Do not sterilize the PEEK healing caps or temporary abutments in the instrument tray.

Refer to Z7LLC-ONE-PIECE-IFU-IMPLANT-v1 “ZiNova Zirconia Implant One-Piece Instructions for Use” for PEEK healing cap and temporary abutment sterilization information.

9. Storage Conditions

Store in a surgical cabinet equipped with sterilizer.