

Instruction for Use

1. Product Description

This product is a set-configured medical device consisting of an implant, endosseous, hand instrument, implant, endosseous, drill/handpiece, implant, endosseous, screwdriver, and a measuring instrument, general-purpose, intended for use in dental implant procedures.

2. Intended Use

- (1) Dental Implant Surgical Instruments: This instrument is intended to be used in dental implant procedures to assist in the handling, positioning, or placement of endosseous dental implants and associated components.
- (2) Dental Implant Surgical Drill: This device is intended to be attached to a surgical handpiece and used for the removal of bone tissue during endosseous dental implant procedures.
- (3) Dental Implant Surgical Screwdriver: This device is intended for use in the assembly of dental implant components by delivering torque to fasteners such as screws or abutments during implant placement.
- (4) Measuring Gauge: This instrument is intended for intraoperative measurement of anatomical structures, such as soft or hard tissues, in order to assist in the accurate placement of dental implants or components.

3. Sterility

- This product must be sterilized in an autoclave at 132°C exposure for 15 minutes with 15 minutes minimum drying time.

4. Procedure

A. Preparation Before Use

- Surgical techniques for dental implants require specialized and complex procedures, so relevant formal education and training for implant procedures are needed.
- Dental instruments are user-sterilized medical devices and should be sterilized in an autoclave at 132°C for 15 minutes and dried for 15 minutes before use.

B. Applications

(1) Dental Implant Surgical Instruments:

- ① Parallel Pin: Used to confirm the position, direction, and path of bone preparation by inserting it into the drilling hole before implant placement.
- ② Drill Extension: Used to extend the length of handpiece instruments.
- ③ Torque Extension: Used to extend the length of Torque Wrench instruments.
- ④ Tissue Punch: Used in Flapless Surgery, which is performed without incising the gingiva during dental implant surgery.
- ⑤ Torque Wrench: An instrument that, when connected to a driver, allows torque to be applied by pulling the bar to match the desired torque value.
- ⑥ Ratchet Wrench: After attaching a ratchet-type dental implant surgical screwdriver to the connection part of the wrench, manually operate the wrench to apply torque to the dental implant surgical screwdriver.

(2) Dental Implant Surgical Drill:

- ① Stopper Drill (Ø2.2): Used for initial drilling at the desired implant placement site. It has a lateral cutting function, allowing for path correction.

- Recommended usage speed for Stopper Drill: 1,200-1,500 rpm for hard bone and normal bone, 800-1,200 rpm for soft bone.
- ② Stopper Drill (F3.5 / F4.0 / F4.5 / F5.0): Used for drilling to the diameter and depth suitable for the implant to be placed.
 - Recommended usage speed for Stopper Drill: 1,200-1,500 rpm for hard bone and normal bone, 800-1,200 rpm for soft bone.
- ③ Cortical Drill: Used after forming the final drill hole in hard bone.
Recommended usage speed for Cortical Drill: 800-1,200 rpm.
- ④ Lance Drill: Used for initial formation of the implant placement hole. Its thin, pointed tip allows for marking the desired placement position and piercing the bone.
- ⑤ OTP Bur: Used to cut and flatten narrow bone using its lateral blade.
- ⑥ Straight Drill: Used for drilling to the diameter and depth suitable for the implant to be placed.
 - Recommended usage speed for Straight Drill: 1,200-1,500 rpm for hard bone and normal bone, 800-1,200 rpm for soft bone.

(3) Dental Implant Surgical Screwdriver:

- ① Implant Driver (H.P): A driver used for implant placement, connected to a handpiece. It has a holding function for moving the implant from the ampule to the oral cavity.
- ② Implant Driver (T.W): A driver used for implant placement, connected to a Torque Wrench.
- ③ Hex Driver (H.P): A 1.2 Hex driver for handpiece connection.
- ④ Hex Driver (T.W): A 1.2 Hex driver for Torque Wrench connection.
- ⑤ Hex Driver (Manual): A 1.2 Hex driver for manual use.

(4) Measuring Gauge:

- ① Depth Gauge: Used to measure the depth of the drilling hole after initial drilling.

C. Management after use

- After the procedure, all used instruments should be immediately disassembled, washed under running water, dried, and stored at room temperature.
- Do not store in areas with potential for contamination.

5. Warning

- Implants must be placed by an experienced dentist, as improper techniques can cause damage to the implant or surrounding bone tissue.
- Improper patient selection and procedure may lead to implant surgery failure or bone loss.
- Movement of the implanted implant, bone loss, and chronic infection can lead to implant surgery failure.

6. Caution

- Contaminated products due to use error during the procedure should not be used.
- Recommended usage limit for drill is 50 times
- If the recommended number of uses for a drill is exceeded, implant failure may occur due to bone heating caused by reduced cutting efficiency of the drill; therefore, adhere to the recommended number of uses.
- Recommended usage limit for driver is 50 times, and the maximum permissible torque for a 1.2 Hex Driver is 35 N.cm.

- If the recommended number of uses and torque are exceeded, implant failure may occur due to wear and fracture of the driver, leading to loss of product function; therefore, adhere to the recommended number of uses.
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- This product is a user-sterilized medical device and should be sterilized in an autoclave at 132°C for 15 minutes and dried for 15 minutes before use.
- Hydrogen peroxide, used as a disinfectant and cleaning agent, is prohibited as it can cause damage or discoloration to TiN-coating, laser marking, and/or color coding.

7. Contraindication

Do not use in the following patients:

- Patients with a history of heart attack or arteriosclerosis
- Patients who are uncooperative or who have mental or physical disabilities that may cause instability, fixation failure or other complications regarding the implant during post-surgical management.
- Patients with conditions affecting bone formation, microcirculation, or blood.
- Pregnant patient.
- Patients with hypertension or diabetes.

8. Storage

Store at room temperature (1~30°C).

9. Disposal

Follow local regulations and laws for the disposal of medical devices.



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