

# Drill Bit / Drill

## INSTRUCTIONS FOR USE



### JEILMEDICAL

Manufacturer:  
**JEILMEDICAL Corporation**  
702-703-704-705-706-707-804-805-807-812-815-ho,  
55, Digital-ro 34-gil, Guro-gu, Seoul, 08378, Rep. of Korea  
Tel. 82 2 850 3500 Fax. 82 2 850 3535

#901-41001-04

작성연월(Issue Date) : 2023.01

Print Date :

Made in Korea

### [INTENDED FOR USE]

This device is the instrument to make hole in the bone to insert screws.

### [DIRECTIONS FOR USE]

#### 1. Before use

- Make sure that there are no detected on the exterior of the product.
- The product is supplied non-sterile. Please check the products have been sterilized before use.
- Make sure that connected with relevant products.
- The product should be used by a licensed physician (medical specialist).
- Before use, inspect the drill bit for damage, any deformations and cracks.

#### 2. How to Use

- Drill Bit
  - Choice the suitable Drill Bit for use in operating.
  - Assemble the sterilized Drill Bit and hand body.
  - Make a hole using Drill Bit.

#### 3. After use

- Used drill bit should be clean according to clean procedure and then should be stored according storage condition. (Refer to Manufacturer's cleaning and sterilization guide for detail)
  - 1) Soak: 45±5°C (Medical weak solution) for 15 minutes
  - 2) Washing; Washing with strong brush
  - 3) Rinse; running water
  - 4) Ultrasonic cleaning; 45±5°C (Medical weak solution) for 15 minutes
  - 5) Rinse; running water for 2 minutes at 20~43°C
  - 6) Ultrasonic cleaning; distilled water (25±5°C) for 15minutes
  - 7) Dry

### [Storage condition]

- Store the device in a dry location at the room temperature.

### [Steam sterilization]

The products are provided in a non-sterile condition. It should be sterilized before use. Sterilization should be performed with recommended method to achieve a degree of sterility equal to at least SAL10-6.

Only use the following steam sterilization methods. Other sterilization methods are not allowed.

Cycle	Temperature	Exposure Time	Load Characteristics	Drying Time
Gravity	132°C	15 min.	Wrapped*	30 min.
Pre-vacuum	132°C	4 min.	Wrapped*	30 min.

\* In the case of load characteristics, we recommend usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation.

### [WARNING]

- Check the products have been sterilized before use.
- Do not take strength too much on the products.
- Do not disassemble or modify the product at your own discretion.
- Check the packaging condition for signs of damage.
- Check the assemble condition after assemble instruments and the other medical device.
- The product should be used by a licensed physician (medical specialist).

### [PRECAUTIONS]

- User should read the instructions before use.
- User should choose the suitable product model and size before use.
- Please check any deformations and cracks before use.
- Check the compatibility of instruments before use.
- Do not use products that fall on the floor. This product should be sterilized before use.
- Check that the drill bit is securely held.
- This product is recommended for up to 100 uses (8 weeks), provided that JEILMEDICAL-recommended conditions of use are followed.
- Be aware in cases of patients that show signs of allergy or hypersensitivity to the chemical components of the material: surgical stainless steel.
- Do not interrupt the rotation of the motor with the Drill inside the surgical cavity, as it can make it difficult to remove or cause the fracture of the Drill.
- Before each procedure, make sure the pieces are properly seated.
- It is the professional's responsibility to use the JEILMEDICAL products according to the instructions for use.
- This product should be sterile.
- The non-replacement of the Drills, as recommended by the manufacturer, can generate improper bone heating, compromising the osseointegration success.
- Do not drilling by excessive torque, time, RPM. It is can generate improper bone heating, compromising the osseointegration success.
- Do not grind.
- Do not use solutions with ammonia, acids or hydrogen peroxide, because they can damage the Drill.
- The use of steel brushes is inadvisable. We recommend the use of nylon brushes.
- The improper planning can jeopardize the performance of the Implant/prosthesis set causing failures to the system, such as loss or break of the Implant, loosening or fracture of the screws.
- Failure to use the drill as recommended by the manufacturer may result in wear, deformation, corrosion, reduced cutting efficiency.

### [STORAGE]

- Keep the product away from direct sunlight, high temperature, flammable liquids or gases.

### [PACKAGING]

All Drill bit are packaged individually. This device is manufactured and sold by JEILMEDICAL Corporation.

### [SYMBOL DESCRIPTIONS]

REF	Catalogue number	LOT	Batch code
	Date of manufacture		Manufacturer
	Non-Sterile		Caution
	Consult instruction for use		Do not use if package is damaged

EC REP Authorized representative in the European Community

**EMERGO EUROPE**  
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands