Dental Implant Surgical Kit - Drill

Instruction for Use

Below is information about using drills. Please read the following information and explanations carefully before using the product.

1. Product Specifications

1.1. Purpose of Usage

Dental Drill is used as dental implant accessories, including the drills required during the dental implant placement process.

1.2. Indications

Tooth deficiencies that cannot be treated with other prosthetic and surgical techniques (conditions with insufficient retention of existing teeth or tissue defects). Situations where dental implants are more beneficial than conventional treatment (short edentulous arches, single tooth missing, orthodontic retention). Cases with similar functional results from conventional treatment and implant treatment. In these cases, the decision for implant treatment is made as a result of personal considerations or aesthetic concerns.

1.3. Sterility Information

The product is supplied non-sterile. It is recommended to be sterilized by the user in an autoclave for 20 minutes at 121 °C before use.

1.4. Usage Area

Dental Drill is produced for the use of authorized persons who are professionals in the dental field.

1.5. Shelf Life

Shelf life has not been determined. The product is non-sterile. Sterility, tightness, etc. risks are not applicable. It is fixed that there is no significant change in the mechanical and corrosion properties of stainless steel, which is a critical feature, under 30 years. Based on this, taking into account MEDDEV 2.2/3 rev 3 clause 4.2.c, shelf life is not defined for the products.

1.6. Storage Conditions

Our product does not have any special storage conditions.

1.7. Reusability

- Products can be resterilized under recommended methods and parameters. It can be reused after sterilization. The number of sterilization cycles is not limited, but it is recommended to use a maximum of 10 times. There is a possibility that the tip of the bur may become blunt after more than 10 uses, which may result in poor performance and reduced clinical success. To ensure that the cutting performance of BIOSTI surgical instruments is not reduced, the following should be considered:
- Avoid contact of the tip of the burs with the surfaces so that it does not become blunt.
- After the surgical application, the blood should be washed immediately before it dries on the instruments.
- Thoroughly clean the instruments with a soft brush after use. All surfaces must be cleaned in disassembled condition.
- Never disinfect, ultrasonically wash, sterilize with hand tools made of different materials.
- Use only with disinfectants and/or cleaning agents suitable for 431 steel. Perform in accordance with the disinfectant or cleaning agent manufacturer's instructions.
- Rinse the disinfectant and cleaning agent thoroughly with water.
- Never leave instruments damp or wet.

1.8. Safety Usage Information

The product usage speed should be 800 rpm and the torque value should be 35 ncm.

1.9. Information of Devices Used Together

The product should be used with a physiodispenser and a anguldurva motor.

2. Patient Population

It is suitable for the entire patient population.

3. Contraindications of Device

Conditions where there is insufficient bone volume and/or quality. Serious internal medical problems, insufficient wound healing capacity, underdeveloped maxillary and mandibular, inadequate general health status, uncooperative and low motivation patient profile, drug and alcohol addiction, psychosis, weak immune system, uncontrollable endocrine problems, stainless steel allergy.

4. Safety and Warnings

Before using the Dental Implant Surgical Kit – Drill, the user should be familiar with its application. The user should learn the operating procedures before using it for the first time.

5. Warnings

It must be re-sterilized before each use. Otherwise, there are risks of biological contamination. For use by professionals, healthcare professionals.

6. Side Effects

It has no known side effects.

	Manufacturer Name / Manufacturer Address	NON STERILE	Non-sterile
	Production date	EC REP	European Authorized Representative
MD	Medical device	REF	Catalog number
LOT	Batch number	eIFU Indicator	Consult electronic instructions for use

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