

EVOSS Surgical Instruments Instruction for use**Definition**

For use with the Evoss Dental Implant System, Umutsan Dışçılık ve El Aletleri San. Tic. Ltd. Şti Surgical instruments manufactured by are designed for temporary use in the oral cavity (maximum 60 minutes at a time).

Indications

Surgical instruments are used to prepare the implant site for Evoss Dental Implants in the lower or upper jaw bone, place the implant, tighten and remove all screws.

Contraindications

When evaluating the patient, in addition to suitability for implant restoration and rehabilitation, it is necessary to consider contraindications that also apply to oral surgery. These are systemic diseases or some local disorders. For example, patients who have had a myocardial infarction, patients with blood diseases, drug addicts, patients who have undergone radiotherapy, severe hormonal disorders, alcohol use, smoking and drug use may cause contraindications.

Local causes: Periodontal diseases, residual oral mucosa diseases, conditions with insufficient bone volume, macroglossia, bruxism, poor oral hygiene, psychologically unstable patients, alcohol or drug addicts, and poorly motivated or uncooperative patients are also eligible for this type of treatment. should not be considered appropriate.

Patients with poor periodontal health should be treated first. In case of a bone deficiency or poor quality of the harvested bone, such as compromising the stability of the implant, appropriate guided tissue generation should be performed before implant treatment. Contraindications also include: allergy to stainless steel, acute or chronic infective diseases, sub-acute chronic maxillary osteitis, pregnancy, breast-feeding, pregnancy, hemophilia, steroid use, diabetes mellitus, renal failure and fibrous dysplasia.

Possible side effects

- Infection
- Pain
- Bleeding



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Liability information

The instruction for use of Evoss Dental Implant surgical instruments should be read before using them. Evoss Dental Implant surgical instruments should only be used with the Evoss system in medical/dental applications. Detailed information is available in the surgical guide. The following explanations are not sufficient for correct use if dentists are not experienced in implant prosthetic treatment. The dentist must be familiar with dental surgery and prosthetics, including diagnosis and preoperative planning and laboratory procedures. Before treatment, the dentist should check that the products are suitable for their intended use. Evoss Dental Implant's liability is non-existent or limited if the user is found to be at fault. It is especially valid if the dentist does not use it in accordance with the instructions for use or warnings or uses it incorrectly.

Security warning

Worn or damaged instruments or system parts should not be used and should be replaced with new ones immediately. Instructions for use must be followed. Instrument or system parts must only be used for their defined purpose. Failure to follow safety instructions may result in injury.

Correct positioning of the patient reduces the risk of aspiration of parts (leaving into the respiratory tract). Necessary safety must be ensured to prevent swallowing or aspiration of all parts used in the mouth.

Application**Treatment procedure/Proper use**

Patients should be informed of the generally applicable safety precautions expected of them prior to the surgical procedure. In addition to the use of placement techniques to determine the drilling depth and exact location, the use of Computed tomography film is recommended. General anesthesia is applied to the application area of the instruments. Preparation and incision of the mucosa tissue and periosteal area is made in accordance with the surgical technique. After marking with a pilot drill, a standard drill (maximum 800 rpm) is used to expand the cavity until the final width is achieved. The drill bits are color coded and compatible with the respective implant diameter. The drilling process should be performed intermittently with continuous external cooling with sterile physiological saline. External cooling prevents bone tissue from overheating and removes bone fragments. Make sure the drill is in a fully upright position and maintain this position during use. Preparation is done at 800 rpm and minimum pressure to the desired depth. Speed must be observed to prevent tools from breaking.



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Measures

Surgical instruments used to achieve and maintain osseointegration should be used by people trained in this method. Preoperative hard tissue or soft tissue deficits may cause risky aesthetic results or improper implant angulation. Preoperative patient evaluation and close collaboration between the surgeon, restorative dentist, and dental laboratory technician are essential for success.

Sterility

Surgical instruments are shipped to the user as a set with implant systems. Surgical instruments provided with implant systems are shipped non-sterile. Before use, it must be cleaned, disinfected and sterilized according to the instructions below. Failure to comply with these warnings may cause infection in the patient.

Cleaning/Disinfection and Sterilization Rules for Evoss Reusable Surgical Instruments**-Use**

To avoid contamination of the set box and damage to sterile gloves with sharp drills, it is recommended to remove devices using a pair of tweezers. Immediately after surgery, rinse the devices with running water to remove visible whole blood, body fluids, and tissues.

-Transport

Prevent mechanical damage, for example, do not mix heavy devices with delicate ones. Pay particular attention to cutting edges, both to avoid injury and to prevent damage to medical devices. Bring medical devices to the area to be cleaned as soon as possible. If transfer to the process area is likely to be delayed, cover medical devices with a damp cloth or store medical devices in closed boxes to prevent dirt and/or debris from drying.

-Preparation and Disassembly

Set boxes must be completely disassembled before cleaning and disinfection.

-Cleaning process

-Ultrasonic Cleaning: Surgical instruments are placed in suitable containers such as perforated tubs or wire baskets, and care is taken not to touch each other. These are placed inside the device where ultrasonic cleaning will be applied. It is recommended to wash in accordance with the ultrasonic device and detergent manufacturer's instructions.



-Manual Cleaning: Surgical instruments are cleaned by washing with soft brushes after sorting after the operation. The cleaning process must be carried out according to the instructions of the selected detergent manufacturer. After manual cleaning and disinfection, rinsing should be done with soft water (distilled water) as much as possible. Demineralized or distilled water is recommended to prevent water spots.

Surgical instruments should be dried very well immediately after the cleaning and rinsing phase.

Note 1: Only cleaning/disinfecting agents specially formulated for this purpose should be used for cleaning/disinfection. For duration and concentration, detergent manufacturers' instructions should be followed.

Note2: Water quality; The quality of water used to dilute cleaning agents and/or disinfectants and rinse medical devices should be carefully evaluated. Mineral residues from hard water and higher contamination with microorganisms and endotoxins can cause staining of the device or prevent effective cleaning and disinfection.

-Assembly and Packaging of set boxes

Where appropriate, medical devices that have been cleaned, disinfected and checked should be installed. Completed set boxes with mounted instruments should be sterilized in a 'ready for use' state. These instruments do not need to be disassembled for sterilization. To sterilize single components and instruments, place them in sterilization bags. Place the set box in a sterilization bag to prevent contact with contaminated instruments until sterilization by autoclave.

Sterilization

The recommended sterilization condition is as follows.

Method	ISO 17665-2
Period	pre-vacuum
Heat	121°C
exposure time	15 minutes
pre-vacuum	3 times <60mbar
Minimum drying time	30 minutes indoors

WARNING: The recommended autoclave sterilization value for autoclave sterilization of surgical sets is the values specified in the table above. If autoclave sterilization of surgical sets is performed above 134°C (273°F), there is a possibility that the sets may be damaged. It is recommended that autoclave sterilization be performed at recommended values.



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Storage

After sterilization, place the devices in a dry, dark place, such as a closed cabinet or drawer.

Reusability

Frequently repeated operations have minor effects on the instruments. The end of product life is determined by wear and damage during use. Therefore, provided that they are undamaged and uncontaminated, instruments can be reused with proper care. Do not use instruments that have exceeded their effective product life, as well as instruments that are damaged and/or contaminated. The product has a limited number of uses; It is 100.

Sharp instruments

If properly maintained and not damaged or contaminated, cutting instruments can be reused up to a maximum of 100 times. (1 use equals the placement of 1 implant.); Beyond this number of uses, the use of damaged and/or contaminated instruments is not allowed.

Meaning Of Symbols

	Lot Number
	Catalog Number
	Manufacturer
	Date of Manufacture
	Non-Sterile
	Refer to Instructions for Use
	Warning
	Do not use if packaging is damaged
	Our products' structure may be affected by sunlight, so labels are applied to the products.
	Keep dry



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	Medical Device
	Unique Device Identification



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