Rex Implants
minimally invasive technology

# INSTRUCTIONS FOR USE

## PIEZOIMPLANT SYSTEM: SURGICAL INSTRUMENTS

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## ENGLISH – UNITED STATES

⚠ **Caution: Federal law restricts this device to sale only by or on the order of a licensed dentist or physician.**

### Device Description

The PiezoImplant System consists of endosseous dental implants, surgical instruments and restorative components in a variety of dimensions to accommodate differing patient anatomy. Dental implants act as a post to anchor an oral prosthesis to the jaw. Abutments facilitate attachment of the prosthesis to dental implants.

PiezoImplants are blade-form endosseous implants having a wedge shape and an apical surface treated with resorbable blast media (grit-blasted and acid passivated). These are provided with a variety of buccolingual thicknesses, widths, and lengths. Cover screws provide protection to the threads of the abutment connection during the tissue healing process. Retention screws fasten the implant and abutment. A variety of PiezoImplant abutments are offered including Straight, Angled, Healing, Provisional Cylinders, and Multi-Unit. Restorations can be screw and/or cement-retained to the abutments. Laboratory analogs, impression transfers, and pins facilitate creation of the prosthetic restoration. Associated surgical instrumentation includes Piezosurgery® Handpiece inserts and rexpanders for site preparation. A torque of 15 Ncm is recommended for cover screws, coping screws, and healing abutments. A torque of 25 Ncm is recommended for retention screws and all other abutments.

The PiezoImplant System implants, abutments, fit gauge, laboratory analogs, impression pins, copings, coping screws, cover screws, and retention screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. Castable copings are manufactured from polymethylmethacrylate (PMMA).

The PiezoImplant System Restorative devices are provided in a non-sterile condition and must be sterilized prior to use.

### Indications for Use

The PiezoImplant System is intended for use in dental implant applications for oral rehabilitation of edentulous and partially dentate adult patients over the age of 21 in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. The prosthetic components are connected to the implants by the corresponding abutments. The PiezoImplant System is intended for delayed loading.

### Contraindications

Do not use the Rex PiezoImplant System in presence of following:

- Patients who suffer from any medical conditions that make surgery inadvisable or may be otherwise deemed to be a contraindication by the treating dental practitioner. Such conditions may include and not be limited to: heart disease, diabetes, cirrhosis, HIV positivity, puberty, pregnancy or breastfeeding, radiotherapy, chemotherapy, immunosuppressant therapy, parafunctional therapy, and psychiatric disorder;
- Bone metabolism disturbances,
- Uncontrolled bleeding disorders,
- Inadequate wound healing capacity,
- Uncompleted growth of the maxilla or mandible,
- Drug or alcohol abuse,
- Xerostomia,
- Weakened immune system,
- Uncontrollable endocrine disorders,
- Steroid use,
- Titanium allergy,
- An insufficient quantity of bone volume (height and width) at the implant site,
- Untreated periodontal diseases (loosening of the teeth),
- Untreated severe grinding or clenching of the teeth,

- Unmanaged occlusal parafunction,
- Infections at the operative site or in the neighboring teeth (pockets, cysts, granulomas), including major sinusitis, or
- Poor hygiene of the mouth and teeth and low compliance (uncooperative or unmotivated).

### Relative Contraindications

- Caution should be exercised in the presence of the following:
- Exposure to long-term use of opioids or bisphosphonate drugs,
- Previously irradiated bone,
- Diabetes Mellitus,
- Anticoagulation drugs,
- Hemorrhagic diatheses,
- Unfavorable anatomic bone conditions,
- Temporomandibular joint disorders,
- Tobacco use, including moderate to heavy smoking, or
- An unbalanced relationship between the upper and lower teeth.

### Warnings and Precautions

- Techniques required to place and restore dental implants are highly complex, requiring specialized knowledge. Practitioners must be trained in implantology techniques and piezoelectric bone cutting techniques as well as the insertion techniques of press-fit implants before using the PiezoImplant System.
- The safe and effective use of implants and associated surgical and restorative devices may be achieved only if qualified surgeons trained in the procedure perform treatment per the instructions provided. Email info@reximplants.com to request information on training course availability.
- Devices must be used as supplied. Modifications to the implants and surgical instruments may result in serious injury or death. Restorative devices may only be modified as directed.
- A careful biomechanical study must be performed by the surgeon and restorative dentist to determine the optimal oral restoration for each patient. However, a one hundred percent implant success rate cannot be guaranteed.
- Poor surgical planning including failure to reconcile the actual dimensions of surgical instruments to the sizes in radiographic measurements may result in drilling beyond the intended depth. This may result in permanent tissue damage that could result in hemorrhage and/or permanent facial numbness.
- It is essential that the surgical procedure minimizes trauma due to bone overheating and damage to adjacent tissues during the piezoelectric osteotomy. Improper surgical technique including a preoperative study that does not properly evaluate the bone volume and the bone quality of the alveolar crest may lead to bone loss and/or implant failure.
- The incorrect use or handling of small parts in the patient's oral cavity may lead to inhaling and/or swallowing of said parts.
- Reusable device reprocessing has been validated for 50 separate cycles. Do not reprocess reusable devices if wear and tear is observed. Over-use of a device may harm a patient, reduce surgical effectiveness, and/or lead to the device failure.
- Follow current local regulations and current facility procedure for the safe disposal of devices; devices should be cleaned and sterilized before disposal.
- Providing instructions to the patient is essential to ensure success of the implant treatment. The patient must be made aware of the limitations of treatment, importance of oral hygiene, avoidance of contraindications, and risk of potential adverse events. During the healing period a soft diet must be prescribed. Patients must be informed to consult a physician if any changes in implant performance occurs including bone resorption, loosening, and/or fracture.
- PiezoImplants may be restored only upon completion of the healing process. Loading must be delayed at least 6 months from implantation. Consult the instructions for use for each PiezoImplant for details on the ability of the implant to support single crowns and the maximum allowable abutment angulation.
- Store devices in a clean, dry, dust-free, dark room at 15° - 30°C.

### Potential adverse events

Potential adverse events must be communicated to the patient prior to surgery. Potential adverse events related to the use of dental implants may include: integration failure; integration reduction; wound dehiscence requiring bone graft; jaw bone fracture; the perforation of the following: maxillary sinus, inferior border of the mandible, labial and lingual bone walls, alveolar canal, and gingiva; abscesses, fistulas, suppuration, inflammation, radiotransparency, persistent pain, sensitivity reduction, paresthesia, hyperplasia, excessive bone reduction requiring surgery, implant fracture, systemic infections, nerve lesions or other nerve damage, and vascular lesions or hemorrhaging, which at times may be serious especially in patients undergoing treatment with anticoagulants and/or antiaggregants.



Failure to comply with the instructions contained in this document, including reuse of products marked as single-use, may cause harm to the patient, including risk of serious injury or death.

### How supplied

The PiezoImplant System restorative components, surgical tray, and surgical instruments are provided non-sterile and must be sterilized prior to use per the instructions provided below. All dental abutments and restorative accessories are indicated as single use.

### Cleaning/Reprocessing

The devices in the PiezoImplant System provided non-sterile must be thoroughly cleaned before use. Reusable devices must be cleaned between uses. While it is recommended that the following validated steps are included in a reprocessing protocol, the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for implants or devices not manufactured by Rex Implants.

Manual Cleaning/Disinfecting Reprocessing Method

1. Rinse device in cold, potable tap water (< 43°C; <109°F) to remove debris and prevent coagulation of blood.
2. Prepare a solution of enzyme detergent* and potable tap water at pH 7, according to the manufacturer's instructions.
3. Place the device in a container. Add a sufficient amount of solution of enzyme detergent in the container to cover them completely.
4. Leave the device immersed for 10 minutes at 40°C (104°F). This will reduce the organic residues. When immersed in the solution of enzyme detergent, gently brush any threaded parts and small grooves on the device.
5. Place the device in an ultrasonic bath containing enzymatic detergent solution at 40°C (104°F) for at least 10 minutes. This will reduce the organic compounds on the devices. After soaking in the ultrasonic bath, gently brush any threaded parts or grooves on the device
6. Under running, warm, potable tap water and using a toothbrush with soft bristles made of nylon, clean the device thoroughly without damaging the surface. Do this until all visible traces of soil are removed. Carry out the final rinse with distilled water.
7. Finish cleaning and inspect the devices under an appropriate light source, paying attention to details that might house soil (e.g., threads, holes, slots) and if necessary repeat the cleaning cycle.
8. Inspect all devices for any signs of wear and tear. Do not use any device whose integrity is visibly compromised.
9. Dry the device in preparation for sterilization.

*Procedure validated with All-in-One 4 enzyme detergent.

Automated Cleaning/Disinfecting Reprocessing Method

1. Perform a pre-cleaning by following steps 1 - 6 of the Manual Cleaning/Disinfecting Reprocessing Method
2. Lay the device in a metallic tray and place it in thermodisinfector.

NOTE: Place the devices in the washing machine so that dead zones do not arise and the water can properly drain. Also, make sure that the devices are properly held in place in the washing basket and cannot move during the washing process, as shocks could damage them.

WARNING: Avoid overloading. Overloading compromises cleaning effectiveness.

3. Set the following sequence and parameters applicable to the cycle:
   - 3 min, Pre-wash with cold, potable tap water;
   - 5 min, Wash with enzymatic cleaner at 45°C ± 2°C (113°F);
   - 2 min, Rinse with cold, potable tap water;
   - 5 min, Thermodisinfect at 93°C (200°F) with demineralized water following the national requirements about A0 values (thermal disinfection at a temperature of 90°C [200°F] for 5min results in an A0 value of 3000)
   - 2 min rinse with cold, de-mineralized water
4. Finish cleaning and inspect the devices under an appropriate light source, paying attention to details that might house soil (e.g., threads, holes, slots) and if necessary repeat the cleaning cycle.
5. Inspect all devices for any signs of wear and tear. Do not use any device whose integrity is visibly compromised.
6. Dry the device in preparation for sterilization.

### Drying

Before starting the sterilization cycle, make sure that the device is thoroughly dry, both externally and internally. For this purpose, blow compressed air both externally and into/through any holes; this will prevent the onset of stains, haloes, or rust on the device.

### Sterilization

The PiezoImplant System abutments, surgical tray, surgical instruments, and restorative accessories are provided non-sterile and must be sterilized prior to use. These instructions are not intended for implants or devices not manufactured by Rex

Implants such as Piezosurgery® Inserts. The surgical tray is not to be used as a sterilization tray. Prior to sterilization, wrap the abutments, surgical tray, surgical instruments, and restorative accessories individually using FDA cleared sterilization pouches. Drying is to be performed inside the steam sterilizer in the prevacuum cycle at 132°C (270°F).

Sterilization validation in an otherwise empty chamber has shown the following recommendations for sterilization to be effective to an SAL of $10^{-6}$.

Method: Steam
Cycle: Prevacuum for three cycles
Temperature: 132°C (270°F)
Exposure Time: 4 minutes
Minimum Drying Time: 20 minutes

### MRI Safety Information

Non-clinical testing has demonstrated the Rex PiezoImplant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3 T
- Maximum spatial field gradient of 1700 gauss/cm
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Rex PiezoImplant is expected to produce a maximum temperature rise of less than 2.2°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 16.2 mm from the Rex PiezoImplant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

For additional information, consult the Rex Implants Restorative Manual.

IFU-01C-US Rev 2, issued December 30, 2022 . Additional information is available at http://www.reximplants.com. Please contact your local distributor to request physical copies of this document.

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| Reference number and symbol | Title of symbol | Description of symbol per Standard[1] |
|---|---|---|
| **5.1.1** | Manufacturer | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC |
| **5.1.2** EC REP | Authorized representative in the European Community | Indicates the Authorized representative in the European Community |
| **5.1.3** | Date of manufacture | Indicates the date when the medical device was manufactured |
| **5.1.4** | Use-by date | Indicates the date after which the medical device is not to be used |
| **5.1.5** LOT | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified |
| **5.1.6** REF | Catalogue number | Indicates the manufacturer's catalogue number so that the medical device can be identified |
| **5.2.8** | Do not use if package is damaged | Indicates a medical device that should not be used if the package has been damaged or opened |
| **5.4.2** | Do not re-use | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure |
| **5.4.3** | Consult instructions for use | Indicates the need for the user to consult the instructions for use |
| **5.4.4** | Caution | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself |
| **5.7.7** MD | Medical device | Indicates the item is a medical device |
| MR **ASMF F2503-20**[2] | MR Conditional | The item poses no known hazards in a specified magnetic resonance imaging (MRI) environment with specified conditions of use |
| RxOnly **21CFR801.109(b)(1)** | Prescription use only | Caution: Federal law restricts this device to sale only by or on the order of a licensed dentist or physician |

[1] Unless otherwise noted, reference numbers (e.g., 5.1.1) and descriptions from ISO 15223-1:2021, Medical Devices – Symbols to be used with information to be supplied by the manufacturer– Part 1: General requirements, FDA recognized standard # 5-134; [2]FDA recognized standard #8-528