Rex Implants
minimally invasive technology

INSTRUCTIONS FOR USE

PIEZOIMPLANT SYSTEM: REX BL 2.9

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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. In the presence of good oral hygiene, the expected lifetime of PiezoImplants could range from 5 to 20 years depending on masticatory and parafunctional habits.

The PiezoImplant REX BL 2.9 endosseous implants are blade-form having a wedge shape and an apical surface treated with resorbable blast media (grit-blasted and acid passivated). These are provided with a buccolingual thickness of 2.9 mm, mesiodistal widths of 4 or 5 mm, and lengths of 9 mm or 11 mm. 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, UCLA, Healing, Cylinder, 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. 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. Associated surgical instrumentation includes an alignment pin, fit gauges, hex drivers, a thumb knob, removal carriers, rexpanders, Piezosurgery® Handpiece inserts for site preparation, and the REX IPD with attachments for implantation.

The PiezoImplant REX BL 2.9 implants are provided single-packed with a cover screw. These devices are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The implant and included cover screw are provided sterile. The PiezoImplant System surgical instruments and restorative components are provided in a non-sterile condition and must be sterilized prior to use.

The REX BL 2.9 implant series has an internal conical restorative platform with a 2.6 mm diameter (2.6mmD).

Indications for Use

The PiezoImplant System is intended for use in dental implant applications for oral rehabilitation of edentulous and partially dentate patients 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 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. Do not use the Rex PiezoImplant System in the presence of following: 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 and piezoelectric bone cutting techniques as well as 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 the implant treatment per the instructions provided. Email info@reximplants.com to request information on training course availability.
- Devices must be used as supplied. Modifications to 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.
- Do not use PiezoImplants in patients if the adequate implant position, sizes, or numbers needed to support functional and eventually parafunctional loading cannot be achieved.
- 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.
- Implants placed in the maxilla should not perforate the sinus floor membrane. If the membrane is perforated, graft inside of implant site preparation with a sponge of platelet-rich fibrin or collagen and prescribe amoxicillin for 3 to 4 days postop.
- Primary implant stability is achieved by lightly tapping with the REX IPD without damaging the bone walls at the surgical site. Forcing the implant deeper than specified may lead to expanding or fracturing the implant site bony walls, which could prevent the implant from being secured effectively. Primary stability is essential to ensure adequate secondary stability, which is necessary for the long-term success of the implant treatment.
- In the event of implant mobility upon insertion or incorrect implant placement, the implant should be placed deeper or removed. In cases with a large amount of bone-implant press-fit, the implant may need to be loosened with a piezoelectric cutting device before removal. If the healing process has not begun, implant removal may be performed using a Removal Carrier BL 2.9 and the REX IPD with the Remover attachment. To remove the implant from the osteotomy, secure the removal carrier to the implant, fully engage the removal carrier with the REX IPD Remover attachment, and initiate the Removal action at the lowest force intensity level. If the implant does not move, incrementally increase the REX IPD force intensity level and repeat until the implant is fully removed from the bone. During explantation, the REX IPD Remover axis must be parallel with the longitudinal implant axis. Do not reuse the implant. Check the removal carrier for damage and do not reuse if damage is observed. Implant treatment should be repeated only after the bone has fully healed.
- Removal Carrier BL 2.9 has been validated for 10 separate reuse cycles. Removal Carrier BL 2.9 D2 has been validated for 50 separate reuse 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 procedures for the safe disposal of devices; devices should be cleaned and sterilized before disposal.
- During the post-operative healing period, it is critical to protect the implant from trauma and promote osseointegration by ensuring adequate clearance between the implant restoration and antagonist teeth, fixed prosthetic bridge elements or removable prosthetic elements.
- Providing instructions to the patient is essential for successful treatment. The patient must be made aware of any 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 the implant performance occurs including bone resorption, loosening, and/or fracture.
- REX BL 2.9 implants may be restored only upon completion of the healing process. Loading must be delayed at least 6 months from implantation.
- The occlusal load on any PiezoImplant should be similar to that of conventional implants. Avoid traumatic and/or parafunctional contacts in the centric relation, right and left laterality, and protrusion.
- The REX BL 2.9 PiezoImplant cannot support a single crown in the molar region even after osseointegration is completed, but can support a single crown in the presence of normal masticatory function if placed elsewhere.
- The all-on-four restoration technique using REX BL 2.9 implants, alone or with other implant types, has not been clinically validated.
- Due to the variety of third-party restorative devices available, Rex Implants cannot verify that all device combinations are safe and effective. Therefore, the use of restorative devices manufactured by Rex Implants is strongly recommended.
- If custom abutments are used with implants in the REX BL 2.9 series, the angulation must be no greater than 17°.
- After implant placement, if more than 40% of a PiezoImplant surface is exposed (i.e. not surrounded by bone), the implant should be removed from the patient.

• 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. Any serious incident that occurs in relation to these devices should be reported to Rex Implants Inc. and the relevant governing agency such as the US FDA or competent authority of the Member State in which the user and/or patient is established.

How supplied

PiezoImplants are single-use products, provided in a triple bag, placed in a carton box and sterilized by gamma irradiation. A cover screw is pre-packaged with each implant.

The implant and included cover screw are provided sterile and should be handled in a safe manner. All sterile products are labeled “STERILE.” Do not use sterile products if the package is damaged or already opened. Do not use the sterile products if the expiration date on the label has passed. Do not clean, re-sterilize or reuse any sterile product. Due to the complex surface characteristics of the PiezoImplants, only gamma radiation has been demonstrated to effectively sterilize these devices.

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. Piezosurgery® inserts, the REX IPD, and REX IPD accessories are also provided non-sterile and must be cleaned and sterilized per the instructions for use provided with the device. All dental abutments and restorative devices are indicated as single use.

Cleaning/Reprocessing

The devices in the PiezoImplant System provided non-sterile must be cleaned before initial use. Reusable devices must be cleaned between uses. The cleaning processes should be performed immediately after use to prevent contaminants from drying onto the devices. 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 and compliance with all appropriate requirements of the relevant governing body such as the US FDA or EU Member State(s). 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 clean container. Add a sufficient amount of solution of enzyme detergent solution in the container to cover 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 using a toothbrush with soft bristles made of nylon until all visible contamination is removed.
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 device. 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 device 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 pre-cleaned 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 cleaning cycle:
   - 1 min, Pre-wash with cold, potable water;
   - 5 min, Wash with alkaline detergent** at 55°C ± 2°C (131°F);
   - 1 min, Neutralization with proper solution** (1/3 cold water, 2/3 warm water);
   - 1 min, Rinse with potable water (1/3 cold water, 2/3 warm water).
4. Disinfection:
   - 5 min, Thermodisinfect at 93°C (200°F) with demineralized water following the national requirements about A0 values;
   - The automated thermodisinfection was not experimentally tested. According to ISO standard 15883-1, Table B.1 [4] the thermodisinfection at a temperature of 90°C [200°F] for 5 min results in an A0 value of 3000;
5. 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.
6. Inspect all devices for any signs of wear and tear. Do not use any device whose integrity is visibly compromised.
7. Dry the device in preparation for sterilization.

**Procedure validated with Miele PG8535 washer/disinfector. Programme Miele DES-VAR-TD. Alkaline detergent: neodisher® FA (0.2 % v/v). Neutralizer liquid: neodisher® Z (0.1 % v/v).

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 cleaned and sterilized prior to use. These instructions are not intended for implants or devices not manufactured by Rex Implants. Prior to sterilization, wrap all instruments individually using FDA cleared, standard, self-sealing sterilization pouches that are large enough not to stretch the seal or tear the packaging. Perform drying inside the steam sterilizer in the prevacuum cycle at 132°C (270°F).

All sterilization phases must be performed by the operator in compliance to ANSI/AAMI/ISO 17665-1, EN ISO 556-1, and ANSI/AAMI ST79. Do not to exceed the maximum load of the autoclave when sterilizing more than one instrument in the same cycle. Sterilization must be carried out using a pre-vacuum autoclave only. Any other sterilization methods must be avoided. At the end of the sterilization cycle, let devices cool down completely prior to use.

Sterilization validation 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; tolerance 0°C to +3°C)
Minimum Exposure Time: 4 minutes
Minimum Drying Time: 20 minutes

MRI Safety Information

Non-clinical testing has demonstrated that the PiezoImplant REX BL 2.9 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, and
- 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 PiezoImplant REX BL 2.9 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 PiezoImplant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Opening the Sterile Packaging

Open the cardboard box and extract its contents using non-sterile gloves. Manually open the Mylar bag and drop the sterile Tyvek pouch into a sterile tray. Do not allow the Tyvek pouch to contact any non-sterile objects. Use sterile gloves to open the Tyvek pouch in the direction of the Chevron peel opening side and pull out the polybag pouch. Hold the packaged implant and open the larger portion of the pouch using surgical scissors without dropping the contents. Hand-tighten Removal Carrier BL 2.9 to the restorative connection and extract the implant from the polypouch. Do not allow the implant to contact any other surface before placement. After the implant has been placed, hold the packaged cover screw and open the smaller portion of the pouch using surgical scissors without dropping the contents. Remove the cover screw from the pouch.

Surgical Technique Synopsis

The proper implant placement procedure consists of several surgical steps, which are briefly described below. The instructions provided below are general guidelines and may not be applicable to every surgical case. A Piezosurgery® device by Mectron should be used for osteotomy creation. A cut is complete when the insert moves freely within the osteotomy. The proper osteotomy depth for each Piezosurgery® Insert must be determined by careful study of the patient anatomy.

Piezosurgery® Inserts recommended for use in this surgical technique are described in the table below. The W1, W2, W4, and W4-H were designed exclusively for use with PiezoImplants.

Piezosurgery® Insert	Function	Maximum Thickness (mm)	Laser Marking (mm of working length)
OT7S-3	Micro-saw for ridge split	0.35	7, 8.5, 10
OT7S-4	Micro-saw for ridge split	0.35	7, 8.5, 10
OT12	Micro-saw for ridge split	0.35	7, 8.5, 10
W1	Create initial pilot osteotomy	1.5	2.6, 9.2
W2	Micro-saw for ridge split	0.6	9, 11, 13, 15
W4	Enlarge osteotomy buccolingually	1.6	3, 5, 7, 9
W4-H	Enlarge osteotomy buccolingually	1.8	1, 2, 3

Step 1 – Preoperative Planning: A PiezoImplant radiographic template for the pre-surgical study of each implant site is provided. The implant radiographic template should be used in combination with cross-section radiographic images or Cone Beam CT (CBCT) scans to evaluate the thickness and quality of the residual crestal bone, to evaluate the proper position of the implant site, and to determine the most suitable PiezoImplant size to be used. For a digital workflow, please contact your software provider to determine if templates for the PiezoImplant System are available.

REX BL 2.9 implants are recommended for the treatment of residual crestal bone with normal or reduced width. Buccolingual ridge width must be at least 3 mm wide for a successful split crest technique with rexpanders; greater ridge width may be required in the presence of highly mineralized bone. Ridge measurement should be performed at the apex of the crest. The coronal-apical distance (height) of the ridge must be greater than the desired implant length, ensuring that the alveolar nerve and other important anatomical features are preserved.

Do not place implants in the presence of local root remains. PiezoImplants require a minimum distance of 3 mm from other implants and 1.5 to 2 mm from proximal teeth.

Step 2 – Surgical Site Measurements: Dental implant surgery must be performed in a sterile field. A surgical stent or guide is recommended to establish the proper implant position. Verify proper measurements with a standard dental probe: 8 - 10 mm from the axis of the last single-rooted tooth in the case of partial edentulism; 6-8 mm mesio-distally from proximal teeth in the case of mono-edentulism. The minimal ridge dimension (mesio-distally) is 7 mm, and the initial osteotomy must be performed in the center of the residual crestal bone.

Step 3 – Pilot Osteotomy: Create a pilot osteotomy at the center of the desired implant position. Use a piezoelectric bone perforation insert (W1) to create a hole that is approximately 1.5 mm in diameter (coronally) and 9 mm in depth. If using Piezosurgery® Insert W1, reach the larger, upper laser marking.

Step 4 – Aligment Pin: Use the alignment pin to verify the proper position and that the angulation of the osteotomy corresponds to the axis of the bone crest. Check the distance with the proximal teeth.

Step 5 – Ridge Osteotomy: Perform a ridge split with a piezoelectric saw insert (W2, OT7S, or OT12). The length of the osteotomy (mesio-distally) should be as long as possible, up to 1 mm from the tooth root at each end. The depth of the osteotomy should be at least 1 millimeter deeper than the length of the implant to be inserted, always ensuring the preservation of sensitive anatomical structures.

Step 6 – Bone Expansion: Start expansion with the 1.6 mm rexpander® of length equal to or greater than that of the planned PiezoImplant for each implant site. Insert the flat end of the 1.6 mm rexpander® into the osteotomy, maintaining a vertical device orientation. Expand bone by applying force until the mechanical stop reaches the bone. Remove the rexpander® by applying reverse force without bending or twisting the device. Place a finger on top of the rexpander® to stabilize it during removal.

Continue to expand the bone using the 2.0 mm rexpander®, then using incrementally larger rexpanders until the site is ready for implant placement.

To avoid risk of fracture when bone elasticity is limited, Piezosurgery® Insert W4 may be used to further enlarge the osteotomy buccolingually. Use Fit Gauge W4 to verify the osteotomy thickness. The degree of under-preparation is dependent on the intended depth of work, and this should be increased with increasing bone density (as previously diagnosed using X-ray or CBCT images).

WARNING: Failure to provide proper buccolingual space in the osteotomy increases the risk of iatrogenic bone fracture. This risk may be increased for shorter implant lengths in highly mineralized bone.

Step 7 – Implant Placement: Extract the implant from the packaging using Removal Carrier BL 2.9. Manually place the PiezoImplant in the osteotomy.

PiezoImplant insertion into the osteotomy site is performed using the REX IPD. Select the insertion action and lowest power level (1) on the REX IPD console. Select the appropriate Striker attachment (anterior or posterior) and secure to the REX IPD handpiece with the Wrench.

Seat the Striker tip into the head of the Removal Carrier. Use the REX IPD to impact the assembly. Continuously monitor the mesio-distal inclination of the PiezoImplant during insertion and correct it if necessary. If the implant does not insert significantly, incrementally increase the intensity level on the REX IPD console. Repeat as necessary until the implant reaches the intended depth. Disengage the REX IPD striker.

Step 8 – Disengage Removal Carrier: Remove the Removal Carrier BL 2.9 from the implant. A 2.5 mm hex driver may be used if necessary.

Step 9 – Cover Screw: Open the cover screw compartment of the perforated poly pouch. Remove the cover screw and hand-tighten to the implant. Connect a 0.050” hex driver to a calibrated torque wrench and tighten the cover screw to 15 Ncm of torque. Suture the soft tissue over the cover screw. In the presence of thick soft tissue or if placement of the implant is beneath bone level, a healing abutment may be used instead of a cover screw.

WARNING: Use of a healing abutment that extends more than 2 mm above the gingival tissue may result in implant failure due to increased tongue pressure during the osseointegration process.

IFU-01E Rev 1, issued April 26, 2024. 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	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	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
5.1.8	Importer	To indicate the entity importing the medical device into the locale
5.1.9	Distributor	To indicate the entity distributing the medical device into the locale
5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
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
5.2.12	Double sterile barrier system	Indicates two sterile barrier systems
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	Medical device	Indicates the item is a medical device
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