ERA® Implant System

Instructions for Use

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ENGLISH

INSTRUCTIONS FOR USE

Before using ERA Implant® System products, the clinician in charge should carefully study the indications, contraindications, recommendations, warnings and instructions, as well as all other product-specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) and fully comply with them. Detailed instructions over and above those contained in this instruction for use concerning the possible combinations, product-specific risks, preparatory steps, indications and contraindications, etc. can be found in the description of the prosthetic instructions for use and technical user's guide. It is also recommended to attend the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the appropriate representatives in the various countries. The manufacturer, the importer and the suppliers of ERA Implant® System products are not liable for complications, other negative effects or damages that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on. The clinician is responsible for any such complications or other consequences. It is also the clinician's responsibility to properly instruct and inform the patient on the functions, handling and necessary care of the product and on all known product risks.

INDICATIONS/INTENDED USE
2.2mm ERA Implants are intended for long-term as well as temporary surgical implantation in the bone of the patient's upper or lower arch to provide immediate load or delayed load of prosthetic systems, such as artificial teeth, in order to restore the patient's chewing function. Immediate loading of ERA Implants should only occur when the position of the implants provides adequate bone quantity and quality to allow proper immediate mechanical stabilization of the self-tapping screw into the bone and where occlusal and lateral forces can be limited with appropriate occlusal design and a soft diet.

3.25mm ERA Implants are intended for permanent as well as temporary surgical implantation in the bone of the patient's upper or lower arch to provide immediate load or delayed load of prosthetic systems, such as artificial teeth, in order to restore the patient's chewing function. Immediate loading of ERA Implants should only occur when the position of the implants provides adequate bone quantity and quality to allow proper immediate mechanical stabilization of the self-tapping screw into the bone and where occlusal and lateral forces can be limited with appropriate occlusal design and a soft diet.

WARNINGS
ERA Implants should not be placed if there is an insufficient volume of alveolar bone to minimally support the implant (minimum 1mm circumferential and 2mm apical). Implants placed in the maxilla should not perforate the sinus floor membrane. Poor bone quality, poor patient oral hygiene, heavy tobacco use, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction, and psychological instability may contribute to lack of integration and/or subsequent implant failure. Severe bruxism, clenching, and overloading, may cause bone loss, screw loosening, component fracture, and/or implant failure. Exposure to radiation and chemotherapy may impact health of the implant. Dental implant patients should be instructed to consult with their physician prior to undergoing such treatment options.

Surgical and restorative techniques required to place dental implants are highly specialized and complex procedures. Practitioners should attend courses of study to familiarize themselves with implantology techniques. Improper technique can cause bone loss and implant failure. ERA Implants are intended to be used only with ERA Implant® System specially designed bone drills and prosthetics attachments. Implants placed at severe angles relative to existing dentition or multiple implants placed at convergent/divergent manner can result in complex restorations that may overload implants, potentially leading to implant failure. A thorough diagnostic work-up and use of surgical templates are recommended to help ensure proper angulation.

Other relative contraindications include steroid and anticoagulant treatment which may affect the surgical site, surrounding tissue, or patient's healing function. Exposure to long-term use of bisphosphonate drugs especially with chemotherapy may impact implant survival. Careful patient selection including consultation with the attending physician is strongly recommended prior to implant treatment. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site and allow site to heal as though it were an atraumatic extraction. Due to the metal conductivity, electrosurgery around the implants and intraoral abutment preparations without irrigation could result in tissue damage and implant failure. Patients should consult with their physician and imaging technician prior to undergoing an MRI procedure.

PRECAUTIONS
Surgical instruments are susceptible to damage and wear and should be inspected before use. If inspection reveals signs of wear, damage, or unrecognizable color identification, replace the instrument(s) accordingly.

Adequate preoperative imaging and diagnostic evaluation are necessary to determine available bone anatomy in prospective implant sites. The location of anatomical features to be avoided should be established prior to use of ERA Implants. Care must be taken to evaluate the quality and quantity of the residual bone, especially after an implant failure and when implants will be immediately placed into extraction sites.

Proper case planning is essential to the long-term success of both the prosthesis and the implant. Overload is one of the key contributors to implant failure. Ensure the implant size and angle corrections are appropriate for the occlusal load.

Breakage
Implant fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. Potential overloading conditions may result from deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g. bruxing, clenching), improper denture manufacture procedures, inadequate denture fit, and physical trauma.

Changes in Performance
It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

Hygiene & Maintenance
Long-term implant health is directly related to the maintenance of oral hygiene. Potential implant candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following implant placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the implant(s). The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

Treatment Planning
Appropriate imaging techniques should be used to determine if adequate bone is available, and to determine the location of important anatomical landmarks, such as the mandibular canal, maxillary sinuses and adjacent teeth. Thorough clinical evaluation is imperative prior to all implant surgeries.

General Considerations
Control of biomechanical stresses is the key factor to long-term success of the prosthesis. Even after implant integration, imbalances in occlusal forces can lead to implant failure. Implant patients should be monitored for signs of peri-implant bone loss and excessive attachment wear as signs of occlusal overloading.

ADVERSE EFFECTS
The following complications may occur relative to implant placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, local and generalized allergic reaction, lack of integration, loss of bone, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

STERILITY
All implants have been gamma radiation sterilized and are for single use only. Do not reuse or resterilize implants. Refer to the specific packaging for verification of sterility.

Single Use
Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

Shelf Life
Dental implants: The product expiration date is indicated by the hourglass symbol on the product label, followed by the year and month of expiration for all implants.
Surgical Instruments: Surgical instruments have no expiration date. They are reusable devices and life expectancy depends on the method, duration and handling of each use.

Caution: Federal (USA) law restricts this device to the sale by or on the order of a dentist (or other licensed practitioner).

Caution: Do not use sterile devices if the packaging providing the sterile barrier is damaged or compromised in any manner.

Product Packaging
ERA Implants are packaged in a double blister package with a heat sealed lid that provides the sterile barrier. Surgical Instruments are packaged in a sealed chevron pouch. These pouches are not autoclavable. Parts need to be removed from pouch prior to autoclaving and placed in an autoclavable pouch or tray.

CLEANING, DISINFECTION AND STERILIZATION OF SURGICAL INSTRUMENTS
Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens. Clinically contaminated implants should not be cleaned and re-sterilized under any circumstances.
The autoclave is to be used according to manufacturer instructions. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

Transport
Avoid mechanical damage. Do not mix heavy devices with small ones. Pay attention to cutting and sharp edges to avoid injury and damage to devices. Minimize time before cleaning, by getting device to cleaning area. When longer delays are expected, immerse devices in lukewarm cleaning solution to avoid drying of soil or debris.

Cleaning and Disinfection of Surgical Instruments
These devices shall be cleaned, disinfected and sterilized prior to each use by the processor.

Drills, Instruments and Components - Disassemble multi-piece components, if applicable. Rinse with cool-to-lukewarm water for two-and-one-half minutes. Flush any through holes with water to remove any debris. For all parts place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Sonicate for 10 minutes. Rinse with tap water for three minutes.

Kits, Trays, and Blocks - Remove all parts and insert from the tray. Clean parts per the above instructions. Thoroughly rinse the kits under running tap water to remove all visible soil. Use a soft bristle brush to clean the kits until all visible soil is removed. A syringe or pipe cleaner may be used to aid in the rinsing. Assure that all hard to reach areas are accessed. After the rinsing, prepare the enzymatic detergent following the manufacturer's specifications. Fully immerse the kit in the prepared detergent and allow the kit to soak in the detergent for a minimum of 5 minutes. Following the soak use a damp cloth and/or a soft bristle brush to wipe and remove any excess debris/soil from each component. A syringe or a pipe cleaner may be used to aid in the cleaning. Rinse the kits with lukewarm tap water to eliminate all residual enzymes and detergent, thoroughly for a minimum of three minutes. Dry the components. Reassemble the contents of the kit and follow the guidelines for sterilization. NOTE: This procedure should be performed after an instrument used during a surgery comes into contact with the surgical tray or prosthetic tray.

Inspection and assembly
Before sterilization, inspect devices visually, unmagnified, under good lighting conditions. Check for any damage on devices after cleaning. Devices should be inspected for visible soil and/or corrosion. Check drills or sharp devices for sharpness.

Sterilization of Surgical Instruments (Reusable)
Individual parts should be placed in appropriate autoclave for moist heat sterilization or in a dry heat pouch for Dry Heat sterilization. When sterilizing parts within a kit, parts should be placed in appropriate locations and kit should be wrapped in sterilization wrap. The following sterilization parameters (method, time and temperature) are required to achieve a 10-6 sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table. Exceeding these sterilization parameters may result in damage to plastic components. Verify the calibration of your unit to ensure recommended temperatures are not being exceeded. To ensure autoclave is performing effectively, periodic use of biologic indicators should be considered. Chemclave sterilization is NOT recommended for any ERA® Implant products.

	Cycle Type	Temperature	Exposure Time	Dry Time (only for kits)
Parts individually Packaged	Gravity (steam)	121˚C 250˚F	40 minutes	n/a
Parts individually pouched or in a kit.	Gravity (steam)	121˚C 250˚F	80 minutes	30 minutes
	Pre-vacuum (steam)	134˚C 273˚F	6 minutes	30 minutes
	Dry Heat	160˚C 320˚F	120 minutes	n/a

SURGICAL PROCEDURE
1. Administer anesthesia in the appropriate manner.
2. Whether the ERA Implants are to be used on a temporary basis or permanently, the ERA® Attachment Head portion of the implant will protrude through the tissue, unless you are using the Angle Correction Implants and the ERA® Female is not cemented to the implant at the time of surgery. Therefore, when placing the ERA Implants, a tissue punch (approximately 4 mm) or a small flap may be used. To use a tissue punch, the ridge must be of adequate width to accommodate the diameter of the head of the ERA Implants (3.4 mm), plus a reasonable amount of additional bone. Also, adequate attached gingiva must be present. If the ERA Implants are to be placed in the posterior or if you are also placing traditional implants or grafting, it is necessary to identify the neurovascular bundles of the mental foramen in the mandible and the borders of the maxillary sinus in the maxilla. This is done by making an incision through the mucosa and attached gingiva along the crest of the ridge and deflecting a full thickness mucoperiosteal flap both lingually (palatally) and facially to expand the operative site. Examine the geometry, quality, and quantity of available bone at the site.
3. The Round Bur is used to make a shallow pilot hole in the bone.

If placing 2.2 mm ERA Implants, prepare the bone in the following man-

ner:

4. There are three different length 2.2 mm Countersink Drills in the surgical kit. These combination tools may be used to prepare a pilot hole (1.6 mm) in the bone that corresponds to the length of the implant. The depth of the preparation corresponds to the length of the untapered section of the implant. The tapered end will self-tap into moderate density bone, but the 1.6 mm drill should be used to extend the depth of the preparation to the complete length of the implant, in dense bone. In very dense bone the 2.2 mm Bone Tap should also be used to create threads in the bone.

   NOTE: The Countersink drill must be used as instructed above. Failure to do so may result in high torque during implant placement which may result in implant breakage.

   NOTE: All drilling should be performed at low speeds (1000 to 1500 RPM) to maintain bone temperature as low as possible.

   The Countersink Drills also create a flat area on the surface of the bone so that the underside of the ERA® Female will seat completely on the bone. If the bone is angled at the implant site, countersink drilling must be continued until the entire underside of the ERA® Female is supported by the bone. Use normal saline solution for irrigation, as required.

   NOTE: When placing 2.2 mm ERA Implants in less dense bone, such as that often found in the maxilla, a modification of the drilling protocol is needed. Only use the 1.6 mm drill to create a shallow pilot hole, approximately one half the length of the screw. Using this technique, the implant will compact the bone in the area immediately around the implant as it is being inserted. You may also wish to reduce the drill speed to less than 1000 RPM to improve tactile sense and to help to avoid oversizing the osteotomy.

If placing the 3.25 mm ERA Implants, prepare the bone in the following manner:

5. Penetrate the bone using the 1.6 mm externally cooled drill. Continue drilling with a straight up and down motion until the proper depth is reached for the planned implant. Use depth markings on the drill (8, 10, 13, and 15 mm) to determine proper depth. The 1.6 mm hole is extended to the full depth of the proposed implant. There are three different length 3.25 mm Countersink Drills in the surgical kit. These combination tools may be used to prepare a pilot hole in the bone (2.4 mm) that corresponds to the length of the implant. The depth of the preparation created by these drills corresponds to the length of the untapered section of the implant. In dense bone, the 3.25 mm Bone Tap may be used to create threads in the bone at slow speed (approximately 15 RPM). The Countersink Drills also create a slight flat area on the surface of the bone so that the underside of the ERA® Female will seat completely on the bone. If the bone is angled at the implant site, countersink drilling must be continued until the bone supports the entire underside of the ERA® Female. On each of these drills is a broad laser etched band. The apical edge of these bands indicates the depth of the preparation.

   Note: When placing 3.25 mm ERA Implants in less dense bone, such as that often found in the maxilla, a modification of the drilling protocol is needed. Only use the 1.6 mm drill to create a shallow pilot hole, approximately one half the length of the screw. Using this technique, the implant will compact the bone in the area immediately around the implant as it is being inserted. You may also wish to reduce the drill speed to less than 1000 RPM to improve tactile sense and to help to avoid oversizing the osteotomy.

6. When placing either ERA® Implant, once the pilot hole is drilled into the bone, the ERA® Angle Gauges (0°, 5°, 11°, or 17°) may be used to determine which angled implant will work best, or if a straight 0° implant will best line up with the desired path of insertion of the denture. The narrow end of these gauges will slide into the 1.6mm or 2.4mm holes and these can be rotated until, through trial and error, they align approximately parallel to each other and to the desired path of insertion for the denture.
7. To remove the implant from the packaging:
   a. Open the outer box, peel back the outer cover on the blister pack, and drop the inner blister package onto the sterile field (Fig. 1). The outer box and outer blister pack should be opened by a non-sterile assistant.
   b. Peel back the cover on the inner blister package and upright the titanium tube that contains the ERA Implant® (Fig. 2). The inner blister is sterile and should be handled only by a sterile assistant.
   c. A hand driven Insertion Tool serves as a carrier to deliver the implant from the package to the implant site and to begin hand driving the implant into the bone (Fig. 3).
   d. Align the laser-etched lines on the sides of the Insertion Tool with corners on the hex of the implant head and push the tool onto the implant hex. Lift the implant out of the titanium tube, insert the implant into the osteotomy, and begin hand driving the implant into the bone. If the insertion cannot be completed using the Insertion Tool, the handpiece driven ERA® Driver is placed into a surgical handpiece and engaged onto the hex of the implant head. Drive the implant at slow speed (15 RPM) with irrigation, and a torque setting no higher than 55 Ncm. The ERA® Socket Insert and Implant Ratchet may be used to complete the final turn or two of the implant placement, seating it firmly on the bone surface. The ERA® Socket/Ratchet combination or an adjustable torque wrench may also be used if the surgical motor lacks the appropriate torque to insert the implants. An adjustable torque wrench may help to prevent you from applying excessive torque during implant insertion. These tools are also used at slow speed (15 RPM). Remember, do not apply excessive torque when inserting the implants. Utilize the bone tap to facilitate easier implant placement when dense bone is encountered.

CAUTION: When inserting the 2.2 mm ERA Implant® in dense bone, if the pilot hole has not been extended to the full length of the implant, the apical end of the implant will reach the unprepared bone before the implant is completely seated (about 3 mm short of complete seating). The implant should always be advancing into the bone while it is turning. In dense bone it is possible for the apical end of the 2.2 mm ERA Implant® to not be able to pierce this undrilled bone, but the implant may still be turning. If that occurs, STOP IMMEDIATELY. Back the implant out of the osteotomy and extend the length of the hole using the 1.6 mm drill.

PROSTHETIC PROCEDURE

NOTE: All ERA Implants have the micro-sized prosthetic heads. Micro-sized components and tools are 20% smaller than the standard size and are, therefore, not cross-compatible. Ensure that only micro-sized components and tools are utilized with the ERA Implant® System.

1. If a one-piece 0° implant is placed skip to step #5.

Placement of the angled ERA® Females:

2. If an angle correction implant is used, the appropriate angled Micro ERA® Female must be cemented into the implant in the correct rotational position. Snap the white nylon Micro ERA® Alignment Handle onto the appropriate angled Micro ERA® Female and snap this assembly into the implant. Position any other angled females as well. If any one-piece implants are used place a nylon handle into that female for reference. Rotate the angled females until all the handles are as close to parallel as possible. Implants should be within 7° of each other and within 7° of the desired path of insertion. Remember there are four angled females (0°, 5°, 11°, and 17°) to choose from. Try other angled females into the same implant to find the ideal angulation if necessary. The females should have a firm mechanical snap into the recepticle of the implant. There are two slots on the underside of each angled female that can be expanded, using a thin bladed instrument, if the snap fit needs adjustment.
3. Mark the position of the female in the base with a vertical line drawn across the joint between the female and the base, using an indelible pen or other suitable marker.
4. Bond the angled female onto the implant with ERA® Lock Cement. (See the separate instructions for use for handling the cement). Make sure the components are aligned using the previously marked position. Make sure components are not mixed. It is essential that the females be bonded into the same bases in which they were originally aligned and marked.

   NOTE: Some or all of the ERA Implants may be loaded on the same day the surgery is performed to stabilize the denture so that the patient can masticate comfortably and effectively with a soft diet. The clinician should determine candidates for immediate loading based on quantity and quality of the bone and the position of the implants, along with the expected amount of load. Implants in patients who are not candidates for immediate load should be allowed to integrate for approximately six to eight weeks prior to loading.

   For those implants that are not being loaded immediately, a Black Fabrication Micro Overdenture Male, or a Black Fabrication Overdenture Male in Metal Jacket, is snapped onto each Micro ERA® Female to act as a protective cap. An area in the denture is hollowed out so that the acrylic does not touch the male during this healing period. At the end of the healing period these males are processed into the denture.

Operatory Placement of Males

5. Snap a Black Fabrication Overdenture Male or a Black Fabrication Male in Metal Jacket onto each female. Block out any remaining exposed metal surface of the implants so that when the self-curing composite or acrylic is added and cures it will not be in contact with the implants. A small piece of rubber dam, punched with a small hole, may be used to achieve this block out. Stretch the rubber dam over the black fabrication male down to the level of the exposed metal areas. Impression material, bite registration material (Sterngold's Quick Bite 220131), or even wax may also be used.
6. Using a round bur, prepare a recess in the denture over each metal jacket. The denture should not touch the metal jacket or it will not be seated properly on the tissue. Also form a lingual window into each recess using a round bur.
7. Carefully add composite or acrylic over the top and sides of the metal jackets. EZ PickUp® (220237) may be used. Make sure the external retention ridge on the outside of the cylindrical housing of each male is completely covered with resin. Place additional resin in the recesses in the overdenture and seat the prosthesis passively in the mouth. This may be achieved if, after checking the occlusal relationship, the dentist holds the denture against the tissue with light finger pressure so that the tissue is not displaced. This passive seating is most important. If the tissue is displaced it will make accurate seating of the attachments very difficult.
8. Remove the denture, fill any defects in the resin and finish the prosthesis. Make occlusal adjustments if required.
9. Replace the Black Fabrication Males with the White Overdenture Males as described in steps 10 – 13 below.

   Note: If the patient desires additional retention, replace the white males with orange. Both colors can be used together in the same overdenture. Other color males are not used at this time.

Changing the ERA® Males

NOTE: Both the Core Cutting Bur (811023) and ERA® Seating Tool (811022), or the package which includes both items (811026), are necessary for the replacement of ERA® males.

10. Place the Core Cutting Bur in a slow speed handpiece.
11. Cut out the core of the male at medium RPMs, using a short cutting cycle and in-and-out motion. Push in for about one second at a time. Check to see if the core is removed. The core will remain in the Core Cutting Bur and can be ejected by sliding a thin blade along the cutter's side slot.
12. Using the ERA® Attachment Extraction Tool (811027) or similar sturdy instrument, slide the tool straight down outside the nylon wall and inside the metal jacket, collapse the remaining ring into the open space created by removal of the core, and lift it out.
13. Set a new male on the seating tool. Place the tool with the new male into the metal jacket in the overdenture and firmly push it in until the male snaps securely into place.

Symbol	Used For	Symbol	Used For
	Do not reuse		Used by YYYY-MM-DD or YYYY-MM
	Batch code		Manufacturer
	Sterilized using irradiation		Symbol for Non-Sterile
	Symbol for "Use by Prescription only"		Caution, consult accompanying documents
	Symbol for "European Conformity"		Catalog number
	Do not re-sterilize		Do not use if package is damaged
	Authorized representative in the European Community		

STORAGE AND HANDLING
The expiration date is provided on the product labeling. Do not use product that has exceeded the expiration date or has a damaged sterile barrier. Place devices in a dry place to prevent damage and/or deterioration.

Software
The ERA Implants do not contain or utilize software.

EMC and Electrical Safety
The ERA Implants do not require EMC and Electrical Safety Evaluation.

MR Safety
The ERA Implants have not been evaluated for safety and compatibility in the MR environment. The ERA Implants have not been tested for heating, migration, or image artifact in the MR environment. The safety of ERA Implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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