Stern Ex Implant System

Instructions for Use

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ENGLISH

INSTRUCTIONS FOR USE

Descriptions: The Stern Ex is a self-tapping, double thread screw implant, manufactured from pure grade 4 titanium. The implant is acid etched. Stern Ex Implants are manufactured with the regular (4.1 mm) platform with a standard external hex, and with a narrow (3.5 mm) platform with external hex. The implants are compatible with Sterngold-ImplaMed's extensive line of regular and narrow platform prosthetics, which are also compatible and interchangeable with the Brånemark System. They provide for non-rotational single and multiple tooth restorations in both the maxilla and mandible. They are packaged sterile in a double blister, which contains: the hex cover screw along with the implant in a titanium tube. A special driver is available for the regular platform implants, which simplifies implant insertion by eliminating the need for an implant mount, under certain circumstances.

Indications: The Sterngold-ImplaMed Stern Ex Implant System can be used in dental implant applications, in all bone qualities, 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.

Contraindications: The following conditions would obviate the use of dental implants: inadequate bone substance or quality, intractable poor oral hygiene, acute or chronic infection, abuse of drugs or alcohol, cirrhosis, allergies to titanium, smoking, cardiopathy, neoplasia in action, systemic conditions that would impair healing, excessive occlusal parafunction, history of radiation or patient otherwise not suitable for long or complicated surgery, or the inability to construct a functional prosthesis.

Patients Precautions: After surgery the patient has to avoid prolonged physical effort, consume only soft foods, and may need to take pain medication and use cold packs.

Warnings: It is possible that an implant may fail to integrate to the surrounding bone, which would lead to loss of the implant and restoration supported by the implant. Potential causes for failure include: lack of bone quantity or quality, inadequate surgical technique, infection, and poor patient oral hygiene. Temporary or permanent numbness (anesthesia), paresthesia, or dysesthesia are possible complications of implant surgery. Loosening or fracture of implant and restoration components may occur over time.

Precautions - Implants: Implant surgery is a highly specialized and complex procedure and special training is required. Practitioners should attend courses designed to teach proper techniques. Improper technique can result in implant failure and substantial loss of surrounding bone. Radiographs or other diagnostic reviews should be performed to determine position and topography of the maxillary sinus, nasal cavities, inferior alveolar nerve, mental foramen, natural tooth positions and other anatomical features that may affect implant placement or prognosis. Consultation between the surgeon, restorative dentist, and dental laboratory is essential for success.

During implant surgery, pay special attention to thermal and surgical trauma to minimize tissue damage, infection and excessive post-operative bleeding. Thermal trauma severely impedes implant integration to the bone. Reduced drill speeds of 1000-1500 r.p.m., the use of sharp drills, sufficient irrigation, and use of pilot drills in successively increasing sizes are essential. Recommended healing period is 3-4 months in the mandible and 4-6 months in the maxilla prior to healing abutment placement , although a number of dentists are using shorter healing periods. Healing abutment should be left in place for approximately 4 weeks prior to prosthetic placement and loading. Where applicable, reline the denture after implant placement to avoid premature loading.

Pre-operatory planning:

Pre-Operative planning should consist of all of the following:

1. A thorough clinical examination.
2. Consultations with each dentist and laboratory technician who is involved in the treatment of the patient.
3. Mounted diagnostic casts.
4. Radiographs for observing the position and topography of the maxillary sinus, nasal cavities, inferior alveolar nerve, mental foramen, natural tooth positions and other anatomic features that may affect implant placement or prognosis.
5. An evaluation of mandibular bone morphology and skeletal jaw classification.
6. A complete review of the patient's medical and dental history.
7. Fabrication of a surgical template which closely duplicates the position of the teeth in the final restoration.
8. Development of a complete restorative plan for the patient.
9. Determination of the type, size, quantity, and location of the implants for optimum esthetics and functional results.

Implant Surgery (Phase 1):

10. Administer anesthesia in the appropriate manner in preparation for dental surgery.
11. Position the surgical template intraorally and mark the position of the ideal surgical site.
12. Utilizing the mark as a preliminary guide, gain access to the surgical site by making an incision through the mucosa and attached gingiva along the crest of the ridge. Deflect a full thickness mucoperiosteal flap both lingually (palatally) and facially. Expand the operative site to identify the neurovascular bundles of the mental foramen in the mandible. In the maxilla, the borders of the maxillary sinus should also be identified. Examine the geometry, quality, and quantity of available bone at the site. Alterations to the predetermined "ideal" position should be made based upon the clinical findings, prior discussions with the restorative dentist and laboratory technician, and all diagnostic information.
13. Re-position the surgical template and penetrate the cortical bone using Sterngold-ImplaMed's Round Marking Bur to mark the site of the osteotomy. Use this mark to guide the direction and angle of subsequent drilling.
14. Penetrate the bone using a Sterngold ImplaMed 2.0 mm Externally Cooled Twist 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 drills to determine proper depth. Verify the osteotomy depth with a Sterngold ImplaMed Implant Depth Probe. Use normal sterile saline solution for external and internal irrigation, as required. All drilling should be performed at low speeds (1000 to 1500 RPM) to maintain bone temperature as low as possible.
15. Prepare to increase hole diameter using a Sterngold ImplaMed Pilot Drill. Use the 2-2.75 mm Pilot Drill if placing a 3.3 mm Narrow Platform implant. Use the 2-3.0 mm Pilot Drill if placing a Regular Platform implant (3.75, 4.0, and 5.0 mm). Drill at low speeds until the depth mark is reached. This will provide a properly aligned starting hole for the 2.75 mm or 3.0 mm drill.
16. For Narrow Platform implants, drill the prepared site with the 2.75 mm Externally Cooled Twist Drill. For Regular Platform implants drill the prepared site with the 3.0 mm Externally Cooled Twist Drill. For multiple implant procedures, use short or long Paralleling Pins as a guide while drilling.
17. Select the appropriate implant type based on bone quality, bone quantity, and physiological needs of the patient. If you are placing the Narrow Platform (3.3 mm) implants, countersink the 2.7 mm hole at 1000 to 1500 RPM using the depth mark on the 3.4 mm Internally Cooled Countersink to indicate proper depth.

    If you are placing the 3.75 mm and 4.0 mm implants, countersink the 3.0 mm hole at 1000 to 1500 RPM using the depth mark on the 4.1 mm Countersink to indicate proper depth. Irrigate during the procedure to reduce heat generated by friction. If the bone is very dense, it may be necessary to enlarge the site slightly by using the 3.3 mm diameter Externally Cooled Twist Drill. It may also be necessary to create internal threads in the osteotomy site. For the 3.3 mm diameter implants use the special 3.3 mm Titanium Bone Tap created for the double thread design, at 10 RPM or less. For the 3.75 mm diameter implants use the special 3.75 mm Titanium Bone Tap created for the double thread. For the 4.0 mm implants use the special 4.0 mm Titanium Bone Tap. The bone-tapping step may be skipped or abbreviated depending on the density and hardness of the bone encountered during the drilling steps. Sterngold ImplaMed Hex Screw type implants are designed to be seated to a depth where the external hex is flush with the adjacent cortical bone.

    If you are placing the 5.0 mm implants, prepare to increase the hole diameter by using the 3-4.0 mm Pilot Drill. Enlarge the osteotomy site using a 4.0 mm diameter Externally Cooled Twist Drill. If the bone is very dense, enlarge the osteotomy site using a 4.3 mm diameter Externally Cooled Twist Drill. If desired, create internal threads using the special 5.0 mm Titanium Bone Tap created for the double thread design, at 10 RPM or less.

Handling and Insertion Procedures:

18. Prepare package-to-patient delivery system by removing the blister pack from the outer box. Patient labels are provided for placement in the patient's chart. To open the blister, hold the bottom of the outer blister and peel away the top lid by pulling at the PEEL HERE tab. Non Sterile Assistant to drop inner blister package into sterile field. Sterile Assistant to peel away inner blister lid by holding bottom of blister and pulling at the PEEL HERE tab. Rotate the tube and implant assembly to the upright position and press the tube down into the round cavity at its base to lock into position. All Stern Ex implants are available in the Direct Delivery format (Implant Mount attached and Cover Screw included in the package). Use the Plastic Holder to transport the implant assembly to the prepared osteotomy site or remove the Plastic Holder and attach an Implant Mount Attachment to transport the implant assembly. Rotate at 10 RPM or less. Allow the implant to self align with the internal threads and feed into the site without downward force. When approximately 2-3 threads are left exposed or when the handpiece no longer has enough torque to continue rotating, remove the Implant Mount Attachment. Complete the insertion of the implant using the Ratchet Wrench or Hi-Torq wrench. Carefully use slow steady strokes with the ratchet until the implant mount assembly is at the proper depth. The groove on the Implant Mount body indicates proper depth. Use caution during this phase since the potential force than can be generated with the wrench can damage the implant or site.

    The Reguar Platform Stern Ex Implants (3.75, 4.0, and 5.0 mm) may also be purchased without the Implant Mount attached. In this case the SternTwist internal grip/driver is used to carry the implant from the package to the surgical site and to drive the implant into the bone, thus eliminating the need for the implant mount. This simplified procedure saves time. Install the SternTwist into the surgical handpiece. Align the SternTwist keys with the keyways in the implant and press into place. Transport the implant from the titanium tube to the prepared site. Apply gentle downward pressure to start the threading of the implant. Rotate at 10 RPM or less. Partially or completely install the implant with the SternTwist. To remove the SternTwist, tip the tool to the side to release the frictional fit and remove it from the implant.

    Note: In dense bone, or when placing an implant where the abutment will engage the outside of the external hex (i.e., single tooth restorations), it is recommended that the implant be only partially installed with the SternTwist. This is to avoid stripping of the internal keyways or possible deformation of the external hex of the implant. Instead, an Implant Mount should be attached to the implant and the insertion completed using the Implant Mount Attachment in the surgical handpiece or with the Hi-Torq Wrench or Ratchet Wrench. Regardless of the bone quality, if the handpiece no longer has enough torque to continue rotating, attach the Implant Mount Attachment to the implant and use the Hi-Torq Wrench or Ratchet Wrench, with slow steady strokes, to complete the insertion of the implant to the proper depth.

    If the SternTwist only was used, you are ready to insert the cover screw. If an implant mount was used, it must be disassembled from the implant using the Open End Wrench to hold the implant mount while unscrewing the implant mount screw with a Wide Slotted Driver or a Large External Hex Driver. The Open End Wrench is designed to help carry the implant mount away from the surgical site.

19. If a Narrow Platform implant was used, tighten the cover screw manually with a .035" hex hand driver. If a Regular Platform implant was used tighten the cover screw manually with a .048" hex hand driver or use the .048" hex end of the Stern Twist.
20. Replace the gingival tissue over the implants and suture the site closed.

Implant Uncovering (Phase 2):

21. After the appropriate healing period, approximately three months for the mandible and approximately six months for the maxilla, expose the implant by making an incision and raising a mucoperiosteal flap. Remove the Cover Screw and discard. Measure the gingival tissue height and insert a Sterngold-ImplaMed standard Healing Abutment or Natural Profile Healing Abutment.
22. Verify that the Healing Abutments are completely seated on the implants. Suture the gingival flap around the Healing Abutments.
23. Remove the sutures in approximately seven days.
24. The Healing Abutment should be left in place for approximately one month to allow adequate healing.

Precautions - Prosthetics: During prosthetic placement procedures, care should be taken to minimize tissue damage and infection. Radiographs and other diagnostic reviews are needed during prosthetic reconstruction to ensure proper fit to implants and abutments. Prosthodontic procedures must consider; proper stress distribution, passive adaptation and fitting of prosthesis to fixture abutments, adjusting of occlusion to opposite jaw, and avoiding excessive transverse load.

Refer to appropriate Sterngold-ImplaMed prosthetic technique sheet for detailed procedural instructions.

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.

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

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

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: The product expiration date is indicated by the hourglass symbol on the product label, followed by the year and month of expiration.

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

Cleaning/Sterilization Information: Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens. Implant products are provided pre-cleaned and sterile. Clinically contaminated implants should not be cleaned and resterilized under any circumstances.

How Supplied: Sterngold-ImplaMed implants are supplied sterile and

should be handled with sterile titanium instruments. Implants are intended for single use only and should not be resterilized if contaminated.

Inspection and Assembly: Not applicable.

	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		

Software: The Stern EX Implant System does not contain or utilize software.

EMC and Electrical Safety: The Stern EX Implant System does not require EMC and Electrical Safety Evaluation.

MR Safety: The Stern EX Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Stern EX Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Transport: Remove device from package and bring it to sterile area.

Storage: Place devices in a dry place to prevent damage and/or deterioration.

Manufactured and Distributed in the U.S.A. by:

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