

Acid Etched Implant System

Instructions For Use



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Descriptions: The Acid Etched is a self-tapping, double thread screw implant, manufactured from pure grade 4 titanium. The implant is acid etched except for the neck, and the head of the implant, which are machined to a smooth finish. Acid Etched 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 Acid Etched 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, relin the denture after implant placement to avoid premature loading.

Pre-operative 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 Internally Cooled Spade Drill or SternGold-ImplaMed Externally Cooled Twist Drill, depending on preference. 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 Internally Cooled "Three Spade" Drill or the 2.75 mm Externally Cooled Twist Drill. For Regular Platform implants drill the prepared site with the 3.0 mm Internally Cooled Spade Drill or 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 either the 3.3 mm diameter Internally Cooled Spade Drill or the 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 either a 4.0 mm diameter Internally Cooled Spade Drill or an Externally Cooled Twist Drill. If the bone is very dense, enlarge the osteotomy site using either a 4.3 mm diameter Internally Cooled "Three Spade" Drill or an 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 Acid Etched 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 a torque 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 Regular Platform Acid Etched 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 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 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 of 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 SternTwist.
 20. Replace the gingival tissue over the implants and suture the site closed.

Implant Uncovering (Phase 2):

21. After the appropriate healing period, approximately 3 months for the mandible and approximately 6 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 1 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.

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.

Where the label indicates, disinfect products supplied non-sterile prior to use.

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

Warranty:

SternGold-ImplaMed warrants its products to be free from defects in material and/or workmanship. No other warranty is expressed or implied. This warranty applies to the original purchaser only. In the unlikely event of a defect, please follow the returned goods policy outlined in the product price list.

Labeling Symbols: Symbols are used for products sold internationally for ease in identification.

- REF Refers to product "Catalog Number"
- LOT Symbol for product "Lot Number"
- △ Symbol for "Refer to Instructions"
- STERILIZED BY Symbol for "Sterilized using Irradiation"
- Ⓜ Symbol for "Use by Date"
- Ⓢ Symbol for "Do Not Reuse"

CE 0197 Symbol for CE Mark

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