Stern IC

Instructions for Use

Sterngold®

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Stern IC Regular Neck Implants

ENGLISH

Descriptions: The Stern IC is a screw implant, manufactured from pure grade 4 titanium. The implant is acid etched except for the neck of the implant, which is machined to a smooth finish. The Stern IC Implants are manufactured with a flared neck, used for one-stage, transgingival, or subgingival implantation. The neck and body include an internal Morse taper and octagon. The implants are compatible with the Straumann ITI implant system, both surgically and prosthetically. 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: implant mount, along with the implant in a titanium tube.

Indications: The Stern IC Dental implant System is intended for long term 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.

The Stern IC Dental Implant System is also indicated for immediate loading with good primary stability and appropriate occlusal loading.

The Stern IC Dental Implants are compatible with the Straumann Rn Synocta, Straumann SynOcta Meso Abutments, Straumann RC Temporary Abutments, and the Straumann RC Cementable abutments.

The Stern IC Dental Implant System is only intended for use with straight abutments.

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 800-1200 RPM, the use of sharp drills, sufficient irrigation, and use of pilot drills in successively increasing sizes are essential. Recommended healing period is 2-3 months or longer if conditions warrant, although a number of dentists are using shorter healing periods. 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 a round marking bur, or Starter Drill, 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 2.2 mm 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 depth probe. Use normal sterile saline solution for external and internal irrigation, as required. All drilling should be performed at low speeds (800 to 1200 RPM) to maintain bone temperature as low as possible.

    Note: For proper strength and function the apical tip of the drills is slightly longer than the length of the implants (up to 0.4 mm). Consider this fact when choosing an implant site.

15. Regular Neck Stern IC Implants have a 4.1 mm and a 3.3 mm diameter screw body and a 4.8 mm diameter neck, with a 1.8 mm smooth collar height. Enlarge the osteotomy using a 2.8 mm drill. Drill at low speeds until the depth mark is reached.

16. For multiple implant procedures, use depth gauges as guides while drilling. When placing the 3.3 mm Stern IC RN Implants, tap the osteotomy using the 3.3 mm tap to the proper depth mark at 15 RPM max. Irrigate during the procedure to reduce heat generated by friction. Use the 2.8 mm SP Profile Drill to create the proper shape in the bone at a maximum speed of 400 RPM.

    When placing the 4.1 mm Stern IC RN Implants, drill the prepared site with a 3.5 mm drill.

17. Select the appropriate implant type based on bone quality, bone quantity, and physiological needs of the patient. Irrigate during the procedure to reduce heat generated by friction. If the bone is dense, when placing the Regular Neck implants with the 1.8 mm collar, use the 3.5 mm profile drill to create the proper shape in the bone, with a maximum speed of 400 RPM, before using the 4.1 mm tap to create threads in the osteotomy.

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 IC implants are packaged in the Direct Delivery format (Implant Mount attached). Use an adapter to transport the implant assembly to the prepared osteotomy site and to begin insertion. Rotate at 15 RPM or less using a ratchet or handpiece. Control the amount of torque applied to the implant to avoid pressure necrosis. Allow the implant to self align with the internal threads and feed into the site without downward force.

    To disassemble implant mount from the implant use the holding key to hold the hex of the implant mount while unscrewing the implant mount screw with a ratchet and adapter, or handpiece and adapter, rotating counter-clockwise.
19. Close the implant using a cover screw or healing cap. Tighten the cover screw or healing cap manually with a .048" hex driver.
20. Replace the gingival tissue up to the neck of the implants and suture the site closed.
21. Remove the sutures in approximately seven days.
22. 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 may be needed during prosthetic reconstruction to ensure proper fit to implants and abutments. Prosthodontic procedures must be considered; proper stress distribution, passive adaptation and fitting of prosthesis to abutments, adjusting of occlusion to opposite jaw, and avoiding excessive transverse load.

How Supplied: Sterngold 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.

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

Warranty: Sterngold 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.

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.

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.

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.

CLEANING/STERILIZATION INFORMATION
Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens. Implant products are provided precleaned and sterile. Clinically contaminated implants should not be cleaned and resterilized under any circumstances.

Non Sterile Abutments shall be sterilized using steam sterilization. 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.

The Stern IC Dental Implant has not been evaluated for safety and compatibility in the MR environment.

The Stern IC Dental implant has not been tested for heating or migration in the MR environment.

	Cycle Type	Temperature	Exposure Time	Dry Time (only for kits)
Parts individually	Gravity (steam)	121˚C 250˚F	40 minutes	n/a
Parts individually	Gravity (steam)	121˚C 250˚F	80 minutes	30 minutes
	Pre-vacuum (steam)	132˚C 270˚F	6 minutes	30 minutes
	Pre-vacuum (steam)	134˚C 273˚F	18 minutes	30 minutes
	Dry Heat	160˚C 320˚F	120 minutes	n/a

Symbol	Used For	Symbol	Used For
②	Do not reuse		Used by YYYY-MM-DD or YYYY-MM
LOT	Batch code		Manufacturer
STERILE R	Sterilized using irradiation	NON STERILE	Symbol for Non-Sterile
Rx only	Symbol for "Use by Prescription only"	!	Caution, consult accompanying documents
CE	Symbol for "European Conformity"	REF	Catalog number

Symbol	Used For	Symbol	Used For
	Do not re-sterilize		Do not use if package is damaged
	Authorized representative in the European Community		

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

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