Sterngold-ImplaMed offers many dental implant designs. Whether Regular, Wide or Narrow Platform all implants have external hex heads that are compatible to and interchangeable with the Brånemark System®. All of the screw type and cylinder type externally hexed head implant designs can be used with Sterngold-ImplaMed’s full line of prosthetic components, offering the restorative dentist the convenience of using three prosthetic platforms (wide, narrow, and regular) when various types of implants are required. Each implant design is ideally engineered to match a variety of surgical sites that may be encountered. Sterngold-ImplaMed believes that properly matching the implant to its final position in the mandible or maxilla is one of the most important elements of the entire implant procedure. All implants provide for non-rotational single and multiple tooth restorations by selecting the appropriate Sterngold-ImplaMed prosthetic components.

The Master Surgical Kit (Order #: 905128) contains all of the instruments needed for installation of any implant within the Sterngold-ImplaMed system.

Warnings
There is always the possibility that an implant may be lost due to failure to integrate to the surrounding bone. This situation can ultimately lead to not only the loss of the implant, but also to the loss of the restoration supported by the implant(s) and bone. Guarantees should not be given to the patient regarding the short or long term success of the implant(s) or prosthesis. Inadequate bone quality or quantity, infection, poor oral hygiene, and patient medical problems are just a few of the causes for loss of implants over time. Permanent numbness (anesthesia), paraesthesia, dysesthesia should be discussed with all patients who are candidates for implants in the mandible. All patients should be made aware of the possibility of implant, abutment screw or gold screw fractures or loosening. All additional potential complications should be discussed with the patient and appropriate consent forms signed. Components, equipment, and dental instruments used in conjunction with implant insertion must be thoroughly cleaned and sterilized prior to use. Sterile operating techniques must be followed and implants cannot be re-sterilized if contaminated.

Contraindications
The following conditions would obviate the use of dental implants: abuse of drugs or alcohol, allergies to titanium, smoking, systemic conditions that would impair healing, excessive occlusal parafunction, history of radiation or patients otherwise not suitable for long or complicated surgery, inability to construct a functional prosthesis, and intractable poor oral hygiene.
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.
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.
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 Narrow Platform implant. Use the 2-3.0 mm Pilot Drill if placing a Regular or Wide Platform implant. 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 Externally Cooled Twist Drill. For Regular or Wide 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. Follow the appropriate site preparation instructions for Hex Screw Implants or Hex Cylinder Implants to prepare the osteotomy site. Complete the placement of the implants by following steps 18-23 for Hex Screw Implants or 24-28 for Hex Cylinder Implants.

Site Preparation – Hex Screw Implants

REGULAR PLATFORM

<table>
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<tr>
<th>Screw Implants 3.75 mm diameter</th>
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<td>STD</td>
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Standard, Self Tapping (SST*), TPS Coated, and HA Coated
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. Create internal threads in the osteotomy site for non-self tapping implants using a 3.75 mm Titanium Bone Tap at 10 RPM or less. 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.

<table>
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Standard, Self Tapping (SST*), TPS Coated, and HA Coated
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. Create internal threads in the osteotomy site for non-self tapping implants using a 4.0 mm Titanium Bone Tap at 10 RPM or less. The bone tapping step may be skipped or abbreviated depending on the density and hardness of the bone encountered during the drilling steps. 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. This type of implant is primarily intended to be used in situations where the 3.75 mm diameter implant has been installed and is immediately judged not to be stable enough due to bone quality, density or irregularities in the shape of the osteotomy. The 4.0 mm diameter implant can be employed as an original implant choice if desired.

<table>
<thead>
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Self Tapping, TPS Coated, and HA Coated
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. Create internal threads.
The specific design of the threads and body of the implant are designed for lower density bone and situations where the buccal and lingual cortical bone can be mechanically engaged for initial stability.

**WIDE PLATFORM**

**Self Tapping (SST*), TPS Coated and HA Coated**
Prepare to increase the hole diameter by using a 3-4.3 mm Internally Cooled or Externally Cooled Pilot Drill. Enlarge the osteotomy site using either a 4.3 mm diameter Internally Cooled "Three Spade" Drill or an Externally Cooled Twist Drill. Countersink the 4.3 mm hole at 1000 to 1500 RPM using the depth mark on the 5.5 mm Internally Cooled Countersink to indicate proper depth. The bone tapping step may be skipped or abbreviated depending on the density and hardness of the bone encountered during the drilling steps when using the self tapping design. If using one of the coated screw designs, create internal threads in the osteotomy site using a WP 5.0 mm Bone Tap at 10 RPM of less.

**Self Tapping (SST*), TPS Coated and HA Coated**

**Site Preparation - Hex Cylinder Implants**

**REGULAR PLATFORM**

**TPS Coated, and HA Coated**
Select either a Titanium Plasma Sprayed (TPS) coated cylinder or a Hydroxylapatite (HA) coated cylinder. Countersink the 3.0 mm hole at 1000 to 1500 RPM using the depth mark on the 4.1 mm Internally Cooled Countersink to indicate proper depth. Enlarge the osteotomy site using either the 3.3 mm diameter Internally Cooled Spade Drill or the Externally Cooled Twist Drill.

**NARROW PLATFORM**

**TPS Coated, and HA Coated**
Select either a Titanium Plasma Sprayed (TPS) coated cylinder or a Hydroxylapatite (HA) coated cylinder. 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 "Three Spade" Drill or an Externally Cooled Twist Drill. The bone tapping step may be skipped or abbreviated depending on the density and hardness of the bone encountered during the drilling steps when using the self tapping design. If using one of the coated screw designs, create internal threads in the osteotomy site using a WP 6.0 mm Bone Tap at 10 RPM of less.

**Cylinder Implants 3.3 mm diameter**

**TPS Coated, and HA Coated**
Select either a Titanium Plasma Sprayed (TPS) coated cylinder or a Hydroxylapatite (HA) coated cylinder. Enlarge the 2.75 mm osteomy site using either the 3.3 mm diameter Internally Cooled Spade Drill or the Externally Cooled Twist Drill.

**Screw Implants 5.0 mm diameter**

**Screw Implants 6.0 mm diameter.**

**Cylinder Implants 4.0 mm diameter**

**Screw Implants 3.3 mm diameter**

*SST–Stern Self Tapping*
Hex Screw

Handling and Insertion Procedures

18. Prepare package-to-patient delivery system by removing the blister pack from the box. Peel back protective cover on outer blister pack and remove the sterile inner blister using standard sterile handling techniques. Remove the protective cover on the sterile inner blister pack to expose the implant and protective titanium tube. Position and secure tube/implant assembly in vertical position. All Hex Screw type implants are available with Implant Mounts pre-assembled on the implant body to eliminate the step of attaching the Implant Mount. If an unmounted implant has been chosen, install Implant Mount using open end wrench and hex driver. Check for hex engagement. Be sure to secure mount with open end wrench to avoid movement of the implant. Transport the implant assembly to the prepared osteotomy site using the Implant Mount Attachment. Apply gentle downward pressure to start the threading of the implant. Rotate at 10 RPM or less.

19. If a Direct Delivery Screw Implant has been selected, use the Plastic Holder to transport the implant assembly to the prepared osteotomy site or remove the Plastic Holder and attach 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.

20. Complete the insertion of the implant using the Ratchet 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 that can be generated with the wrench can damage the implant or site.

21. Disassemble the implant mount 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.

22. Remove cover screw from packaging. Install cover screw into implant using hex driver. Cover screws are seated into the internal threads of the implant and protect the precision prosthetic interface area during the three to six months of healing.

23. Replace the gingival tissue over the implants and suture the site closed.

Hex Cylinder

Handling and Insertion Procedures

24. Several types of patented\(^\text{®}\) Hex Cylinder Implants are available. Two types of coatings are available in 3.3 mm and 4.0 mm diameters. All have external hex heads with 3.3 and 4.0 mm diameters in Regular Platform and 3.3 mm in Narrow Platform. The choices of coatings are: Titanium Plasma Spray (TPS) and a combination Hydroxyapatite/Titanium Plasma Spray Coating (HA). Sterngold-ImplaMed’s HA Cylinder Implant has a TPS layer beneath the HA to increase the surface area and to improve the bond strength.

25. Prevent the coatings of these implants from coming in contact with anything except the osteotomy site. Sterngold-ImplaMed Hex Cylinder type implants are packaged with a pre-assembled hex cover screw attached to a disposable plastic holder which helps transport the implant to the prepared site without touching the coatings.

26. Prepare package-to-patient delivery system by removing the blister pack from the box. Peel back protective cover on outer blister pack and remove the sterile inner blister using standard sterile handling techniques. Remove the protective cover on the sterile inner blister pack to expose the implant and protective titanium tube. Position and secure tube/implant assembly in vertical position. Grabbing the disposable plastic holder with surgical forceps or fingers position the implant into the osteotomy site. Seating of the implant in the site requires tapping a Cylinder Seating Tool with a Surgical Mallet to drive the implant into the site. This type of implant achieves initial stability in low density bone often found in the posterior mandible and maxilla by having a very snug fit into the prepared osteotomy site. The implants are designed to be seated to a depth where the external hex is flush with the adjacent cortical bone.

27. After the Hex Cylinder implants have been properly seated into the bone, remove the plastic holder and discard.

28. Replace the gingival tissue over the implants and suture the site closed.

Implant Uncovering (Phase 2)

29. 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 4.0 mm, 6.0 mm or 8.0 mm Healing Abutment or Natural Profile Healing Abutment.

30. Verify that the Healing Abutments are completely seated on the implants. Suture the gingival flap around the Healing Abutments.

31. Remove the sutures in approximately seven days.

32. The Healing Abutment should be left in place for approximately 1 month to allow adequate healing.

Prosthetic Restorations

Be sure to note whether the implants placed are Regular, Wide, or Narrow Platform. Each type has particular restorative components that must be used. These products are listed in Sterngold-ImplaMed’s Restorative Catalog. Castable abutments should use only High Noble Class III or Class IV dental Alloys. For all restorative prosthetic components carefully read and follow the manufacturer’s instructions for use.

Caution: Federal law (USA) restricts implant devices and components to sale by or on the order of a licensed dentist or physician.

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 catalog.