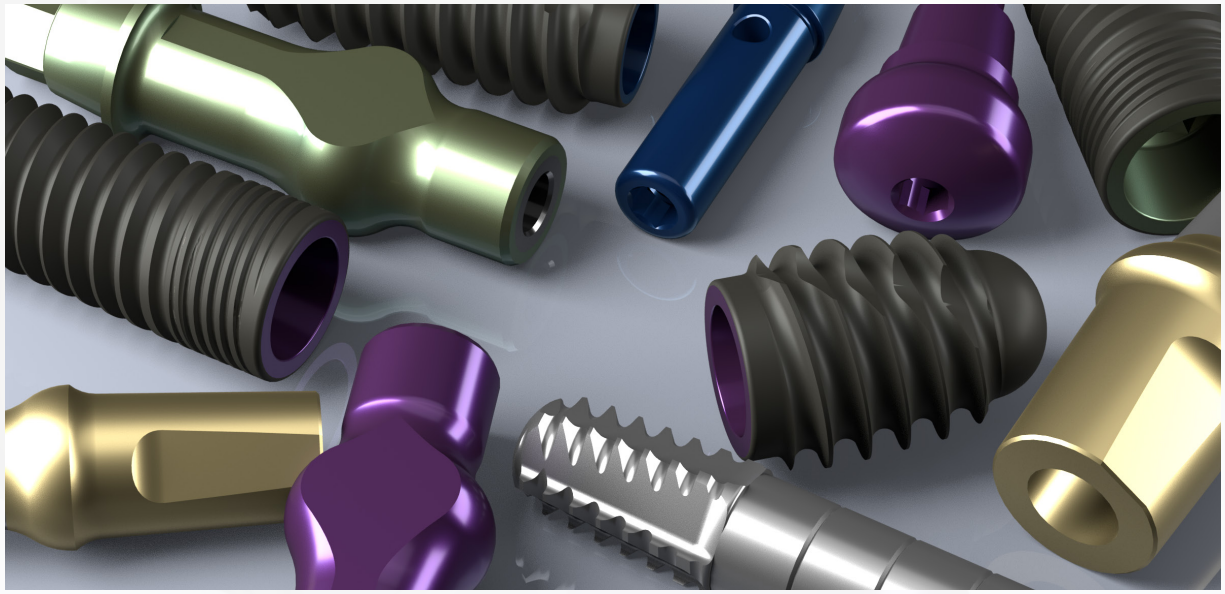
IMPLANT ONE



Implant One Implants

Surgical Manual

Implant Logistics, Inc.
711 Spartan Drive
Sparta, WI 54656
Phone: (608) 498-4855
Fax: (608) 260-7706

Implant-One™ Implants Instructions for Use

Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed dentist or physician.

IMPORTANT NOTE TO CLINICIAN
For safe and effective use of these products or devices they should only be used by trained professionals. Poor technique can result in implant failure and loss of supporting bone.

It is expected that clinicians placing Implant-One Dental Implants have a good understanding of the principals of implant surgery and final restorations before surgically placing these implants. Individual indications and the type of implant placement will dictate any pre-medications required. Depending on the type of surgical event (flapless or flapped, bone graft or not) some patients may be given an antibiotic prior to the surgical appointment.

Post-surgical antibiotics may also be given at the clinician's discretion.

Local anesthesia is required at time of placement and possibly during the surgical event based on the complexity of the case. Draping sterile sheets over the patient at the time of surgery is also recommended.

Device Description

The Implant-One™ Dental Implant System consists of endosseous dental implants, cover screws, healing caps, abutments and abutment screws in a variety of sizes to accommodate differing patient anatomy.

Endosseous implants are self-tapping and threaded, and offered having root form or wide thread form. Root-form implant diameters range from 3.25mm to 5.5mm having lengths from 8mm to 14mm. Wide thread implant diameters are available in 4.1 and 4.5mm (8mm to 14mm lengths), 5.5mm (8mm to 12mm lengths) and 6.5mm (8mm to 10mm lengths). Cover screws and healing caps provide protection to the threads of the abutment connection during endosseous and gingival healing. Cover screws are pre- packaged with each implant. Healing caps are provided as an alternative to the cover screw and are packaged separately. The Implant-One™ dental implants and cover screws are provided sterile.

Implant-One™ abutments are fastened to the implant using either an abutment screw or integral retaining threads. Abutment options include standard, ball, MUA, angled, patient-specific, glueless, denture-retaining, post, anatomical angled (15° and 30°), solid, straight, temporary and wide post having various platform heights. Specific instructions for the clinical use of these abutments can be found in the Implant Logistics online Resource Library at implantlogistics.com.

Not all abutments can be used for single-unit restorations. The MUA, angled MUA, ball, denture-retaining and glueless abutments are intended only for multi-unit loaded restorations. The ball, denture-retaining and glueless abutments are to be used in fully removable dentures. The MUA and angled MUA are to be used in screw retained dentures. A titanium sleeve will be used to allow for screw retention.

The final design parameters for the patient-specific abutment are as follows. Maximum total height: 15mm; minimum/maximum gingival height: 0.5mm/8mm; minimum post height: 4mm; maximum angulation: 30°; minimum wall thickness: 0.78mm (at 1.5mm above the proximal end); minimum diameter: 3.75 mm for the 300 Series, 4.25 mm for the 400 Series and 4.75 mm for the 500 Series.

All Implant-One™ components (implants, abutments, cover screws, healing caps and abutment screws) are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 or wrought titanium alloy (Ti-6Al-4V) as described by ASTM F1472.

How Supplied

The Implant-One™ dental implants, cover screws, and carrier/impression posts are supplied sterile. All sterile products are labeled 'STERILE' – the individual package labels contain sterilization information. All products sold sterile are for single use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave sterilized implants. Do not reuse implants.

Implant-One™ abutments, healing caps, abutment screws and instruments are supplied non-sterile. These components must be removed from the packaging then thoroughly cleaned and sterilized prior to surgery. Do not reuse abutments (including cover screws, healing abutments, abutment screws and abutments).

Cleaning and Sterilization

Reusable devices must be cleaned before their first use and then between uses. The non-sterile abutments and screws must be cleaned before their first use. The following validated steps are recommended as the cleaning protocol. These instructions are not intended for implants or single-use surgical instruments.

Cleaning:

1. Prepare All-in-One 4 Enzyme Detergent, per manufacturer's instructions
2. Rinse in cold water (<43°C) to remove gross debris and to prevent coagulation of blood
3. Place instruments in container ensuring sufficient amount of Enzymatic Cleaner to cover instruments with solution.
4. Sonicate instruments for a minimum of ten (10) minutes in an ultrasonic cleaner containing enzymatic detergent at 40°C.
5. Remove additional soil from challenging design feature (i.e. holes, lumens, hinged/mating surfaces, interfaces, crevices, serrations) using common hospital cleaning tools.
    a. Move and/or retract all moveable parts and remove soil using a brush.
    b. Scrub lumens or holes with a brush of an appropriate size to ensure that the full width and depth is accessed. Use a twisting action with the brush. Small diameter lumens may be irrigated with the cleaning solution using a syringe.
    c. Open hinged devices and scrub hinged area with a brush.
    d. Scrub crevices with a brush.
6. Rinse thoroughly with warm water, making sure to irrigate the challenging design features. Note: Final rinsing should be carried out using demineralized water. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.
7. Inspect device under adequate lighting for visible soil. Repeat step 6 until all visible soil has been removed.

Sterilization:

- Return the reusable devices to their appropriate locations within the surgical tray.
- Enclose the surgical tray in an FDA cleared sterilization wrap or autoclave bags twice.
- Sterilization validation has shown these recommendations for sterilization are effective to a sterility assurance level (SAL) of 10^{-6}:

Storage and Handling

Implant components and sterile implant packaging should be handled and stored appropriately to protect them from unintentional damage.

Method:	*Steam*	Temperature:	*132°C (270°F)*
Cycle:	*Pre-vacuum*	Dry Time:	*30 minutes*
Exposure time:	*4 minutes*		

Indications for Use

The Implant-One™ system is indicated for surgical placement in partially or completely edentulous upper or lower jaws to provide a means for prosthetic attachment to restore a patient's chewing function. The Implant-One™ system is indicated for immediate loading only when primary stability is achieved and with the appropriate occlusal loading.

Contraindications

Some general contraindications for placement include:

- Alcohol and drug abuse
- Recently radiated placement sites
- Patients with uncontrolled diabetes
- Patients with mental psychosis
- Medical conditions such as blood disorders or uncontrolled hormonal conditions.

Local contraindications for placement:

- Inadequate bone quantity and/or quality necessary for implant support.
- Clinical signs of pathology in or near the implant site.
- Poor oral hygiene.

Procedural Precautions, Bone-Implant Relationship

- The prepared osteotomy must be prepared so that heat necrosis is minimized.
- The prepared osteotomy must be prepared so that pressure necrosis is minimized.
- Primary stability is achieved at time of placement.
- Vital structures must not be compromised at time of placement. These include cortical plates, nasal cavities and the inferior alveolar nerve canal. Some bone-implant factors to consider at time of placement:
  - Diameter of the implant site.
  - Depth of the implant site.
  - Bone quality and quantity.
  - Cone Beam Computed Tomographic images are highly recommended to evaluate implant sites relative to available bone, position of vital structures and adjacent dentition.
  - It is recommended that small diameter implants not be restored with angled abutments in the molar region.

Warnings

- Excessive bone loss or breakage of a dental implant or restorative device may occur when an implant or abutment is loaded or tightened beyond its functional capability. Physiological and anatomic conditions may negatively affect the performance of dental implants.
- Mishandling of small components inside the patient's mouth carries a risk of aspiration and/or swallowing.
- Forcing the implant into the osteotomy deeper than the depth established by the drills can result in stripping the driver hex interface inside the implant, stripping the driver, or stripping the walls of the osteotomy that may prevent an effective initial implant fixation.
- Small diameter implants and angled abutments should not be used in the premolar or molar region.

MRI Safety Information

The Implant-One™ 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 Implant-One™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Procedural Precautions, Surgery

During the planning phase, it is important to determine the vertical dimension, the actual space available between the alveolar crest and the opposing dentition, in order to confirm that the available space will accommodate the proposed abutment and the final crown restoration. This information varies with each patient and abutment; therefore, it should be carefully evaluated before placing any dental implant. The final prosthesis should be considered prior to the placement of the dental implant. Utilize continuous irrigation with a cool, sterile irrigating solution to avoid excessive damage to the surrounding tissue and to prevent compromising Osseo integration. This is mandatory during all procedures. Avoid excessive pressure during preparation of the bone site. As the drilling speed varies based on the instrument and the surgical procedure, recommendations for speed can be found in the Surgical Manual.

Only sharp instruments of the highest quality should be used for any surgical procedure involving bone.

Minimizing trauma to the bone and surrounding tissue enhances the potential for successful Osseo integration. In order to eliminate contaminants and other sources of infection, all nonsterile devices should be cleaned and/or sterilized prior to use, per the instructions on the individual product labels.

Procedural Precautions, Post-Operative Care

If the patient experiences any unusual discomfort after implant placement they should be seen immediately. The decision as to when to load the implants should be left up to the clinician and should incorporate the following clinical considerations:

- Initial primary stability.
- Mandibular (shorter time period) or maxillary (longer time period) arch placement.
- Status of occlusal forces being in balance.

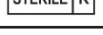
Long term clinical success can be best achieved if the final restorations are not placed until 4 to 6 months after placement. This gives the bone adequate time to integrate with the implant. The bone undergoes remodeling for the first four to ten weeks and loading the bone during this time creates significant risks to implant success. Early loading or immediate loading of the implant can be done at the clinician's discretion but has additional risks when compared to delayed loading.

Potential Adverse Events

Potential adverse events associated with the use of dental implants may include:

- Failure to integrate.
- Persistent pain, numbness, paresthesia.
- Loss of integration.
- Hyperplasia.
- Dehiscence of the implant, requiring bone grafting.
- Perforation of the maxillary sinus, inferior border of the mandible, lingual plate or labial plate.
- Implant breakage or fracture.
- Nerve injury from violation of the inferior alveolar canal space during surgery.
- Temporary or permanent paresthesia.
- Systemic infection.
- Infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency.

Symbols Glossary

Symbol	Title	Ref. No.
	Manufacturer	5.1.1
	Use-by date	5.1.4
	Sterilized using irradiation	5.2.4
	Do not re-use	5.4.2
	Consult instructions for use	5.4.3
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	N/A

Treatment and Preoperative Planning

General Information:
These instructions will facilitate practitioners in the use of Implant-One's Implant System. This manual is not intended for use as a substitute for professional training and experience.

Treatment Planning:
Patient Evaluation and Selection
• Several important factors must be considered when evaluating a patient prior to implant surgery. The pre-surgical evaluation must include a cautious and detailed assessment of the patient's general health, current medical status, medical history, oral hygiene, motivation and expectations. Factors such as heavy tobacco use, chewing patterns and alcohol consumption should also be considered. In addition, the clinician should determine if the case presents an acceptable anatomical basis conducive to implant placement. An extensive intraoral examination should be undertaken to evaluate the oral cavity for any potential bone or soft tissue pathology. The examiner should also determine the perio-dontal status of the remaining teeth, the health of the soft tissue, or the presence of occlusal abnormalities such as bruxism or crossbite. The presence of other conditions that could adversely affect any existing natural dentition or healthy tissue surrounding the implant should also be evaluated.

• Diseases of the mucous membrane and connective tissues, pathologic bone disease and severe malocclusion could affect the determination of whether the patient is a suitable implant candidate.

• The use of anticoagulants and the existence of metabolic diseases, such as diabetes, allergies, chronic renal or cardiac disease and blood dyscrasia could significantly influence the patient's ability to successfully undergo implant procedures.

• If the patient's medical history reveals an existing condition or signals a potential problem that may compromise treatment and/or the patient's wellbeing, consultation with a physician is recommended.

Preoperative Planning:
• Proper treatment planning, as well as the selection of the proper implant length and diameter, are crucial to the long-term success of the implant and restoration. Before an implant can be selected, the anatomical foundation available to receive the implant must be carefully assessed. Several steps should be taken to complete the evaluation:

• Clinical examination of the oral cavity can provide important information about the health of the soft tissue at the proposed implant site. Tissue tone and the state of the superficial tissues should be evaluated. In addition, the patient should demonstrate an adequate dimension of attached mucosa or keratinized tissue at the site selected for implantation. In partially edentulous cases, the periodontal status of the remaining dentition should be assessed and interaction between the implant restoration and the adjacent natural dentition should be considered.

• The bony foundation and ridge need to be clinically analyzed to ensure the presence of proper dimensions and the amount of bone for implant placement. At least one millimeter of bone should be present at the buccal and lingual aspects of the implant following placement. During the planning state, it is useful to measure the existing bone foundation.

CT Scans:
• Computed tomography (CT) scans help surgeons view parts of the body with the help of three-dimensional images. Image guided surgical planning allows surgeons to see anatomical landmarks like nerves, sinus cavities and bony structures in order to plan for the placement of dental implants and prostheses.

• Through the use of CT scans, clinicians are able to more precisely measure the locations of anatomical structures, dimensions of the underlying bone and ascertain bone densities in order to plan and perform clinically demanding cases.

Surgical Precautions
Clinical Considerations
• True bone contours can only be evaluated after tissue flaps have been reflected at the time of surgery or via preoperative CT scans of sufficient quality. Even if bone dimensions are painstakingly measured prior to surgery, the doctor and patient must accept the possibility that inadequate bone anatomy might be discovered during surgery and preclude implant placement.

• During the presurgical planning phase, it is important to determine the vertical dimension the actual space available between the alveolar crest and the opposing dentition to confirm that the available space will accommodate the proposed abutment and the final crown restoration. The height required by the abutment may vary with the type of abutment; therefore, the surgeon and restorative dentist should carefully evaluate the abutment size. The final prosthesis should be conceptually designed prior to the placement of the implant.

• Study models should be used preoperatively to evaluate the residual ridge and to determine the position and angulations of all implants. These models allow the clinician to evaluate the opposing dentition and its effect on the implant position. A surgical guide stent, which is critical for determining the precise position and angulation of the implant, can be constructed on the study model.

• Several software companies offer planning software that allows clinicians the ability to plan implant placement three dimensionally in conjunction with the CT scans. From plans created in these software packages, surgical guides can be made to aide in the preparation and placement of implants.

• To prevent damage to the bone tissue and to prevent compromising osseointegration, abundant and continuous irrigation with a cool, sterile, irrigating solution is mandatory during all drilling procedures. The application of excessive pressure during preparation of the bone site must be avoided.

• Bone surgery utilizes a high torque electric drilling unit that can be operated in forward and reverse modes at speeds ranging from 0 to 2000 rpm, depending on the surgical requirements. Sharp instruments of the highest quality should be utilized during implant site preparation to reduce possible overheating and trauma to the bone. Minimizing trauma enhances the potential for successful osseointegration.

• The time elapsed between surgical placement of the implant and final abutment placement can vary or be modified, depending on the quality of the bone at the implantation site, bony response to the implant surface and other implanted materials and the surgeon's assessment of the patient's bone density at the time of the surgical procedure. Extreme care must be taken to avoid excessive force being applied to the implant during this time.

Twist Drills
• Implant-One Drills are used to prepare the osteotomy for placement of Implant-One Tapered Implants.

• Implant-One Depth Measurement System includes drill depth marks on each drill that correspond to the placement of the implant. Implant-One's Protocol follows the principles of protecting the implant from premature loading by recommending placing the implant 1-2 millimeters sub-crestally. However, the implant can be placed at crest of ridge and/or supracrestally.

• The Twist Drills have been designed with precise laser etched markings to assess proper depth. The clinician should become familiar with these depth landmarks to prevent over or under preparation of the osteotomy site.

• **Twist Drill Speed:** Implant-One twist drills should be operated between 800 –1200rpm.

• **Twist Drill Technique:** For either crestal or subcrestal implant placement, drill to the top of either the crestal or subcrestal depth landmarks on the twist drill.

• When using a twist drill to prepare the implant site, the drill should advance into the osteotomy site with light pressure. If the drill does not advance easily, a pumping action of the drill is recommended to avoid constant contact of the drill to the bone, which can generate excessive heat and potential heat necrosis and implant integration failure.

• Sharp drill are also required, using a worn or dull drill will also generate excessive heat, bone necrosis and potential implant integration failure.

• If the drill does not pull out easily, tap the foot pedal while pulling drill out. In addition to preserving the integrity of the osteotomy site, this technique maximizes autogenous bone recovery from the shaping drill flutes.

• When placing a tapered implant in soft bone (Type IV), the surgeon should consider under sizing the osteotomy by one drilling sequence size (i.e. if placing a tapered 5mm diameter X 10mm length implant in soft bone (Type IV), the surgeon should use the 4.5mm x 10mm drilling sequence recommended in this surgical manual and directly place the implant.

• *NOTE: During preparation of the osteotomy, the twist drill should advance into the osteotomy using light pressure. The need to push heavily on the drill may indicate the need to replace the drill because of dullness or that the previous drill depth was inadequate.*

• Due to the geometrical differences that exist between a tapered and a parallel walled implant, there are several important technique adjustments that are required when placing tapered implants:

- *The surgeon should determine the appropriate vertical position of the implant (supracrestal, crestal or subcrestal) at the time of osteotomy preparation.*
- The surgeon should prepare the osteotomy so that when the implant is fully seated, the implant seating surface is at the desired position.
- The Implant Depth/Direction Indicator (PARALLEL PIN) was designed to simulate the implant position prior to placement. After preparation of the osteotomy with the final drill, suction out the osteotomy to remove debris. Select the corresponding PARALLEL PIN and place the appropriate end into the osteotomy. Check the position (crestal or subcrestal) of the PARALLEL PIN in relation to the adjacent bone. This position locates where the platform of the implant will be positioned when properly placed.
- If during placement with the power drill, the implant platform is higher in relation to the bone than was demonstrated with the PARALLEL PIN, the clinician should consider using a hand ratchet to complete the implant placement so that the implant body conforms correctly to the osteotomy.

• Over Preparing the osteotomy depth and then placing the implant at a crestal level may result in a conical space around the apical and coronal aspects of the implant with minimal thread engagement This placement position may result in decreased implant to osteotomy contact, with contact occurring only along the parallel coronal portion of the implant, resulting in decreased stability of the implant.

• Under Preparing the osteotomy depth and then placing the implant more apical relative to the prepared depth may result in increased pressure along the tapered portion of the osteotomy and on the collar contact areas of the implant profile Under Prepared Subcrestal Placement. This may result in the implant spinning and losing rotational resistance.

• The clinician may consider under-sizing the osteotomy in soft bone (Type IV).

Soft Bone (Type IV) Subcrestal Implant Placement Protocol

Internal Taper Connection Implants
If planning to place a tapered implant in soft bone, under sizing the osteotomy by one size drilling sequence, is recommended.

Parallel Pins for depth
• The Implant Parallel Pins are used to simulate the implant platform position prior to placing the implant. Parallel pins have markings to show depth in millimeters.

• STEP 1: Verify the parallel pin's position in reference to the crest of the bone. This also verifies the depth of the osteotomy that has been created. The parallel pin's platform should be at the level you desire the implant platform to attain. If the parallel pin platform is too high, then re-drilling to the correct depth is required. If the parallel pin platform is too deep versus the desired position, this indicates some degree of osteotomy over preparation has taken place. To ensure proper engagement of the implant, it must be seated to the depth demonstrated by the parallel pin. A longer implant can be considered. The clinician may consider verifying the position of the parallel pin with a radiograph.

• STEP 2: When placing the implant, the implant platform should reach the same position that the parallel pin platform previously attained. If the implant platform is positioned higher in relation to the crest of the bone than the platform of the parallel pin previously demonstrated, or if the surgical motor stalls prior to full placement of the implant due to insufficient torque, then hand ratcheting is recommended to achieve the proper final implant seating position. First back the implant out about one rotation then drive the implant back into the osteotomy to the desired depth.

These guidelines will help ensure good bone-to-implant contact and primary stability of the implant.

Preparation for Placement of Tapered Implant

1. Once the implant site has been determined, mark site with pilot drill or lance drill. The recommended drill speed is 800–1200 rpm.
2. Continue with the pilot drill to a depth of 6 to 8 mm.
3. Verify the direction and position of the preparation by inserting the parallel pin into the osteotomy. Dental floss should still be through the hole to prevent accidental swallowing.
4. Upsize the drills to the desired diameter for the implant being placed and continue with the osteotomy. Final drill size should be determined by the clinician as part of the treatment planning process.
5. The use of an implant tap may be needed in some cases for final placement.
6. Remove contents from the implant box.
7. The non-sterile assistant should then peel back the tray lid, which holds the Implant and cover screw container. The Implant and cover screw container can be placed into the appropriate locations on the surgical tray.
8. When ready to install the implant, hold the container by the grips, then twist and pull the cap. Install the implant with the ratchet wrench, thumb screw, or motorized hand piece utilizing adapter supplied in surgical kit. Snap to the exposed carrier and release the assembly from the container tube.
9. Carry the implant to the mouth facing upward to prevent accidental dislodging. Place the implant in the prepared site with the attached device.

Final Placement of the Implant

10. Place implant approximately half-way down or until finger tight into the osteotomy, utilizing the attached carrier.

    CAUTION: Because the carrier is only intended as a carrier of the implant and NOT a driver, the Driver Tool found in the surgical kit must be utilized for final installation.
11. After the implant is placed down the osteotomy, the carrier may be removed. This is done by carefully placing the .050 hex driver into the carrier hole and turning counterclockwise. The counterclockwise action will lift and loosen the carrier from the implant, thereby removal of the carrier can be completed.
12. Attach the appropriate Driver Tool (10mm/Series 300, 400 or 500), as supplied in the surgical kit, to the implant.
13. The driver tool, from the surgical kit, can be attached to either the torque wrench or Motor Hand-piece and the final seating utilizes the depth marks on the according to the clinical plan. The implant should be installed to a 70 Ncm maximum torque.
14. At this point, a cover screw or healing cap may be installed, based upon the clinical plan.

    a. If using the cover screw, unscrew the supplied cover screw from the Implant-One implant package, utilizing the .050 Hex Driver in the surgical kit.

    b. If utilizing a healing cap, the same .050 Hex Driver can be used for installation

15. Place the Cover Screw or Healing Cap onto the implant and drive it until finger tight.
16. Close and suture if needed.