

35 Ncm, wait for 5 minutes for the screw to “relax” and then re-torqued again to 35 Ncm.

The one piece healing abutments are firmly hand tightened, or if a torque wrench is used only tighten to 10 Ncm.

There are some instances where due to anatomical structures, (e.g. - interior alveolar nerve, sinus floor, etc.), and thin soft tissues, that the bevel on the collar of the implant is supra-gingival. For the final prosthesis/crown to have an emergence profile that looks like it is emerging from the soft tissues, like a natural tooth, it becomes necessary to prep the coronal aspect of the implant, including the roughened collar as far sub-gingival as necessary to create a sub-gingival crown margin on the implant collar. There is no difference in technique than prepping a one piece implant. It causes no harm to the implant itself or the surrounding tissues.

Do Not Reuse this Product – Reuse of this device presents a potential risk of corrosion, which may lead to device failure. Reuse of this device may also present potential risk of cross-contamination which may lead to infection or transmission of blood born pathogens to patients and users.

Contra-indications:

*Small Children *Pregnant Women *Women who are Nursing
*Smokers *Inadequate diet or dental hygiene
*Patients with serious medical problems or poor general health, uncontrolled bleeding disorders, drug or alcohol abuse weakened immune system, current local infection, metabolic bone disease that affects bone or wound healing, uncontrollable endocrine disorder or titanium sensitivity.

Potential Risks:

*Fracturing of Bone *Bone Loss *Tissue Trauma or Soft Tissue Irregularities *Nerve Trauma *Infection *Aspiration or Swallowing of Implant *Pain *Complications Associated with Anesthesia and/or Dental Surgery.

Sterilization Procedure For Implants Prior to Use

1. Remove outer wrapping of the implant and inspect inner wrapper to ensure its integrity. If the wrapping is damaged, return to the supplier for replacement.
2. Sterilize inner wrapper with its contents in a vacuum autoclave in accordance with the manufacturer’s written procedure of wrapped hollow items. This sterilization phase of the process is at a temperature between 134(minimum)-137 degrees Centigrade (273 degrees Fahrenheit) for a full cycle time of three minutes and a minimum drying time of 20 minutes.

CAUTION: Hollow and wrapped implants CANNOT be considered sterile unless they have been processed in a vacuum sterilizer.

Note: “Tatum Surgical” is a trade name of Suncoast Dental.



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Tatum Surgical Integrity Dental Implant System Instructions for Dental Implant Placement

The implant placement and prosthetic restoration should be done by a properly trained dentist or team of dentists. The patient should have ***no contra-indications** for the procedure, be **fully informed** of the benefits and risks and have executed an appropriate consent form.

A suitably equipped dental operator is required as well as having auxiliary personally competently trained in aseptic techniques. The implant surgery must be performed in an aseptic technique, including skin prepping, draping, sterile instruments and drills throughout the procedure. In addition, the dentist should have a pre-op protocol, including mouth rinses with an antiseptic and an appropriate pre-op antibiotic regimen.

The osteotomy site that corresponds to the implant size is prepared with drills in the Tatum Surgical Integrity implant kit at 900-1500 RPM’s using copious amounts of external saline irrigation. Bone expansion can also be used to create the appropriate osteotomy site that matches to the selected implant. A combination of drilling and expansion can also be used. The surface cortical bone, especially on the mandible is frequently thick and dense and may require the use of either a bone scalpel and/or a high speed carbide bur to penetrate 1-3 mm through the cortices to access the softer medullary bone. Then the medullary bone is easily penetrated to the desired length based on the bone anatomy, (e.g.- Inferior Alveolar Nerve Canal; floor of the sinus; etc), by then using the drills that come in the Integrity implant kit or Tatum Osteotomes that are used to expand and condense the available bone.

In all cases, it is imperative to preserve the available attached gingival. Studies have shown one of the keys to long term implant/prosthetic success is healthy attached tissue surrounding the emergent profile of either an implant, the abutment, or the prosthetics.

After the initial cortical bone penetration, the osteotomy will be enlarged and lengthened in an incremental fashion (from small diameter progressing to larger diameters) using either the Tatum Integrity drills or Tatum osteotomes. The implant kit and the

osteotome kit has “finishing” drills and osteotomes that match to the sizes of the Integrity Implants. There is a final drill or final osteotome that is matched to the size (diameter, shape, and length) of the Integrity Implant the dentist has determined will be appropriate for that prepared site in the bone. In softer bone frequently an undersized, by .5 to 1 mm, osteotomy will be adequate to accommodate to the chosen implant. This is especially true in the maxilla. As the Tapered Integrity Implant is inserted into an undersized, in terms of diameter, osteotomy, the implant itself will do the final bone expansion and be seated fully. If there is hard dense cortical bone, on the crest, yet softer expandable medullary bone it may be necessary to open the crestal cortical bone fully to the diameter of the implant prior to allowing the implant to expand the medullary bone in an under prepared site. This is especially true in the mandible and if not done the implant may not seat to the desired depth. Open the crestal bone to the diameter of the implant when necessary.

The implant is delivered to the operating field in an aseptic manor. The assistant (circulating assistant) whom is not scrubbed for the surgery will peel open the sterile package being careful not to touch the package contents. The surgical assistant or dentist, using a sterile forceps, will carefully remove the package contents and place them into the sterile field. The Integrity Implant package contains:

1. The Integrity Implant
2. A triple purpose abutment that can be used as:
 - A. An implant level impression transfer abutment.
 - B. A temporary abutment
 - C. A final abutment
3. An abutment screw to hold in the abutment. It can safely be torqued to 35Ncm.
4. A one-piece healing abutment

The implant is held in the inner sterile package, a scissors is used to cut open the package and there are then 2 ways to insert the implant into to osteotomy:

1. HT .09 Latch Grip Driver - used with the hand piece for the diameters of Integrity Implants in the 3.7mm - 5.0mm range;

HT .09L Latch Grip Driver - used with the hand piece for the diameters of Integrity Implants in the 6.0mm - 8.0mm range.

2. HT .06 / HT .07 short or long – used with the surgical ratchet for the diameter of Integrity Implants in the 3.7mm - 5.0mm range; HT .06L / HT .07L, short or long – used with the surgical ratchet for the diameter of Integrity Implants in the 6.0 mm - 8.0mm range.

(Using either method, the implant is not touched by the surgeons’ gloves. The implant insertion tool is inserted into the sterile package engaging the internal connection pentagon of the implant. The insertion tool of choice should already be either attached to the hand piece or the surgical ratchet prior to engaging the internal implant connection.)

It is imperative, which ever implant drivers are used, that the driver is fully inserted into the implants pentagon internal connection.

The implant will be placed into the created osteotomy using the selected method, either hand piece driver or surgical ratchet driver to deliver the tapered end of the implant into the site.

If the hand piece is used, the settings on the control unit are:

1. Clockwise rotation
2. 10-20 RPM’s
3. 50-70 Ncm insertion torques

If the surgical ratchet is used:

1. Clockwise rotation till the implant is fully seated at the desired depth.

Frequently, especially with good bone quality, even at 70 Ncm the implant will not fully seat. The surgical motor will stop at whatever preset Ncm limits it has been programmed with. When this happens remove the Latch Grip Driver from the implant internal connection and insert the surgical ratchet driver into the internal connection of the implant and finish seating the implant by hand using the surgical ratchet.

How far do you insert the implant into the bone? (See implant photo)

1. All threaded portions of the implant must be fully encased in the bone.

2. The roughened (non-shiny), not threaded surface of the implant collar can be in either bone or in soft tissue.
3. The polished collar and bevel on the collar (site of crown margin) is never inserted into the bone.

Thus, there is a leeway as to how much of the implant can be inserted into the bone.

How much of the Integrity Implant goes in the bone:

Implant Length	Minimum in Bone (threaded portion)	Maximum in Bone (threaded portion plus roughened collar)
11mm	7mm	Up to - 9.5mm
14mm	10mm	Up to - 12.5mm
17mm	13mm	Up to - 15.5mm
20mm	16mm	Up to - 18.5mm

Please Note: The roughened (dull) part of the polished collar can be all in the bone, partly in the bone and soft tissue, or all in the soft tissue. The highly polished part of the collar, this includes the bevel does not go in the bone.

This than takes into consideration certain anatomical consideration when deciding how far into the bone the implant should be inserted. Some of the considerations are:

1. Surgical anatomy: e.g. - location of boney undercuts, inferior alveolar nerve location, floor of nose, floor of the sinus, etc.
2. Soft tissue consideration: e.g. - thickness of soft tissues that will surround the neck of the implant.
3. Prosthetic considerations: e.g. - future emergence profile of the abutment and crown and the desired sub-gingival margin depth.

When the soft tissue is thick, 3-5mm, the implants may be .5 to 3mm sub-gingival. When the soft tissue is thin, 1-3mm, the implant

may be .5 -1.5mm sub-gingival. The dentist placing the implants needs to have a thorough understanding of prosthetics emergence profiles and how they will be created using this system.

What is unique about the Tatum Integrity Implant and the Tatum Traditional Implant is that they are designed to have a crown margin on the implant itself. After placing the Integrity Implant the restorative dentist may want the crown margins more sub-gingival than the bevel on the implant. The dentist then preps the implant creating the margin- chamfer to whatever depth is necessary.

After the implant has been fully seated into the bone, and assuming this is not an immediate load scenario, the one- piece healing abutment is seated on the implant with hand tightening or 10 N/CM using a .050 Hex driver. This is a one stage implant and is not meant to be fully buried under the soft tissues. [Please do not confuse one stage with immediate loading.] The treating dentist(s) will determine when the appropriate time to do the restorative phase(s) is to begin. With very careful case selections immediate loading (temporization or denture seating) may be an option. More typically a healing period of 4 months is adequate although in either softer bone or recently grafted sites, 6 months for a waiting period is appropriate for adequate Osseointegration to occur.

For Crown and Bridge (and some bar cases) there will be 3 ways to create the margins of the prosthesis:

1. The implant has a beveled collar that has been designed to be a margin for the final crown seated over an abutment.
2. The implant collar, including the roughened non-threaded surface, can be prepared after final abutment seating. It can be prepped based on any scalloping design or desired su-gingival depth for the margins of the crown to achieve proper emergence profiles.
3. A lab can fabricate a custom abutment (often called UCLA style abutment) with the final crown margins finishing on either the implant or the abutment.

All retention screws for the prosthetic abutments take a .050 driver. One piece abutments are available and they also are inserted with the .050 driver as is the one piece healing cuff. The prosthetic abutment screws and one piece abutments should be torqued to