Tatum Surgical Integrity Dental Implant System
Instructions for Dental Implant Placement

The implant placement and prosthetic restoration should be done by a properly trained dental professional. 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 operatory is required as well as having auxiliary personnel competently trained in surgical and sterilization procedures. The patient must be correctly prepped and draped and a sterile field containing all instruments be in place for the duration of the procedure. All medications and anesthetics should be maintained during and after the procedure and the patients' vital signs monitored. (A pre-operative protocol should be followed).

INDICATIONS
The Integrity Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prothesis to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

CONTRAINDICATIONS
The mandibular or maxillary bone quantity and quality is insufficient to provide initial stability to the implant, poor patient oral hygiene, heavy tobacco use, uncontrolled systematic diseases (diabetes, etc.), reduced immunity, chemical dependance, current local infection, metabolic bone disease that affects bone or wound healing, uncontrollable endocrine disorder or titanium sensitivity, children, and women pregnant or breastfeeding.

WARNINGS
Small diameter implants and angled abutments are not recommended for the posterior region.

MRI Safety Information
The Tatum Dental Implant Systems have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Tatum Dental Implant Systems in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

PRECAUTIONS
Proper case planning is essential to the long-term success of both the prosthesis and the implant. Overload is one of the key contributors to implant failure. Ensure the implant size and abutment angulation are appropriate for the occlusal load.

Splinting should be considered where appropriate. Appropriate tightening of the Abutment Screw is essential to prevent premature loosening.

ADVERSE EFFECTS
The following complications may occur relative to implant placement: pain, discomfort, fracturing of bone, bone loss, tissue trauma or soft tissue irregularities, infection, inflammation, nerve trauma, infection, aspiration or swallowing of implant, complications associated with anesthesia and/or dental surgery.

STERILITY
All implants are provided sterile. Do not use sterile devices if the packaging providing the sterile barrier has been damaged or compromised in any way.
All other components within the Tatum Surgical Integrity Implant System are provided non-sterile and intended to be sterilized prior to use. Refer to packaging for sterility.

Single Use Only - 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 borne pathogens to patients and users.

STERILIZATION INFORMATION

1. Implants are provided sterile.
2. Non-sterile titanium abutments and retention housings are intended to be sterilized by the user. Place product in a pouch that is cleared by the FDA for the indicated cycle. Sterilize in a pre-vacuum autoclave at 135 °C for 3 minutes and dry for 20 minutes.
3. Retention inserts (O-rings) should be disinfected per typical standard of care within the facility.

TECHNIQUE INFORMATION

Osteotomy

The osteotomy site that corresponds to the implant size is prepared with appropriate drills while drilling at 900-1500 RPM's and 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. By using the drills, 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 keratinized gingiva. Studies have shown one of the keys to long term implant/prosthetic success is healthy keratinized 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 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.

Implant Placement

The implant is provided sterile. Deliver the implant 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 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.** A Healing Cuff – Tissue-Level Implant.
   B. A Cover Screw – Bone Level Implant

The implant is not touched by the surgeon's gloves, it is held in the inner sterile package, scissors are used to cut open the package and there are then 2 ways to insert the implant into to the 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

When the surgical ratchet is used:
1. Clockwise rotation till the implant is fully seated at the desired depth.
2. Position one of the vertical lines on either the HT.06 or HT.07 buccally. This will orient the abutment to lean lingual if a angled abutment is used.

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?
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 rarely 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 Tissue-Level Implant goes into the bone:

Implant Length	**Minimum in Bone** (threaded portion)	**Maximum in Bone** (threaded portion plus roughened collar)
9mm	5mm	Up to – 7.5mm
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 then takes into consideration certain anatomical considerations 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: e.g. - thickness of soft tissues that will surround the neck of the implant.
3. Prosthetic: 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.

After the implant has been fully seated into the bone, and assuming this is not an immediate load scenario, the Healing Cuff is seated on the implant with hand tightening or 10 Ncm 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 nonthreaded surface, can be prepared after final abutment seating. It can be prepped based on any scalloping design or desired sub-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.

When the soft tissue models from either impression method 2 or 3 are made it is time for Tissue -Level Abutment (PITI) selection. There are a variety of stock PITI to choose from. The choices include:

1. Straight stock PITI in 0° normal and large diameters options.
2. Angled stock PITI in 15° configuration.
3. **Maximum Angulation of Abutments: 30°.**

All stock abutments include an abutment retention screw. It is wise to use a new abutment retention screw at the final seating of an abutment or screw retained crown intra orally. After the proper abutment is chosen, it can be modified as need be and then either a screw retained or cement retained crown can be fabricated.

All retention screws for the prosthetic abutments take a .050 driver. One-Piece Abutments are available and 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 35 Ncm, wait for 5 minutes for the screw to “relax” and then re-torqued again to 35 Ncm.

The Healing Cuffs 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.

Integrity Bone-Level Implant

The Bone level Integrity Implant (ITI-B) has an aluminum oxide blasted outer surface up to and including the bevel on the implant shoulder.

The ITI-B is placed into the bone so that the most coronal aspect of the implant is level with the bone crest.

After the implant placement the surgeon has three choices (see below), with hand tightening, using the .050 wrench.

1. Place a cover screw into the implant and suture the tissue flaps closed, thus burying the implant. A healing period of 4-6 months will pass before it is time for the restorative phase.

2. Place a Platform-Switch Healing Cuff (HCS-ITI-PS) into the implant with a .050 wrench and hand tighten. There are three heights (1,3,5 mm) to accommodate the variations in gingival thickness the surgeon will encounter. The chosen cuff height will either be flush with the gingiva or slightly supra gingival after the tissue flaps have been approximated.

3. Choose an appropriate Platform Switch Abutment (PITI-PS), place it into the implant and secure it with the appropriate retention screw at 15 Ncm. [Any tighter may cause the implant to also turn and go deeper into the osteotomy, possibly too deep to restore. Also, it could alter the initial alignment of the implant by turning the implant from its initial alignment.] A temporary crown is then fabricated over the abutment.

After the healing is complete, osseointegration has occurred. Then the final abutment will be secured with the abutment screw torqued to 35 Ncm, wait 5 minutes and retorque to 35 Ncm.

Implant Diameter	**Abutment Retention Screw Diameter**	**Final Torque Value**	**Wrench Size**
3.7mm	2.0mm	35Ncm	0.050
4.0mm	2.0mm	35Ncm	0.050
4.5mm	2.0mm	35Ncm	0.050
5.0mm	2.0mm	35Ncm	0.050
6.0mm	2.5mm	35Ncm	0.050
7.0mm	2.5mm	35Ncm	0.050
8.0mm	2.5mm	35Ncm	0.050

Whether option 1, 2 or 3 is chosen there is a variety of options for the final restoration. (With all of the options, the margin of the crown or bridge will finish on the margin of abutment.) Crowns can either be screw retained or cement retained.

Prior to choosing an abutment an implant level impression and subsequent soft tissue model is fabricated.

There are 3 methods of taking an implant level of impression:
1. Scan Body (NT-3D) Technique:
It can be used for intra oral digital scans and then CAD/CAM technology is used to fabricate a custom abutment and a crown.
2. Open-Tray Technique:

An Open-Tray Transfer Abutment (ITI-OT-Xfer) is used to take an impression and after the Retention screw is removed the impression is removed from the mouth. An implant analog is secured to the ITI-OTXfer and a soft tissue model is fabricated.

3. Closed-Tray Technique:

A Closed-Tray Transfer Abutment (ITI-Xfer) is secured to the implant at 10 Ncm (hand tighten equivalent). After the impression is taken, it is removed from the mouth. The ITI-Xfer is then removed from the implant. Reinsert the HCS-ITI-PS into the implant. Place the ITI-Xfer into an implant analog of the same diameter as the implant and insert into the impression. It is reinserted carefully into the impression aligning exactly with the features (two flat sides and one dimple) created in the impression of the ITI-Xfer. A soft tissue model is then fabricated.

When the soft tissue models from either impression method 2 or 3 are made it is time for Platform-Switch Abutment (PITI-PS) selection. There are a variety of stock PITI-PS to choose from. The choices include:

1. Straight stock PITI-PS in 0° normal and large diameters options.
2. Angled stock PITI-PS in 15° or 30° configurations
3. **Maximum Angulation of Abutments: 30°.**

All stock abutments include an abutment retention screw. It is wise to use a new abutment retention screw at the final seating of an abutment or screw retained crown intra orally. After the proper abutment is chosen, it can be modified as need be and then either a screw retained or cement retained crown can be fabricated.

Placement of the Ball Post Abutment and O-Ring Attachment Instructions
(Applies to both Tissue and Bone Level Implants)

After the secondary gingival healing period is complete, remove the healing cap.
It is imperative that all bone and soft tissue be removed from the superior aspect of the implant body to guarantee complete seating of the Implant Abutment.
To select the proper Abutment, determine the type of implant and the diameter being used. Then measure the tissue thickness (height) from the coronal rim of the implant body to the crest of the gingiva.

Use the Ball Post Abutment Driver (HT-14) to thread the Abutment into the implant. The driver fits into a Tatum Ratchet or a standard torque wrench using an HT.26 Adaptor. A maximum seating force 35Ncm will help prevent screw loosening.

Blockout

Place a piece of rubber dam over the ball and surrounding area; this will block out any undercuts.
Place the rubber O-Ring into the housing, and seat on the abutment.

Pickup

Relieve the denture to receive the O-Ring housings. Make sure that the denture can fully seat without any premature contact between the housings (and blockout material) and the denture.

Use a small round bur to cut escape vents from the relieved area out to the lingual of the denture. These lingual escape vents will eliminate the lifting or hydraulic effect of acrylic resin, as well as provide an “escape” for any excess acrylic. It is preferable that excess acrylic flows to the lingual instead of underneath the attachments. After cutting the lingual escape vents, prime the existing acrylic with monomer.

Place a low viscous mix of self-curing acrylic resin into the relieved area of the denture, and seat the denture with finger pressure only on the attachment area. Do not have the patient come into full occlusion and displace soft tissue in the saddle area. This will cause the prosthesis to tilt, or rotate anterior to posterior, and take the attachments out of alignment.

The prosthesis is seated in the mouth for approximately 6 minutes, or what the acrylic resin manufacturer indicates. Remove any excess resin as well as rubber dam. Finish and polish. The female may be easily changed in the metal housing to adjust retention.

Instruct the patient on the path of insertion. Have the patient insert and remove the appliance several times.

Symbols Glossary
ANSI/AAMI/ ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol	Title of Symbol (Reference Number)	Symbol	Title of Symbol (Reference Number)
	Caution (5.4.4)		Use-by date (5.1.4)
	Sterilized using steam or dry heat (5.2.5)		Date of manufacture (5.1.3)
			Manufacturer (5.1.1)
	Do not use if package damaged (5.2.8)		Catalogue number (5.1.6)
	Do not re-use (5.4.2)		Batch code (5.1.5)
	Do not resterilize (5.2.6)		Use by prescription only
	Consult instructions for use (5.4.3)		Unique device identifier

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

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