Tatum Surgical Unipost 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 operatory should be used and the auxiliary personnel should be 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 Tatum Surgical Unipost 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.

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 Unipost 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 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 depth 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 Tatum 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 the drills. It is best to establish the desired length of the osteotomy with an initial pilot drill.

The implants will be exposed during healing and no second stage exposure surgery will be required. Minimal incisions are used without reflection of periosteal flaps. If wider exposure is needed or movement of attached gingiva is desired, split thickness tissue flaps are used. The socket is usually prepared in the selected, suitable bone site with the correct incremental use of the drill and tap set.

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. Tatum Surgical "T" and "S" Implant package contains:

1. An Implant
2. A Healing Screw

The implant is not touched by the surgeon's gloves, it is held through the inner sterile package. Scissors are used to cut away the top of the package to expose the implant. The **S implant** and the **T implant** are removed with one of the implant drivers contained in the surgical kit, carried to the prepared socket and screwed into position with a slow (5 - 25 rpm) handpiece drive, a ratchet drive, or hand driven instrument.

If any soft tissue opening exists, the tissue is closed around the exposed implant neck with a 3-0 resorbable suture.

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.

A post guide is used to determine the prosthetic post which will be used during the restorative phase. The healing screw is placed into the implant and seated with **counter-clockwise rotations** with the HT.10 hex driver in a slow (5 - 25 rpm) handpiece or hand tightened with the HT.11 Hex Driver. Any prosthetic device is relieved to not allow any contact or trauma to the implant during a 4 - 6 month healing period. A periodontal type dressing may be placed following a post-operative radiograph and the patient is discharged with appropriate instructions and medications. A post-surgical visit usually occurs in 7 - 14 days for evaluation and post-operative care.

Restoration

Following an uncomplicated healing period of 4 months for the mandible and 6 months for the maxilla:

A Throat Pack is always recommended when using small instruments in the mouth.

1. Using Hand Tool (HT.11) remove healing screw from implant by turning right. Select post to use by checking:
    a. Diameter (same as implant; smaller than implant will create a nice shoulder)
    b. Angles include: 0°, 10°, 20°, 30° increments.
    c. Height (we offer both 5mm and 9mm lengths). ALL posts tighten to the LEFT with left-hand threading.
    d. **Maximum Angulation of Abutments: 30°.**
2. If an angled post is chosen, you will notice when placed in the implant it will rotate 360 degrees and not tighten up.
   This was designed so the clinician could place the post at any position and obtain perfect parallelism. Once orientation is achieved, use the (GW2) carbide bur to score post extending onto the implant body, using this as an indicating marker. This point of reference is where the post should rotate to during cementation.
3. Using high speed handpiece and a carbide SS White (GW2) carbide bur, score the post at approximate vertical height required.
4. Using Hand Tool (HT.11) remove post from mouth turning to the right while pulling up on the post.
5. Screw post into hand-held post holder instrument.
6. Use SS White (GW2) or (GW Ultra) carbide bur in handpiece to reduce vertical height. Place post back into implant to check clearances.
7. If significant reduction of the post is required to achieve parallelism, again remove post from mouth, insert post into post holder and adjust with a carbide SS White (GW Ultra #16 or #18).
8. Return post to implant making final touch-up modifications in the mouth and add the margin onto the implant body using a diamond SS White Piranha.
9. Cement post to implant using Resiment or Panavia (metal on metal) epoxy. Mix only one batch per

post as cement will set quickly.

10. **Using a GW Ultra #16 or #18 (carbide bur), prepare a wide vertical groove down the side of the abutment extending onto the neck of the implant*.** This groove will be captured when the impression is taken and will also serve as an anti-rotational keyway in your restoration.
    ***This step is a MUST in order to prevent the loosening of the post.**
11. Now you are ready to take your final impression.

Placement of the Ball Post Abutment and O-Ring Attachment Instructions
After the secondary gingival healing period is complete, remove the healing screw.
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 apical rim of the implant body to the crest of the gingiva.

Use the O-Ring Abutment Driver (HT-14) to thread the Abutment into the implant. The driver fits into a standard torque wrench. 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 the 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.

If a crown or an overdenture casting is to be used, the post and implant neck will be prepared with tungsten carbide and diamond burs to form a conventional preparation. The vertical groove in the post will be tapered and extended into the body of the implant extending the groove apically to pass over the post-implant joint. The margin will be properly positioned to the gingiva for health and the creation of the proper emergence profile of the crown. Appropriate gingival retraction is achieved and conventional impression and laboratory steps are followed for the fabrication of the prosthesis which, when completed, will be cemented.

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

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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