Tatum Surgical "P" Plateau 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 "P" Plateau 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 for single or multiple unit restorations and are indicated for delayed loading, placed with conventional two-stage surgical process with secondary and transmucosal healing.

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 "P" Plateau 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 or 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.

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 "P" Implant package contains:
1. The Tatum Surgical "P" Implant
2. A One-Piece Healing Abutment

The implant is not touched by the surgeon's gloves, it is held through the inner sterile package. Scissors are then used to cut open the package to access the implant. The Healing Abutment is inserted into the sterile package engaging the internal connection of the implant and then placed into the created osteotomy using hand pressure.

How far do you insert the implant into the bone? No more than 2 mm subcrestal taking into consideration anatomical anatomy. Some of the considerations are: e.g. – location of boney undercuts, inferior alveolar nerve location, floor of nose, floor of the sinus, etc.

After the Implant has been hand delivered into the prepared osteotomy, the Healing Abutment is removed from the implant. A titanium driver of either straight or offset design, is inserted into the implant. A weighted surgical mallet is then used in conjunction with the driver to seat the implant to the desired depth, no more than 2 mm subcrestal. After the implant has been fully seated into the bone, the Healing Abutment is seated into the implant with hand pressure. If any soft tissue opening exists, the tissue is closed using 3.0 resorbable sutures.

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
The treating dentist(s) will determine when the appropriate time is to begin the restorative phase. 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.

After the healing phase is over, the Restorative Dentist will remove the healing abutment using forceps in a twisting fashion. The doctor will then tap the desired abutment (either 0° or 15°, **Maximum Angulation**

of Abutments: 15°.) into the Implant Morse Taper using a titanium Abutment seating tool and weighted surgical mallet. The Abutment is prepped as needed for adequate crown thickness, crown retention and appropriate clearance from the opposing occlusion using a high-speed hand piece, copious irrigation and the preferred crown and bridge burs. A traditional crown and bridge impression is made for crown fabrication.

Subsequently, if Ball-Posts are being utilized, the prosthetics can be completed at this time.

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 abutment.
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 SB Abutment Driver (HT-14) with the EZ-Implant Driver (Hex), to tap the Abutment into the Implant Morse Taper using a weighted surgical mallet.

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.

The Tatum Surgical “P” Implant is available in these diameters and lengths:

Diameters	**Lengths**		
4.5 mm	6 mm	8 mm	11 mm
5.0 mm	6 mm	8 mm	11 mm

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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