Tatum Surgical One-Piece 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 personally 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 One-Piece 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 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 One-Piece 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 drills in the Tatum Surgical One-Piece Implant Kit at 900-1500 RPM's using copious amounts of external saline irrigation. Bone expansion is another technique that can 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 1-3mm through the cortices to access the softer medullary bone. By using 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 from the One-Piece 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 gingiva. 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 Tatum One-Piece Drills or Osteotomes. The implant kit and the osteotome kit have "finishing" drills and osteotomes that match to the sizes of the implants. There is a final drill or final osteotome that is matched to the size (diameter, shape, and length) of the implant that the dentist has determined will be appropriate for that prepared site in the bone. In softer bone, frequently an undersized, by .5 to 1mm, osteotomy will be adequate to accommodate the chosen implant. This is especially true in the maxillae. As the 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 cortical bone of the mandible can be thick, dense bone. Even after preparing an osteotomy to the appropriate size (typically .5mm less in diameter than the selected implant), the implant may not insert with the driver to the desired depth.

[A word of caution - Panoramic x-rays are 2 dimensional and don't reveal mandibular lingual undercuts that typically are composed of dense, cortical bone. Use 3-D cone beam scans when treatment planning for proper implant length in the mandible. The scan reveals the undercuts.]

Preparing the Osteotomy for 3.0mm diameter Tatum One-Piece Implants

With the implant kit there are 2 pilot drills:

1.5mm diameter x 20mm long
2.0mm diameter x 20mm long

In softer bone a 1.5mm in diameter drill is used to the desired length and may be all that is needed. The 2.5mm or 3.0mm diameter implant may seat fully upon insertion. If the implant won't seat to the proper depth then use the 2.0mm diameter pilot drill to the desired depth. The implant should now seat fully.

Preparing the Osteotomy for 3.5mm and larger in diameter Tatum One-Piece Implants

First use the 1.5mm pilot drill and then the 2.0mm pilot drill to achieve the desired depth. Then use, in sequence, the drills in the kit leading up to the final drill for the diameter of implant you have chosen. You will notice these drills only go to a length of 14mm, yet the implants in the diameters 3.5mm and larger are available up to 17mm in length. You will have established your length up to 17mm using the previously mentioned pilot drills, and your "final" drill only goes to 14mm in length. The uniqueness of the apical end of the One-Piece implant is its self-drilling and self-tapping feature. The implant will seat to the full 17mm depth. The implant will engage the osteotomy upon insertion into the full depth of the pilot hole that had been initially prepared, using either the 1.5mm pilot drill and if needed the 2.0mm pilot drill (for denser bone being encountered) to the desired depth. Always establish your working length with the pilot drill(s).

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 One-Piece Implant package contains:
1. Either a CB or CBA Implant, includes the Implant only.
2. SB Implant, includes an Implant, O-ring Housing, and a Red and Black O-ring.

The implant is not touched by the surgeon's gloves, it is held through the inner sterile package. The implant insertion tool is inserted into the sterile package engaging the implant. The insertion tool of choice should already either be attached to the hand piece or the surgical ratchet prior to engaging the implant. Scissors are used to cut away the top of the package to expose the implant. There are then 2 ways to insert the implant into the osteotomy:

The kit contains both handpiece drivers and surgical ratchet drivers specific to each diameter implant. This is true for both the straight and the angled Tatum One-Piece Implants.

It is imperative the correct insertion drivers that match specifically to the implant diameter is used.
1. If the handpiece is used, the settings on the control unit are:
    1. Clockwise rotation
    2. 10-20 RPM's
    3. 50-70 N/CM insertion torques
2. 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 has been programmed. When this happens, remove the driver from the implant and insert the surgical ratchet driver onto 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 roughed (non-shiny), not threaded surface of the implant collar can either be in the bone or in the soft tissue.
3. The polished collar is not inserted into the bone.

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

Depth the Tatum One-Piece Implant goes in the bone:

Implant Length	**Minimum in Bone** (threaded portion)	**Maximum in Bone (threaded portion plus roughened collar)**
11mm	8mm	Up to - 9.5mm
14mm	11mm	Up to - 12.5mm
17mm	14mm	Up to - 15.5mm

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, does not go in the bone.

This then 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 crown and desired sub-gingival margin depth.

The dentist placing the implants needs to have a thorough understanding of prosthetics emergence profiles and how they will be created using this system.

Preparing for the Crown on the Tatum CB and CBA One-Piece Implant(s)

Tatum One Piece Implants offered:

1. Straight Abutments (0°): 3.0, 3.5, 4.0, 4.5, 5.0, 6.0 mm Diameters.
2. Angled Abutments (15°): 3.0, 3.5, 4.0 mm Diameters.
3. **Maximum Angulation of Abutments: 15°.**

High speed drills with copious irrigation, using carbides, diamond burs or a combination of both, are used to prepare the abutment part of the one piece implant.

The implant collar, including the roughened non-threaded surface, can be prepared. 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.

Preparing for the Denture on the Tatum One-Piece SB Implant

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 can’t, 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 tin spacer and black rubber spacer. 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.

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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Effective: 07/15/2022