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 One-Piece Implant.

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.

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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Instructions for Tatum One-Piece 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 operatory 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 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. 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 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.

Tatum Surgical recommends to use a bone tap, to then further prepare the site. The Tatum Surgical Taps are available in a kit. The diameters of the taps are: 4.5mm, 5.0mm, 6.0mm, 7.0mm, and 8.0mm. The available taps are offered in lengths of: 11mm, 14mm, 17mm, and 20mm.

It is rare that bone taps are ever needed for the maxillae since the cortical bone is thinner and less dense than the mandible.

[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).

The implant must be sterilized before use (see sterilization procedure referenced below). 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 implant 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 the osteotomy:

[* In either method, the implant is not touched by the surgeons’ gloves, 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.]

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
20mm*	17mm	Up to - 18.5mm
23mm*	20mm	Up to - 21.5mm

*The 20mm and 23mm length implants are only available in the 3.0mm and 3.5mm diameter Tatum One-Piece Implants.

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