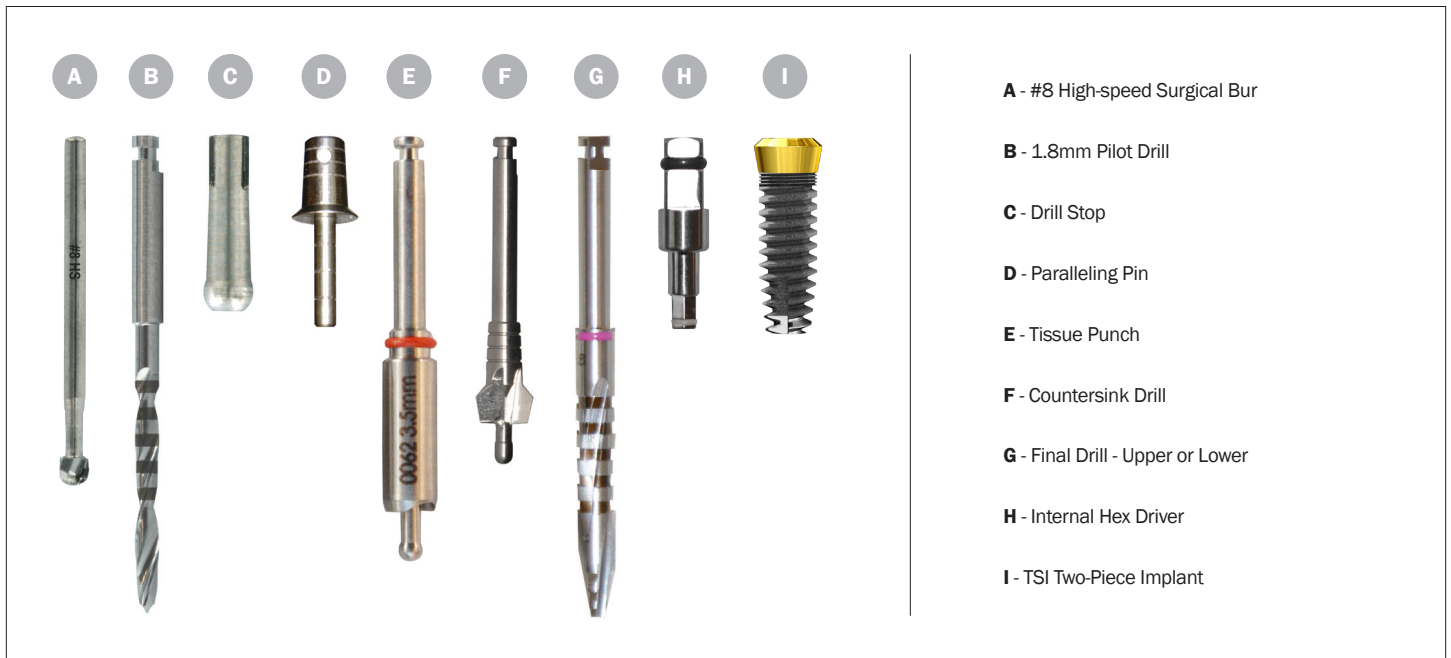


Protocol & Procedure for Placement of the OCO Biomedical TSI Two-Piece Implant



Proper Drill Sequence for TSI Two-Piece Implant (3.25, 4.0, 5.0mm diameters)

- 1 - #8 High-speed Surgical Bur** - Penetrate soft tissue if flapless, otherwise use to divot crest **A**
- 2 - 1.8mm Pilot Drill** - Place 8mm drill stop onto pilot drill and drill full length stopping at soft tissue **B C**
- 3 - Paralleling Pin** - Place paralleling pin to evaluate implant size and trajectory **D**
- 4 - Tissue Punch** - Remove soft tissue if placing implant flapless **E**
- 5 - Countersink Drill** - Take top of blades approximately 1 - 1.5mm below soft tissue **F**
- 6 - 1.8mm Pilot Drill** - Take pilot drill to full length of intended implant **B**
- 7 - Final Drill** - Take final drill to full length of osteotomy. Use upper drill for maxillary/soft bone and lower for mandibular/hard bone.* **G**
- 8 - Internal Hex Driver** - Drive implant into final position **H I**

**In harder bone (D1), a serial progression of final drills is recommended to create osteotomy*

For questions on the TSI implant placement and restorative techniques please visit www.ocobiomedical.com, call 800-228-0477 +1 (505)-293-0025 international or email info@ocobiomedical.com.



Protocol and Procedure for Placement of the OCO Biomedical TSI Two-Stage Implant

Indications

The TSI dental implants are artificial root structures intended for permanent surgical implantation in the bone for the purpose of single or multiple tooth replacements (splinted or free standing), or for stabilization of a prosthetic system, such as artificial teeth in order to restore the patient's chewing function. The TSI can be placed in the anterior or posterior mandible/maxilla for immediate or delayed loading purposes. Immediate loading is only intended when good primary stability is achieved and appropriate occlusal loading.

Warnings

Implant surgery is a procedure requiring special training. Practitioners should obtain training in dental implantology before placing these implants. Improper technique can result in implant failure and loss of bone surrounding the implant.

VERY IMPORTANT

Implants should be stable after being placed. There must not be any mobility. If so, there is an error in placement. If the bone is dense enough and the body of the implant has not penetrated the cortical bone encasement, remove, and use the next larger diameter implant.

For short implants, clinicians should closely monitor patients for any of the following conditions: preimplant bone loss, changes to implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. If the clinician chooses a short implant, then the clinician should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible implant. Allow longer periods for osseointegration and avoid immediate loading.

The TSI Implant System has not been evaluated for safety and compatibility in the MR environment. The TSI Implant system has not been tested for heating or migration in the MR environment.

Internal Hex Implant Driver (TSI, ERI, ENGAGE™, ENGAGE™ PLUS)

Attention

Do not use the hex driver if defects are observed.
Do not exceed 90 N-Cm. Sterilize before use.

.050 Hex Driver

Attention

Do not use the hex driver if defects are observed. **Do not exceed 45 N-Cm.** Sterilize before use. It is recommended to replace the .050 hex driver after 15–20 uses to ensure optimal performance and safety

Laboratory

Study models are prepared for a diagnostic wax-up in the area of the desired final restoration. From the model, a vacuum formed clear tooth matrix is made. This will aid in placing the TSI implant(s) and in positioning them relative to adjacent natural teeth or implants previously placed.

Sterility

TSI Two-Piece Implants are supplied sterile and ready for use when enclosed & sealed in original packaging. Re-sterilization is not recommended by OCO Biomedical, Inc. If packaging is damaged or open upon receipt of product, please call OCO Biomedical at 800-228-0477 (or 505-293-0025) for a replacement product. Sterile products are sterilized using gamma irradiation. Re-Sterilization is not recommended by OCO Biomedical.

OCO Biomedical Abutments / Instruments are packaged and supplied non-sterile. Please follow the recommended sterilization procedures provided by the manufacturer of your sterilization unit. OCO Biomedical recommends using a steam sterilization unit at 121 degrees Celsius for 15 minutes with a drying time of 30 minutes.

Contraindications

OCO Biomedical Implants must not be placed in patients determined to be medically unsuitable for implant therapy. Prior to any surgical intervention, patients should undergo a comprehensive clinical and medical evaluation to identify risk factors that may compromise surgical outcomes or osseointegration.


Implant placement is contraindicated in patients with, but not limited to, the following conditions:

- Significant vascular diseases
- Uncontrolled diabetes mellitus
- Coagulation abnormalities or active anticoagulant therapy
- Metabolic bone disorders
- Current or recent chemotherapy and/or radiation therapy
- Active or chronic periodontal disease
- Inadequate soft-tissue coverage at the surgical site
- Systemic or metabolic conditions known to impair wound or bone healing
- Use of medications known to affect bone metabolism or remodeling
- Conditions impacting the ability to maintain effective daily oral hygiene
- Uncontrolled parafunctional habits (e.g., bruxism)
- Insufficient bone volume (height and/or width) or inadequate interarch space

Additionally, treatment of pediatric patients is not recommended until craniofacial growth is complete and epiphyseal closure has occurred.

Additional Information:

<https://www.fda.gov/medical-devices/dental-devices/dental-implants-what-you-should-know>

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