Protocol and Procedure for Placement of the OCO Biomedical ERI Two-Piece Implant System (w/Drill Stops)

Indications

The TSI and ERI 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 and ERI 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.

Proper Drill Sequence

ERI 3.25 mm Implant

- #8 High-speed Surgical Bur
- Pilot Drill 1.8 mm (with Drill Stops)
- Tissue Punch
- 2.8 mm Final Drill – Max.
- 3.0 mm Final Drill – Mand.
- Insert Tool/ERI/TSI Driver & Thumb Wrench
- For Dense Bone: Ratchet and/or Gear Reduced Hand-piece

ERI 4.0 mm Implant

- #8 High-speed Surgical Bur
- Pilot Drill 1.8 mm (with Drill Stops)
- Tissue Punch
- 3.5 mm Final Drill – Max.
- 3.7 mm Final Drill – Mand.
- Insert Tool/ERI/TSI Driver & Thumb Wrench
- For Dense Bone: Ratchet and/or Gear Reduced Hand-Piece

ERI 5.0 mm Implant

- #8 High-speed Surgical Bur
- Pilot Drill 1.8 mm (with Drill Stops)
- Tissue Punch
- 4.5 mm Final Drill – Max.
- 4.7 mm Final Drill – Mand.
- Insert Tool/ERI/TSI Driver & Thumb Wrench
- For Dense Bone: Ratchet and/or Gear Reduced Hand-Piece

Warnings

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

WARNING - VERY IMPORTANT

Implants should be absolutely 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.

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 ERI implant(s) and in positioning them relative to adjacent natural teeth or implants previously placed.

Sterility

ERI 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.

OCO Biomedical Abutments 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

Patient's health history is extremely important for proper treatment planning. The patient must be willing to maintain good oral hygiene to ensure a successful outcome. Patients with the following health conditions are not good candidates for this procedure.

- Diabetes (uncontrolled)
- Chemotherapy / Radiation
- Smokers - averaging more than 10 cigarettes per day

NOTE: For questions on ERI implant placement and restorative techniques please call 800-228-0477 (+505-293-0025 international) or email sales@ocobiomedical.com.

ERI Two-Piece Implant System


(Drill Stop for Pilot Drill)


Pilot Drill


Tissue Punch


Final Drill


ERI/TSI Driver (Long)


ERI/TSI Driver (Short)


ERI Two-Piece Implant

(Procedural example below features a 12 mm ERI Two-Piece Implant, and a Contoured Straight Shielded Abutment.)

1 - The good implant candidate must have a healthy pre-operative condition.

2 – Use the #8 HS surgical bur & high-speed handpiece with water spray to mark the spot for placement. Drill through gingiva into the cortical bone.

3 – Attach the 10 mm drill stop to the 1.8 mm pilot drill. Use with a low-speed handpiece between 1,000 and 1,500 RPM.

4 - Align with adjacent teeth or implants. Use the pilot drill & drill stop to penetrate into soft tissue & bone until drill stop reaches gingival crest.

5 – Use the paralleling pin (shaped like the C&B abutment) to check the alignment. Re-drill and recheck if misaligned.

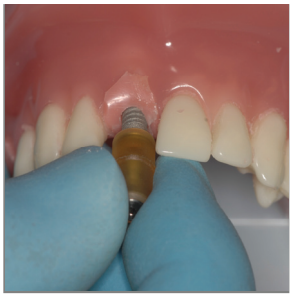
6 – Use the tissue punch with center guide pin to drill down through the gingiva and into the bone through the periosteum.

7 - With a curette or irrigated highspeed handpiece and a #8 HS surgical bur, remove the tissue plug and tags.

8 - Attach 12 mm drill stop to 1.8 mm pilot drill (if using a 12mm length implant).

9 - Using a low-speed handpiece, the pilot drill and drill stop, drill down pilot hole until drill stop reaches bone level for final depth.

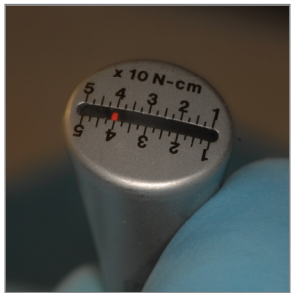
10 – The final drill is designed to stop at the final depth established by the pilot drill (set depth ring set 2-mm higher than the implant length).



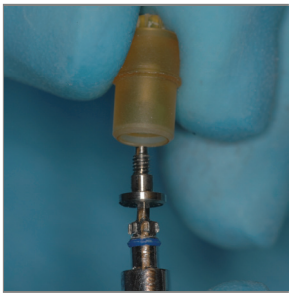
11 – Remove implant from package & remove color-coded cap. Remove implant from vial & screw implant w/amber delivery cap until resistance is met.

12 – Engage the Thumb Knob to the ERI/TSI Driver and manually thread the implant into the osteotomy.

13 – Remove the Thumb Knob and engage the Ratchet Wrench to the ERI/TSI Driver and drive the implant to its final seating depth.



14 – Use Ratchet/Torque Combo Wrench and ERI/TSI Driver to firmly seat implant; turn additionally up to 40 n/cm (maxilla) or no less than 30 n/cm (mandible) to condense bone and immediately load.



15 – **If the case cannot be immediately loaded**, remove healing screw from the ultem cap (from the implant packaging), and thread into implant using the Thumb Knob and ERI/TSI Driver.

16 – When using a two-piece abutment, tighten fixation screw to 20 n/cm. Wait a few minutes for stress release of the metal, then re-tighten to the same torque. When using a fixed, taper one-piece abutment, tighten to 30 n/cm.