



**OCO BIOMEDICAL**

# Protocol and Procedure for Placement of the OCO Biomedical ISI Complete® One-Piece Implant System (w/Drill Stops)

## Indications

Mandibular or maxillary bridge, partial or full overdenture prosthesis, single or multiple tooth replacement. Healed and selected new extraction sites (when an implant with a diameter larger than the tooth removed can be placed). Federal law restricts the sale of this device to a licensed physician/dentist.

## Proper Drill Sequence

### ISI 3.25 mm Implant

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

### ISI 4.0 mm Implant

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

### ISI 5.0 mm Implant

- #8 High-speed Surgical Bur
- Pilot Drill 1.8 mm (with Drill Stops)
- Tissue Punch
- 5.0 mm Countersink Drill
- 4.5 mm Final Drill – Max.
- 4.7 mm Final Drill – Mand.
- Insert Tool/ISI 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 ISI implant(s) and in positioning them relative to adjacent natural teeth or implants previously placed.

## Sterility

ISI Complete® One 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.

## 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 ISI implant placement and restorative techniques please call 800-228-0477 (+505-293-0025 international) or email [sales@ocobiomedical.com](mailto:sales@ocobiomedical.com).

## ISI Complete® One-Piece Implant System



# Protocol & Procedure for Placement of the ISI Complete® One-Piece Implant System (w/Drill Stops)

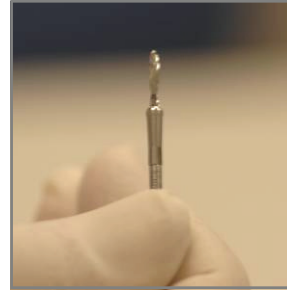
*(Procedural example below features a 12 mm ISI Complete® One-Piece Crown & Bridge Implant.)*



**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.



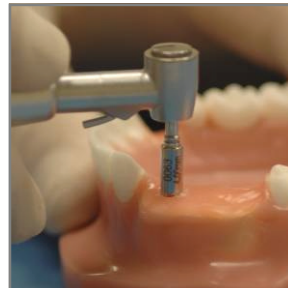
**3** - Attach the 10 mm drill stop to the 1.8 mm pilot drill. Use with a low-speed handpiece between 1,000 and 1,500 RPM.



**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.



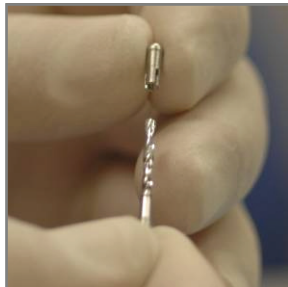
**6** - Use the tissue punch with center guide pin to drill down through the gingiva and into the bone through the periosteum.



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



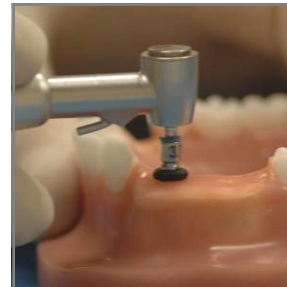
**8** - Use the countersink drill to countersink the implant collar if there is a thin band of attached gingiva - assuring collar is below gingival crest.



**9** - Attach 12 mm drill stop to 1.8 mm pilot drill.



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



**11** - 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).



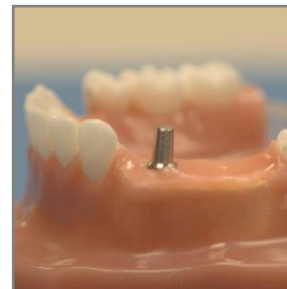
**12** - Remove implant from package & remove color-coded cap. Remove implant from vial & screw implant w/amber delivery cap until resistance is met.



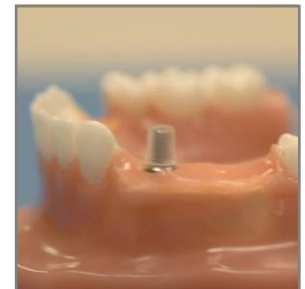
**13** - Use the thumb wrench (or ratchet wrench) and ISI driver to screw the implant to its final seating depth.



**14** - Use ratchet/torque combo wrench and ISI driver to firmly seat implant; turn additionally up to 30 n/cm (maxilla) or no less than 40 n/cm (mandible) to condense bone.



**15** - The ISI Complete® One-Piece Implant is now fully seated. If needed, modify the abutment for the crown with a #557 carbide bur in a high-speed handpiece (use irrigation).



**16** - Implant is ready for temporary crown in light occlusion. Place acrylic coping on implant. Fill temporary crown w/acrylic & place over coping. When set, remove, trim & place w/temp cement.