Protocol and Procedure for Placement of the OCO Biomedical ISI Complete® One-Piece Implant System

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
- 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
- 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
- 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.

ISI Complete® One-Piece Implant System


Pilot Drill


Tissue Punch

Countersink Drill

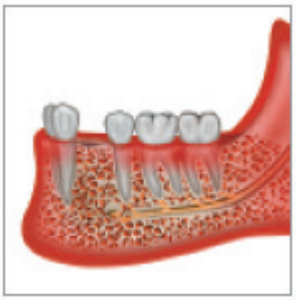

Final Drill

ISI Crown & Bridge Driver (long & short available)

ISI O-Ball Driver (long & short available)


ISI Complete® One-Piece Implant (Crown & Bridge)

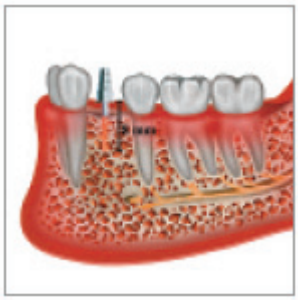

ISI Complete® One-Piece Implant (O-Ball)



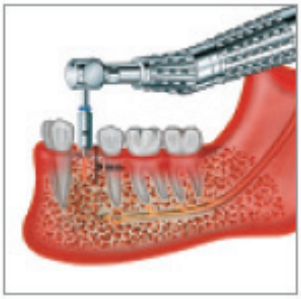
1 - The good implant candidate must have a healthy pre-operative condition.

2 - A #8 HS surgical bur and high-speed handpiece mark the spot for placement and drills through into the cortical bone.

3 - Use a low-speed handpiece, pilot drill, and guide ring to penetrate 8–10 mm into soft tissue and bone. Align with adjacent teeth or implants.

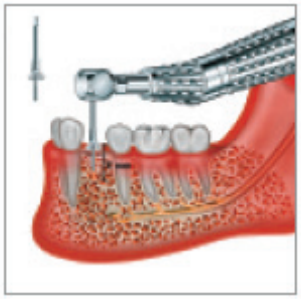


4 - A paralleling pin (shaped like the abutment) checks alignment. Re-drill and recheck if misaligned.

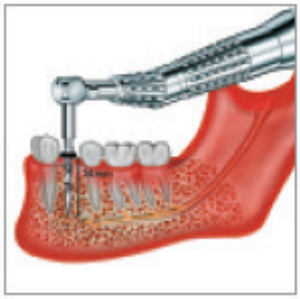


5 - The tissue punch with center guide pin drill down through the gingiva and into the bone through the periosteum.

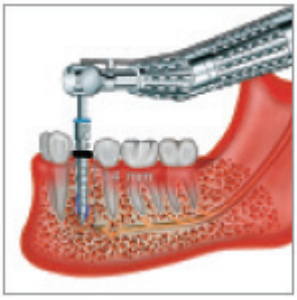
6 - With a curette or irrigated highspeed drill and a #8 HS surgical bur, remove the tissue plug and tags.



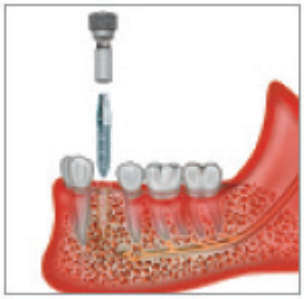
7 - Use the countersink drill to countersink the implant collar if there is a thin band of attached gingiva - assuring collar is below gingival crest.



8 - With the depth ring 2-mm higher than the implant length, drill down the pilot hole for the final depth.

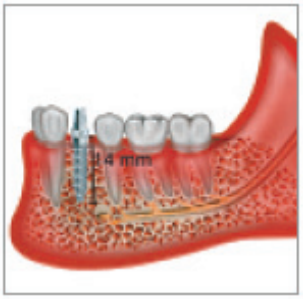


9 - The final drill is designed to stop at the final depth established by the pilot drill (w/depth ring set 2-mm higher than the implant length).

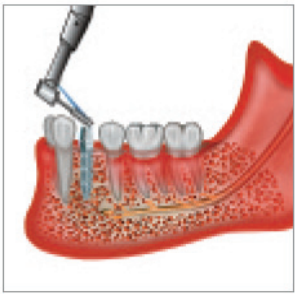


10 – Place the implant - a thumb wrench (or ratchet) and ISI Driver are used to screw the implant to its final seating depth.

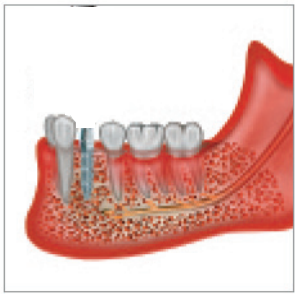
11 – Use ratchet/torque wrench & ISI driver to firmly seat implant; turn additionally up to 30 n/cm (maxilla) or no less than 40 n/cm (mandible) to condense bone.



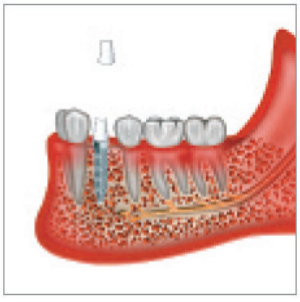
12 - The ISI Complete® One-Piece Implant is now fully seated.



13 – If needed, modify the abutment for the crown with a #557 carbide bur in a high-speed handpiece (use irrigation).



14 – The implant with modified head is ready for a temporary crown.



15 – Place acrylic coping on implant. Fill a temporary crown with acrylic and place it over the coping. When set, remove and trim it. Cement to place with temp cement.

16 – Temporary crown in place in light occlusion.