

INCLUSIVE® MINI IMPLANTS

Instructions for Use

Caution: Federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

IMPORTANT: PLEASE READ

CASE PLANNING

When patient evaluation is complete, establish the number of Inclusive Mini Implants required for denture stabilization and identify the appropriate implant sites. Place Inclusive Mini Implants with approximately 6 mm–8 mm space between implants and at least 7 mm anterior to the mental foramen for Inclusive Mini Implants placed in the mandible.

1. Drilling Protocol

Mark each implant site on the patient's tissue. Select the appropriate cortical bone drill, as determined by the patient's bone density and the diameter of the implant to be placed. Carefully place the drill directly above the implant site and gently drill through the tissue and alveolar crest using an in-and-out motion and profuse, sterile irrigation to a depth of one-third (1/3) to one-half (1/2) the length of the implant threads. For the majority of implant sites, this is the extent of the drilling that is required. In dense bone, the drilling depth may need to be greater. The goal is to achieve high primary stability with an insertion torque of approximately 35 Ncm, taking care not to exceed the recommended maximum of 45 Ncm.

2. Implant Placement

Open the Inclusive Mini Implant vial. Grasping the plastic carrier, remove the implant from the vial, taking care not to touch the sterilized implant body. Transport the implant to the implant site, and insert into the pilot hole. Rotate clockwise while applying downward pressure to engage the self-tapping threads. Avoid lateral cantilever forces, which can affect the angulation and final

alignment of the implant. Stop when significant cortical resistance to the self-tapping process is encountered, or when the plastic carrier separates from the implant head upon reaching its maximum torque threshold (approximately 15 Ncm).

NOTE: Alternately, locking titanium forceps may be used to hold the implant body while the plastic carrier is removed and the implant driver is attached to the implant head. The forceps may then be removed, and the implant placed in its site using the implant driver.

3. Implant Advancement

With the implant securely threaded, remove the plastic carrier, if still attached, to expose the implant head. (If uncertain of initial implant stability, hold the exposed length of the implant body with locking titanium forceps.) Attach the implant driver of desired length (5 mm or 13 mm) to the head of the implant, until it latches into place. Grasping the implant driver, continue to rotate clockwise while applying downward pressure. Avoid lateral cantilever forces, which can affect the final angulation of the implant. Stop when cortical resistance halts further advancement.

4. Final Insertion

Slide the torque/ratchet wrench fully into place over the implant driver (employing the round-square wrench adaptor, if necessary). Turn the wrench clockwise in small increments of approximately 90°, pausing between rotations to allow frictional heat from the self-tapping process to dissipate, and for the bone to expand. Avoid lateral cantilever forces, which can affect the final angulation of the implant. Optimal final insertion of the implant leaves the implant head above the collar fully exposed, while the collar is embedded in the gingiva with no threads visible. For immediate loading of the implant, final torque at seating should be 30–35 Ncm minimum. Exceeding 45 Ncm torque during implant placement is not recommended. If the implant cannot be fully seated using the recommended torque, a shorter implant may be required.

⚠ For positive long-term prognosis, solid resistance must be met during final insertion. Inadequate resistance contraindicates primary stability and loading. In such instances, an implant of wider diameter and/or greater length should be placed, or a new implant site determined.

HARD RELINE

A hard denture reline procedure is used to incorporate the retention caps (O-ring Housings) that cover the Inclusive Mini Implants in the patient's final prosthesis. This loading procedure can typically be performed immediately after placement of the Inclusive Mini Implants, provided primary stability and appropriate occlusal loading are assured. Primary stability is generally indicated when a minimum of 30–35 Ncm of torque resistance is achieved, with implants seated at the appropriate gingival depth.

1. Preparing the Denture

- Relieve the patient's existing denture to make room for the O-ring housings by creating a space for each housing, or a trough.

2. Blocking out the Implant Heads

- Trim the blockout shims to the appropriate length in order to completely mask the exposed neck of each implant beneath the O-ball head. This is critical to prevent pick-up material from flowing under the O-ball.
- Place an O-ring housing on each mini implant,

checking for passive fit over the blockout shims.

- Place the denture in the patient's mouth, checking for passive fit over implants and housings.

3. Lining the Denture

- Apply a thin layer of adhesive on the intaglio surface of the denture.
- Place hard pick-up material directly onto the O-ring housings and into the denture trough (or housing spaces).
- Seat the denture in the patient's mouth. Instruct

the patient to close with normal pressure into centric occlusion.

- Allow seven to nine (7–9) minutes for the hard pick-up material to set.

4. Final Preparation

- Remove the denture and all blockout shims. Trim and polish.
- Instruct the patient to keep the denture in place for the first 48 hours following implant placement, to prevent gingival overgrowth.

SOFT RELINE

A soft denture reline procedure is used when immediate loading with the O-rings is contraindicated, as in the case of a transitional prosthesis, or whenever the Inclusive Mini Implants are placed in soft bone (such as the maxilla or a Type III mandible). Approximately four to six (4–6) months after a soft reline, the soft inner liner can be replaced with a hard pick-up of the O-ring housings to increase the level of retention.

1. Preparing the Denture

- Relieve the patient's existing denture to make room for the heads of the implants. The positions of the implants can be identified using a Thompson Stick, or by lining the intaglio surface of the denture with impression or bite registration material. An acrylic bur can then be used to relieve the denture.
- Lightly roughen the tissue-facing surface of the denture with an acrylic bur, and degrease the surface with isopropyl alcohol.

2. Lining the Denture

- Apply the selected soft reline material onto the tissue-facing surface of the denture.
- Seat the denture in the patient's mouth. Instruct the patient to close with normal pressure into centric occlusion.
- Allow seven (7) minutes for the soft reline material to set.

3. Final Preparation

- Remove the denture from the patient's mouth and trim excess material with fine scissors or a surgical blade. Do not remove the palate of a maxillary denture during this stage.
- Instruct the patient to keep the denture in place for the first 48 hours following placement, to prevent gingival overgrowth.



Sterile with Gamma Radiation



Use by yyyy-mm



Lot/Batch Number



Single Use Only



Do Not Restерilize

Manufactured by
Prismatik Dentalcraft, Inc.
2181 Dupont Drive, Irvine, CA 92616
Made in U.S.A.

©Glidewell Direct 2012. All rights reserved

Distributed by

GLIDEWELL DIRECT
CLINICAL AND LABORATORY PRODUCTS

Technical Support

888-303-3975

www.glidewelldental.com

3006013 Rev. 01 GL-2483-0112