INCLUSIVE® MINI IMPLANT SYSTEM

Instructions for Use

Caution: *Federal U.S. 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

- **a.** 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

- **a.** 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.
- **b.** Place an O-ring housing on each mini implant, checking for passive fit over the blockout shims.
- **c.** Place the denture in the patient's mouth, checking for passive fit over implants and housings.

3. Lining the Denture

- **a.** Apply a thin layer of adhesive on the intaglio surface of the denture.
- **b.** Place hard pick-up material directly onto the O-ring housings and into the denture trough (or housing spaces).
- **c.** Seat the denture in the patient's mouth. Instruct the patient to close with normal pressure into centric occlusion.
- **d.** Allow seven to nine (7-9) minutes for the hard pick-up material to set.

4. Final Preparation

- **a.** Remove the denture and all blockout shims. Trim and polish.
- **b.** 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

- **a.** 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.
- **b.** Lightly roughen the tissue-facing surface of the denture with an acrylic bur, and degrease the surface with isopropyl alcohol.

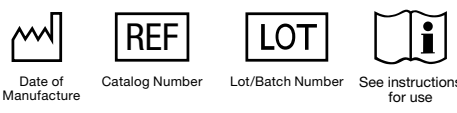
2. Lining the Denture

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

3. Final Preparation

- **a.** 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.
- **b.** Instruct the patient to keep the denture in place for the first 48 hours following placement, to prevent gingival overgrowth.

Inclusive Mini Implant



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3007340 Rev. 01 GL-2483-0612

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Information for Use

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IMPORTANT: PLEASE READ

■ Description of the Product

Inclusive Mini Implants are manufactured from titanium alloy. Restorative components are produced from titanium alloy as well as polymers. Inclusive Mini Implants are compatible with the prosthetic components of the Inclusive Mini Implant System.

■ Indications for Use

Inclusive Mini Implants are self-tapping threaded titanium screws indicated for long-term applications. Inclusive Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long-term stabilization of dentures and provisional stabilization of dentures while standard implants heal. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

■ Insertion Protocol and Immediate Loading

The insertion protocol for Inclusive Mini Implants is considered minimally invasive, and should be strictly adhered to. Using the correct insertion protocol will allow Inclusive Mini Implants to be immediately loaded after placement, provided primary stability and appropriate occlusal loading are assured.

■ Contraindications

Patients should be evaluated before the time of surgery for factors that put them at risk from the implant placement procedure, or that may affect healing of bone or surrounding soft tissue. Implant placement in patients medically unfit for oral surgical procedures is contraindicated. Patients with systemic, localized or pharmaceutical treatment factors that compromise their ability to heal should be carefully evaluated. Do not place Inclusive Mini Implants if there is not adequate bone width or height to contain the implant. Do not reuse Inclusive Mini Implants. Reuse of Inclusive Mini Implants carries the risk of pathogenic patient cross-contamination. Inclusive Mini Implants are not indicated for abutment or crown restorations.

■ Surgical Procedure Precautions

Minimizing tissue damage is crucial to successful implant osseointegration. In particular, care should be taken to eliminate sources of infection, contaminants, surgical and thermal trauma. Risk of osseointegration failure increases as tissue trauma increases. All drilling procedures should be performed at 2000 rpm or less under continual and copious irrigation. All surgical instruments used must be in good condition and should be used carefully to avoid damage to implants or other components. Implants should be placed with sufficient stability; however, insertion torque greater than 45 Ncm may result in implant fracture, or fracture or necrosis of the implant site. The proper surgical protocol should be strictly adhered to. Since implant components and their instruments are very small, precautions should be taken to ensure that they are not swallowed or aspirated by the patient.

■ Prosthetic Procedure Precautions

Following successful placement of Inclusive Mini Implants, verify primary stability and appropriate occlusal loading before proceeding with the placement of a permanent or provisional prosthesis. All components that are used intraorally should be secured to prevent aspiration or swallowing. Distribution of stress is an important consideration. Care should be taken to avoid excessive loads significantly transverse to the implant axes.

■ Sterility

Inclusive Mini implants are shipped sterile. They should not be resterilized. They are for single use only, prior to the expiration date. Do not use implants if the packaging has been compromised or previously opened. Instruments are shipped non-sterile. Steam sterilize the surgical tray and instruments for twenty (20) minutes at 132°C/270°F minimum.

WARNINGS:

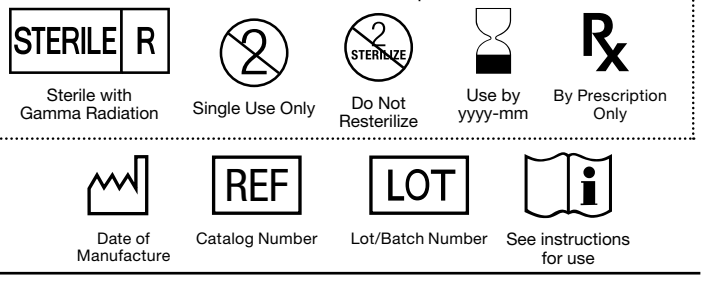
Inclusive Mini Implants may only be used for their intended purpose in accordance with general rules for dental/surgical treatment, occupational safety and accident prevention. They must only be used for dental procedures with the restorative components they were designed for. If the indications and use are not clearly specified, treatment should be suspended until these considerations have been clarified.

The following instructions are not sufficient to allow inexperienced clinicians to administer professional prosthetic dentistry. Inclusive Mini Implants, surgical and restorative components must only be used by dentists and surgeons with training/experience with oral surgery, prosthetics and biomechanical requirements, as well as diagnosis and preoperative planning.

The implant site should be inspected for adequate bone by radiographs, palpations and visual examination. Determine the location of nerves and other vital structures and their proximity to the implant site before any drilling to avoid potential injury, such as permanent numbness to the lower lip and chin. Prior to surgery, ensure that the needed components, instruments and help materials are complete, functional and available in the correct amounts. Treatment of children is not recommended until growth is finished and epiphyseal closure has occurred.

Inclusive Mini Implants should always be used in sufficient quantity to prevent excessive stress on the implants; at least one pair in all cases. Absolute success cannot be guaranteed. Factors such as infection, disease and inadequate bone quality and/or quantity can result in osseointegration failures following surgery or initial osseointegration. Inclusive Mini Implants can distort images obtained via magnetic resonance imaging (MRI). Prismatik Dentalcraft, Inc. is not liable for damages resulting from treatment outside of our control. The responsibility rests with the provider.

Inclusive Mini Implant



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3007340 Rev. 01 GL-2434-0612