Instructions for Use

IMPORTANT INFORMATION — PLEASE READ

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

- **General Information**

The Inclusive Mini Implant System consists of dental implants, prosthetic components, surgical instrumentation, and related accessories packaged under the Inclusive brand name for use by qualified, licensed clinicians and laboratory technicians fully trained in their application.

For specific product identification and contents, please refer to individual product labels and the following catalog:

- Inclusive Dental Implant System Product Catalog (**MKT 787**)

For detailed information on the specifications and intended use of a particular product, please refer to the following user manual:

- Inclusive Dental Implant System Surgical Manual (**UM 4236**)

- **Online Documentation**

This Instructions for Use (IFU) document has been made available for viewing or downloading in a variety of languages at **inclusivedental.com/library/**. To retrieve this particular document, simply locate the IFU number (**4990**) and select the desired language.

- **Disclaimer of Liability**

The guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry, and are not intended to substitute for formal clinical or laboratory training. Inclusive devices should only be used by individuals with training and experience specific to their clinically accepted application.

Prismatik Dentalcraft, Inc. is not liable for damages resulting from treatment outside of our control. The responsibility rests with the provider.

- **MRI**

The Inclusive Mini Implant System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Inclusive Mini Implant System in the MR environment is therefore unknown. Magnetic resonance imaging (MRI) scans of a patient who bears this device may result in patient injury.

MINI IMPLANTS

- **Description**

Inclusive Mini Implants are endosseous devices manufactured from titanium alloy. They are compatible with the prosthetic components and surgical instrumentation 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. To be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

- **Contraindications**

Inclusive Mini Implants should not be placed in patients discovered to be medically unfit for the intended treatment. Prior to clinical intervention, prospective patients must be thoroughly evaluated for all known risk factors and conditions related to oral surgical procedures and subsequent healing. Contraindications include but are not limited to:

- vascular conditions
- uncontrolled diabetes
- clotting disorders
- anticoagulant therapy
- metabolic bone disease
- chemotherapy or radiation therapy
- chronic periodontal inflammation
- insufficient soft tissue coverage
- metabolic or systemic disorders associated with wound and/or bone healing
- use of pharmaceuticals that inhibit or alter natural bone remodeling
- any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene
- uncontrolled parafunctional habits
- insufficient height and/or width of bone, and insufficient interarch space.

Treatment of children is not recommended until growth is finished and epiphyseal closure has occurred. Inclusive Mini Implants are not indicated for abutment or crown restorations.

- **Warnings**

- Do not reuse Inclusive Mini Implants. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection.
- 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 intended use are not clearly specified, treatment should be suspended until these considerations have been clarified.
- Inclusive Mini Implants are not recommended for the posterior region of the mouth.
- The following instructions are not sufficient to allow inexperienced clinicians to administer professional prosthetic dentistry. Inclusive Mini Implants, surgical instruments, 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.
- 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.

■ **Precautions**

Surgical Procedures

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. For best results, please observe the following precautions:

- All drilling procedures should be performed at 2000 RPM or less under continual, 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, excessive insertion torque 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.
- Prior to surgery, ensure that the needed components, instruments and ancillary materials are complete, functional and available in the correct quantities.

Prosthetic Procedures

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.

■ **Storage and Handling**

Inclusive Mini Implants must be stored in a dry location at room temperature, in their original packaging. Inclusive Mini Implants are packaged sterile. Do not handle implant surfaces directly. Users are advised to visually inspect packaging to ensure seals and contents are intact prior to use.

■ **INSTRUCTIONS FOR USE**

Case Planning

Prescribed implant length and diameter should take into account crestal width, cortical thickness, bone density, and any other relevant clinical factors. Use appropriate radiography in mandibular cases to identify the location of the inferior alveolar nerve, including a possible anterior loop. Use appropriate radiography in maxillary cases to identify the location of the sinuses. When patient evaluation is complete, establish the number of Inclusive Mini Implants required for denture stabilization and identify the appropriate implant sites. In mandibular cases, it is recommended that four (4) mini implants be placed within the symphysis area with as wide an anterior-posterior spread as possible while still ensuring an adequate margin of safety from the nerve. In maxillary cases, it is recommended that six (6) mini implants be placed anterior to the sinuses. Wider implants are often preferred for softer bone types. Mini implants should be placed with a minimum of 7 mm between implants, to accommodate the size of the O-ring housings. The housings can accommodate up to 30 degrees of angular divergence between mini implants. However, implants should be placed as parallel to one another as possible to provide ideal prosthetic fit and to avoid excessive wearing of the O-rings. There should be at least 8 mm of vertical space from the top of the implant collar to allow for adequate thickness of the prosthesis. The denture teeth would be in addition to this space.

Drilling Protocol

Mark each implant site on the patient's tissue. Select the appropriate Cortical Bone Drill (1.5 mm, 1.7 mm, or 2.4 mm), 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. If placing 3.0 mm diameter Inclusive Mini Implants, continue drilling to a depth of at least two-thirds (2/3) the length of the implant threads. For the majority of implant sites, this is the extent of the drilling that is required. However, 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.

Implant Placement

Remove the titanium implant holder from its packaging and place it onto a sterile field. Use slight finger pressure to pinch the occlusal end of the implant in its holder while inserting the appropriate Mini Implant Driver. Gently rotate implant and holder, allowing the driver to engage the implant connection. With the driver securely attached to the implant, squeeze the opposing end of the holder to disengage the implant from the holder. Transport the implant to the prepared site, and insert into the osteotomy. Rotate clockwise with applied pressure to engage the self-tapping threads. Avoid lateral forces, which can affect the angulation and final alignment of the implant.

NOTE: Apply pressure to ensure the driver is fully engaged with the implant prior to disengaging the titanium holder.

Final Insertion

With the implant threaded securely in its proper site, slide the Ratchet Wrench fully into place over the mini implant driver. Turn the wrench clockwise in small increments of approximately 90 degrees, pausing between rotations to allow the bone to expand. Avoid lateral forces, which can affect the final angulation of the implant. Optimal final insertion of the implant leaves the implant head 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.

NOTE: If the implant cannot be fully seated using the recommended torque, it may be necessary to reverse the implant from the site and drill again to increase the depth of the osteotomy. For positive long-term prognosis, solid resistance must be met during final insertion. Inadequate resistance contraindicates primary stability and loading. In such instances, a larger implant should be placed, or a new implant site determined.

Impression Procedure

An impression procedure is required whenever a new removable prosthesis is going to be fabricated. Based on the clinician's preference, the O-ring housings can be processed into the denture, or space made and the housings picked up chairside.

Step 1: Seat the Copings – Snap a Mini Implant Impression Coping onto the head of each Inclusive Mini Implant. If gingival tissue prevents full engagement of a coping onto an implant, take an impression of the mini implant without the use of impression copings, or trim the tissue.

Step 2: Seat the Impression – Standard impression techniques are used to pick up the impression copings, recording each implant's position easily and accurately.

Step 3: Remove the Impression – Once the impression has fully set, carefully remove the tray from the patient's mouth and verify that all impression copings have been captured accurately in the impression.

Step 4: Insert the Replicas – This step can be performed in the clinic or at the dental laboratory. Align the squared neck of a Mini Implant Replica with the squared opening at the base of the impression coping. Press the replica into the coping until it snaps into proper position. Insert a replica into each coping and prepare the impression to be used to fabricate a stone model.

Step 5: Fabricate the Model – Use standard laboratory procedure to fabricate a soft tissue model.

Soft Denture 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). Following an appropriate healing period, the soft inner liner can be replaced with a hard pick-up of the O-ring housings to increase the level of retention.

Step 1: Prepare the Denture – Relieve the patient's existing denture to make room for the implant heads. The positions of the implants can be identified using a color transfer applicator, 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. The denture must be sufficiently relieved to seat passively, without resting on or against the implant heads. Lightly roughen the tissue-facing surface of the denture with an acrylic bur, and degrease the surface with isopropyl alcohol.

Step 2: Line 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 the soft reline material to set.

Step 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.

Hard Denture 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 35 Ncm of torque resistance is achieved, with implants seated at the appropriate gingival depth.

Step 1: Prepare the Denture – Mark the location of the implants on the intaglio surface of the patient's existing denture. This can be done using a color transfer applicator, or by lining the intaglio surface of the denture with impression or bite registration material. Relieve the denture to make room for the O-ring housings. This can be done by creating a space for each housing where marked (or by burring a full trough). The denture must be sufficiently relieved to seat passively, without resting on or against the implant heads.

Step 2: Block Out the Implant Heads – Use a rubber dam or 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.

Step 3: Line 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 housing spaces (or trough) in the denture. Seat the denture in the patient's mouth. Instruct the patient to close with normal pressure into centric occlusion. Allow the hard pick-up material to set.

Step 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.

PROSTHETIC COMPONENTS

- **Description**

Prosthetic components of the Inclusive Mini Implant System, consisting of O-ring housings, analogs, impression copings, and related restorative accessories, are manufactured from titanium alloy or polymers. They are compatible with Inclusive Mini Implants. For product-specific descriptions and sterility information, please refer to the individual product labels and appropriate Inclusive product catalog and/or user manual.

- **Warnings**

Inclusive Mini Implant prosthetic components are intended to be used on an individual patient only. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection.

- **Adverse Effects**

The following adverse effects have been observed when using prosthetic components and accessories:

- Components used in the patient's mouth have been aspirated or swallowed.
- Components are not fully seated due to inadequate application of force.

- **Precautions**

Inclusive Mini Implant prosthetic components may only be used for their intended purpose in accordance with general rules for dental/prosthetic treatment, occupational safety, and accident prevention. They must only be used for dental procedures with the Inclusive Mini Implant System. If the indications and intended use are not clearly specified, treatment should be suspended until these considerations have been clarified. All components that are used intraorally must be secured to prevent aspiration or swallowing. Prior to placement, ensure that the required components, instruments, and ancillary materials are complete, functional, and available in the correct quantities.

- **Side Effects**

No side effects, according to current knowledge.

- **Sterility**

Inclusive Mini Implant prosthetic components are shipped non-sterile. Non-sterile components must be cleaned, disinfected, and sterilized prior to clinical use, according to a validated method.

- ***Cleaning***: Wash using a broad spectrum cleaning solution, followed by thorough rinsing.

The recommended disinfection process is based on ANSI/AAMI ST79 guidelines, as follows:

- ***Disinfection***: Immerse abutments in disinfectant[1], rinse with distilled water.

The recommended sterilization process is based on the ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79 guidelines, as follows:

- ***Sterilization***: Gravity-fed sterilizers: Autoclave in sterilization pouch for 30 minutes at 121°C (250°F)[2]. Devices are to be used immediately after sterilization.

NOTE: The validated procedures require the use of FDA-cleared sterilization trays, wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The healthcare facility should monitor the sterilizer for the facility according to an FDA-recognized sterility assurance standard such as ANSI/AAMI ST79.

[1]Oral disinfectant containing *Chlorhexidine* is recommended; refer to the disinfectant manufacturer's instructions. [2]ANSI/AAMI ST79

SURGICAL INSTRUMENTS

Description

Inclusive surgical instruments and surgical/restorative accessories are made out of the following materials: titanium alloy, gold alloy, polymers, and stainless steel. They are designed for use with Inclusive dental implants and prosthetic components. For specific product identification and contents, please refer to individual component packaging and appropriate product catalogs and/or user manuals.

Sterility

Surgical instruments are shipped non-sterile. Surgical tray and instruments must be cleaned, disinfected, and sterilized prior to clinical use, according to a validated method as per the ANSI/AAMI/ISO 17665-1.

Warnings

Prior to surgery, ensure that instruments and accessories are complete, functional, and available in the correct quantities.

Precautions

For best results, please observe the following precautions:

- Proper surgical protocol should be strictly adhered to.
- All surgical instruments used must be in good condition and should be used carefully to avoid damage to implants or other components.
- 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.

SYMBOLS

	Sterile with Gamma Radiation
	Non-Sterile
	Single Use Only
	Do not Resterilize
	Use by (yyyy-mm)
	By Prescription Only
	Date of Manufacture
	Catalog Number
	Lot/Batch Number
	Consult Instructions For Use
	Manufacturer
	European Authorized Representative

CE 0086

EC REP

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