

INCLUSIVE® MINI IMPLANTS

Information for Use

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

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.

■ 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.

■ 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 intra-orally 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 are for single use only, prior to the expiration date. Do not use implants if the packaging has been compromised or previously opened. Steam sterilize the surgical tray 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 pre-operative 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. Prismatic Dentalcraft, Inc. is not liable for damages resulting from treatment outside of our control. The responsibility rests with the provider.



See instructions
for use



Sterile with
Gamma Radiation



Use by
yyyy-mm



Lot/Batch Number



Single Use Only



Do Not
Resterilize

Manufactured by
Prismatic Dentalcraft, Inc.
2212 Dupont Drive
Irvine, CA 92616

Made in U.S.A.

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888-303-3975

www.glidewell dental.com