INCLUSIVE® DENTAL IMPLANT SYSTEM

English

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 Dental 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. Inclusive devices may be associated with one or more of the following product families:

- Inclusive® Tapered Implant System
- Inclusive® Mini Implant System
- Inclusive® Prosthetic Components (compatible with various implant systems and platform sizes)

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

- Inclusive Dental Implant System Product Catalog (Document No. 3019958)
- Inclusive Prosthetic Components Product Catalog (Document No. 3008614)

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

- Inclusive Dental Implant System Surgical Manual (Document No. 3019960)
- Inclusive Prosthetic Components Restorative Manual (Document No. 3021302)

■ 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.

DENTAL IMPLANTS

■ Description

Inclusive dental implants are endosseous devices manufactured from titanium alloy. They are compatible with the prosthetic components and surgical instrumentation of the Inclusive Dental Implant System.

■ Indications for Use

Tapered Implants

Inclusive Tapered Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

Mini Implants

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 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 dental implants. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection. Inclusive dental implants may only be used for their intended purpose in accordance with general rules for dental/surgical treatment, occupational safety, and accident prevention. They may only be used for dental procedures with the restorative components they were designed for. If the indication and intended 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 dentistry. Inclusive dental implants, surgical instruments, and prosthetic components should only be used by dentists and surgeons with training in implant planning, surgical and prosthetic techniques, 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. 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 dental 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 must be secured to prevent aspiration or swallowing. Distribution of stress is an important consideration. Care should be taken to avoid excessive load transverse to the implant axes.

■ Sterility

Inclusive dental 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.

■ MRI

Inclusive dental implants have not been evaluated for safety and compatibility in the MR environment, and have not been tested for heating or migration in the MR environment. They can distort images obtained via magnetic resonance imaging (MRI).

■ Storage and Handling

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

INSTRUCTIONS FOR USE — INCLUSIVE® TAPERED IMPLANTS

Soft Tissue Reflection

Following administration of appropriate anesthesia, make an incision of appropriate design for elevation of a flap. Perform alveoloplasty on the crest of the ridge, if needed, to create a more even plane in which to place the implant.

Site Preparation

Step 1: Lance Drill – With proper irrigation, perforate the alveolar crest using a surgical stent, if necessary, as a reference for proper positioning.

Step 2: Pilot Drill – Select the 2.3/2.0 mm Pilot Drill. If any change is needed in trajectory, it may be corrected at this time. With proper irrigation, drill a pilot hole to the appropriate depth marking on the drill.

Check the orientation of the initial osteotomy using a Parallel Pin. If placing more than one implant and parallelism is desired, begin drilling the next site and align as the trajectory of the bone permits.

Step 3: Surgical Drills – Depending on implant diameter and the density of bone at the osteotomy site, it may become necessary to utilize one or more of the Surgical Drills to widen the osteotomy. To avoid over-preparation, widening drill diameters should be used in ascending sequence, and proper succession. Select the desired Surgical Drill, accounting for the density of bone at the osteotomy site and the diameter of the implant to be placed. With proper irrigation, drill to the appropriate depth marking on the drill. The final drill for each implant diameter should be based on bone density (soft or hard), as charted below. The goal is to achieve high primary stability upon implant placement.

Drilling Sequence Chart							
Implant Size	Lance Drill (Ø1.5 mm)	Pilot Drill (Ø2.3/2.0 mm)	Surgical Drill (Ø2.8/2.3 mm)	Surgical Drill (Ø3.4/2.8 mm)	Surgical Drill (Ø3.8/3.4 mm)	Surgical Drill (Ø4.4/3.8 mm)	Surgical Drill (Ø4.9/4.4 mm)
Ø3.7 mm	Soft/Hard	Soft/Hard	Soft/Hard	Hard Only			
Ø4.2 mm	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Hard Only		
Ø4.7 mm	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Hard Only	
Ø5.2 mm	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Hard Only

Step 4: (Optional) Dense Bone Tap – If indicated by the presence of dense bone, select the Screw Tap with a diameter matching that of the implant. The tap may be used as an alternative to the dense bone drill. Place the tap into the prepared implant site. Apply firm pressure and begin slowly rotating the tap (25 RPM maximum). When the threads begin engaging the bone, allow the tap to feed into the site without applying additional pressure. The osteotomy should be tapped through the cortical bone. Reverse the tap out of the site.

Implant Placement

Step 1: Implant Selection – Remove the sterile vial from its tamper-proof pouch and place it onto a sterile field.

Step 2: Initial Placement – Remove the implant from the vial by its plastic carrier, taking care not to touch the implant body. Transport the implant to the prepared site, and insert into the osteotomy. Rotate clockwise with applied pressure to engage the self-tapping groove. Avoid lateral forces, which can affect the angulation and final alignment of the implant. The plastic carrier will separate from the implant head upon reaching a torque threshold of approximately 15 Ncm.

Step 3: Advancement and Final Seating – Continue threading the implant into the osteotomy site using the preferred placement method. A minimum torque value of 35 Ncm upon final seating indicates good primary stability.

Methods of Implant Placement

Option 1: Handpiece Implant Placement – Place the Handpiece Implant Driver into the handpiece. Seat the driver into the internal hex connection of the implant, and press firmly to fully engage the connection. Thread the implant into the osteotomy at approximately 25 RPM until fully seated.

Option 2: Manual Implant Placement – Select the Torque/Ratchet Wrench and assemble it with the Implant Driver. (The Implant Driver may also be used separately as a hand driver.) With the implant threaded securely in its site, seat the driver into the internal hex connection of the implant, and press firmly to fully engage the connection. Turn the wrench clockwise in increments of approximately 90 degrees. Avoid lateral forces, which can affect final alignment of the implant.

Implant Positioning

The implant should be rotated at the time of placement to ensure optimal positioning of the internal hex connection. This will allow the restoring clinician to take full advantage of the anatomical abutment contours and minimize the need for abutment preparation. Adjust the final position of the implant so that any one of the six flats of the internal hex connection is oriented toward the facial.

Healing Component Placement

Following implant placement, prepare the site for healing by placing either a Healing Abutment (single-stage surgical protocol) or the Cover Screw (two-stage surgical protocol).

Option 1: Healing Abutment – If observing a single-stage surgical protocol, select a Healing Abutment of the appropriate height and diameter. Thread the abutment into place atop the implant. To secure the abutment, assemble the Handpiece Hex Driver with the Instrument Adaptor and use this combination driver to hand-tighten.

Option 2: Cover Screw – If observing a two-stage surgical protocol, assemble the Handpiece Hex Driver with the Instrument Adaptor. Use this combination driver to unthread the Cover Screw from the plastic carrier contained in the sterile vial. Carry the Cover Screw to the implant and hand-tighten.

Closure and Suturing

If the soft tissue was reflected, close and suture the flap utilizing the desired technique. Take a postoperative radiograph to use as a baseline, and advise the patient as to the recommended postoperative procedures.

Second-Stage Uncovery (Two-Stage Surgical Protocol)

Following the appropriate healing period, make a small incision in the gingiva over the implant site to expose the Cover Screw. Use the Hex Driver to remove the Cover Screw, and place a healing abutment or temporary abutment of the appropriate height and diameter.

INSTRUCTIONS FOR USE — INCLUSIVE® MINI IMPLANTS

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 any 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 to be used and identify the appropriate corresponding 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 implant spacing is often preferred for softer bone types. Mini implants should be placed with a minimum of 7 mm between implants. 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 pick-up 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's 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 of approximately 35 Ncm, taking care not to exceed the recommended maximum of 45 Ncm.

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 with applied pressure to engage the self-tapping threads. Avoid lateral forces, which can affect the angulation and final alignment of the implant. The plastic carrier will separate from the implant head upon reaching a torque threshold of approximately 15 Ncm. Alternately, locking titanium forceps may be used to hold the implant body while the plastic carrier is removed and the implant driver is secured to the implant head. The forceps may then be removed and the implant placed into its site using the implant driver.

Final Insertion

With the implant threaded securely in its proper site, slide the Torque/Ratchet Wrench fully into place over the implant driver (utilizing the Round-Square Wrench Adaptor, if necessary). Turn the wrench clockwise in small increments of approximately 90 degrees, pausing between revolutions 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 and the threads are no longer 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 when 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 colorant 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 angulation and final alignment of the denture. Relieve the denture to create enough space over 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 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 at this time. Instruct the patient to keep the denture in place for the first 48 hours following implant 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 colorant 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. The denture must be sufficiently relieved to seat passively, without resting on or against the implant housings.

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 onto each mini implant, checking for passive fit over the implants and housings.

Step 3: Line the Denture – Apply a thin layer of adhesive onto 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 fill in 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

Inclusive Prosthetic Components, consisting of abutments, screws, analogs, copings, and related restorative accessories, are manufactured from titanium alloy, gold alloy, or polymers. Inclusive Prosthetic Components are shipped non-sterile (except for multi-unit abutments). For product-specific descriptions and sterility information, please refer to the individual product labels and applicable Inclusive catalogs and/or user manuals.

■ Indications for Use

Inclusive Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

Multi-Unit Abutments are intended to provide support and retention for multi-unit screw-retained restorations. The 30-degree multi-unit abutments must be used within 45 degrees of parallel for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallel for a splinted restoration.

■ Contraindications

Inclusive Abutments

- Wall thickness less than 0.5 mm
- Gingival margin diameter less than 0.5 mm wider than implant
- Angle corrections of more than 20 degrees
- Less than 0.5 mm margin height
- Less than 4 mm abutment height

Multi-Unit Abutments

- Greater than 45 degrees divergence from parallel for a splinted restoration when using 30-degree multi-unit abutments
- Greater than 32 degrees divergence from parallel for a splinted restoration when using 17-degree multi-unit abutments

■ Warnings

An Inclusive abutment is 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. Small-diameter implants and angled abutments are not recommended for the molar region of the mouth.

■ 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.
- The abutment screw has fractured due to application of excessive torque.
- The abutment is not adequately secured due to inadequate application of torque.

■ Precautions

Inclusive abutments may only be used for their intended purpose in accordance with general rules for dental/prosthetic treatment, occupational safety, and accident prevention. Inclusive abutments must only be used for dental procedures with the implant systems they were designed for. 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

Multi-Unit Abutments are shipped sterile. They should not be resterilized. They are for single use only, prior to the expiration date.

Non-sterile abutments and screws must be cleaned, disinfected, and sterilized prior to clinical use, according to a validated method.

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

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

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].

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] Refer to the disinfectant manufacturer's instructions. [2] ANSI/AAMI ST79

■ MRI

Inclusive abutments have not been evaluated for safety and compatibility in the MR environment, and have not been tested for heating or migration in the MR environment. They can distort images obtained via magnetic resonance imaging (MRI).

■ Dental Implant Compatibility and Recommended Torque Values

Inclusive Prosthetic Components manufactured by Prismatik Dentalcraft are generally compatible with the implant systems listed in the table below. The availability of a particular type of prosthetic component varies by implant system, and may be limited by geographical territory. The platform-specific compatibility of each component is indicated on the individual product label. For a complete product listing, please refer to the Inclusive Prosthetic Components Product Catalog, or contact an Inclusive sales representative.

Implant System and Platform Sizes	Manufacturer's Recommended Torque (Ncm): Titanium Abutment / Screw	Multi-Unit Abutment / Screw	Multi-Unit Prosthetic Screw
Biomet 3i® Certain® 3.4 mm, 4.1 mm, 5.0 mm, 6.0 mm	20 Ncm	20 Ncm	15 Ncm
Camlog® Screw-Line 3.3 mm, 3.8 mm, 4.3 mm, 5.0 mm, 6.0 mm	20 Ncm	20 Ncm	15 Ncm
Dentsply Implants Ankylos® A (3.5 mm), B (4.5 mm), C (5.5 mm), D (7.0 mm)	25 Ncm	25 Ncm	15 Ncm
Dentsply Implants Astra Tech Implant System® X-Small (2.5 mm) / Small (2.9 mm) / Large (3.9 mm)	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm
Inclusive® Tapered Implant System 3.5 mm, 4.5 mm	35 Ncm	30 Ncm	15 Ncm
Nobel Biocare Brånemark System® RP (3.75 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelActive® NP (3.5 mm), RP (4.3 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelReplace® NP (3.5 mm), RP (4.3 mm), WP (5.0 mm), 6.0 (6.0 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Bone Level NC (3.3 mm), RC (4.1 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Tissue Level NN (3.5 mm), RN synOcta® (4.8 mm), WN synOcta® (6.5 mm)	35 Ncm	35 Ncm	15 Ncm
Zimmer Dental Screw-Vent® 3.5 mm, 4.5 mm, 5.7 mm	30 Ncm	30 Ncm	15 Ncm

NOTE: Any screw-retained prosthetic component not listed in the table above should be hand-tightened only.

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INSTRUCTIONS FOR USE — INCLUSIVE® TITANIUM ABUTMENTS

Inclusive Titanium Abutments are prefabricated, screw-retained intraoral abutments intended to be connected directly to endosseous dental implants for retention of a cemented dental prosthesis. They may be indicated for single- and multiple-tooth restorations. Titanium abutments are machined from titanium alloy and attached to the implant fixture with a titanium screw compatible with the internal instrumentation of the specified implant system.

Capture Implant Placement

Take an implant-level impression utilizing the preferred technique (direct, indirect, or intraoral scan). Submit the impression to the laboratory.

Laboratory — Fabricate the Restoration

1) Follow pouring procedures for the appropriate die stone to produce a working model and articulate with a bite registration.

2) Select the appropriate Inclusive Titanium Abutment based on the system, platform size, location, and occlusal clearance of the implant seated in the patient's mouth.

3) Seat the abutment completely into the implant analog on the working model, making sure that the anti-rotational features of the connection interface are fully engaged and the contours of the emergence profile (if applicable) are esthetically oriented.

4) Insert the Inclusive Titanium Screw (provided) into the abutment's screw access hole and hand-tighten using the appropriate driver.

5) Fabricate the restoration using conventional casting or CAD/CAM techniques. Veneer as necessary. If a screw-retained hybrid restoration is indicated, lute the ceramic crown to the titanium abutment.

Deliver the Final Restoration

1) Seat the titanium abutment or screw-retained hybrid restoration completely into the implant, making sure that the anti-rotational features of the connection interface are fully engaged and the contours of the sculpted emergence profile are esthetically oriented.

2) Insert the Inclusive Titanium Screw (provided) into the screw access hole and hand-tighten using the appropriate driver. It is strongly recommended that a radiograph of the connection site be taken to confirm complete seating of the abutment or hybrid restoration before proceeding.

3) Using the appropriate driver in conjunction with a properly metered torque wrench, tighten the abutment or hybrid restoration to the implant manufacturer's recommended torque value.

4) Fill the screw access hole with cotton, Teflon tape, gutta-percha, or other suitable material.

5) If the restoration is of a screw-retained hybrid design, cover the screw access hole with flowable composite, and cure. Otherwise, follow applicable cementation procedures to affix the definitive restoration to the abutment.

INSTRUCTIONS FOR USE — INCLUSIVE® MULTI-UNIT ABUTMENTS

Inclusive Multi-Unit Abutments are prefabricated, screw-retained intraoral abutments intended to be connected directly to endosseous dental implants in partially or fully edentulous patients for the retention of cast or milled bar overdentures. For implant-supported prostheses, six or more implants are recommended in the maxilla, four or more in the mandible. If clinical conditions dictate fewer implants, an implant-retained, tissue-supported prosthesis is indicated. Multi-unit abutments are machined from titanium alloy, and are available with a variety of collar heights to achieve optimal emergence from shallow or deep gingival wells. Each Inclusive Multi-Unit Abutment is delivered sterile, suspended in an aseptic vial from a carrier color-coded to indicate the restorative platform of the seated implant.

Straight multi-unit abutments lack any anti-rotational features at the implant-abutment interface. The apical portion of a straight multi-unit abutment is threaded for integration with the internal cavity of a seated implant. For abutment delivery, the occlusal surface features a male hex head compatible with the multi-unit driver recommended by the implant manufacturer. Angled multi-unit abutments of 17 degrees or 30 degrees enable clinicians to compensate for the divergence of seated implants or to better accommodate the angled path of insertion. Angled multi-unit abutments feature an anti-rotational connection interface specific to the matching implant platform, and are attached to the implant fixture with an angled multi-unit abutment screw compatible with the internal instrumentation of the specified implant system. Both straight and angled multi-unit abutments feature a female connection oriented to the coronal apex, to allow for the attachment of screw-retained or fixed-removable definitive prostheses with a multi-unit restorative screw (Inclusive Prosthetic Screw).

The axial tilt of an Inclusive Angled Multi-Unit Abutment (angular divergence from path of insertion) is designed and manufactured to lie along a plane of the implant connection geometry, as opposed to a corner junction. To maximize the angle-correcting attributes of the multi-unit abutment, be sure to rotate the implant upon final seating so that one side of the internal connection geometry (flat or lobe) is oriented to serve as the basis of angulation, in accordance with the restorative treatment plan.

Place the Multi-Unit Abutment

1) Select the appropriate Inclusive Multi-Unit Abutment based on platform size, endosseous implant angle, and depth of the soft-tissue well.

2) Remove the lid from the aseptic vial and retrieve the abutment by lifting the abutment carrier straight out. To maintain the sterility of the multi-unit abutment, be careful to handle only by the carrier.

3)(a) For Straight Abutments: Using the carrier, seat the abutment into the implant and hand-tighten. Remove the carrier by pulling the apex of the carrier toward the facial. (b) For Angled Abutments: Using the carrier, seat the abutment into the implant until the anti-rotational features of the connection interface are engaged. Lift and rotate as necessary to orient to the preferred angled direction. Hand-tighten the Inclusive Angled Multi-Unit Abutment Screw using the appropriate driver. Twist the carrier counter-clockwise to remove.

NOTE: It is strongly recommended that a radiograph of the connection site be taken to confirm complete seating of the abutment before proceeding.

4) Using the appropriate driver in conjunction with a properly metered torque wrench, tighten the multi-unit abutment or angled multi-unit abutment screw to the implant manufacturer's recommended torque value.

Passive Temporization of Multi-Unit Abutments

1) If the initial stability of the seated implants is insufficient for loading, cover each Inclusive Multi-Unit Abutment with an Inclusive Multi-Unit Temporary Healing Cap and hand-tighten with the Inclusive Prosthetic Screw provided, using the appropriate driver. Do not overtighten.

2) Using the patient's existing denture or other prosthesis, relieve the area directly above the placement of each temporary healing cap until the denture rests on the ridge.

3) Follow procedures to reline the denture over the temporary healing caps, using soft reline material only. The temporized denture can be used during a healing phase until the implants obtain sufficient load-bearing stability.

NOTE: For a temporization technique involving loading, please refer to the Inclusive Prosthetic Components Restorative Manual.

Capture Multi-Unit Abutment Placement

When stability permits, take an abutment-level impression utilizing the preferred technique (direct, indirect, or intraoral scan). Submit the impression to the laboratory for the fabrication of a working cast and verification index.

Denture Protocol

Follow appropriate denture protocol in accordance with the patient-specific treatment plan. When trying in the various setups (e.g., verification index, occlusal rim, wax setup, retention bar), hand-tighten to the multi-unit abutments with prosthetic screws, using the appropriate driver. Start from the distal and move forward, alternating between sides of the ridge. Always confirm complete, passive seating, modifying the setup as needed.

Deliver the Final Restoration

1) Remove any temporary prosthesis.

2) Confirm that each multi-unit abutment is tightened to the implant manufacturer's recommended torque value.

3) Line the prosthesis onto the abutments. Beginning with the midmost screw access channel, hand-tighten an Inclusive Prosthetic Screw into the multi-unit abutment. Repeat for each abutment, working outward and alternating left to right.

4) Confirm appropriate seating. With the same middle-out, left-to-right technique, tighten each prosthetic screw to 15 Ncm.

5) Check comfort and occlusion, and make any necessary adjustments.

6) Fill each screw access channel with gutta-percha, silicone, or other suitable temporary material.

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. Inclusive prosthetic components are designed to be compatible with the restorative instrumentation of the specified implant system.

For specific product identification and contents, please refer to individual component packaging and appropriate Inclusive product catalogs and/or user manuals.

■ Sterility

Surgical instruments are shipped non-sterile. Surgical tray and instrument 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

Proper surgical protocols 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 instruments are very small, precautions should be taken to ensure that they are not swallowed or aspirated by the patient.

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INCLUSIVE® GEBITSIMPLANTAATSYSTEEM

Dutch

Instructies voor gebruik

BELANGRIJKE INFORMATIE — ZORGVULDIG DOORLEZEN

Let op: volgens de Amerikaanse federale wetgeving mag dit product alleen door of op voorschrift van een bevoegde tandarts of arts worden verkocht.

■ Algemene informatie

- Inclusive® taps toelopend implantaatsysteem
- Inclusive® mini-implantaatsysteem
- Inclusive® prothetische componenten (compatibel met diverse implantaatsystemen en platformafmetingen)

- Productcatalogus voor Inclusive-gebitsimplantaatsysteem (documentnr. 3019958)
- Productcatalogus voor Inclusive prothetische componenten (documentnr. 3008614)

- Chirurgische handleiding voor Inclusive-gebitsimplantaatsysteem (documentnr. 3019960)
- Restauratieve handleiding voor Inclusive prothetische componenten (documentnr. 3021302)

■ Afwijzing van aansprakelijkheid

GEBITSIMPLANTATEN

■ Beschrijving

■ Indicaties voor gebruik

Taps toelopende implantaten

Mini-implantaten

■ Contra-indicaties

■ Waarschuwingen

■ Voorzorgsmaatregelen

Chirurgische procedures

Prothetische procedures

■ Steriliteit

■ MRI

■ Opslag en hantering

INSTRUCTIES VOOR GEBRUIK — INCLUSIVE® TAPS TOELOPENDE IMPLANTATEN

Tabel boorvolgorde							
Implantaatgrootte	Lansboor (Ø1,5 mm)	Centreerboor (Ø2,3/2,0 mm)	Chirurgische boor (Ø2,8/2,3 mm)	Chirurgische boor (Ø3,4/2,8 mm)	Chirurgische boor (Ø3,8/3,4 mm)	Chirurgische boor (Ø4,4/3,8 mm)	Chirurgische boor (Ø4,9/4,4 mm)
Ø3,7 mm	Zacht/hard	Zacht/hard	Zacht/hard	Alleen hard			
Ø4,2 mm	Zacht/hard	Zacht/hard	Zacht/hard	Zacht/hard	Alleen hard		
Ø4,7 mm	Zacht/hard	Zacht/hard	Zacht/hard	Zacht/hard	Zacht/hard	Alleen hard	
Ø5,2 mm	Zacht/hard	Zacht/hard	Zacht/hard	Zacht/hard	Zacht/hard	Zacht/hard	Alleen hard

INSTRUCTIES VOOR GEBRUIK — INCLUSIVE® MINI-IMPLANTATEN

PROTHETISCHE COMPONENTEN

■ Beschrijving

■ Indicaties voor gebruik

■ Contra-indicaties

Inclusive-abutments

- Wanddikte van minder dan 0,5 mm.
- Tandvleesrand van minder dan 0,5 mm breder dan het implantaat.
- Hoekcorrecties van meer dan 20 graden.
- Randhoogte van minder dan 0,5 mm.
- Abutmenthoogte van minder dan 4 mm.

Multi-unitabutments

■ Waarschuwingen

■ Ongewenste effecten

■ Voorzorgsmaatregelen

■ Bijwerkingen

Geen bijwerkingen volgens de huidige kennisstand.

■ Steriliteit

[1] Raadpleeg de instructies van de fabrikant van het desinfecteermiddel. [2] ANSI/AAMI ST79

■ MRI

■ Compatibiliteit van gebitsimplantaten en aanbevolen toriewaarden

Afmetingen implantaatsysteem en platform	Door de fabrikant aanbevolen aanhaalmoment (Ncm): Titanium abutment/schroef	Multi-unitabutment/schroef	Prothetische multi-unit schroef
Biomet 3i® Certain® 3,4 mm, 4,1 mm, 5,0 mm, 6,0 mm	20 Ncm	20 Ncm	15 Ncm
Camlog® Screw-Line 3,3 mm, 3,8 mm, 4,3 mm, 5,0 mm, 6,0 mm	20 Ncm	20 Ncm	15 Ncm
Dentsply Implants Ankylos® A (3,5 mm), B (4,5 mm), C (5,5 mm), D (7,0 mm)	25 Ncm	25 Ncm	15 Ncm
Dentsply Implants Astra Tech Implant System® Extra klein (2,5 mm) / Klein (2,9 mm) / Groot (3,9 mm)	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm
Inclusive® taps toelopend implantaatsysteem 3,5 mm, 4,5 mm	35 Ncm	30 Ncm	15 Ncm
Nobel Biocare Brånemark System® RP (3,75 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelActive® NP (3,5 mm), RP (4,3 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelReplace® NP (3,5 mm), RP (4,3 mm), WP (5,0 mm), 6,0 (6,0 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Bone Level NC (3,3 mm), RC (4,1 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Tissue Level NN (3,5 mm), RN synOcta® (4,8 mm), WN synOcta® (6,5 mm)	35 Ncm	35 Ncm	15 Ncm
Zimmer Dental Screw-Vent® 3,5 mm, 4,5 mm, 5,7 mm	30 Ncm	30 Ncm	15 Ncm

INSTRUCTIES VOOR GEBRUIK — INCLUSIVE®-TITANIUM ABUTMENTS

INSTRUCTIES VOOR GEBRUIK — INCLUSIVE® MULTI-UNITABUTMENTS

CHIRURGISCHE INSTRUMENTEN

■ Beschrijving

■ Steriliteit

■ Waarschuwingen

■ Voorzorgsmaatregelen

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Verenigde Staten

SYSTÈME D'IMPLANTS DENTAIRES INCLUSIVE®

French

Mode d'emploi

IMPORTANT: À LIRE ATTENTIVEMENT

Avertissement: selon la loi fédérale américaine, cet appareil ne peut être vendu que par un médecin ou un dentiste, ou sur prescription médicale.

■ Informations générales

- Système d'implants coniques Inclusive®
- Système de mini-implants Inclusive®
- Composants prothétiques Inclusive® (compatibles avec différents systèmes d'implant et tailles de plateformes)

- Catalogue des Systèmes d'implants dentaires Inclusive (Référence n° 3019958)
- Catalogue des composants prothétiques Inclusive (Référence n° 3008614)

- Manuel chirurgical des Systèmes d'implants dentaires Inclusive (Référence n° 3019960)
- Manuel de restauration des composants prothétiques Inclusive (Référence n° 3021302)

■ *Déni de responsabilité

IMPLANTS DENTAIRES

■ Description

■ Indications

Implants coniques

Mini-Implants

■ Contre-indications

■ Mises en garde

■ Précautions d'emploi

Interventions chirurgicales

Interventions prothétiques

■ Stérilité

■ IRM

■ Stockage et manipulation

MODE D'EMPLOI — IMPLANTS CONIQUES INCLUSIVE®

Tableau de la séquence de forage							
Taille de l'implant	Foret pointeur (Ø1,5 mm)	Foret pilote (Ø2,3/2,0 mm)	Foret chirurgical (Ø2,8/2,3 mm)	Foret chirurgical (Ø3,4/2,8 mm)	Foret chirurgical (Ø3,8/3,4 mm)	Foret chirurgical (Ø4,4/3,8 mm)	Foret chirurgical (Ø4,9/4,4 mm)
Ø3,7 mm	Mou/dur	Mou/dur	Mou/dur	Dur uniquement			
Ø4,2 mm	Mou/dur	Mou/dur	Mou/dur	Mou/dur	Dur uniquement		
Ø4,7 mm	Mou/dur	Mou/dur	Mou/dur	Mou/dur	Mou/dur	Dur uniquement	
Ø5,2 mm	Mou/dur	Mou/dur	Mou/dur	Mou/dur	Mou/dur	Mou/dur	Dur uniquement

MODE D'EMPLOI — MINI-IMPLANTS INCLUSIVE®

COMPOSANTS PROTHÉTIQUES

■ Description

■ Indications

■ Contre-indications

Piliers Inclusive

- Épaisseur de paroi inférieure à 0,5 mm
- Diamètre de marge gingivale moins de 0,5 mm plus large que l'implant
- Correction d'angle de plus de 20 degrés
- Hauteur de marge inférieure à 0,5 mm
- Hauteur de pilier inférieure à 4 mm

Piliers Multi-Unit

■ Mises en garde

■ Effets indésirables

■ Précautions d'emploi

■ Effets secondaires

Aucun effet secondaire à l'état actuel des connaissances.

■ Stérilité

[1] Consulter les instructions du fabricant du désinfectant. [2] ANSI/AAMI ST79

■ IRM

■ Compatibilité des implants dentaires et valeurs de couple recommandées

Systèmes d'implants et taille de plateforme	Couple recommandé par le fabricant (Ncm): Pilier/vis en titane	Pilier/vis Multi-Unit	Vis prothétiques Multi-Unit
Biomet 3i® Certain® 3,4 mm, 4,1 mm, 5,0 mm, 6,0 mm	20 Ncm	20 Ncm	15 Ncm
Camlog® Screw-Line 3,3 mm, 3,8 mm, 4,3 mm, 5,0 mm, 6,0 mm	20 Ncm	20 Ncm	15 Ncm
Dentsply Implants Ankylos® A (3,5 mm), B (4,5 mm), C (5,5 mm), D (7,0 mm)	25 Ncm	25 Ncm	15 Ncm
Dentsply Implants Astra Tech Implant System® Très petit (2,5 mm) / Petit (2,9 mm) / Grand (3,9 mm)	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm
Système d'implants coniques Inclusive® 3,5 mm, 4,5 mm	35 Ncm	30 Ncm	15 Ncm
Nobel Biocare Brånemark System® RP (3,75 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelActive® NP (3,5 mm), RP (4,3 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelReplace® NP (3,5 mm), RP (4,3 mm), WP (5,0 mm), 6,0 (6,0 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Bone Level NC (3,3 mm), RC (4,1 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Tissue Level NN (3,5 mm), RN synOcta® (4,8 mm), WN synOcta® (6,5 mm)	35 Ncm	35 Ncm	15 Ncm
Zimmer Dental Screw-Vent® 3,5 mm, 4,5 mm, 5,7 mm	30 Ncm	30 Ncm	15 Ncm

MODE D'EMPLOI — PILIERS EN TITANE INCLUSIVE®

MODE D'EMPLOI — PILIERS MULTI-UNIT INCLUSIVE®

INSTRUMENTS CHIRURGICAUX

■ Description

■ Stérilité

■ Mises en garde

■ Précautions d'emploi

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INCLUSIVE® ZAHNIMPLANTSYSTEM

German

Gebrauchsanweisung

WICHTIGE INFORMATIONEN — BITTE LESEN

Achtung: Gemäß US-amerikanischer Gesetzgebung darf dieses Produkt nur durch einen Zahnarzt, Arzt oder auf zahnärztliche bzw. ärztliche Anordnung verkauft werden.

■ Allgemeine Informationen

- Inclusive® konisches Implantatsystem
- Inclusive® Mini-Implantatsystem
- Inclusive® Prothetikkomponenten (mit verschiedenen Implantatsystemen und Plattformgrößen kompatibel)

- Inclusive Zahnimplantatsystem – Produktkatalog (Dokumentnr. 3019958)
- Inclusive Prothetikkomponenten – Produktkatalog (Dokumentnr. 3008614)

- Inclusive Zahnimplantatsystem – Handbuch Chirurgie (Dokumentnr. 3019960)
- Inclusive Prothetikkomponenten – Handbuch Restauration (Dokumentnr. 3021302)

■ Haftungsausschluss

ZAHNIMPLANTATE

■ Beschreibung

■ Indikationen

Konische Implantate

Mini-Implantate

■ Kontraindikationen

■ Warnhinweise

■ Vorsichtsmaßnahmen

Chirurgische Verfahren

Prothetische Verfahren

■ Sterilität

■ MRT

■ Lagerung und Handhabung

GEBRAUCHSANWEISUNG — INCLUSIVE® KONISCHE IMPLANTATE

Tabelle der Bohrreihenfolge							
Implantatgröße	Schneidbohrer (Ø1,5 mm)	Pilotbohrer (Ø2,3/2,0 mm)	Chirurgischer Bohrer (Ø2,8/2,3 mm)	Chirurgischer Bohrer (Ø3,4/2,8 mm)	Chirurgischer Bohrer (Ø3,8/3,4 mm)	Chirurgischer Bohrer (Ø4,4/3,8 mm)	Chirurgischer Bohrer (Ø4,9/4,4 mm)
Ø3,7 mm	Weich/Hart	Weich/Hart	Weich/Hart	Nur hart			
Ø4,2 mm	Weich/Hart	Weich/Hart	Weich/Hart	Weich/Hart	Nur hart		
Ø4,7 mm	Weich/Hart	Weich/Hart	Weich/Hart	Weich/Hart	Weich/Hart	Nur hart	
Ø5,2 mm	Weich/Hart	Weich/Hart	Weich/Hart	Weich/Hart	Weich/Hart	Weich/Hart	Nur hart

GEBRAUCHSANWEISUNG — INCLUSIVE® MINI-IMPLANTATE

PROTHETIKKOMPONENTEN

■ Beschreibung

■ Indikationen

■ Kontraindikationen

Inclusive Abutments

- Wandstärke von weniger als 0,5 mm.
- Gingivarand ist im Durchmesser nicht mindestens 0,5 mm breiter als das Implantat.
- Winkelkorrekturen von mehr als 20 Grad.
- Weniger als 0,5 mm Randhöhe.
- Weniger als 4 mm Abutmenthöhe.

Multi-Unit Abutments

- Mehr als 45 Grad Divergenz von der Parallele einer geschienten Restauration bei Verwendung des 30-Grad Multi-Unit Abutments.
- Mehr als 32 Grad Divergenz von der Parallele einer geschienten Restauration bei Verwendung des 17-Grad Multi-Unit Abutments.

■ Warnhinweise

■ Nebenwirkungen

- Einatmen oder Schlucken der im Mund des Patienten befindlichen Komponenten.
- Bruch der Abutmentschraube aufgrund eines zu hohen Drehmoments beim Festziehen der Schraube.
- Ungenügender Sitz der Abutmentschraube aufgrund eines unzureichenden Drehmoments beim Festziehen der Schraube.

■ Vorsichtsmaßnahmen

■ Nebenwirkungen

Nach aktuellem Wissensstand keine Nebenwirkungen.

■ Sterilität

[1] Anweisungen des Herstellers des Desinfektionsmittels beachten. [2] ANSI/AAMI ST79

■ MRT

■ Kompatibilität des Zahnimplantats und empfohlene Drehmomente

Implantatsystem und Plattformgrößen	Vom Hersteller empfohlenes Drehmoment: Titanabutment / Schraube	Multi-Unit Abutment / Schraube	Multi-Unit Prothetikschraube
Biomet 3i® Certain® 3,4 mm, 4,1 mm, 5,0 mm, 6,0 mm	20 Ncm	20 Ncm	15 Ncm
Camlog® Screw-Line 3,3 mm, 3,8 mm, 4,3 mm, 5,0 mm, 6,0 mm	20 Ncm	20 Ncm	15 Ncm
Dentsply Implants Ankylos® A (3,5 mm), B (4,5 mm), C (5,5 mm), D (7,0 mm)	25 Ncm	25 Ncm	15 Ncm
Dentsply Implants Astra Tech Implant System® X-Small (2,5 mm) / Small (2,9 mm) / Large (3,9 mm)	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm
Inclusive® konisches Implantatsystem 3,5 mm, 4,5 mm	35 Ncm	30 Ncm	15 Ncm
Nobel Biocare Brånemark System® RP (3,75 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelActive® NP (3,5 mm), RP (4,3 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelReplace® NP (3,5 mm), RP (4,3 mm), WP (5,0 mm), 6,0 (6,0 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Bone Level NC (3,3 mm), RC (4,1 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Tissue Level NN (3,5 mm), RN synOcta® (4,8 mm), WN synOcta® (6,5 mm)	35 Ncm	35 Ncm	15 Ncm
Zimmer Dental Screw-Vent® 3,5 mm, 4,5 mm, 5,7 mm	30 Ncm	30 Ncm	15 Ncm

GEBRAUCHSANWEISUNG — INCLUSIVE® TITANABUTMENTS

GEBRAUCHSANWEISUNG — INCLUSIVE® MULTI-UNIT-ABUTMENTS

CHIRURGISCHE INSTRUMENTE

■ Beschreibung

■ Sterilität

■ Warnhinweise

■ Vorsichtsmaßnahmen

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INCLUSIVE® FOGÁSZATI IMPLANTÁTUM RENDSZER

Hungarian

Használati utasítás

FONTOS INFORMÁCIÓ - OLVASSA EL

Figyelmeztetés: az amerikai szövetségi törvények értelmében a termék kizárólag gyakorló fogorvosok vagy orvosok által, illetve ezek felírására értékesíthető.

■ **Általános információkt**

- Inclusive® kúpos implantátum rendszer
- Inclusive® mini implantátum rendszerek
- Inclusive® protetikai összetevők (különböző implantátum rendszerekkel és platform méretekkel kompatibilis)

- Inclusive fogászati implantátum rendszerek termékkatalógus (dokumentum száma: 3019958)
- Inclusive protetikai összetevők termékkatalógus (dokumentum száma: 3008614)

- Inclusive fogászati implantátum rendszerek sebészeti kézikönyve (dokumentum száma: 3019960)
- Inclusive protetikai összetevők fogpótlási kézikönyve (dokumentum száma: 3021302)

■ **A felelősség kizárása**

A Prismatik Dentalcraft, Inc. nem vállal felelősséget az irányítása alatt nem álló kezelésekből származó károkért. Az ilyen jellegű felelősség a fogászati szakembert terheli.

FOGÁSZATI IMPLANTÁTUMOK

■ **A termék bemutatása**

■ **Felhasználási javallat**

Kúpos implantátumok

Mini implantátumok

■ **Ellenjavallatok**

■ **Figyelmeztetések**

■ **Óvintézkedések**

Sebészeti beavatkozások

Protetikai eljárások

■ **Sterilitás**

■ **Mágneses rezonanciás vizsgálatok (MRI)**

■ **Tárolás és kezelés**

HASZNÁLATI UTASÍTÁS – INCLUSIVE® KÚPOS IMPLANTÁTUMOK

Tabela kolejności wiercenia							
Rozmiar implantu	Wiertło znacznikowe (Ø1,5 mm)	Wiertło pilotowe (Ø2,3/2,0 mm)	Wiertło chirurgiczne (Ø2,8/2,3 mm)	Wiertło chirurgiczne (Ø3,4/2,8 mm)	Wiertło chirurgiczne (Ø3,8/3,4 mm)	Wiertło chirurgiczne (Ø4,4/3,8 mm)	Wiertło chirurgiczne (Ø4,9/4,4 mm)
Ø3,7 mm	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Tylko twarda			
Ø4,2 mm	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Tylko twarda		
Ø4,7 mm	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Tylko twarda	
Ø5,2 mm	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Miękka/Twarda	Tylko twarda

HASZNÁLATI UTASÍTÁS – INCLUSIVE® MINI IMPLANTÁTUMOK

PROTETIKAI ÖSSZETEVŐK

■ **Bemutatás**

■ **Felhasználási javallat**

■ **Ellenjavallatok**

Inclusive műcsonkok

- 0,5 mm-nél vékonyabb fal.
- Az ínyszél átmérője kevesebb mint 0,5 mm-rel szélesebb az implantátumnál.
- 20 fokot meghaladó szögkorrekció.
- 0,5 mm-nél alacsonyabb szél.
- 4 mm-nél alacsonyabb műcsonk.

Többdarabos műcsonk készlet

- 45 foknál nagyobb eltérés a párhuzamostól, ha sínre szerelt fogpótláshoz 30 fokos többdarabos műcsonk készlet kerül felhasználásra.
- 32 foknál nagyobb eltérés a párhuzamostól, ha sínre szerelt fogpótláshoz 17 fokos többdarabos műcsonk készlet kerül felhasználásra.

■ **Figyelmeztetések**

■ **Kedvezőtlen hatások**

- A páciens szájában használt eszközök belélegzése vagy lenyelése.
- A műgyökér törése a túlzott meghúzási nyomaték következtében.
- Nem megfelelően rögzített műcsonk a nem megfelelő nyomaték alkalmazásának következtében.

■ **Óvintézkedések**

■ **Mellékhatások**

A jelenlegi ismeretek szerint a terméknek nincsenek mellékhatásai.

■ **Sterilitás**

[1] Lásd a fertőtlenítőszer gyártójának utasításait. [2] ANSI/AAMI ST79

■ **Mágneses rezonanciás vizsgálatok (MRI)**

■ **A fogászati implantátumok kompatibilitása és javasolt nyomatékértékek**

Implantátum rendszer és platform méretek	A gyártó által javasolt nyomaték (Ncm): Titán műcsonk / műgyökér	Többdarabos titán műcsonk / műgyökér készlet	Többdarabos protetikai csavar készlet
Biomet 3i™ Certain® 3,4 mm, 4,1 mm, 5,0 mm, 6,0 mm	20 Ncm	20 Ncm	15 Ncm
Camlog® Screw-Line 3,3 mm, 3,8 mm, 4,3 mm, 5,0 mm, 6,0 mm	20 Ncm	20 Ncm	15 Ncm
Dentsply Implants Ankylos® A (3,5 mm), B (4,5 mm), C (5,5 mm), D (7,0 mm)	25 Ncm	25 Ncm	15 Ncm
Dentsply Implants Astra Tech Implant System® X-Small (2,5 mm) / Small (2,9 mm) / Large (3,9 mm)	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm	15 Ncm / 20 Ncm / 25 Ncm
Inclusive® System implantów dentystycznych stożkowych 3,5 mm, 4,5 mm	35 Ncm	30 Ncm	15 Ncm
Nobel Biocare Brånemark System® RP (3,75 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelActive® NP (3,5 mm), RP (4,3 mm)	35 Ncm	35 Ncm	15 Ncm
Nobel Biocare NobelReplace® NP (3,5 mm), RP (4,3 mm), WP (5,0 mm), 6,0 (6,0 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Bone Level NC (3,3 mm), RC (4,1 mm)	35 Ncm	35 Ncm	15 Ncm
Straumann® Tissue Level NN (3,5 mm), RN synOcta® (4,8 mm), WN synOcta® (6,5 mm)	35 Ncm	35 Ncm	15 Ncm
Zimmer Dental Screw-Vent® 3,5 mm, 4,5 mm, 5,7 mm	30 Ncm	30 Ncm	15 Ncm

***MEGJEGYZÉS:** A fentebbi táblázatban nem szereplő csavaros rögzítésű protetikai összetevő kizárólag kézzel húzható meg.*

HASZNÁLATI UTASÍTÁS – INCLUSIVE® TITÁN MŰCSONKOK

HASZNÁLATI UTASÍTÁS – INCLUSIVE® TÖBBDARABOS MŰCSONK KÉSZLET

SEBÉSZETI FELSZERELÉSEK

■ **Bemutatás**

■ **Sterilitás**

■ **Figyelmeztetések**

■ **Óvintézkedések**

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2212 Dupont Drive
Irvine, CA 92612

SISTEMA DI IMPIANTO DENTALE INCLUSIVE®

Italian

Istruzioni per l'uso

INFORMAZIONI IMPORTANTI — LEGGERE CON ATTENZIONE

Attenzione: la legge federale degli Stati Uniti autorizza la vendita di questo dispositivo esclusivamente da parte o su prescrizione di un dentista o medico abilitato.

■ Informazioni generali

- Sistema di impianto conico Inclusive®
- Sistema di mini impianto Inclusive®
- Componenti protesici Inclusive® (compatibili con vari sistemi di impianto e dimensioni di piattaforma)

- Catalogo prodotti del sistema di impianto dentale Inclusive (n. documento 3019958)
- Catalogo prodotti dei componenti protesici Inclusive (n. documento 3008614)

- Manuale chirurgico del sistema di impianto dentale Inclusive (n. documento 3019960)
- Manuale per la ricostruzione con componenti protesici Inclusive (n. documento 3021302)

■ Esclusione di responsabilità

Prismatik Dentalcraft, Inc. non è responsabile di danni derivanti dal trattamento al di fuori del nostro controllo. La responsabilità spetta al fornitore.

IMPIANTI DENTALI

■ Descrizione
Gli impianti dentali sono utilizzati per sostituire singoli denti o intere arcate perse a causa di patologie come carie, malattie delle gengive, traumi o anomalie congenite. Questi impianti sono costituiti da una vite in titanio che viene inserita chirurgicamente nell'osso mandibolare o mascellare, su cui viene successivamente fissata una corona, un ponte o una protesi dentale. Il titanio è un materiale biocompatibile, il che significa che è ben tollerato dal corpo umano e non provoca reazioni avverse. Gli impianti dentali offrono numerosi vantaggi rispetto alle tradizionali protesi rimovibili, come una maggiore stabilità e comfort, una migliore capacità masticatoria e un aspetto più naturale. Inoltre, gli impianti dentali possono aiutare a prevenire la perdita ossea che può verificarsi dopo la perdita dei denti, poiché stimolano la crescita di nuovo tessuto osseo intorno alla vite dell'impianto.

■ Indicazioni per l'uso
Impianti conici

Impianto conico inclusivo con sovradimensionamento per sostituzione immediata di elementi singoli in zona estetica

- Spessore della parete minore di 0,5 mm
- Distanza minima tra margine gengivale e spalla maggiore di 0,5 mm in più rispetto all'impianto
- Correzioni angolari di oltre 20 gradi
- Altezza del margine minore di 0,5 mm
- Altezza dell'abutment minore di 4 mm

Abutment multi-unità

- Divergenza angolare fra gli gradi dalla parallelismo per ricostruzione splintata quando si utilizzano abutment multi-unità a 30 gradi.
- Divergenza angolare fra gli gradi dalla parallelismo per ricostruzione splintata quando si utilizzano abutment multi-unità a 17 gradi.

■ Avvertenze
Gli abutment inclusivo sono destinati esclusivamente all'uso su singoli pazienti. Il riutilizzo di abutment già sottoposti a impianto può comportare rischi di infezione, contaminazione crociata e compromissione della funzionalità dell'impianto. Gli abutment inclusivo devono essere maneggiati e conservati in condizioni igieniche adeguate per evitare contaminazioni prima dell'uso.

■ Effetti avversi
Gli abutment multi-unità sono componenti accessori protesici sono stati osservati i seguenti effetti avversi:

- I componenti utilizzati nella bocca del paziente sono stati aspirati o ingoiati.
- La vite dell'abutment si è rotta a causa dell'applicazione di una coppia eccessiva.
- L'abutment multi-unità si è allentato a causa di un'applicazione di coppia insufficiente.

■ Precauzioni
Gli abutment inclusivo sono progettati esclusivamente per l'impiego in combinazione con componenti originali per garantire la corretta adattabilità e funzionalità. Si raccomanda di seguire le istruzioni del produttore per la corretta installazione, la manutenzione e la rimozione degli abutment, nonché di utilizzare strumenti appropriati per evitare danni ai componenti. Prima dell'uso, gli abutment devono essere ispezionati visivamente per verificare l'assenza di difetti o danni che potrebbero compromettere la loro integrità. Si raccomanda di eseguire radiografie periodiche per monitorare la stabilità dell'impianto e la corretta posizione degli abutment, soprattutto in pazienti con fattori di rischio per la perdita ossea.

■ Avvertenze
Gli abutment multi-unità sono destinati esclusivamente all'uso in combinazione con impianti dentali compatibili. Non devono essere utilizzati con impianti di altri produttori, poiché ciò può compromettere la stabilità e la funzionalità della protesi. Gli abutment multi-unità devono essere installati solo da professionisti qualificati, come dentisti o chirurghi orali, che abbiano ricevuto una formazione adeguata sull'uso di questi componenti. Un'installazione errata può causare danni all'impianto, all'osso circostante o alla protesi stessa.

■ Precauzioni
Gli abutment multi-unità devono essere maneggiati con cura per evitare graffi, deformazioni o contaminazioni che possano compromettere la loro integrità. Prima dell'installazione, è importante verificare che la superficie di contatto tra l'abutment e l'impianto sia pulita e priva di detriti. Durante il serraggio della vite dell'abutment, è fondamentale rispettare la coppia di serraggio raccomandata dal produttore per evitare sovraccarichi meccanici che potrebbero portare a fratture o allentamenti. Si consiglia di eseguire controlli periodici per assicurarsi che la vite dell'abutment non si sia allentata nel tempo.

■ Avvertenze
Gli abutment multi-unità non devono essere utilizzati in presenza di infezioni attive nella bocca del paziente, poiché ciò può aumentare il rischio di complicazioni infettive. Prima dell'installazione, è importante eseguire una valutazione completa della salute orale del paziente, compresa la presenza di infezioni gengivali o parodontali. Se si sospetta un'infezione, è necessario trattarla prima di procedere con l'inserimento degli abutment. Inoltre, i pazienti con condizioni sistemiche che compromettono la risposta immunitaria, come il diabete non controllato o l'uso di farmaci immunosoppressori, devono essere valutati attentamente per determinare se l'intervento sia appropriato.

■ Precauzioni
Gli abutment multi-unità devono essere maneggiati con cura per evitare danni alla superficie, che potrebbero compromettere la loro integrità e funzionalità. Durante l'installazione, è importante seguire le istruzioni del produttore per il corretto posizionamento e serraggio della vite dell'abutment, utilizzando gli strumenti appropriati per evitare sovraccarichi meccanici. Dopo l'installazione, è consigliabile eseguire radiografie di controllo per verificare l'adattamento corretto e l'assenza di spazi tra l'abutment e l'impianto, che potrebbero portare a infezioni o riassorbimento osseo. Infine, è importante educare il paziente sull'importanza di una buona igiene orale per prevenire infezioni e garantire la longevità dell'impianto.

■ Avvertenze
Gli abutment multi-unità non devono essere utilizzati in presenza di condizioni sistemiche che possono compromettere la guarigione ossea, come malattie autoimmuni non controllate o l'uso di farmaci immunosoppressori. Prima dell'installazione, è fondamentale eseguire una valutazione completa della salute generale del paziente, compresa la storia medica e l'esame clinico, per identificare eventuali fattori di rischio che possano influenzare il successo dell'impianto. Inoltre, i pazienti con abitudini dannose, come il fumo o il consumo eccessivo di alcol, devono essere informati dei potenziali rischi associati a queste abitudini e incoraggiati a modificarle per migliorare le probabilità di successo a lungo termine