HAHN™ TAPERED 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 Hahn Tapered Implant System consists of dental implants, prosthetic components, surgical instrumentation, and related accessories 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:

- Hahn Tapered Implant System Product Catalog (**MKT 1297**)

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

- Hahn Tapered Implant System Surgical Manual (**UM 3341**)
- Hahn Tapered Implant System Restorative Manual (**UM 3342**)

- **Online Documentation**

This Instructions for Use (IFU) document has been made available for viewing or downloading in a variety of languages at **hahnimplant.com/library.aspx**. To retrieve this particular document, simply locate the IFU number (**570**) and select the desired language.

- **Explanation of Label Symbols**

The symbols glossary is provided on page 7 of this IFU document.

- **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. These 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 Hahn Tapered 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 Hahn Tapered Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

DENTAL IMPLANTS

- **Description**

Hahn Tapered Implants are endosseous devices manufactured from titanium alloy. They are compatible with the prosthetic components and surgical instrumentation of the Hahn Tapered Implant System.

- **Indications for Use**

Tapered Implants

Hahn 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.

- **Contraindications**

Hahn Tapered 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.

- **Warnings**

- Do not reuse Hahn Tapered Implants. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection.
- Hahn Tapered 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.

- The following instructions are not sufficient to allow inexperienced clinicians to administer professional prosthetic dentistry. Hahn Tapered Implants, surgical instruments, and prosthetic components must only be used by dentists and surgeons with training/experience with oral surgery, prosthetic 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 Hahn Tapered 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**

Hahn Tapered 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**

Hahn Tapered Implants must be stored in a dry location (30% to 85% relative humidity) at room temperature (20°C to 25°C), in their original packaging. Hahn Tapered 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. Please refer to the individual product label for all relevant product information and cautions.

■ **INSTRUCTIONS FOR USE — HAHN TAPERED IMPLANTS**

Soft Tissue Reflection

Following administration of anesthesia, make an incision designed 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. Irrigation should be used for all modifications of the bone.

Site Preparation

Step 1: Twist Drill Ø1.5 mm – With copious irrigation, perforate the alveolar crest. Utilize a surgical guide, if necessary, as a reference for proper positioning.

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 2: Twist Drill Ø2.4/1.5 mm – If any change is needed in trajectory, it may be corrected at this time. With copious irrigation, drill a pilot hole to the appropriate depth (up to 16 mm).

Step 3: Twist Drill Ø2.8/2.4 mm – Select a drill of the appropriate length for the prescribed implant. With copious irrigation, drill to the desired depth.

NOTE: If placing a 3.0 mm diameter Hahn Tapered Implant, this should be the final diameter of drill used. If placing a larger-diameter Hahn Tapered Implant, proceed to *Step 4: Shaping Drills*.

Step 4: Shaping Drills (for Ø3.5 mm – Ø7.0 mm Implants) – If placing a Hahn Tapered Implant that is 3.5 mm in diameter or greater, Shaping Drills are used sequentially to widen the osteotomy to the matching diameter. To avoid over-preparation, widening drill diameters should be used only as needed, and in proper succession. Each Shaping Drill is length-specific, to match the length of the prescribed implant. Osteotomy depth may be increased sequentially, beginning with shorter drill lengths, provided sufficient depth is achieved with the final drill. Select the desired Shaping Drill, accounting for bone density and the size of the implant to be placed. With copious irrigation, drill to depth. The final drill should correspond with the matching implant size, as charted below, with the goal of achieving high primary stability upon implant placement.

	Drilling Sequence Chart				
Drill	***Ø3.0 mm***	***Ø3.5 mm***	***Ø4.3 mm***	***Ø5.0 mm***	***Ø7.0 mm***
Twist Drill (Ø1.5 mm)	Step 1	Step 1	Step 1	Step 1	Step 1
Twist Drill (Ø2.4/1.5 mm)	Step 2	Step 2	Step 2	Step 2	Step 2
*Twist Drill (Ø2.8/2.4 mm)**	**Step 3 - Final**	Step 3	Step 3	Step 3	Step 3
*Shaping Drill (Ø3.5 mm)**		**Step 4 - Final**	Step 4	Step 4	Step 4
*Shaping Drill (Ø4.3 mm)**			**Step 4 - Final**	Step 4	Step 4
*Shaping Drill (Ø5.0 mm)**				**Step 4 - Final**	Step 4
*Shaping Drill (Ø7.0 mm)**					**Step 4 - Final**

*Available in various lengths to match corresponding implant length.

Step 5: (Optional) Dense Bone Tap – If indicated by the presence of dense bone, select the Screw Tap with a diameter matching that of the implant. 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 titanium implant holder from its packaging and place it onto a sterile field.

Step 2: Initial Placement – Engage the implant connection with the appropriate driver. With the implant securely attached to the driver, 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 grooves. Avoid lateral forces, which can affect the angulation and final alignment of the implant.

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 appropriate 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 – Assemble the Adjustable Torque Wrench with the Surgical Adaptor and appropriate Implant 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 healing abutment into place atop the implant. Hand-tighten with the appropriate Prosthetic Driver.

Option 2: Cover Screw – If observing a two-stage surgical protocol, thread the Cover Screw into place atop the implant. Hand-tighten with the appropriate Prosthetic Driver.

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. Using the Prosthetic Driver, remove the Cover Screw, and place a healing abutment or temporary abutment of the appropriate height and diameter.

PROSTHETIC COMPONENTS

■ **Description**

Prosthetic components for Hahn Tapered Implants, consisting of abutments, screws, analogs, copings, and related restorative accessories, are manufactured from titanium alloy, gold alloy, or polymers. Hahn 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 appropriate catalog and/or user manuals.

Indications for Use

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

Hahn Tapered Implant 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 parallelism for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.

Contraindications

Hahn Tapered Implant Abutments

- Wall thickness less than 0.5 mm
- Gingival margin diameter less than 0.5 mm wider than implant
- Angle corrections of more than 30 degrees
- Less than 0.5 mm margin height
- Less than 4.0 mm abutment post height above the gingival collar

Hahn Tapered Implant 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

A Hahn Tapered Implant 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 posterior 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

Hahn Tapered Implant abutments may only be used for their intended purpose in accordance with general rules for dental/prosthetic treatment, occupational safety, and accident prevention. Hahn Tapered Implant abutments must only be used for dental procedures with the implant system 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.

Storage and Handling

Hahn Prosthetic Components labeled STERILE should be stored in a dry location (30% to 85% relative humidity) at room temperature (20°C to 25°C), in their original packaging. Users are advised to visually inspect packaging to ensure seals and contents are intact prior to use. Please refer to the individual product label for all relevant product information and cautions. Sterile products are intended for single-use only, prior to the expiration date. Do not use sterile products if the packaging has been compromised or previously opened. Do not resterilize.

Products labeled NON-STERILE should be cleaned and sterilized according to a validated method prior to use in the oral environment.

Sterility

Hahn Tapered Implant 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 and sterilized prior to clinical use, according to a validated method.

- ***Cleaning***: Prepare cleaning solution using 5 mL of dish soap per gallon of tap water. Fully immerse the devices in solution and scrub them with a soft-bristle brush. Remove the components and rinse them under running tap water. Dry the devices with a clean, lint-free cloth.

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). 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.

Prosthetic Compatibility

Prosthetic components for the Hahn Tapered Implant System are compatible with Hahn Tapered Implants. The platform-specific compatibility of each component is indicated on the individual product label. The availability of a particular type of prosthetic component may be limited by restorative platform, geographical territory, or other considerations. For a complete product listing, please refer to the *Hahn Tapered Implant System Product Catalog*, or contact a sales representative.

Recommended Torque Values

The recommended torque value for affixing Hahn Tapered Implant abutments and multi-unit abutments to Hahn Tapered Implants is 35 Ncm. The recommended torque value for affixing Hahn Tapered Implant multi-unit accessories utilizing the multi-unit prosthetic screw is 15 Ncm. Any other screw-retained prosthetic components, such as impression copings or scanning abutments, should be hand-tightened only.

INSTRUCTIONS FOR USE — HAHN TAPERED IMPLANT TITANIUM ABUTMENTS

Hahn Tapered Implant titanium abutments are prefabricated, screw-retained intraoral abutments intended to be connected directly to an endosseous implant 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 restorative instrumentation of the Hahn Tapered 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.

CAD/CAM Preparation

Laboratory — Design the Restoration

1) Create a soft tissue study model from an implant-level impression.

2) Select the appropriate laboratory scanning abutment to capture the implant angulation, position, and abutment connection orientation. Follow manufacturer instructions to obtain all necessary scans to construct an accurate, complete 3-D model.

3) Design the abutment according to the patient's clinical needs, taking care to ensure adequate support for the eventual restoration, including appropriate interproximal and occlusal space. Produce a digital design file.

4) Send the digital design file to a milling center to manufacture the patient-specific implant abutment.

Milling Center — Fabricate the Restoration

1) Select the appropriate Hahn™ Abutment Blank based on the system, platform size, location, and occlusal clearance of the implant seated in the patient's mouth.

2) Fabricate the restoration using CAD/CAM techniques. Veneer as necessary. If a screw-retained hybrid restoration is indicated, fabricate the superstructure (i.e., zirconia coping or crown) and lute it to the titanium abutment. The superstructure is to be bonded to the titanium abutment using MonoCem® Self-Adhesive Resin Cement (Shofu Dental Corporation; San Marcos, Calif.).

Non-CAD/CAM Preparation

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 Hahn Tapered Implant Titanium Abutment based on platform size, location, and occlusal clearance of the Hahn Tapered 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 a Titanium Screw into the abutment's screw access hole and hand-tighten using the Hahn prosthetic driver.

5) Fabricate the restoration using conventional casting techniques. Veneer as necessary. If a screw-retained hybrid restoration is indicated, lute the zirconia coping to the titanium abutment. The ceramic crown is to be bonded to the titanium abutment using MonoCem Self-Adhesive Resin Cement.

Manual Adjustment

NOTE: Due to the high thermal conductivity of titanium, titanium abutments should not be modified in the oral cavity. Any necessary modifications should be made extraorally.

1) Seat the abutment completely into an implant analog retained by an analog holder or the implant analog captured in 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.

2) Insert a Hahn Titanium Screw into the abutment's screw access hole and hand-tighten using the appropriate driver.

3) Using a fine-diamond or carbide bur, modify the abutment as needed.

4) With a silicone-based rubber wheel or point, refine the abutment along the margins.

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 a Titanium Screw into the screw access hole and hand-tighten using the Hahn prosthetic 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 Hahn prosthetic driver in conjunction with a properly metered torque wrench, tighten the abutment or hybrid restoration to the following recommended torque values:

Implant Diameter	Recommended Torque
3.0 mm	15 Ncm
3.5 mm, 4.3 mm, 5.0 mm, 7.0 mm	35 Ncm

4) Fill the screw access hole with a 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 — HAHN TAPERED IMPLANT MULTI-UNIT ABUTMENTS

Hahn Tapered Implant multi-unit abutments are prefabricated, screw-retained intraoral abutments intended to be connected directly to endosseous 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 Hahn Tapered Implant Multi-Unit Abutment is delivered sterile, with 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 otherwise accommodate an 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 restorative instrumentation of the Hahn Tapered Implant System. Both straight and angled multi-unit abutments feature a female connection port at the coronal apex, to allow for the attachment of a screw-retained or fixed-removable dental prosthesis with a multi-unit restorative screw (Prosthetic Screw).

The axial tilt of an 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 or 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) is oriented to serve as the base of angulation, in accordance with the restorative treatment plan.

Place the Multi-Unit Abutment

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

2) Retrieve the abutment from its packaging. 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 the angle in the required direction. Hand-tighten the Angled Multi-Unit Abutment Screw using the Hahn prosthetic driver. Turn the carrier counterclockwise to unscrew the carrier from the abutment.

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 Hahn prosthetic driver in conjunction with a properly metered torque wrench, tighten the multi-unit abutment or angled multi-unit abutment screw to 35 Ncm.

Passive Temporization of Multi-Unit Abutments

1) If the initial stability of the seated implant is insufficient for loading, cover each Hahn Tapered Implant Multi-Unit Abutment with a Multi-Unit Temporary Healing Cap and hand-tighten with the Prosthetic Screw provided, using the Hahn prosthetic 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 *Hahn Tapered Implant System 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 Hahn prosthetic 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 35 Ncm.

3) Place the prosthesis onto the abutments. Beginning with the midmost screw access channel, hand-tighten a Hahn Tapered Implant 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**

  Hahn Tapered Implant 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 Hahn Tapered Implants and Hahn Tapered Implant restorative components.

  For specific product identification and contents, please refer to individual component packaging and appropriate product catalog 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**

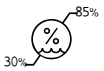
  Prior to surgery, ensure that instruments and accessories are complete, functional, and available in the correct quantities.

- **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 GLOSSARY

Symbol	Symbol Ref. No.	Symbol Title	Designation No.	Explanatory Text
STERILE R	5.2.4	Sterile with Gamma Radiation	EN ISO 15223-1	This symbol indicates that this device has been sterilized using irradiation.
	5.2.8	Do Not Use if Package is Damaged	EN ISO 15223-1	This symbol indicates that this device should not be used if the package has been damaged or opened.
	5.2.7	Non-Sterile	EN ISO 15223-1	This device has not been subjected to a sterilization process.
	5.4.2	Do not Re-use	EN ISO 15223-1	This device is intended for one use, or for use on a single patient during a single procedure.
	5.2.6	Do not Resterilize	EN ISO 15223-1	This symbol indicates that this device is not to be resterilized.
	5.3.7	Temperature Limitation	EN ISO 15223-1	Store at 20 degrees Celsius to 25 degrees Celsius.
	5.3.8	Humidity Limitation	EN ISO 15223-1	Store at 30% to 85% relative humidity.
	5.1.4	Use-by Date	EN ISO 15223-1	This symbol indicates the date (YYYY-MM-DD) after which this device is not to be used.
Rx Only	Sec. 801.109(b)(1)	By Prescription Only	21 CFR Part 801	Caution: Federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.
REF	5.1.6	Catalog Number	EN ISO 15223-1	This symbol indicates Prismatik Dentalcraft's catalog number so that this device can be identified.
LOT	5.1.5	Lot/Batch Number	EN ISO 15223-1	This symbol indicates Prismatik Dentalcraft's lot/batch number so that the lot/batch of this device can be identified.
	5.4.3	Consult Instructions For Use	EN ISO 15223-1	This symbol indicates the need of the user to consult the instructions for use.
	5.1.1	Manufacturer Date of Manufacture (YYYY-MM-DD)	EN ISO 15223-1	This symbol indicates the manufacturer and the date of manufacture of this device.
EC REP	5.1.2	European Authorized Representative	EN ISO 15223-1	This symbol indicates the authorized representative in the European Community.

CE 0086

EC REP

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30175 Hannover, Germany

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