HAHN™ TAPERED IMPLANT GUIDED SURGERY 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 Guided Surgery System Surgical Manual (**UM 6539**)
- 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 (**IFU 6538**) and select the desired language.

- **Explanation of Label Symbols**

The symbols glossary is provided on page 5 of this IFU document.

- **Compatibility**

The Hahn Tapered Implant Guided Surgery System may only be used in conjunction with Hahn Tapered Implants. Use of third-party systems is not recommended and can lead to mechanical failure and/or unsatisfactory results.

- **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 the 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.
- All instruments used for guided procedures should be inserted as far as possible through the guide sleeve.
- 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 Preparation

Option 1: Tissue Excision – Following administration of anesthesia, seat the surgical guide. If applicable, secure the guide in place, using anchor pins as needed. Select the Tissue Punch with a diameter matching that of the prescribed implant. With copious irrigation, drill until the Tissue Punch meets the bone. Remove the circular patch of soft tissue.

Option 2: Tissue Reflection – Following administration of anesthesia, make an incision designed for elevation of a flap. Seat the surgical guide; secure the guide in place with anchor pins, if applicable.

Site Preparation

Step 1: Alignment Drill – Select the Alignment Drill with a diameter matching that of the implant. With copious irrigation, perforate the alveolar crest.

NOTE: If placing a Hahn Tapered Implant that is 3.0 mm in diameter, proceed to *Step 3: Shaping Drill*.

Step 2: Pilot Drill (for Ø3.5 mm – Ø5.0 mm Implants) – If placing a Hahn Tapered Implant that is 3.5 mm in diameter or greater, Pilot Drills are used to deepen the osteotomy. Each Pilot Drill is labeled according to the diameter of implant for which it is intended to be used. Pilot Drills are available in three lengths: A (8 mm), B (10 mm), C (13 mm). Select the appropriate Pilot Drill, accounting for the size of the implant to be placed, taking care not to exceed the length of the implant. If placing an implant that is 8 mm in length, Pilot Drill A should be used. If placing an implant that is 10 mm or 11.5 mm in length, Pilot Drill B should be used. If placing an implant that is 13 mm or 16 mm in length, Pilot Drill C should be used. With copious irrigation, drill a pilot hole to depth.

Step 3: Shaping Drill – Each Shaping Drill is both diameter- and length-specific, to match the size of the prescribed implant. Select the appropriate Shaping Drill, taking care not to exceed the length of the implant. With copious irrigation, drill to depth. The drill should correspond with the matching implant size, with the goal of achieving high primary stability upon implant placement.

Step 4: (Optional) Dense Bone Shaping Drill – If indicated by the presence of dense bone, select the Dense Bone Shaping Drill with a diameter and length matching that of the prescribed implant. With copious irrigation, drill to depth.

Step 5: (Optional) Screw 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.

NOTE: Do not rotate the tap after the flange makes contact with the guide sleeve, as this might damage the threads prepared in the bone and result in less than optimal primary stability.

	Drilling Sequence Chart			
Drill	***Ø3.0 mm***	***Ø3.5 mm***	***Ø4.3 mm***	***Ø5.0 mm***
*Alignment Drill**	Step 1	Step 1	Step 1	Step 1
*Pilot Drill**	↓	Step 2	Step 2	Step 2
*Shaping Drill**	Step 3	Step 3	Step 3	Step 3
*Dense Bone Shaping Drill**	**Optional** Step 4	**Optional** Step 4	**Optional** Step 4	**Optional** Step 4
Screw Tap	**Optional** Step 5	**Optional** Step 5	**Optional** Step 5	**Optional** Step 5

*Available in various sizes corresponding to implant diameter and length.
Do not use any drill that exceeds the diameter or length of the prescribed implant.

Implant Placement

Step 1: Implant Selection – Remove the titanium implant holder from its packaging and place it onto a sterile field.

NOTE: The plastic tray contains a Cover Screw, for use when following a two-stage surgical protocol. Do not discard the Cover Screw upon removal of the implant.

Engage the implant connection with the appropriate Implant Mount. Fasten the assembly using the screw captured in the Implant Mount. With the implant securely attached to the mount, squeeze the opposing end of the holder to disengage the implant from the holder.

Step 2: Initial Placement – Transport the implant to the prepared site, then insert it through the guide and into the osteotomy. Rotate clockwise with applied pressure to engage the self-tapping grooves.

Step 3: Advancement and Final Seating – Assemble the Ratchet Wrench with the Surgical Adaptor. With the implant secured to the Implant Mount, seat the adaptor atop the mount and engage the connection. Turn the wrench clockwise in increments of approximately 90 degrees. Continue threading the implant into the osteotomy site until the hex flange on the Implant Mount meets the hex of the guide sleeve. Adjust the final position of the implant by aligning the hex on the Implant Mount with the hex of the guide sleeve. This will allow the restoring clinician to take full advantage of the anatomical abutment contours and minimize the need for abutment preparation. A minimum torque value of 35 Ncm upon final seating indicates good primary stability.

NOTE: The Mount Wrench may be used to make fine adjustments. Do not rotate after the flange fully meets the guide sleeve and the corresponding hexes are aligned. Doing so may cause the osteotomy to strip.

Following implant placement, ensure that the flats of the Implant Mount and guide sleeve are aligned. Remove the Implant Mount by unscrewing it from the implant. Then remove the surgical guide. Prepare the site for healing by placing either a Healing Abutment (single-stage surgical protocol) or the Cover Screw (two-stage surgical protocol).

Healing Component Placement

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.

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

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

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

- ***Disinfection***: Immerse 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 15 minutes at 132°C (270°F). Allow sterilized components to dry for at least 30 minutes.

NOTE: The validated procedures require the use of FDA-cleared sterilization trays, wraps, biological indicators, chemical indicators, and other sterilization

accessories labeled for the sterilization cycle recommended. The healthcare facility should monitor the sterilizer for the facility according to an FDA-recognized sterility assurance standard such as ANSI/AAMI ST79.

[1]Oral disinfectant containing *Chlorhexidine* is recommended; refer to the disinfectant manufacturer's instructions.

Warnings

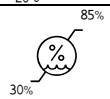
Prior to surgery, ensure that instruments and accessories are complete, functional, and available in the correct quantities. Instruments may be used for up to five preparations. For best results, replace regularly.

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
	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.
	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.
	5.1.6	Catalog Number	EN ISO 15223-1	This symbol indicates Prismatik Dentalcraft's catalog number so that this device can be identified.
	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.
	5.1.2	European Authorized Representative	EN ISO 15223-1	This symbol indicates the authorized representative in the European Community.

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EC REP

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