

Instructions for Use

IMPORTANT INFORMATION — PLEASE READ

■ 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 (**7061**) and select the desired language.

■ Disclaimer of Liability

The guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry, and are not intended to substitute for formal clinical or laboratory training. 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.

■ Description

Hahn Tapered Implant Osteotomes are surgical instruments manufactured from Grade 23 titanium alloy (Ti-6Al-4V ELI). They are designed for site preparation prior to the placement of Hahn Tapered Implants in soft bone.

■ Explanation of Label Symbols

The symbols glossary is provided on page 2 of this IFU document.

■ Indications for Use

Hahn Tapered Implant Osteotomes are indicated for bone compaction, ridge expansion, or sinus floor elevation in soft bone.

■ Contraindications

Hahn Tapered Implant Osteotomes should not be used in surgical sites characterized by dense bone.

■ Warnings

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

■ Precautions

For best results, please ensure that all surgical instruments are in good condition prior to use, and that proper surgical protocol is strictly adhered to.

■ Sterility

Hahn Tapered Implant Osteotomes are shipped non-sterile. They 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 disinfectant¹, 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 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.

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

■ Storage and Handling

Hahn Tapered Implant Osteotomes must be stored in a dry location at room temperature.

■ INSTRUCTIONS FOR USE

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, taking care not to exceed the length of the implant.

Step 3: Osteotome Ø3.0 mm – Place the Osteotome into the prepared implant site. Simultaneously press and rotate until the desired depth is achieved. Keep the Osteotome in place for 10 seconds to allow the bone to relax. With a twisting motion in the opposite direction, reverse the Osteotome out of the site.

NOTE: If placing a 3.0 mm diameter Hahn Tapered Implant, this should be the final diameter of osteotome used. If placing a larger-diameter Hahn Tapered Implant, proceed to Step 4: Osteotome Ø3.5 – Ø5.0 (for Ø3.5 mm – Ø5.0 mm Implants).

Step 4: Osteotome Ø3.5 – Ø5.0 (for Ø3.5 mm – Ø5.0 mm Implants) – If placing a Hahn Tapered Implant that is 3.5 mm in diameter or greater, Osteotomes are used sequentially to widen the osteotomy to the matching diameter. To avoid over-preparation, widening Osteotome diameters should be used only as needed, and in proper succession. Each Osteotome is diameter-specific, to match the diameter of the prescribed implant. Osteotomy depth may be increased incrementally, provided sufficient depth is achieved with the final Osteotome. Select the desired Osteotome, accounting for bone density and the size of the implant to be placed. Simultaneously press and rotate until the desired depth is achieved. Keep the Osteotome in place for 10 seconds to allow the bone to relax. With a

twisting motion in the opposite direction, reverse the Osteotome out of the site. The final Osteotome should correspond with the matching implant size, as charted below, with the goal of achieving high primary stability upon implant placement.


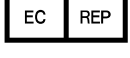
For additional information pertaining to the surgical placement of Hahn Tapered Implants, please refer to the following:

- Hahn Tapered Implant System IFU – Multilanguage (IFU 7176)
- Hahn Tapered Implant System Surgical Manual (UM 3341)

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

Do not use any drill or osteotome that exceeds the diameter or length of the prescribed implant.

SYMBOLS GLOSSARY

Symbol	Symbol Ref. No.	Symbol Title	Designation No.	Explanatory Text
	5.2.7	Non-Sterile	EN ISO 15223-1	This device has not been subjected to a sterilization process.
	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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