HAHN™
TAPERED IMPLANT

Surgical Manual | *November 2019*

hahnimplant.com

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Prismatik Dentalcraft, Inc.
a wholly owned subsidiary of
Glidewell Laboratories
2212 Dupont Drive
Irvine
California
92612
USA

DUNS Number: 02-276-1689

Holds certificate No: **MDSAP 694953**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Canada - Medical Devices Regulations - Part 1- SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Design and manufacturing of dental restorative products. Design and development, manufacture and distribution of software used with milling systems for dental restorations.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-02-05 Effective Date: 2019-02-05 Expiry date: 2022-02-04

BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

INTRODUCING THE HAHN™ TAPERED IMPLANT SYSTEM

Combining decades of clinical experience with cutting-edge design, the Hahn Tapered Implant System is a contemporary dental implant system tailored to the demands of modern implant dentistry. Precisely engineered to meet the exacting requirements of implant pioneer Dr. Jack Hahn, this advanced system addresses today's clinical challenges with a blend of time-tested features and innovation.

Like most clinicians, I want an implant system that serves to simplify treatment and increase case efficiency. Being able to address all kinds of cases quickly and capably is a win-win. That's what the Hahn Tapered Implant is designed to offer: a simple, efficient solution for every indication.

It's the best implant system I've used yet, and I can't wait to share it with my fellow clinicians. I'm biased, of course, but I wouldn't put my name on it if I didn't believe it.

ABOUT THE MANUFACTURER

Prismatik Dentalcraft was established in 2006 with the mission of making implant dentistry the standard of care for edentulous patients across the economic spectrum. To realize this goal, we carefully assembled a team of experts with decades of combined experience in the design, engineering, and manufacture of dental implants. With a support staff of highly respected researchers, material scientists, clinical specialists, and dental technicians, Prismatik is dedicated to advancing implant therapies by combining proven treatment protocols with progressive materials, technologies, and techniques.

Expert Personnel

Our team of experts have decades of combined experience in the design and manufacture of dental implants.

State-of-the-Art Equipment

Our Swiss-type lathes and multi-axis milling machines are ideal for implants and prosthetics requiring extreme precision.

Made in the U.S.A.

Our ISO-certified facility in Irvine, Calif. operates under FDA Current Good Manufacturing Practices (CGMPs).

CONTENTS

Hahn™ Tapered Implant is a trademark of Prismatik Dentalcraft, Inc.

SURGICAL CONSIDERATIONS

Scope

This manual outlines the appropriate procedures for placing Hahn™ Tapered Implants.

The procedures and 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. Hahn Tapered Implants 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 its control. Responsibility rests with the provider.

CAUTION: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

Intended Use

Hahn Tapered Implants are intended for use in partially or fully edentulous patients to retain or support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations in provisional or long-term applications. The implants are to be used for immediate loading only in the presence of adequate 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
- 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.

SURGICAL CONSIDERATIONS

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

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.

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.

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

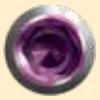
Hahn Tapered Implants must be stored in a dry location (30% to 85% relative humidity) at room temperature (20°C to 25°C), in their original packaging. Hahn Tapered Implants are packaged sterile. Do not handle implant surfaces directly. Users are advised to visually inspect packaging to ensure seals and contents are intact prior to use. Please refer to the individual product label for all relevant product information and cautions.

SURGICAL CONSIDERATIONS

Implant Selection

Hahn Tapered Implants are available in five diameters (3.0 mm, 3.5 mm, 4.3 mm, 5.0 mm, 7.0 mm) and five lengths (8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm). The narrowest implants (3.0 mm) are intended for anterior applications only, and therefore limited to longer lengths. The widest implants (7.0 mm) are intended for posterior applications only, and therefore limited to shorter lengths. All 3.5 mm and 4.3 mm diameter Hahn Tapered Implants share the same prosthetic platform.

The Hahn Tapered Implant System utilizes color-coding for easy component identification. Color-coding is featured consistently across system articles such as surgical tray, radiographic template, screw taps, and the implant carrier, with colors reflecting either the implant diameter or restorative platform, as indicated in the legend below:

Ø3.0 mm	Ø3.5 mm	Ø4.3 mm	Ø5.0 mm	Ø7.0 mm
				
	 Ø3.5 x 8 mm 70-1154-IMP0004	 Ø4.3 x 8 mm 70-1154-IMP0009	 Ø5.0 x 8 mm 70-1154-IMP0014	 Ø7.0 x 8 mm 70-1154-IMP0019
	 Ø3.5 x 10 mm 70-1154-IMP0005	 Ø4.3 x 10 mm 70-1154-IMP0010	 Ø5.0 x 10 mm 70-1154-IMP0015	 Ø7.0 x 10 mm 70-1154-IMP0020
 Ø3.0 x 11.5 mm 70-1154-IMP0001	 Ø3.5 x 11.5 mm 70-1154-IMP0006	 Ø4.3 x 11.5 mm 70-1154-IMP0011	 Ø5.0 x 11.5 mm 70-1154-IMP0016	 Ø7.0 x 11.5 mm 70-1154-IMP0021
 Ø3.0 x 13 mm 70-1154-IMP0002	 Ø3.5 x 13 mm 70-1154-IMP0007	 Ø4.3 x 13 mm 70-1154-IMP0012	 Ø5.0 x 13 mm 70-1154-IMP0017	
 Ø3.0 x 16 mm 70-1154-IMP0003	 Ø3.5 x 16 mm 70-1154-IMP0008	 Ø4.3 x 16 mm 70-1154-IMP0013	 Ø5.0 x 16 mm 70-1154-IMP0018	

SURGICAL CONSIDERATIONS

Radiographic Template

A radiographic template is available to clinicians who place Hahn Tapered Implants. This transparency is to be used as a diagnostic tool in selecting an implant of the appropriate size.

⚠ NOTE: This image is for illustrative purposes only, and is not intended for clinical use.

INSTRUMENTATION

The Hahn™ Tapered Implant Surgical Kit and the Hahn™ Tapered Implant Prosthetic Kit include tooling that is machined from corrosion-resistant, surgical stainless steel, and features standard connectivity.

Hahn™ Tapered Implant Osteotomes are 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.

All instrumentation is manufactured in the U.S.A. or Switzerland. For specific country of origin, please refer to the individual product label.

Instruments are shipped non-sterile. All instruments should be cleaned, disinfected, and sterilized according to a validated method prior to use in the oral environment.

- ***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 of the Hahn Tapered Implant Surgical Kit and the Hahn Tapered Implant Prosthetic Kit:*** Gravity-fed sterilizers: Autoclave in sterilization pouch for fifteen (15) minutes at 132°C (270°F). Allow sterilized components to dry for at least thirty (30) minutes.

- ***Sterilization of Hahn Tapered Implant Osteotomes:*** Gravity-fed sterilizers: Autoclave in sterilization pouch for thirty (30) minutes at 132°C (270°F). Allow sterilized components to dry for at least thirty (30) minutes.

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

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.

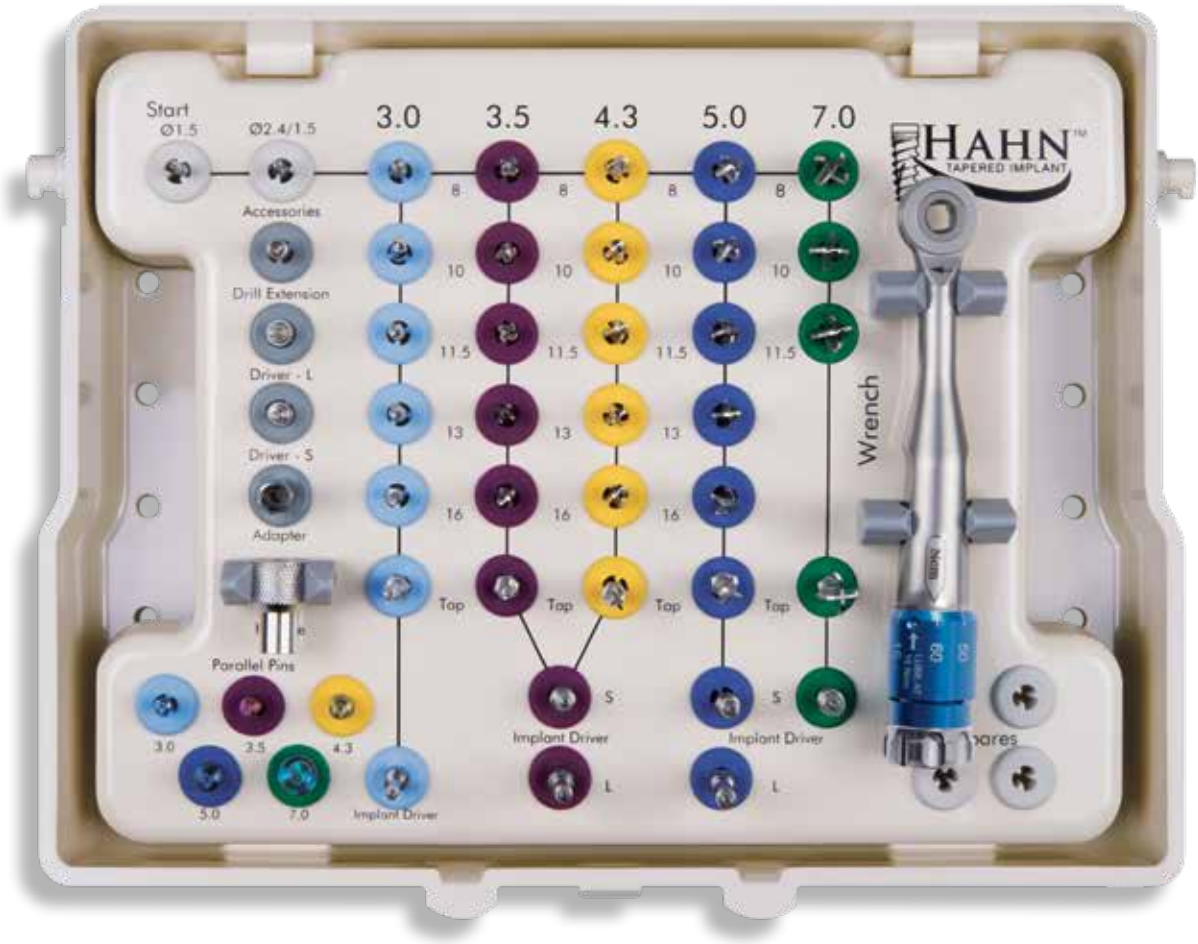
General Cleaning Information:

- Observe universal precautions for the handling of contaminated or biohazardous materials.
- Clean promptly after each use, to prevent biological fluids and tissues from drying on the instruments.
- When applicable, disassemble parts and instruments prior to cleaning.
- Do not rely solely on automatic cleaning. Thorough manual cleaning is recommended.
- Preliminary cleaning should consist of wiping parts, soaking them in a lukewarm enzymatic solution for a minimum of twenty (20) minutes, and rinsing them with running water.
- Routine cleaning should consist of (a) washing parts using a broad spectrum cleaning solution, followed by thorough rinsing and drying; and (b) sonicating parts fully submerged in cleaning solution for at least ten (10) minutes, preferably at 45-50 kHz, followed by thorough rinsing and drying.
- Dry promptly and completely to avoid oxidation.

INSTRUMENTATION

Surgical Kit

The surgical kit allows the clinician to easily organize, store, and transport the instrumentation components of the Hahn Tapered Implant System. Drills are arranged from left to right in order of increasing diameter, following the recommended drilling sequence. Color-coded fields indicate the corresponding diameter of Hahn Tapered Implant.



⚠ NOTE: Some instruments sold separately. For a detailed product listing, please refer to the *Hahn Tapered Implant System Product Catalog*, or contact a sales representative.

INSTRUMENTATION

1 **Twist Drill Ø2.8/2.4 x 8 mm**
70-1071-SRG0166

2 **Twist Drill Ø2.8/2.4 x 10 mm**
70-1071-SRG0167

3 **Twist Drill Ø2.8/2.4 x 11.5 mm**
70-1071-SRG0168

4 **Twist Drill Ø2.8/2.4 x 13 mm**
70-1071-SRG0169

5 **Twist Drill Ø2.8/2.4 x 16 mm**
70-1071-SRG0170

8 **Shaping Drill Ø3.5 x 8 mm**
70-1071-SRG0055

9 **Shaping Drill Ø3.5 x 10 mm**
70-1071-SRG0056

10 **Shaping Drill Ø3.5 x 11.5 mm**
70-1071-SRG0057

11 **Shaping Drill Ø3.5 x 13 mm**
70-1071-SRG0058

12 **Shaping Drill Ø3.5 x 16 mm**
70-1071-SRG0059

16 **Shaping Drill Ø4.3 x 8 mm**
70-1071-SRG0060

17 **Shaping Drill Ø4.3 x 10 mm**
70-1071-SRG0061

18 **Shaping Drill Ø4.3 x 11.5 mm**
70-1071-SRG0062

19 **Shaping Drill Ø4.3 x 13 mm**
70-1071-SRG0063

20 **Shaping Drill Ø4.3 x 16 mm**
70-1071-SRG0064

22 **Shaping Drill Ø5.0 x 8 mm**
70-1071-SRG0065

23 **Shaping Drill Ø5.0 x 10 mm**
70-1071-SRG0066

24 **Shaping Drill Ø5.0 x 11.5 mm**
70-1071-SRG0067

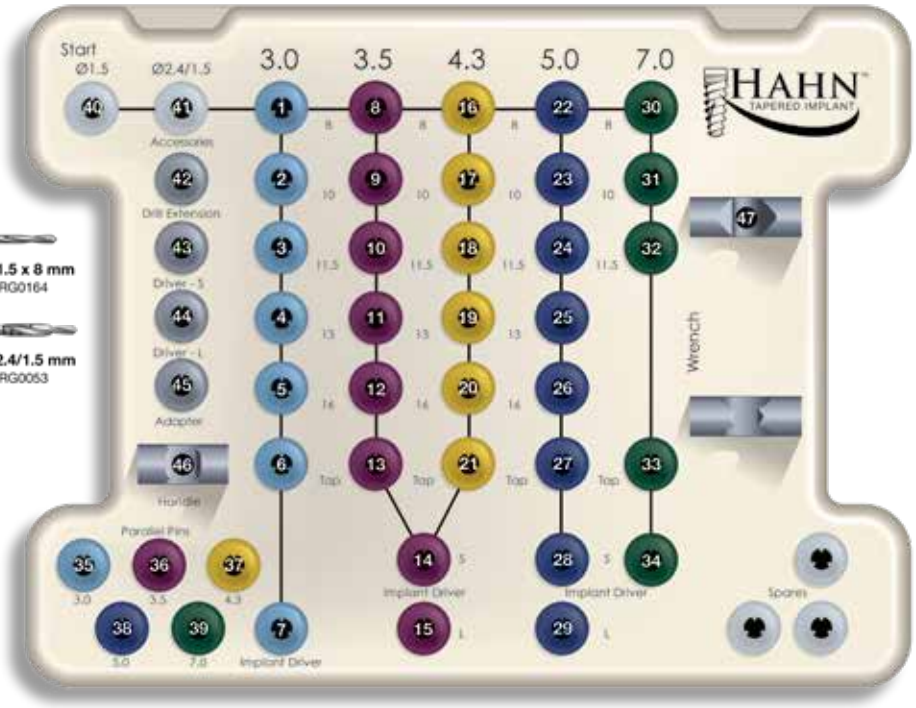
25 **Shaping Drill Ø5.0 x 13 mm**
70-1071-SRG0068

26 **Shaping Drill Ø5.0 x 16 mm**
70-1071-SRG0069

30 **Shaping Drill Ø7.0 x 8 mm**
70-1071-SRG0070
(Sold Separately)

31 **Shaping Drill Ø7.0 x 10 mm**
70-1071-SRG0071
(Sold Separately)

32 **Shaping Drill Ø7.0 x 11.5 mm**
70-1071-SRG0072
(Sold Separately)



40 **Twist Drill Ø1.5 x 8 mm**
70-1071-SRG0164

41 **Twist Drill Ø2.4/1.5 mm**
70-1071-SRG0053

47 **Adjustable Torque Wrench**
70-1071-SRG0155

42 **Drill Extender**
70-1071-SRG0014

43 **Prosthetic Driver, Short**
70-1153-PRC0057

44 **Prosthetic Driver, Long**
70-1153-PRC0056

45 **Surgical Adaptor**
70-1071-SRG0089

46 **Inclusive® Driver Handle**
70-1071-SRG0049

35 **Parallel Pin Ø3.0 mm**
70-1071-SRG0078

36 **Parallel Pin Ø3.5 mm**
70-1071-SRG0079

37 **Parallel Pin Ø4.3 mm**
70-1071-SRG0080

38 **Parallel Pin Ø5.0 mm**
70-1071-SRG0081

39 **Parallel Pin Ø7.0 mm**
70-1071-SRG0082
(Sold Separately)

7 **Driver Ø3.0 Long**
70-1071-SRG0083

14 **Driver Ø3.5/4.3 Short**
70-1071-SRG0084

15 **Driver Ø3.5/4.3 Long**
70-1071-SRG0085

28 **Driver Ø5.0 Short**
70-1071-SRG0086

29 **Driver Ø5.0 Long**
70-1071-SRG0087

34 **Driver Ø7.0 Short**
70-1071-SRG0088
(Sold Separately)

6 **Screw Tap Ø3.0 mm**
70-1071-SRG0073

13 **Screw Tap Ø3.5 mm**
70-1071-SRG0074

21 **Screw Tap Ø4.3 mm**
70-1071-SRG0075

27 **Screw Tap Ø5.0 mm**
70-1071-SRG0076

33 **Screw Tap Ø7.0 mm**
70-1071-SRG0077
(Sold Separately)

INSTRUMENTATION

Surgical Drills

The Hahn Tapered Implant System features a full range of surgical drills, including three diameters of Twist Drills (1.5 mm, 2.4/1.5 mm, 2.8/2.4 mm) and four diameters of Shaping Drills (3.5 mm, 4.3 mm, 5.0 mm, 7.0 mm). All are designed to achieve maximum cutting efficiency while effectively removing bone from the osteotomy. Drills may be used for up to five preparations, depending on bone density. For best results, replace regularly.

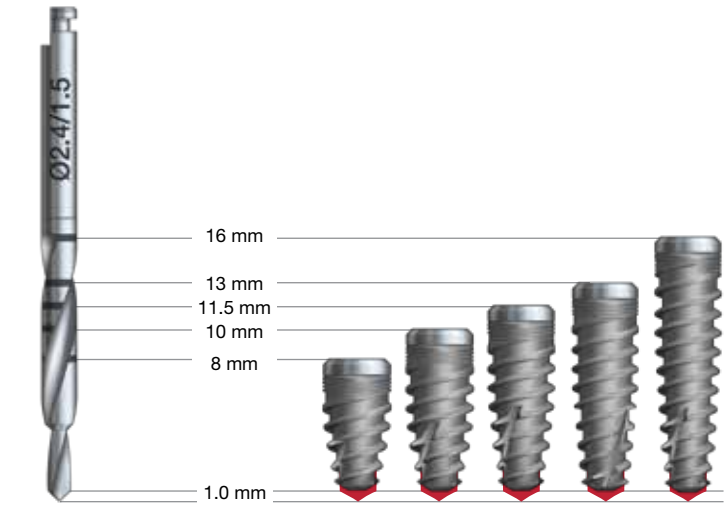
Larger Twist Drills are stepped to accommodate the tapered design of the implant. The first two diameters (1.5 mm and 2.4/1.5 mm) are considered pilot drills. The largest diameter (2.8/2.4 mm) is available in five lengths (8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm), corresponding to the available implant lengths. Drill length is calculated to indicate where the top of the implant will reside when fully seated to that depth.

Each Shaping Drill is both diameter- and length-specific, to match the size of the prescribed implant.

Twist Drill 2.4/1.5 mm Depth Markings

While Hahn Tapered Implant Shaping Drills are length-specific, the 2.4/1.5 mm diameter Twist Drill contains multiple depth markings in order to minimize the number of surgical instruments required. Care should be taken not to exceed the planned depth when preparing the initial osteotomy using this variable Twist Drill.

The illustration below demonstrates the correlation between laser-etched depth markings on the 2.4/1.5 mm diameter Twist Drill and the corresponding implant length.



Twist Drill
Ø2.4/1.5 mm

NOTE: Due to the cutting tip, the osteotomy preparation typically extends 1 mm longer than the stated length of the implant. This added length must be taken into account when planning the case.

Screw Taps *(Optional for Dense Bone)*

For the placement of Hahn Tapered Implants in extremely dense bone, it may be necessary to utilize a thread-forming screw tap corresponding to the diameter of the implant body. Due to the tap design and implant cutting efficiency, one tap is used for multiple implant lengths. The coronal head of each screw tap is slightly flared, resulting in a gentle expansion of the cortical plate for receiving the wider neck of the implant.

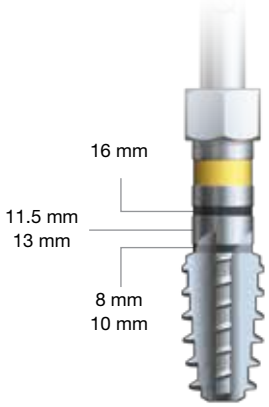
Screw Tap
Ø3.0 mm

Screw Tap
Ø3.5 mm

Screw Tap
Ø4.3 mm

Screw Tap
Ø5.0 mm

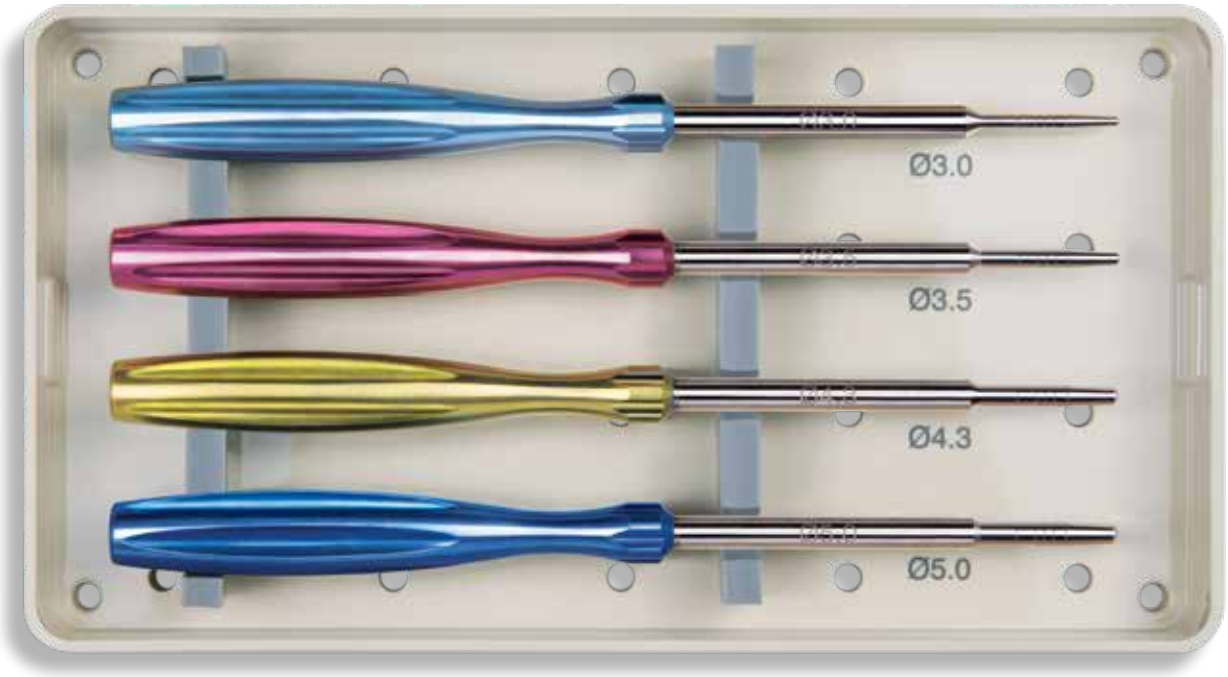
Screw Tap
Ø7.0 mm



INSTRUMENTATION

Osteotome Kit

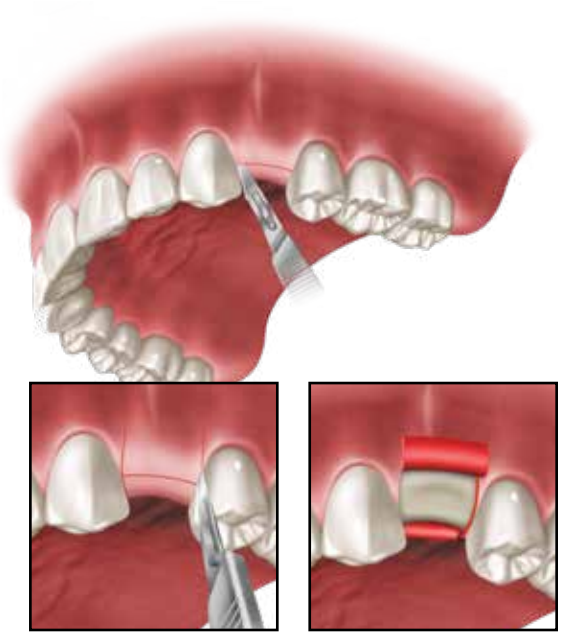
The osteotome kit allows the clinician to easily organize, store, and transport Hahn Tapered Implant Osteotomes. Intended for use in the placement of Hahn Tapered Implants in areas of soft bone, the osteotomes are designed to compress and condense available bone during osteotomy preparation. The result is a denser osseous surface to facilitate implant placement. Each osteotome is diameter-specific, to match the diameter of the prescribed implant.



⚠ NOTE: Hahn™ Tapered Implant Osteotomes not sold individually.

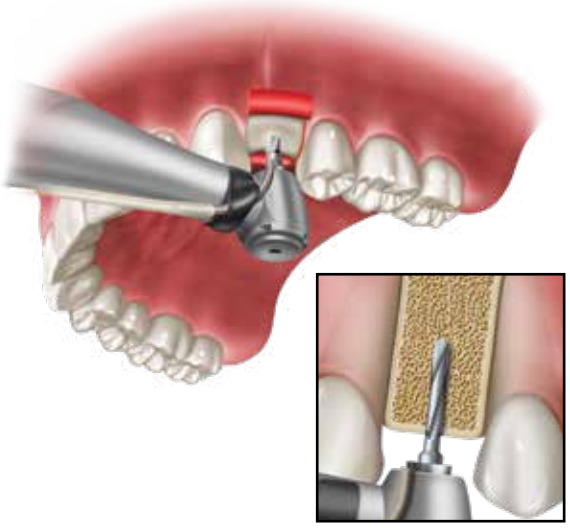
■ Soft Tissue Reflection

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.



■ General Drilling Guidelines

- A speed of 800–1200 RPM is recommended when using the Twist Drills or Shaping Drills.
- Screw Tap speed should be no greater than 25 RPM.
- All drilling and tapping procedures should be performed using copious, sterile irrigation.
- Do not apply lateral pressure during drilling and tapping procedures.
- Drill the osteotomy using light pressure along the long axis of the osteotomy.



■ Osteotomy 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.

Twist Drill
Ø1.5 mm

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.

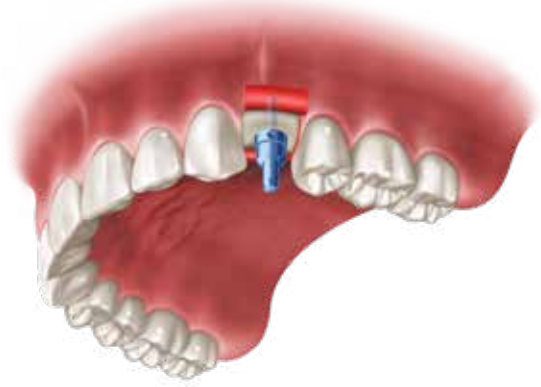
Parallel Pin
Ø3.0 mm

Parallel Pin
Ø3.5 mm

Parallel Pin
Ø4.3 mm

Parallel Pin
Ø5.0 mm

Parallel Pin
Ø7.0 mm

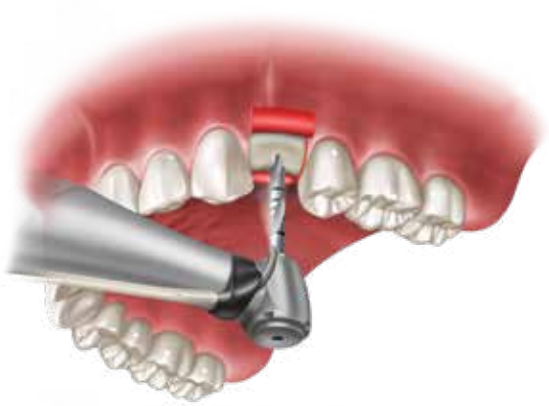


STANDARD SURGICAL PROTOCOL

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).

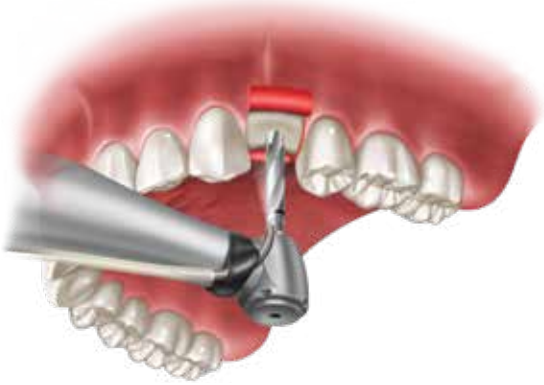
Twist Drill
Ø2.4/1.5 mm



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.

Twist Drill
Ø2.8/2.4 mm



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)

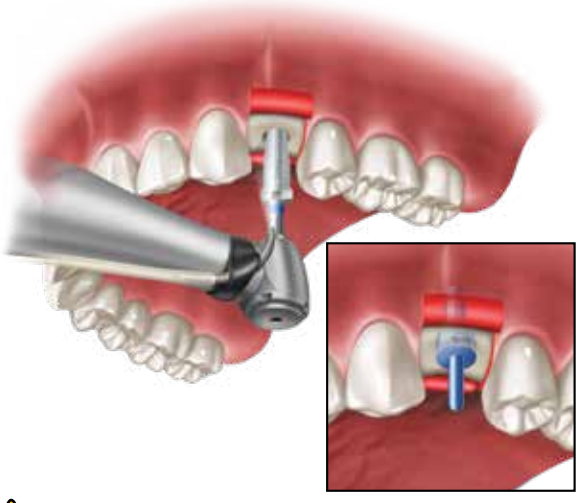
If placing a Hahn Tapered Implant that is 3.5 mm in diameter or greater, Shaping Drills are used sequentially to widen the osteotomy to the matching diameter. To avoid over-preparation, widening drill diameters should be used only as needed, and in proper succession. Each Shaping Drill is length-specific, 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 on the following page) with the goal of achieving high primary stability upon implant placement.

Shaping Drill Ø3.5 mm

Shaping Drill Ø4.3 mm

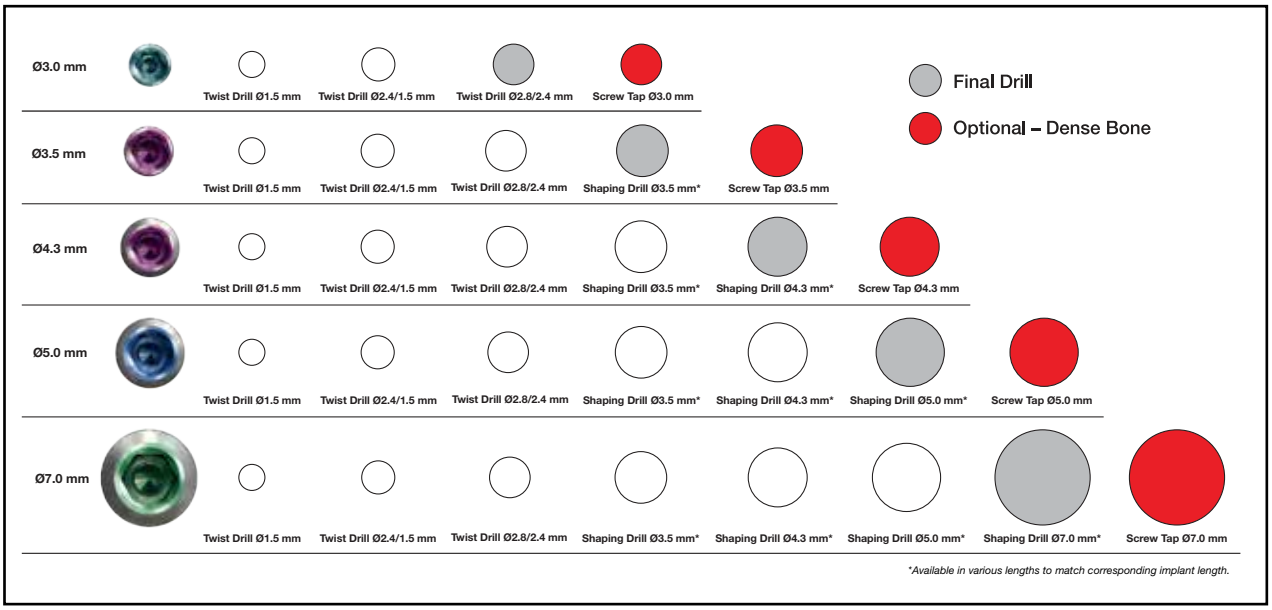
Shaping Drill Ø5.0 mm

Shaping Drill Ø7.0 mm



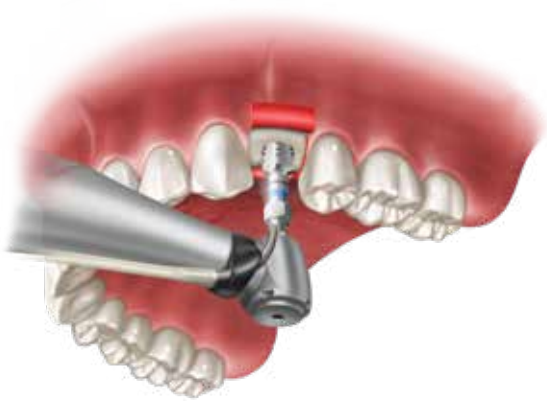
NOTE: If preparing multiple osteotomies, check parallelism as needed using the diameter-specific end of the parallel pin.

Drilling Sequence Chart

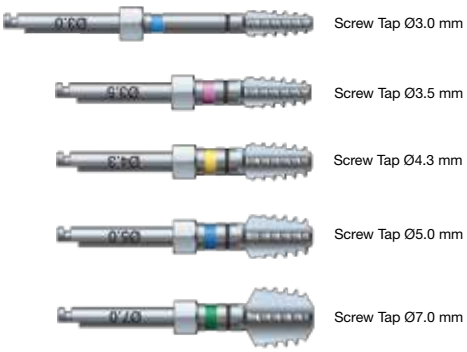


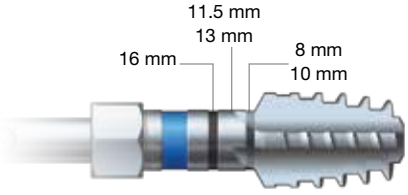
Step 5: (Optional) Screw Tap

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 over-tighten the tap in the site, as this might damage the threads prepared in the bone and result in less than optimal primary stability.

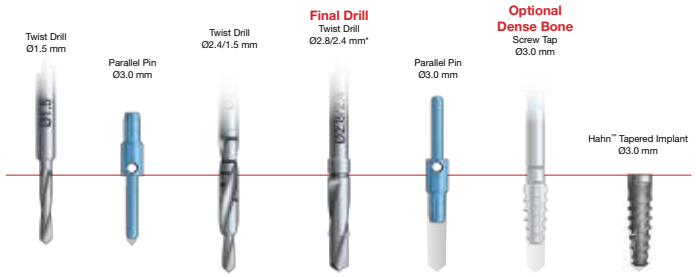




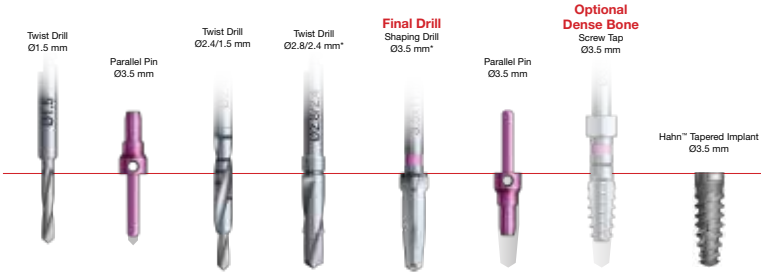
STANDARD SURGICAL PROTOCOL

■ Drilling Sequences

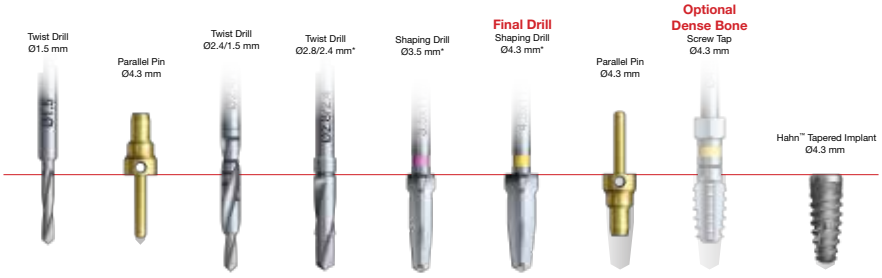
Hahn™ Tapered Implant Ø3.0 mm



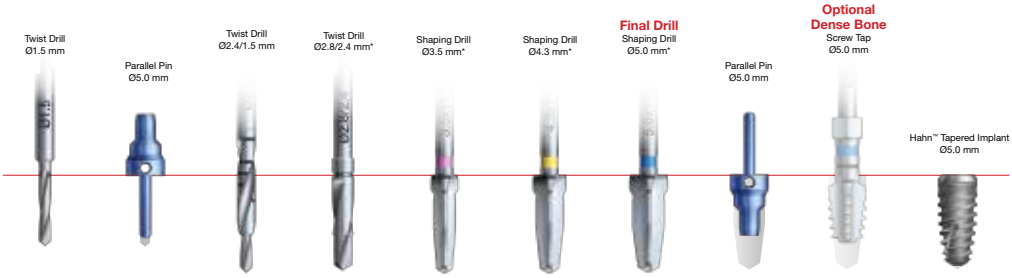
Hahn™ Tapered Implant Ø3.5 mm



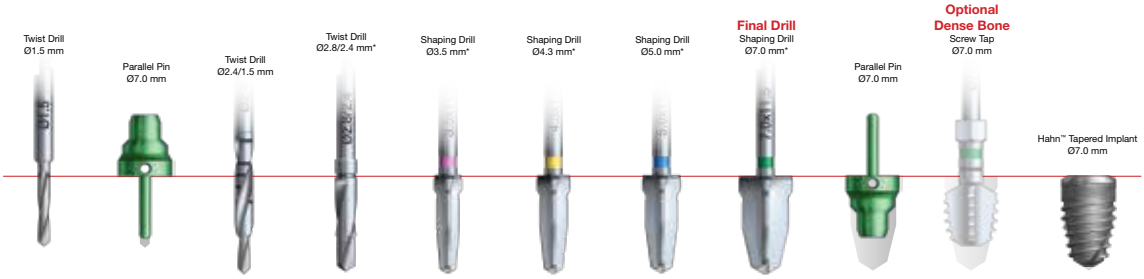
Hahn™ Tapered Implant Ø4.3 mm



Hahn™ Tapered Implant Ø5.0 mm



Hahn™ Tapered Implant Ø7.0 mm



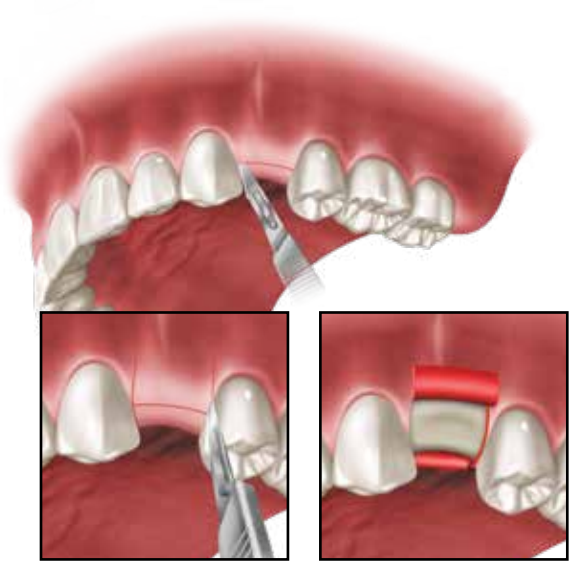
Ensure all surgical instruments are available prior to surgery.

**Available in various lengths.*

SOFT BONE SURGICAL PROTOCOL USING OSTEOTOMES

■ 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.



■ General Drilling Guidelines

- A speed of 800–1200 RPM is recommended when using the Twist Drills.
- All drilling procedures should be performed using copious, sterile irrigation.

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.

Twist Drill
Ø1.5 mm

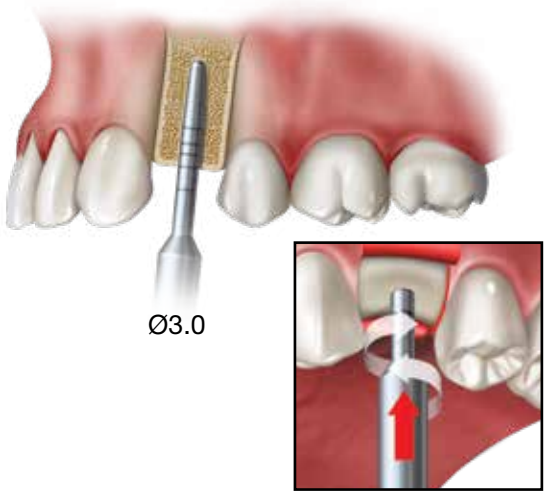
Step 2: Twist Drill Ø2.4/1.5 mm

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.

Twist Drill
Ø2.4/1.5 mm

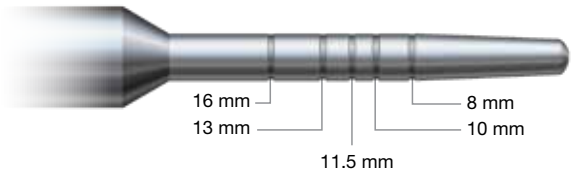
Step 3: Osteotome Ø3.0 mm

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.



Ø3.0

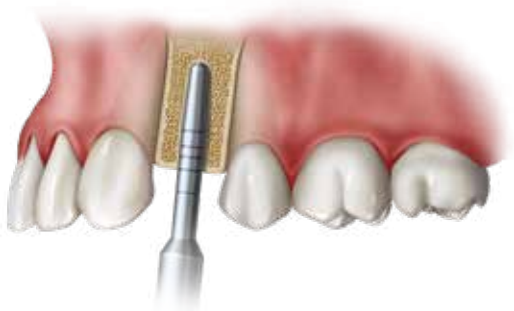
SOFT BONE SURGICAL PROTOCOL USING OSTEOTOMES



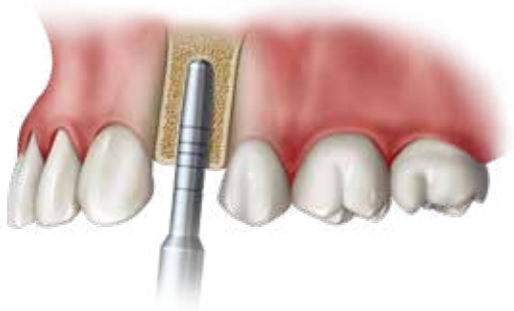
NOTE: If placing a Ø3.0 mm Hahn Tapered Implant, this should be the final diameter of osteotome used. Proceed to Implant Placement on page 22. If placing a larger-diameter Hahn Tapered Implant, proceed to *Step 4: Osteotome Ø3.5 – Ø5.0 (for Ø3.5 mm – Ø5.0 mm Implants).*

Step 4: Osteotome Ø3.5 – Ø5.0 (for Ø3.5 mm – Ø5.0 mm Implants)

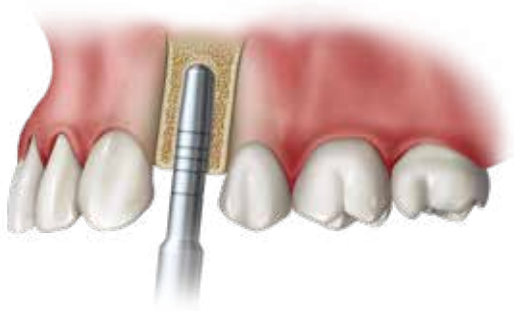
If placing a Hahn Tapered Implant that is 3.5 mm in diameter or greater, Osteotomes are used sequentially to widen the osteotomy to the matching diameter. To avoid over-preparation, widening Osteotome diameters should be used only as needed, and in proper succession. Each Osteotome is diameter-specific, 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.



Ø3.5

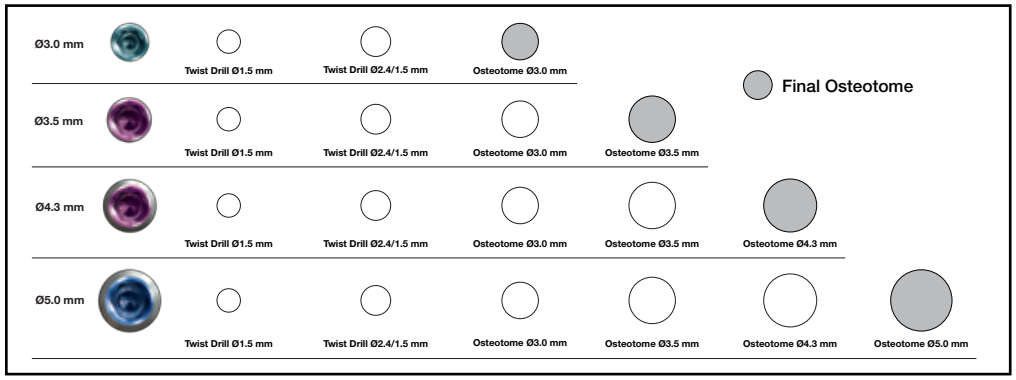


Ø4.3



Ø5.0

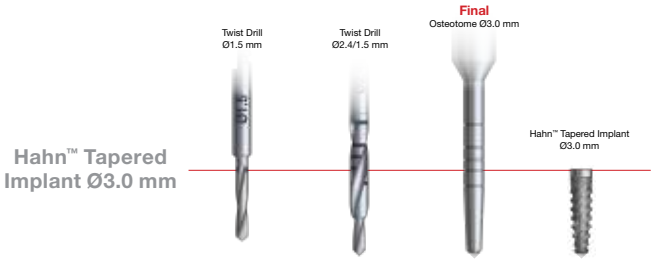
Osteotome Sequence Chart

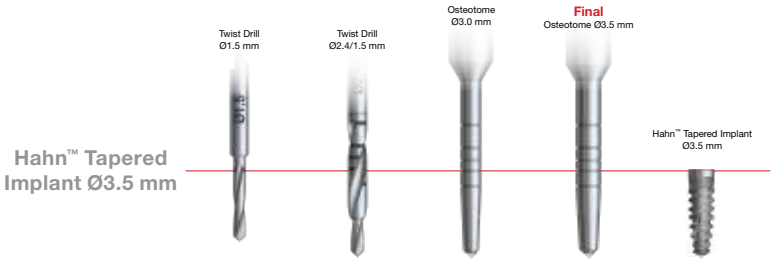


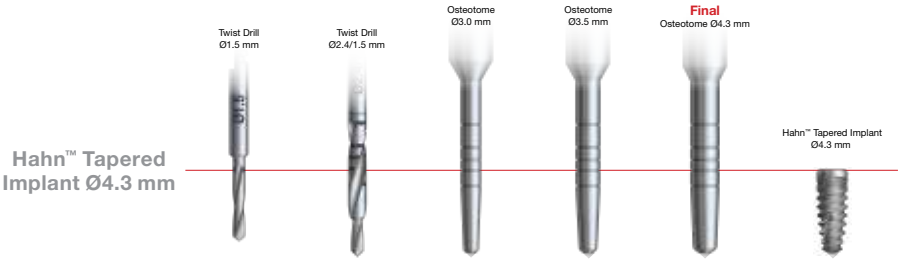
Do not use any drill or osteotome that exceeds the diameter or length of the prescribed implant.

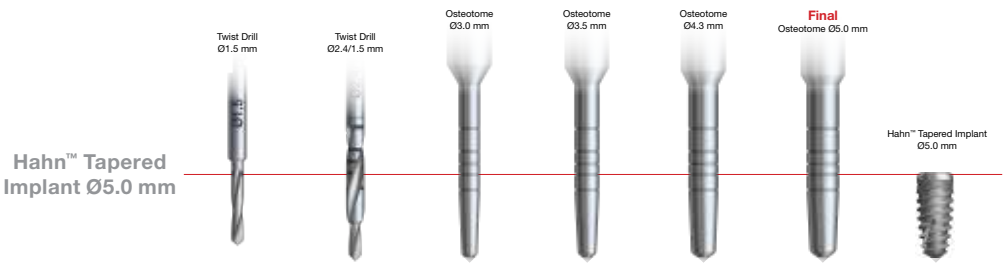
SOFT BONE SURGICAL PROTOCOL USING OSTEOTOMES

■ Preparation Sequences with Osteotomes









Ensure all surgical instruments are available prior to surgery.

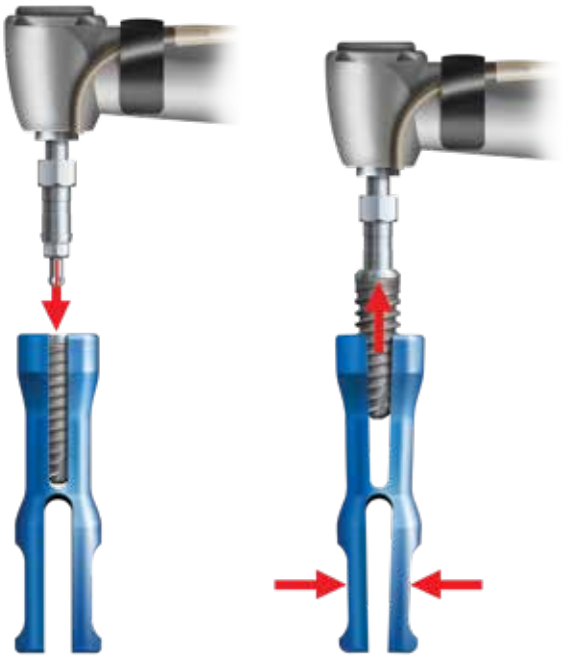
IMPLANT PLACEMENT

■ Implant Placement

Step 1: Implant Selection

Remove the titanium implant holder from its packaging and place it onto a sterile field.

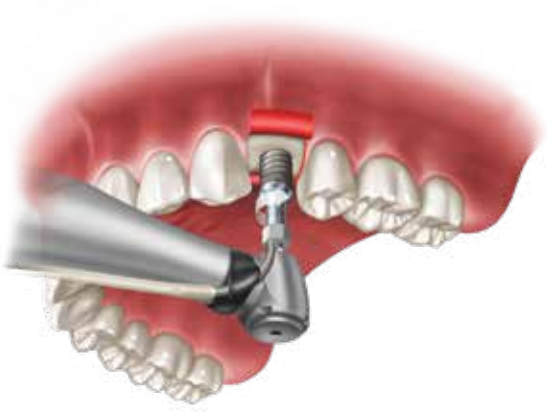
⚠ NOTE: The plastic tray contains a Cover Screw, for use when following a two-stage surgical protocol. Do not discard the Cover Screw upon removal of the implant.



Step 2: Initial Placement

Use slight finger pressure to pinch the occlusal end of the implant in its holder while inserting the appropriate Implant Driver. Gently rotate implant and holder, allowing the driver to engage the implant connection. With the driver securely attached to the implant, 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.

⚠ NOTE: Apply pressure to ensure the driver is fully engaged with the implant prior to disengaging the titanium holder.



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.

Adjustable Torque Wrench

Surgical Adaptor

Implant Driver Ø3.0 mm Long

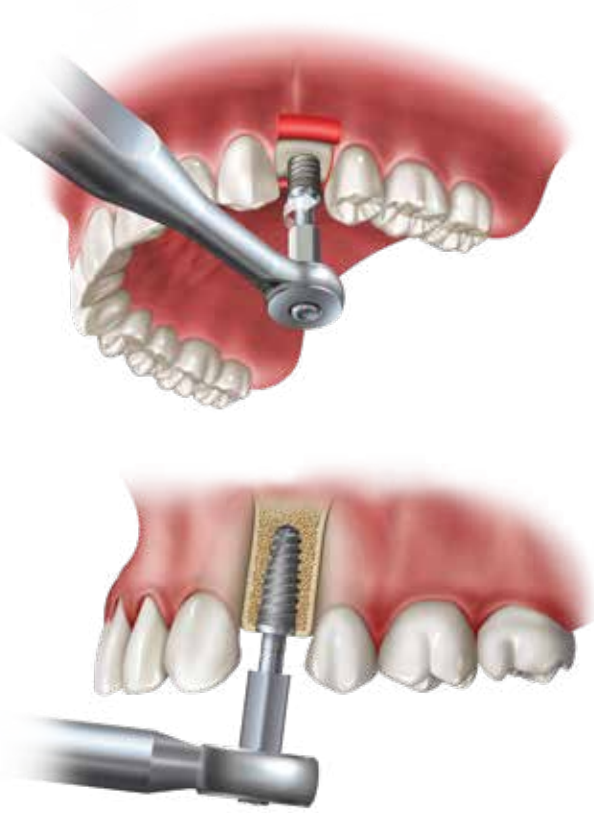
Implant Driver Ø3.5/4.3 mm Short

Implant Driver Ø3.5/4.3 mm Long

Implant Driver Ø5.0 mm Short

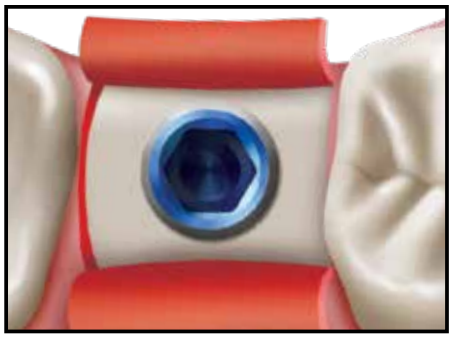
Implant Driver Ø5.0 mm Long

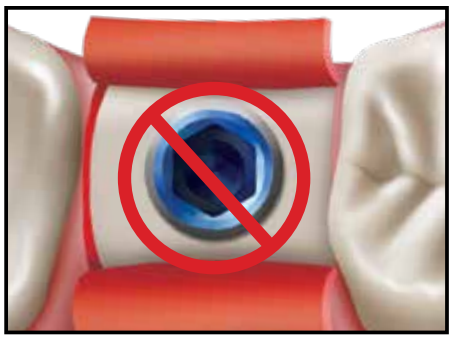
Implant Driver Ø7.0 mm Short



■ 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

■ 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.

Healing Abutment

Option 2: Cover Screw

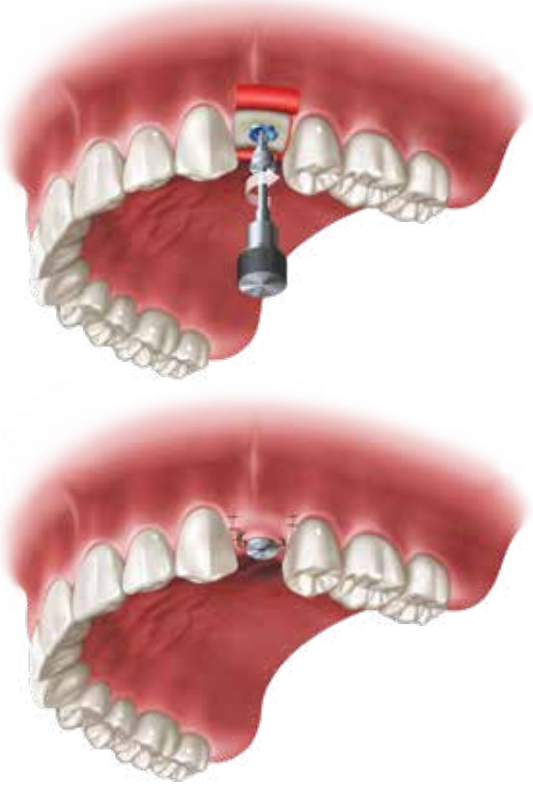
If observing a two-stage surgical protocol, thread the Cover Screw into place atop the implant. Hand-tighten with the appropriate Prosthetic Driver.

Cover Screw

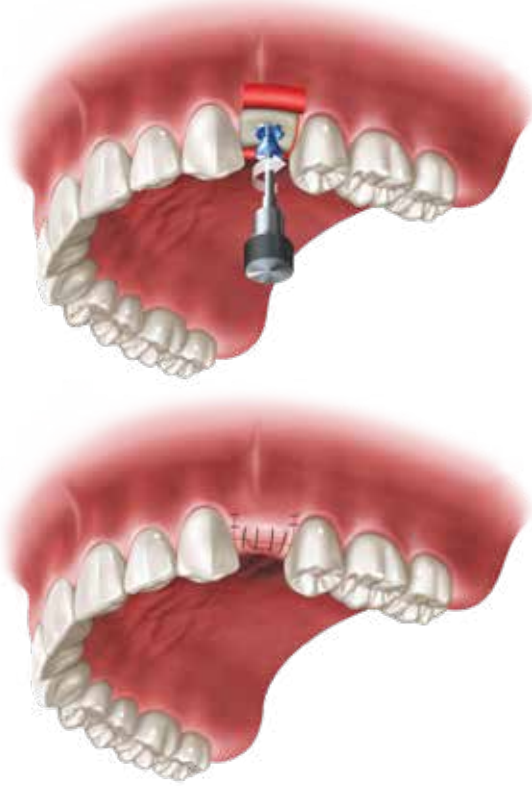
■ Closure and Suturing

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.

Single-Stage Surgical Protocol

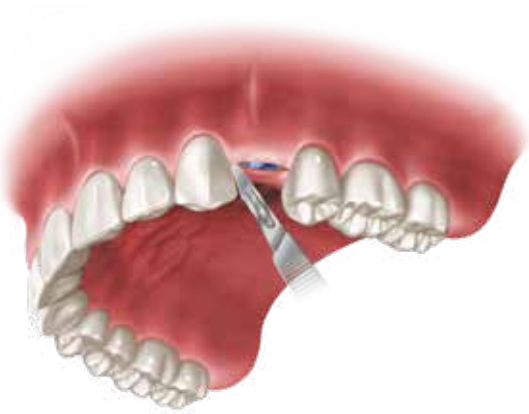


Two-Stage Surgical Protocol

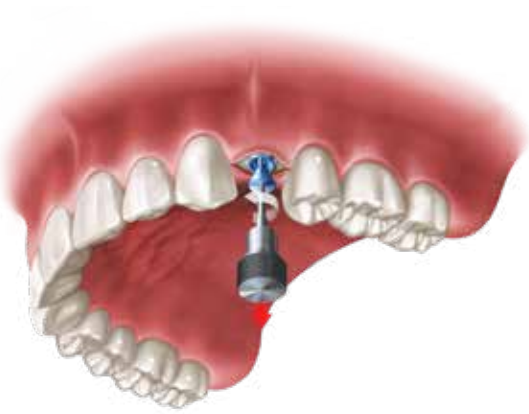


SECOND-STAGE UNCOVERY (TWO-STAGE SURGICAL PROTOCOL)

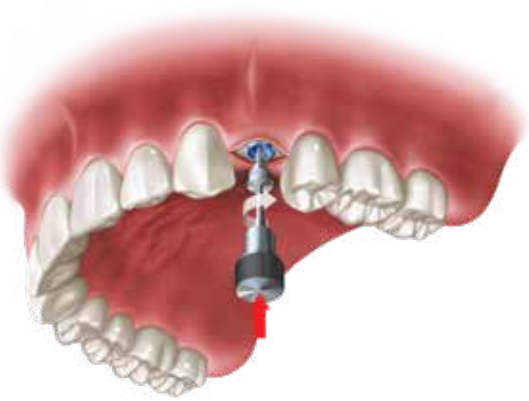
Following the appropriate healing period, make a small incision in the gingiva over the implant site to expose the Cover Screw. Using the Prosthetic Driver, remove the Cover Screw and place a Healing Abutment or Temporary Abutment of the appropriate height and diameter.



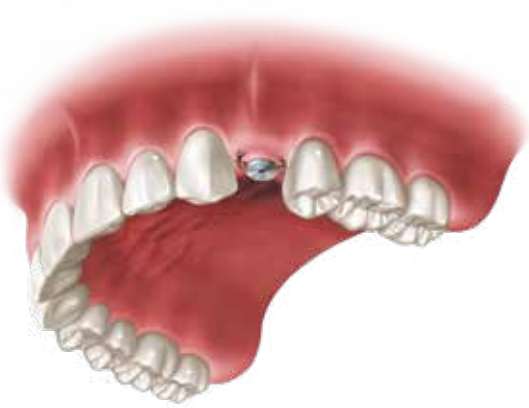
Step 1: Expose the Cover Screw



Step 2: Remove the Cover Screw



Step 3: Place Healing Abutment



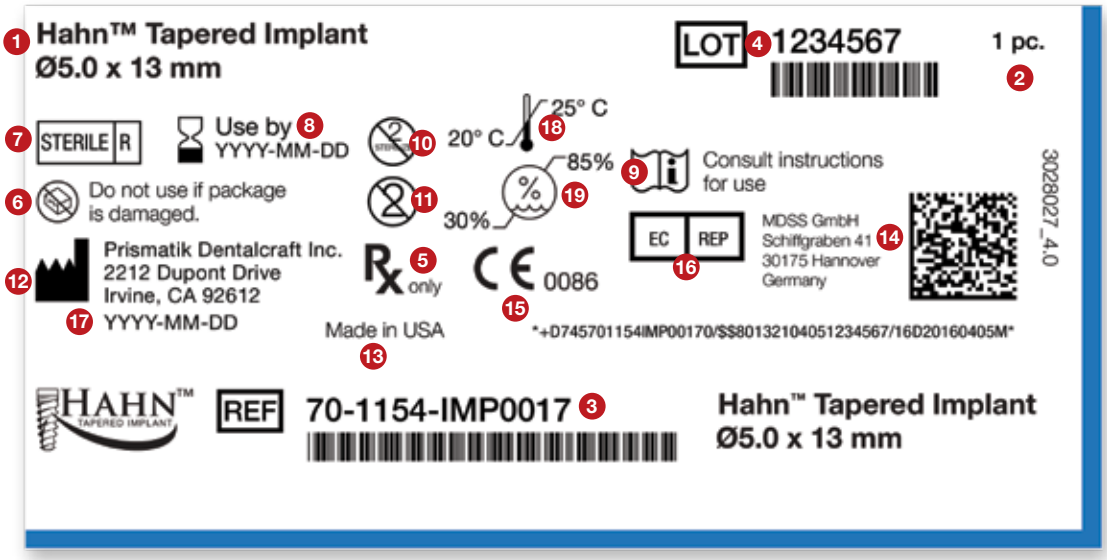
Step 4: Close and suture

IMPLANT PACKAGING

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. 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.

Explanation of Label Codes:

1. Official product description
2. Quantity
3. Reference number (product code)
4. Lot number
5. By prescription only
6. Do not use if tampered with
7. Gamma sterilization symbol
8. Expiration date
9. Consult Instructions for Use (IFU)
10. Do not re-sterilize
11. For single-use only
12. Manufacturer
13. Country of origin
14. FDA Unique Device Identification (UDI)
15. Notified body number
16. European Authorized Representative
17. Date of manufacture
18. Store at room temperature
19. Store at 30% to 85% relative humidity



Product Return Policy

Products may be returned at the customer's expense for credit within 30 days of invoice date. All returned products must meet the following conditions:

- A copy of the original invoice must accompany the products.
- Products must be packaged to arrive at the seller's facility undamaged.
- Discontinued, obsolete, expired, damaged, or opened items will not be accepted for return.
- Amount credited will be based on invoice price, less 15 percent for restocking fee.
- Shipping charges are the responsibility of the customer and will not be credited.

Product & Pricing Changes

Because products and equipment are continually undergoing refinement in design and manufacturing methods, we reserve the right to improve, modify, or discontinue products and equipment or change pricing at any time without incurring any obligation and without prior notice.

Warranty

Limited Warranty—Prismatik Dentalcraft, Inc.

Prismatik Dentalcraft, Inc. ("Prismatik"), is the manufacturer of dental products (the "product"), including Hahn™ Tapered Implants ("implants"). For a period from the original purchase date of seven (7) years for implants and six (6) months for ceramic blanks and any other product ("the warranty period"), Prismatik will at its option replace or refund the purchase price of any product, to the original purchaser ("user"), that is returned due to defects in material and manufacture.

NO GUARANTEE OR WARRANTY IS IMPLIED OTHER THAN EXPRESSLY STATED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Prismatik shall not be liable for any incidental or consequential damages, whether foreseeable or not, caused by defects in the product or dental devices produced using said product. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, user's exclusive remedy and Prismatik's sole obligation shall be replacement or refund of the purchase price of the product. For replacement or refund under this warranty, the original purchaser shall send the product at its own expense, postage prepaid, to the seller.

HAHN™
TAPERED IMPLANT

Designed & Manufactured in the U.S.A.
by

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DENTALCRAFT, INC.

(A wholly owned subsidiary of Glidewell Laboratories)
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