

Surgical Manual



glidewell-ht.com

The Glidewell HT™ Implant System

The Glidewell HT™ Implant System, formerly known as the Hahn™ Tapered Implant System, is a premium implant solution that simplifies surgery and provides you with unrivaled support from the most experienced dental lab in the U.S. With a 99.2% success rate backed by an implant-to-crown lifetime warranty, the Glidewell HT Implant promotes success in implant dentistry while lowering your surgical and restorative costs.

- Simple and efficient Easy to use, with a streamlined surgical protocol and length-specific drills
- Cut your costs Priced at a fraction of comparable implant systems and saves you 20% on your lab bill when you restore your implant case with Glidewell*
- Clinically proven 99.2% success rate and 0.2 mm mean bone loss¹
- High primary stability Deep, sharp threads maximize initial stability and engage bone where directed

The **Glidewell HT Implant System** is engineered to help dentists provide implant treatment for more patients through **ease of use**, **reduced costs** and our **unwavering commitment to support your practice** — from implant placement to final restoration.

Jim Glidewell, CDT Founder and President of Glidewell



About the Manufacturer

Prismatik Dentalcraft was established in 2006 and includes a carefully assembled team of experts with a proven track record in the design, engineering, and manufacture of dental implants. Bolstered by 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.



Vertical Integration

Our ownership of the entire manufacturing process behind our implant products ensures quality and helps reduce costs for our customers.



State-of-the-Art Equipment

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



Made in the USA

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

*Discount offered only at Glidewell and cannot be combined with any other special offers. Case must include an implant-level or multi-unit abutment-level impression with a Glidewell HT transfer coping or a digital scan with a Glidewell HT scan body. Impressions over cementable abutments are not eligible for discount.

1. Kerr M, Allen B, Park N. Clinical and radiographic evaluation of tapered implants with an aggressive reverse buttress thread and crestal microthreads: a retrospective study. For the full report, visit glidewell.com/ht-2-year.

Surgical Considerations

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Scope

This manual outlines the appropriate procedures for placing Glidewell HT™ 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. Glidewell HT 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

Glidewell HT 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

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

MRI

The Glidewell HT 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 Glidewell HT Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Sterility

Glidewell HT 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

Glidewell HT Implants must be stored in a dry location at room temperature, in their original packaging. Glidewell HT 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.

Implant Selection

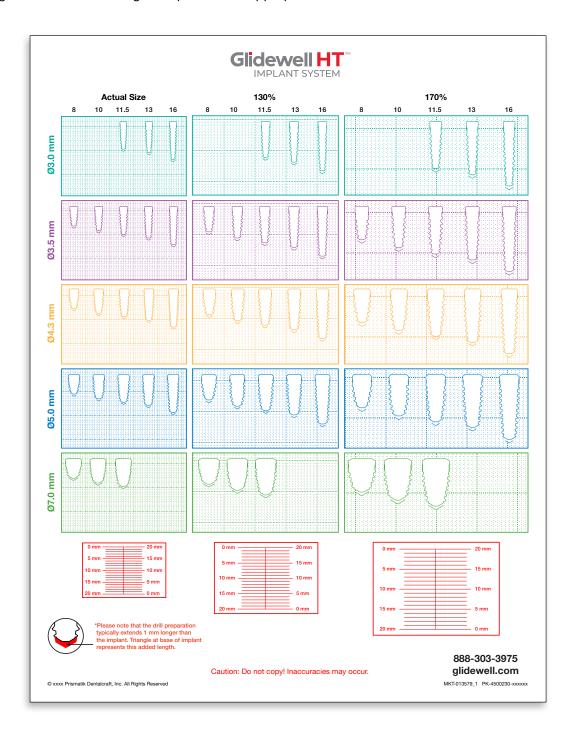
Glidewell HT Implants are available in five diameters (3.0 mm, 3.5 mm, 4.3 mm, 5.0 mm, 7.0 mm) and five lengths (8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm). The narrowest implants (3.0 mm) are intended for anterior applications only, and therefore limited to longer lengths. The widest implants (7.0 mm) are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

The Glidewell HT 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
③				
	Ø3.5 x 8 mm 70-1189-IMP0004	Ø4.3 x 8 mm 70-1189-IMP0009	Ø5.0 x 8 mm	Ø7.0 x 8 mm 70-1189-IMP0019
	Ø3.5 x 10 mm	Ø4.3 x 10 mm	Ø5.0 x 10 mm	Ø7.0 x 10 mm 70-1189-IMP0020
Ø3.0 x 11.5 mm 70-1189-IMP0001	Ø3.5 x 11.5 mm 70-1189-IMP0006	Ø4.3 x 11.5 mm	Ø5.0 x 11.5 mm	Ø7.0 x 11.5 mm 70-1189-IMP0021
Ø3.0 x 13 mm 70-1189-IMP0002	Ø3.5 x 13 mm	Ø4.3 x 13 mm 70-1189-IMP0012	Ø5.0 x 13 mm	
Ø3.0 x 16 mm 70-1189-IMP0003	Ø3.5 x 16 mm 70-1189-IMP0008	Ø4.3 x 16 mm 70-1189-IMP0013	Ø5.0 x 16 mm 70-1189-IMP0018	

Radiographic Template

A radiographic template is available to clinicians who place Glidewell HT 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.

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

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

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.

- *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:

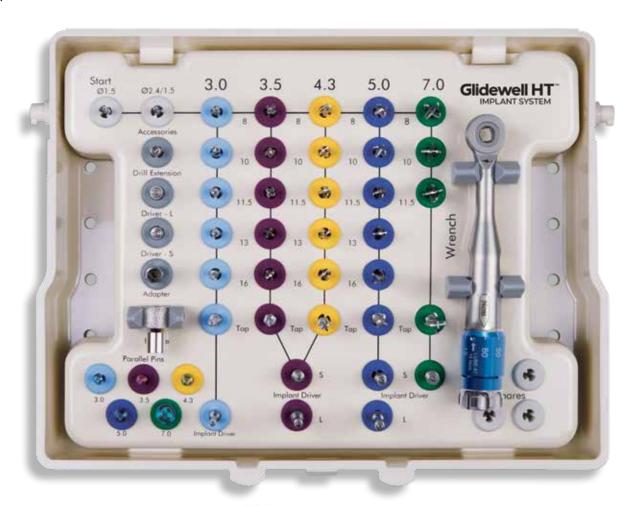
• Sterilization: Gravity-fed sterilizers: Autoclave in sterilization pouch for 15 minutes at 132°C (270°F). Allow sterilized components to dry for at least 30 minutes.

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.

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

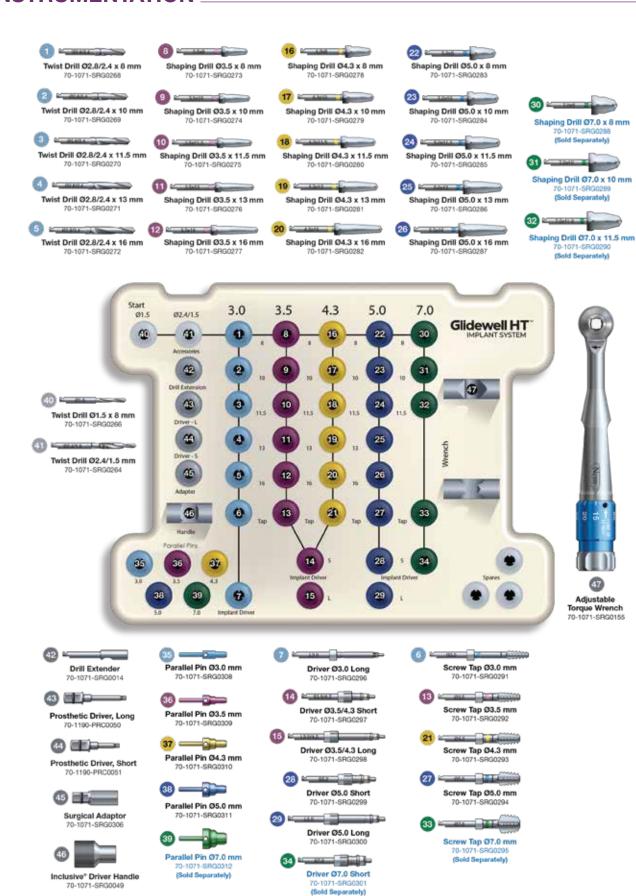
Surgical Kit

The surgical kit allows the clinician to easily organize, store, and transport the instrumentation components of the Glidewell HT 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 the Glidewell HT Implant.





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



Surgical Drills

The Glidewell HT 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.

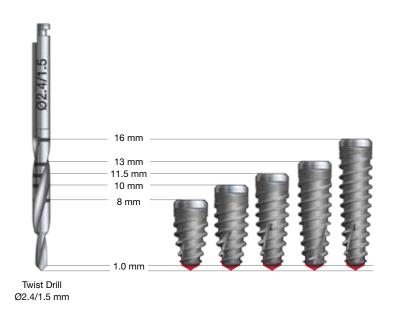


Each Shaping Drill is both diameter- and length-specific, to match the size of the prescribed implant.

Twist Drill 2.4/1.5 mm Depth Markings

While Glidewell HT 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.



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 Glidewell HT Implants in extremely dense bone, it may be necessary to utilize a threadforming 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.



STANDARD SURGICAL PROTOCOL

■ 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

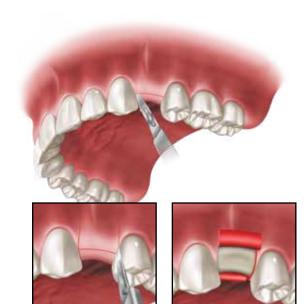
Step 1: Twist Drill Ø1.5 mm

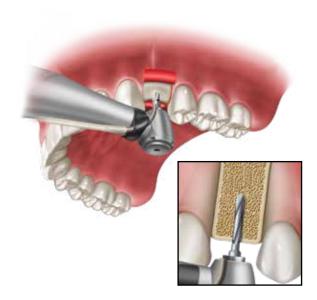
With copious irrigation, perforate the alveolar crest. Utilize a surgical guide, if necessary, as a reference for proper positioning.

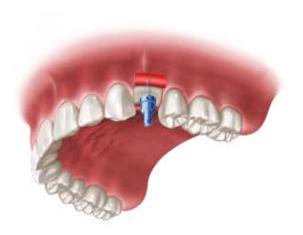


Check the orientation of the initial osteotomy using a Parallel Pin. If placing more than one implant and parallelism is desired, begin drilling the next site and align as the trajectory of the bone permits.









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).



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.

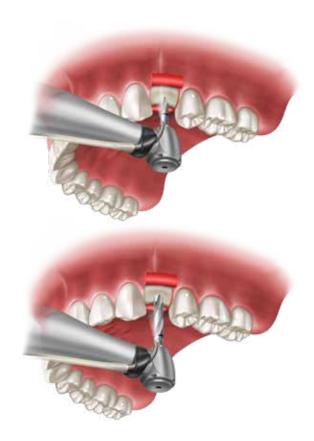


NOTE: If placing a 3.0 mm diameter Glidewell HT Implant, this should be the final diameter of drill used. If placing a larger-diameter Glidewell HT Implant, proceed to Step 4: Shaping Drills.

Step 4: Shaping Drills (for Ø3.5 mm – Ø7.0 mm Implants)

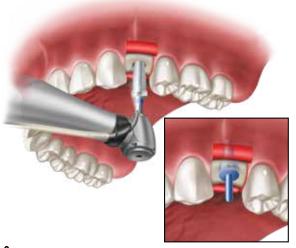
If placing a Glidewell HT Implant that is 3.5 mm in diameter or greater, Shaping Drills are used sequentially to widen the osteotomy to the matching diameter. To avoid over-preparation, widening drill diameters should be used only as needed, and in proper succession. Each Shaping Drill is length-specific, 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.





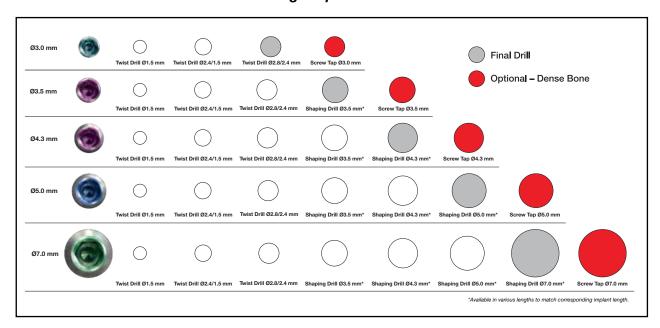






NOTE: If preparing multiple osteotomies, check parallelism as needed using the diameter-specific end of the parallel pin.

Drilling Sequence Chart

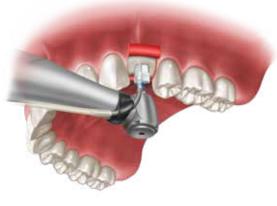


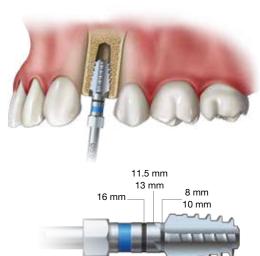
Step 5: (Optional) Screw Tap

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.



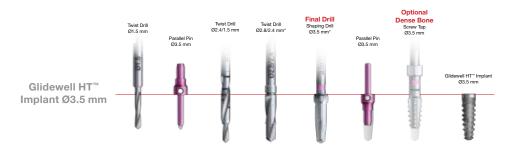


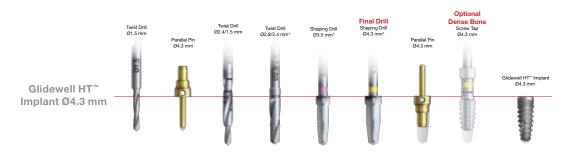


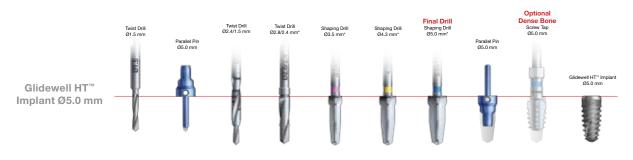
STANDARD SURGICAL PROTOCOL

■ Drilling Sequences











Ensure all surgical instruments are available prior to surgery.

*Available in various lengths.

■ 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.

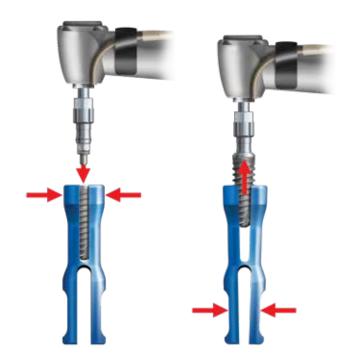
Step 3: Advancement and Final Seating

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.



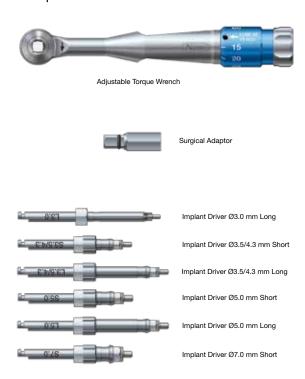




IMPLANT PLACEMENT

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.

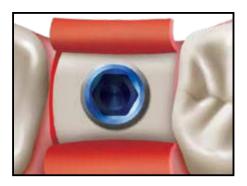




The implant should be rotated at the time of placement to ensure optimal positioning of the internal hex connection. This will allow the restoring clinician to take full advantage of the anatomical abutment contours and minimize the need for abutment preparation. Adjust the final position of the implant 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.



Option 2: Cover Screw

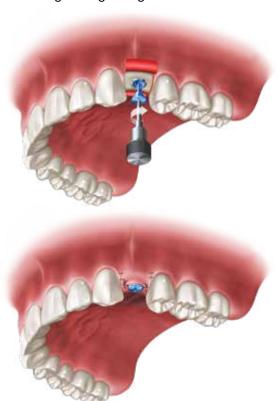
If observing a two-stage surgical protocol, thread the Cover Screw into place atop the implant. Hand-tighten with the appropriate Prosthetic Driver.



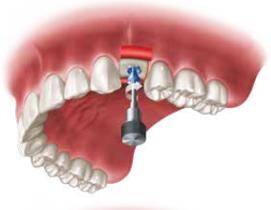
■ Closure and Suturing

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.

Single-Stage Surgical Protocol



Two-Stage Surgical Protocol





SECOND-STAGE UNCOVERY (TWO-STAGE SURGICAL PROTOCOL)

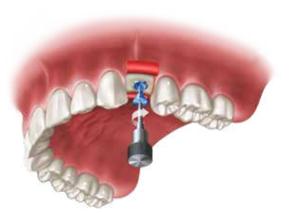
Following the appropriate healing period, make a small incision in the gingiva over the implant site to expose the Cover Screw. Using the Prosthetic Driver, remove the Cover Screw and place a Healing Abutment or Temporary Abutment of the appropriate height and diameter.



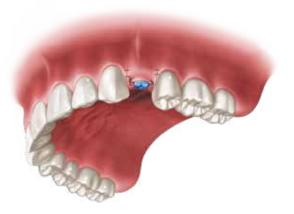
Step 1: Expose the Cover Screw



Step 2: Remove the Cover Screw



Step 3: Place Healing Abutment



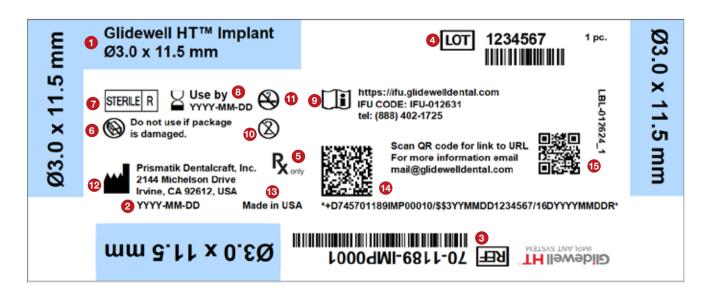
Step 4: Close and suture

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Explanation of Label Codes:

- 1. Official product description
- 2. Date of Manufacture (YYYY-MM-DD)
- 3. Catalog Number
- 4. Lot/Batch Number
- 5. By prescription only
- 6. Do Not Use if Package is Damaged
- 7. Sterile with Gamma Radiation
- 8. Use-by Date
- 9. Consult Instructions for Use
- 10. Do not Re-use
- 11. Do not Resterilize
- 12. Manufacturer
- 13. Country of origin
- 14. Unique Device Identification (UDI)
- 15. QR code for IFU website





POLICIES AND WARRANTY

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 Glidewell HT[™] Implants ("implants"). Prismatik warranties the Glidewell HT Implant for the life of the patient originally receiving the implant from the date of placement, and for a period of 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.







2144 Michelson Drive • Irvine, CA 92612, USA

DENTALCRAFT, INC.

glidewell-ht.com