Glidewell HT™
IMPLANT SYSTEM

Surgical Manual

888-303-3975 | 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.[1]

- **Simple and efficient** — Easy to use, with a streamlined surgical protocol, length-specific drills, and new and improved surgical kits based on eight years of clinical feedback
- **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 loss[1]
- **High primary stability** — Deep, sharp threads maximize initial stability and engage bone where directed

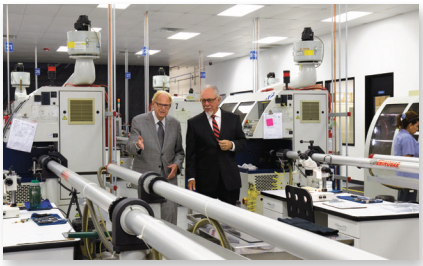
> *"The **Glidewell HT™ Implant System** is engineered to help dentists provide implant treatment for more patients through **ease of use, reduced costs** and our **unwavering commitment to support your practice** — from implant placement to final restoration."*
>
> **Jim Glidewell, CDT**
> *Founder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

CONTENTS

Glidewell HT™ Implant is a trademark of Prismatik Dentalcraft, Inc.

SURGICAL CONSIDERATIONS

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.

Compatibility

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

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.

SURGICAL CONSIDERATIONS

- 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

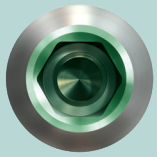
Glidewell HT Implants must be stored in a dry location at room temperature, in their original packaging. Glidewell HT Implants are packaged sterile. Do not handle implant surfaces directly. Users are advised to visually inspect packaging to ensure seals and contents are intact prior to use. Please refer to the individual product label for all relevant product information and cautions.

SURGICAL CONSIDERATIONS

Implant Selection

Glidewell HT Implants are available in six diameters (3.0 mm, 3.5 mm, 4.3 mm, 5.0 mm, 6.0 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.

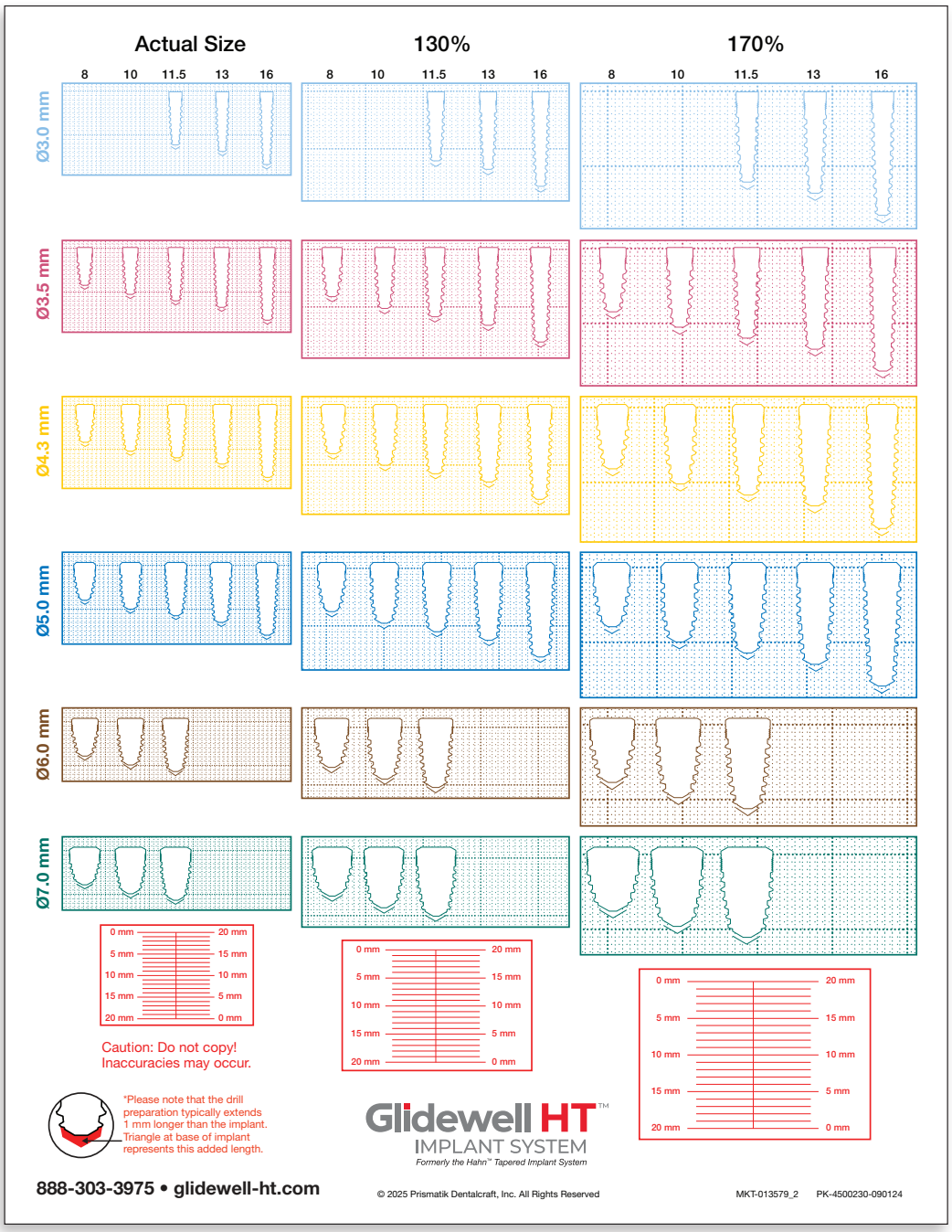
The Glidewell HT Implant System utilizes color-coding for easy component identification. Color-coding is featured consistently across system articles such as surgical tray, radiographic template, screw taps, and the implant carrier, with colors reflecting either the implant diameter or restorative platform,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

Ø3.0 mm	Ø3.5 mm	Ø4.3 mm	Ø5.0 mm	Ø6.0 mm	Ø7.0 mm
					
	 Ø3.5 x 8 mm 70-1189-IMP0004	 Ø4.3 x 8 mm 70-1189-IMP0009	 Ø5.0 x 8 mm 70-1189-IMP0014	 Ø6.0 x 8 mm 70-1189-IMP0022	 Ø7.0 x 8 mm 70-1189-IMP0019
	 Ø3.5 x 10 mm 70-1189-IMP0005	 Ø4.3 x 10 mm 70-1189-IMP0010	 Ø5.0 x 10 mm 70-1189-IMP0015	 Ø6.0 x 10 mm 70-1189-IMP0023	 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 70-1189-IMP0011	 Ø5.0 x 11.5 mm 70-1189-IMP0016	 Ø6.0 x 11.5 mm 70-1189-IMP0024	 Ø7.0 x 11.5 mm 70-1189-IMP0021
 Ø3.0 x 13 mm 70-1189-IMP0002	 Ø3.5 x 13 mm 70-1189-IMP0007	 Ø4.3 x 13 mm 70-1189-IMP0012	 Ø5.0 x 13 mm 70-1189-IMP0017		
 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		

SURGICAL CONSIDERATIONS

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.

INSTRUMENTATION

All instrumentation is manufactured in the U.S.A., Switzerland, Denmark or Germany. For specific country of origin, please refer to the individual product label. **Instruments may be used for up to five preparations. For best results, replace regularly.**

Cleaning and Sterilization Instructions:

Autoclavable Cassettes and surgical instruments are delivered non-sterile and must be cleaned and sterilized before the first use, after every use, and every time they are contaminated. Automated cleaning may not be effective. The manual cleaning process below is validated and recommended.

⚠ CAUTION:

- Use of non-sterile devices may lead to infection of tissue or infectious diseases.
- Use of a non-FDA-cleared sterilization pouch may result in non-sterile device even when the sterilization process is followed.
- If sterile barrier has been compromised, device must be re-sterilized prior to use.
- Never let surgical residues (blood, secretions, tissue residues) dry on the device before cleaning.

Point of Use:

1) After surgery, collect used instruments separately, and place them in a sterile water bath to prevent contamination from drying. Do not place soiled instruments in the tray.

2) Use an enzymatic spray or wipe to prevent contamination from drying on the Autoclavable Cassette.

Containment and Transportation:

Follow the clinical internal procedures for the transportation of contaminated devices. Perform cleaning as soon as possible. When longer delays are expected, immerse the devices in a sterile water bath to avoid drying of debris.

⚠ CAUTION: Delay in reprocessing must be kept to a minimum to avoid contaminants drying. Prolonged storage in a sterile water bath may result in degradation of the product.

Pre-Treatment:

1) Remove all instruments from the Autoclavable Cassette. Properly dispose of any damaged instruments.

2) Disassemble the Autoclavable Cassette to Lid, Tray, and Base.

Manual Cleaning for Autoclavable Cassette:

1) Rinse the lid, tray, and base of the Autoclavable Cassette under running, cold utility water for a minimum of 1 minute to remove excess contamination.

2) Prepare an enzymatic detergent per the manufacturer's recommendations using utility water.

3) Fully immerse all components of the Autoclavable Cassette in the prepared detergent bath and allow them to soak for minimum duration recommended by the manufacturer.

INSTRUMENTATION

4) After the soak, but while still immersed, use a clean, soft-bristled brush to brush all components of the Autoclavable Cassette to remove visible soil. Use a soft bristled lumen/tube brush to remove visible soil from the holes of the Autoclavable Cassette, as needed.

NOTE: Ensure to brush all hard-to-reach areas, such as the parts between the grommets. Remove the grommet if visible soil is present between the grommet and the tray interface by pushing the grommets up from the bottom. For offset grommets, push down from the top.

5) Remove all components of the Autoclavable Cassette from the prepared detergent bath and rinse them under running Critical water for a minimum of 1 minute to remove detergent residuals.

6) Dry the Autoclavable Cassette and components using lint-free cloths and/or filtered pressurized air.

7) Inspect the Autoclavable Cassette and components for visible contamination. Repeat steps 1 through 6 if contamination is observed.

Manual Cleaning for Instruments:

1) If present, special Instructions for Torque Wrench: Disassemble and clean the Torque Wrench as per manufacturer's instructions for use.

2) Rinse gross debris for a minimum of thirty (30) seconds under running cold utility water.

3) While completely submerged, brush the exterior of device with a soft bristled brush to remove visible debris for a minimum of 20 seconds. If applicable, clean the interior lumina of instrument with lumen/pipe brushes.

- Flush the inner surfaces, lumina, and cavities (where applicable) with 20 ml cold utility water using an irrigation needle connected to a disposable syringe.
- While completely submerged, brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized lumen/pipe brush for a minimum of 20 seconds until all visible soil is removed.

4) Inspect instruments visually and check for cleanliness, and for visible damage and/or wear. Discard damaged or worn instrument. If any remaining bone fragments, visible soil, or residual debris remain repeat the scrubbing and rinsing procedure as necessary.

5) Prepare an enzymatic solution for ultrasonic cleaner per the manufacturer's recommendations.

6) Place instruments in a single layer into the ultrasonic bath. Make sure the instruments are completely submerged and do not touch one another. Turn on ultrasonic bath for five (5) minutes. Note: process Titanium instruments separately from Stainless Steel instruments.

7) Remove the device and thoroughly rinse all surfaces of device with tepid running critical water for a minimum of ten (10) seconds to remove all cleaning agent.

8) Flush the inner surfaces, lumina, and cavities (where applicable) with 20 ml of tepid critical water using a new irrigation needle connected to a new disposable syringe.

9) Dry instrument using lint-free cloths and/or filtered pressurized air.

10) If the instrument is still dirty, repeat the cleaning steps 1 through 9 above.

INSTRUMENTATION

Sterilization:

1) Reassemble the Autoclavable Cassette. Place all instruments in the designated slots in the Autoclavable Cassette; replace any missing or damaged instruments. Do not place any additional instruments in the Autoclavable Cassette. Ensure instruments and Autoclavable Cassette are thoroughly dry before placing into sterilization pouch.
2) Place the Autoclavable Cassette in a 510(k) cleared sterilization pouch. Ensure pouch is properly sealed before placing into autoclave. Ensure that the pouch is orientated so that the see-through side of the pouch is on the top side of the Autoclavable Cassette, and the opaque side of the pouch is on the bottom of the Autoclavable Cassette.
3) Do not stack Autoclavable Cassettes during sterilization.
4) Sterilization Parameters:

Sterilizer Type:	Pre-Vacuum
Temperature:	132°C
Pulses:	4
Fully Cycle Exposure Time:	4 minutes
Dry Time:	30 minutes

⚠ CAUTION:

- **Failure to completely dry the Autoclavable Cassette and instruments during autoclaving can lead to moisture retention, causing discoloration, oxidation, and corrosion.**
- **This process has been validated. Any deviation from these instructions may result in potential adverse effects.**

Storage

The device should be stored in a dry place at room temperature.

Disposal of Material:

Disposal should be handled in an environmentally sustainable manner according to local regulations.

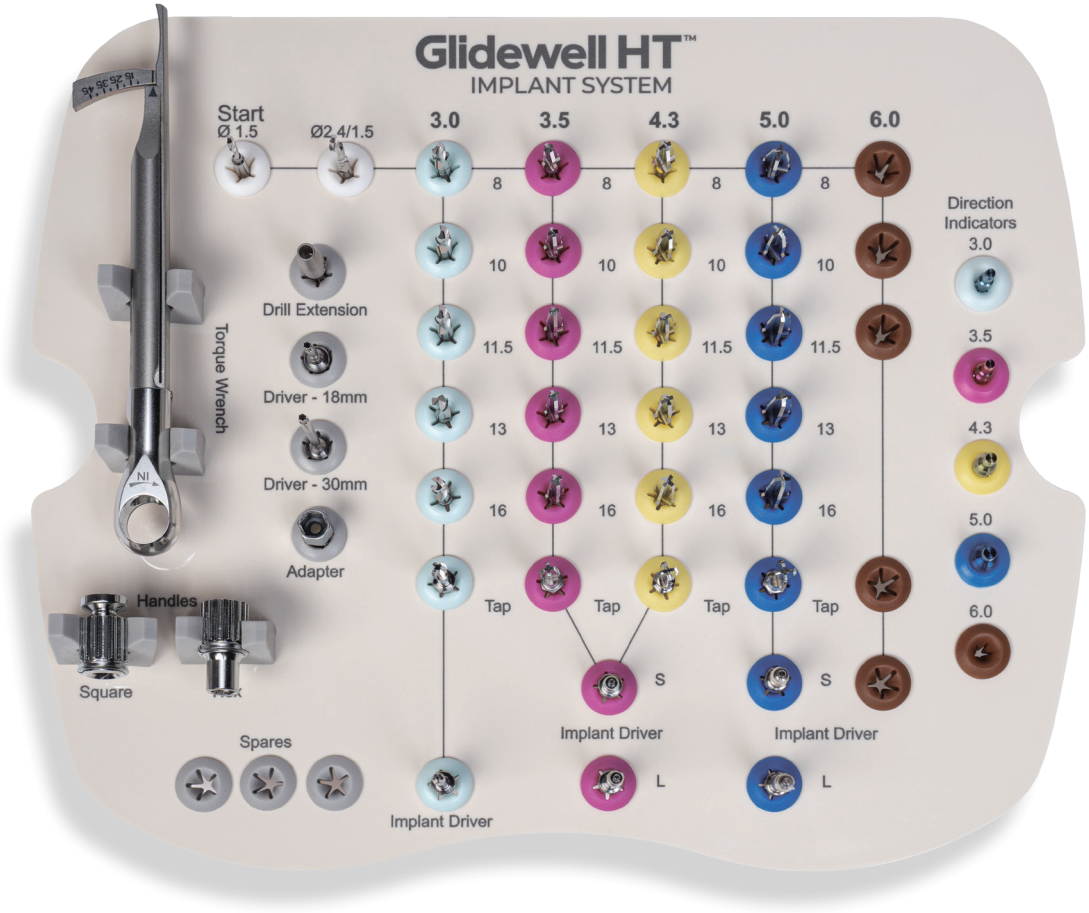
Life Cycle:

The Autoclavable Cassette has been validated for up to 100 cycles of use with reprocessing (one use equals one surgical or clinical procedure), provided the recommended conditions of use are followed. Instruments may be used for up to five preparations. The health professional should always assess the product's condition before and after each use regardless of the number of times the device has been used. Do not use the product if damage, deformation, or cracking is observed.

INSTRUMENTATION

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 coding indicates the corresponding diameter of the Glidewell HT Implant, and each drill includes laser etching that indicates the diameter and length.



NOTE: Ø6.0 mm and Ø7.0 mm instruments are sold separately. For a detailed product listing, please refer to the *Glidewell HT Implant System Product Catalog, visit glidewelldirect.com,* or contact a sales representative.

INSTRUMENTATION

1 **Twist Drill Ø1.5 x 8 mm**
70-1071-SRG0266

2 **Twist Drill Ø2.4/1.5 mm**
70-1071-SRG0264

3 **Twist Drill Ø2.8/2.4 x 8 mm**
70-1071-SRG0268

4 **Twist Drill Ø2.8/2.4 x 10 mm**
70-1071-SRG0269

5 **Twist Drill Ø2.8/2.4 x 11.5 mm**
70-1071-SRG0270

6 **Twist Drill Ø2.8/2.4 x 13 mm**
70-1071-SRG0271

7 **Twist Drill Ø2.8/2.4 x 16 mm**
70-1071-SRG0272

8 **Shaping Drill Ø3.5 x 8 mm**
70-1071-SRG0273

9 **Shaping Drill Ø3.5 x 10 mm**
70-1071-SRG0274

10 **Shaping Drill Ø3.5 x 11.5 mm**
70-1071-SRG0275

11 **Shaping Drill Ø3.5 x 13 mm**
70-1071-SRG0276

12 **Shaping Drill Ø3.5 x 16 mm**
70-1071-SRG0277

13 **Shaping Drill Ø4.3 x 8 mm**
70-1071-SRG0278

14 **Shaping Drill Ø4.3 x 10 mm**
70-1071-SRG0279

15 **Shaping Drill Ø4.3 x 11.5 mm**
70-1071-SRG0280

16 **Shaping Drill Ø4.3 x 13 mm**
70-1071-SRG0281

27 **Shaping Drill Ø4.3 x 16 mm**
70-1071-SRG0282

18 **Shaping Drill Ø5.0 x 8 mm**
70-1071-SRG0283

19 **Shaping Drill Ø5.0 x 10 mm**
70-1071-SRG0284

20 **Shaping Drill Ø5.0 x 11.5 mm**
70-1071-SRG0285

21 **Shaping Drill Ø5.0 x 13 mm**
70-1071-SRG0286

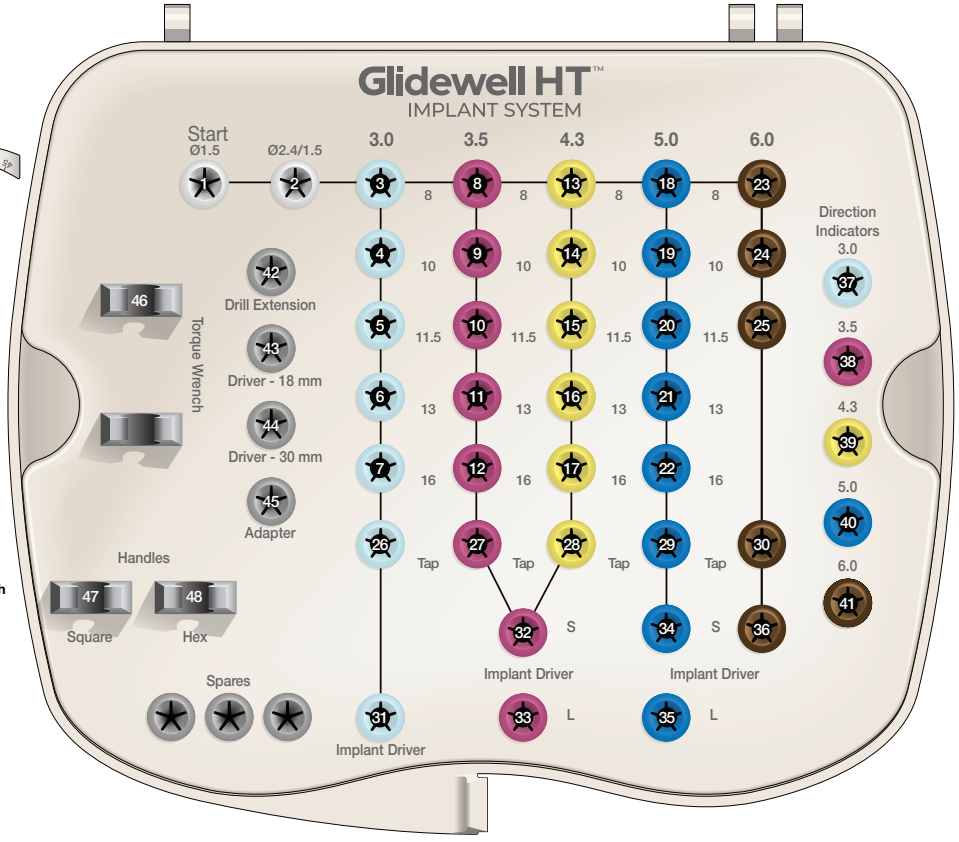
22 **Shaping Drill Ø5.0 x 16 mm**
70-1071-SRG0287

26 **Screw Tap Ø3.0 mm**
70-1071-SRG0291

27 **Screw Tap Ø3.5 mm**
70-1071-SRG0292

28 **Screw Tap Ø4.3 mm**
70-1071-SRG0293

29 **Screw Tap Ø5.0 mm**
70-1071-SRG0294



Torque Wrench
70-C35120

23 **Shaping Drill Ø6.0 x 8 mm**
70-1071-SRG0415
(Sold Separately)

24 **Shaping Drill Ø6.0 x 10 mm**
70-1071-SRG0416
(Sold Separately)

25 **Shaping Drill Ø6.0 x 11.5 mm**
70-1071-SRG0417
(Sold Separately)

30 **Screw Tap Ø6.0 mm**
70-1071-SRG0414
(Sold Separately)

Shaping Drill Ø7.0 x 8 mm
70-1071-SRG0288
(Sold Separately)

Shaping Drill Ø7.0 x 10 mm
70-1071-SRG0289
(Sold Separately)

Shaping Drill Ø7.0 x 11.5 mm
70-1071-SRG0290
(Sold Separately)

Screw Tap Ø7.0 mm
70-1071-SRG0295
(Sold Separately)

37 **Direction Indicator Ø3.0 mm**
70-1071-SRG0308

38 **Direction Indicator Ø3.5 mm**
70-1071-SRG0309

39 **Direction Indicator Ø4.3 mm**
70-1071-SRG0310

40 **Direction Indicator Ø5.0 mm**
70-1071-SRG0311

41 **Direction Indicator Ø6.0 mm**
70-1071-SRG0413
(Sold Separately)

Direction Indicator Ø7.0 mm
70-1071-SRG0312
(Sold Separately)

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

45 **Surgical Adaptor - Short**
70-1071-SRG0307

43 **Prosthetic Driver - 18 mm**
70-1190-PRC0054

47 **Driver Handle - Square**
70-C35120

31 **Driver Ø3.0 - Long**
70-1071-SRG0296

32 **Driver Ø3.5/4.3 - Short**
70-1071-SRG0297

34 **Driver Ø5.0 - Short**
70-1071-SRG0299

36 **Driver Ø6.0 - Short**
70-1071-SRG0419
(Sold Separately)

44 **Prosthetic Driver - 30 mm**
70-1190-PRC0056

48 **Driver Handle - Hex**
70-C35120

33 **Driver Ø3.5/4.3 - Long**
70-1071-SRG0298

35 **Driver Ø5.0 - Long**
70-1071-SRG0300

Driver Ø7.0 - Short
70-1071-SRG0301
(Sold Separately)

INSTRUMENTATION

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 five diameters of Shaping Drills (3.5 mm, 4.3 mm, 5.0 mm, 6.0 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.**

The first two diameters of Twist Drills (1.5 mm and 2.4/1.5 mm) are considered pilot drills and are used in all drilling sequences.

Ø3.0 mm Glidewell HT Implants: The 2.8/2.4 mm Twist Drills are stepped to accommodate the tapered design of the implant and are available in five lengths corresponding to the available implant lengths.

Ø3.5 mm – Ø7.0 mm Glidewell HT Implants: The Shaping Drills are stepped to accommodate the tapered design of the implant and are both diameter- and length-specific, corresponding to the available implants.

Twist Drills Ø1.5 mm

8 mm

Twist Drills Ø2.4/1.5 mm

8 -16 mm

Twist Drills Ø2.8/2.4 mm

8 mm 10 mm 11.5 mm 13 mm 16 mm

Shaping Drills Ø3.5 mm

8 mm 10 mm 11.5 mm 13 mm 16 mm

Shaping Drills Ø4.3 mm

8 mm 10 mm 11.5 mm 13 mm 16 mm

Shaping Drills Ø5.0 mm

8 mm 10 mm 11.5 mm 13 mm 16 mm

Shaping Drills Ø6.0 mm

8 mm 10 mm 11.5 mm

Shaping Drills Ø7.0 mm

8 mm 10 mm 11.5 mm

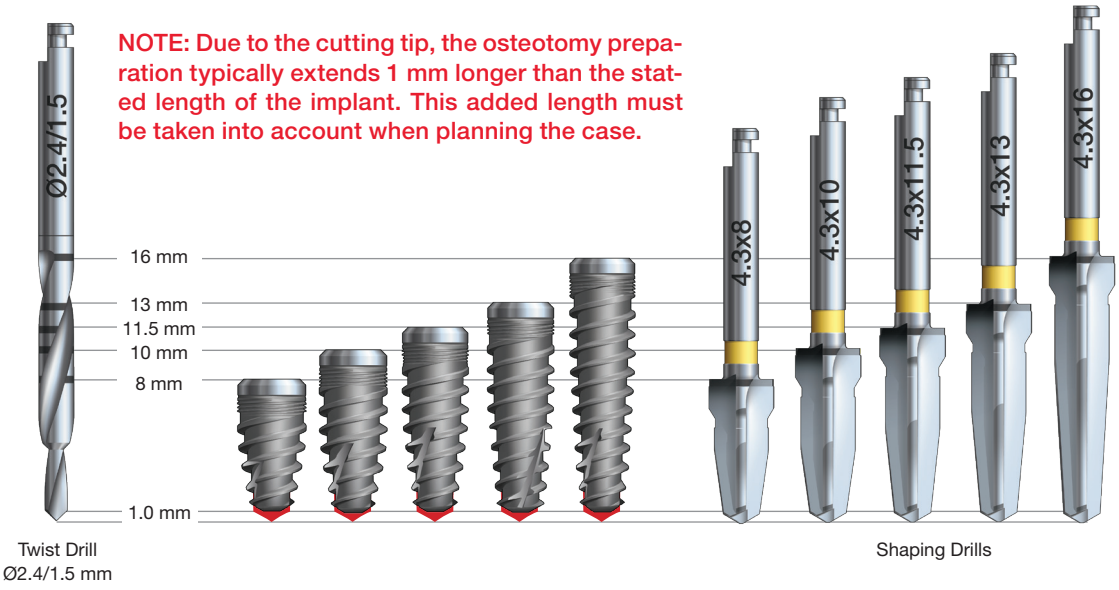
INSTRUMENTATION

Depth Markings

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.

Glidewell HT Implant Shaping Drills are length-specific and include a laser-etched depth marking.

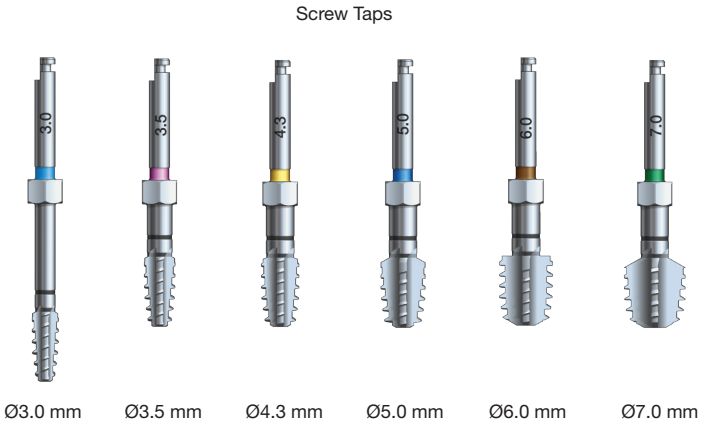
The illustration below demonstrates the correlation between laser-etched depth markings and the corresponding implant length.

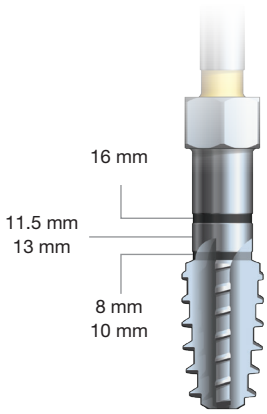


Screw Taps *(Optional for Dense Bone)*

For the placement of Glidewell HT Implants in extremely dense bone, it may be necessary to utilize a thread-forming screw tap corresponding to the diameter of the implant body. 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. Due to the tap design and implant cutting efficiency, one tap is used for multiple implant lengths.

Each Screw Tap contains multiple depth markings in order to minimize the number of surgical instruments required. Care should be taken not to exceed the planned depth.

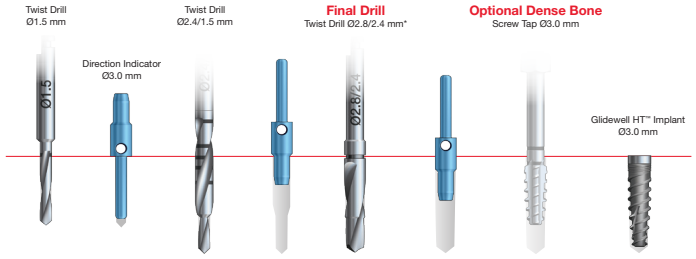




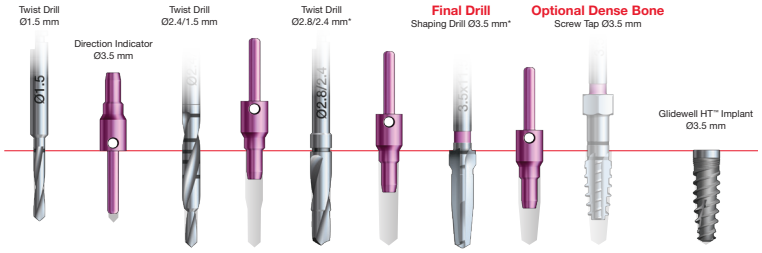
STANDARD SURGICAL PROTOCOL

■ Drilling Sequences

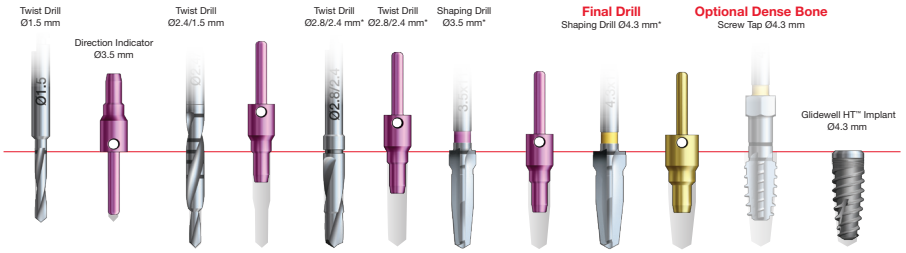
Glidewell HT™ Implant Ø3.0 mm



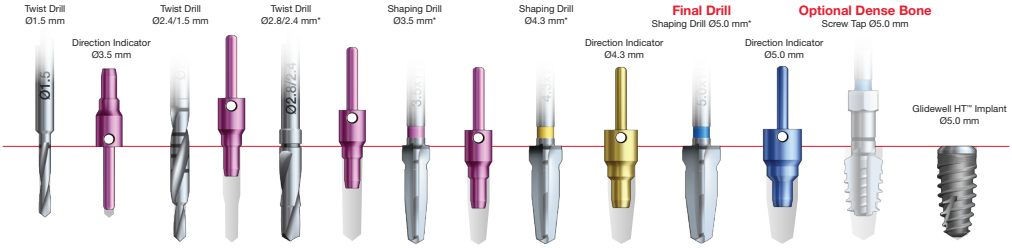
Glidewell HT™ Implant Ø3.5 mm



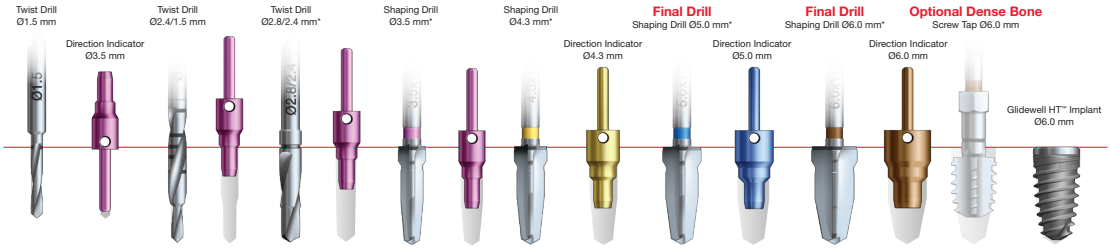
Glidewell HT™ Implant Ø4.3 mm



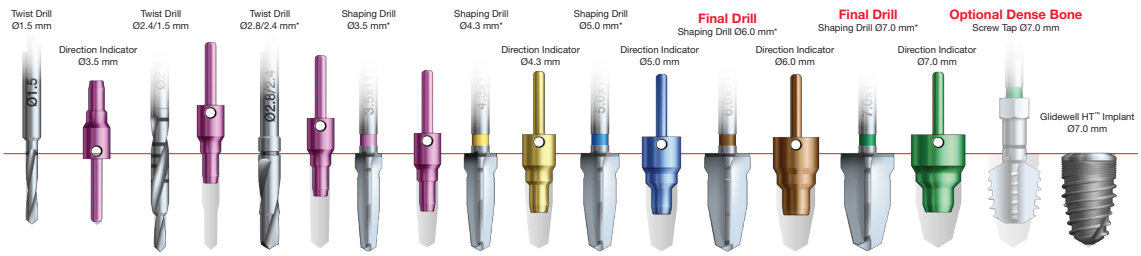
Glidewell HT™ Implant Ø5.0 mm



Glidewell HT™ Implant Ø6.0 mm



Glidewell HT™ Implant Ø7.0 mm



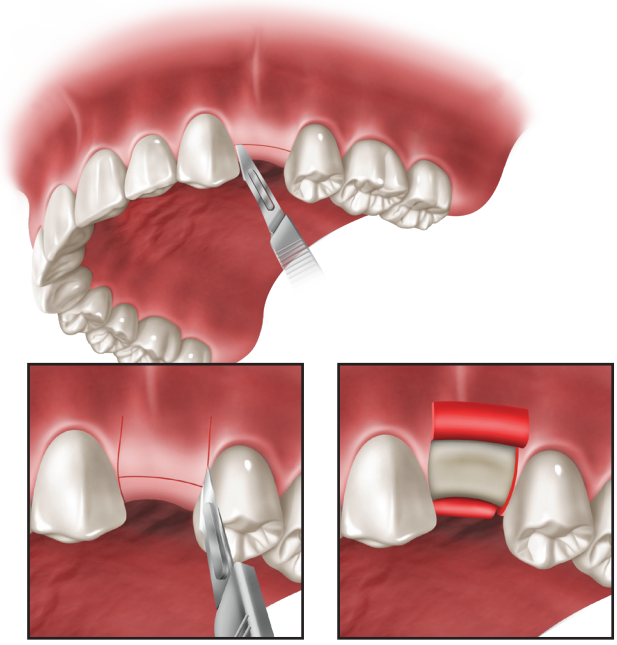
Ensure all surgical instruments are available prior to surgery.

**Available in various lengths.*

STANDARD SURGICAL PROTOCOL

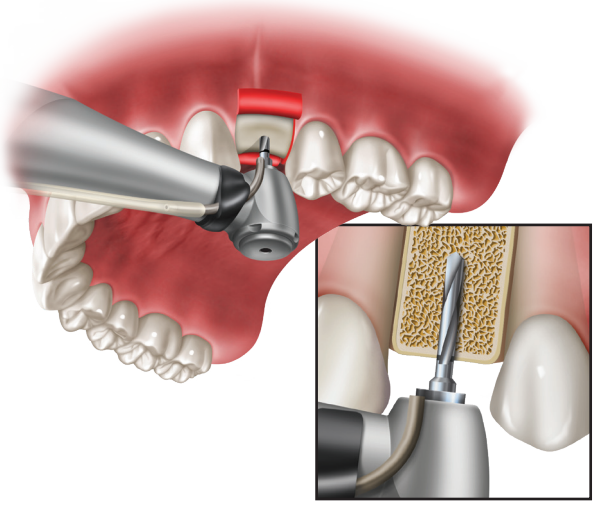
■ Soft Tissue Reflection

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

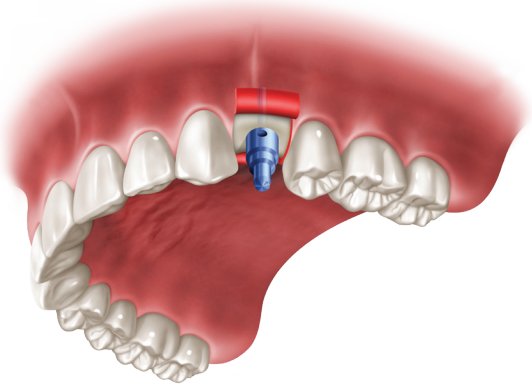
With copious irrigation, perforate the alveolar crest. Utilize a surgical guide, if necessary, as a reference for proper positioning.

Twist Drill
Ø1.5 mm

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

Direction Indicators

Ø3.5 mm Ø4.3 mm Ø5.0 mm

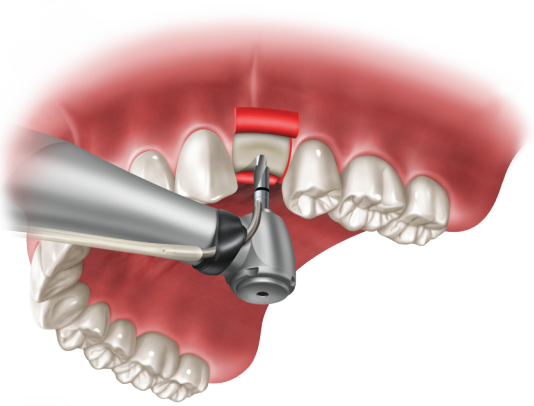


STANDARD SURGICAL PROTOCOL

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

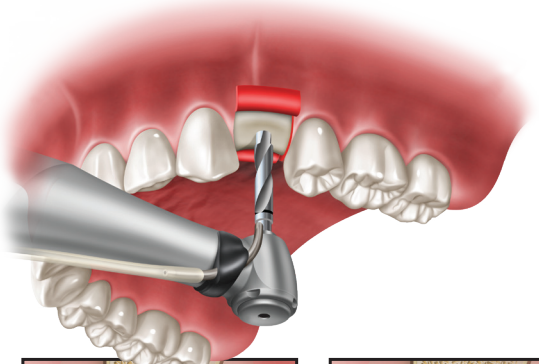


Step 3: Twist Drill Ø2.8/2.4 mm

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

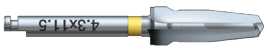
NOTE: If placing a 3.0 mm diameter Glidewell HT Implant, this should be the final diameter of drill used. If placing a larger-diameter Glidewell HT™ Implant, proceed to *Step 4: Shaping Drills*.



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

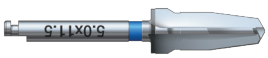
If placing a Glidewell HT Implant that is 3.5 mm in diameter or greater, Shaping Drills are used sequentially to widen the osteotomy to the matching diameter. To avoid over-preparation, widening drill diameters should be used only as needed, and in proper succession. Each Shaping Drill is length-specific,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

Ø3.5 mm

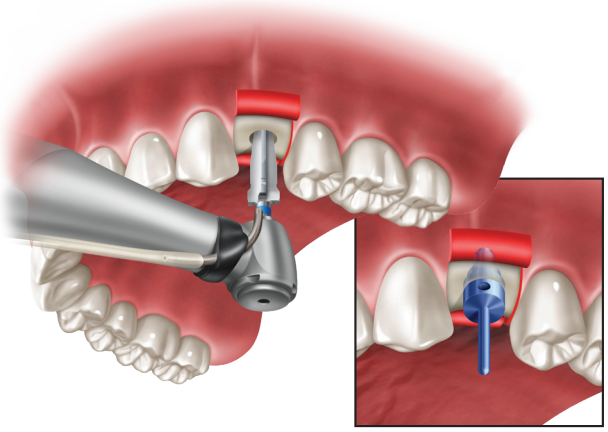


Ø4.3 mm

Shaping Drills

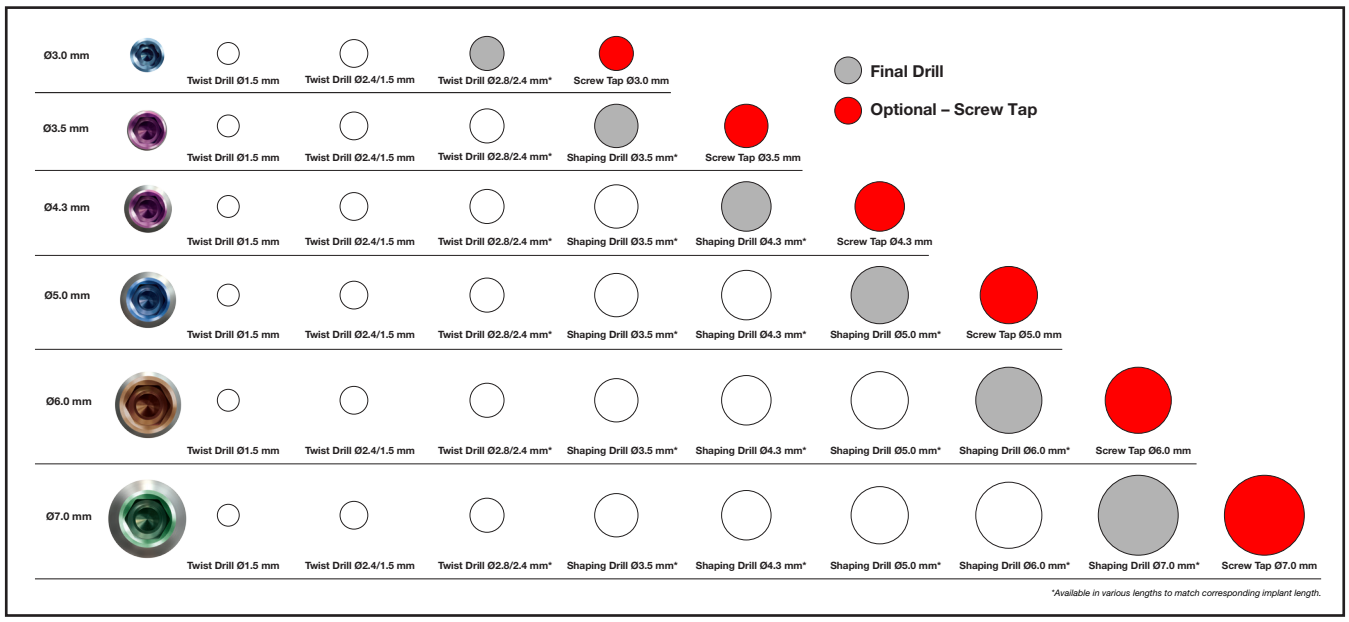


Ø5.0 mm



NOTE: As the osteotomy is widened, Direction Indicators should be used to confirm the trajectory of the osteotomy. If preparing multiple osteotomies, check parallelism as needed using the diameter-specific end of the Direction Indicator.

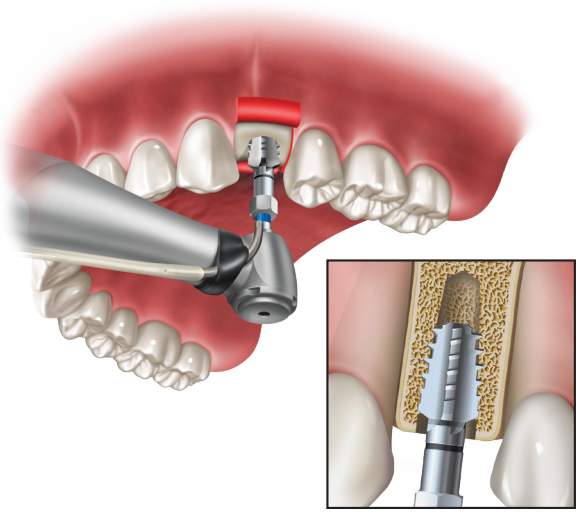
Drilling Sequence Chart

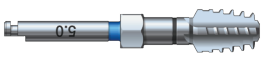


Step 5: (Optional) Dense Bone Tap

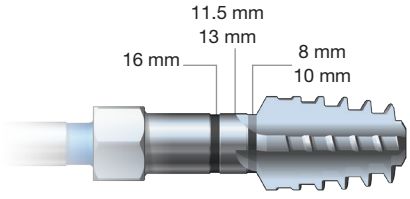
If indicated by the presence of dense bone, select the Screw Tap with a diameter matching that of the implant. Place the tap into the prepared implant site. Apply firm pressure and begin slowly rotating the tap (**25 RPM maximum**). When the threads begin engaging the bone, allow the tap to feed into the site without applying additional pressure. The osteotomy should be tapped through the cortical bone. Reverse the tap out of the site. Do not pull the tap out of the site. Use a drill extender when additional reach or access is needed for dental procedures.

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.





Screw Tap Ø5.0 mm



IMPLANT PLACEMENT

■ Implant Placement

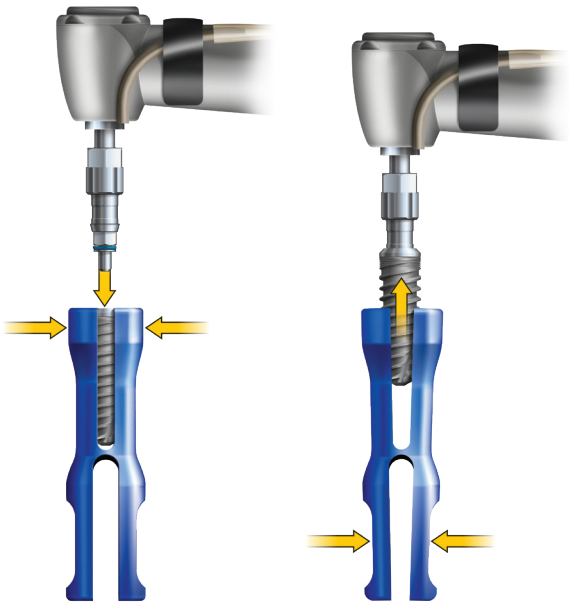
Step 1: Implant Selection

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

Engage the implant connection with the appropriate driver. With the implant securely attached to the driver, squeeze the opposing end of the holder to disengage the implant from the holder. Transport the implant to the prepared site, and insert into the osteotomy. Rotate clockwise with applied pressure to engage the self-tapping grooves. Avoid lateral forces, which can affect the angulation and final alignment of the implant.

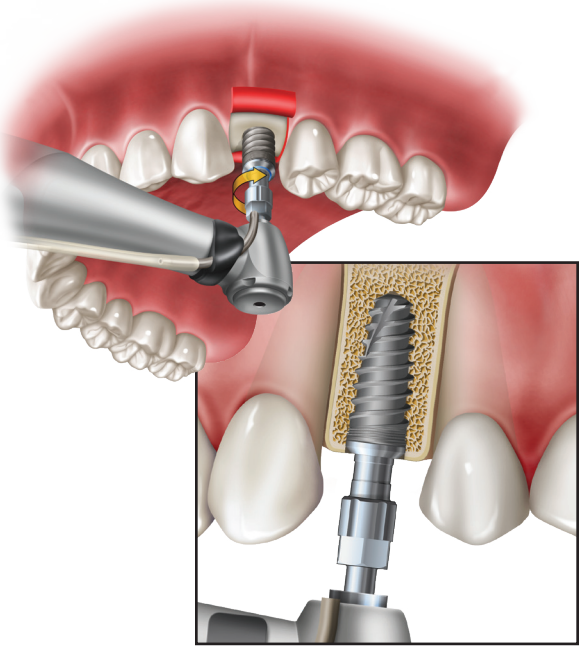


NOTE: Apply pressure to the driver is fully engaged with the implant prior to disengaging the titanium holder.

Step 3: Advancement and Final Seating

Continue threading the implant into the osteotomy site using the preferred placement method.

Refer to the recommended Torque Values in the table below. A minimum torque value upon final seating indicates good primary stability.



Torque Value

Diameter	Minimum	Maximum
3.0 mm	15 Ncm	35 Ncm
3.5 mm	35 Ncm	
4.3 mm	35 Ncm	
5.0 mm	35 Ncm	
6.0 mm	35 Ncm	
7.0 mm	35 Ncm	

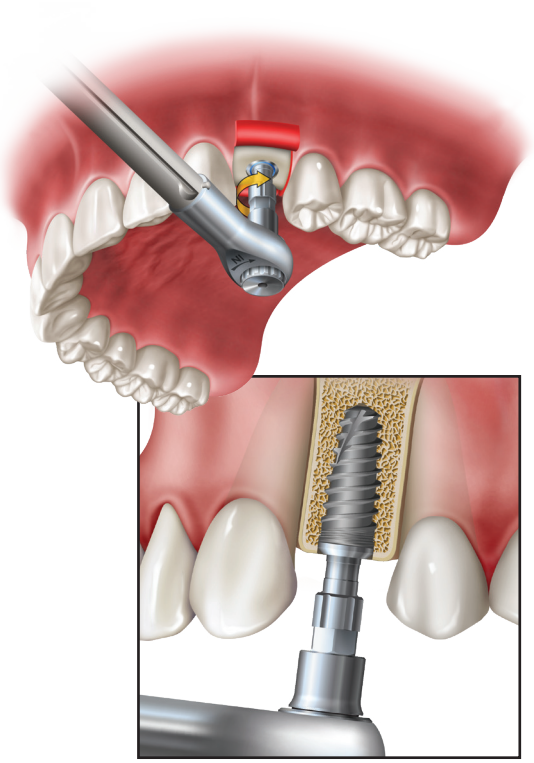
■ Methods of Implant Placement

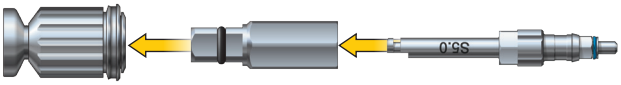
Option 1: Handpiece Implant Placement

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 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.





Driver Handle, Square Surgical Adaptor Implant Driver Ø5.0 mm Short

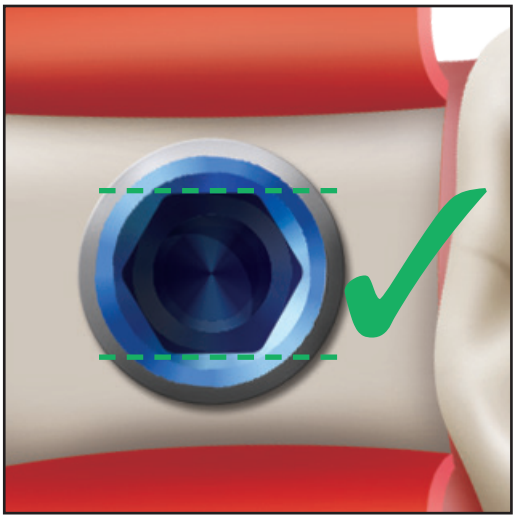
Driver Handle, Hex Implant Driver Ø5.0 mm Long

Torque Wrench

IMPLANT PLACEMENT

■ Implant Positioning

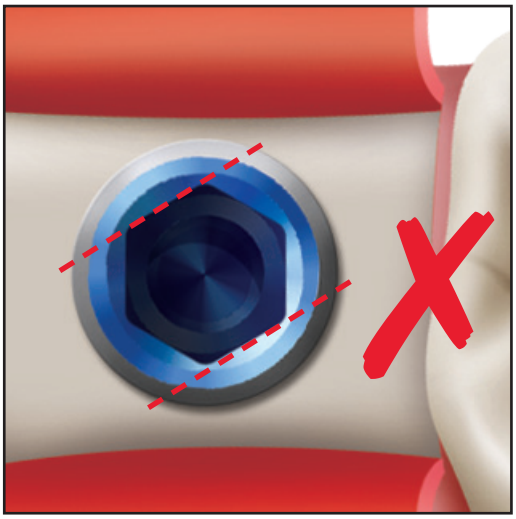
The implant should be rotated at the time of placement to ensure optimal positioning of the internal hex connection. This will allow the restoring clinician to take full advantage of the anatomical abutment contours and minimize the need for abutment preparation. Adjust the final position of the implant so that any one of the six flats of the internal hex connection is oriented toward the facial.



■ Bone Profiling

If indicated by subcrestal placement of the implant or excess bone around the restorative platform, select the appropriate Bone Profiler based on the implant's platform size. Insert the tip of the profiler into the implant's connection interface, taking care to ensure a parallel orientation with the implant. Using finger pressure, maintain parallelism while gently rotating the profiler clockwise until the profiler reaches a stop against the implant platform (progressing no farther with continued rotation). Remove the profiler when finished. With suction, irrigate site to ensure removal of bone debris.

NOTE: Failing to maintain parallelism between the profiler and the implant my result in damage to the implant interface, or lead to incorrect profiling of the bone.



■ 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 Abutments

3 mmH 5 mmH 7 mmH

Option 2: Cover Screw

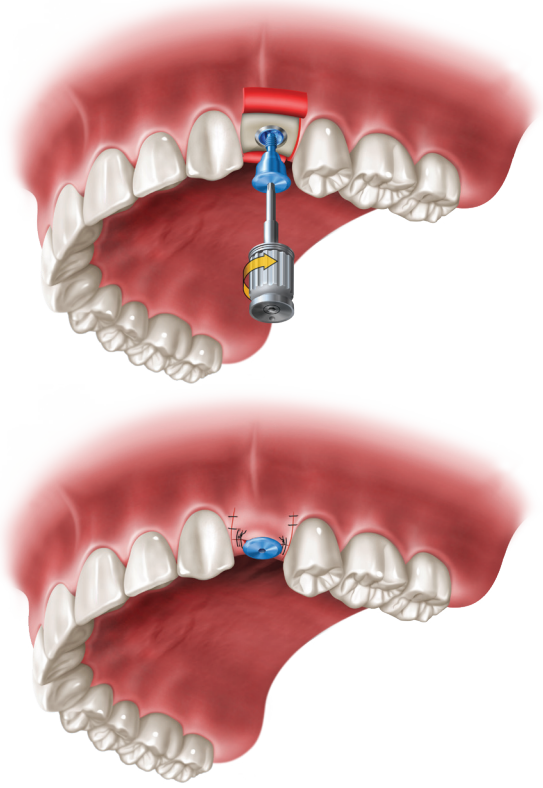
If observing a two-stage surgical protocol, thread the Cover Screw into place atop the implant. Hand-tighten with the appropriate Prosthetic Driver.

Cover Screw

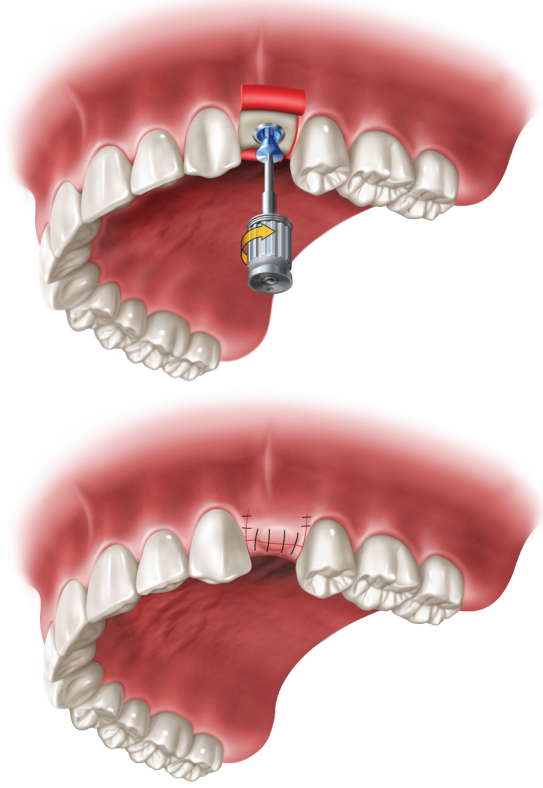
■ Closure and Suturing

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

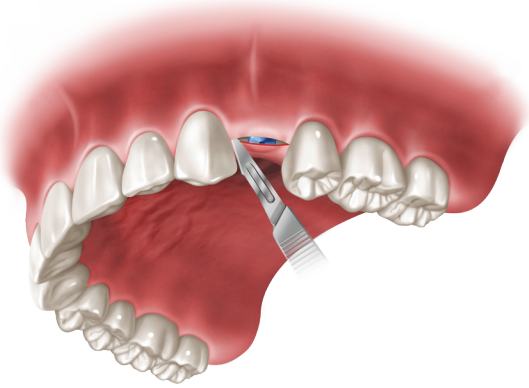


Two-Stage Surgical Protocol

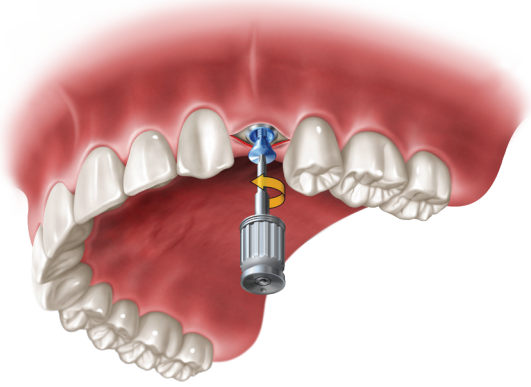


SECOND-STAGE UNCOVERY (TWO-STAGE SURGICAL PROTOCOL)

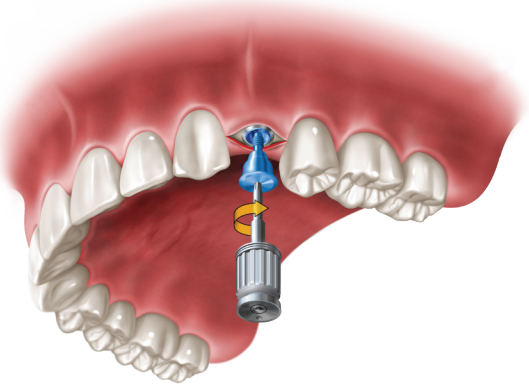
Following the appropriate healing period, make a small incision in the gingiva over the implant site to expose the Cover Screw. Using the Prosthetic Driver, remove the Cover Screw and place a Healing Abutment or Temporary Abutment of the appropriate height and diameter.



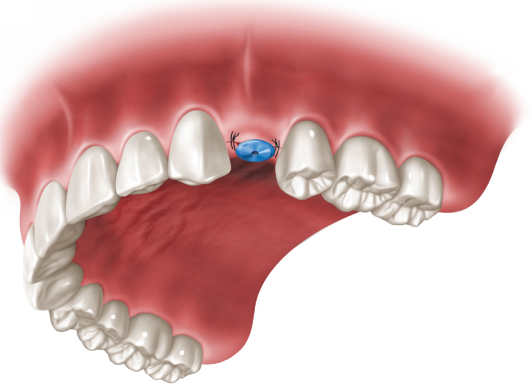
Step 1: Expose the Cover Screw



Step 2: Remove the Cover Screw



Step 3: Place Healing Abutment



Step 4: Close and suture

IMPLANT PACKAGING

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. 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. 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

Ø3.0 x 11.5 mm

1 **Glidewell HT™ Implant**
Ø3.0 x 11.5 mm

4 LOT 1234567 1 pc.

7 STERILE R

Use by 8
YYYY-MM-DD

11

9 https://ifu.glidewelldental.com
IFU CODE: IFU-12631
tel: (888) 402-1725

6 Do not use if package is damaged.

10

LBL-012624_1

5 Rx only

Scan QR code for link to URL
For more information email
mail@glidewelldental.com

15

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2144 Michelson Drive
Irvine, CA 92612, USA

2 YYYY-MM-DD

13 Made in USA

14 *+D745701154IMP00120/$$8013251201234567/16D202012106*

Ø3.0 x 11.5 mm

3 REF 70-1189-IMP0001

Glidewell HT™ IMPLANT SYSTEM

Ordering Information

Order at glidewelldirect.com or call Glidewell Direct at 888-303-3975. Our product specialists are committed to answering questions in a timely fashion to ensure your ordering is easy and efficient. We are available Monday–Friday from 6:00 a.m.–5:00 p.m. (PST).

Shipping Policy

- Orders placed after 3 p.m. (PST) will be processed on the following business day. Business days do not include Saturdays, Sundays, or U.S. holidays.
- Online shopping cart available to U.S. customers only.

Terms

All accounts are payable within 30 days of invoice date. Accounts not paid within the stated terms will be subject to COD status and a late charge of 2 percent of the unpaid balance. We accept American Express, Visa, MasterCard, and Discover. All prices are subject to change without notice.

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 and Glidewell Direct hereinafter are referred to collectively as Glidewell. 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"). Glidewell 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.

Glidewell 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 Glidewell'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 Glidewell Direct, 18651 Von Karman Ave, Irvine, CA 92612.

Glidewell HT™
IMPLANT SYSTEM

Official implant of the

RESNIK IMPLANT INSTITUTE

Designed & Manufactured in the USA
by

PRISMATIK DENTALCRAFT, INC.

2144 Michelson Drive • Irvine, CA 92612, USA

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