Glidewell HT™
IMPLANT SYSTEM

Guided Surgery Manual

888-303-3975 | glidewell-ht.com

THE GLIDEWELL HT™ IMPLANT SYSTEM

With the **Glidewell HT™ Implant Guided Surgery System**, you can place more implants in less time while maximizing predictability and lowering surgical and restorative costs. Featuring the latest advancements in digital treatment planning a new and improved guided surgical kit based on eight years of clinical feedback, this innovative system enables clinicians of all experience levels to deliver premium-quality, clinically proven Glidewell HT Implants with the utmost precision and confidence.[1]

By executing a highly precise, digitally guided surgical procedure, clinicians can place Glidewell HT Implants in the exact location needed for a predictable, esthetic outcome, while avoiding vital patient anatomy and surprises on the day of surgery. And with a 99.2% success rate and the implant-to-crown lifetime guarantee offered by Glidewell, you and your patients can count on results you can trust for life.[2]

Eliminate the guesswork, reduce your costs and make Glidewell HT guided surgery part of your practice today.

> *"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."*

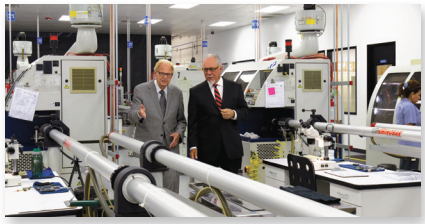
Jim Glidewell, CDT
Founder and President of Glidewell

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).

1. Anderson S, Park N. Long-term clinical and radiographic evaluation of a novel implant design: a retrospective study. For the full report, visit glidewell.com/ht-6-year.

2. 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 guided placement of 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 designed 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.
- All instruments used for guided procedures should be inserted through the guide sleeve to the indicated mark or flange stop.
- 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 the 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.

SURGICAL CONSIDERATIONS

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

The Glidewell HT Implant Guided Surgery System is designed for the guided placement of Glidewell HT Implants in four diameters (3.0 mm, 3.5 mm, 4.3 mm, 5.0 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. All 3.5 mm and 4.3 mm diameter Glidewell HT Implants share the same prosthetic platform.

The Glidewell HT Implant Guided Surgery System utilizes color-coding for easy component identification. Color-coding is featured consistently across system articles such as surgical tray, surgical drills, 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
			
	 Ø3.5 x 8 mm 70-1189-IMP0004	 Ø4.3 x 8 mm 70-1189-IMP0009	 Ø5.0 x 8 mm 70-1189-IMP0014
	 Ø3.5 x 10 mm 70-1189-IMP0005	 Ø4.3 x 10 mm 70-1189-IMP0010	 Ø5.0 x 10 mm 70-1189-IMP0015
 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
 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

INSTRUMENTATION

All instrumentation is manufactured in the U.S.A., Switzerland, Denmark or Israel. 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:

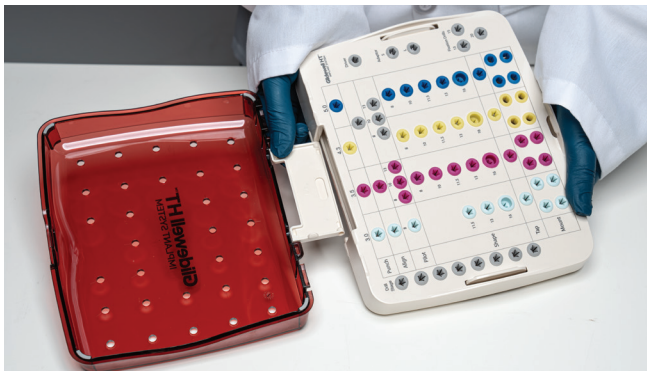
Follow the clinical internal procedures for the transportation of contaminated devices. Perform cleaning as soon as possible. When longer delays are expected, immerse the devices in a sterile water bath to avoid drying of debris.

⚠ 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.



To remove lid from base, first remove the bottom tray, then gently pull on one side of the hinge until the nub disengages.

INSTRUMENTATION

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.

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.

INSTRUMENTATION

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.

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:

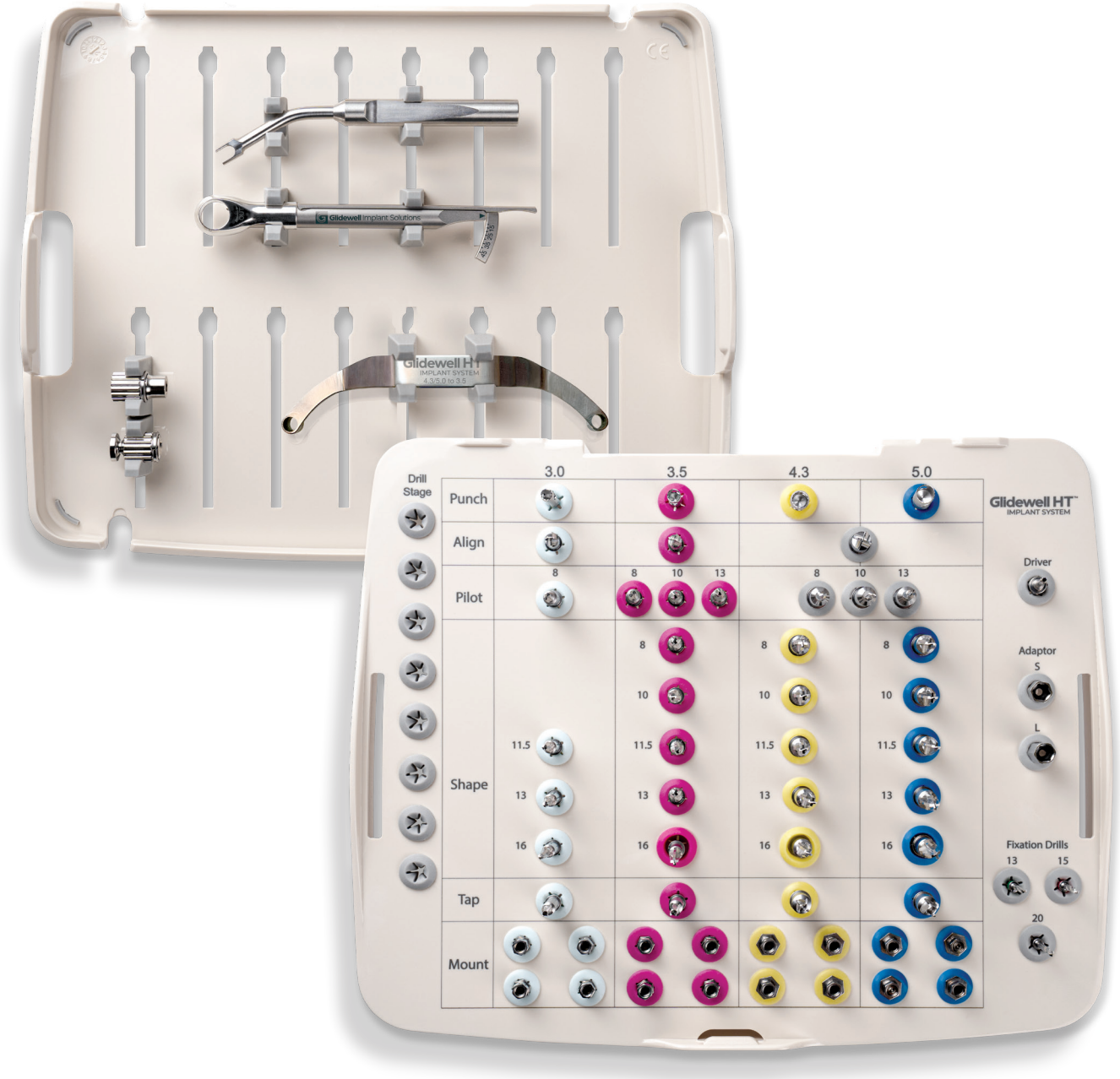
The Autoclavable Cassette has been validated for up to 100 cycles of use with reprocessing (one use equals one surgical or clinical procedure), provided the recommended conditions of use are followed. Instruments may be used for up to five preparations. The health professional should always assess the 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

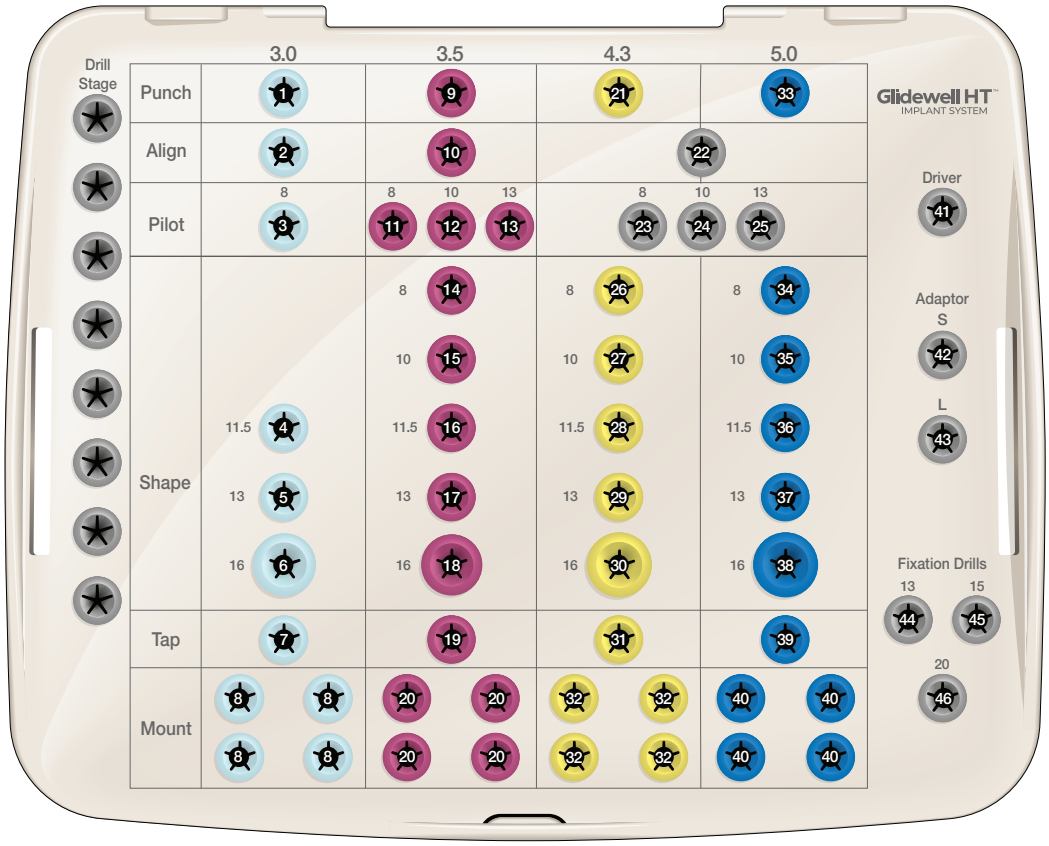
Guided Surgical Kit

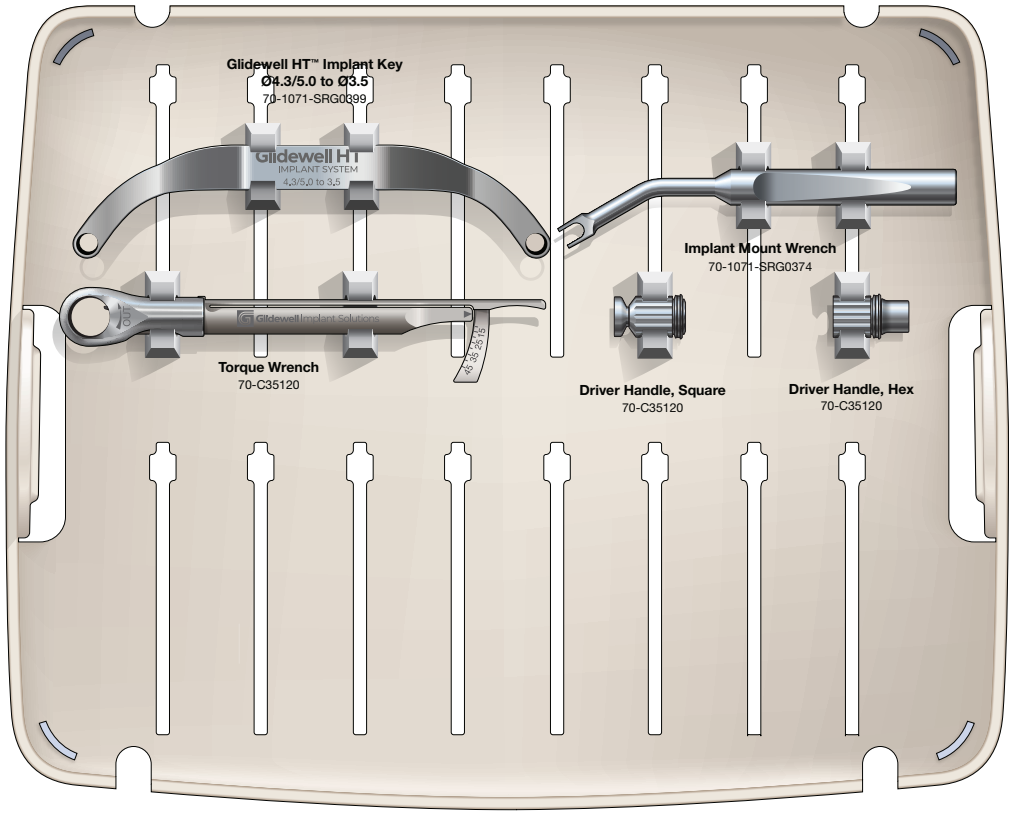
The guided surgical kit allows the clinician to easily organize, store, and transport the instrumentation components of the Glidewell HT Implant Guided Surgery System. Drills are arranged from left to right in order of increasing diameter, following the recommended drilling sequence. Color coding indicates the corresponding diameter of the Glidewell HT Implant, and each drill includes laser etching that indicates the diameter and length.

The drills in the Glidewell HT Guided Surgical Kit are specifically designed with a barrel diameter that fits into the corresponding, color-coded surgical guide sleeve. A built-in flange stop indicates to the clinician that the drill is at full depth. These design features simplify the surgical protocol and eliminate the need for additional instrumentation.



INSTRUMENTATION





INSTRUMENTATION

1 
Tissue Punch Ø3.0 mm
70-1071-SRG0313

2 
Alignment Drill Ø3.0 mm
70-1071-SRG0317

3 
Pilot Drill Ø3.0 x 8 mm
70-1071-SRG0387

4 
Shaping Drill Ø3.0 x 11.5 mm
70-1071-SRG0326

5 
Shaping Drill Ø3.0 x 13 mm
70-1071-SRG0327

6 
Shaping Drill Ø3.0 x 16 mm
70-1071-SRG0328

7 
Screw Tap Ø3.0
70-1071-SRG0362

8 
Mount Ø3.0
70-1071-SRG0366

9 
Tissue Punch Ø3.5 mm
70-1071-SRG0314

10 
Alignment Drill Ø3.5 mm
70-1071-SRG0318

11 
Pilot Drill Ø3.5 x 8 mm
70-1071-SRG0388

12 
Pilot Drill Ø3.5 x 10 mm
70-1071-SRG0389

13 
Pilot Drill Ø3.5 x 13 mm
70-1071-SRG0390

14 
Shaping Drill Ø3.5 x 8 mm
70-1071-SRG0329

15 
Shaping Drill Ø3.5 x 10 mm
70-1071-SRG0330

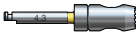
16 
Shaping Drill Ø3.5 x 11.5 mm
70-1071-SRG0331

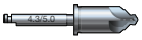
17 
Shaping Drill Ø3.5 x 13 mm
70-1071-SRG0332

18 
Shaping Drill Ø3.5 x 16 mm
70-1071-SRG0333

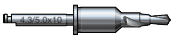
19 
Screw Tap Ø3.5
70-1071-SRG0363

20 
Mount Ø3.5
70-1071-SRG0367

21 
Tissue Punch Ø4.3 mm
70-1071-SRG0315

22 
Alignment Drill Ø4.3/5.0 mm
70-1071-SRG0319

23 
Pilot Drill Ø4.3/5.0 x 8 mm
70-1071-SRG0391

24 
Pilot Drill Ø4.3/5.0 x 10 mm
70-1071-SRG0392

25 
Pilot Drill Ø4.3/5.0 x 13 mm
70-1071-SRG0393

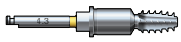
26 
Shaping Drill Ø4.3 x 8 mm
70-1071-SRG0334

27 
Shaping Drill Ø4.3 x 10 mm
70-1071-SRG0335

28 
Shaping Drill Ø4.3 x 11.5 mm
70-1071-SRG0336

29 
Shaping Drill Ø4.3 x 13 mm
70-1071-SRG0337

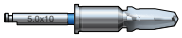
30 
Shaping Drill Ø4.3 x 16 mm
70-1071-SRG0338

31 
Screw Tap Ø4.3
70-1071-SRG0364

32 
Mount Ø4.3
70-1071-SRG0368

33 
Tissue Punch Ø5.0 mm
70-1071-SRG0316

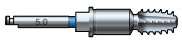
34 
Shaping Drill Ø5.0 x 8 mm
70-1071-SRG0339

35 
Shaping Drill Ø5.0 x 10 mm
70-1071-SRG0340

36 
Shaping Drill Ø5.0 x 11.5 mm
70-1071-SRG0341

37 
Shaping Drill Ø5.0 x 13 mm
70-1071-SRG0342

38 
Shaping Drill Ø5.0 x 16 mm
70-1071-SRG0343

39 
Screw Tap Ø5.0
70-1071-SRG0365

40 
Mount Ø5.0
70-1071-SRG0369

41
Prosthetic Driver - 24 mm
70-1190-PRC0055

42
Surgical Adaptor - Short
70-1071-SRG0307

43
Surgical Adaptor
70-1071-SRG0306

44
Fixation Drill Ø1.5 x 13 mm
70-1071-SRG0400

45
Fixation Drill Ø1.5 x 15 mm
70-1071-SRG0401

46
Fixation Drill Ø1.5 x 20 mm
70-1071-SRG0402

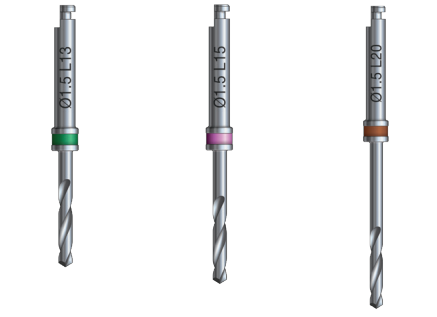
NOTE: For a detailed product listing, please refer to the *Glidewell HT Implant System Product Catalog*, visit glidewelldirect.com, or contact a Glidewell Direct sales representative at 888-303-3975.

INSTRUMENTATION

Fixation Drills

Fixation Drills are used for initial fixation of a surgical guide for dental implant surgery. Fixation Drills are inserted through the Fixation Guide Sleeve to create a temporary osteotomy in the mandible or maxilla to facilitate insertion of the Fixation Pin. They are available in three lengths (13 mm, 15 mm, 20 mm) to match the length of the corresponding Fixation Pin.

Fixation Drills

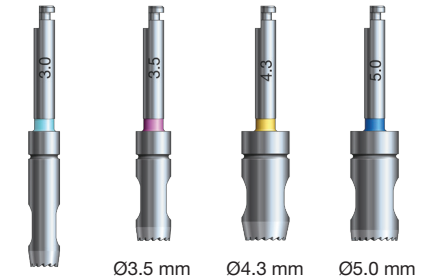


Ø1.5 x 13 mm Ø1.5 x 15 mm Ø1.5 x 20 mm

Tissue Punches

Tissue Punches are designed for atraumatic excision of soft tissue at the surgical site. They are available in four diameters (3.0 mm, 3.5 mm, 4.3 mm, 5.0 mm) to match the diameter of the prescribed implant.

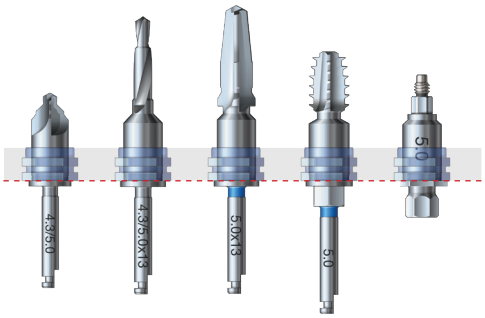
Tissue Punches

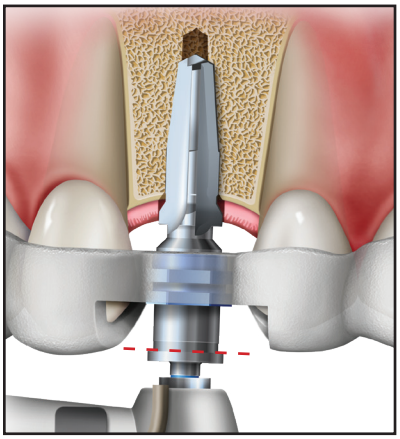


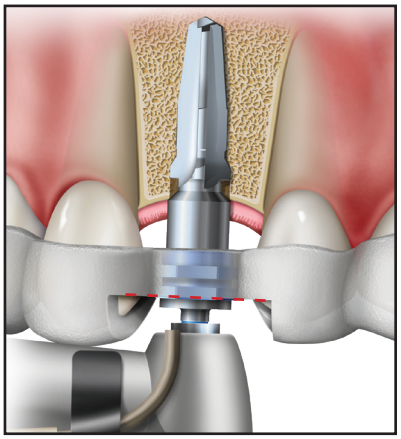
Ø3.0 mm Ø3.5 mm Ø4.3 mm Ø5.0 mm

Surgical Drills

The Glidewell HT Implant Guided Surgery System features a full range of surgical drills, including three diameters of Alignment Drills (3.0 mm, 3.5 mm, 4.3/5.0 mm), three diameters of Pilot Drills (3.0 mm, 3.5 mm, 4.3/5.0 mm), and four diameters of Shaping Drills (3.0 mm, 3.5 mm, 4.3 mm, 5.0 mm). All feature a flange stop for depth control and are designed to achieve maximum cutting efficiency while effectively removing bone from the osteotomy.



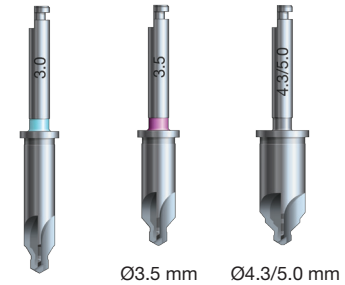




INSTRUMENTATION

Alignment Drills are used to perforate the alveolar crest and establish proper concentric alignment for the drills that follow.

Alignment Drills



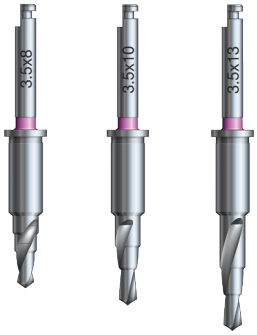
Ø3.0 mm Ø3.5 mm Ø4.3/5.0 mm

Pilot Drills are stepped to accommodate the tapered design of the implant. Three lengths are available: 8 mm, 10 mm, 13 mm. Drill length is calculated to indicate where the top of the implant will reside when fully seated to that depth.

Pilot Drill Ø3.0 mm

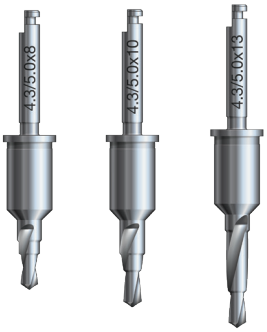
8 mm

Pilot Drills Ø3.5 mm



8 mm 10 mm 13 mm

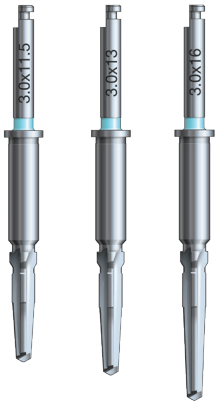
Pilot Drills Ø4.3/5.0 mm



8 mm 10 mm 13 mm

All **Shaping Drills** are both diameter- and length-specific, to match the size of the prescribed implant.

Shaping Drills Ø3.0 mm



11.5 mm 13 mm 16 mm

Shaping Drills Ø3.5 mm

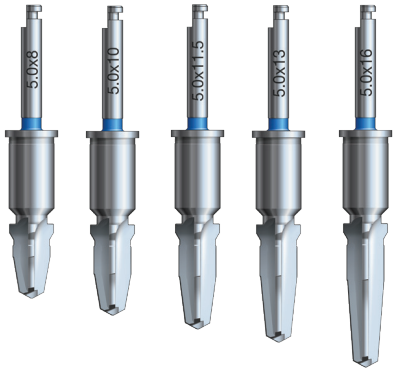
8 mm 10 mm 11.5 mm 13 mm 16 mm

Shaping Drills Ø4.3 mm

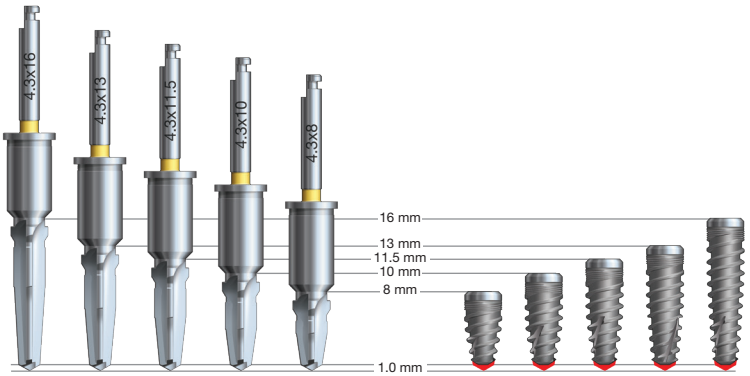
8 mm 10 mm 11.5 mm 13 mm 16 mm

INSTRUMENTATION

Shaping Drills Ø5.0 mm



8 mm 10 mm 11.5 mm 13 mm 16 mm

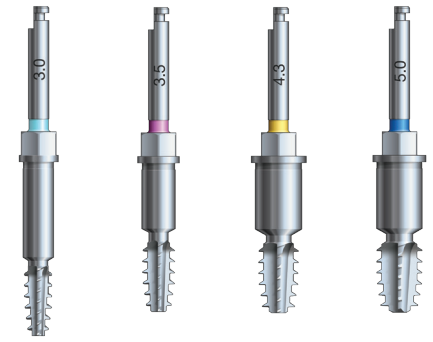


NOTE: The drill preparation typically extends 1 mm longer than the implant. Triangle at base of implant represents this added length.

Screw Taps

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. 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.

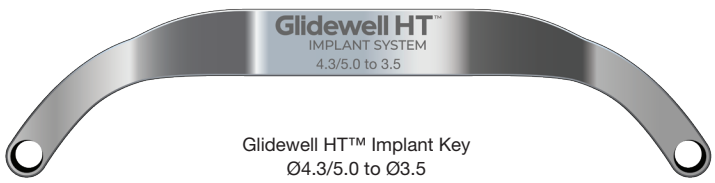
Screw Taps



Ø3.0 mm Ø3.5 mm Ø4.3 mm Ø5.0 mm

Implant Key

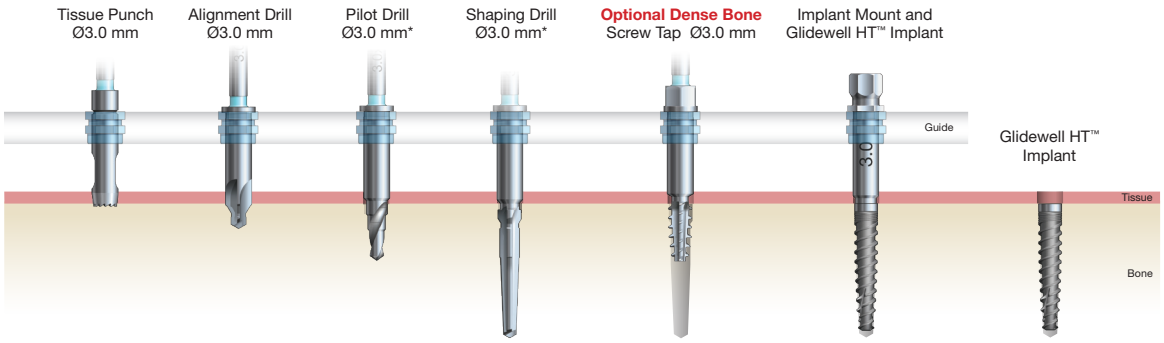
The Implant Key is used to undersize an osteotomy with guided surgery. The Implant Key when inserted into the Implant Guide Sleeve acts as a drill guide, aiding in the creation of an osteotomy that is smaller than the final implant diameter.



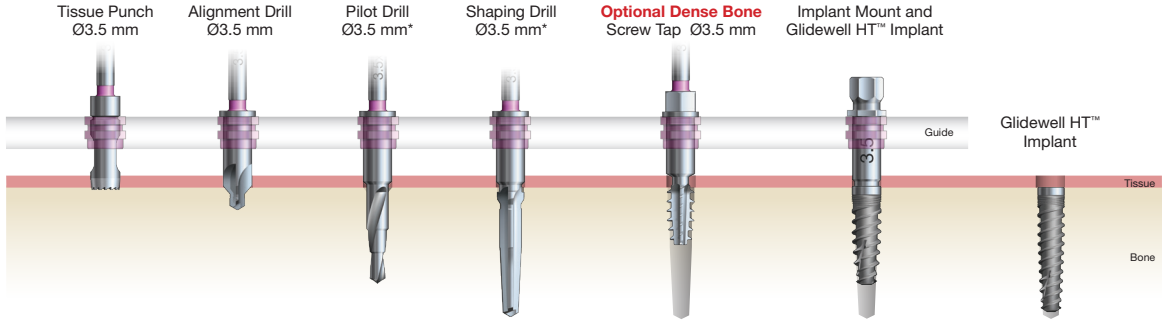
Glidewell HT™ Implant Key
Ø4.3/5.0 to Ø3.5

GUIDED DRILLING SEQUENCES

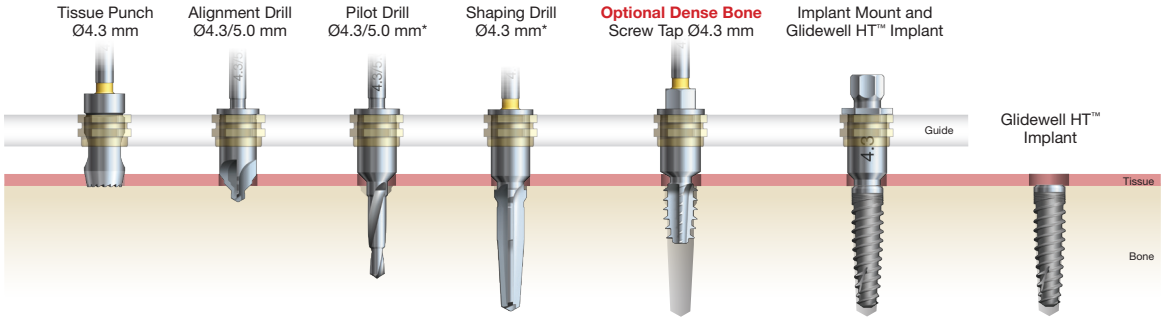
Glidewell HT™ Implant Ø3.0 mm



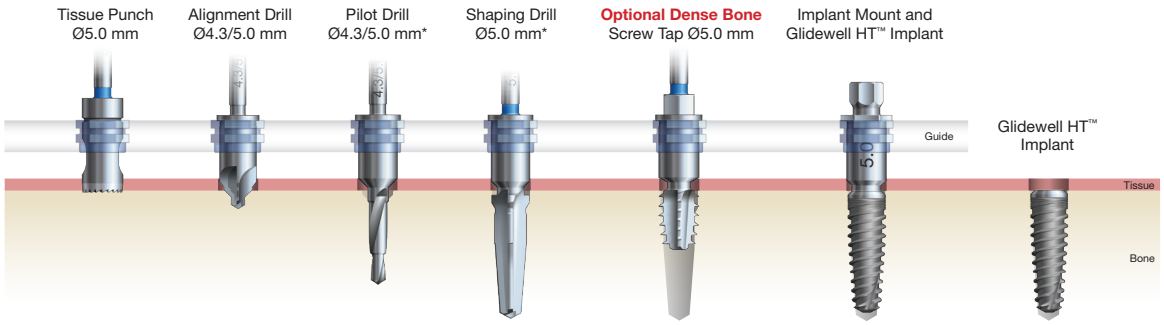
Glidewell HT™ Implant Ø3.5 mm



Glidewell HT™ Implant Ø4.3 mm



Glidewell HT™ Implant Ø5.0 mm

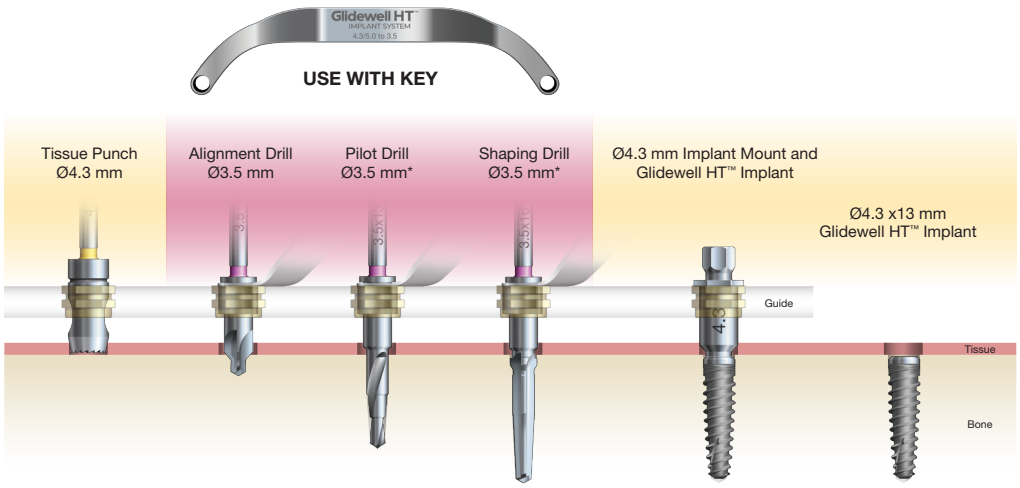


Ensure all surgical instruments are available prior to surgery. Do not use any drill that exceeds the diameter or length of the prescribed implant.
**Available in various lengths.*

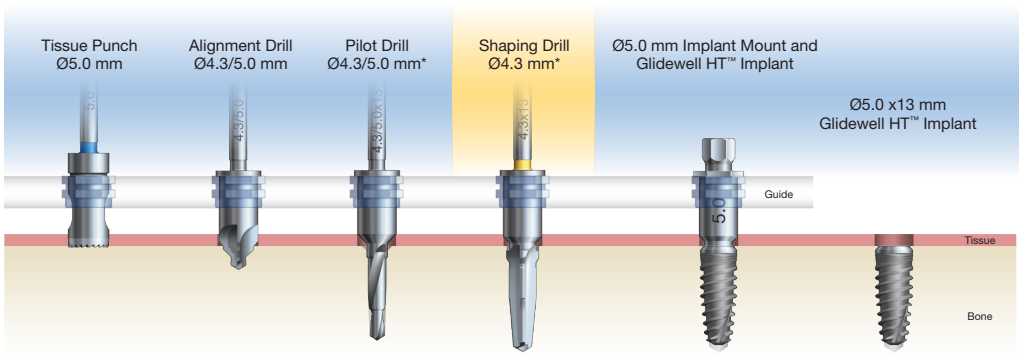
GUIDED DRILLING SEQUENCES

Procedure for Undersizing the Osteotomy in Soft Bone

Glidewell HT™ Implant Ø4.3 mm Using Implant Key



Glidewell HT™ Implant Ø5.0 mm



NOTE: The Pilot Drill length corresponds to the implant length.

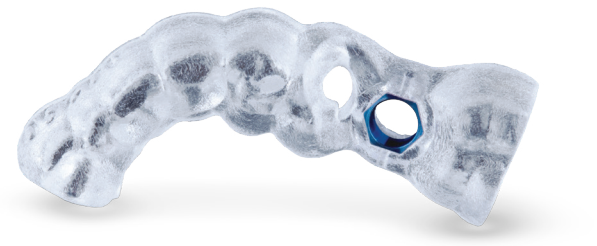
Pilot Drill	Implant Length
8 mm	8 mm
10 mm	10 mm and 11.5 mm
13 mm	13 mm and 16 mm

Ensure all surgical instruments are available prior to surgery. Do not use any drill that exceeds the diameter or length of the prescribed implant.
**Available in various lengths.*

SURGICAL PROTOCOL

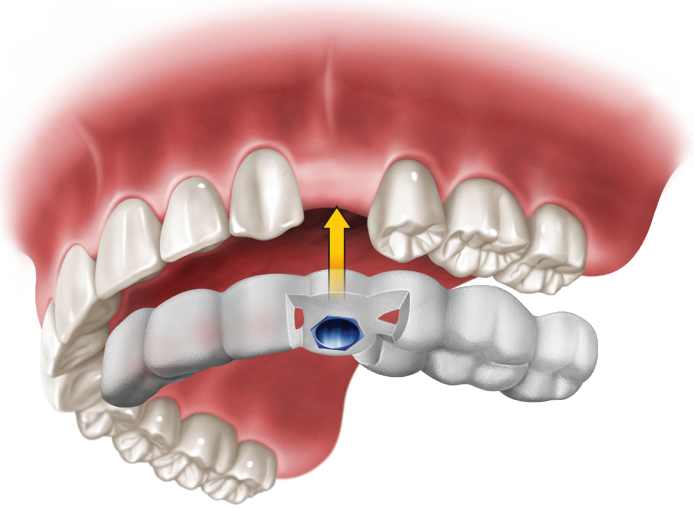
Surgical Plan and Guide Procurement

To support an open workflow, the Glidewell HT Implant Guided Surgery System is compatible with a variety of digital treatment planning software programs and surgical guide manufacturers. For detailed workflow and ordering information, please contact the software company or guide manufacturer of your choice, or contact Glidewell at 866-497-3692.



Preoperative Procedures

- Thoroughly review the surgical plan, ensuring that the position of each sleeve in the guide corresponds with the surgical plan.
- Disinfect or sterilize the surgical guide following the recommendations of the surgical guide manufacturer.
- Try in the surgical guide to confirm stability and fit.
- Ensure that the guide sleeves are not touching the soft tissue.



General Drilling Guidelines

- All instruments used for guided procedures should be inserted through the guide sleeve to the indicated mark or flange stop.
- Motor speed should be 30–100 RPM when using any of the Tissue Punches.
- A speed of 800–1200 RPM is recommended when using the Fixation Drills, Alignment Drills, Pilot 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.

Drilling Sequence Chart

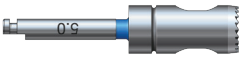
	Tissue Punch	Alignment Drill	Pilot Drill*	Shaping Drill*	Screw Tap
Ø3.0 mm	Ø3.0	Ø3.0	Ø3.0	Ø3.0	Ø3.0
Ø3.5 mm	Ø3.5	Ø3.5	Ø3.5	Ø3.5	Ø3.5
Ø4.3 mm	Ø4.3	Ø4.3/5.0	Ø4.3/5.0	Ø4.3	Ø4.3
Ø5.0 mm	Ø5.0	Ø4.3/5.0	Ø4.3/5.0	Ø5.0	Ø5.0

Final Drill — Optional Dense Bone Screw Tap — *Available in various lengths.

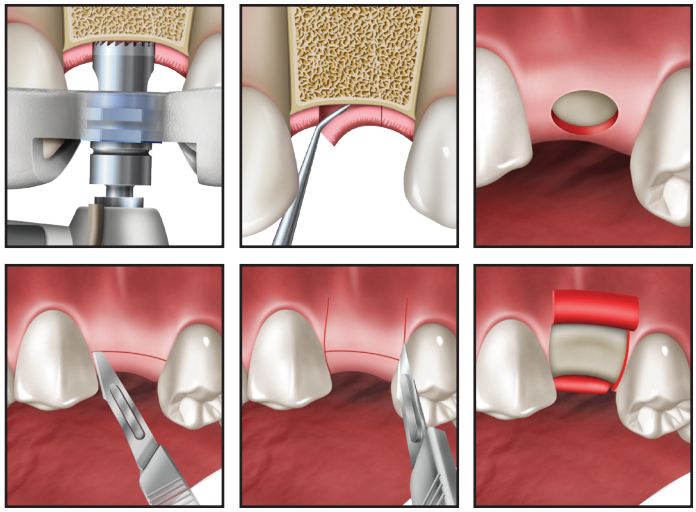
■ Soft Tissue Preparation

Option 1: Tissue Excision

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



Tissue Punch Ø5.0 mm



Option 2: Tissue Reflection

Following administration of anesthesia, make an incision designed for elevation of a flap. Seat the surgical guide; secure the guide in place with fixation pins, if applicable.

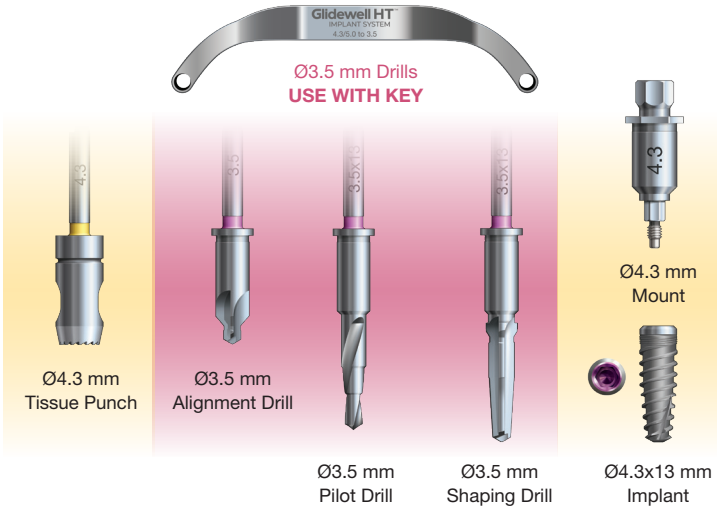
■ Undersizing the Osteotomy

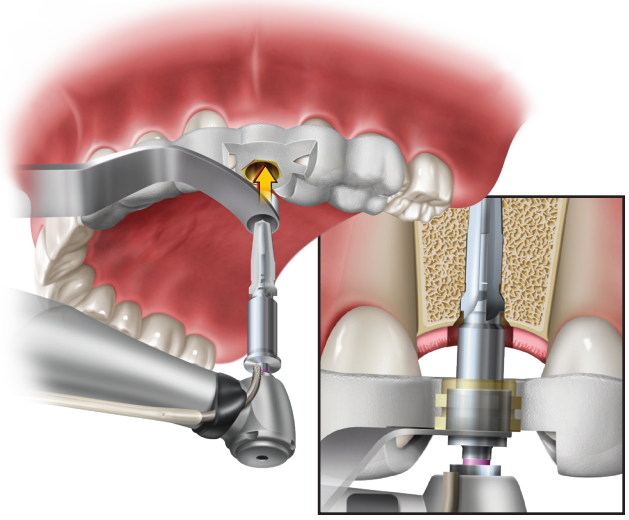
In cases of low bone density, undersizing the osteotomy can increase bone-to-implant contact by compressing the bone around the implant, thereby improving primary stability.

The surgical drills for the Ø4.3 mm and Ø3.5 mm do not share a common barrel diameter. To allow for more flexibility, the Glidewell HT Guided Surgical Kit includes a key that acts as an adapter, fitting the Ø3.5 mm drill to the Ø4.3 mm sleeve to ensure proper guidance.

The surgical drills for the Ø4.3 mm and Ø5.0 mm implants share a common barrel diameter. To undersize a Ø5.0 mm osteotomy, use the Ø4.3 mm drill sequence directly through the provided surgical guide sleeve. Although the sleeves for the Ø4.3 mm and Ø5.0 mm drills share the same diameter, they are color-coded to correspond with the respective implant diameters.

Undersizing the Osteotomy for Ø4.3 mm Glidewell HT Implant

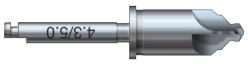




■ Osteotomy Site Preparation

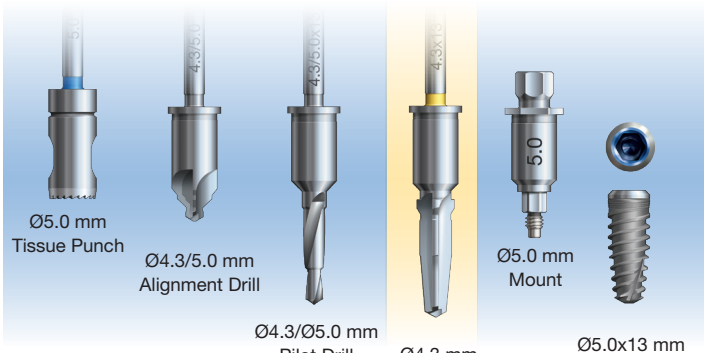
Step 1: Alignment Drill

Select the Alignment Drill with a diameter matching that of the implant. With copious irrigation, perforate the alveolar crest, creating a purchase point.



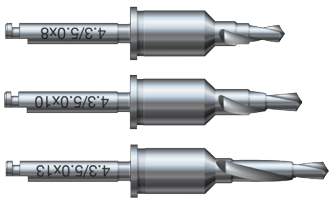
Alignment Drill Ø4.3/5.0 mm

Undersizing the Osteotomy for Ø5.0 mm Glidewell HT Implant



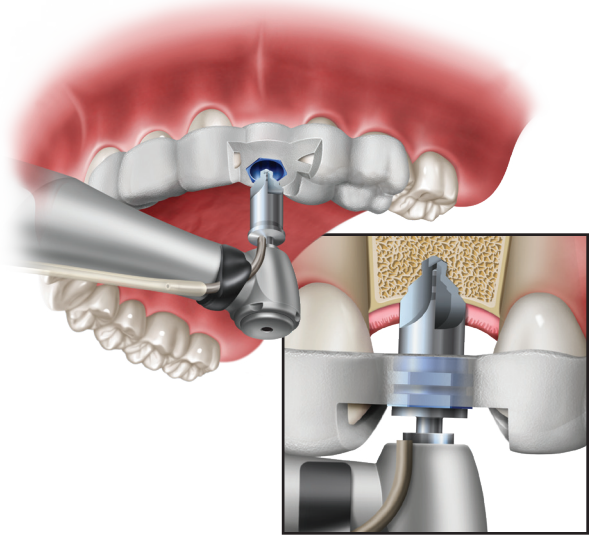
Step 2: Pilot Drill (for Ø3.0 mm – Ø5.0 mm Implants)

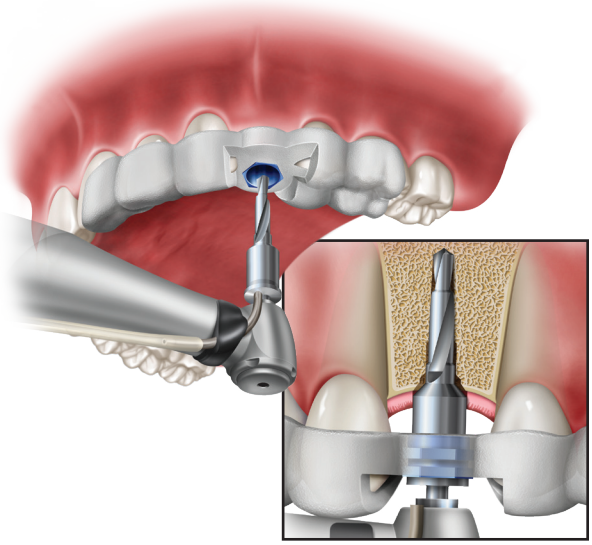
If placing a Glidewell HT Implant that is 3.0 mm in diameter or greater, Pilot Drills are used to deepen the osteotomy. Each Pilot Drill is labeled according to the diameter of implant for which it is intended to be used. Pilot Drills are available in three lengths: 8 mm, 10 mm and 13 mm for Ø3.5 mm – Ø5.0 mm Implants. For Ø3.0 mm Implants, the pilot drill is only available in 8 mm. Select the appropriate Pilot Drill, accounting for the size of the implant to be placed, taking care not to exceed the length of the implant. If placing an implant that is 8 mm in length, the 8 mm Pilot Drill should be used. If placing an implant that is 10 mm or 11.5 mm in length, the 10 mm Pilot Drill should be used. If placing an implant that is 13 mm or 16 mm in length, the 13 mm Pilot Drill should be used. Except for the Ø3.0 mm Implant size, the 8 mm Pilot Drill should be used for implant lengths ranging from 11.5 mm to 16 mm. With copious irrigation, drill a pilot hole to depth.



Pilot Drill	Implant Length
8 mm	8 mm
10 mm	10 mm and 11.5 mm
13 mm	13 mm and 16 mm

Pilot Drills Ø4.3/5.0 mm



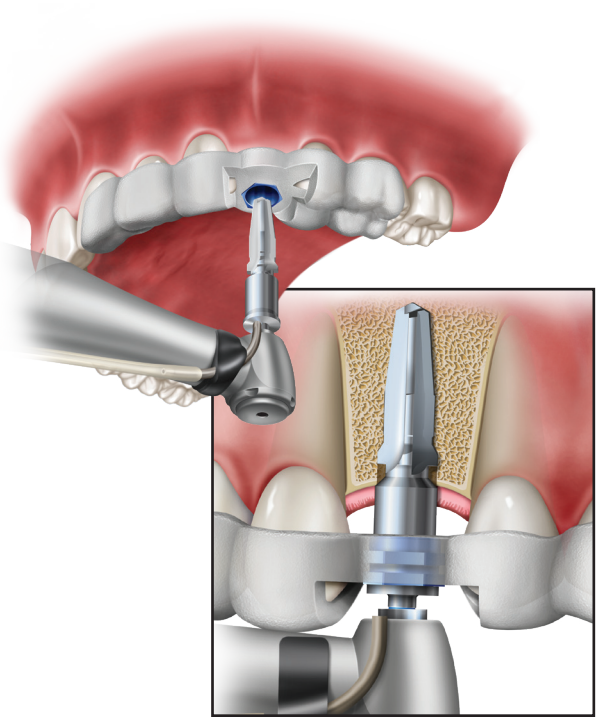


Step 3: Shaping Drill

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

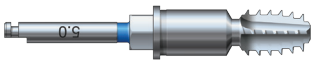
Select the appropriate Shaping Drill, taking care not to exceed the length of the implant. With copious irrigation, drill to depth. The drill should correspond with the matching implant size, with the goal of achieving high primary stability upon implant placement.

Shaping Drills Ø5.0 mm



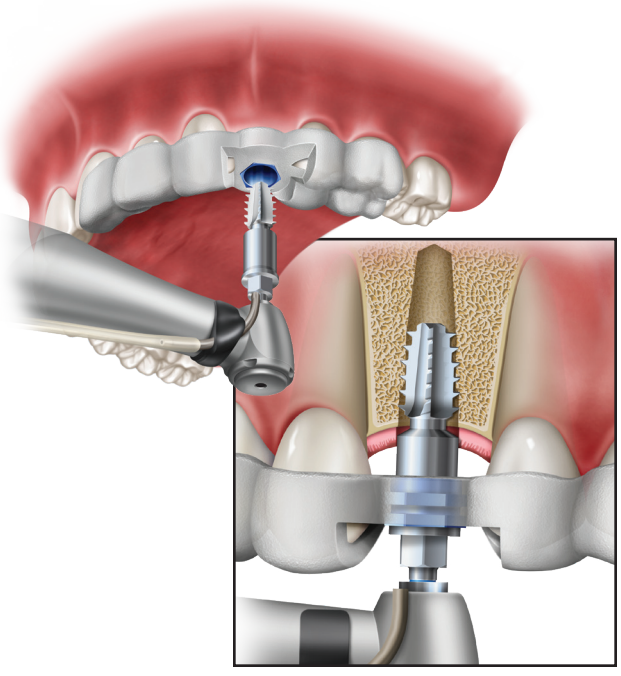
Step 4: (Optional) Screw Tap

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. Reverse the tap out of the site. **Do not pull the tap out of the site.**



Screw Tap Ø5.0 mm

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



SURGICAL PROTOCOL

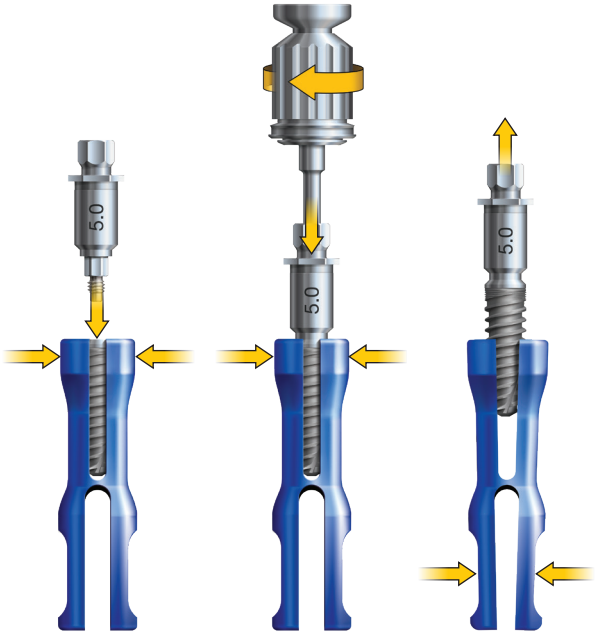
■ Implant Placement

Step 1: Implant Selection

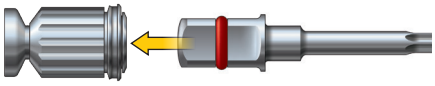
Remove the titanium implant holder from its packaging and place it onto a sterile field.

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

Engage the implant connection with the appropriate Implant Mount. Using the Driver Handle and Prosthetic Driver, fasten the assembly using the screw captured in the Implant Mount. With the implant securely attached to the mount, squeeze the opposing end of the holder to disengage the implant from the holder.



Implant Mount



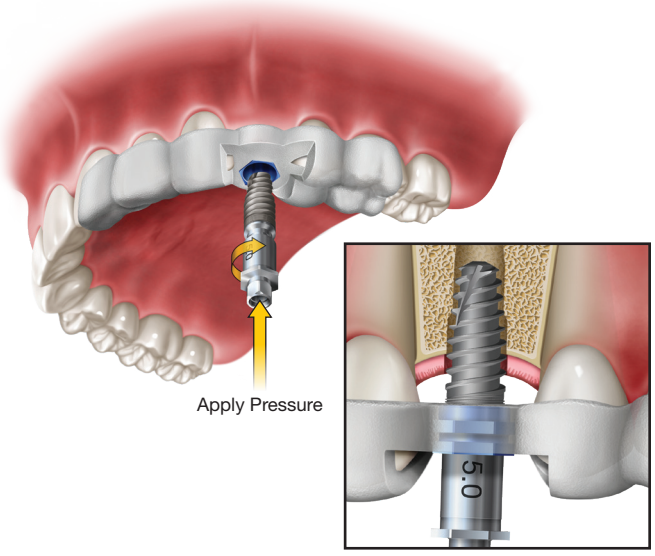
Driver Handle, Square Prosthetic Driver - 18 mm

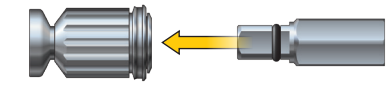
Step 2: Initial Placement

Using fingers, transport the implant to the prepared site and then insert it through the guide and into the osteotomy. Rotate clockwise with applied pressure to engage the self-tapping grooves.

Step 3: Advancement and Final Seating

Assemble the Torque Wrench with the Surgical Adaptor. With the implant secured to the Implant Mount, seat the adaptor atop the mount and engage the connection. Turn the wrench clockwise in increments of approximately 90 degrees. Continue threading the implant into the osteotomy site until the hex flange on the Implant Mount meets the hex of the guide sleeve.





Driver Handle, Square Surgical Adaptor, Long

Torque Wrench

Adjust the final position of the implant by aligning the hex on the Implant Mount with the hex of the guide sleeve. This will allow the restoring clinician to take full advantage of the anatomical abutment contours and minimize the need for abutment preparation. Refer to the recommended Torque Values in the table below. A minimum torque value upon final seating indicates good primary stability.

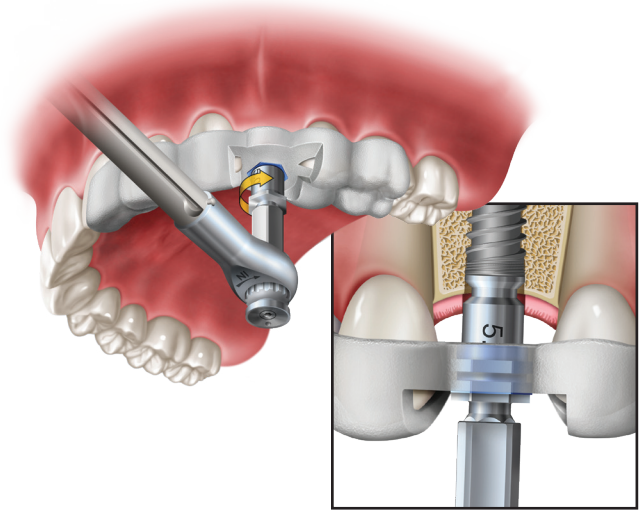
Torque Value

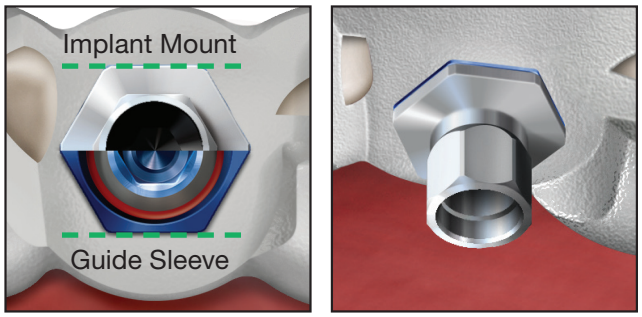
Diameter	Minimum	Maximum
3.0 mm	15 Ncm	35 Ncm
3.5 mm	35 Ncm	
4.3 mm	35 Ncm	
5.0 mm	35 Ncm	

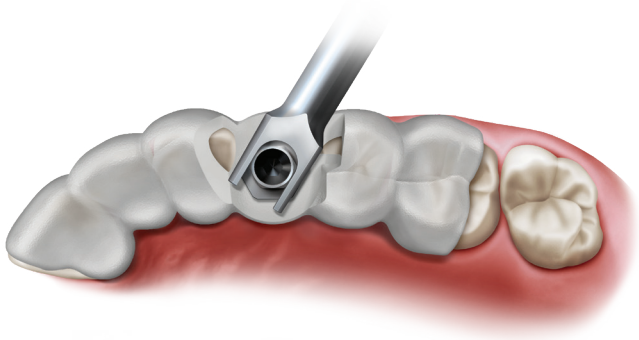
NOTE: The Mount Wrench may be used to make fine adjustments. Do not rotate after the flange on the Implant Mount fully meets the guide sleeve and the corresponding hexes are aligned. Doing so may cause the osteotomy to strip.

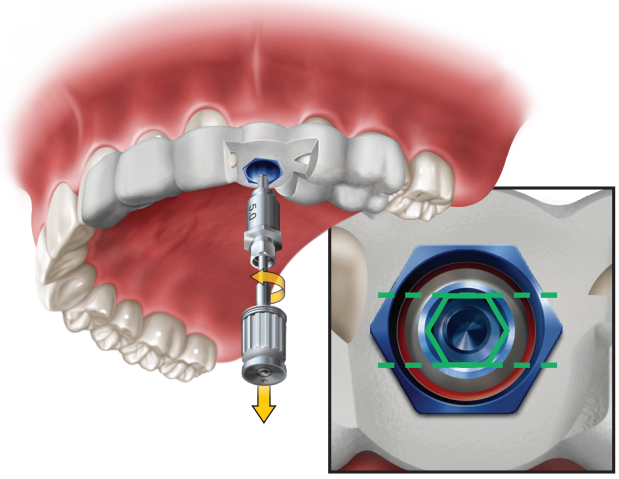
Mount Wrench

Following implant placement, ensure that the flats of the Implant Mount and guide sleeve are aligned. Remove the Implant Mount by unscrewing it from the the implant, utilizing the Driver Handle and Prosthetic Driver. After loosening the screw of the Implant Mount, use the Mount Wrench to disengage the Implant Mount using a gentle rocking motion. Then remove the surgical guide. Prepare the site for healing by placing either a provisional restoration (single-stage surgical protocol), a Healing Abutment (single-stage surgical protocol) or the Cover Screw (two-stage surgical protocol).









SURGICAL PROTOCOL

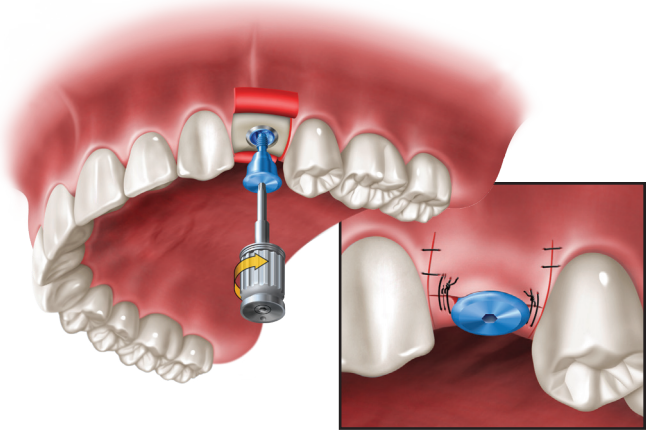
■ Healing Component Placement

Option 1: Healing Abutment

If observing a single-stage surgical protocol, select a Healing Abutment of the appropriate height and diameter. Thread the healing abutment into place atop the implant. Hand-tighten with the appropriate Prosthetic Driver.

Healing Abutment

Single-Stage Surgical Protocol

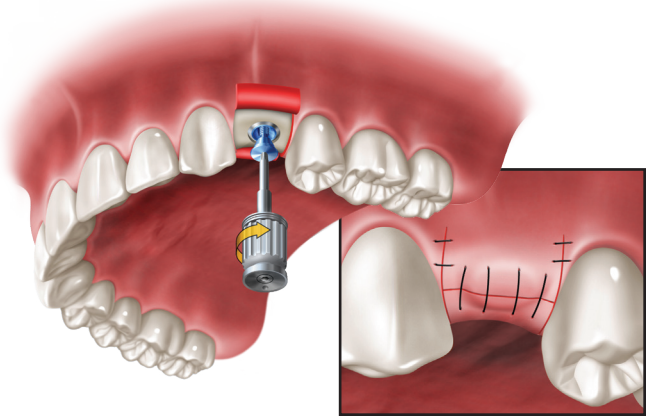


Option 2: Cover Screw

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

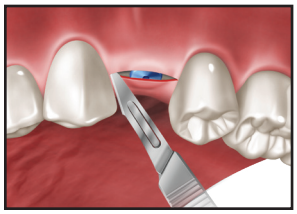
Cover Screw

Two-Stage Surgical Protocol

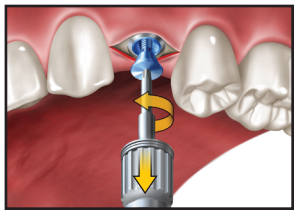


■ Closure and Suturing

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.



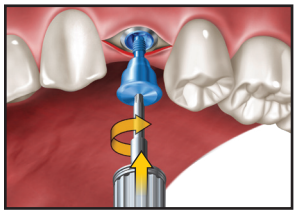
Expose the Cover Screw



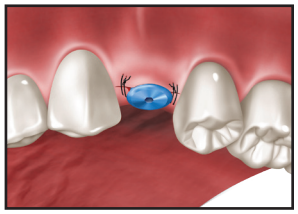
Remove the Cover Screw

■ 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 provisional restoration.



Place Healing Abutment



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

LBL-012624_1

6 Do not use if package is damaged.

10

5 Rx only

12 Prismatik Dentalcraft, Inc.
2144 Michelson Drive
Irvine, CA 92612, USA

2 YYYY-MM-DD

13 Made in USA

14

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

15

+D745701154IMP00120/$$8013251201234567/16D202012106

Ø3.0 x 11.5 mm

3 REF 70-1189-IMP0001

Glidewell HT™ IMPLANT SYSTEM

POLICIES AND WARRANTY

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.

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IMPLANT SYSTEM

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Designed & Manufactured in the USA
by

PRISMATIK DENTALCRAFT, INC.

2144 Michelson Drive • Irvine, CA 92612, USA

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