

Genesis

Surgical Manual



GENESIS IMPLANT SURGICAL MANUAL

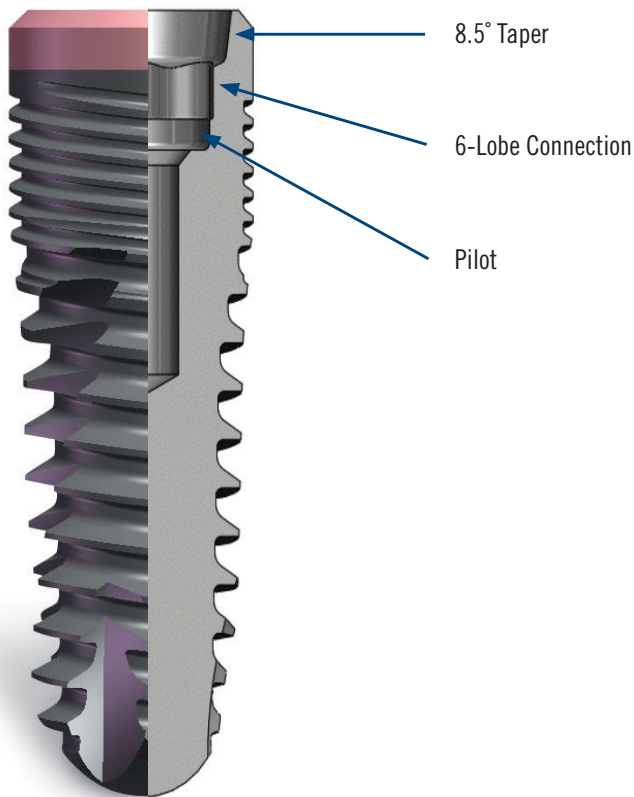
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Product specifications are subject to change without notice.
Items illustrated are not to scale.



Design Features

The Genesis dental implant features a TiLobe® connection. This internal 6-lobe connection combines the benefits of a tapered, internal lobed design and integrated pilot (self-aligning feature), providing a secure implant/abutment connection. The same Abutment Screw can be used for all implant diameters.



Dimensions

- The $\varnothing 3.5$ mm and $\varnothing 3.8$ mm Genesis implants share the same prosthetic connection.
- The $\varnothing 5.5$ mm and $\varnothing 6.5$ mm Genesis implants share the same prosthetic connection.

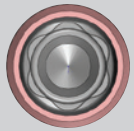
3.5 The $\varnothing 3.5$ mm tapered Genesis is available in 10, 11.5, 13 and 16 mm lengths and can be restored with 4.0 and 5.0 prosthetic components.

3.8 The $\varnothing 3.8$ mm tapered Genesis is available in 8.5, 10, 11.5, 13 and 16 mm lengths and can be restored with 4.0 and 5.0 prosthetic components.

4.5 The $\varnothing 4.5$ mm tapered Genesis is available in 8.5, 10, 11.5, 13 and 16 mm lengths and can be restored with 5.0 and 6.0 prosthetic components.

5.5 The $\varnothing 5.5$ mm tapered Genesis is available in 8.5, 10, 11.5, and 13 mm lengths and can be restored with 5.0 and 6.0 prosthetic components.

6.5 The $\varnothing 6.5$ mm tapered Genesis is available in 8.5, 10, 11.5, and 13 mm lengths and can be restored with 6.0 prosthetic components.



Considerations

INDICATIONS

The Genesis Implant System is intended for use in single-stage or two-stage surgical procedures in all types of bone in partially or fully edentulous mandibles and maxillae. The Genesis Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis implants are intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established and appropriate occlusal loading is applied.

CONTRAINDICATIONS

- Patients with uncontrolled or severe cases of hyperthyroidism, diabetes, malignancies, renal disease, liver problems, hypertension, leukemia, severe vascular heart disease, hepatitis, immunosuppressive disorders, collagen and bone diseases, or other serious illnesses
- Patients with titanium allergies
- Patients with alveolar ridge dimensions that are not sufficient to accommodate and sustain proper implant placement
- Patients with systemic, local oral, or respiratory infection

For additional information, please consult the *Genesis Implant Instructions for Use*.

SOFT TISSUE HEALING AND TEMPORIZATION

Following the placement of a Genesis implant, soft tissue can be contoured using a titanium Healing Abutment or a custom fabricated temporary abutment.

A Temporary Abutment can be placed at this time for immediate temporization. The acrylic portion of the Temporary Abutment bonds with dental composite/acrylic allowing for custom esthetic contouring directly to the Temporary Abutment.

PATIENT EVALUATION AND SELECTION

Successful implant treatment requires the coordinated efforts of the implanting surgeon, the restorative dentist, and the dental laboratory technician. Proper patient selection is important for long-term function of a dental implant. The following factors should be considered prior to implant surgery:

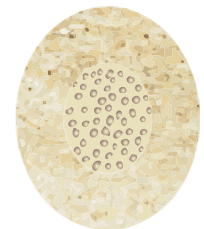
- General medical history
- Oral hygiene
- Patient's expectations
- General dentistry and product indications and contraindications
- Anatomical landmarks related to implant positioning
- Inter-occlusal clearance (the space available between alveolar crest and opposing dentition)
- Ridge width in relation to the implant diameter
- Emergence profile of the restoration in relation to prosthetic platform diameters

BONE QUALITY

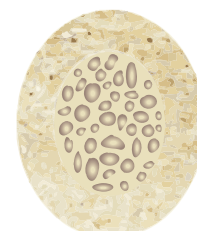
While one method of classifying bone density is shown in the images below, different combinations of cortical and trabecular bone in varying thicknesses and densities can occur. These typically differ by jaw location. The clinician is responsible for assessing bone density of the surgical site and choosing the appropriate protocol.



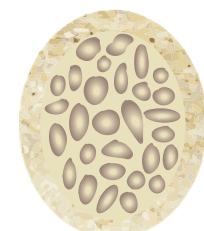
D1 Bone
Cortical bone



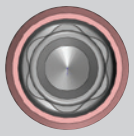
D2 Bone
Cortical bone/trabecular



D3 Bone
Cortical bone/trabecular



D4 Bone
Cortical bone/trabecular



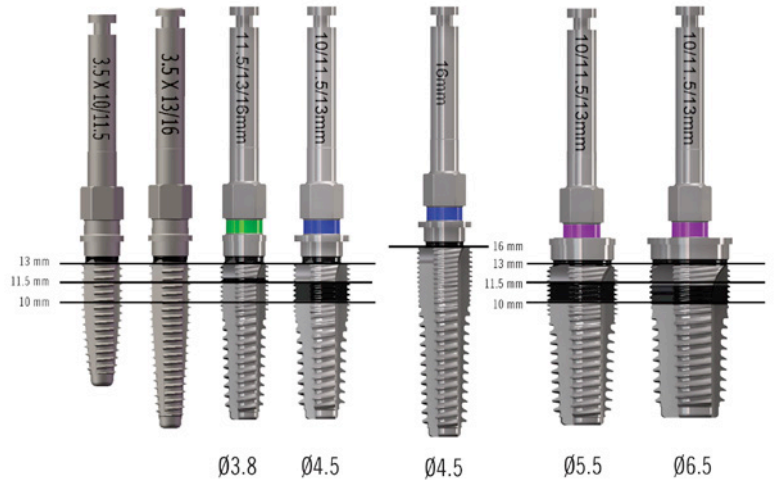
Surgical Guide

Available planning software provides both clinicians and technicians the ability to plan implant placement three-dimensionally in conjunction with CT scans. A surgical guide could aid in the site preparation and placement of implants.

Tapping Procedure

Tapping is essential when placing a Genesis implant in dense bone. Without tapping, the insertion torque will increase making it difficult to seat the implant. Refer to the drill and tap sequences on pages 11-13 for tapping recommendations.

Surgical Taps Laser Marking



Implant Selection

Implant selection should be made with the final restorative result as the primary consideration.

Selecting implants in this manner aids in maximizing biomechanical stability and proper contouring of the soft tissue. Choosing an implant with a slightly smaller platform than the emergence of the tooth being replaced will provide support of the soft tissue and optimize the esthetic result.

Implant placement and healing abutment selections should be based on the following:

- Emergence profile of the restoration in relation to the prosthetic platform diameter
- Height and diameter of the crown as it emerges through the tissue

Implant selection can also be completed with the use of sizing overlays. Transparent implant sizing overlays (100% and 125% magnification) are available.



Surgical Kit

The Surgical Kit must be cleaned and sterilized prior to use. For further information, please consult Keystone Dental's *Instructions for Use*.

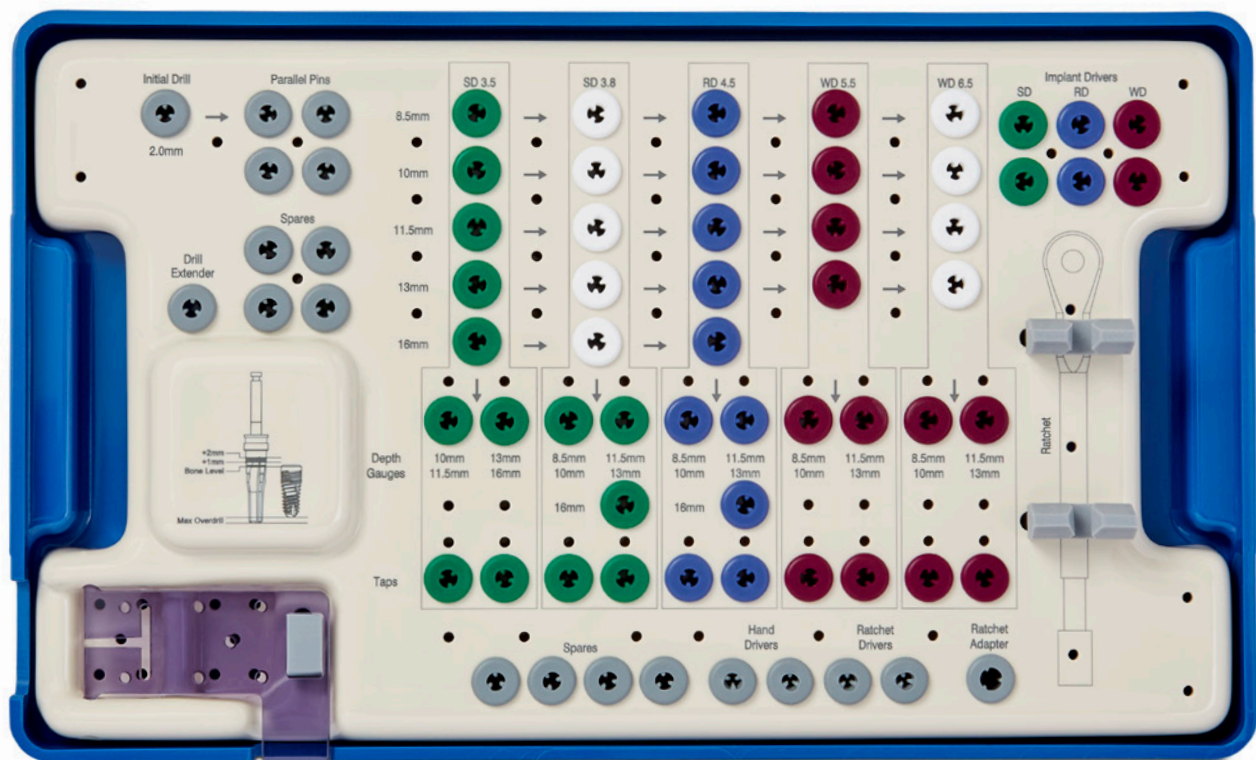
- All surgical instruments are provided non-sterile.
- All drills are non-irrigated and require external irrigation when preparing the osteotomy.
- All drills must be inspected for signs of wear, damage or discoloration.

The drill markings and color-coding facilitate proper instrument selection. It is recommended to inspect the latch-lock shank after each use. Surgical instruments are susceptible to damage and wear and should be inspected before use. The number of uses per drill will vary and depends on a variety of factors including bone density, proper handling and cleaning. It is recommended to replace drills after 20 osteotomies, as repeated sterilizations and use may affect cutting efficiency and color appearance.

Drilling and Tapping Procedures

The Final Drills are designed to collect bone. During surgery, it is recommended to remove the collected bone from the drill before proceeding to the final depth marking. This will reduce the downward force applied to the handpiece.

- In certain instances, tapping is required (see Surgical Sequence, Step 8). Depending on bone density, a maximum tapping speed of 20-50 rpm is recommended.
- It is recommended to avoid lateral pressure during drilling and tapping procedures as the resulting osteotomy may be oversized and/or redirected.
- When using the Final Drills, it is not recommended to use an in-and-out technique as this may inadvertently enlarge the site.





Instrument Care

Instruments must be cleaned and sterilized prior to first and after each use based on established procedures. Proper instrument care is an important part of successful implant dentistry.

PRE-CLEANING

- Used instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva and tissue residue.
- Used surgical trays including grommets must be cleaned with a suitable disinfectant.
- Multiple-part instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue of instruments must be removed with a soft brush.
- Instruments should be inspected, cleaned separately and discarded if damaged.

PRINCIPLE CLEANING

- Best results are achieved if surgical instruments are cleaned by material type.
- Instruments and trays can be cleaned and disinfected in a dedicated dishwasher or alternatively by hand, followed by an ultrasonic bath with a detergent appropriate for surgical instruments.
- Instruments and trays must be rinsed and dried thoroughly.

STERILIZATION

Instruments and tray should be autoclaved with a sufficient drying cycle to avoid instrument corrosion. Instruments should be placed in the tray and wrapped in sterilization paper or sterilization packs featuring indicating tape and date of sterilization.

- Steam Sterilization Gravity Cycle: 134°C (~273°F)
20 minute exposure / 40 minute dry time
- Steam Sterilization Pre Vacuum Cycle: 134°C (~273°F)
4 minute exposure / 40 minute dry time

SURGICAL MOTOR AND HANDPIECE

Cleaning and maintenance instructions for W&H handpieces and motors can be found on www.wh.com.

Implant Packaging

Each Genesis implant is gamma-sterilized, packaged in a vial, sealed in a tray with a Tyvek® lid. The flip-open lid on the vial contains a cover screw. The sealed tray contains a label identifying the implant type, diameter and length, as well as other important device information. Inside, pre-printed patient labels with product data and the lot number are provided. These are adhesive labels that should be affixed to the patient's chart.

Opening instructions:

1. The Tyvek lid on the tray is peeled back and placed into the sterile field.
2. The patient labels are affixed to the patient's chart.
3. The implant lid is flipped open to gain access to the selected Genesis implant.

The implant may now be removed from the vial, delivered to the site and placed using one of the following options.

Implant Delivery

The implant is delivered to the osteotomy with an Implant Driver.

- The Implant Driver is aligned with the implant. While pressure is applied, the Implant Driver is rotated at a speed less than 20 rpm until the lobes of the Implant Driver engage the implant lobes. A tactile and/or audible click may occur indicating the Implant Driver is engaged. The implant is lifted out of the vial and placed into the osteotomy.
- The Implant Driver is pulled straight up to disengage the Implant Driver from the implant. Special care should be taken in very soft bone to not disrupt primary stability.

Depending on the clinical situation and accessibility, two different Implant Drivers are available. The Implant Driver/latch type can be used with a surgical motor, a Surgical Ratchet or a Surgical Hand Driver. For limited inter-occlusal clearance, a direct-to-ratchet Implant Driver is available.

Implant Placement

The final implant position is at the discretion of the surgeon. Each case should be evaluated on the basis of placement, protocol and type of implant prior to osteotomy preparation. It is recommended to place a Genesis implant at bone level.

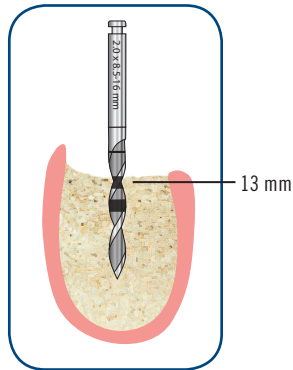


Surgical Sequence - Genesis Ø4.5 mm x 13 mm

(For demonstration purposes)

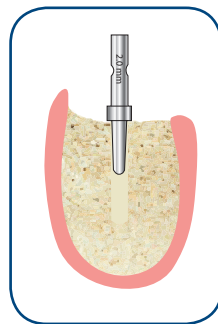
Step 1

An incision of the appropriate design is made and the flap elevated. The Ø2.0 mm Initial Drill has markings at lengths of 8.5, 10, 11.5, 13 and 16 mm and should be inserted to the required depth, at 1200-1500 rpm.



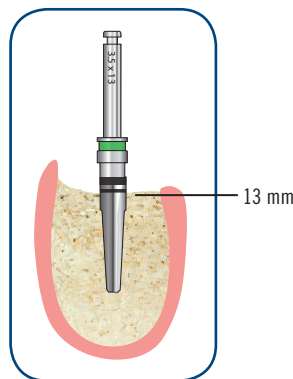
Step 2

The proper position of the osteotomy is verified with the Parallel Pin. It is recommended to thread floss through the opening of the Parallel Pin to ensure retrieval if dislodged.



Step 3

The osteotomy is further widened with a Ø3.5 mm Final Tapered Drill to the required depth, at 600-800 rpm.

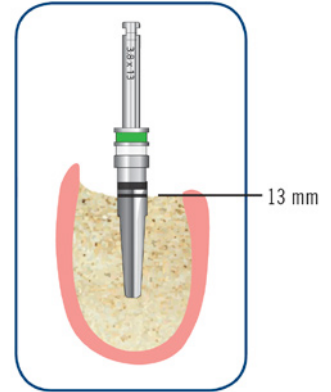


Step 4 (Optional)

At this point the osteotomy is cleared of bone debris and optionally, the Ø3.5 mm Implant Depth Gauge can be inserted.

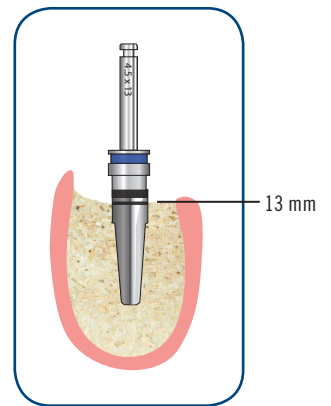
Step 5 (Optional)

Again, the osteotomy is widened with a Ø3.8 mm Final Tapered Drill to the required depth, at 600-800 rpm. A Ø3.8 mm Implant Depth Gauge can be placed for verification of the osteotomy.



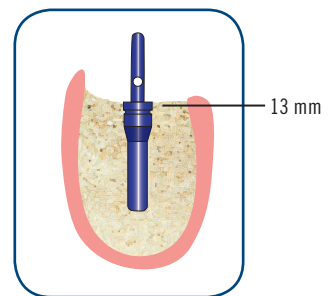
Step 6

Then the osteotomy is further widened with the Ø4.5 mm Final Tapered Drill at 600-800 rpm.



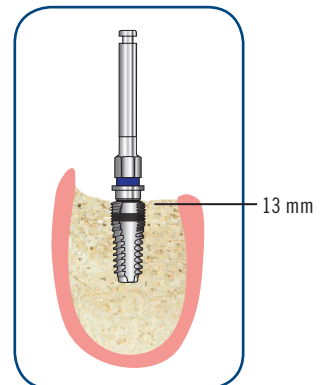
Step 7

The osteotomy is cleared of bone debris and the Ø4.5 mm Implant Depth Gauge is inserted. It is recommended to verify the proper osteotomy depth with a radiograph.



Step 8

In bone quality D1 and D2, it is recommended to use a Surgical Tap to finalize the osteotomy. In this case, a Ø4.5 mm Surgical Tap is inserted with slight pressure at 20-50 rpm to the appropriate depth. The Surgical Tap is then removed by reversing the rotation.

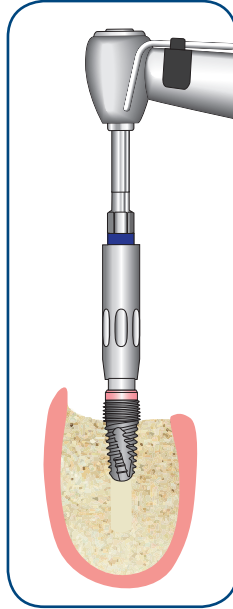




Step 9

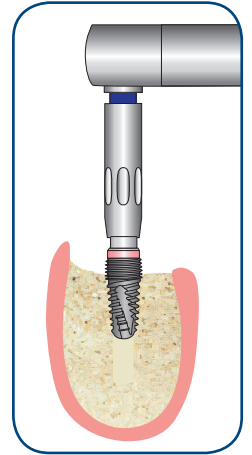
Handpiece Insertion

With the Implant Driver connected to the handpiece, the internal lobes are fully engaged by the Implant Driver and carefully removed from the vial. It is then carried to the osteotomy and inserted at 15-20 rpm.



Ratchet Insertion

The Surgical Ratchet can be used in addition or instead of a handpiece to finalize the insertion of the implant by engaging the Implant Driver into the Ratchet.

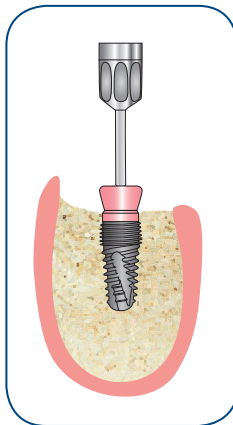


NOTE: Depending on bone quality and osteotomy preparation, the insertion torque may vary from 20-60 Ncm.

Step 10

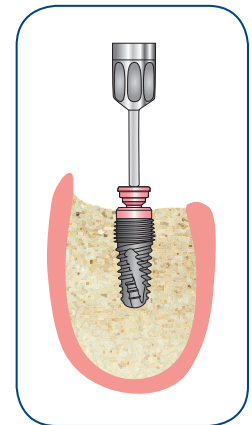
Single-Stage Surgery

In a single-stage surgery the healing abutment is placed with a Quad Driver to help contour the soft tissue during the healing phase. The flap margins are positioned around the Healing Abutment and sutured in a tension-free manner.



Two-Stage Surgery

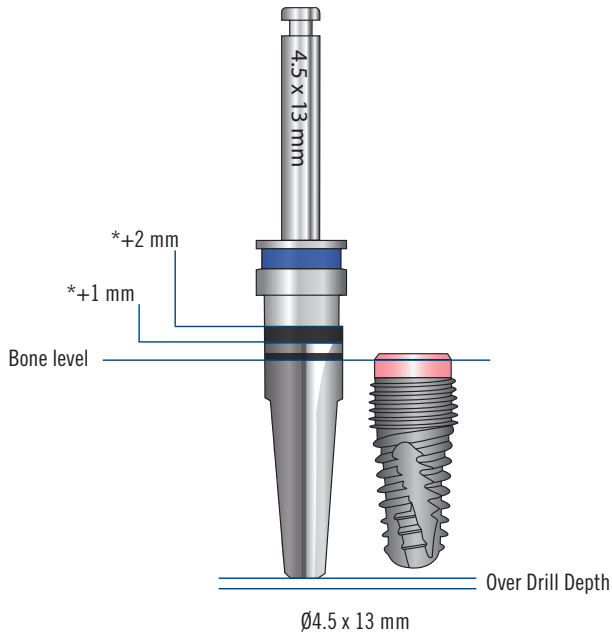
In a two-stage surgery the Cover Screw is placed with a Quad Driver and the flap margins are repositioned and sutured in a tension-free manner.





Depth Markings

Genesis Drilling Sequence $\varnothing 4.5 \times 13 \text{ mm}$



*The Genesis implant drills feature the following laser markings:

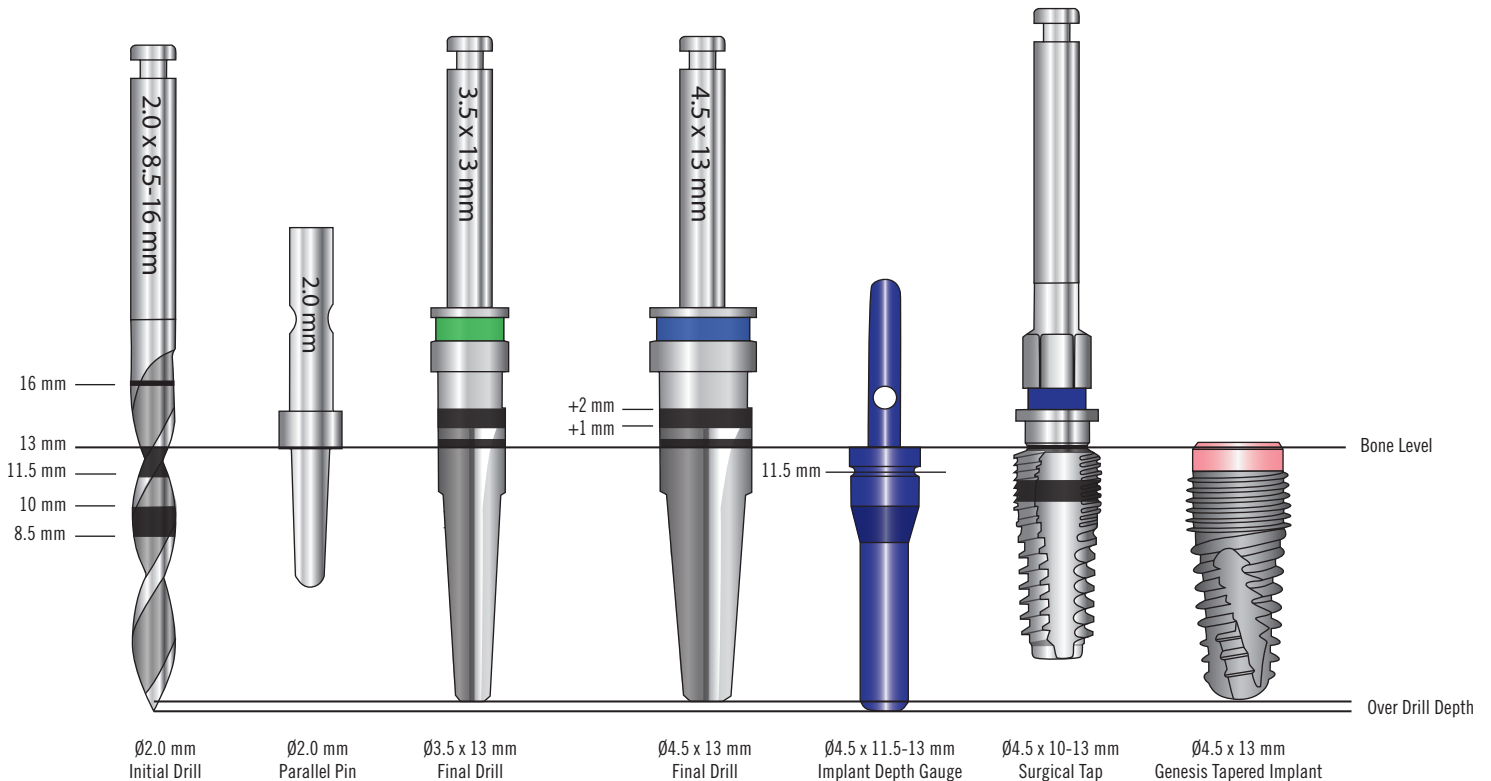
- Thin laser mark represents implant length
- Bottom of thick laser mark represents implant length + 1 mm sub-crestal
- Top of thick laser mark represents implant length + 2 mm sub-crestal

The actual drill tip is not included in the designated drill length and must be considered when preparing the osteotomy.

Final Drills	Over Drill Depth
$\varnothing 3.5 \text{ mm}$ Tapered Final Drills	+1.29 mm
$\varnothing 3.8 \text{ mm}$ Tapered Final Drills	+1.35 mm
$\varnothing 4.5 \text{ mm}$ Tapered Final Drills	+1.45 mm
$\varnothing 5.5 \text{ mm}$ Tapered Final Drills	+1.45 mm
$\varnothing 6.5 \text{ mm}$ Tapered Final Drills	+1.95 mm

Depth Markings

Genesis Drilling Sequence $\varnothing 4.5 \times 13 \text{ mm}$





DRILLING SEQUENCE

Implant Length	Ø3.5 Drilling Sequence				
10 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 10 mm Final Drill	→ 3.5 mm Depth Gauge	→ 3.5 mm Tap
11.5 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 11.5 mm Final Drill	→ 3.5 mm Depth Gauge	→ 3.5 mm Tap
13 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 13 mm Final Drill	→ 3.5 mm Depth Gauge	→ 3.5 mm Tap
16 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 16 mm Final Drill	→ 3.5 mm Depth Gauge	→ 3.5 mm Tap

Implant Length	Ø3.8 Drilling Sequence					
8.5 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 8.5 mm Final Drill	→ 3.8 x 8.5 mm Final Drill	→ 3.8 mm Depth Gauge	
10 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 10 mm Final Drill	→ 3.8 x 10 mm Final Drill	→ 3.8 mm Depth Gauge	
11.5 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 11.5 mm Final Drill	→ 3.8 x 11.5 mm Final Drill	→ 3.8 mm Depth Gauge	→ 3.8 mm Tap
13 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 13 mm Final Drill	→ 3.8 x 13 mm Final Drill	→ 3.8 mm Depth Gauge	→ 3.8 mm Tap
16 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 16 mm Final Drill	→ 3.8 x 16 mm Final Drill	→ 3.8 mm Depth Gauge	→ 3.8 mm Tap

Implant Length	Ø4.5 Drilling Sequence					
8.5 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 8.5 mm Final Drill	→ 4.5 x 8.5 mm Final Drill	→ 4.5 mm Depth Gauge	
10 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 10 mm Final Drill	→ 4.5 x 10 mm Final Drill	→ 4.5 mm Depth Gauge	→ 4.5 mm Tap
11.5 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 11.5 mm Final Drill	→ 4.5 x 11.5 mm Final Drill	→ 4.5 mm Depth Gauge	→ 4.5 mm Tap
13 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 13 mm Final Drill	→ 4.5 x 13 mm Final Drill	→ 4.5 mm Depth Gauge	→ 4.5 mm Tap
16 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 16 mm Final Drill	→ 4.5 x 16 mm Final Drill	→ 4.5 mm Depth Gauge	→ 4.5 mm Tap



Implant Length	Ø5.5 Drilling Sequence						
8.5 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 8.5 mm Final Drill	→ 4.5 x 8.5 mm Final Drill	→ 5.5 x 8.5 mm Final Drill	→ 5.5 mm Depth Gauge	→ 5.5 mm Tap
10 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 10 mm Final Drill	→ 4.5 x 10 mm Final Drill	→ 5.5 x 10 mm Final Drill	→ 5.5 mm Depth Gauge	→ 5.5 mm Tap
11.5 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 11.5 mm Final Drill	→ 4.5 x 11.5 mm Final Drill	→ 5.5 x 11.5 mm Final Drill	→ 5.5 mm Depth Gauge	→ 5.5 mm Tap
13 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 13 mm Final Drill	→ 4.5 x 13 mm Final Drill	→ 5.5 x 13 mm Final Drill	→ 5.5 mm Depth Gauge	→ 5.5 mm Tap

Implant Length	Ø6.5 Drilling Sequence							
8.5 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 8.5 mm Final Drill	→ 4.5 x 8.5 mm Final Drill	→ 5.5 x 8.5 mm Final Drill	→ 6.5 x 8.5 mm Final Drill	→ 6.5 mm Depth Gauge	→ 6.5 mm Tap
10 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 10 mm Final Drill	→ 4.5 x 10 mm Final Drill	→ 5.5 x 10 mm Final Drill	→ 6.5 x 10 mm Final Drill	→ 6.5 mm Depth Gauge	→ 6.5 mm Tap
11.5 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 11.5 mm Final Drill	→ 4.5 x 11.5 mm Final Drill	→ 5.5 x 11.5 mm Final Drill	→ 6.5 x 11.5 mm Final Drill	→ 6.5 mm Depth Gauge	→ 6.5 mm Tap
13 mm	2.0 Initial Drill	→ Parallel Pin	→ 3.5 x 13 mm Final Drill	→ 4.5 x 13 mm Final Drill	→ 5.5 x 13 mm Final Drill	→ 6.5 x 13 mm Final Drill	→ 6.5 mm Depth Gauge	→ 6.5 mm Tap

Tap Protocol:

D1 & D2 – Required

D3 – Clinicians Discretion

D4 – Not recommended



NOTE: When placing a Ø4.5 mm or larger implant, the 3.8 mm Final Drills may not be necessary. Use of Implant Depth Gauges is optional until the Final Drill for the diameter of implant being placed.



Keystone Dental, Inc.

5 Holland, Building 209
Irvine, CA 92618 USA

Keystone Dental, Inc.

Global Headquarters

154 Middlesex Turnpike
Burlington, MA 01803 USA
General Inquiries: 781-328-3600
Customer Relations: 866-902-9272 or 781-328-3490
Fax: 866-903-9272 or 781-328-3400
Email: info@keystonedental.com



EMERGO Europe B.V

Prinsessgracht 20
2514 AP The Hague
The Netherlands



0086 Caution, consult accompanying documents

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