Keystone

GENESIS

SURGICAL MANUAL

GENESIS OVER 10 YEARS OVER A DECADE OF CLINICAL EXCELLENCE

GENESIS

A KeystoneDentalGroup Brand

GEN

ESIS

SCIENCE MEETS AESTHETICS


GENESIS
SURGICAL KIT

CONTENTS

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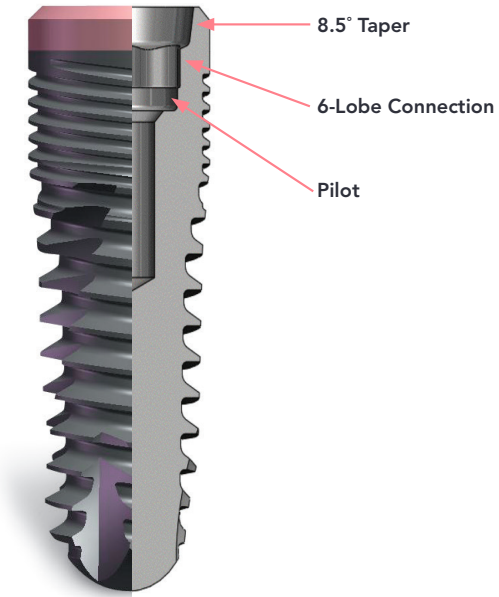
Product specifications are subject to change without notice.
Items illustrated are not to scale.

IMPLANT CHARACTERISTICS

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 Ø 3.5 mm and Ø 3.8 mm Genesis implants share the same prosthetic connection.

The Ø 5.5 mm and Ø 6.5 mm Genesis implants share the same prosthetic connection.

The Ø 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.

The Ø 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.

The Ø 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.

The Ø 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.

The Ø 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.

SURGICAL CONSIDERATIONS

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.

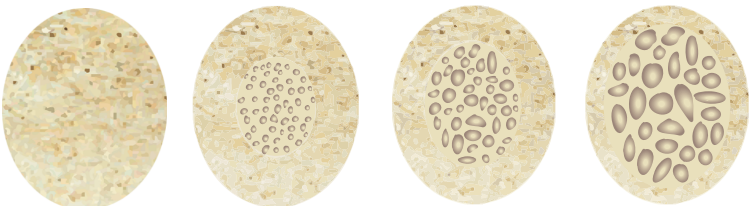
PATIENT EVALUATION AND SELECTION

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 26-27 for tapping recommendations.

IMPLANT SELECTION

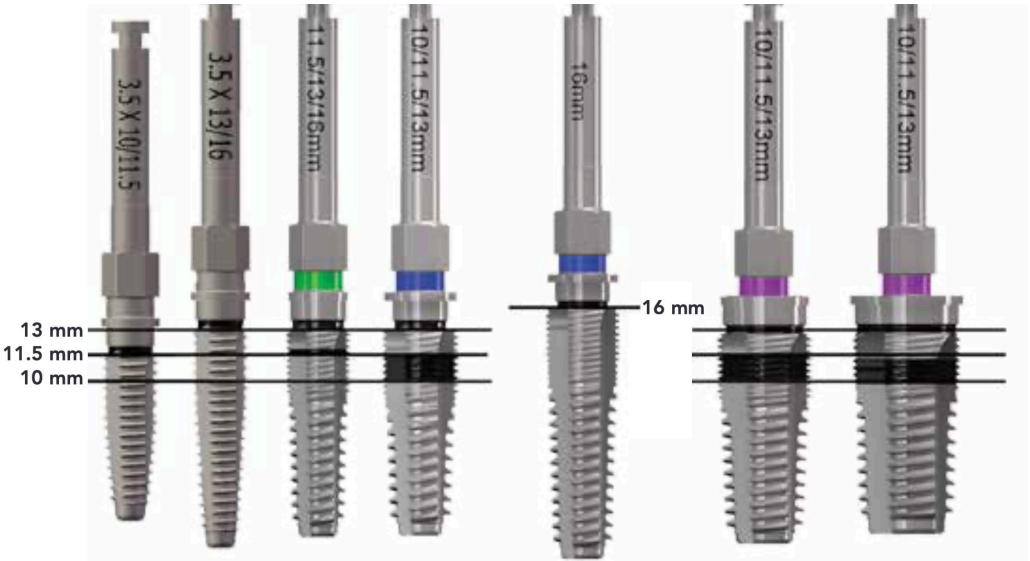
Implant selection should be made with the final restorative result as the primary consideration.

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 TAPS LASER MARKING



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.

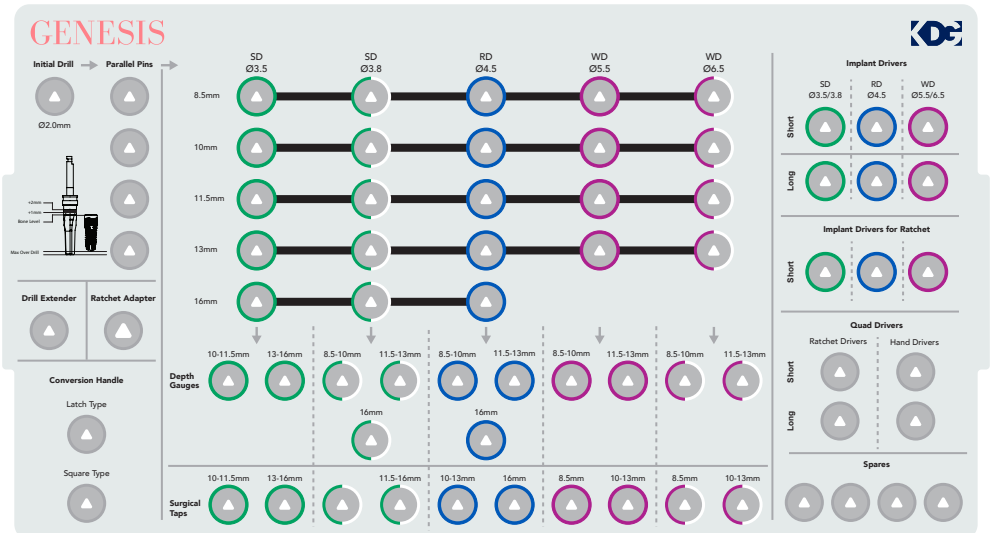
The drill markings and color-coding facilitate proper instrument selection. It is recommended to inspect the latch-lock shank after each use. Surgical instruments are susceptible to damage and wear and should be inspected before use. The number of uses per drill will vary and depends on a variety of 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.

SURGICAL KIT



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. Automated washers should not be used as it may reduce the life of the instruments.

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 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.

STERILIZATION (CONT)

- 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

Genesis implants are delivered sterile. The intact sterile packaging protects the gamma-sterilized implant from outside influences and, if stored correctly, ensures sterility up to the expiration date. When removing the implant from the sterile packaging, the rules of asepsis must be observed. The sterile packaging must not be opened until immediately prior to insertion of the implant. Implants with damaged sterile packaging must not be used due to risk of contamination. It is recommended to have a replacement implant on hand.

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.

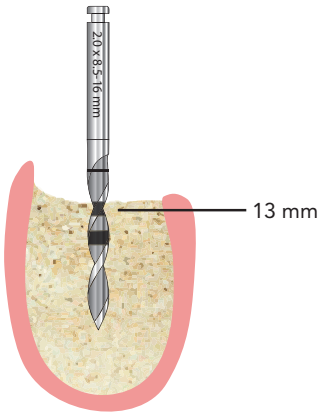
SURGICAL SEQUENCE

Genesis Ø 4.5 mm x 13 mm

(For demonstration purposes)

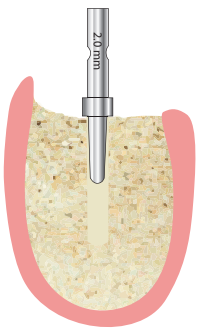
Step 1

An incision of the appropriate design is made and the flap elevated. The Ø 2.0 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.



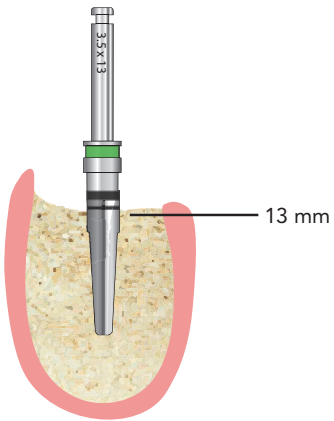
Step 2

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



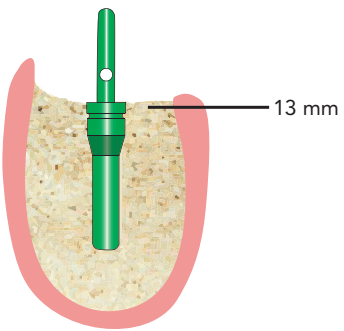
Step 3

The osteotomy is further widened with a Ø 3.5 mm Final Tapered Drill to the required depth, at 600-800 rpm.



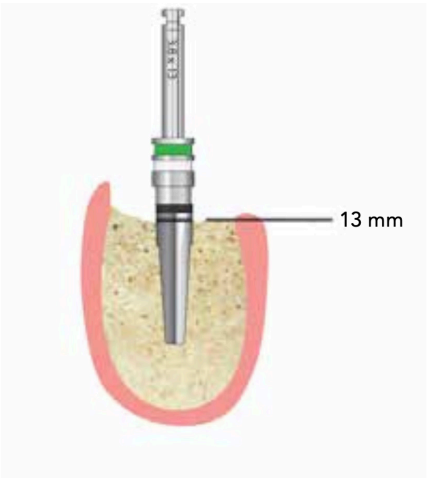
Step 4 (Optional)

At this point the osteotomy is cleared of bone debris and optionally, the Ø 3.5 mm Implant Depth Gauge can be inserted.



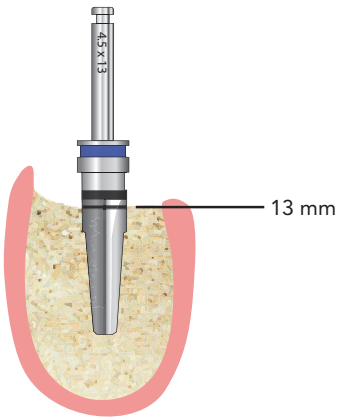
Step 5 (Optional)

Again, the osteotomy is widened with a Ø 3.8 mm Final Tapered Drill to the required depth, at 600-800 rpm. A Ø 3.8 mm Implant Depth Gauge can be placed for verification of the osteotomy.



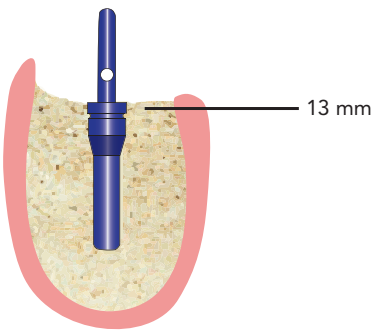
Step 6

Then the osteotomy is further widened with the Ø 4.5 mm Final Tapered Drill at 600-800 rpm.



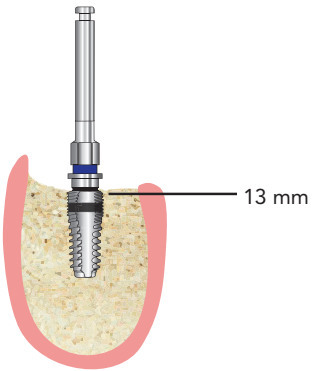
Step 7

The osteotomy is cleared of bone debris and the Ø 4.5 mm Implant Depth Gauge is inserted. It is recommended to verify the proper osteotomy depth with a radiograph.



Step 8

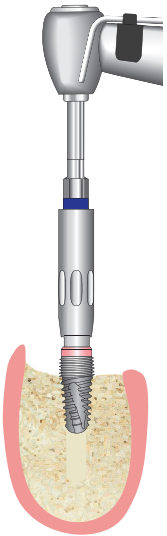
In bone quality D1 and D2, it is recommended to use a Surgical Tap to finalize the osteotomy. In this case, a Ø 4.5 mm Surgical Tap is inserted with slight pressure at 20-50 rpm to the appropriate depth. The Surgical Tap is then removed by reversing the rotation.



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.



The Genesis® implant is packaged in an outer vial with shrink wrap. This outer vial holds an inner titanium sleeve and inner cap with the implant and cover screw. The implant only comes in contact with the sleeve or cover screw. Remove the implant from the vial just prior to implant placement. To maintain the sterility of the products, remove from the outer vial in the following manner.

Step 10

Non-sterile dental assistant removes the plastic shrink packaging from the vial.

Non-sterile dental assistant grasps the outervial and opens the sealed cap by twisting in the counter-clockwise direction and lifting the cap away. The assistant removes the outer vial cap, without touching the inner sleeve and cap.

Step 11

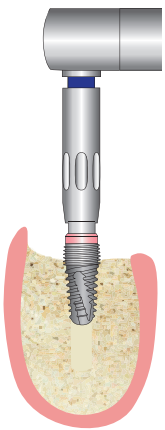
Assistant tips the outer vial so that the inner sleeve and cap fall onto the sterile surgical field (tray); the implant is protected by the sleeve. Clinician (sterile) grips the inner sleeve and does not come into contact with the outer vial.

Clinician removes the inner plastic cap and places it on the surgical field with the plastic side down and the cover screw side up.

Step 12

RATCHET INSERTION

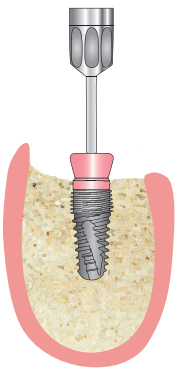
The Surgical Ratchet can be used in addition or instead of a handpiece to finalize the insertion of the implant by engaging the Implant Driver into the Ratchet.



Step 13

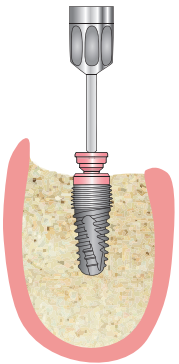
SINGLE-STAGE SURGERY

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



DEPTH MARKINGS

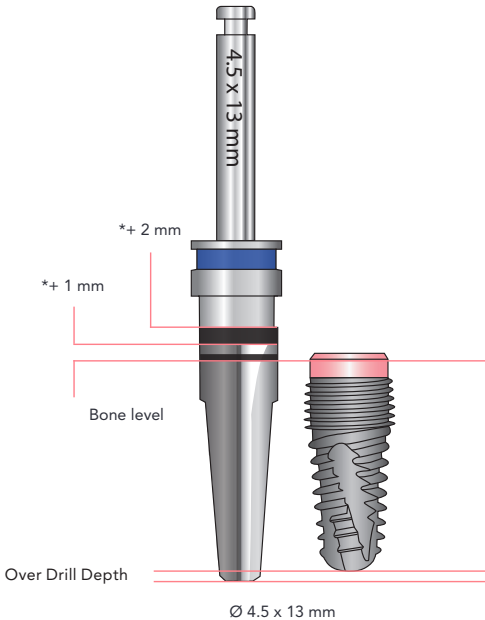
GENESIS Drilling Sequence Ø 4.5 x 13 mm

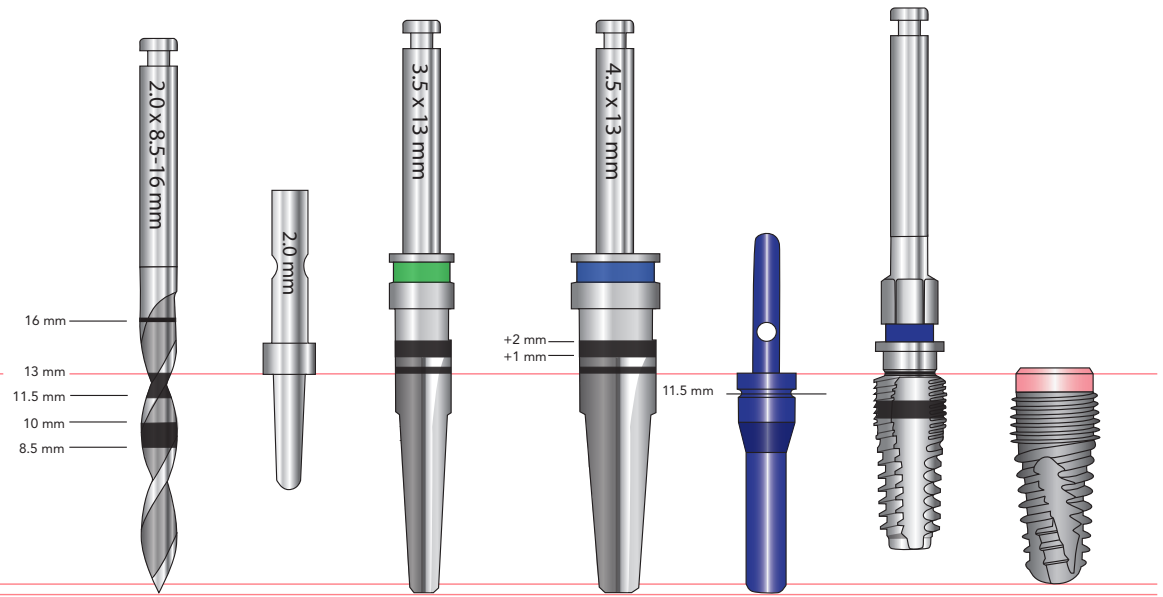
***The Genesis implant drills feature the following laser markings:**

- 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
Ø 3.5 mm	+1.29 mm
Ø 3.8 mm	+1.35 mm
Ø 4.5 mm	+1.45 mm
Ø 5.5 mm	+1.45 mm
Ø 6.5 mm	+1.95 mm





Ø 2.0 mm
Initial Drill

Ø 2.0 mm
Parallel Pin

Ø 3.5 x 13 mm
Final Drill

Ø 4.5 x 13 mm
Final Drill

Ø 4.5 x 11.5 - 13 mm
Implant Depth
Gauge

Ø 4.5 x 10 - 13 mm
Surgical Tap

Ø 4.5 x 13 mm
Genesis Tapered
Implant

DRILLING SEQUENCE

Implant Length	Ø 3.5 Drilling Sequence				
10.0 mm	2.0 mm 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 mm Initial Drill	Parallel Pin	3.5 x 11.5 mm Final Drill	3.5 mm Depth Gauge	3.5 mm Tap
13.0 mm	2.0 mm Initial Drill	Parallel Pin	3.5 x 13 mm Final Drill	3.5 mm Depth Gauge	3.5 mm Tap
16.0 mm	2.0 mm Initial Drill	Parallel Pin	3.5 x 16 mm Final Drill	3.5 mm Depth Gauge	3.5 mm Tap

TAP PROTOCOL:
D1 & D2 – Required
D3 – Clinicians Discretion
D4 – Not recommended

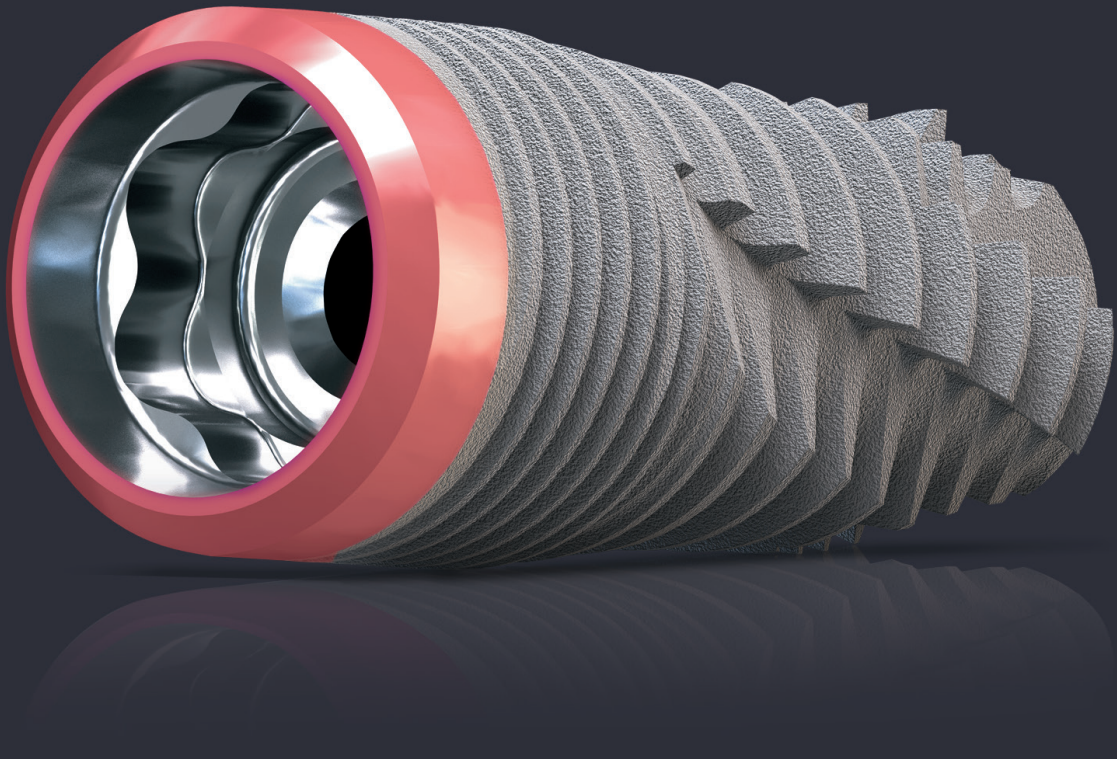
Implant Length	Ø 3.8 Drilling Sequence					
8.5 mm	2.0 mm Initial Drill	Parallel Pin	3.5 x 8.5 mm Final Drill	3.8 x 8.5 mm Final Drill	3.8 mm Depth Gauge	
10.0 mm	2.0 mm Initial Drill	Parallel Pin	3.5 x 10 mm Final Drill	3.8 x 10 mm Final Drill	3.8 mm Depth Gauge	
11.5 mm	2.0 mm Initial Drill	Parallel 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
13.0 mm	2.0 mm 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
16.0 mm	2.0 mm 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

NOTE: When placing a Ø 4.5 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.

Implant Length	Ø 4.5 Drilling Sequence					
8.5 mm	2.0 mm 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	
10.0 mm	2.0 mm 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 mm 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
13.0 mm	2.0 mm 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
16.0 mm	2.0 mm 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	Ø 5.5 Drilling Sequence						
8.5 mm	2.0 mm 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
10.0 mm	2.0 mm 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 mm 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
13.0 mm	2.0 mm 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	Ø 6.5 Drilling Sequence							
8.5 mm	2.0 mm 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
10.0 mm	2.0 mm 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 mm 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
13.0 mm	2.0 mm 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



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Caution, consult accompanying documents.

AMERICAN CANCER SOCIETY

Keystone Dental makes a charitable donation to the American Cancer Society for every Genesis implant sold.

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