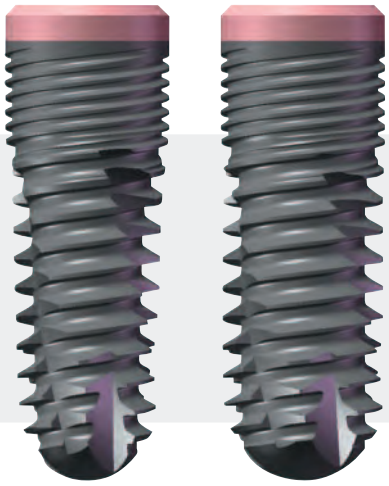
Keystone dental



GENESIS Implant System

Surgical Manual

Genesis

The Biomimetic Implant System™

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Genesis
The Biomimetic Implant System™

table of contents

Symbols Key

= Caution = Note = Tip

PRODUCT CHARACTERISTICS

1. Surface Technology

All Genesis Implants are manufactured with Grade 4 biocompatible titanium and treated with the BioSpark™ process. They are indicated for all bone types and are intended to be used in the following clinical applications:

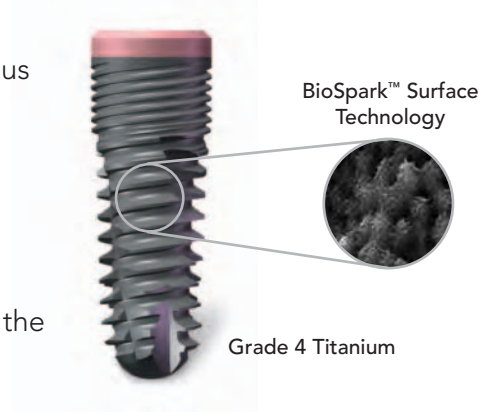
a. Single missing tooth, partially edentulous, or fully edentulous

b. Upper and lower jaws, anterior and posterior regions

c. One or two stage protocols

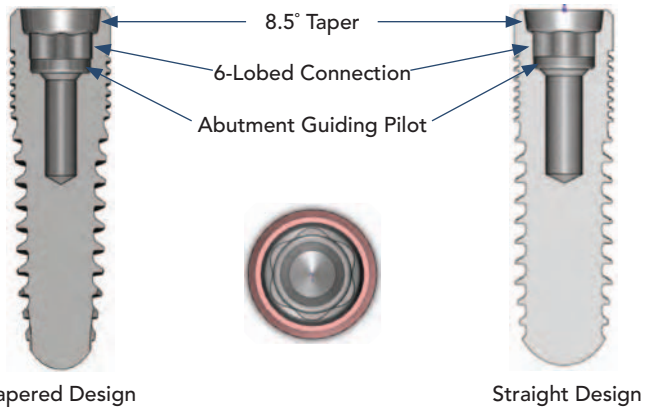
d. Placement at time of extraction and/or immediate temporization

The BioSpark™ process is a surface modification that is unique to the Genesis Implant System.



2. Connection

Keystone Dental's Genesis Implant System incorporates TiLobe™ Technology, a patented internal 6-lobed connection that combines the benefits of a taper, internal lobed design and integrated pilots, providing a secure implant/abutment connection. The TiLobe™ connection utilizes the same screw throughout all implant diameters. The 5.5 and 6.5mm implant diameters also share the same prosthetic connection.



3. Icon Descriptions

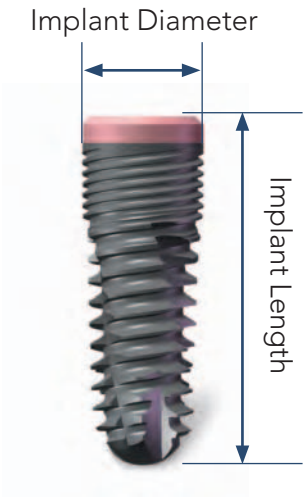
The Genesis Implant System is designed with color-coded icons on the product labeling to help the clinician identify the correct abutment for a specific implant diameter. Each icon below represents the diameters of the Genesis Implant System that are currently available.

3.8mm Ø Straight and Tapered
Available in lengths of 8.5, 10, 11.5, 13, and 16mm

4.5mm Ø Straight and Tapered
Available in lengths of 8.5, 10, 11.5, 13, and 16mm

5.5mm Ø Tapered Only
Available in 8.5, 10, 11.5, and 13mm lengths

6.5mm Ø Tapered Only
Available in 8.5, 10, 11.5, and 13mm lengths



Using the color coded implant icon that was selected, the clinician chooses the correct abutment by matching it to one of many options that share a similar color-coded identifier. The scheme below identifies the abutments that can be used with each implant diameter.

Can use 4.0 and 5.0 prosthetic components to mate with the 3.8mm Ø Implant.

Can use 5.0 and 6.0 prosthetic components to mate with the 4.5mm Ø Implant.

Can use 5.0 prosthetic components to mate with the 5.5mm Ø Implant.

Can use 6.0 prosthetic components to mate with the 5.5mm and 6.5mm Ø Implants.

PRE-SURGICAL CONSIDERATIONS (Treatment Planning)

1. Patient Evaluation and Selection

Successful implant treatment requires the coordinated efforts of the implanting surgeon, the restorative dentist, and the dental laboratory technician. Pre-surgical treatment option discussions between these individuals determine the appropriate treatment strategy and add balance between the surgical objectives and aesthetic, phonetics, and function of the final prosthesis. In addition, this coordinated approach ensures that treatment is complete, there is no omission of important technical considerations such as the use of a surgical guide for implant positioning, and that the biomechanics of the final prosthesis are maintained.

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
- Bone volume at the implant site in relationship to the implant diameter
- Emergence profile of the restoration in relation to the diameter of the prosthetic platform

2. Biomechanics

Proper stress distribution is essential to the long-term success of both the prosthesis and the implant. Overload of the implant or one particular area of the implant are key contributors to failure and are especially critical in placements in the cuspid and molar regions.

To minimize excessive and improperly distributed loads, the following guidelines apply:

- Decrease occlusal forces transferred to the implant by reducing the occlusal table width of the prosthesis
- Distribute occlusal forces optimally by maximizing the number of abutments used to support the prosthesis
- Use implants to maximize the potential for long-term aesthetics and restorative success
- Plan the position and inclination of the implants to ensure good prosthetic design, function, and aesthetics
- Direct forces of occlusion along the long axis of the implant

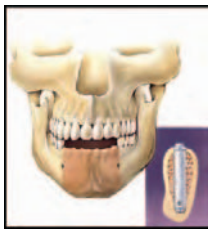
- Avoid cantilevering wherever possible
- Strengthen the overall treatment plan in patients with a heavy muscular profile or whose occlusal analysis indicates a strong bite
- Consider the forces from the opposing dentition

3. Bone Quality

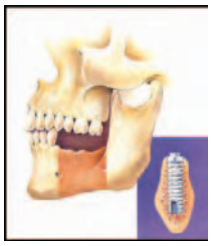
Bone quality should be considered because it is an important factor when selecting the number, length and diameter of implants. Use particular care in selection and placement of implants dependent on the type of surrounding bone environment. The following bone classifications are depicted by regions where they are typically found in the oral cavity and should be considered when implant selection decisions are made.

Cortical – Dense bone

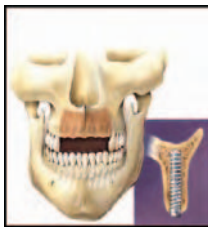
Trabecular – Soft bone



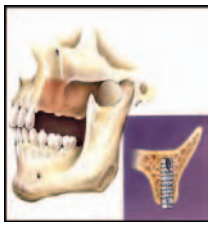
D1 Bone
Cortical Bone



D2 Bone
Cortical Bone
Some dense Trabecular



D3 Bone
Thin Cortical
Medium density Trabecular



D4 Bone
Very thin Cortical
Low density Trabecular

4. Surgical Guide

The implanting surgeon, the restoring dentist, and the laboratory technician should work together to produce diagnostic wax-ups and a surgical guide. This teamwork assists the implanting surgeon in the proper positioning of the implant(s). A surgical guide is used to indicate practical boundaries for the placement of implants and may prevent implants from being placed too buccal/lingually or mesial/distally. This process helps to ensure functional placement of implants and aesthetic results. The implanting surgeon should communicate to the laboratory technician any conditions that may affect guide design (e.g., the type of incision that will be used, expected reflection of tissue, etc.)

Keystone Dental offers the EasyGuide™ dental implant planning and placement system; a planning software that allows virtual planning of dental implant surgery cases based on the patient's Computed Tomography (CT) scan data, and a service where the radiographic guide worn by the patient during the CT scan is then converted into a precise surgical guide. Refer to the EasyGuide literature for detailed information on the products and procedures.

5. Implant Selection

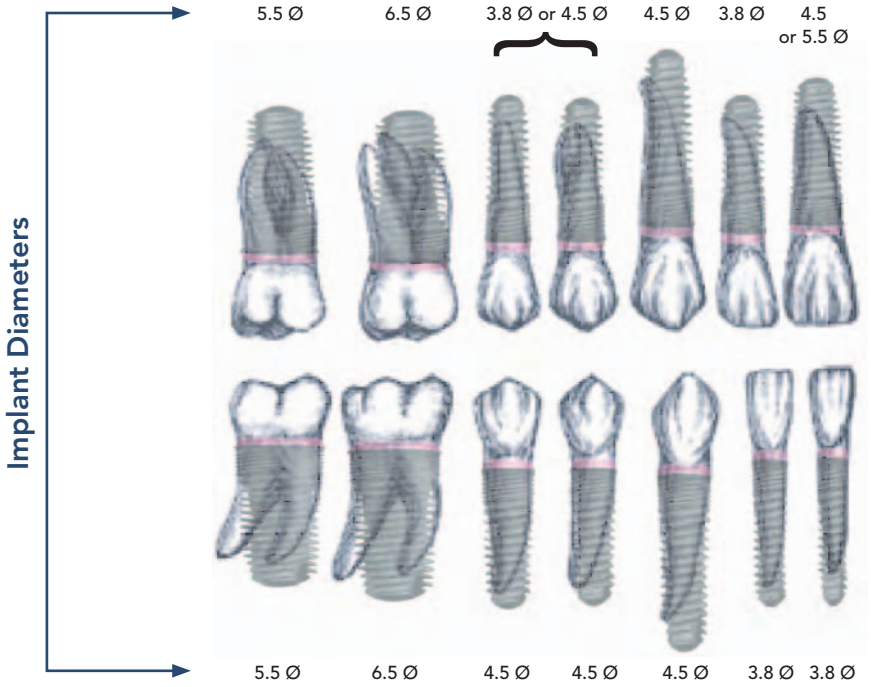
Implant selection should be made with the final restorative result as the primary consideration. This leads to better selection of the appropriate diameter and length based on the structure of the bone where the implant is intended to be placed and the inter-dental space that is available.

Selecting implants in this manner will provide maximum 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 aesthetic result.

Implant placement and healing abutment selections are based on the relationship of the following key measurements:

- Emergence of the restoration in relation to the diameter of the implant
- Height and diameter of the crown as it emerges through the tissue
- Bone quality and quantity in relation to the implant diameter and length

The following guide can be used to determine the appropriate implant diameters that are recommended based on the tooth shapes shown below.



6. Implant Sizing Overlays

Implant selection can also be made with the use of sizing overlays which are used as part of the pre-surgical assessment. Overlays are to be used in conjunction with radiographs. Transparent Implant Sizing Overlays (100% and 125% magnification) are included with each Genesis Surgical Kit.

SURGERY

1. Surgical Kit

The first step in surgery is for you and your surgical staff members to become familiar with the surgical kit. The Genesis Surgical Kit holds all the instrumentation needed to place all diameters and lengths of Genesis tapered and straight implants. Drills and Taps are sold as sets and can be purchased separately depending on the clinician's implant preference. These additional instruments are designed to be placed within the kit in their defined locations. All drills are non-irrigated and require external irrigation when preparing the osteotomy.

Instrumentation

NOTE: All Genesis Implant System surgical instruments are provided non-sterile and require sterilization prior to use. Always remove the instruments from the packaging before sterilization.

Prior to using any instrumentation, always inspect to ensure that there is no visible damage or excess wear. Also, ensure that sterilization has been completed. It is important to observe the number of sterilization cycles or uses to which drills have been subjected as drills will become dull after multiple uses. This could impact cutting performance ultimately minimizing the potential for success of the procedure. Keystone Dental recommends drill replacement after 20 osteotomies, although wearing may occur more rapidly in denser bone surgeries. Always have a backup drill sterile and available.

2. Drilling and Tapping Procedures

- Drilling speeds of 600 - 800 rpm are recommended when using Full Depth Twist and Intermediate drills.
- Drilling speeds should not exceed 600 rpm when using Final drills.
- In certain instances, tapping is required (see Step 12 in Surgical Procedure Section). When tapping of the bone is required, a maximum tapping speed of 20 rpm is recommended.
- All drilling and tapping procedures should be performed using copious external irrigation.
- Do not apply lateral pressure during drilling and tapping procedures as osteotomy may be oversized and/or redirected.
- Drill the osteotomy using light pressure. When using the Initial and Intermediate Drills, drill in an in-and-out motion along the long axis of the osteotomy.
- When using tapered or countersink drills, do not use the in-and-out technique since this may inadvertently enlarge the site. Instead, drill the site to the desired depth in one motion.

3. Cleaning and Sterilization of Instruments

It is important to ensure all instrumentation, surgical handpieces, and equipment that are provided non-sterile are sterilized prior to use to prevent the possible contamination of the components and surgical field. Always remove these components from their packaging prior to introduction into the sterile field.

It is recommended that the proper biological indicators for the selected sterilization method accompany each load prior to sterilization and that the appropriate sterile packaging be used to maintain sterility until use. Each dental office is responsible for the proper, routine sterilization of instruments. All sterilization techniques should follow guidelines recommended by the sterilizer manufacturer.

Perform the following to properly clean and sterilize the instruments:

Cleaning Procedure for Surgical Trays and Instrumentation

1. Disassemble the surgical kit and wash the tray using a detergent solution. Rinse the tray with water and dry thoroughly.
2. Place the instruments in a beaker of detergent solution and sonicate for approximately 10 minutes. Rinse thoroughly.

3. Remove any visible debris or bone fragments with a soft bristle brush. Rinse thoroughly.
4. Rinse the instruments with alcohol to remove soap residue and minerals. (This is important to help prevent corrosion.)
5. Blot the instruments with a clean towel(s) and allow to air dry completely.
6. Return the instruments to their appropriate locations in the surgical tray.
7. Wrap the kit in a double-layer of autoclave-wrap.
8. Sterilize the kit according to the sterilization method specified in the next section.

CAUTION: Do not remove the surgical kit from the autoclave until the dry cycle is complete. Upon removal from the autoclave, visually ensure instruments are dry as corrosion potential increases with exposure to moisture.

CAUTION: The use of hydrogen peroxide or other oxidizing agents will cause damage to the surface of the instruments.

CAUTION: It is important to handle all drills carefully. Even slight damage to their cutting edges impedes the drills cutting performance considerably. Proper care of the instruments is essential to maintaining performance. Keep drills separate during cleaning in order to prevent dulling by contact with other instruments.

Sterilization Method

Autoclave:

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

CAUTION: Do not exceed 140°C (284°F) for either cycle used.

CAUTION: Autoclave sterilization can only be accomplished by placing the individual components in the surgical tray, a sealed autoclave bag or in a surgical towel.

CAUTION: To minimize the potential for drill rusting, always use a drying cycle following sterilization.

CAUTION: Do not use chemclave sterilization procedures as they may damage surgical trays and/or instruments.

4. Cleaning of Surgical Ratchet/Torque Wrench

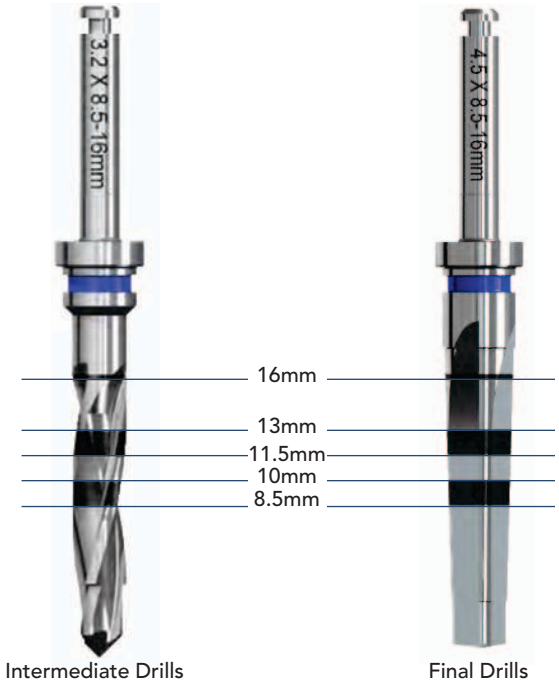
After each use the surgical ratchet/torque wrench should be dismantled, disinfected and sterilized. To prevent drying of contaminants, place the instrument parts in a disinfectant/detergent solution. Do not use solutions containing oxalic acid or a high concentration of chlorine. If appropriate, combine with ultrasound cleaning. Rinse the instrument parts in hot water and dry thoroughly. Follow the above Sterilization Method for autoclave procedure.

5. Drilling Depth Marking Information and Sequence

The Genesis Implant System drill laser markings define placement depth of the implant. These laser marks indicate full implant lengths; plus an overdrill length (see page 11 for overdrill length). The implant placement protocol is to position the implant so the pink collar is at bone level.

As a secondary visual check to ensure proper osteotomy depth, a depth gauge is included in the surgical kit. The depth gauge also has corresponding laser markings to indicate osteotomy depth.

The figures to the right show the various laser markings used on Genesis Implant System surgical instrumentation where needed to indicate the corresponding implant depth.



Intermediate Drills Final Drills

CAUTION: Ensure drill tip length is considered when drilling near critical anatomical locations (e.g., nerve canal).

The length of the drill tip is not included in the depth marking measurement calculation. The actual drill length including the tip must be considered when preparing the osteotomy. The charts below list the lengths of the drill tips for each drill in the Genesis Implant System and show the various laser markings to indicate corresponding implant depth.

Intermediate Drills	Over drill length
2.7mm Intermediate Drill	0.93mm
3.2mm Intermediate Drill	1.03mm
4.2mm Intermediate Drill	1.03mm
5.2mm Intermediate Drill	1.53mm

Final Drills	Over drill length
3.8mm Tapered Final Drills	0.93mm
4.5mm Tapered Final Drills	1.03mm
5.5mm Tapered Final Drills	1.03mm
6.5mm Tapered Final Drills	1.53mm
3.8mm Straight Final Drills	0.93mm
4.5mm Straight Final Drills	1.03mm

6. Implant Packaging

Each Genesis Implant is packaged in an aseptic vial, sealed in a tray with a Tyvek® lid and gamma-sterilized. The vial has a titanium insert to support the implant during shipment. The flip-open lid on the vial contains a pink cover screw, to mimic gingival tissue, and is included with every implant. The tray is placed in an outer package and sealed with a label identifying the implant type, diameter and length, as well as other important device information. Inside the sealed tray you will find pre-printed patient labels with product data and the lot number. These are adhesive labels that should be affixed to the patient's chart. Below you will find the steps to opening the implant packaging.

1. Remove implant tray from outer package.
2. Peel back the Tyvek lid on the tray and place the sterile implant vial into the sterile field.
3. Place the patient labels in the patient's chart.
4. Remove the seal from the vial.
5. Flip open the implant vial to gain access to the selected Genesis Implant.
6. The implant may now be removed from the vial, delivered to the site and placed using one of the options found in Section # 7 (Implant Insertion).

7. Implant Insertion

Depending on the clinical situation and accessibility, there are three different options to insert the Genesis Implant:

1. Surgical Motor with Implant Driver/Latch Type

2. Surgical Ratchet with Implant Driver/Ratchet

3. Hand Driver with Implant Driver/Latch Type

Mountless Delivery System

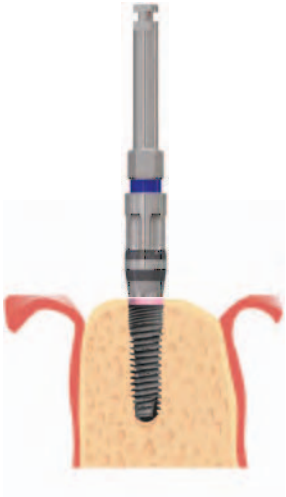
The Genesis Implant System is designed with a mountless delivery system to facilitate the delivery of the implant from the vial to the osteotomy. Care should always be taken when inserting the implant driver tip into the implant. Each implant diameter requires its own specific implant driver, except for the 5.5mm and 6.5mm implants, which share a common connection. With the Implant Driver/Latch Type, align the Implant Driver over the connection of the implant. Press down firmly until the driver firmly engages with the connection of the implant. Remove the implant from the vial and carry to the implant site

The implant cover screw is located within the cap of the vial. Placement of the cover screw into the implant can be achieved with the use of the Quad Driver, Swivel Head found in the surgical kit.

The following demonstrates removal from the vial and placement of the implant into the osteotomy using the Implant Driver/Latch type:

Flip open Implant Vial to expose the implant. Using your Implant Driver/Latch type

Pick up the implant and remove it from the vial



Deliver the implant to the osteotomy

8. Implant Placement

Final placement of a Genesis Implant is up to the discretion of the implanting surgeon. Each case should be evaluated on the basis of placement, protocol and type of implant before the osteotomy is drilled. The availability of the two types of Genesis implants (straight or tapered) allows the surgeon to address different anatomical situations, weigh the advantages of each, and choose the type that best suits the individual case. Keystone Dental recommends placement of a Genesis Implant at bone level.

Tapered Implants

Genesis Tapered Implants are designed to address anatomic conditions such as converging roots of adjacent teeth, lingual undercuts in the mandible, and labial concavities in the maxilla. By utilizing a tapered implant design in these conditions, optimal implant placement and ideal aesthetics can be achieved. The chart below describes the Genesis Implant System catalog numbers for the various tapered implant diameters and lengths:

Implant	8.5mm (L)	10mm (L)	11.5mm (L)	13mm (L)	16mm (L)
3.8mm Ø	G21130	G21131	G21132	G21133	G21135
4.5mm Ø	G21137	G21138	G21139	G21140	G21142
5.5mmØ	G21144	G21145	G21146	G21147	
6.5mm Ø	G21150	G21151	G21152	G21153	

Straight Implants

Genesis Straight Implants are consistent in design, self-tapping and can be used for all treatment indications in which sufficient bone volume is available. The straight design provides placement versatility and is suitable for virtually all case designs. The chart below describes the Genesis Implant System catalog numbers for the various straight implant diameters and lengths:

Implant	8.5mm (L)	10mm (L)	11.5mm (L)	13mm (L)	16mm (L)
3.8mm Ø	G21117	G21118	G21119	G21120	G21122
4.5mm Ø	G21123	G21124	G21125	G21126	G21128

SURGICAL PROCEDURE — TAPERED & STRAIGHT IMPLANTS

Place all instrumentation and implants onto the sterile work field in the order they will be used. This makes for a natural progression through the sequence of the case. For convenience, the surgical kit is also set up in this configuration.

NOTE: For demonstration purposes the instructions provided below are for the Genesis 4.5 x 13mm Implant only. For implants with other diameters refer to the drilling sequence charts found in the back of this manual.

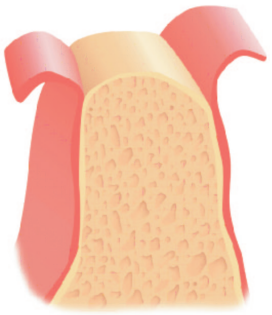
Drilling and Tapping Procedure (Full Flap Reflection)

Step 1 – Anesthesia

Anesthesia requirements are left to the discretion of the treating surgeon. If traditional flap reflection type surgery is desired, the administration of local anesthesia may be used.

Step 2 – Incision

Make an incision of appropriate design to elevate a flap. When working with the anterior mandible, locate the mental foramen and the inferior alveolar nerve. Perform alveoloplasty on the crest of the ridge, if needed, to create a more even plane in which to place the implant.



Step 3 - Implant Selection

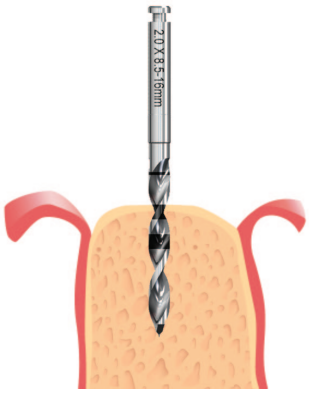
Using the guidelines provided above, select the appropriate implant diameter and length.

NOTE: Optional: Drill Extender – A Drill Extender is provided within the Genesis Implant System surgical kit to provide additional length to the drills for tight areas between teeth. To use the Drill Extender extension, insert the latch-end of a drill into the drill extender and push until it is firmly seated.

Step 4 – 2.0mm Full Depth Twist Drill

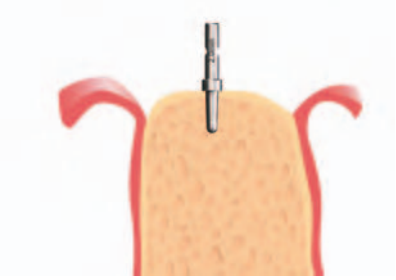
(Recommended drilling speed 600 - 800 rpm)

Select the 2.0 mm Full Depth Twist Drill. Drill directly through the alveolar crest. Continue to penetrate the bone below the crest to the 13mm depth line on the drill. A round bur may be used as a guide to penetrate the bone at the marked implant site. These drills will provide valuable information about the bone quality.



Step 5 – 2.0 Parallel Pin

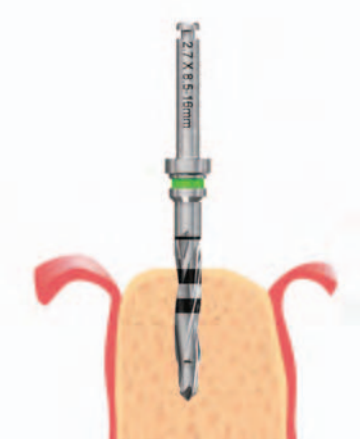
Verify the correct direction and position of the osteotomy by use of the Parallel Pin. Insert the smaller end of the pin into the osteotomy. It is recommended to thread floss through the hole to prevent slippage and possible accidental swallowing.



Step 6 – 2.7mm Intermediate Drill

(Recommended drilling speed is 600 – 800 rpm)

Use the 2.7 mm Intermediate Drill and enlarge the osteotomy by drilling to the 13mm depth line.

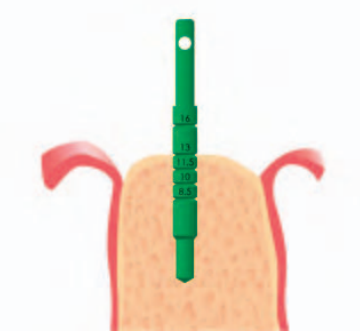


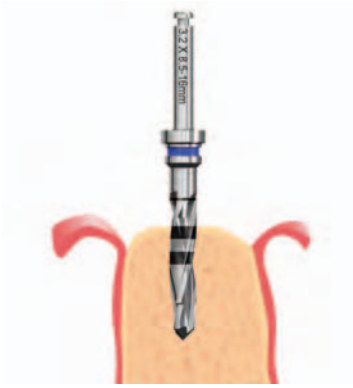
NOTE: Intermediate Drills feature multiple depth indicators. Complete depth marking Information can be found in the Drilling Depth Marking Information and Sequence section.

NOTE: With the exception of the 2.0mm Initial Drill, all drill tips have a built-in step that is the same diameter as the preceding drill. This tip allows the drill to seat into the prepared osteotomy without causing damage or skittering on the bone.

Step 7 – Radiographic 2.7mm Depth Gauge (Optional)

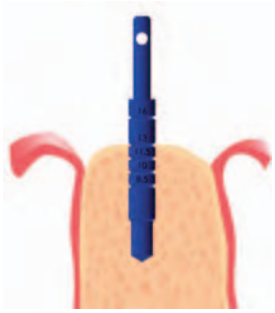
If desired, use the 2.7mm Depth Gauge to verify that the osteotomy has been prepared to the required depth. If necessary the 2.7mm Depth Gauge may be left in the site for radiographic verification.





Step 8 – 3.2mm Intermediate Drill
(Recommended drill speed 600 – 800 rpm)

Use the 3.2mm Intermediate Drill and enlarge the osteotomy by drilling to the 13mm depth line.



Step 9 – Radiographic 3.2 Depth Gauge (Optional)

If desired, use the 3.2mm Depth Gauge to verify that the osteotomy has been prepared to the required depth. If necessary the 3.2mm Depth Gauge may be left in the site for radiographic verification.

IF PLACING A STRAIGHT IMPLANT PROCEED TO STEP 10B, 11B & 12B

Step 10A – 4.5mm Tapered Countersink Drill *(Tapered Protocol Only)*

Once the final desired osteotomy depth has been verified, select the 4.5mm Countersink drill. This will prepare the superior portion of the osteotomy for adaptation of the coronal portion of the implant. The countersink corresponds to the actual diameter of the coronal aspect of the implant. Drill to the appropriate laser mark on the drill.

NOTE: Use of a countersink for ***tapered*** implants is required in Type I and Type II bone. It is up to the clinician's discretion in Type III and Type IV bone. (Countersink use for the 3.8 and 4.5mm implants in Type IV bone is **NOT** recommended).

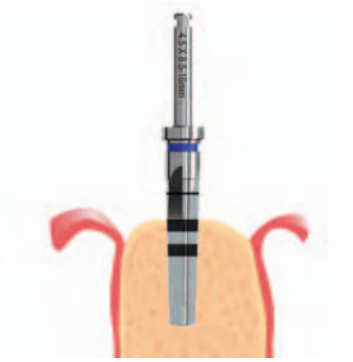
Step 10B – 4.5mm Straight Countersink Drill *(Straight Protocol Only)*

Once the final desired osteotomy depth has been verified, select the 4.5mm Countersink drill. This will prepare the superior portion of the osteotomy for adaptation of the coronal portion of the implant. The countersink corresponds to the actual diameter of the coronal aspect of the implant. Drill to the appropriate laser mark on the drill.

NOTE: Use of a countersink for ***straight*** implants is required in Type I and Type II bone. It is up to the clinician's discretion in Type III bone. Countersink use in Type IV bone is **NOT** recommended.

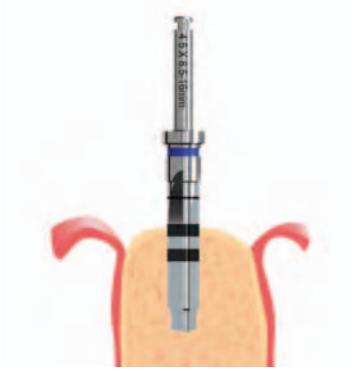
Step 11A – 4.5mm Tapered Final Drills *(Tapered Protocol Only)*

Select the 4.5mm Tapered Final Drill to shape the osteotomy in preparation for the implant. Drill to the 13mm laser mark.



Step 11B – 4.5mm Straight Final Drills *(Straight Protocol Only)*

Select the 4.5mm Straight Final Drill to shape the osteotomy in preparation for the implant. Drill to the 13mm laser mark.



Step 12A – 4.5mm Tapered Tapping Procedure (20 rpm)

NOTE: Tapping for ***tapered*** implants is required in Type I and Type II bone (except for the 3.8/4.5 x 8.5mm and 3.8 x 10mm implants). Tapping in Type III and Type IV bone is **NOT** recommended.

Place the 4.5 surgical Tap into the osteotomy. While applying "slight" pressure begin rotating the tap (assure 20 rpm maximum). When the threads begin engaging the bone, allow the tap to feed into the site without applying any additional pressure. Tap to the laser mark. Reverse the tap out of the osteotomy. The implant is now ready to be placed.

Step 12B – 4.5mm Straight Tapping Procedure (20 rpm)

NOTE: Tapping for all ***straight*** implants is required in Type I and Type II bone. Tapping in Type III and Type IV bone is **NOT** recommended.

Select the appropriate short or long tap, tap to the 13mm mark. Place the 4.5 surgical Tap into the osteotomy. While applying "slight" pressure begin rotating the tap (assure 20 rpm maximum). When the threads begin engaging the bone, allow the tap to feed into the site without applying any additional pressure. Reverse the tap out of the osteotomy. The implant is now ready to be placed.

Implant Procedure

Step 13 – Implant Placement

Open the outer implant package and remove the sealed tray containing the implant.

A. Peel back the Tyvek® lid to expose the implant vial.

B. Invert the tray and allow the vial to "drop" into the sterile field.

In the sterile field using a sterile technique, flip open the implant vial cap to expose the Genesis Implant. The implant may now be removed from the vial, delivered to the site and placed using:

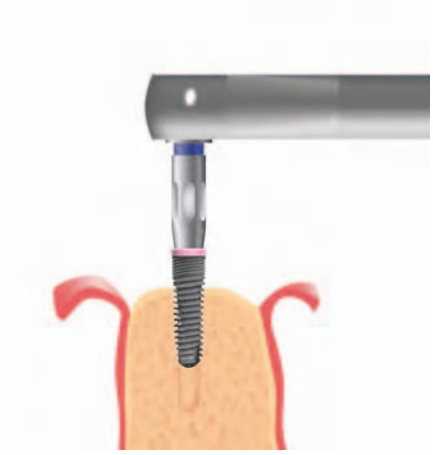
1. Surgical Motor with Implant Driver/LatchType

2. Surgical Ratchet with Implant Driver/Ratchet

3. Hand Driver with Implant Driver/Latch Type

Thread the implant into the osteotomy at approximately 20 rpm until the coronal portion of the implant is flush with the top of the bone. Do not over-tighten the implant in the site, as this could damage the threads prepared in the bone, cause too much bone-to-implant pressure and result in a less than optimal fixation.

NOTE: In some clinical situations, the clinician may prefer to use the *Surgical Ratchet with Implant Driver/Ratchet to manually tighten* the last few rotations and fully seat the implant. This allows for a better tactile feel during seating.



Recommended Bone Level Placement of Genesis Implants

The Genesis surgical protocol is designed to place the implant at the crest of the bone. Specifically, the base of the taper angle at the medialized connection should be aligned as indicated by "RECOMMENDED PLACEMENT" in FIG. 1, with an expanded view in FIG. 2.

By following the recommended surgical protocol, you will ensure the creation and maintenance of sufficient over drill length beneath the implant (the over drill lengths based on the recommended surgical protocol are listed in TABLE 1). As illustrated in FIG. 3, this over drill length is important because:

- IIt minimizes interference between the apical end of the implant and the base of the osteotomy.
- It shapes the osteotomy with the correct micro/macro thread transition and engagement.

FIG 1 **RECOMMENDED GENESIS IMPLANT PLACEMENT**

FIG. 2 **RECOMMENDED PLACEMENT**

Implant Diameter	Over Drill Length
3.8mm Tapered	0.93mm
4.5mm Tapered	1.03mm
5.5mm Tapered	1.03mm
6.5mm Tapered	1.53mm
3.8mm Straight	0.93mm
4.5mm Straight	1.03mm

TABLE 1

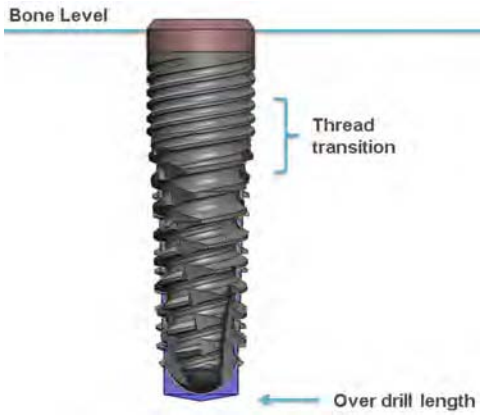


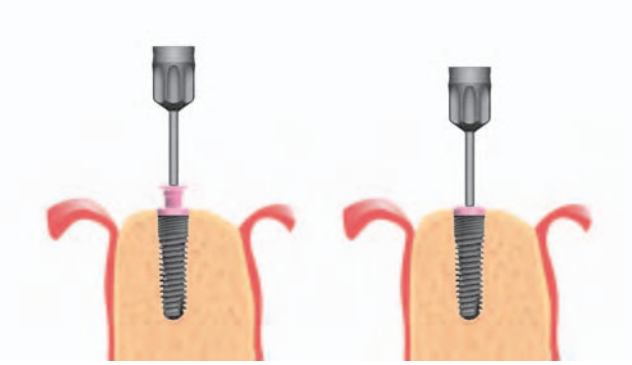
FIG. 3 **RECOMMENDED PLACEMENT AND OVER DRILL LENGTH**

Non-Recommended Placement

We do not recommend deviations from the protocol above. However, we do recognize that there will be specific situations in which the clinician may decide to deviate from this protocol. In these cases, it is important to allow for the appropriate over-drill length (See TABLE 1) during the final placement of the implant at other than the recommended bone level.

Step 14 – Cover Screw Placement

The cover screw is located in the vial cap. To remove the Cover Screw from the cap, connect the Quad Implant Driver to the Cover Screw, turn counterclockwise and free the Cover Screw from the cap. Carry the Cover Screw to the Implant and tighten.



Step 15 – Closure and Suturing

Close and suture the tissue flap utilizing the desired technique. It is suggested that a radiograph be taken to use as a baseline of the implant-to-bone height.

Post-Surgery

Patients should be instructed to follow a routine post-surgical regimen that includes ice or cold packs for 24 hours post-implantation and to consume a soft, high-nutrient diet, if possible. According to individual preference, consideration should also be given to advise dietary supplements with high protein, high vitamin and high mineral content for up to a month. Anti-edema steroid therapy may be initiated prior to surgery and continued for a period of 24 hours to one week post surgery. Antibiotic treatment may be initiated one day pre-op and up to one week post-op as the patient's condition dictates.

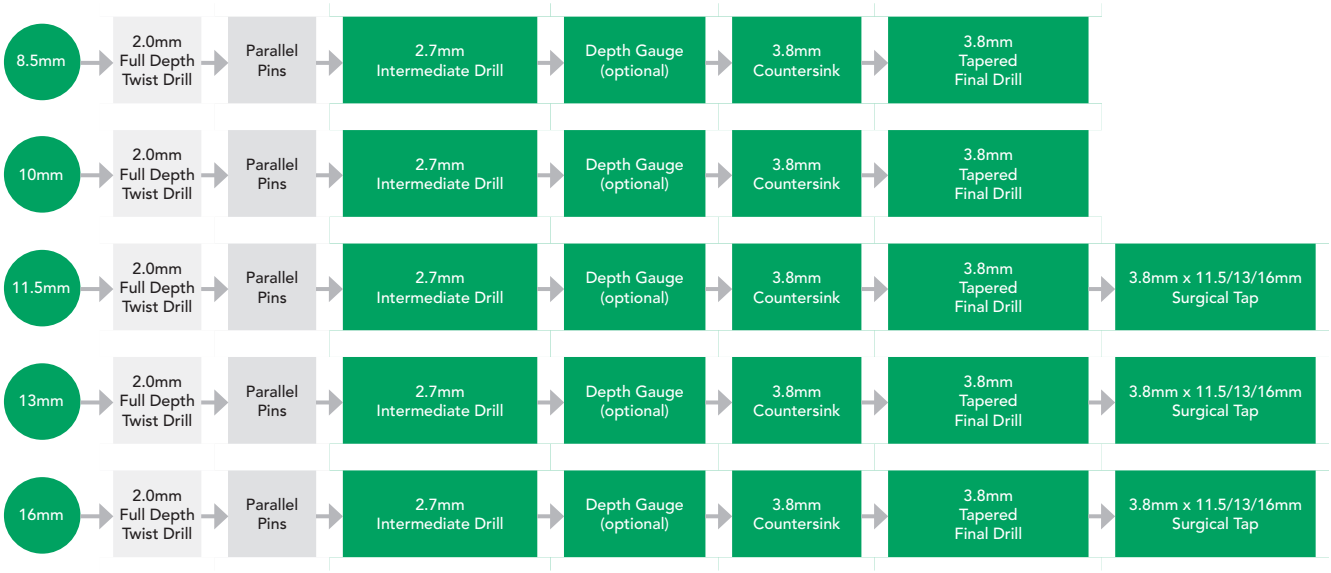
Remove all sutures after approximately 10 days following implant placement or as an individual's soft tissue healing dictates. If a removable prosthesis is used during this initial healing phase, it is recommended that a soft liner material be used to prevent pressure on the surgical site. The prosthesis should be relieved over the implant site prior to the soft liner application. It is also advised that the patient be examined periodically using radiographic evaluations to monitor healing of the soft tissues and bone.

QUICK REFERENCE GUIDE

The information found in this section is a Quick Reference Guide to the drilling sequence for placement of all lengths and diameters found in the Genesis Implant System.

DRILL SEQUENCE – TAPERED IMPLANTS

3.8MM TAPERED IMPLANT LENGTHS

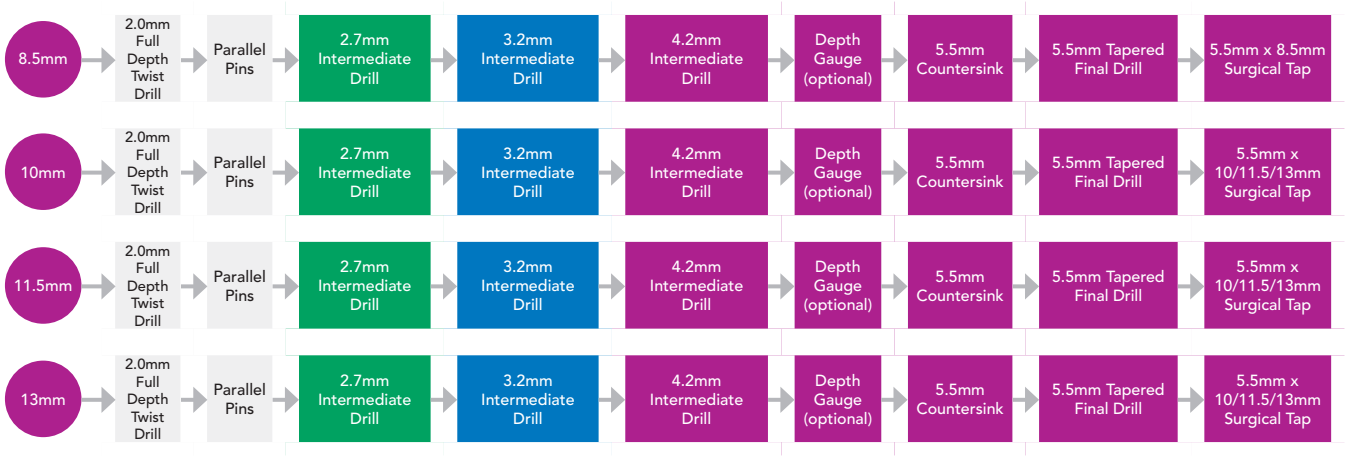


4.5MM TAPERED IMPLANT LENGTHS

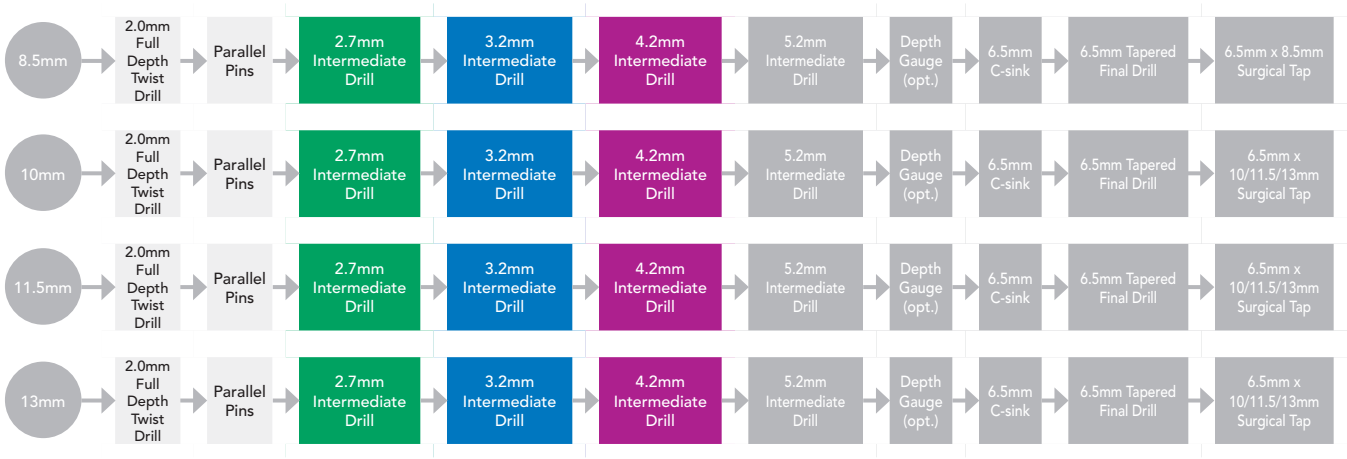
NOTE: Tapping for ***tapered*** implants is required in Type I and Type II bone (except for the 3.8/4.5 x 8.5mm and 3.8 x 10mm implants). Tapping in Type III and Type IV bone is **NOT** recommended.

DRILL SEQUENCE – TAPERED IMPLANTS

5.5MM TAPERED IMPLANT LENGTHS



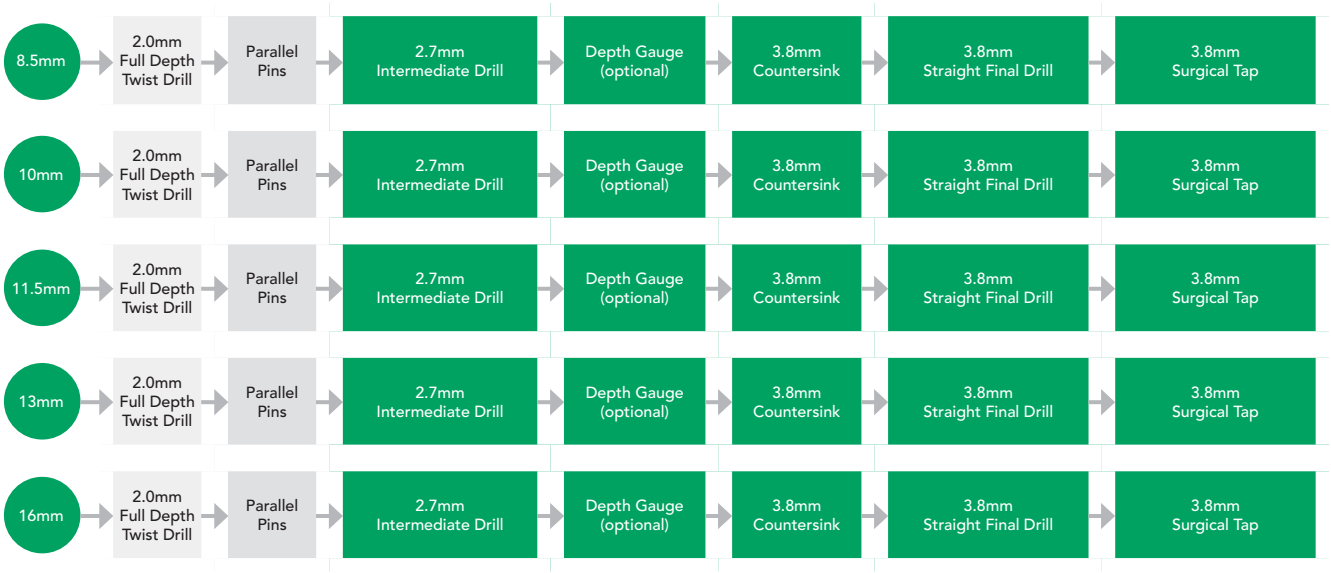
6.5MM TAPERED IMPLANT LENGTHS



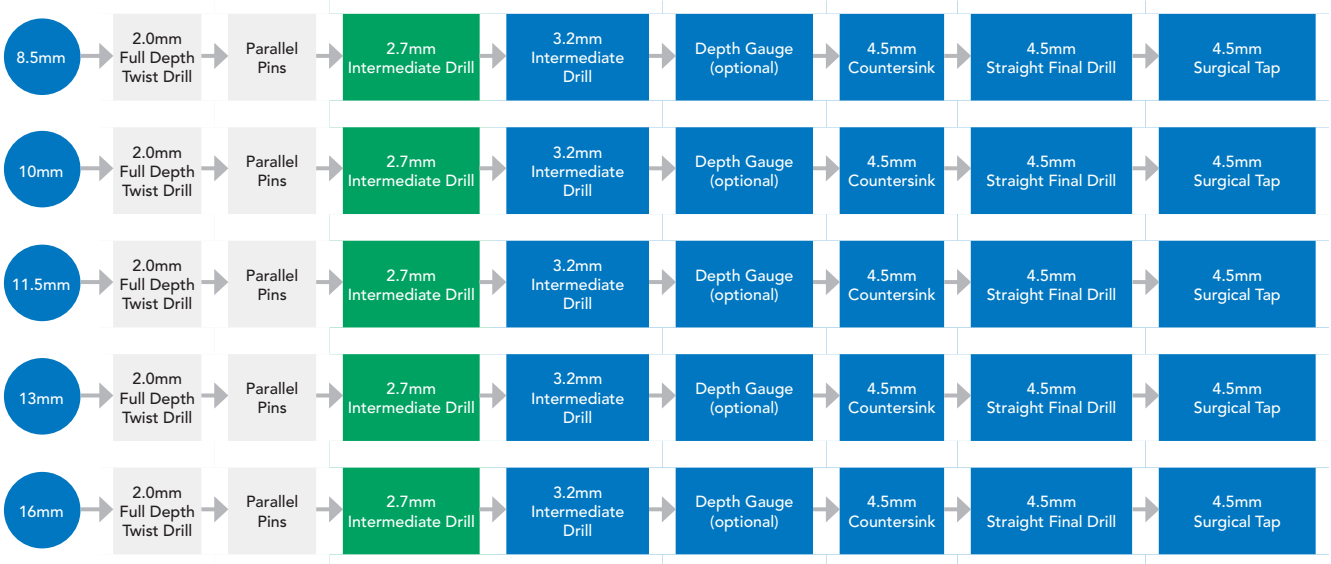
NOTE: Tapping for ***tapered*** implants is required in Type I and Type II bone (except for the 3.8/4.5 x 8.5mm and 3.8 x 10mm implants). Tapping in Type III and Type IV bone is **NOT** recommended.

DRILL SEQUENCE – STRAIGHT IMPLANTS

3.8MM STRAIGHT IMPLANT LENGTHS



4.5MM STRAIGHT IMPLANT LENGTHS



NOTE: Tapping for ***straight*** implants is required in Type I and Type II bone. Tapping in Type III and Type IV bone is **NOT** recommended.

3.8MM IMPLANTS – TAPERED (TAP)

3.8MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Not Recommended	Not Recommended	Not Recommended	Not Recommended
10mm Implant	Not Recommended	Not Recommended	Not Recommended	Not Recommended
11.5mm Implant	Required	Required	Not Recommended	Not Recommended
13mm Implant	Required	Required	Not Recommended	Not Recommended
16mm Implant	Required	Required	Not Recommended	Not Recommended

4.5MM IMPLANTS – TAPERED (TAP)

4.5MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Not Recommended	Not Recommended	Not Recommended	Not Recommended
10mm Implant	Required	Required	Not Recommended	Not Recommended
11.5mm Implant	Required	Required	Not Recommended	Not Recommended
13mm Implant	Required	Required	Not Recommended	Not Recommended
16mm Implant	Required	Required	Not Recommended	Not Recommended

5.5MM IMPLANTS – TAPERED (TAP)

5.5MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Clinician's Discretion	Clinician's Discretion	Not Recommended	Not Recommended
10mm Implant	Required	Required	Not Recommended	Not Recommended
11.5mm Implant	Required	Required	Not Recommended	Not Recommended
13mm Implant	Required	Required	Not Recommended	Not Recommended

6.5MM IMPLANTS – TAPERED (TAP)

6.5MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Clinician's Discretion	Clinician's Discretion	Not Recommended	Not Recommended
10mm Implant	Required	Required	Not Recommended	Not Recommended
11.5mm Implant	Required	Required	Not Recommended	Not Recommended
13mm Implant	Required	Required	Not Recommended	Not Recommended

3.8MM IMPLANTS – STRAIGHT (TAP)

3.8MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Required	Required	Not Recommended	Not Recommended
10mm Implant	Required	Required	Not Recommended	Not Recommended
11.5mm Implant	Required	Required	Not Recommended	Not Recommended
13mm Implant	Required	Required	Not Recommended	Not Recommended
16mm Implant	Required	Required	Not Recommended	Not Recommended

4.5MM IMPLANTS – STRAIGHT (TAP)

4.5MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Required	Required	Not Recommended	Not Recommended
10mm Implant	Required	Required	Not Recommended	Not Recommended
11.5mm Implant	Required	Required	Not Recommended	Not Recommended
13mm Implant	Required	Required	Not Recommended	Not Recommended
16mm Implant	Required	Required	Not Recommended	Not Recommended

countersink protocols

3.8MM IMPLANTS – TAPERED (COUNTERSINK)

3.8MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Required	Required	Clinician's Discretion	Not Recommended
10mm Implant	Required	Required	Clinician's Discretion	Not Recommended
11.5mm Implant	Required	Required	Clinician's Discretion	Not Recommended
13mm Implant	Required	Required	Clinician's Discretion	Not Recommended
16mm Implant	Required	Required	Clinician's Discretion	Not Recommended

4.5MM IMPLANTS – TAPERED (COUNTERSINK)

3.8MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Required	Required	Clinician's Discretion	Not Recommended
10mm Implant	Required	Required	Clinician's Discretion	Not Recommended
11.5mm Implant	Required	Required	Clinician's Discretion	Not Recommended
13mm Implant	Required	Required	Clinician's Discretion	Not Recommended
16mm Implant	Required	Required	Clinician's Discretion	Not Recommended

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10mm Implant	Required	Required	Clinician's Discretion	Clinician's Discretion
11.5mm Implant	Required	Required	Clinician's Discretion	Clinician's Discretion
13mm Implant	Required	Required	Clinician's Discretion	Clinician's Discretion

6.5MM IMPLANTS – TAPERED (COUNTERSINK)

5.5MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Required	Required	Clinician's Discretion	Clinician's Discretion
10mm Implant	Required	Required	Clinician's Discretion	Clinician's Discretion
11.5mm Implant	Required	Required	Clinician's Discretion	Clinician's Discretion
13mm Implant	Required	Required	Clinician's Discretion	Clinician's Discretion

3.8MM IMPLANTS – STRAIGHT (COUNTERSINK)

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11.5mm Implant	Required	Required	Clinician's Discretion	Not Recommended
13mm Implant	Required	Required	Clinician's Discretion	Not Recommended
16mm Implant	Required	Required	Clinician's Discretion	Not Recommended

4.5MM IMPLANTS – STRAIGHT (COUNTERSINK)

3.8MM IMPLANTS	TYPE 1 BONE	TYPE II BONE	TYPE III BONE	TYPE IV BONE
8.5mm Implant	Required	Required	Clinician's Discretion	Not Recommended
10mm Implant	Required	Required	Clinician's Discretion	Not Recommended
11.5mm Implant	Required	Required	Clinician's Discretion	Not Recommended
13mm Implant	Required	Required	Clinician's Discretion	Not Recommended
16mm Implant	Required	Required	Clinician's Discretion	Not Recommended

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consult accompanying documents

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US 5,996,779, US 6,142,296, US 7,249,949, and applicable international patents.
Additional patents are pending.

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