Internal / Single-stage Surgical Manual

BIOHORIZONS®

SCIENCE • INNOVATION • SERVICE

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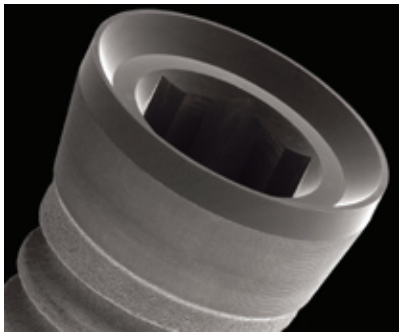
Science-based products | Game-changing Innovation | Unparalleled Service



Esthetics enhanced by biotechnology

In 2007, BioHorizons began introducing **Laser-Lok® microchannels** to the collars of its dental implants. Laser-Lok is a patented laser-machined surface treatment with over 15 years of *in vitro*, animal and human studies. Laser-Lok has been shown through SEM analysis and human histology to inhibit epithelial downgrowth, achieve connective tissue attachment and retain crestal bone.[1]

Esthetic restorations depend on healthy peri-implant tissue. Laser-Lok gives you a competitive edge in meeting patient expectations.

Innovative options... not compromises

No single implant design is perfect for every indication so BioHorizons lets clinicians choose the implant best suited to their preferences and the needs of their patients. No other company offers more choices of specialty implants, body shape, connection type, surface treatment and restorative paths than BioHorizons.

All BioHorizons implants and components are precision manufactured to the tightest mechanical tolerances in the industry. This yields products with a form, fit and function you have to experience with your own hands to appreciate.

Patient satisfaction: Delivered

Happy patients are the driving force of successful dental practices, and clinicians know they don't want implants; they want teeth. But traditionally, companies have only guaranteed their implants!

However, beginning in 2008, restorations made on our implants at select laboratories using an approved treatment plan are **guaranteed for life**. If the prosthesis fails, BioHorizons covers the cost of the rework… no red tape, no small print.

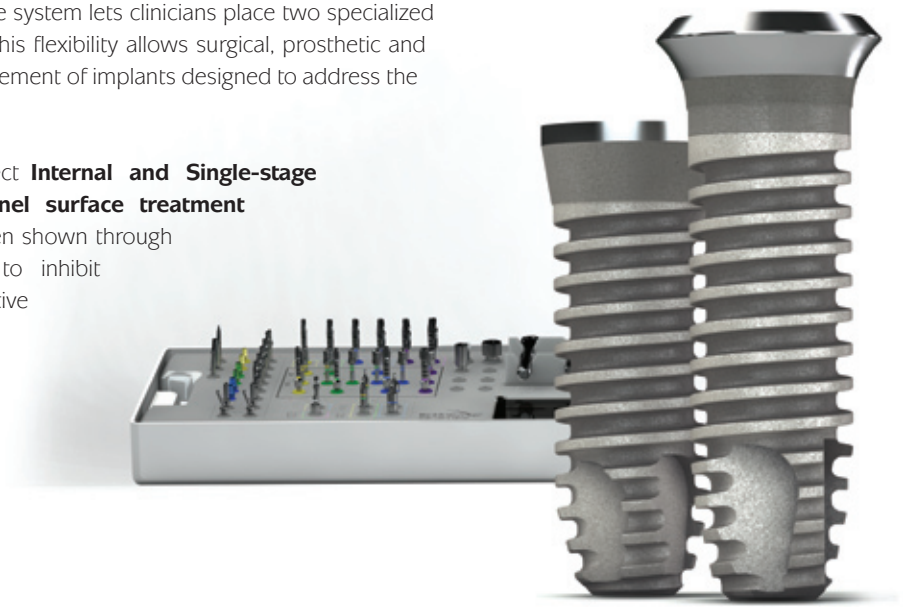
This is just one example of the **world-class customer service** you can expect from BioHorizons. Does your implant company offer as much?

BIOHORIZONS®
internal & single-stage

Two Implant Designs | One Surgical Kit | No Compromises

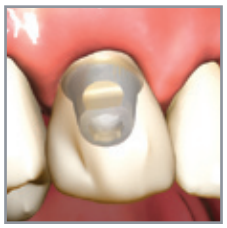
No single implant design is perfect for every surgical or prosthetic indication so the BioHorizons Internal / Single-stage system lets clinicians place two specialized implant designs using one Surgical Kit. This flexibility allows surgical, prosthetic and esthetic demands to be met through placement of implants designed to address the specific requirements of each case.

Clinicians now have the option to select **Internal and Single-stage implants with Laser-Lok microchannel surface treatment** on the crest module. Laser-Lok has been shown through SEM analysis and human histology to inhibit epithelial downgrowth, achieve connective tissue attachment and retain crestal bone.[1] To learn more about this revolutionary technology please turn to page 4.

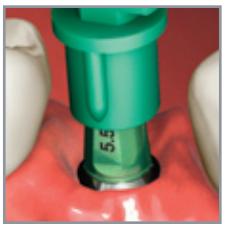


Complete Restorative Flexibility | Sophisticated to Simple

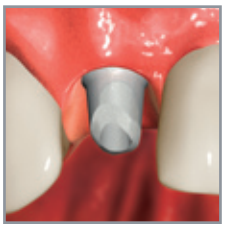
Today's practitioners need to offer treatment plans **from fixed-prosthetics in the esthetic zone to implant stabilized dentures,** and everything in between. BioHorizons has a comprehensive prosthetic line ranging from the value and simplicity of the gold-hued *3inOne*™ Abutment included with every Internal implant, to the ease of use of the Simple Solutions Snapcap components. Sophisticated esthetic demands can be addressed with a full line of Zirconia and Titanium esthetic abutments. A full array of overdenture abutments including the popular Locator® Abutments are also available.



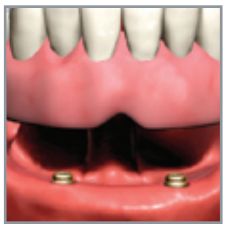
Esthetic gold-hued *3inOne* Abutment included with each Internal Implant



Simple Solutions Abutments and components are available for both systems



A comprehensive selection of esthetic zirconia and titanium abutments is available



A full array of overdenture abutments, including the Zest Locator, are available

Biomechanical Thread Form | Backed with Science

Internal and Single-stage implants feature the time-proven, biomechanical square thread which has been demonstrated to provide **increased bone-to-implant contact and yield higher reverse-torque values**.

	V-thread	Modified-square
Reverse Torque Value (Ncm)	15.58 ± 6.07	23.17 ± 9.68
% Bone-to-Implant Contact	65.46 ± 9.64	74.37 ± 8.63

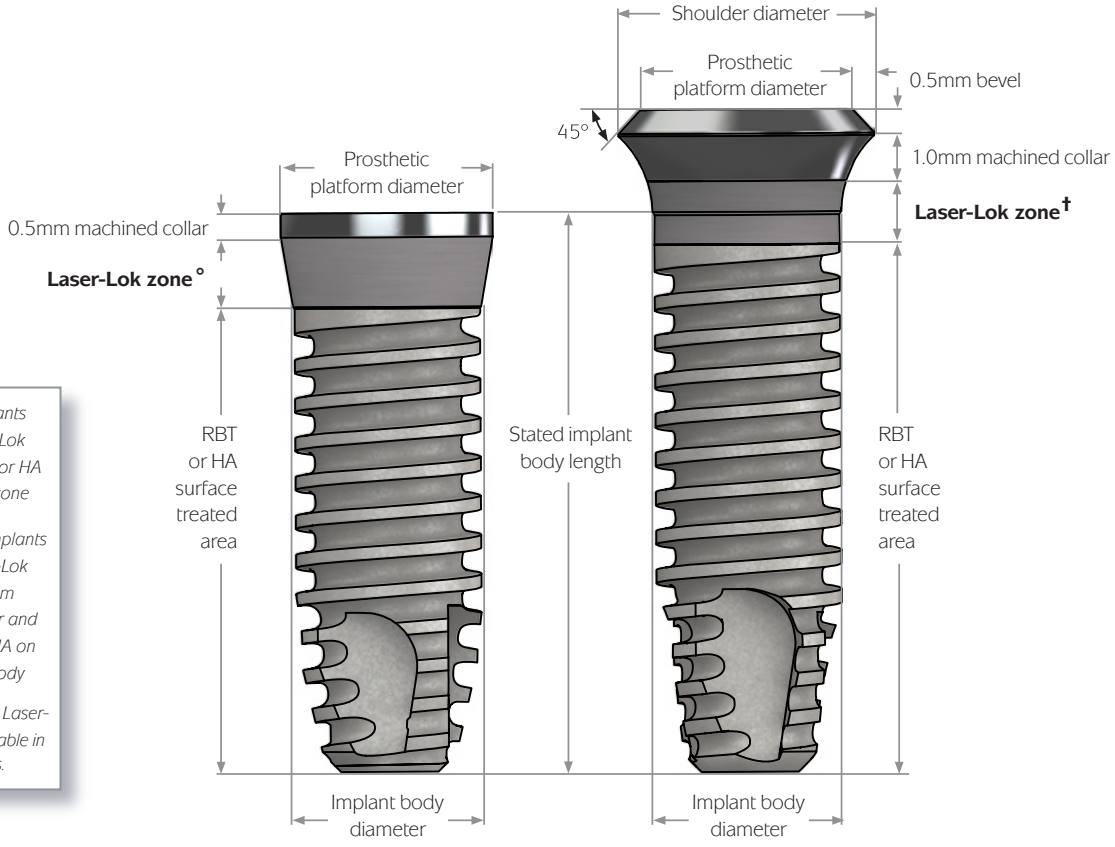
Steigenga J, Al-Shammari K, Misch C, Nociti F and Wang H-L. *Effects of Implant Thread Geometry on Percentage of Osseointegration and Resistance to Reverse Torque in the Tibia of Rabbits.* J Periodontology 2004;75:1233-1241

Multiple studies have demonstrated the BioHorizons square thread to be extremely reliable in immediate loading protocols. One study, summarized below, followed 242 BioHorizons implants through immediate functional and non-functional loading.

BioHorizons Implants	N Implants	N Failures	% Implant Survival	% Prostheses Survival
Immediate Functional Loading	126	0	100%	100%
Immediate Non-Functional Loading	116	0	100%	100%

Degidi and Piattelli. *Immediate Functional and Non-Functional Loading of Dental Implants: A 2- to 60-Month Follow-Up Study of 646 Titanium Implants.* J Periodontology 2003;74:225-241.

Two Implant Designs | Enhanced by Laser-Lok®

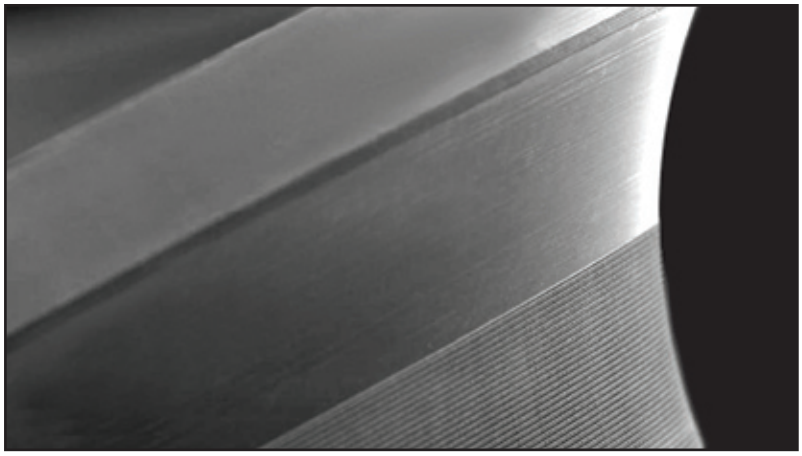


° Internal implants without Laser-Lok have either RBT or HA surface in this zone

† Single-stage implants without Laser-Lok have a 1.8mm machined collar and either RBT or HA on the implant body

Implants without Laser-Lok are not available in all countries.

Laser-Lok Technology



Microchannels viewed using scanning electron microscopy (SEM) at 1000X

In vitro Research

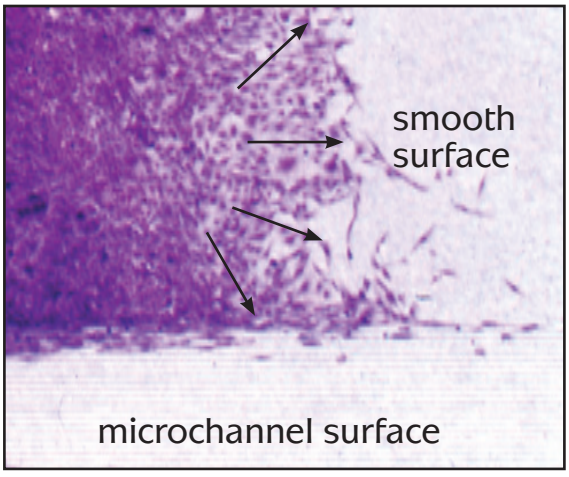
Cellular activity was studied on a variety of surface finishes including smooth, roughened and specifically engineered microgeometries. The engineered microgeometries were designed in a variety of repeating patterns and in a number of different sizes. Through various cell model designs, it was shown a linear grooved pattern in the range of 8 to 12 microns was optimal for inhibiting cell growth,[3] maximizing cellular contact guidance[4] and providing a directed tissue response.[5]

In vivo Validation

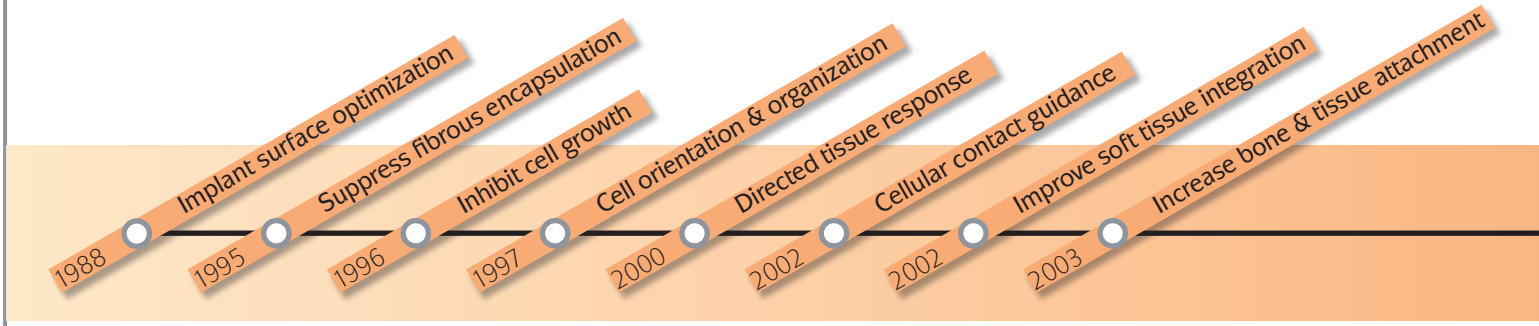
A series of animal studies (rabbit and canine) were conducted in both an implantable chamber model (intended to assess biologic response) and a dental model to assess the differences in tissue response to an engineered microgeometry versus a machined surface (control). Through these studies, it was shown a microchannel pattern of 8 to 12 microns improved soft tissue integration,[6] controlled cell ingrowth,[7] increased bone and tissue attachment[8] and reduced bone loss.[9]

Laser-Lok microchannels are a series of precision-engineered cell-sized channels laser-etched onto the collar of BioHorizons dental implants. This patented surface is unique within the industry as the only surface treatment shown to achieve connective tissue attachment as well as attach and retain both hard and soft tissue.

Laser-Lok microchannels are the result of over 15 years of research and documented studies at leading Universities. As part of the research, numerous *in vitro*, animal and human studies were conducted to (1) understand how bone and soft tissue cells react to various types of surface geometries and (2) evaluate how specific surface microgeometries affect crestal bone and the biologic width around dental implants.[2]



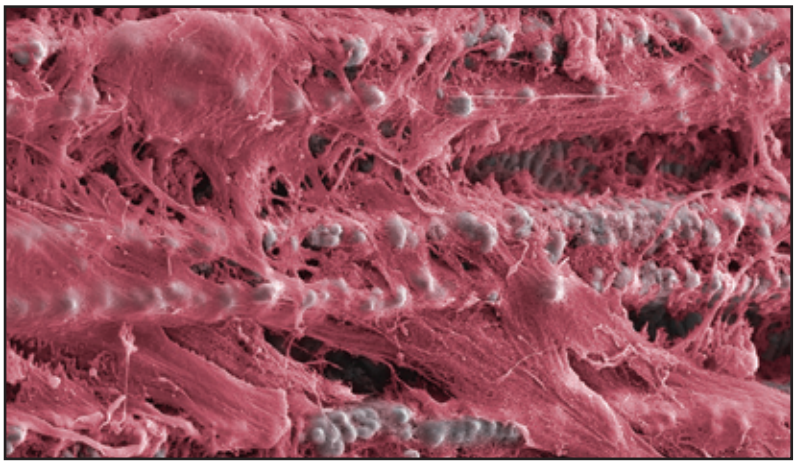
Human bronchial epithelial cell colony on smooth and microchannel surfaces



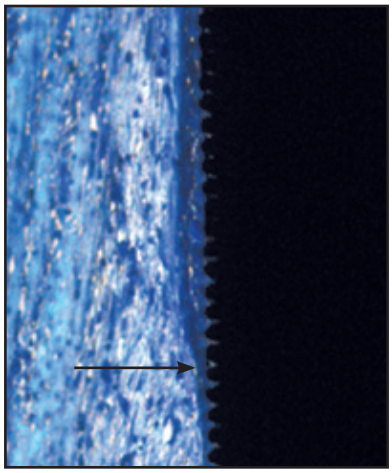
Laser-Lok Technology Timeline

Clinical Evidence

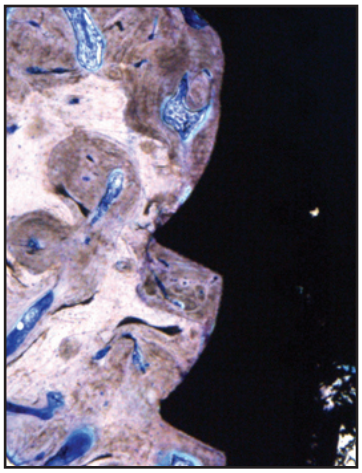
To evaluate how dental implants treated with the Laser-Lok microchannels benefit patients, a series of human histologic case studies and prospective controlled studies have been conducted. In a prospective, controlled multi-center study conducted by the Group for Implant Research in Italy, it was shown, at 37 months post-op, the mean crestal bone loss for implants with Laser-Lok microchannels was only 0.59mm versus 1.94mm for the control implant. The Laser-Lok treated implants formed a stable soft-tissue seal above the crestal bone.[10]



Colorized SEM showing human evidence of connective tissue attachment[1]

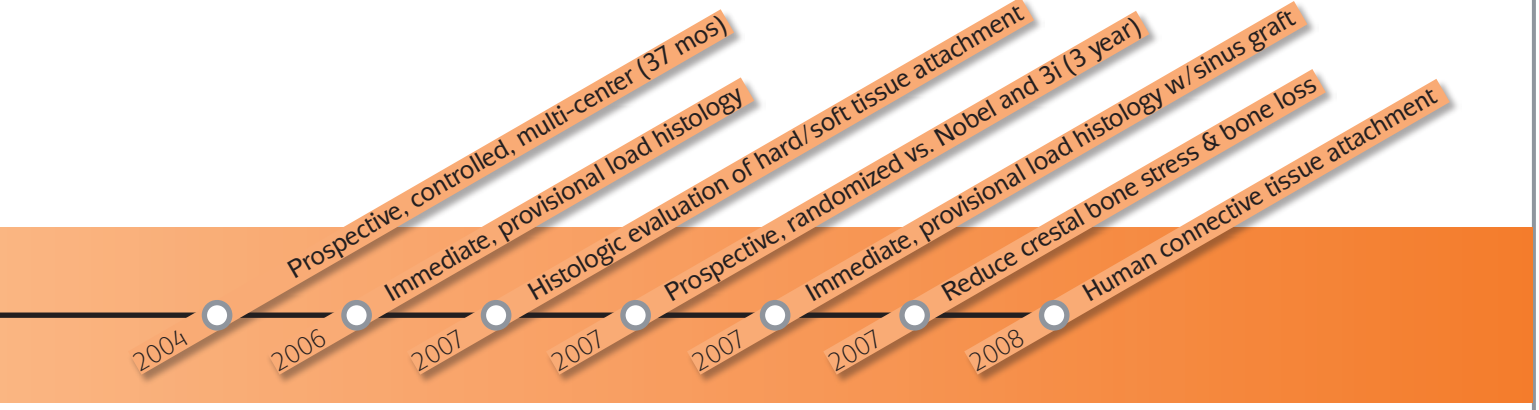


High magnification identifies the apical extent of the junctional epithelium (black arrow)[1]



SEM showing high degree of bone-to-implant contact[1]

In another study, SEM analysis and human histology revealed Laser-Lok can produce connective tissue attachment which appears to be instrumental in preserving the alveolar bone crest and inhibiting apical migration of the epithelium.[2] A prospective, randomized study has been initiated comparing an implant with Laser-Lok microchannels to the 3i Osseotite® NT implant and the Nobel-Biocare Select. This study is evaluating the peri-implant bone and soft tissue complex in patients at 6, 12, 24 and 36 months post-restoration.



This Surgical Manual serves as a reference for BioHorizons Internal and Single-stage implants and surgical instruments. It is intended solely to provide instructions on the use of BioHorizons products. It is not intended to describe the methods or procedures for diagnosis, treatment planning, or placement of implants, nor does it replace clinical training or a clinician's best judgment regarding the needs of each patient. BioHorizons strongly recommends appropriate training as a prerequisite for the placement of implants and associated treatment.

The procedures illustrated and described within this manual reflect idealized patient presentations with adequate bone and soft tissue to accommodate implant placement. No attempt has been made to cover the wide range of actual patient conditions which may adversely affect surgical and prosthetic outcomes. **Clinician judgment as related to any specific case must always supersede any recommendations made in this or any BioHorizons literature**.

Before beginning a surgical procedure with BioHorizons implants:

- Read and understand the Instructions for Use accompanying the products.
- Clean and sterilize the surgical tray and instruments per instructions.
- Become thoroughly familiar with all instruments and their uses.
- Study Surgical Kit layout, color-coding scheme and iconography.
- Design a surgical treatment plan to satisfy the prosthetic requirements of the case.

Treatment Planning

For ideal results in implant dentistry, the treatment team should be in agreement and in communication throughout all stages of therapy. The patient, the restorative and surgical doctors, as well as the dental laboratory should understand and agree upon the treatment plan. The treatment plan should determine the design, number and position of the implants.

Placement of small diameter implants or the use of angled abutments is not recommended in the posterior region of the mouth.

Diagnostic Casts

Mounted study casts and a diagnostic wax-up are the foundation for determining implant location.

Surgical Guide Templates

Once the diagnostic wax-up is finalized, the restorative doctor or dental laboratory fabricates the surgical guide template. This guide directs the surgeon to the implant location offering the best support for the prosthesis, as well as optimal esthetics and hygiene requirements. The surgical guide also provides information about the tooth and supporting structures which have been lost.

Laboratory Guide Templates

A matrix of the diagnostic wax-up may also be utilized by the laboratory when developing the final prosthesis. The matrix acts as a guide for position and contour of the prosthesis.

Two-stage Surgical Protocols

The original protocol for placing modern dental implants was two-stage (submerged) surgery, and it is still widely used today. The implant is placed below the soft tissue and protected from occlusal function and other forces during osseointegration. A low-profile Cover Cap is placed on the implant to protect it from the ingress of soft tissue.

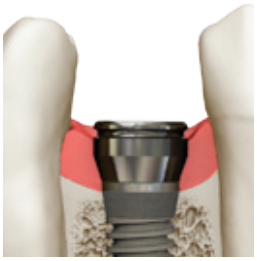
Following osseointegration, a second surgery exposes the implant and a transmucosal Healing Abutment is placed to allow for soft tissue healing and development of a sulcus. Prosthetic restoration begins after soft tissue healing.

Internal implant with Cover Cap in a submerged, two-stage protocol.

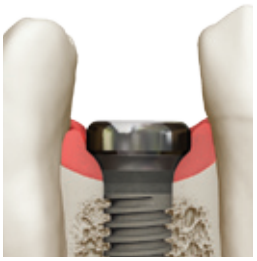
Single-stage Surgical Protocols

Single-stage surgery leaves the implant/abutment connection exposed to the oral cavity via an integrated transmucosal element (e.g. BioHorizons Single-stage), or a removable Healing Abutment (e.g. BioHorizons Internal). This eliminates the need for a second surgery to expose the implant. Although the implant is not in occlusal function, some forces can be transmitted to it through the exposed transmucosal element.

Prosthetic restoration begins following osseointegration of the implant and soft tissue healing.



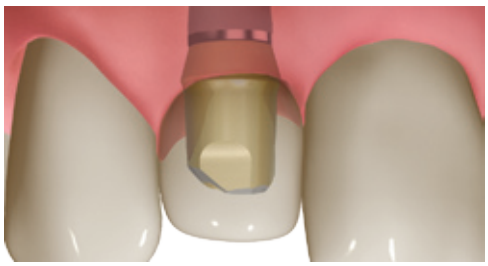
Internal implant with removable Healing Abutment as transmucosal element.



Single-stage implant with its integrated 1.8mm transmucosal element.

Non-functional Immediate Restorations

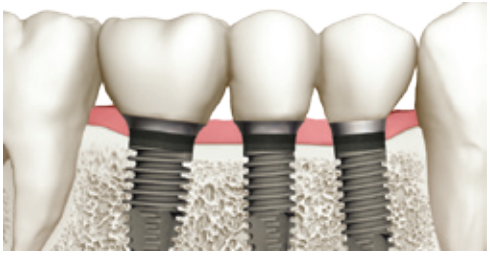
Single-stage surgery with non-functional immediate restoration provides patients a non-occlusal provisional prosthesis early in the treatment plan. An abutment is placed on the implant at or shortly after surgery, and a provisional restoration is secured to it with temporary cement. The provisional can help contour the soft tissue profile during healing.



Internal implant restored with a non-functional provisional prosthesis.

Immediate Function Restorations

Single-stage surgery with Immediate Function is possible in good quality bone where multiple implants exhibiting excellent initial stability can be splinted together. Splinting implants together can offer a significant biomechanical advantage over individual, unsplinted crowns.

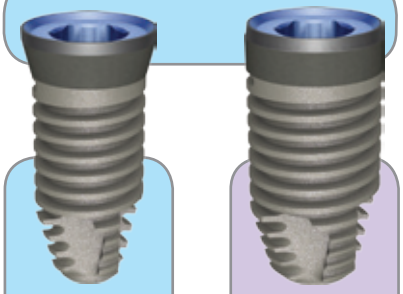


Single-stage implants with a splinted prosthesis in immediate function.

BIOHORIZONS® internal

Surgical Specifications:

- Two-stage or single-stage protocol
- Choice of three surface treatment configurations:
  - Laser-Lok crest module / RBT body
  - RBT crest module and body
  - HA crest module and body
- Body diameters: 3.5mm / 4.0mm / 5.0mm / 6.0mm
- Implant lengths: 9mm / 10.5mm / 12mm / 15mm
- Prosthetic platforms: 3.5mm (yellow) / 4.5mm (green) / 5.7mm (blue)
- Shares common surgical kit (ref. 122-800) with Single-stage implants
- Titanium Alloy (Ti-6Al-4V)

Prosthetic Platform	3.5mm	4.5mm	5.7mm	
				
Body Diameter	3.5mm	4.0mm	5.0mm	6.0mm
Apical Diameter	2.0mm	2.1mm	2.5mm	3.5mm
Minimum Ridge Width	5.5mm	6.5mm	7.7mm	8.0mm
Minimum Mesial / Distal Space	6.5mm	7.5mm	8.7mm	8.7mm
Implant Lengths	9.0mm 10.5mm 12.0mm 15.0mm	9.0mm 10.5mm 12.0mm 15.0mm	9.0mm 10.5mm 12.0mm 15.0mm	9.0mm 10.5mm 12.0mm 15.0mm

INTERNAL SYSTEM SPACING CONSIDERATIONS

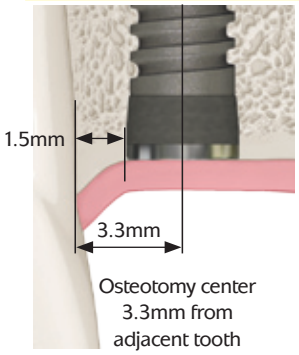
All spacing recommendations given within this literature are general guidelines. Clinicians must apply their best judgement as to whether these guidelines are appropriate for individual patient presentations.

Spacing considerations for BioHorizons Internal implants:

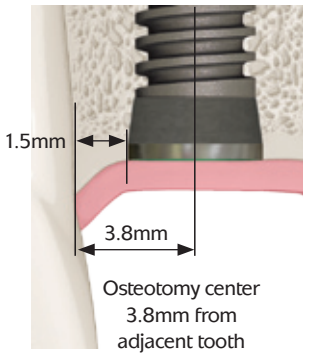
- Proper spacing is essential for esthetic restorations and hygiene considerations
- Measurements are taken at osseous crest
- Consider the prosthetic platform diameter (3.5 / 4.5 / 5.7mm) rather than implant body diameter
- Maintain 1.5mm to 2.0mm from contact at crest to the edge of the implant
- Maintain 3.0mm edge-to-edge spacing between adjacent implants
- Watch for tooth roots tipped or angled beyond the contact region of the crown
- Minimum spacing guidelines are illustrated below *(figures rounded up to the next 0.1mm)*

The osteotomy centerpoint required to maintain a 1.5mm implant-to-tooth spacing is derived using the following calculation: **½ [prosthetic platform diameter] + 1.5mm**. The measurements for the 3 Internal prosthetic platforms are shown below.

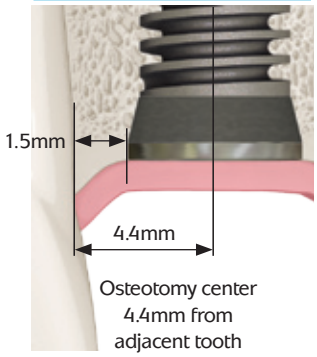
Ø3.5mm prosthetic platform



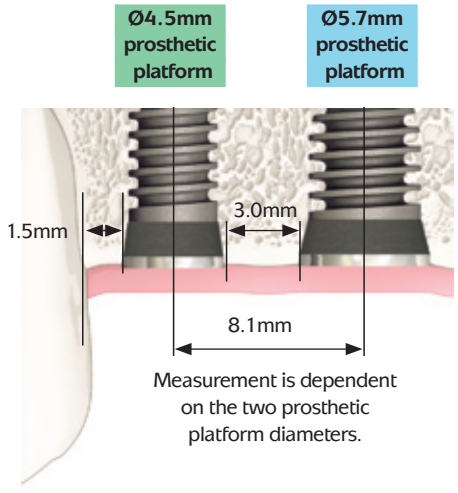
Ø4.5mm prosthetic platform



Ø5.7mm prosthetic platform



The osteotomy center-to-center measurement required to maintain a 3.0mm edge-to-edge spacing between Internal implants is derived using the following calculation: **½ [sum of 2 prosthetic platforms] + 3.0mm.** The table below lists the permutations.



prosthetic platform	Ø3.5mm	Ø4.5mm	Ø5.7mm
Ø3.5mm	6.5mm		
Ø4.5mm	7.0mm	7.5mm	
Ø5.7mm	7.6mm	8.1mm	8.7mm

Minimum center-to-center spacing for Internal implants

BIOHORIZONS®
single-stage

Surgical Specifications:

- Designed for single-stage surgical protocols
- Laser-Lok zone with RBT body
- Implant lengths: 7mm / 9mm / 10.5mm / 12mm / 15mm
- 3 Prosthetic Platforms; each with 2 Body Diameter options
- Shares common surgical kit (ref. 122-800) with Internal implants
- Titanium Alloy (Ti-6AL-4V)

Prosthetic Platform	3.5mm	4.5mm	5.7mm	
Shoulder Diameter	4.5mm	5.5mm	6.7mm	
Body Diameter	3.5mm	4.0mm	5.0mm	6.0mm
Apical Diameter	2.0mm	2.1mm	2.5mm	3.5mm
Minimum Ridge Width	5.5mm	6.0mm	7.0mm	8.0mm
Minimum Mesial/Distal space	7.5mm	8.0mm	9.0mm	10.0mm
Implant Lengths	7.0mm 9.0mm 10.5mm 12.0mm 15.0mm	7.0mm 9.0mm 10.5mm 12.0mm 15.0mm	7.0mm 9.0mm 10.5mm 12.0mm 15.0mm	7.0mm 9.0mm 10.5mm 12.0mm 15.0mm

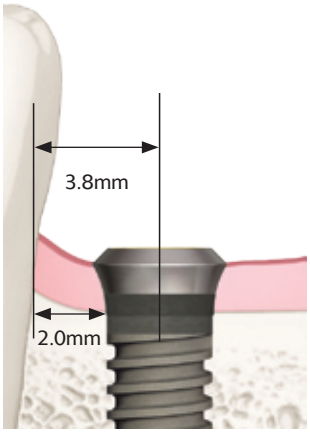
SINGLE-STAGE SYSTEM SPACING CONSIDERATIONS

All spacing recommendations given within this literature are general guidelines. Clinicians must apply their best judgement as to whether these guidelines are appropriate for individual patient presentations.

Spacing considerations for BioHorizons Single-stage implants:

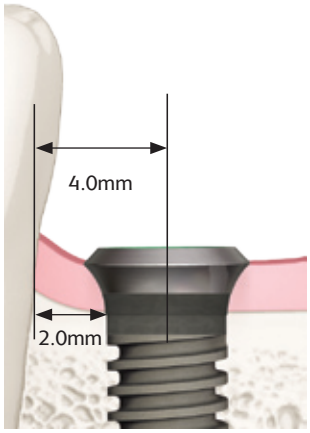
- Proper spacing is essential for esthetic restorations and hygiene considerations
- Measurements are taken at osseous crest
- Consider the implant body diameter (3.5 / 4.0 / 5.0 / 6.0mm) unless the implant will be countersunk
- Maintain 2.0mm from contact at crest to the edge of the implant
- Maintain 3.0mm edge-to-edge spacing between adjacent implants
- Watch for tooth roots tipped or angled beyond the contact region of the crown
- Minimum spacing guidelines are illustrated below *(figures rounded up to the next 0.1mm)*

The osteotomy centerpoint required to maintain a 2.0mm implant-to-tooth spacing for Single-stage implants is derived using the following calculation: **½ [implant body diameter] + 2.0mm**. The figures below illustrate the measurements for the 4 implant body diameters.



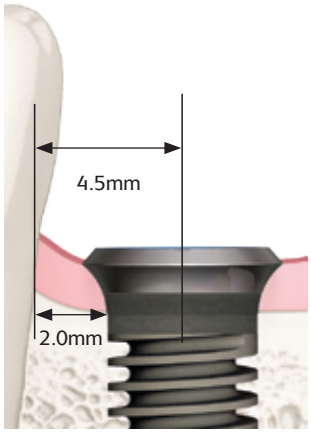
Ø3.5mm body diameter

Center 3.8mm from bone contact



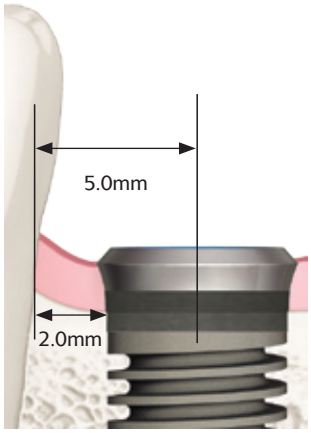
Ø4.0mm body diameter

Center 4.0mm from bone contact



Ø5.0mm body diameter

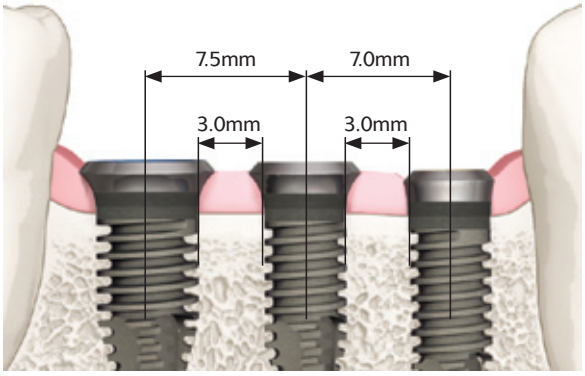
Center 4.5mm from bone contact



Ø6.0mm body diameter

Center 5.0mm from bone contact

The osteotomy center-to-center measurement required to maintain a 3.0mm edge-to-edge spacing for Single-stage implants is derived using the following calculation: **½ [sum of 2 implant body diameters] + 3.0mm**. The table below lists the different permutations.

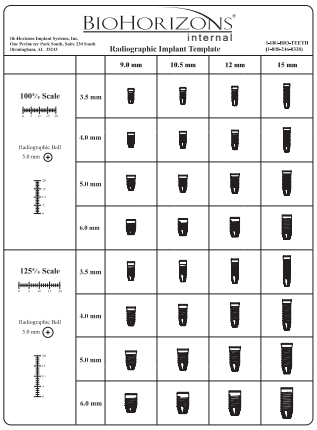


Ø5.0mm implant body | **Ø4.0mm implant body** | **Ø4.0mm implant body**

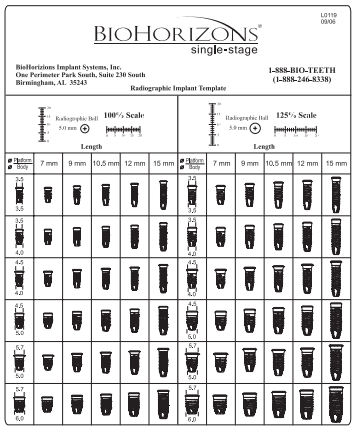
body diameter	Ø3.5mm	Ø4.0mm	Ø5.0mm	Ø6.0mm
Ø3.5mm	6.5mm			
Ø4.0mm	6.8mm	7.0mm		
Ø5.0mm	7.3mm	7.5mm	8.0mm	
Ø6.0mm	7.8mm	8.0mm	8.5mm	9.0mm

Minimum center-to-center spacing for Single-stage implants

A 1mm margin of safety should be factored into any treatment plan adjacent to a vital anatomic structure.



Internal Radiographic Template
REF# L0114
Actual size 8.5" x 11" (21.5cm x 28cm)



Single-stage Radiographic Template
REF# L0119
Actual size 8.5" x 11" (21.5cm x 28cm)

Purpose: Aids clinician in preoperative determination of options for implant length and diameter.

Used: Both templates are provided with the BioHorizons Internal / Single-stage Surgical Kit.

- All implants are shown at 100% scale and 125% scale (for panoramic radiography). Be aware panoramic radiography varies in magnification from 115% to 135%.

- 5mm circular representations are shown at 100% and 125% for the radiographic ball technique. This technique uses radiographic marking balls embedded in a plastic template prior to radiographic examination of the patient. These marking balls will be visible on the radiographic image.

- Measurements can be taken to determine the magnification factor of the radiograph and help the practitioner accurately determine the amount of available bone for implant placement. The following example shows the calculation of a magnification factor and the subsequent determination of available bone:

  Step 1. The radiographic marking ball has a known diameter of 5mm.

  Step 2. A direct measurement of the marking ball appears on the radiograph to have a diameter of 6mm.

  Step 3. The magnification factor is calculated as: 6 ÷ 5 = 1.2 or 120%.

  Step 4. Assume the distance between the crest of the ridge and the superior aspect of the mandibular nerve canal appears on the radiograph to have a length of 15mm.

  Step 5. The actual distance between the crest of the ridge and the mandibular canal would be calculated as: 15mm ÷ 1.2 = 12.5mm.

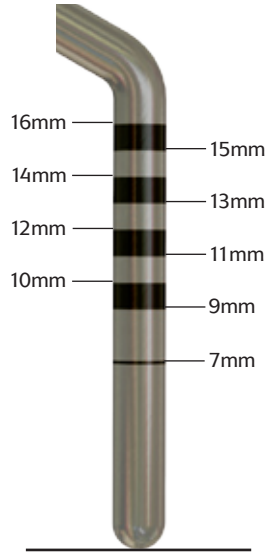
IMPLANT SPACER / DEPTH PROBE

Purpose: Multi-function instrument for intraoral measurements.

Used: With BioHorizons Internal and Single-stage implants.

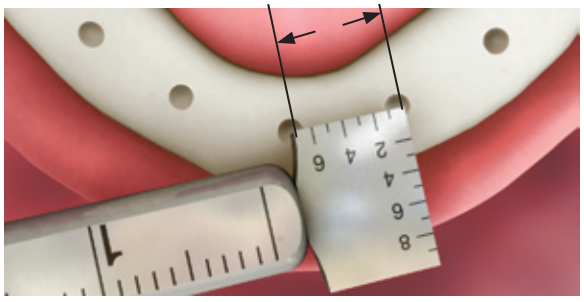
- Ø2.0mm probe tip measures osteotomy depth in millimeter increments
- Five centimeter graduated ruler on shaft
- Measures implant-to-implant, mesial/distal and buccal/lingual space
- Measures implant spacing adjacent to an existing tooth

The rectangular end of the tool provides intraoral measurements of buccal/lingual and mesial/distal space.

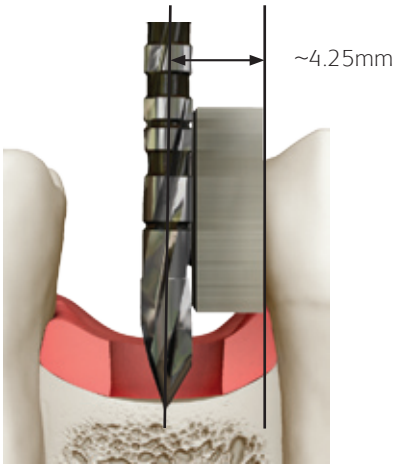


Probe tip measures osteotomy depth.

Center-to-center implant spacing



Useful for marking center-to-center implant spacing on the ridge prior to multiple implant placement.



Using the rectangular end as shown against an existing tooth centers the osteotomy approximately 4.25mm from the contact.

The Internal / Single-stage Surgical Kit (ref. 122-800) uses an intuitive layout to guide surgeons through the instrument sequence. The sequence begins in the upper left hand corner and works left-to-right and then down. Color-coded lines, instruments and grommets further aid in instrument identification and selection.

Prior to use, clean and sterilize the surgical tray and instruments per instructions and study the surgical kit layout, color-coding and iconography. Surgical assistants should also be thoroughly familiar with all instruments and their uses.

Surgical instruments for osteotomy preparation are color-coded by the implant-body diameter with which they are used, and the grommets housing these instruments are color-coded in the same fashion (see below). Implant-level Drivers and Trial Abutments used with specific prosthetic platforms are color-coded as to match the platform (see below). Counter-sink Drills utilize two color-coded bands: one designating implant body diameter, and the other designating prosthetic platform (see page 23).

Implant Body Color-code

Below is the color-code scheme used to designate implant body diameter. Please note the same colors may also be used in the prosthetic platform color scheme, as shown below.

Ø3.5mm implant body

Ø4.0mm implant body

Ø5.0mm implant body

Ø6.0mm implant body

Prosthetic Platform Color-code

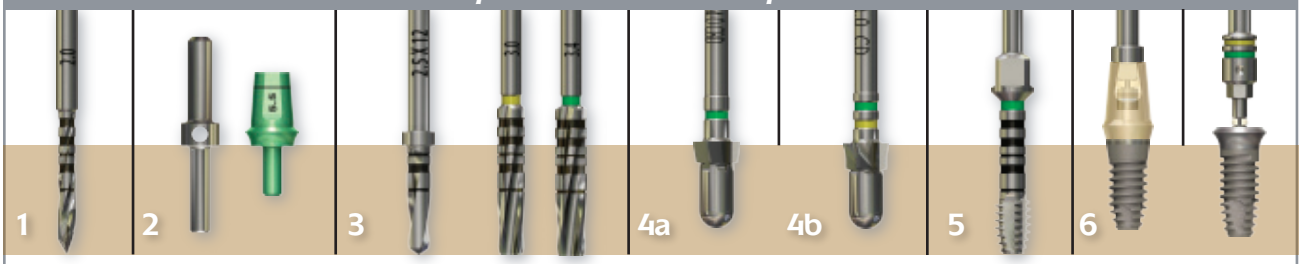
Below is the color-code scheme used to designate prosthetic platform diameter. Please note the same colors are also used in the implant diameter color scheme, as shown above.

Ø3.5mm prosthetic platform

Ø4.5mm prosthetic platform

Ø5.7mm prosthetic platform

Implant Placement Sequence



1	2	3	4a	4b	5	6
Starter Drill	Parallel Pins and Trial Abutments	Depth and Width Increasing Drill Sequence	Internal Crestal Bone Drill	Single-stage Counter-sink Drill	Internal / Single-stage Bone Tap	Abutment-level Driver or Implant-level Driver

Placement of Internal / Single-stage implants is accomplished in **6** sequential steps.

Ø2.0mm Starter Drill *(Internal / Single-stage)*

- No color-coding / grey grommet

Parallel Pins / Trial Abutments *(Internal / Single-stage)*

- Parallel Pins used following Ø2.0 and Ø2.5mm drills
- Trial Abutments used following Ø2.0 Starter Drill

Ø2.5mm Depth Drills *(Internal / Single-stage)*

- One Drill without a depth stop
- Five Drills with implant-length specific depth stops (7mm, 9mm, 10.5mm, 12mm and 15mm)
- No color-coding / grey grommets

Ø3.0 to 5.4mm Width Increasing Drills *(Internal / Single-stage)*

- Non-end cutting geometry
- Color-coded to smallest implant body diameter with which they are used

Internal Crestal Bone Drills *(Internal only)*

- **Site specific -** Removes cortical bone at crest to allow pressure-free seating of implant
- Color-coded by implant body diameter

Single-stage Counter-sink Drills *(Single-stage only)*

- **Protocol specific -** Prepares crest when counter-sinking of the transmucosal collar is desired
- Color-coded by implant body diameter / prosthetic platform combination

Bone Taps *(Internal / Single-stage)*

- Prepares cortical bone to receive the threaded implant body
- **Site specific -** Not typically used in D3 or D4 type bone
- Color-coded by implant body diameter

Internal Abutment-level Drivers *(Internal only)*

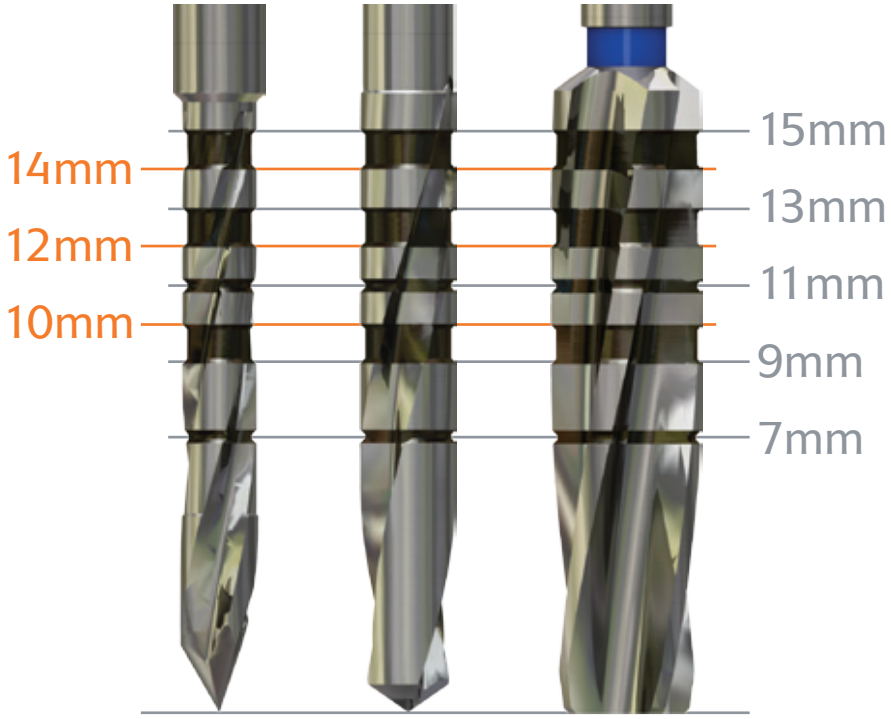
- Choice of two drive mechanisms: Handpiece or Ratchet
- Interfaces with all diameter Internal surgical mounts *(the included 3inOne Abutment)*

Implant-level Drivers *(Single-stage / Internal)*

- Choice of two drive mechanisms: Handpiece or Ratchet
- Exclusive method for seating Single-stage implants
- May also be used with Internal implants following removal of the *3inOne* Abutment
- Color-coded to specific prosthetic platforms (3.5/4.5mm or 5.7mm)

The Surgical Drills described in this literature are specific to the Internal / Single-stage Surgical Kit (ref. 122-800). If you possess any other BioHorizons Surgical Kits or Drills, please refer to important Instructions for Use on page 42.

The Surgical Drills included in the Internal / Single-stage Surgical Kit are externally irrigated and designed to be used at speeds of 850-2,500 rpm[11] with steady sterile irrigation. Reduced drill speed may be desired in softer bone or as drill diameter increases.



The depth marks are consistent throughout the Starter Drill, Depth Drills, Width Increasing Drills and Bone Taps. The thick bands are each one millimeter wide. Thin lines are used to mark 7mm and 11mm.

Drilling Considerations

Peri-operative oral rinses with a 0.12% Chlorhexidine Digluconate solution have been shown to significantly lower the incidence of post-implantation infectious complications.[12] A preoperative 30-second rinse is recommended, followed by twice daily rinses for two weeks following surgery.

Drilling must be done under a constant stream of sterile irrigation. A pumping motion should be employed to prevent over-heating the bone. Surgical drills and taps should be replaced when they are worn, dull, corroded or in any way compromised. BioHorizons recommends the replacement of drills after 12 to 20 osteotomies.[13] A Drill-usage Tracking Chart is available from BioHorizons to aid offices in archiving this important information.

There is a risk of injury to the mandibular nerve associated with surgical drilling in lower posterior regions. To minimize the risk of nerve injury, it is imperative the clinician understand the drill depth markings in order to correlate implant length with the actual drilling depth to produce the desired vertical placement of the implant.

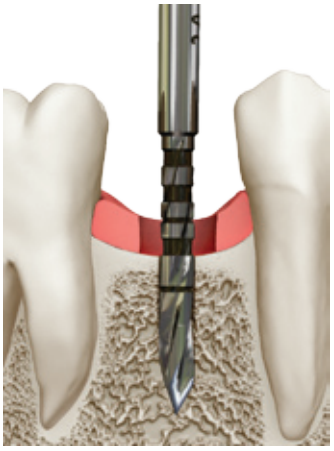
Ø2.0mm Starter Drill

Purpose: Initiates osteotomy.

Used: With Internal and Single-stage implants.

- Chisel-tip design eliminates "skating" on osseous crest
- Initiates osteotomy to desired depth
- Prepares site for Trial Abutments and Paralleling Pins

An Extended Shank version is available which adds 8mm of overall length. Depth markings are identical to standard length drills. Call for availability of this product in your market.

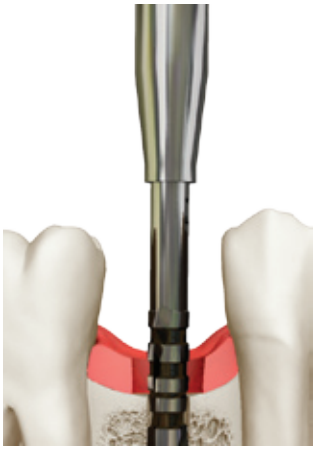


Drill Extender

Purpose: Extends overall length of latch-type drills and burs.

Used: With Internal and Single-stage Drills and Burs.

- Adds 16 millimeters to overall length of drills and burs
- Provides access between long crowns
- Internal geometry engages drill's latch geometry
- Compatible with latch-type handpieces, burs and drills

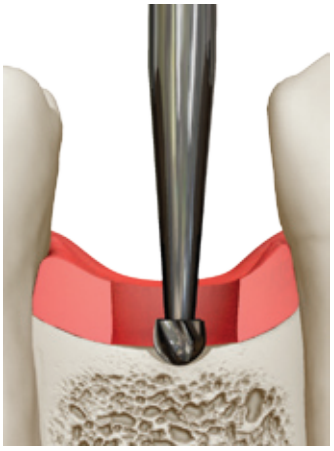


#6 Round Bur

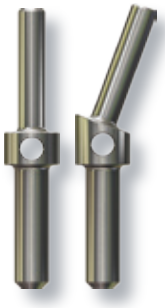
Purpose: Marking osteotomy sites and making minor osseous modification.

Used: With Internal and Single-stage implants.

- May be used to adjust osteotomy position or angle between successive surgical drills
- Marks osteotomy sites with small depression to prevent "skating" of subsequent drills
- Compatible with latch-type handpieces



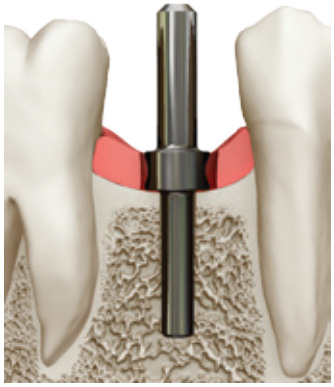
PARALLELING PINS

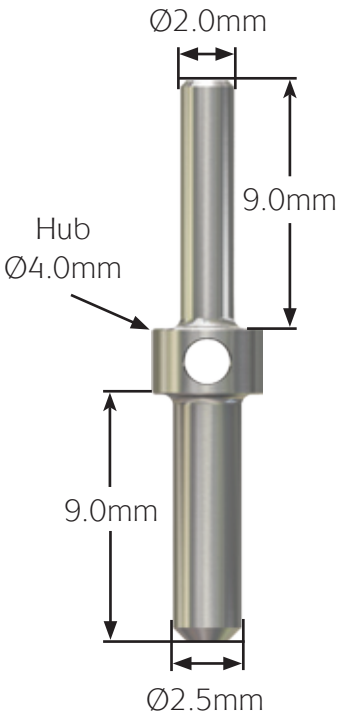


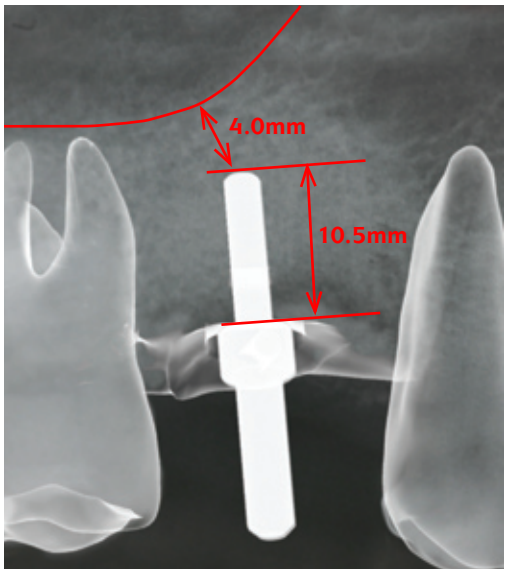
Purpose: Evaluation of osteotomy position and angle.

Used: With Internal and Single-stage implants.

- Provided straight or with a 20° angle
- Used after Ø2.0mm Starter Drill and Ø2.5mm Depth Drills
- 9mm shank for radiographic evaluation of proximity to adjacent anatomy
- Hub diameter is 4.0mm







Magnified length of the shank on the radiograph measures 10.5mm, versus known actual length of 9.0mm.

Dividing the measured (apparent) length from the radiograph by the known length determines the radiographic magnification factor.

Paralleling Pins may be used following the Ø2.0mm Starter Drill to evaluate any changes needed to improve implant angulation and position. The Paralleling Pins are provided both straight or with a 20° angle. The large end of the paralleling pin may be used after the osteotomy is enlarged to Ø2.5mm.

Radiographic evaluation of the osteotomy's proximity to adjacent anatomy can be made using the pins as reference, **however the level of radiographic magnification must be taken into account**. Divide the feature's apparent length on the image by the known actual length to calculate the magnification factor (apparent length ÷ actual length = magnification factor).

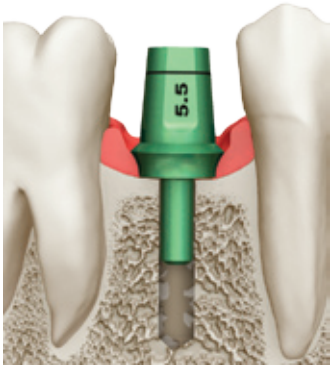
By example: if the shank measures 10.5mm on the radiograph, the magnification factor is: 10.5 ÷ 9 = 1.16 or 116%. Therefore if the Parallel Pin appears on the radiograph to be 4.0mm away from a structure, the actual distance is 4.0mm ÷ 1.16, or 3.4mm.

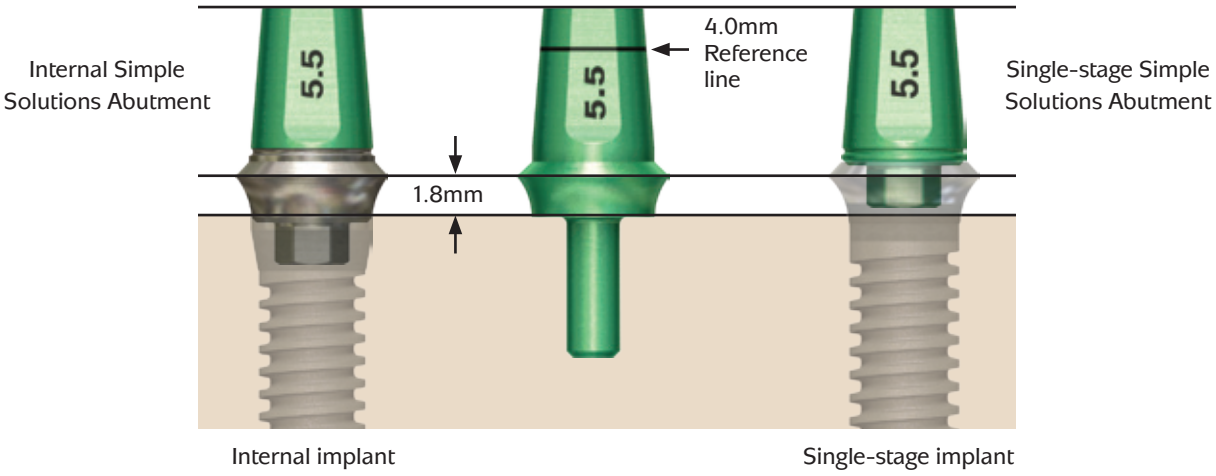
SIMPLE SOLUTIONS TRIAL ABUTMENTS

Purpose: Evaluation of osteotomy position in respect to a Simple Solutions Abutment.

Used: With Internal and Single-stage implants.

- Available for the three prosthetic platforms
- Represents either:
  - Single-stage implant with 5.5mm high Abutment; or
  - Internal implant with 5.5mm high/1.8mm collar Abutment
- **Assumes implant placed without counter-sinking**
- Reference line for 4.0mm high Simple Solutions Abutment
- Used following Ø2.0mm Starter Drill
- Shank 5.0mm long and 2.0mm in diameter

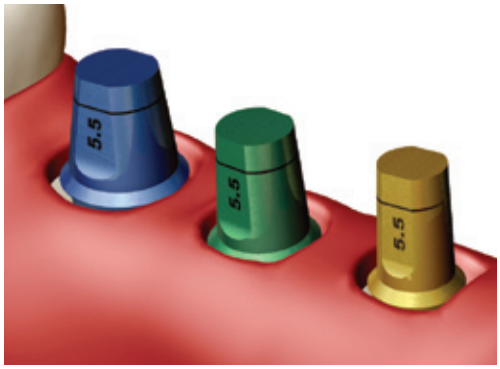




Trial Abutments allow clinicians to evaluate initial osteotomy position with respect to the restorative shoulder and abutment height. They approximate the intra-oral position of either a 5.5mm high Single-stage Simple Solutions Abutment on a Single-stage implant, or 5.5mm high / 1.8mm collar Internal Simple Solutions Abutment on an Internal implant.

A horizontal reference line reflects the approximate height of a 4.0mm high Simple Solutions Abutment.

A minimum of 1.5mm clearance on the occlusal aspect of the Simple Solutions Abutments is recommended to allow adequate thickness for the framework and veneer of the laboratory fabricated restoration. Failure to leave adequate space may make use of Simple Solutions restorative components impractical.



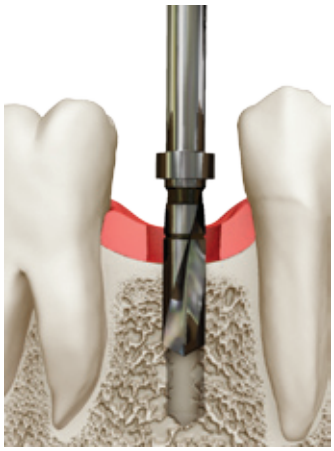
Ø2.5MM DEPTH DRILLS

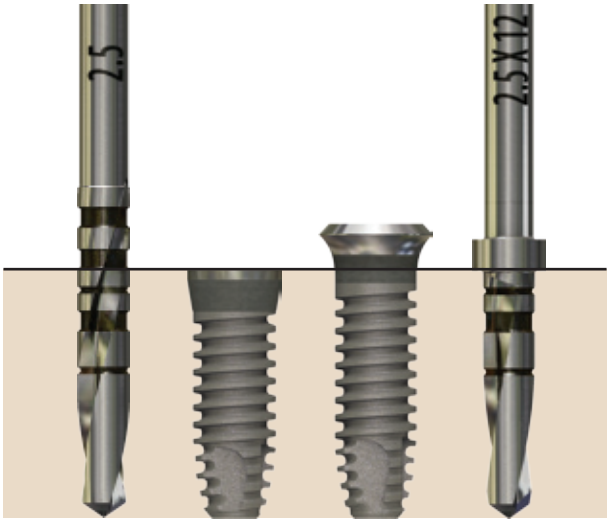
Purpose: Sets osteotomy depth following use of the Ø2.0mm Starter Drill.

Used: With Internal and Single-stage implants.

- Efficient cutting drill design collects bone for autografting
- Offered with and without length-specific stops
- Use Drill without stop when counter-sinking implant

Extended Shank versions are available which add 8mm of overall length. Depth markings are identical to standard length drills. Call for availability of these products in your market.





2.5mm Drill without Stop | 12mm long Internal Implant | 12mm long Single-stage Implant | 2.5 x 12mm Stop Drill

Depth Drills - The Ø2.5mm Depth Drills are designed to increase and/or set the depth of the osteotomy following use of the Ø2.0mm Starter Drill. They may also be the first drills used to set the osteotomy depth for implant placement in an extraction socket.

There are Ø2.5mm Drills with five depth stop options corresponding to the standard placement depths of the implants, as well as one with no depth stop. The stated length of drills provided in the Internal / Single-stage Surgical Kit (ref. 122-800) is the actual length (i.e. "Y" dimension included), and they correspond to the implant body length as illustrated in the figure above.

Depth-Stop Option - These drills have a fixed circular ring which acts as a "stop" to prevent the surgeon from drilling beyond the pre-determined depth (7mm, 9mm, 10.5mm, 12mm or 15mm). **These drills should not be used where subcrestal placement of the implant is desired.** Preparation to the full length permitted by a depth stop allows placement of the corresponding implant as shown above. For added reference these drills have standard depth markings below the stop.

No Depth-Stop Option - This drill has standard depth marks ranging from 7mm to 15mm. The clinician must manually stop the drill at the desired depth based on the depth marks on the shaft. This drill should be used if the prosthetic platform or transmucosal collar will be placed subcrestal (countersunk).

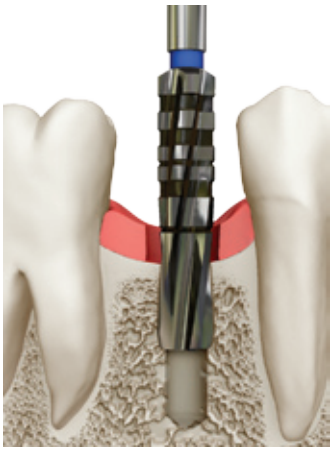
Ø3.0 - 5.4MM WIDTH INCREASING DRILLS

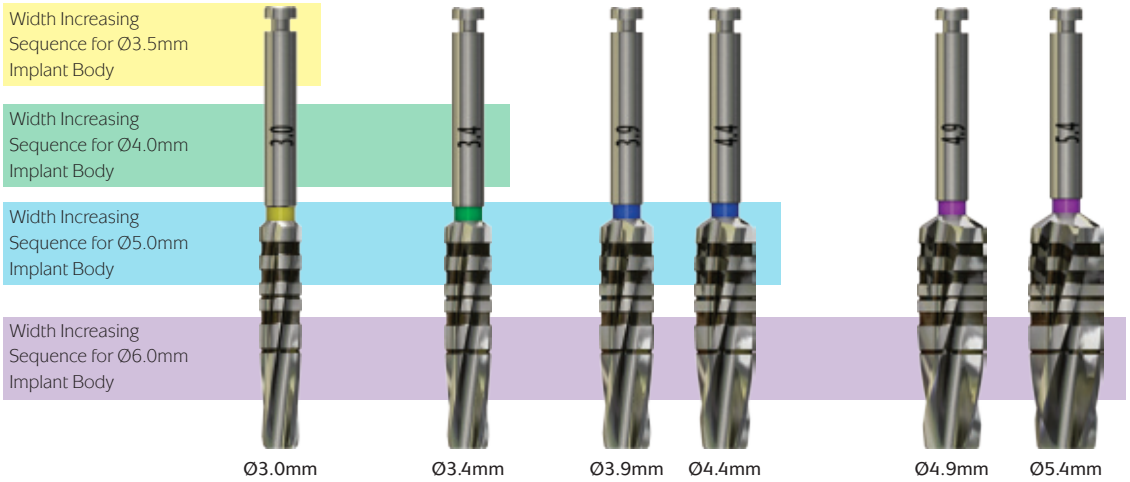
Purpose: Incrementally widens the osteotomy without creating excessive heat.

Used: With Internal and Single-stage implants.

- Non-end cutting geometry for added safety
- Efficient cutting drill design collects bone for autografting
- Designed to not cut beyond depth set by Depth Drills

Extended Shank versions are available which add 8mm of overall length. Depth markings are identical to standard length drills. Call for availability of these products in your market.





Width Increasing Drills - Used to widen the diameter of the osteotomy in roughly 0.5mm increments after the depth has been established with a Ø2.5mm Depth Drill. The gradual removal of bone reduces heat generation in the surrounding tissue. The cutting flutes extend the length of the drill body and collect bone which may be saved for intraoperative grafting procedures.

The Width Increasing Drills feature a highly efficient cutting geometry. The drills lack end-cutting geometry, thereby creating a built-in stop in dense bone to assist the surgeon in preventing osteotomy preparation beyond the planned depth.

Variations in bone density may be encountered within an osteotomy. Clinicians must observe the depth marks as the primary determinant of drilling depth, rather than relying exclusively on the non-end cutting geometry to stop the drill.

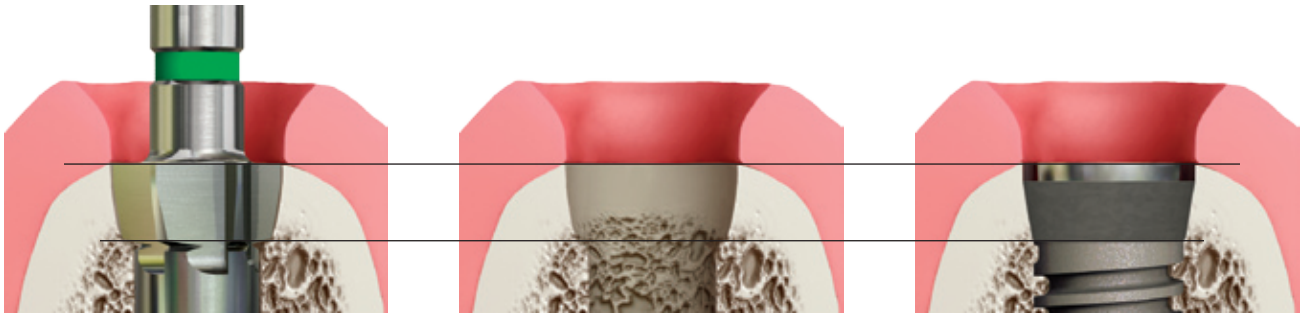
If a Width Increasing Drill fails to reach the desired depth as shown by the depth marks, use the Ø2.5mm Depth Drill to re-establish the depth and recommence the Width Increasing Sequence with the Ø3.0mm Width Increasing Drill.

INTERNAL CRESTAL BONE DRILLS

Purpose: Removes cortical bone at ridge crest to facilitate pressure-free seating of the crest module of BioHorizons Internal implants.

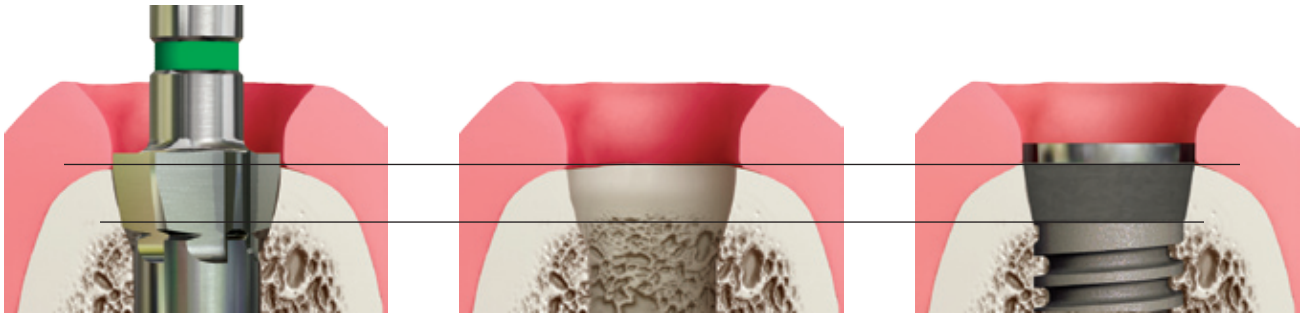
Used: Only Internal implants.

- **Site Specific.** Indicated when cortical bone is present at crest
- 850-2,500 rpm with steady sterile irrigation[11]
- Rounded non-end cutting hub centers drill in osteotomy
- Used following the final Width Increasing Drill for each implant



Example 1. Full cutting geometry used.

Implant platform level with osseous crest.



Example 2. Only partial cutting geometry used.

Machined collar left above osseous crest.

Internal Crestal Bone Drills prepare dense crestal bone to receive the crest module of a BioHorizons Internal implant. The crest module is the area beneath the prosthetic platform and above the implant threaded area. This drill is optional in less dense bone which often lacks cortical bone at the crest.

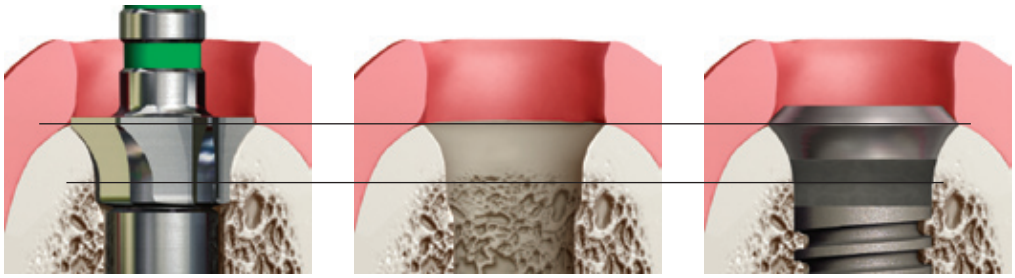
Preparing the bone to the top of the drill's cutting geometry allows the implant to be placed with the prosthetic platform level with the crestal ridge (**Example 1**). Do not use the full length of the cutting geometry if all or part of the 0.5mm machined collar is to be left supracrestal (**Example 2**).

SINGLE-STAGE COUNTER-SINK DRILLS

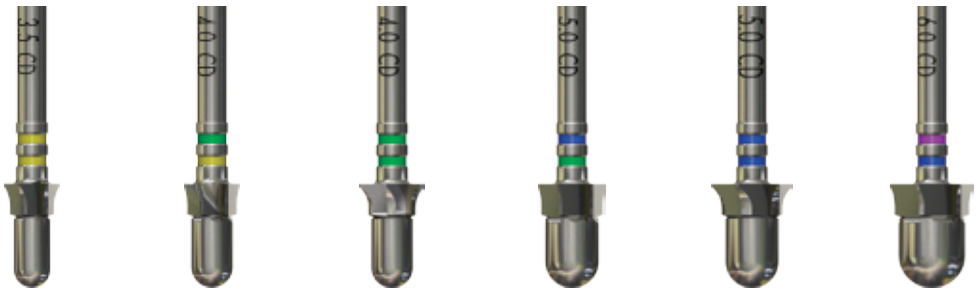
Purpose: Used for subcrestal placement of transmucosal collar on BioHorizons Single-stage implants.

Used: Only with BioHorizons Single-stage implants.

- **Protocol Specific**. **NOT USED UNLESS** all or part of the transmucosal collar is to be placed subcrestal
- 850-2,500 rpm with steady sterile irrigation[11]
- Rounded non-end cutting hub centers drill in osteotomy
- Used following the final Width Increasing Drill for each implant



Counter-sink Drills are available for each of the six Implant Body/Prosthetic Platform combinations available in the Single-stage system. **They must ONLY be used if the flared transmucosal collar is to be placed below the osseous crest.** Using the Counter-sink Drill to full depth of the cutting geometry prepares the site to allow the implant to be placed with the top of the transmucosal collar level with the crest, **assuming the osteotomy has been prepared to accept the extra depth.** When only a portion of the collar is to be countersunk, only the corresponding proportion of the drill's cutting geometry is used.



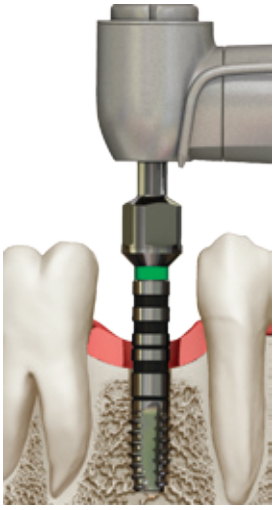
Implant Body	**3.5mm**	**4.0mm**	**4.0mm**	**5.0mm**	**5.0mm**	**6.0mm**
Prosthetic Platform	**3.5mm**	**3.5mm**	**4.5mm**	**4.5mm**	**5.7mm**	**5.7mm**

Each of the six Single-stage Counter-sink Drills provided in the Surgical Kit has a unique double color-code band signifying the Implant Body/Prosthetic Platform combination with which it must be used. Be certain the Counter-sink Drill being used matches the Implant Body/Prosthetic Platform combination of the implant being placed.

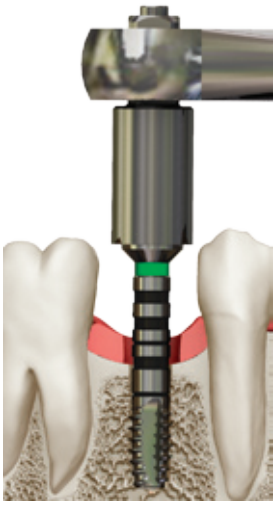
Purpose: Prepares dense cortical bone for implant threads.

Used: With BioHorizons Internal and Single-stage implants.

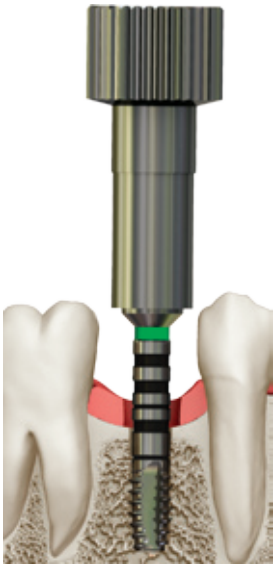
- **Site Specific**. Not typically used in soft (D3-D4) bone
- **30 rpm or less**[14]
- Final osteotomy preparation instrument prior to implant placement
- Square drive shaft interfaces with Ratchet and Hand Wrench



Handpiece



Ratchet &
Extender



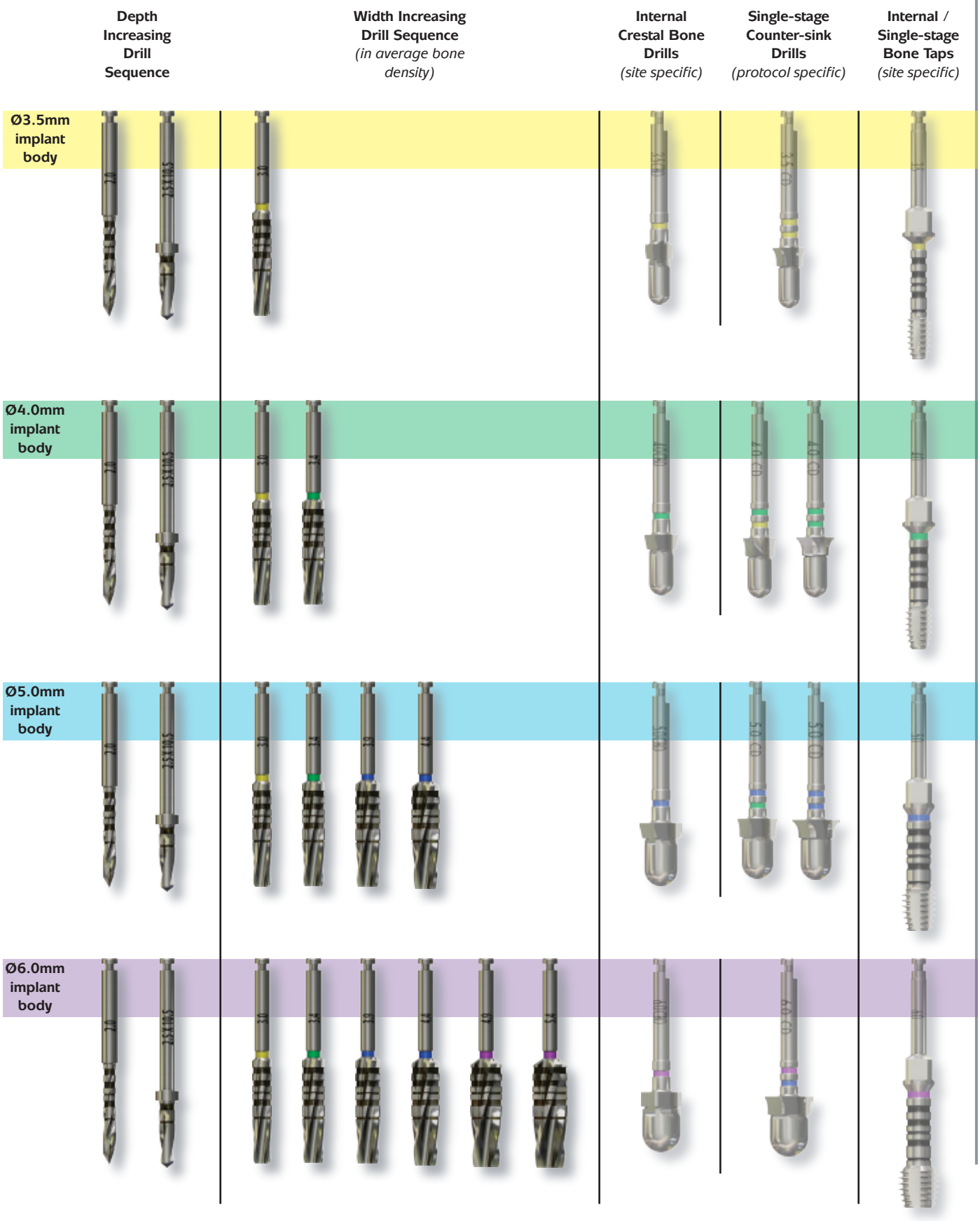
Hand Wrench &
Extender

Bone Taps - The osteotomy should be tapped in dense bone (D1-D2) to prepare the site to accept the implant's threads without creating excessive pressure. The use of a Bone Tap may also be indicated in less dense bone when one or more sides of the osteotomy is in contact with a lateral plate of cortical bone.

The Bone Taps may be driven with either a Handpiece, Ratchet, Hand Wrench or by the BioHorizons Surgical Driver (purchased separately, ref. 150-000). The Ratchet and Hand Wrench Extender may be used when additional length is needed.

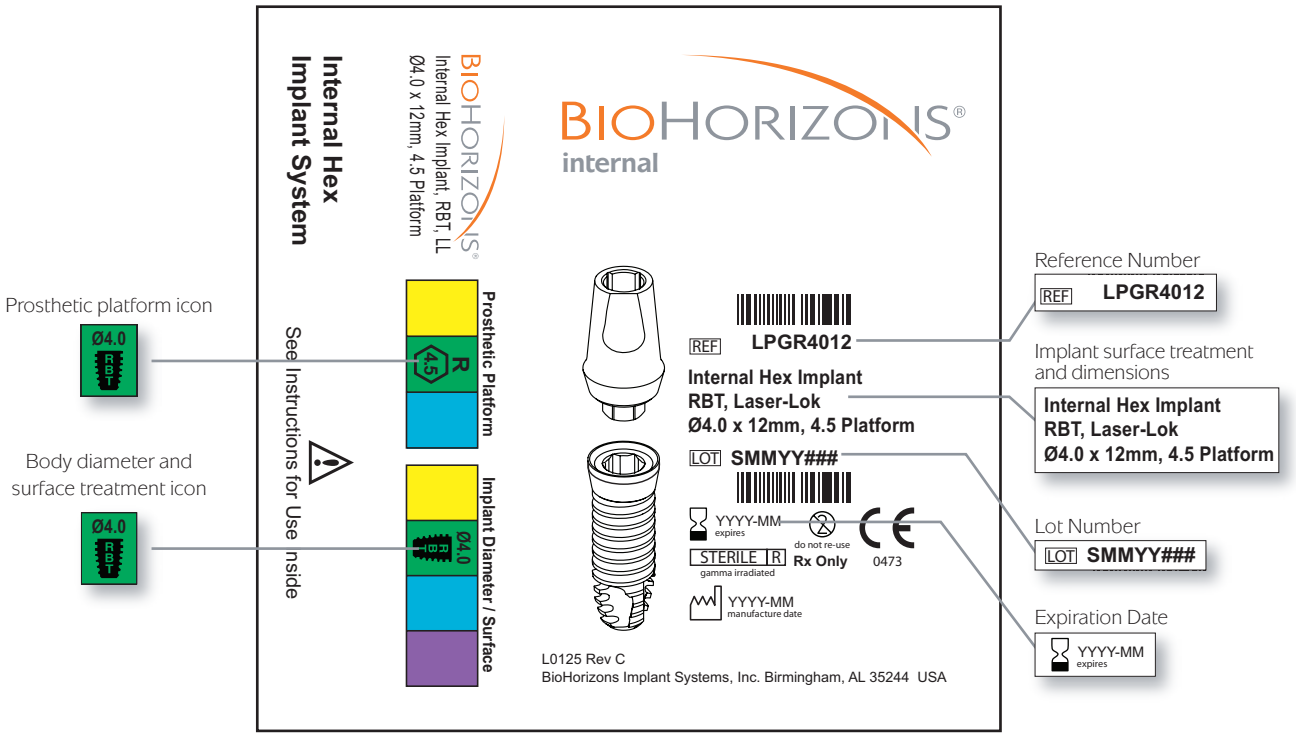
Place the tip of the Bone Tap into the osteotomy, apply firm apical pressure and begin rotating slowly in a clockwise direction (30 rpm or less is recommended)[14]. When the threads engage, allow the tap to feed without excessive pressure. To remove, rotate the Bone Tap in a counter-clockwise direction, allowing it to back out of the osteotomy. ***Do not pull on the Bone Tap to remove it from the site***.

INSTRUMENT SEQUENCE REVIEW



INTERNAL IMPLANT PACKAGING

BioHorizons Internal implants are provided in double-layer packaging. A cardboard sleeve protects a blister pack containing the implant in a sterile inner vial. Only the sterile inner vial should be introduced into the sterile surgical field. The blister tray lid has multiple peel-and-stick labels for affixing to the patient's chart.

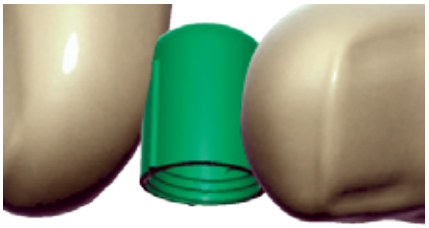


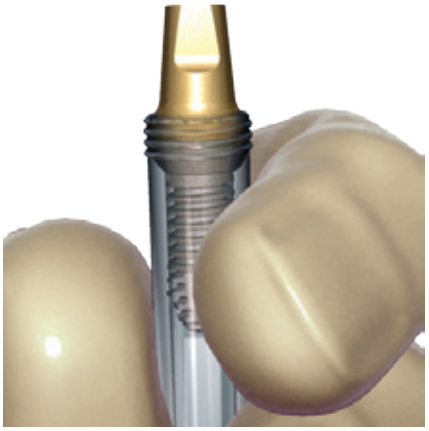
INTERNAL IMPLANT PICK-UP

Removing the lid of the blister tray exposes the inner implant vial, which may then be introduced in the sterile surgical field. While holding the vial in an upright fashion, remove the cap by rotating it in a counter-clockwise direction. The implant can then be removed from the vial by engaging the premounted *3inOne* Abutment with the Abutment-level Driver for Handpiece (PHA) or the Abutment-level Driver for Ratchet (PRA).

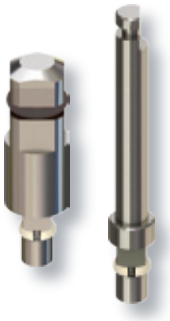
Please see the following page for additional information on Abutment-level Driver / Abutment Square engagement.

The implant is carried to the surgical site on the driver. Take care not to touch the implant surface during the transfer. The peel-and-stick labels on the blister tray should be placed in the patient's chart as a record of the device(s) used.





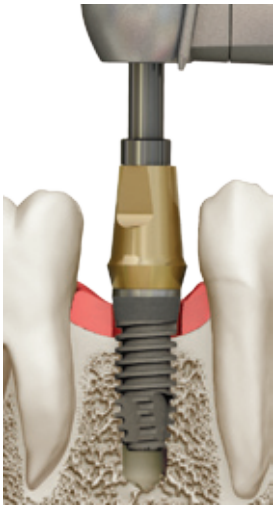
INTERNAL ABUTMENT-LEVEL DRIVERS



Purpose: Engages the *3inOne* Abutment of an Internal Implant allowing it to be driven into the osteotomy.

Used: Only with BioHorizons Internal implants.

- Pre-mounted *3inOne* Abutment serves as the surgical drive mount
- Drivers interface with the internal square of the *3inOne* Abutment
- PEEK plastic snap ring secures implant to be carried to osteotomy
- Electric handpiece or manual insertion options
- 30 rpm or less[14]



Abutment-level Drivers engage Internal implants via the square in the interior coronal aspect of the pre-mounted *3inOne* abutment. Remove the cap from the implant sterile inner vial and seat the chosen driver, either Handpiece- or Ratchet-driven. Remove the implant from the vial and carry it to the osteotomy on the driver, taking precautions not to touch the implant surface during the transfer.

If the driver's square does not engage the abutment's square during pick-up, the plastic snap ring WILL secure the implant for transport to the osteotomy. The squares will engage when the driver is slowly rotated under apical pressure.

Place the apex of the implant into the osteotomy, apply firm apical pressure and begin rotating slowly (30 rpm or less is recommended).[14] When the threads engage, allow the implant to feed without excessive pressure.

Overtightening the implant in the osteotomy may cause osseous microfracture. Too much pressure at the crest may also compromise surgical results. Manual seating via the Driver for Ratchet may be desired to gain a tactile sense of final implant placement. If too much resistance is felt during insertion, remove the implant and revise the osteotomy with the appropriate Crestal Bone Drill or Bone Tap as deemed necessary to reduce insertion torque.

The stated length of BioHorizons Internal implants is measured from the apex of the implant to the top of the prosthetic platform (see page 3). The placement level should be driven by the prosthetic necessities of each case. Contributing factors include: available inter-occlusal space, soft tissue thickness and planned prosthesis type.

Crestal Placement

To place the implant level with the osseous crest, use the drill markings or depth stops to create an osteotomy as deep as the stated implant length: e.g. drill to 12mm for a 12mm length implant.

Supracrestal Placement

Supracrestal placement puts the 0.5mm machined collar above the osseous crest. Use the drill markings or depth stops to create an osteotomy 0.5mm shallower than the stated implant length: e.g. drill to 11.5mm for a 12mm length implant. Prior to closure, verify the implant has initial stability and the soft tissue coverage is adequate.

Placement in Uneven Ridges

When placing an Internal implant in an uneven ridge, use the drill markings or depth stops to create an osteotomy as deep as the stated implant length: e.g. drill to 12mm for a 12mm length implant. This allows crestal placement at the high point of the ridge, and leaves the machined collar/Laser-Lok/surface treatment in contact with the soft tissue.

If the discrepancy is more than 1.5mm, leveling the ridge should be considered.

Internal *3inOne* Abutment Removal

To remove the *3inOne* Abutment engage the Abutment Screw with the .050" (1.25mm) Hex Driver. Apply firm apical pressure to the Hex Driver and rotate counter-clockwise until the screw is completely disengaged from the implant body. The *3inOne* Abutment may then be removed.

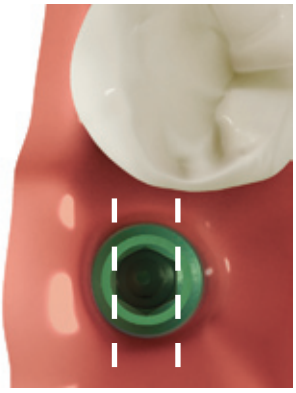
In soft bone, or when the implant lacks initial stability, an Abutment Clamp (ref. IMPAH, sold separately) should be used to grasp the outside of the abutment to provide counter-torque during the loosening of the Abutment Screw. The *3inOne* Abutment may be removed once the Abutment Screw has been completely loosened.

The *3inOne* Abutment (and Abutment Screw) should be retained with the patient's chart. It can later be used by the restoring dentist in the impression making procedure and as a temporary or final abutment for cement retention.

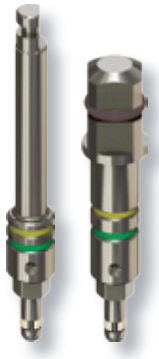
Internal Hex Orientation

The flat surface on the external aspect of the *3inOne* Abutments is indexed to one of the six flats of the implant's internal hexagon. In most cases one of the hex flats should be oriented to the facial aspect, as it allows for angulation correction with stock angled abutments (shown at right). It also allows the flat of the *3inOne* Abutment to be placed to the facial which leaves more room for porcelain in that area on the final prosthesis.

The implant's rotational position can be adjusted following removal of the *3inOne* Abutment using the Implant-level Drivers as described on the opposite page.



Implant-level Drivers



Purpose: Engages implant's internal hex allowing its position to be adjusted in the osteotomy.

Used: With BioHorizons Internal implants (and Single-stage implants).

- May be used with Internal implants following removal of the *3inOne* Abutment
- Offers a narrower path of insertion and better clearance than the *3inOne* Abutment / Abutment-level Driver option
- Handpiece or manual insertion options
- 30 rpm or less[14]

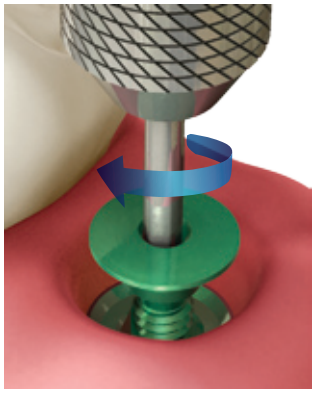
The rotational position (hex flat orientation) or the placement level of Internal implants can be adjusted with the Implant-level Drivers following removal of the *3inOne* Abutment. Engage the implant's internal hex with the appropriate driver and rotate to the desired position. The dimple found on Implant-level Drivers is indexed to one of the internal hex flats and can be used to help achieve the desired hex orientation.

Internal Cover Caps

Purpose: Protects prosthetic platform in two-stage (submerged) surgical protocols.

Used: With BioHorizons Internal implants.

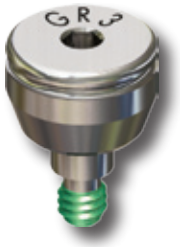
- Packaged with every Internal Implant
- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver
- Color-coded by prosthetic platform



Remove the *3inOne* Abutment and thoroughly irrigate the inside of the implant to remove blood and other debris. Unscrew the Cover Cap (included in each implant vial) from its holder and screw it into the implant using the .050" (1.25mm) Hex Driver. An antibacterial paste may be placed on the end of the Cover Cap to help seal it with the implant body and decrease the risk of bacterial growth within the implant body during the healing phase. Following placement of the Cover Cap, the surgical site should be irrigated and the soft tissue adapted in a normal surgical fashion. Take precautions to prevent the Cover Cap from being aspirated by the patient.

Note: Internal Cover Caps may be used with Single-stage implants of corresponding prosthetic platform diameter. However, they will not contour tissue away from the implant shoulder.

NARROW / REGULAR / WIDE INTERNAL HEALING ABUTMENTS



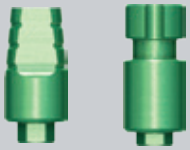
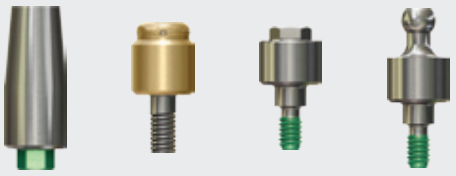
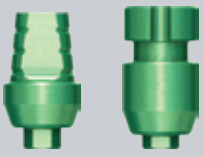
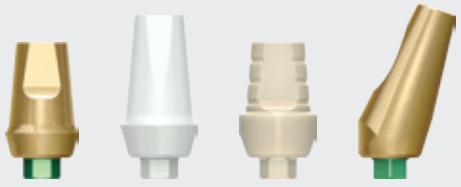
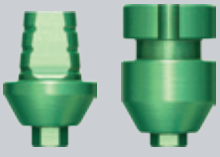
Purpose: Transmucosal element for developing soft tissue emergence with Narrow, Regular or Wide Emergence Internal system prosthetic components.

Used: Only with BioHorizons Internal implants.

- Available in three emergence profiles to match final abutments
- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver
- Color-coded by prosthetic platform
- Encoded for easy intraoral identification, for example:
  GR3 = **G**reen (4.5mm) platform / **R**eg. Emerg. / **3**mm High

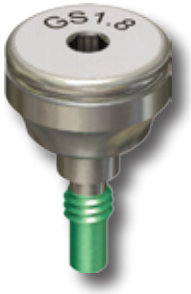
Healing Abutments are placed after uncovery in a two-stage surgical protocol, or in lieu of a Cover Cap in a single-stage (non-submerged) protocol. Internal Healing Abutments are specific to each of the three prosthetic platform diameters (Ø3.5mm, Ø4.5mm and Ø5.7mm), and come in three heights (1mm, 3mm and 5mm) with the choice of Narrow, Regular and Wide emergence profiles. The emergence should be chosen to match that of the intended restorations to ensure interference free seating of the impression components and abutments. The chart below shows examples of prosthetic components of each emergence in the 4.5mm prosthetic platform.

Prior to seating the Healing Abutment, thoroughly irrigate the inside of the implant to remove blood and other debris. An antibacterial paste may be placed on the screw portion to help seal the Healing Abutment with the implant body and decrease the risk of bacterial growth within the implant body during the healing phase. Following seating, irrigate the surgical site and adapt the soft tissue in normal surgical fashion. A gingivectomy or apically positioned flap technique may be used to reduce the soft tissue thickness and to decrease sulcular depth around the implant. The suture groove on the Healing Abutment may be used to apically position the soft tissue flap. Take precautions to prevent the Healing Abutment from being aspirated by the patient.

	Healing Abutments	Impression Components	Internal System Abutments
Narrow Emergence			
Regular Emergence			
Wide Emergence			

NOTE: 3.5mm and 5.7mm prosthetic components are not shown in this chart.

INTERNAL SIMPLE SOLUTIONS HEALING ABUTMENTS



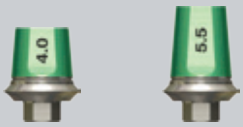
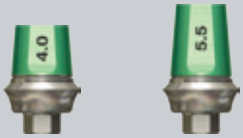
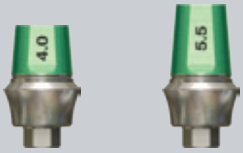
Purpose: Transmucosal element for developing soft tissue emergence with Internal Simple Solutions prosthetic components.

Used: Only with BioHorizons Internal implants.

- Select by prosthetic platform and desired collar height
- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver
- Color-coded by prosthetic platform
- Encoded for easy intraoral identification, for example:
  GS1.8 = **G**reen (4.5mm) platform / **S**imp. Sol. / **1.8**mm collar

Internal Simple Solutions Healing Abutments are placed after uncovery in a two-stage surgical protocol, or in lieu of a Cover Cap in a single-stage (non-submerged) protocol. They are specific to each of the three prosthetic platform diameters and come in three collar heights (0.8mm, 1.8mm and 2.8mm) matched to the collar heights of the Internal Simple Solutions Abutments. Matching the Healing Abutment height to the Abutment collar height develops the soft tissue emergence for interference-free abutment seating. The chart below shows examples of Internal Simple Solutions components of each collar height in the 4.5mm prosthetic platform.

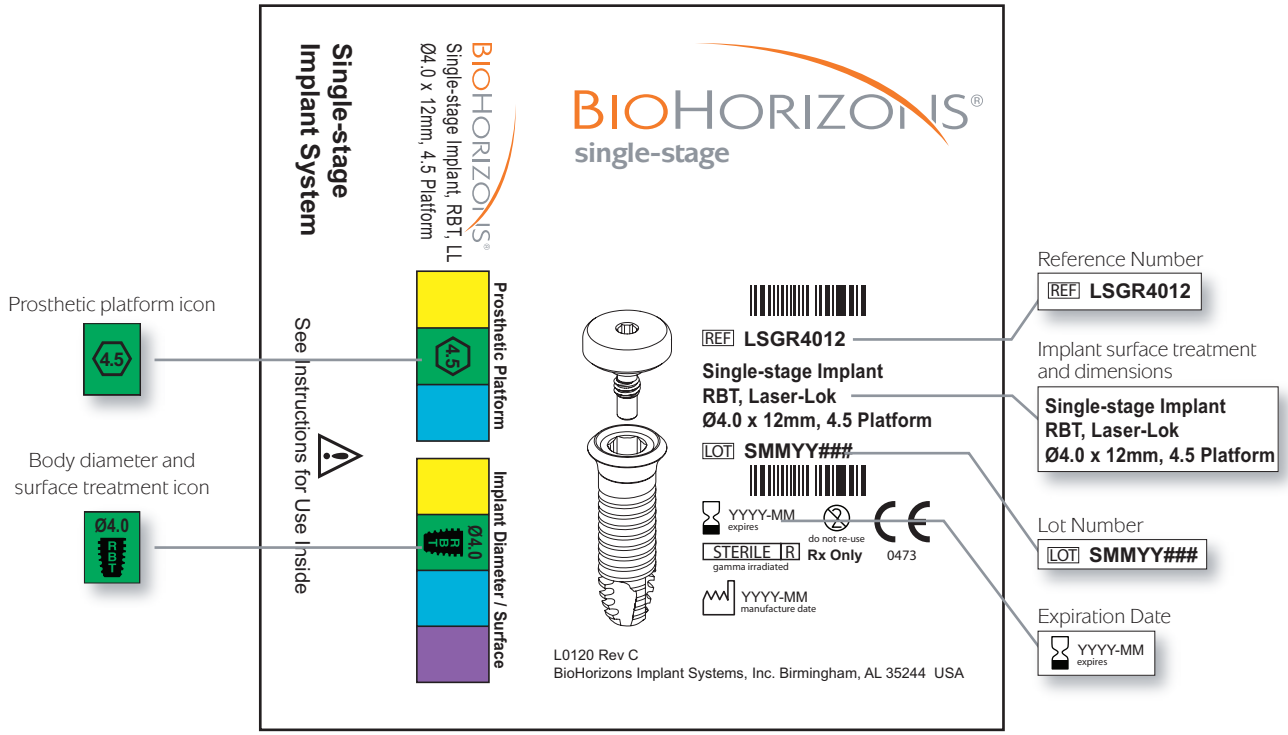
Prior to seating the Healing Abutment, thoroughly irrigate the inside of the implant to remove blood and other debris. An antibacterial paste may be placed on the screw portion to help seal the Healing Abutment with the implant body and decrease the risk of bacterial growth within the implant body during the healing phase. Following seating, irrigate the surgical site and adapt the soft tissue in normal surgical fashion. A gingivectomy or apically positioned flap technique may be used to reduce the soft tissue thickness and to decrease sulcular depth around the implant. The suture groove on the Healing Abutment may be used to apically position the soft tissue flap. Take precautions to prevent the Healing Abutment from being aspirated by the patient.

	Simple Solutions Healing Abutments	Internal Simple Solutions Abutments
0.8mm Collar		
1.8mm Collar		
2.8mm Collar		

NOTE: 3.5mm and 5.7mm prosthetic components are not shown in this chart.

SINGLE-STAGE IMPLANT PACKAGING

BioHorizons Single-stage implants are provided in double-layer packaging (as depicted below). A cardboard sleeve protects a blister pack containing the implant in a sterile inner vial. Only the sterile inner vial should be introduced into the sterile surgical field. The blister tray lid has multiple peel-and-stick labels for affixing to the patient's chart.

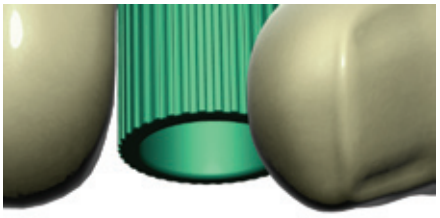


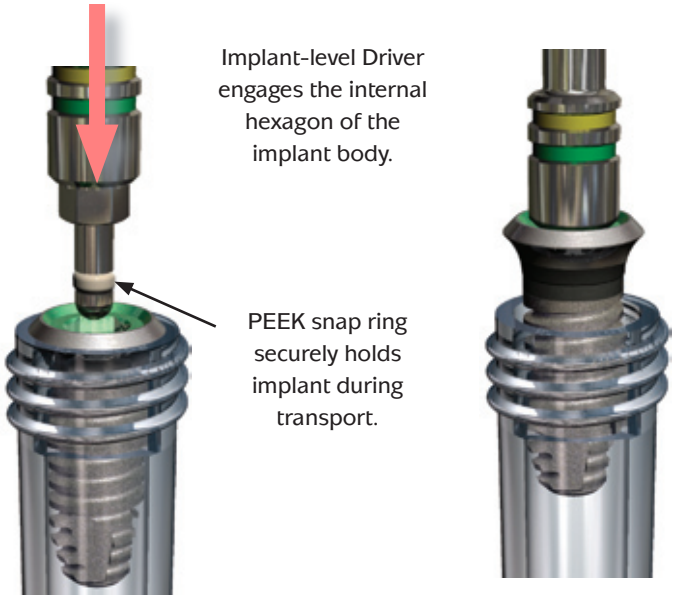
SINGLE-STAGE IMPLANT PICK-UP

When the lid of the blister tray is removed, the implant vial is exposed and may then be placed in the sterile field. While holding the vial in an upright fashion, remove the cap by rotating it in a counter-clockwise direction. The implant can then be removed from the vial by engaging the internal hexagon with the appropriate Implant-level Driver.

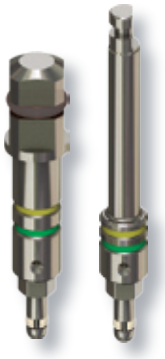
Please see the following page for additional information on Implant-level Driver / Implant engagement.

The implant is carried to the surgical site on the driver. Take care not to touch the implant surface during the transfer. The peel-and-stick labels on the blister tray should be placed in the patient's chart as a record of the device(s) used.





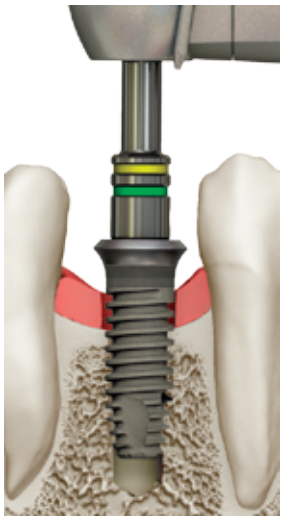
IMPLANT-LEVEL DRIVERS



Purpose: Engages implant's internal hex allowing it to be driven into the osteotomy.

Used: With BioHorizons Single-stage and Internal implants.

- Exclusive method for placing Single-stage implants
- May also be used with Internal implants following removal of *3inOne* Abutment
- Handpiece or manual insertion options
- 30 rpm or less[14]



Implant-level Drivers - Handpiece and Ratchet

Implant-level Drivers engage Single-stage implants via the implant's internal hex. Remove the cap from the sterile inner vial and seat the appropriate driver, either Handpiece- or Ratchet-driven, depending on preference. Remove the implant from the vial and carry it to the osteotomy on the driver, taking precautions not to touch the implant surface during the transfer.

If the driver's hex does not engage the implant internal hex during pick-up, the plastic snap ring WILL secure the implant for transport to the osteotomy. The hexagons will engage when the driver is slowly rotated under apical pressure.

Place the apex of the implant into the osteotomy, apply firm apical pressure and begin rotating slowly (30 rpm or less is recommended).[14] When the threads engage, allow the implant to feed without excessive pressure.

Overtightening the implant in the osteotomy may cause osseous microfracture. Too much pressure at the crest may also compromise surgical results. Manual seating via the Driver for Ratchet may be desired to gain a tactile sense of final implant placement. If too much resistance is felt during insertion, remove the implant and revise the osteotomy with the appropriate Counter-sink Drill or Bone Tap as deemed necessary to reduce insertion torque.

Hex Orientation

In most cases one of the implant's internal hex flats should be oriented to the facial aspect, as it allows for angulation correction with stock angled abutments. It also allows for easier indexing of Simple Solutions and other prosthetic components.

The dimple found on Implant-level Drivers is indexed to one of the internal hex flats and can be used to help achieve the correct hex orientation.

Crestal versus Subcrestal Placement

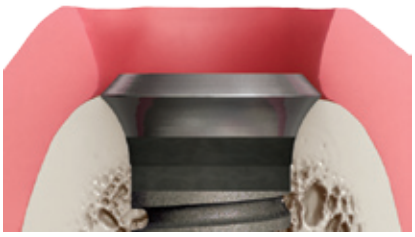
The stated length of BioHorizons Single-stage implants is measured from the apex of the implant to the coronal aspect of the 12 micron Laser-Lok band (see page 3). The 1.8mm transmucosal collar begins at the apical aspect of the 8 micron Laser-Lok band and extends coronally to the implant shoulder. Typical placement positions the transmucosal collar in soft tissue, and the rest of the implant in bone. Counter-sinking the transmucosal collar is considered a subcrestal placement.

The actual placement level is usually driven by the prosthetic necessities of each case. Contributing factors include: available inter-occlusal space, soft tissue thickness and planned prosthesis type.

Typical (crestal) Placement

Transmucosal collar above the osseous crest.
Prepare osteotomy to implant's stated length.

Subcrestal Placement



Transmucosal collar counter-sunk below osseous crest.
Increase osteotomy to accommodate added depth.

Subcrestal placement of the transmucosal collar requires a proportionate increase of the osteotomy depth and use of the appropriate Counter-sink Drill.

Healing Abutment Placement

Purpose: Protect prosthetic platform & contour tissue away from implant shoulder.

Used: Only with BioHorizons Single-stage implants.

- **2mm high Healing Abutment packaged with each Single-stage Implant**
- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver
- Available 4mm height with a suture groove to help apically position tissue
- Color-coded by prosthetic platform
- Encoded for easy intraoral identification, for example:
  SG2 = **S**ingle-stage / **G**reen (4.5mm) platform / **2**mm High

Single-stage Healing Abutments are available in two heights (2mm and 4mm) to accommodate variable tissue thickness. They contour tissue away from the implant shoulder to interference-free seating of prosthetic components. A 2mm Healing Abutment is included with each Single-stage implant. The 4mm high Healing Abutments have a suture groove which may be used to apically position the soft tissue.

An antibacterial paste may be placed on the screw portion to help seal the Healing Abutment with the implant body and decrease the risk of bacterial growth within the implant body during the healing phase. Following seating, irrigate the surgical site and adapt the soft tissue in normal surgical fashion. A gingivectomy or apically positioned flap technique may be used to reduce the soft tissue thickness and to decrease sulcular depth around the implant. Take precautions to prevent the Healing Abutment from being aspirated by the patient.

Internal Bone Profilers

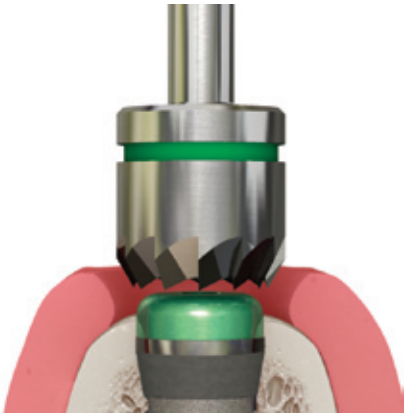
Bone Profiler

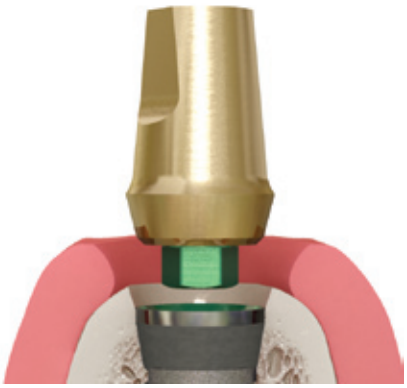
Profiler Guide

Purpose: Remove and contour excess bone and soft tissue from the area of the prosthetic platform.

Used: Only with BioHorizons Internal implants.

- BioHorizons Ref. # PYBP / PGBP / PBBP
- 850-2,500 rpm drill speed with steady sterile irrigation[11]
- Compatible with latch-type, speed-reducing handpieces
- Profiler Guide protects implant platform
- **Color-coded by prosthetic platform**





Bone Profilers remove and contour excess bone and soft tissue from the coronal aspect of the implants to allow seating prosthetic components. There is a color-coded Bone Profiler and Guide for each of the three Internal prosthetic platforms

To use, remove the surgical Cover Cap from the implant and place the Profiler Guide [both use the .050" (1.25mm) Hex Driver]. The Guide aligns the Bone Profiler and protects the implant from damage. **Do not use the Profiler without the Guide in place.** The Profiler is used in a latch-type handpiece under copious amounts of sterile irrigation. Following removal of the excess bone and soft tissue, unscrew the Guide from the implant and seat the desired prosthetic component.

Bone Profilers are not included in the Surgical Kit, but may be purchased separately from the BioHorizons Internal / Single-stage Product Catalog (ref. ML 0115).

Ø2.0mm Lindemann Drill

Purpose: Side-cutting drill for correction of osteotomy position and/or angulation.

Used: With latch-type, speed-reducing handpieces.

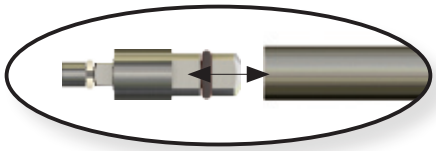
- BioHorizons Ref. # 122-110
- Compatible with latch-type, speed-reducing handpieces
- 850-2,500 rpm with steady sterile irrigation[11]

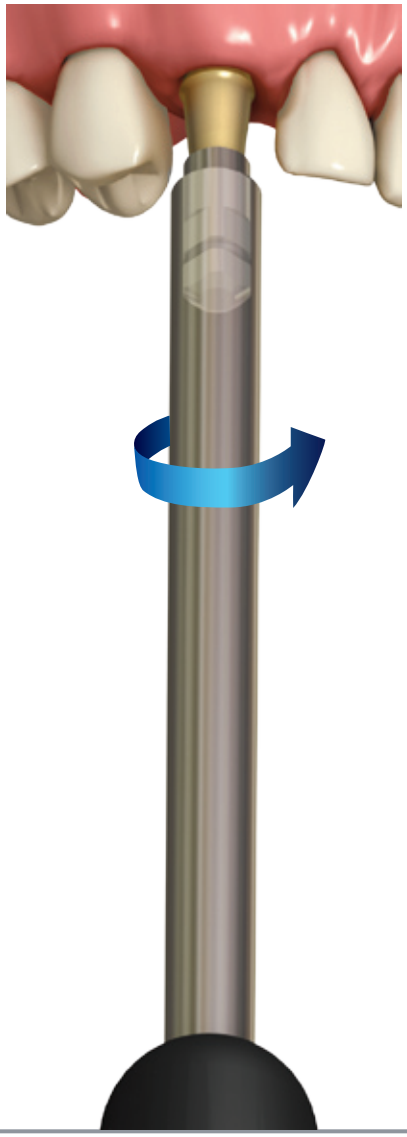
Surgical Driver

Purpose: Manual implant placement.

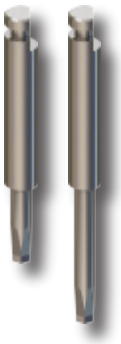
Used: As a drive tool in lieu of the Ratchet or Hand Wrench.

- BioHorizons Ref. # 150-000
- May be used to drive the following instruments:
  - Implant-level and Abutment-level Drivers for Ratchet
  - .050" Hex Drivers (regular and long)
  - Bone Taps





.050" (1.25mm) Handpiece Hex Driver



Purpose: Removal and placement of Cover Caps, Healing Abutments and Abutment Screws.

Used: With latch-type, speed-reducing handpieces.

- BioHorizons Ref. # 134-350 (regular) and 134-450 (long)
- Use a surgical motor with torque-limiting capabilities when using drivers to tighten components
- Compatible with most torque wrenches utilizing latch-type connection drivers

Surgical Kit Cleaning

BioHorizons Surgical Kits are provided non-sterile and must be cleaned and sterilized prior to use following the accompanying Instructions for Use. Always remove instruments from the packaging prior to sterilization, and remove and discard packaging materials used to stabilize and secure kits during shipment. Double-check your surgical instruments to ensure their functionality prior to surgery. Verify the dimensional accuracy of drill shanks using a Bur Testing Gauge (opposite). It is recommended to have back-up sterile drills available prior to any surgical procedures.

Caution: The use of hydrogen peroxide or other oxidizing agents will cause damage to the surface of the instruments. Towel- or air-dry all instrumentation before sterilizing. Drills and taps should be replaced when wear is noticed, such as a decrease in cutting efficiency or when signs of discoloration appear. BioHorizons recommends replacing the drills after approximately 12 to 20 osteotomy cycles, depending on the bone density.[13]

It is also recommended proper testing, cleaning and calibration of sterilization equipment occur frequently to assure the units are in proper working order. Equipment operating conditions vary and it is the responsibility of each dental office to ensure proper sterilization technique for instrumentation is followed.

Clinicians may opt to lay out all the surgical instruments into the sterile field in the order of use prior to surgery. This may help assure a correct progression through the surgical sequence.

Bur Testing Gauge

Also called a "Go / No-Go Gauge," the Bur Testing Gauge is used to verify the dimensional accuracy of drill shanks of latch-type burs. Burs in proper condition **WILL** fit into the larger diameter hole, but **WILL NOT** fit into the smaller hole (marked red).

Burs failing either of these criteria are unfit for use and may become stuck in the handpiece if used. The gauge is included with all W&H starter packages, and may also be ordered from the BioHorizons Internal/Single-stage catalog.

Post-operative Considerations

A period of unloaded healing time is often recommended. This is dependent on individual patient healing rates and bone quality of the implant site. Each case must be independently evaluated. This unloaded healing period allows for integration between the bone and implant surface.

The patient must be instructed to follow a post-surgical regimen including cold packs for 24 hours post-implantation. The patient's diet should consist of soft foods and possibly dietary supplements. Pharmacological therapy should be considered as the patient's condition dictates.

If a removable prosthesis is used during the initial healing phase, it is recommended a soft liner material be used to prevent pressure on the surgical site. This soft liner should be relieved over the implant site. The patient should be checked periodically to monitor healing of the soft tissues and bone using clinical and radiographic evaluations.

Ongoing hygiene for the implant patient is vital. Hygiene recall appointments at three month intervals are suggested. Instruments designed for implant scaling, such as Implacare® instruments from Hu-Friedy® should be utilized. The stainless steel handles may be fitted with assorted tip designs used for hygiene on natural teeth. The Implacare® scalers will not damage implant abutments and contain no glass or graphite fillers which can scratch titanium implant abutments.

Important Information Regarding Previous Internal Surgical Kits (ref. PSKC)

In April 2007 BioHorizons introduced a new surgical drill design in conjunction with the launch of the combined BioHorizons Internal / Single-stage Surgical Kit (ref. 122-800). **The information below applies only to clinicians with earlier-version Internal Surgical Kits (ref. PSKC). These kits were provided with the previous design drills. It is important clinicians be able to distinguish between previous and new drill designs. Affected drills include:**

Starter Drill
Ref. 122-103
Ø2.5mm Depth Drills
Ref. 122-225, 122-12509, 122-125105, 122-12512 and 122-12515
Width Increasing Drills
Ref. 122-230, 122-232, 122-237, 122-242, 122-247 and 122-252

The design and diameter (2.0mm) of the new Starter Drill obviates the need for Ø2.0mm Depth Drill Series (122-220, 122-12009, 122-120105, 122-12012 and 122-12015), and therefore, these drills have been removed from the drilling sequence.

BioHorizons recommends against intra-operative commingling of the previous and new drill designs, as doing so may result in an inaccurate osteotomy depth. However, clinician judgment as related to any specific case or the use of any instrument always supersedes any recommendations made in this or any other BioHorizons literature.

Previous and New Design Drills may be differentiated by observation of the cutting flutes. The flutes on the previous design stop below the depth marks. New Design Drills have cutting flutes extending through the Depth Marks (see Diagram A). Please consult your BioHorizons Product Support Specialist or Customer Care if you are uncertain of which design drills you have.

With the exception of the elimination of the Ø2.0mm Depth Drills, the new design does not alter the recommended Drilling Sequence for the Internal Surgical Kit (ref. PSKC), or placement of instruments within the kit. Please refer to the Internal Catalog and Technique Manual (ML 0115 OCT 2006) for detailed instructions for use.

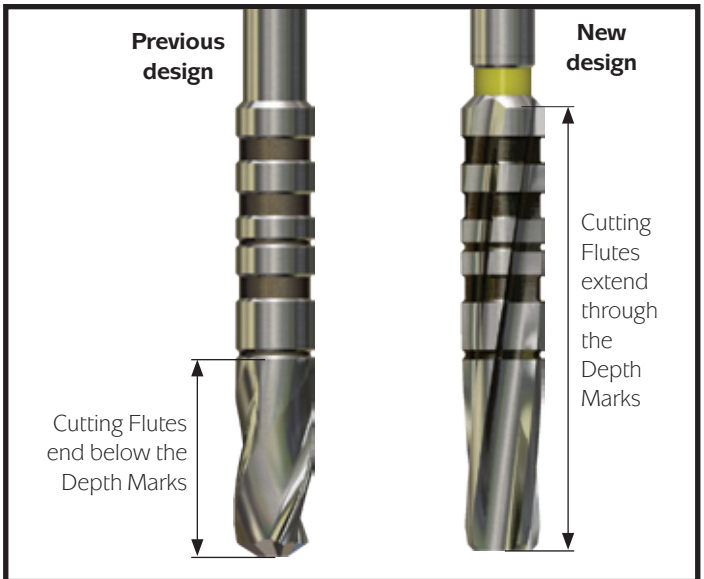


Diagram A. Differentiating between drill designs

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BioHorizons implants and prosthetic components carry a Lifetime Warranty. We will replace any BioHorizons implant or prosthetic component if removal of that product due to failure (excluding normal wear to overdenture attachments) is required for any reason, at any time.

Warranties on Instruments, Surgical Drills, Taps and Torque Wrenches:

BioHorizons warranties instruments, surgical drills, taps and torque wrenches for the period specified for each in (1) & (2) below. During the specified warranty period we will replace or repair any product with a defect in material or workmanship.

(1) The warranty on BioHorizons instruments extends for a period of one (1) year from the date of initial invoice. This includes drivers, sinus lift components, implant site dilators and other BioHorizons tools used in the placement or restoration of our implants, with the exception of surgical drills and taps (see below).

(2) The warranty on BioHorizons Surgical Drills and Taps extends for a period of ninety (90) days from the date of initial invoice. Surgical drills and taps should be replaced when they are worn, dull, corroded or in any way compromised. BioHorizons recommends the replacement of drills after 12 to 20 osteotomies.[13]

Return Policy:

Instructions for initiating returns can be found on the reverse side of the invoice that was shipped with the product. Please contact Customer Care if you need a copy of the instructions or if you have additional questions or requests.

Symbol descriptions for product labeling

LOT	Lot/batch number
REF	Reference/part number
STERILE R	Sterile by gamma irradiation
NON-STERILE	Non-sterile
Rx Only	Caution: Federal (USA) law restricts these devices by, or on the order of, a dentist or physician.
	Single use only
	Refer to Instructions for Use
	Use before expiration date (YYYY-MM)
	Manufacture date (YYYY-MM)
CE	BioHorizons products carry the CE mark and fulfill the requirements of the Medical Devices Directive 93/42/EEC

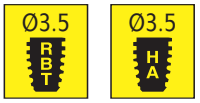
Prosthetic platform

Ø3.5mm Prosthetic Platform

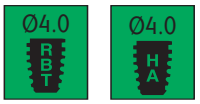
Ø4.5mm Prosthetic Platform

Ø5.7mm Prosthetic Platform

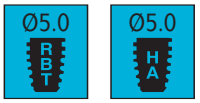
Implant diameter : surface treatment



Ø3.5mm Implant: RBT/HA



Ø4.0mm Implant: RBT/HA



Ø5.0mm Implant: RBT/HA

Ø6.0mm Implant: RBT/HA

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This literature serves as reference for BioHorizons Internal/Single-stage implants, prosthetics and instrumentation. It is not intended to describe the methods or procedures for diagnosis, treatment planning, or placement of implants; nor does it replace clinical training or a clinician's best judgment regarding the needs of each patient. BioHorizons strongly recommends completion of postgraduate dental implant education and strict adherence to the Instructions for Use (IFU) that accompany our products.

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