

tapered internal implant system



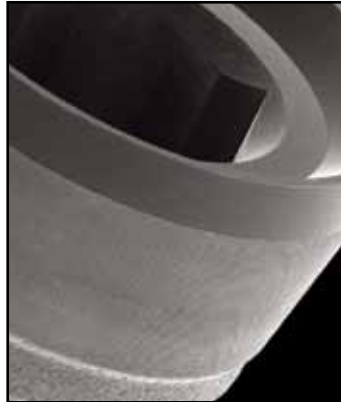
*high-end aesthetic performance
and excellent primary stability*

BIOHORIZONIS[®]
SCIENCE • INNOVATION • SERVICE

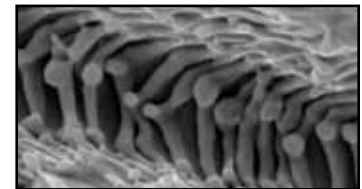
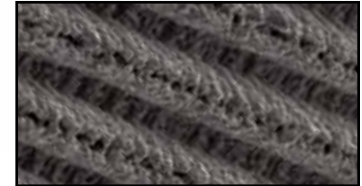
Laser-Lok Technology

Laser-Lok overview

Laser-Lok microchannels is a proprietary dental implant surface treatment developed from over 20 years of research initiated to create the optimal implant surface. Through this research, the unique Laser-Lok surface has been shown to elicit a biologic response that includes the inhibition of epithelial downgrowth and the attachment of connective tissue (unlike Sharpey fibers).^{1,2} This physical attachment produces a biologic seal around the implant that protects and maintains crestal bone health. The Laser-Lok phenomenon has been shown in post-market studies to be more effective than other implant designs in reducing bone loss.^{3,4,5,6}



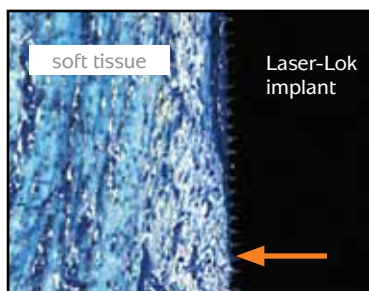
SEM image at 30X showing the Laser-Lok zone on a BioHorizons implant.



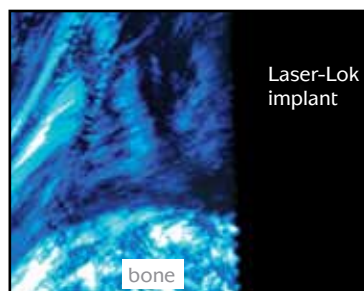
The uniformity of the Laser-Lok microstructure and nanostructure is evident using extreme magnification.

Unique surface characteristics

Laser-Lok microchannels is a series of cell-sized circumferential channels that are precisely created using laser ablation technology. This technology produces extremely consistent microchannels that are optimally sized to attach and organize both osteoblasts and fibroblasts.^{7,8} The Laser-Lok microstructure also includes a repeating nanostructure that maximizes surface area and enables cell pseudopodia and collagen microfibrils to interdigitate with the Laser-Lok surface.



Human histology shows the apical extent of the junctional epithelium below which there is a supracrestal connective tissue attachment to the Laser-Lok surface.¹



Polarized lights show the connective tissue is functionally oriented.¹



Colorized SEM of a dental implant harvested at 6 months post-op shows the connective tissue is physically attached and interdigitated with the Laser-Lok surface.

Different than other surface treatments

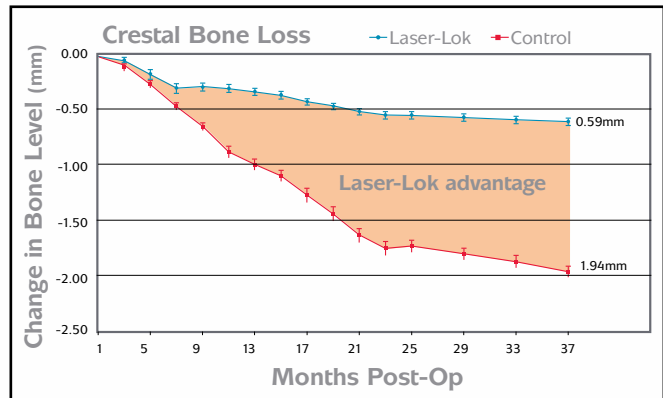
Virtually all dental implant surfaces on the market are grit-blasted and/or acid-etched. These manufacturing methods create random surfaces that vary from point to point on the implant and alter cell reaction depending on where each cell comes in contact with the surface.⁹ While random surfaces have shown higher osseointegration than machined surfaces,¹⁰ only the Laser-Lok surface has been shown using light microscopy, polarized light microscopy and scanning electron microscopy to also be effective for soft tissue attachment.^{1,11}

The clinical advantage

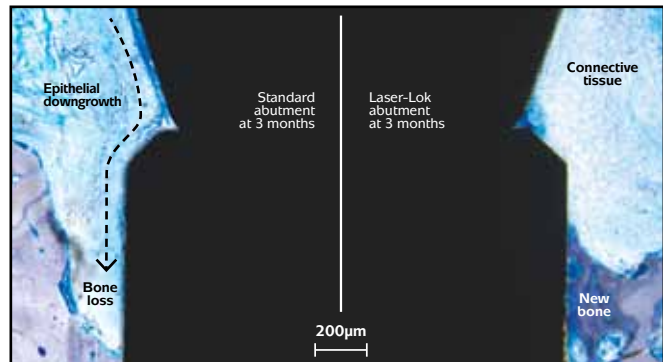
The Laser-Lok surface has been shown in several studies to offer a clinical advantage over other implant designs. In a prospective, controlled multi-center study, Laser-Lok implants, when placed alongside identical implants with a traditional surface, were shown at 37 months post-op to reduce bone loss by 70% (or 1.35mm).³ In a retrospective, private practice study, Laser-Lok implants placed in a variety of site conditions and followed up to 3 years minimized bone loss to 0.46mm.⁴ In a prospective, University-based overdenture study, Laser-Lok implants reduced bone loss by 63% versus NobelReplace™ Select.⁵

Latest discoveries

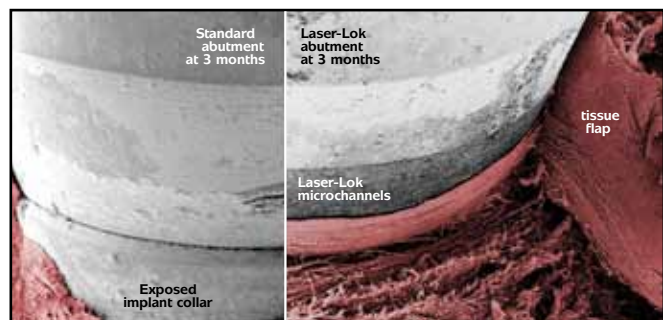
The establishment of a physical, connective tissue attachment (unlike Sharpey fibers) to the Laser-Lok surface has generated an entirely new area of research and development: Laser-Lok applied to abutments. This could provide an opportunity to use Laser-Lok abutments to create a biologic seal and Laser-Lok implants to establish superior osseointegration⁸ – a solution that offers the best of both worlds. Alternatively, Laser-Lok abutments could support peri-implant health around implants without Laser-Lok. In a recent study, Laser-Lok abutments and standard abutments were randomly placed on implants with a grit-blasted surface to evaluate the differences. In this proof-of-principle study, a small band of Laser-Lok microchannels was shown to inhibit epithelial downgrowth and establish a connective tissue attachment (unlike Sharpey fibers) similar to Laser-Lok implants.¹¹ This time, however, the attachment was established above the dental implant-abutment connection and even on implants with a machined collar.¹¹ The resulting crestal bone levels were higher than what was seen with standard abutments and provides some insight into the role soft tissue stability may play in maintaining crestal bone health.



In a 3-year multicenter perspective study, the Laser-Lok surface showed superior bone maintenance over identical implants without the Laser-Lok surface.³



Comparative histologies show the biologic differences between standard abutments and Laser-Lok abutments including changes in epithelial downgrowth, connective tissue and crestal bone health.¹¹



Comparative SEM images show the variation in tissue attachment strength on standard and Laser-Lok abutments when a tissue flap is incised vertically and manually lifted using forceps.¹¹

Laser-Lok Technology is available on Laser-Lok 3.0, Tapered Internal, Single-stage & Internal implants

shop online at www.biohorizons.com

• NobelReplace is a trademark of Nobel Biocare.

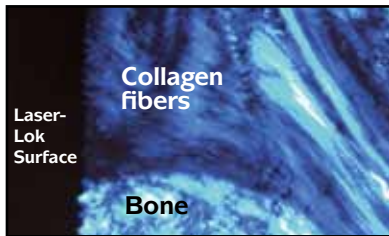
tapered internal

Designed for clinicians who prefer a tapered implant, the Tapered Internal is all about high-end, aesthetic performance and is the “flagship” of the BioHorizons implant line. With its aggressive buttress thread and tapered apical six millimeters, the Tapered Internal achieves high initial torque values and excellent primary stability. The Laser-Lok collar and uniquely-designed drills give clinicians the flexibility to select the ideal implant level for optimal aesthetics.

- Excellent primary stability from anatomically tapered body
- Compressive bone loading from proprietary buttress threads
- Stable soft tissue seal and flexible implant placement from Laser-Lok microchannels



Comprehensive line of internally hexed prosthetics.



Laser-Lok shown to have functionally-oriented connective tissue attachment.¹



Buttress threads have a wide, flat leading edge for increased functional surface area, improved axial load distribution and primary stability.



TAPERED INTERNAL IMPLANTS

Tapered Internal Implants with Laser-Lok

Laser-Lok collar with Resorbable Blast Texturing (RBT) on implant body. Comes packaged with Cover Cap, Abutment Screw and pre-mounted *3inOne* aesthetic abutment that serves as a fixture mount, closed-tray transfer and final abutment. Titanium Alloy.



		TLR4607	4.6mm x 7.5mm	TLR5807	5.8mm x 7.5mm
TLR3809	3.8mm x 9mm	TLR4609	4.6mm x 9mm	TLR5809	5.8mm x 9mm
TLR3810	3.8mm x 10.5mm	TLR4610	4.6mm x 10.5mm	TLR5810	5.8mm x 10.5mm
TLR3812	3.8mm x 12mm	TLR4612	4.6mm x 12mm	TLR5812	5.8mm x 12mm
TLR3815	3.8mm x 15mm	TLR4615	4.6mm x 15mm	TLR5815	5.8mm x 15mm

Mount-free Tapered Internal Implants with Laser-Lok

Packaged mount-free for quick placement and maximum site visibility. Includes a Cover Cap.

In January 2011, a running change was made to expand the Laser-Lok zone and eliminate the 0.3mm machined collar.



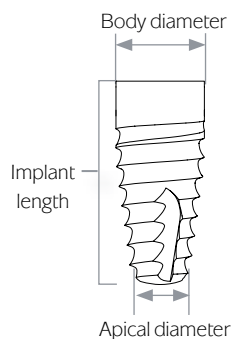
		TLX4607	4.6mm x 7.5mm	TLX5807	5.8mm x 7.5mm
TLX3809	3.8mm x 9mm	TLX4609	4.6mm x 9mm	TLX5809	5.8mm x 9mm
TLX3810	3.8mm x 10.5mm	TLX4610	4.6mm x 10.5mm	TLX5810	5.8mm x 10.5mm
TLX3812	3.8mm x 12mm	TLX4612	4.6mm x 12mm	TLX5812	5.8mm x 12mm
TLX3815	3.8mm x 15mm	TLX4615	4.6mm x 15mm	TLX5815	5.8mm x 15mm

Short Tapered Internal Implants with Laser-Lok Complete

Laser-Lok surface technology across the entire implant body with no machined collar for faster osseointegration and higher bone to implant contact. Ideal for anatomically challenging conditions. Packaged with Cover Cap. Mount-free delivery. Titanium Alloy.



TL4607	4.6mm x 7.5mm	TL5807	5.8mm x 7.5mm
TL4609	4.6mm x 9mm	TL5809	5.8mm x 9mm



	3.8mm Implants	4.6mm Implants	5.8mm Implants
Body Diameter	3.8mm	4.6mm	5.8mm
Platform Diameter	3.5mm	4.5mm	5.7mm
Apical Diameter	2.8mm	3.1mm	3.9mm

Tapered Internal Surgical Kit



TSK2021

Tapered Internal Surgical Kit (complete)

Reduced height tray with increased ventilation for shorter drying times and convenient drill measurement guide. Includes all instruments shown on pages 5 & 6.

TSK2011

Tapered Internal Tray & Lid (without instruments)

Individual Kit Components



TSD2020

2.0mm Starter Drill (matte finish)

TSD2025

2.5mm Depth Drill (matte finish)



122-100

Drill Extender

(adds 16mm to length of drill)



144-100

Straight Parallel Pins (2 per kit)

144-200

20° Angled Parallel Pins (2 per kit)



TSD2032

3.2mm Width Increasing Drill (matte finish)

TSD2037

3.7mm Width Increasing Drill (matte finish)

TSD2041

4.1mm Width Increasing Drill (matte finish)

TSD2047

4.7mm Width Increasing Drill (matte finish)

TSD2054

5.4mm Width Increasing Drill (matte finish)



TSC2038

3.8mm Crestal Bone Drill

TSC2046

4.6mm Crestal Bone Drill

TSC2058

5.8mm Crestal Bone Drill



TST2038

3.8mm Bone Tap

TST2046

4.6mm Bone Tap

TST2058

5.8mm Bone Tap

SURGICAL INSTRUMENTS

Individual Kit Components



TDG2038 3.8mm Depth Gauge
TDG2046 4.6mm Depth Gauge
TDG2058 5.8mm Depth Gauge



PHA Abutment-level Driver, Handpiece*
PRA Abutment-level Driver, Ratchet*



SYGIDR 3.5/4.5mm Implant-level Driver, Ratchet*
SBIDR 5.7mm Implant-level Driver, Ratchet*



SYGIDH 3.5/4.5mm Implant-level Driver, Handpiece*
SBIDH 5.7mm Implant-level Driver, Handpiece*



130-000
Ratchet



144-300
Implant Spacer / Depth Probe



300-400
Hand Wrench*



135-351
.050" (1.25mm) Hex Driver
In January 2011, a running change was made to improve abutment screw retention and handling.



300-206
4mm Square Drive Extender*
Replaced 300-205 starting in June 2010. Includes PEEK C-ring for durable retention in Ratchet. Cannot be used with bone taps.

**instrument o-rings & c-rings wear out over time. If an instrument is no longer held securely by its associated driver, order a replacement ring through Customer Care. shop online at www.biohorizons.com*

2.5mm Tapered Depth Drills with stops



- TSD202507** 2.5mm Tapered Depth Drill, 7.5mm Stop
- TSD202509** 2.5mm Tapered Depth Drill, 9mm Stop
- TSD202510** 2.5mm Tapered Depth Drill, 10.5mm Stop
- TSD202512** 2.5mm Tapered Depth Drill, 12mm Stop
- TSD202515** 2.5mm Tapered Depth Drill, 15mm Stop

Stops are set to same length as each implant for crestal placement.
Laser-etched line set 1 mm shorter for supracrestal placement.

Extended Shank Drills



- TSD4020** 2.0mm Ext. Shank Starter Drill
- TSD4025** 2.5mm Ext. Shank Depth Drill
- TSD4032** 3.2mm Ext. Shank Width Increasing Drill
- TSD4037** 3.7mm Ext. Shank Width Increasing Drill
- TSD4041** 4.1mm Ext. Shank Width Increasing Drill
- TSD4047** 4.7mm Ext. Shank Width Increasing Drill
- TSD4054** 5.4mm Ext. Shank Width Increasing Drill

Extended Shank Drills are 8mm longer than our standard drills.

Lindemann Bone Cutter



- 122-110** 2.0mm Lindemann Bone Cutter

Side-cutting drill used to correct eccentric osteotomy preparations.

Handpiece Hex Drivers

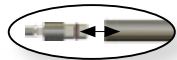


- 134-350** .050" (1.25mm) Handpiece Hex Driver
- 134-450** .050" (1.25mm) Handpiece Hex Driver, Long

For installation and removal of Cover Screws, Healing Abutments and Abutment Screws. The Handpiece Hex Drivers are used with latch-type contra-angle handpieces. The Handpiece Hex Driver, Long (134-450) is 5mm longer than the standard version (134-350).

ANCILLARY INSTRUMENTS

Drivers



150-000
Surgical Driver

Use to drive implants into the osteotomy, particularly in the anterior region. The driver holds the Abutment-level Driver, Ratchet which interfaces with the *3inOne* Abutment. Also interfaces with the .050" (1.25mm) Hex Drivers as well as Bone Taps and the Implant-level Drivers, Ratchet.



PADHH
**Abutment-level Driver,
Hex-chuck Handpiece***

Use with compatible W&H Hexagon Chucking System Handpieces to prevent deformation of the ISO shank latch connection in high-torque applications.

Adjustable Torque Wrenches



EL-C12374 **Elos Adjustable Torque Wrench**

Lightweight titanium design is easy to use as an adjustable torque wrench or a ratchet. Quickly disassembles for cleaning. No calibration required. Call for availability.



ATW **ITL Precise Adjustable Torque Wrench**

Place both implants and abutments with 9 distinct torque settings (15, 20, 25, 30, 35, 40, 45, 50 and 60 Ncm). A simple twist of the handle locks in precision-engineered torque values and guarantees accuracy and repeatability.

Tissue Punches

- PYTP** **3.5mm Tissue Punch**
- PGTP** **4.5mm Tissue Punch**
- PBTP** **5.7mm Tissue Punch**

Use in a latch-type handpiece to remove the soft tissue from the crest of the ridge prior to osteotomy preparation in a flapless surgical procedure. Available in three platform diameters.



Bone Profiling Burs

- PYBP** **3.5mm Bone Profiling Bur & Guide**
- PGBP** **4.5mm Bone Profiling Bur & Guide**
- PBBP** **5.7mm Bone Profiling Bur & Guide**

Use at implant uncover to contour crestal bone for abutments when the implant is subcrestal. The Profiler's internal geometry matches the geometry of the included Profiler Guide. The Guide is screwed into the implant and then aligns the Profiler for precise removal of tissue surrounding the platform. Available in three sizes.



**instrument o-rings & c-rings wear out over time. If an instrument is no longer held securely by its associated driver, order a replacement ring through Customer Care. shop online at www.biohorizons.com*



BioHorizons proudly distributes W&H implant motors, handpieces and accessories. Additional W&H products and re-order items are available. For more information, contact your BioHorizons representative or visit the online catalog (www.biohorizons.com).

W&H Motor Kits

Motor Kits include: console, motor with 1.8m attached cable, standard (ElcoMED) or premium (ImplantMED) foot pedal, (3) complete disposable irrigation tubes, USB documentation (ElcoMED), handpiece, bur testing gauge, spray cap and service oil (ships separately).



WH-310L

ElcoMED SA-310 Professional Kit with LED

Includes LED handpiece (WH-10207530).

WH-310

ElcoMED SA-310 Professional Kit

Includes handpiece (WH-10207510).



WH-915L

ImplantMED 915 Starter Kit with LED

Includes mono block LED handpiece (WH-10207560).

WH-915

ImplantMED SI-915 Starter Kit

Includes mono block handpiece (WH-10207550).

W&H Motors

Ref. Code	Description
WH-00900103	ImplantMED SI-915 (S-NU Foot Pedal) 1.8m Cable, Blue Console
WH-00900107	ImplantMED SI-915 (SN-1 Foot Pedal) 1.8m Cable, Blue Console
WH-15933100	ElcoMED SA-310 (with Documentation) 1.8m Cable
WH-15933102	ElcoMED SA-310 (without Documentation) 1.8m Cable

W&H ElcoMED SA-310 and ImplantMED SI-915 Re-Order items

Ref. Code	Description
WH-ITC915	Disposable Irrigation Tubing, 2.2m ImplantMED SI-915 and ElcoMED SA-310 (box of 6)
WH-IC	Irrigation Spray Clip for External and Internal Irrigation (set of 3)
WH-MD400	MD-400 Service-Oil F1
WH-OSC	Oil Spray Cap for WH-MD400
WH-05046200	S-N1 Premium Foot Pedal, ImplantMED SI-915

Surgical Handpieces

WH-10207530

WS-75 E/KM LED G Surgical 20:1 Contra-Angle

LED, 20:1, hexagon chucking system, press-button chuck system, for surgical burs and cutters with a 2.35mm contra-angle shank, internal and external cooling system. Dismantle for easy cleaning.



WH-10207510

WS-75 E/KM Surgical 20:1 Contra-Angle

20:1, hexagon chucking system, press-button chuck system, for surgical burs and cutters with a 2.35mm contra-angle shank, internal and external cooling system. Dismantle for easy cleaning.



WH-10207560

WI-75 E/KM LED G Surgical 20:1 Contra-Angle, Mono Block

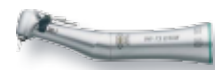
LED, 20:1, hexagon chucking system, press-button chuck system, for surgical burs and cutters with a 2.35mm contra-angle shank, internal and external cooling system.



WH-10207550

WI-75 E/KM Surgical 20:1 Contra-Angle, Mono Block

20:1, hexagon chucking system, press-button chuck system, for surgical burs and cutters with a 2.35mm contra-angle shank, internal and external cooling system.



WH-10209201

WS-92 E/3 Surgical 1:2.7 Contra-Angle

1:2.7, press-button chuck system with triple spray, for surgical burs and cutters with a 1.6mm friction grip shank. Dismantle for easy cleaning.



WH-10101200

S-12 Surgical 1:2 Angled

1:2, angled, extra slim tip for increased vision, lever chuck system, for surgical burs and cutters 2.35mm >70mm extra long shaft. Dismantle for easy cleaning.



WH-00001100

S-11 Surgical 1:1 Straight

1:1, straight, lever chuck system, for surgical burs and cutters 2.35mm >45mm shaft. Dismantle for easy cleaning.



Prosthodontic Screwdriver

WH-16934000

IA-400 Prosthodontic Screwdriver

Cordless handpiece with precise torque control from 8-40 Ncm, 80:1 contra-angle handpiece with hexagon chucking system, charging station, rechargeable Li-ion battery, and power cable.



Bur Testing Gauge

WH-BTG

Bur Testing Gauge

Use to verify the condition of latch-type burs. Burs in proper condition will fit into larger diameter hole, but will not fit into the smaller hole (marked red). Burs that fail either of these tests are unfit for use, and may cause damage to the handpiece.



Healing Abutments



Abutment height
(1, 3 or 5mm)

Hand-tighten with the .050" (1.25mm) Hex Driver. Titanium Alloy.
Laser marked for easy intraoral identification; for example:
GR3 = Green (4.5mm) platform / Regular Emergence / 3mm High

Regular Emergence

Platform diameter	Abutment diameter
3.5mm	4.5mm
4.5mm	5.5mm
5.7mm	6.6mm

Prosthetic platform	1 mm high	3mm high	5mm high
3.5mm Regular Healing Abutment		PYRHA3	PYRHA5
4.5mm Regular Healing Abutment		PGRHA3	PGRHA5
5.7mm Regular Healing Abutment		PBRHA3	PBRHA5

Narrow Emergence

3.5mm	3.8mm
4.5mm	4.7mm
5.7mm	5.9mm

3.5mm Narrow Healing Abutment	PYNHA1	PYNHA3	PYNHA5
4.5mm Narrow Healing Abutment	PGNHA1	PGNHA3	PGNHA5
5.7mm Narrow Healing Abutment	PBNHA1	PBNHA3	PBNHA5

Wide Emergence

3.5mm	5.8mm
4.5mm	6.8mm

3.5mm Wide Healing Abutment	PYWHA3	PYWHA5
4.5mm Wide Healing Abutment	PGWHA3	PGWHA5

Surgical Cover Cap



PYCC	3.5mm Cover Cap
PGCC	4.5mm Cover Cap
PBCC	5.7mm Cover Cap

Use during submerged surgical healing. Hand-tighten with the .050" (1.25mm) Hex Driver. Titanium Alloy. *Included with implant but can also be ordered separately.*

SIMPLE SOLUTIONS ABUTMENTS WITH LASER-LOK TECHNOLOGY

With the success of BioHorizons Laser-Lok technology on implants, BioHorizons breaks new ground by applying this innovative technology to abutments. The Simple Solutions abutment with Laser-Lok is designed to be seated at the time of implant placement or uncovering and remain in place through final restoration^{12,13}. This establishes and maintains the connective tissue attachment.



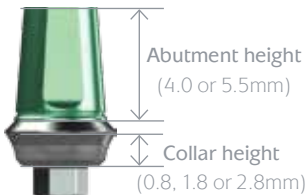
Laser-Lok has been shown to:

- Inhibit epithelial downgrowth^{1,11}
- Attract a physical connective tissue attachment^{1,11} (unlike Sharpey fiber attachment)
- Preserve the coronal level of bone^{1,11}

Laser-Lok Abutment Packs



Prosthetic platform / Abutment height	0.8mm collar	1.8mm collar	2.8mm collar
3.5mm Abutment, 4.0mm	PY4008L	PY4018L	PY4028L
3.5mm Abutment, 5.5mm	PY5508L	PY5518L	PY5528L
4.5mm Abutment, 4.0mm	PG4008L	PG4018L	PG4028L
4.5mm Abutment, 5.5mm	PG5508L	PG5518L	PG5528L
5.7mm Abutment, 4.0mm	PB4008L	PB4018L	PB4028L
5.7mm Abutment, 5.5mm	PB5508L	PB5518L	PB5528L



Simple Solutions crowns finish on the restorative shoulder of the abutment. There are three options for transmucosal collar height: 0.8mm / 1.8mm / 2.8mm. Select the collar height that positions the restorative shoulder as close as possible to the desired position of the crown margin. Packaged with Abutment Screw (PXAS) and Healing Cap. Titanium Alloy. Final torque: 30Ncm.

Restorative Packs



SYRP40	3.5mm Restorative Pack, 4.0mm Height
SYRP55	3.5mm Restorative Pack, 5.5mm Height
SGRP40	4.5mm Restorative Pack, 4.0mm Height
SGRP55	4.5mm Restorative Pack, 5.5mm Height
SBRP40	5.7mm Restorative Pack, 4.0mm Height
SBRP55	5.7mm Restorative Pack, 5.5mm Height

Each restorative pack contains impression cap, replica and two waxing sleeves.

This Surgical Manual serves as a reference for using the Tapered Internal 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 that 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 any implant surgical procedure with BioHorizons implants:



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



Small diameter implants with angled abutments are intended for the anterior region of the mouth and are not intended for the posterior region of the mouth due to possible failure of the implant.

Indications

Tapered Internal Implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately:

- (1) with a temporary prosthesis that is not in functional occlusion,
- (2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or
- (3) for denture stabilization using multiple implants in the anterior mandible and maxilla.

The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

VIP Treatment Planning



Virtual Implant Placement (VIP) treatment planning software is a user-friendly solution that reduces clinical challenges and enhances post-operative outcomes.

- **Interactive 2D and 3D treatment planning**
- **Self processing DICOM converter**
- **Case viewer available for download from BioHorizons website**

Two-stage Protocol



Implant with Cover Cap in a two-stage protocol.

In a two-stage surgery, 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 procedure 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.

Single-stage Protocol



Implant with removable Healing Abutment in a single-stage protocol.

Single-stage surgery may be accomplished by placing a healing abutment at the time of implant surgery. This eliminates the need for a second procedure. 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.

Non-functional Immediate Restoration



Implant restored with a non-functional provisional prosthesis.

Single-stage surgery with non-functional immediate provisionalization provides the patient a non-functioning 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 using temporary cement. The provisional can help shape the soft tissue profile during healing.

Immediate Function Restoration



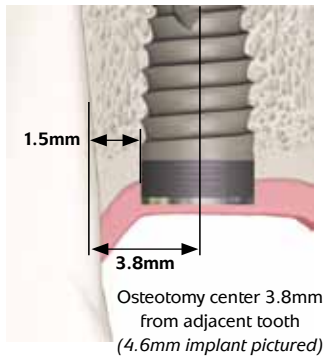
Implants with a splinted prosthesis in immediate function.

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 prostheses.



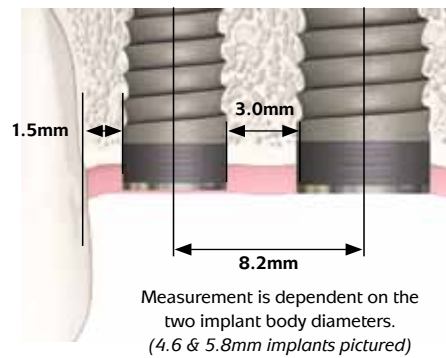
During implant placement, clinicians must apply their best judgment as to the appropriate spacing for individual patient conditions.

The osteotomy centerpoint required to maintain a 1.5mm implant-to-tooth spacing (generally accepted) is $\frac{1}{2}$ [implant body diameter] + 1.5mm.



body diameter	osteotomy center from adjacent tooth
3.8mm	3.4mm
4.6mm	3.8mm
5.8mm	4.4mm

The osteotomy center-to-center measurement required to maintain a 3.0mm edge-to-edge spacing (generally accepted) between Tapered Internal implants is $\frac{1}{2}$ [sum of 2 implant body diameters] + 3.0mm.



body diameter	3.8mm	4.6mm	5.8mm
3.8mm	6.8mm		
4.6mm	7.2mm	7.6mm	
5.8mm	7.8mm	8.2mm	8.8mm

Implant center to center

Implant Spacer / Depth Probe

Purpose: Multi-function instrument for intraoral measurements.

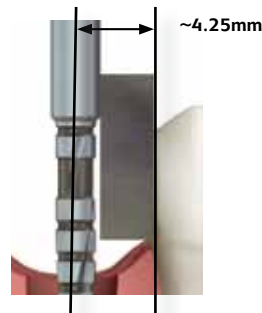
- Five centimeter graduated ruler on shaft



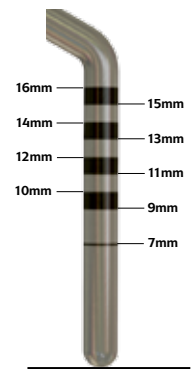
The rectangular end of the tool provides intraoral measurements.



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



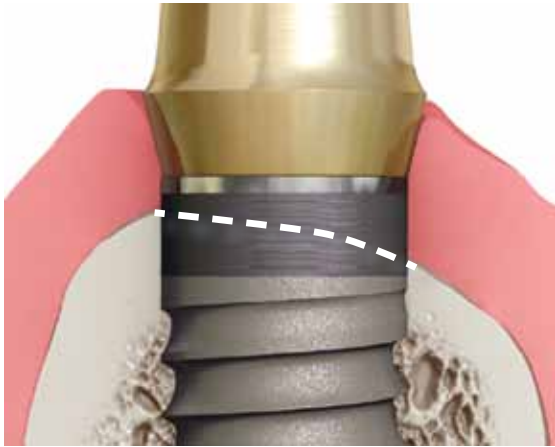
The rectangular end against an existing crown places the osteotomy ~ 4.25 mm from the contact.



Probe tip measures osteotomy depth. **Note:** these markings are different than the tapered drill markings

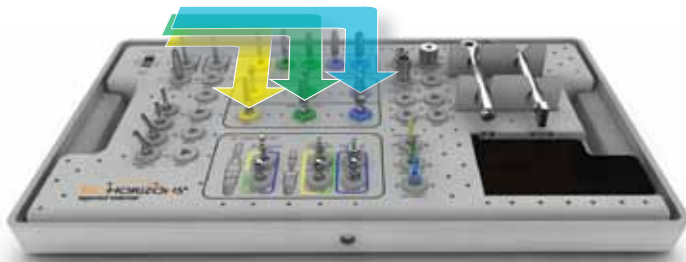
IMPLANT PLACEMENT LEVEL & SURGICAL KIT LAYOUT

Placement in Uneven Ridges



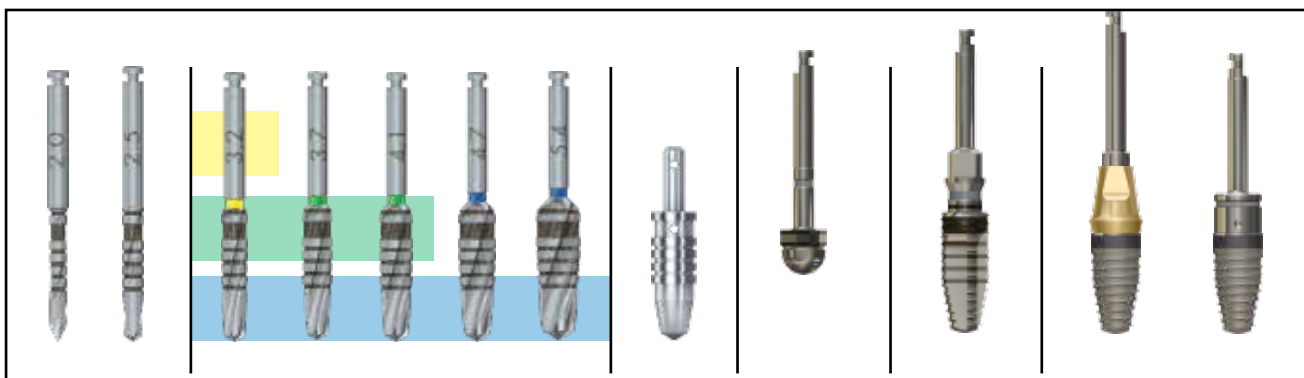
When placing the Tapered Internal implant in an uneven ridge, prepare the osteotomy and place the implant so that the bone/soft-tissue junction is within the Laser-Lok transition zone. If the discrepancy is more than the Laser-Lok transition zone, leveling the ridge can be considered.

Surgical Kit Layout



The Tapered Internal Surgical Kit uses an intuitive layout to guide the surgeon 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 are matched with each implant and further aid in instrument selection and identification.

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



Depth Drill Sequence

Width Increasing Drill Sequence

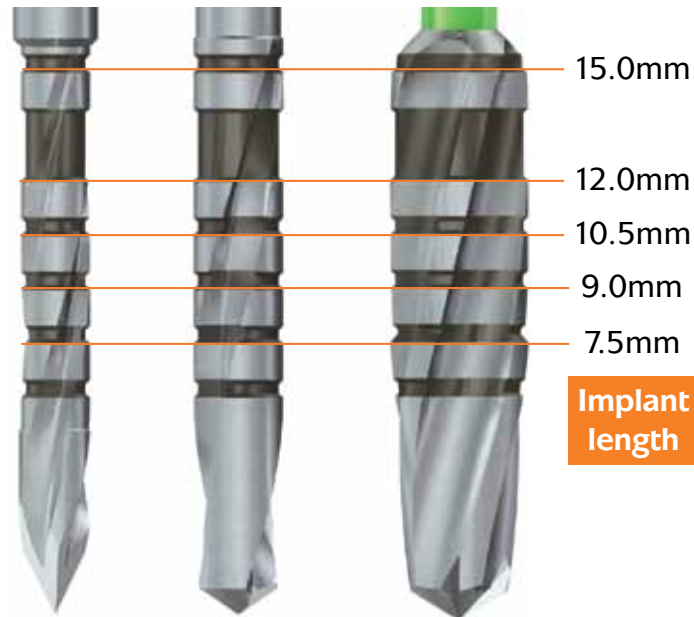
Depth Gauges

Crestal Bone Drills

Bone Taps

Abutment-level and/or Implant-level Drivers

All surgical drills included with this system are externally irrigated and designed to be used at drill speeds of 850–2500 rpm¹⁴ with steady sterile irrigation. Reduced drill speed may be indicated in softer bone or as drill diameter increases.



Note: The depth marks are consistent throughout the Starter Drills, Depth Drills and Width Increasing Drills

Important 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.¹⁵ A pre-operative 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 replacing drills after 12 to 20 osteotomies.¹⁶ A Drill-usage Tracking Chart is available to record this important information.
- There is a risk of injury to the mandibular nerve associated with surgical drilling in posterior mandibular regions. To minimize the risk of nerve injury, it is imperative that the clinician understands the drill depth markings as they relate to the implant length to produce the desired vertical placement of the implant.

OSTEOTOMY INITIALIZATION

2.0mm Starter Drill

Purpose: Initiate osteotomy.

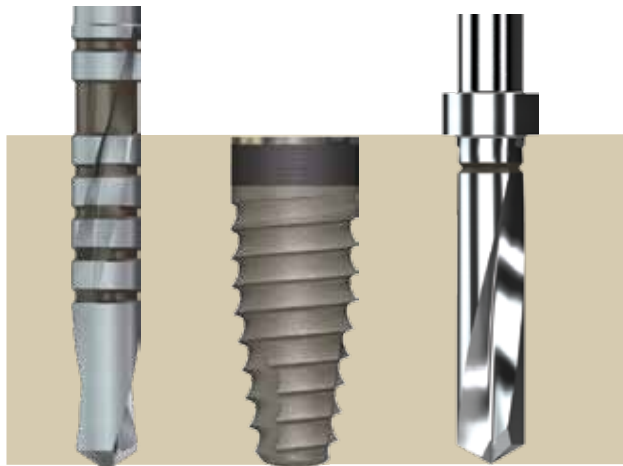
- Chisel-tip design eliminates “skating” on osseous crest
- Prepares site for Paralleling Pins
- Matte finish for increased visibility under operator lights



2.5mm Depth Drill

Purpose: Set osteotomy depth.

- Efficient cutting drill design collects bone for autografting
- Matte finish for increased visibility under operator lights



The 2.0mm and 2.5mm depth drills are designed to increase and/or set the depth of the osteotomy.

2.5mm Depth Drills with Stops

Purpose: Set osteotomy depth when access or visibility is poor.

- Fixed circular ring acts as a definitive drill stop
- One drill length for each implant length
- 1mm laser-etched line guides supracrestal implant placement
- BioHorizons Surgical Kit includes spare slots for Depth Drills with Stops or Extended Shank Drills



Paralleling Pins



Purpose: Evaluate osteotomy position and angle.

- Provided straight or with a 20° angle
- Use after 2.0mm Starter Drill and 2.5mm Depth Drill
- 9mm shank for radiographic evaluation of proximity to adjacent anatomy
- Hub diameter is 4.0mm



3.2 - 5.4mm Width Increasing Drills



Purpose: Incrementally widen the osteotomy to reduce heat generation.

- Depth-marked for reference
- Efficient cutting drill design collects bone for autografting
- The drill tip has limited end cutting. However, the osteotomy depth can be increased with these drills as needed
- Matte finish for increased visibility under operator lights

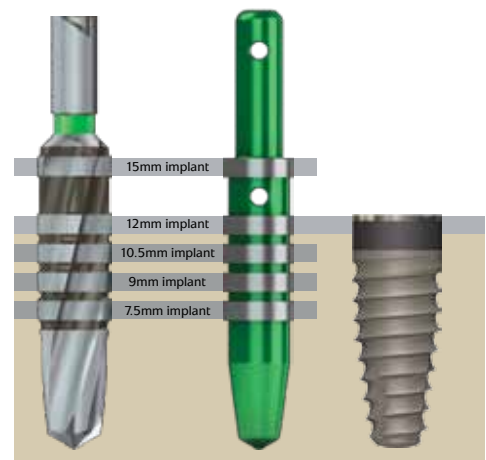


Depth Gauges



Purpose: Verify osteotomy depth.

- Depth marks for reference
- Use following the final Width Increasing Drill for each implant
- Place the depth gauge into the osteotomy site, adjust osteotomy depth as necessary
- Can also be used after 2mm drill by inverting



Width Increasing Drill

Depth Gauge

12mm Implant with Laser-Lok

FINAL BONE PREPARATION & DRIVERS

Crestal Bone Drills

Purpose: Remove cortical bone at ridge crest for pressure-free seating of the implant collar.

- Use when dense cortical bone is present at crest
- Rounded non-end cutting hub centers drill in osteotomy
- Use following the final Width Increasing Drill for each implant



Fully seat drill.

Implant level with osseous crest.



Bone Taps



Purpose: Prepare dense cortical bone for implant threads.

- Site specific
- 30 rpm or less¹⁷
- Final instrument prior to implant placement
- Can be driven with a handpiece, Ratchet or Hand Wrench

Place into the osteotomy, apply firm apical pressure and rotate slowly in a clockwise direction. 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.**



Abutment-Level Drivers

Purpose: Engage the pre-mounted *3inOne* Abutment to drive into the osteotomy.



- Drivers interface with the internal square of the *3inOne* Abutment
- PEEK plastic snap ring secures *3inOne* Abutment
- 30 rpm or less¹⁷

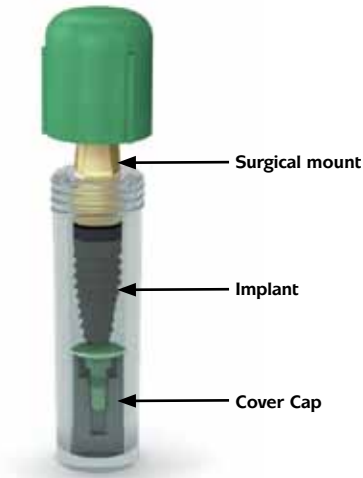
Implant-level Drivers

Purpose: Engage the implant's internal hex to drive mount-free implants into the osteotomy.

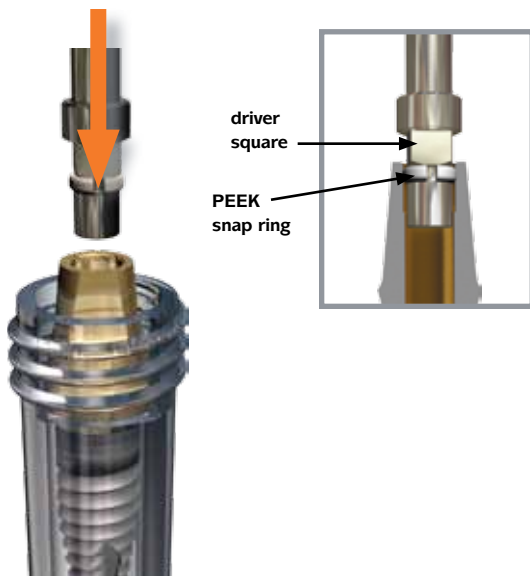


- May also be used following removal of the *3inOne* Abutment
- Offers a narrower path of insertion than placing with a mount
- 30 rpm or less¹⁷

3inOne Mount Transfer



The Cover Cap for a two-stage surgical protocol is mounted on a plastic base and packaged in the vial underneath the implant.

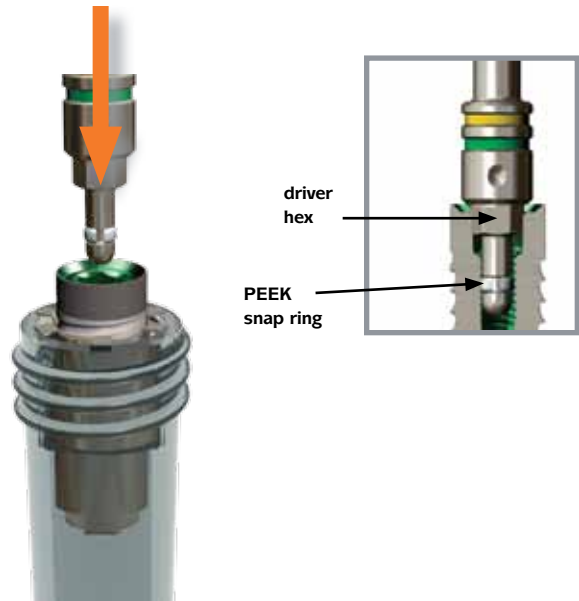


Abutment-level Driver engages the *3inOne* Abutment's internal square. If the driver square does not engage the abutment square during pick-up, the plastic snap ring WILL secure the implant for transport to the osteotomy. The square will automatically engage when the driver is slowly rotated under apical pressure.

Mount-free Transfer



The Cover Cap for a two-stage surgical protocol is mounted in the vial cap.



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

PLACEMENT & ORIENTATION

Implant Placement



Place the apex of the implant into the osteotomy, apply firm apical pressure and begin rotating slowly (30 rpm or less is recommended)¹⁷. When the threads engage, allow the implant to feed without excessive pressure. If the handpiece is unable to fully seat the implant, remove the *3inOne* and complete placement using the implant-level driver, ratchet.



To avoid bone damage, the *3inOne* abutment is designed to yield prior to the implant. This yield can occur at insertion torque levels above 120 Ncm. If an abutment yield occurs, placement can be completed at the implant level and a new *3inOne* Abutment can be used for impression making.

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.

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 and the Abutment Screw should be retained with the patient's chart. They can later be used in the impression making procedure and as a temporary or final abutment for cement retention.



Difficulty removing the *3inOne* Abutment may indicate that the yield point of the abutment has been exceeded. It is possible that this can create up to a 10° rotational impression error if the lab uses a substitute *3inOne* Abutment when creating the stone model. If this occurs, a new impression with a new *3inOne* Abutment must be made.

Internal Hex Orientation



When seating the implant, use the corresponding dimples on the driver to orient one internal hex flat perpendicular to the implant angulation plane. Doing so verifies that an angled abutment will correct the angulation.

Post-Operative Instructions

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

The patient should 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, a soft liner material should be used to prevent pressure on the surgical site. Relieve the prosthesis over the implant site prior to the soft liner application. Periodically check the patient's soft tissue and bone healing 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 abutment scaling, such as Implacare® instruments from Hu-Friedy® should be utilized. The stainless steel handles may be fitted with assorted tip designs for hygiene on natural teeth. The Implacare® scalers contain no glass or graphite fillers that can scratch titanium implant abutments.

Surgical Kit Cleaning

All BioHorizons Surgical Kits are provided non-sterile and must be cleaned and sterilized prior to use. Always remove instruments from packaging prior to sterilization, and remove and discard packaging materials used to stabilize and secure kits during shipment. Double-check all surgical instruments to ensure their functionality prior to surgery. Backup sterile drills are also recommended.



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. After sterilization, use an adequate drying cycle to evaporate any moisture that can stain the instruments. Drills and taps should be replaced when wear is noticed, such as a decrease in cutting efficiency or when signs of discoloration appear. Drills should be replaced after approximately 12 to 20 osteotomy cycles, depending on the bone density.¹⁶ Drill usage charts can be downloaded from www.biohorizons.com.

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

Bone Profilers

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



- Compatible with latch-type, speed-reducing handpieces
- 850-2,500 rpm drill speed with steady sterile irrigation¹⁴
- Profiler Guide protects implant platform
- Bone Profiler cuts away excess bone and soft tissue
- Color-coded by specific prosthetic platform

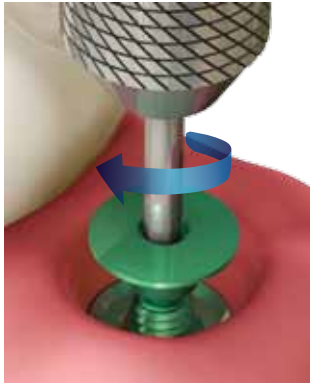


Do not use the Profiler without the Guide in place.



To use, remove the surgical Cover Cap from the implant and place the Profiler Guide [both use the .050" (1.25mm) Hex Driver]. Use the Profiler with copious amounts of sterile irrigation. Once the excess bone and soft tissue are removed, unscrew the Guide and seat the appropriate prosthetic component.

Cover Caps for two-stage protocol



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

- Irrigate implant to remove blood and other debris
- Use an antibacterial paste to decrease the risk of bacterial growth
- Thread clockwise into implant body
- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver
- Color-coded by prosthetic platform



Healing Abutments for single-stage protocol



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

- Irrigate implant to remove blood and other debris
- Use an antibacterial paste to decrease the risk of bacterial growth
- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver
- Color-coded by prosthetic platform
- Laser marked for easy intraoral identification, for example:
GR3 = Green (4.5mm) platform / Reg. Emerg. / 3mm High



Immediate Provisional Restorative Options

Temporary Abutments

Purpose: Easily modified for fabrication of cement or screw-retained provisional restorations. A Direct Coping Screw (PXDCS, purchased separately) may be used to maintain a screw access hole during the fabrication of a screw-retained provisional prosthesis.



Simple Solutions

Purpose: When a Simple Solutions restoration is planned, the tooth-colored Healing Cap that comes packaged with the abutment may be used as a coping for an immediate provisional restoration.



Symbol Descriptions for Product Labeling

REF Reference/article number

LOT Lot/batch number

Use before expiration date (YYYY-MM)

Manufacture date (YYYY-MM)

STERILE IR Sterile by gamma irradiation

NON-STERILE Non-sterile

Rx Only Caution: Federal (USA) law restricts these devices to the sale, distribution and use by, or on the order of, a dentist or physician.

Artwork label number

Prosthetic platform

- 3.5mm Prosthetic Platform
- 4.5mm Prosthetic Platform
- 5.7mm Prosthetic Platform

Single use only

Refer to Instructions for Use

CE 0473 BioHorizons products carry the CE mark and fulfill the requirements of the Medical Devices Directive 93/42/EEC

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ORDERING & WARRANTY INFORMATION

Product Support Specialist: _____

Cell phone: _____

Fax: _____

BioHorizons Lifetime Warranty on Implants and Prosthetics: All BioHorizons implants and prosthetic components include a Lifetime Warranty. BioHorizons implant or prosthetic components will be replaced if removal of that product is due to failure (excluding normal wear to overdenture attachments).

Additional Warranties: BioHorizons warranties instruments, surgical drills, taps, torque wrenches and Virtual Implant Placement (VIP) treatment planning software.

(1) Surgical Drills and Taps: Surgical drills and taps include a warranty period of ninety (90) days from the date of initial invoice. Surgical instruments should be replaced when they become worn, dull, corroded or in any way compromised. Surgical drills should be replaced after 12 to 20 osteotomies.¹⁶

(2) Instruments: The BioHorizons manufactured instrument warranty extends for a period of one (1) year from the date of initial invoice. Instruments include drivers, sinus lift components, implant site dilators and BioHorizons tools used in the placement or restoration of BioHorizons implants.

(3) VIP treatment planning software: VIP treatment planning software warranty extends for a period of ninety (90) days from the date of initial invoice. The warranty requires that VIP be used according to the minimum system requirements.

(4) Compu-Guide surgical templates: Compu-Guide surgical templates are distributed without making any modifications to the submitted Compu-Guide Prescription Form and VIP treatment plan ("as is"). BioHorizons does not make any warranties expressed or implied as it relates to surgical templates.

Return Policy: Product returns require a Return Authorization Form, which can be acquired by contacting Customer Care. The completed Return Authorization Form should be included with the returned product. For more information, please see the reverse side of the invoice that was shipped with the product.

Disclaimer of Liability: BioHorizons products may only be used in conjunction with the associated original components and instruments according to the Instructions for Use (IFU). Use of any non-BioHorizons products in conjunction with BioHorizons products will void any warranty or any other obligation, expressed or implied.

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Compu-Guide surgical templates are ordered under the control of a Clinician. The Clinician recognizes responsibility for use. Therefore, regardless of the real or proven damages, the liability to BioHorizons is limited to the price of the product directly related to the reason for the claim.

Distributed Products: For information on the manufacturer's warranty of distributed products, please refer to their product packaging. Distributed products are subject to price change without notice.

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Availability: Not all products shown or described in this literature are available in all countries. BioHorizons continually strives to improve its products and therefore reserves the right to improve, modify, change specifications or discontinue products at any time.

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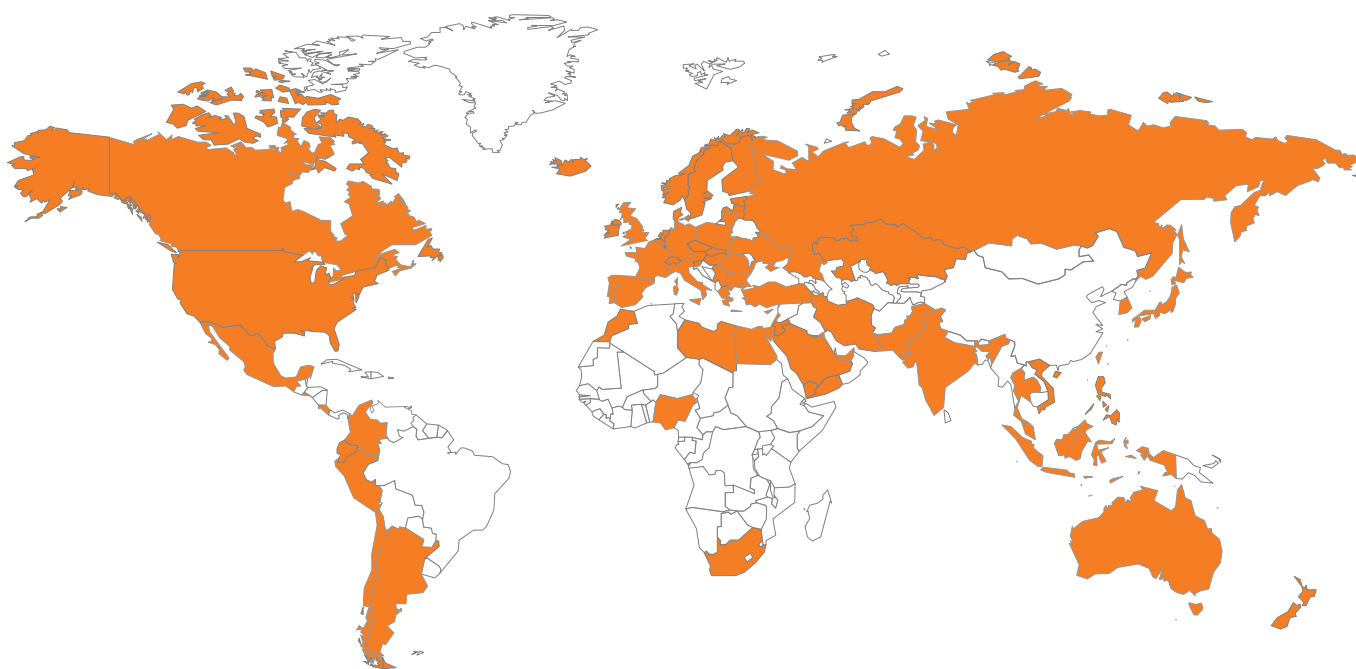
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