

internal & single-stage implant systems



*maximum surface area
for long-term stability*

BIOHORIZONS[®]
SCIENCE • INNOVATION • SERVICE

99.2%
average
implant
success
rate¹



BioHorizons is dedicated to developing evidence-based and scientifically proven products. From the launch of the External implant system (Maestro) in 1997, to the Laser-Lok 3.0 implant in 2010, dental professionals as well as patients have confidence in our comprehensive portfolio of dental implants and biologics products.

Our commitment to science, innovation and service has aided us in becoming one of the fastest growing companies in the dental industry. BioHorizons has helped restore smiles in 85 markets throughout Asia, North America, South America, Africa, Australia and Europe.

global
leader for
biologic
based
solutions



SCIENCE

BioHorizons uses science and innovation to create unique products with proven surgical and esthetic results.

INNOVATION

Our advanced implant technologies, biologic products and computer guided surgery software have made BioHorizons a leading dental implant company.

products
sold
in 85
markets



SERVICE

BioHorizons understands the importance of providing excellent service. Our global network of professional representatives and our highly trained customer care support team are well-equipped to meet the needs of patients and clinicians.

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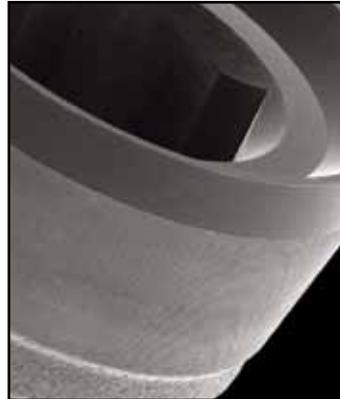
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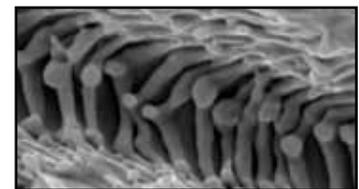
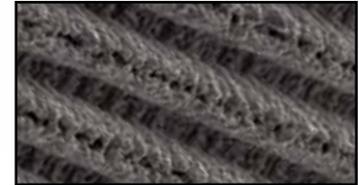
Laser-Lok Technology

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).^{2,3} 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.^{4,5,6,7}



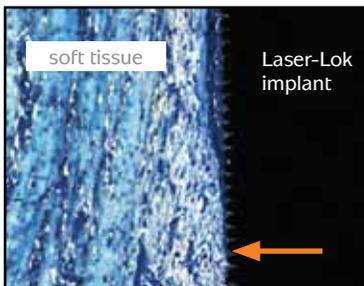
SEM image at 30X showing the Laser-Lok zone on a BioHorizons implant.



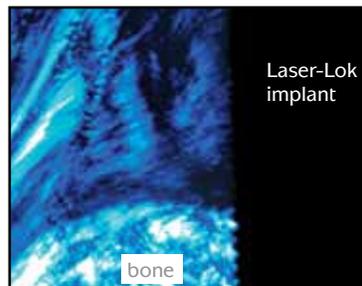
The uniformity of the Laser-Lok microstructure and nanostructure is evident using extreme magnification.

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.^{8,9} 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.²



Polarized lights show the connective tissue is functionally oriented.²



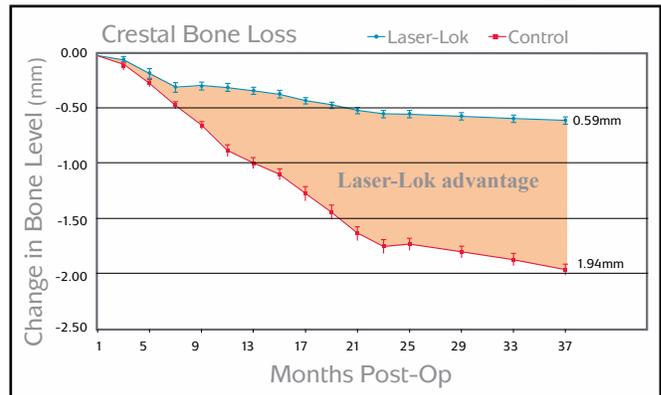
Colorized SEM of a dental implant harvested at 6 months post-op shows the connective tissue is physically attached and interdigitated with the Laser-Lok surface.

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.¹⁰ While random surfaces have shown higher osseointegration than machined surfaces,¹¹ 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.^{2,12}

The clinical advantage

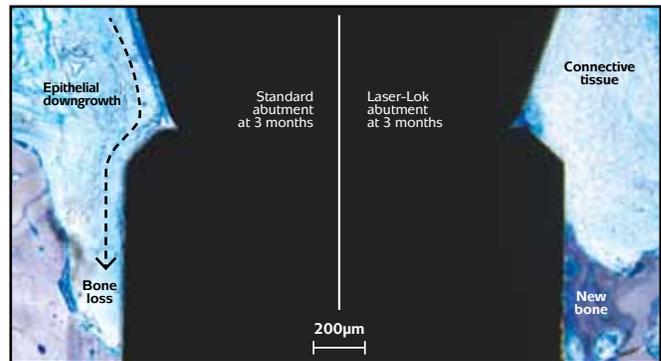
The Laser-Lok surface has been shown in several studies to offer a clinical advantage over other implant designs. In a prospective, controlled multi-center study, Laser-Lok implants, when placed alongside identical implants with a traditional surface, were shown at 37 months post-op to reduce bone loss by 70% (or 1.35mm).⁴ 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.⁵ In a prospective, University-based overdenture study, Laser-Lok implants reduced bone loss by 63% versus NobelReplace™ Select.⁶



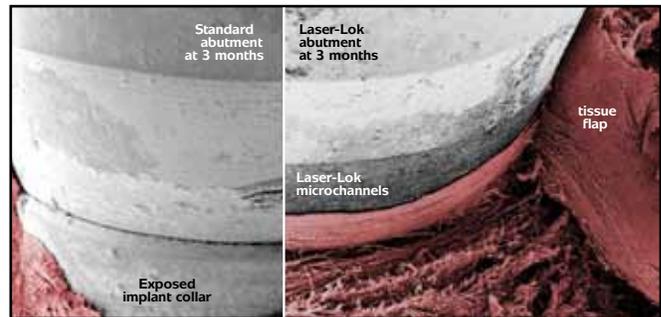
In a 3-year multicenter perspective study, the Laser-Lok surface showed superior bone maintenance over identical implants without the Laser-Lok surface.⁴

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 osseointegration⁹ – 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.¹² This time, however, the attachment was established above the dental implant-abutment connection and even on implants with a machined collar.¹² 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.



Comparative histologies show the biologic differences between standard abutments and Laser-Lok abutments including changes in epithelial downgrowth, connective tissue and crestal bone health.¹²



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.¹²



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

internal

Internal dental implants provide maximum surface area through the use of a parallel-walled body and square thread design. It also is available with Laser-Lok microchannels to create a physical, connective tissue attachment (unlike Sharpey fibers) and long-term crestal bone maintenance.²

FEATURES

Proprietary biomechanical thread design maximizes implant surface area.¹³

Most widely used connection in implant dentistry.

delivery options	mount-free 3inOne abutment
connection	internal hex
body-type	parallel-wall
placement	bone level
surface treatment	RBT body optional Laser-Lok collar
implant lengths	9.0mm 10.5mm 12.0mm 15.0mm



Supported by a comprehensive line of internally hexed prosthetics.



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

INTERNAL/SINGLE-STAGE OVERVIEW



delivery options	mount-free
connection	internal hex
body-type	parallel-wall
placement	tissue level
surface treatment	RBT body optional Laser-Lok collar
implant lengths	7.0mm 9.0mm 10.5mm 12.0mm 15.0mm

single-stage

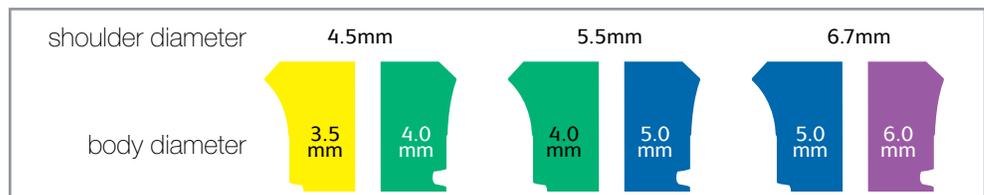
Unlike similar “soft-tissue level” implant designs, the Single-stage dental implant features the BioHorizons power thread with maximum surface area to support the high occlusal forces often seen in the posterior. This gives dentists confidence that their placements will remain secure long-term even with limited ridge height and in softer bone.

FEATURES

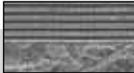
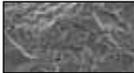
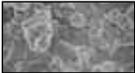
Power thread provides up to 154% greater surface area.¹³

Two body diameters for each platform.

Greater flexibility than other “soft tissue” implants.



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

Internal implants are available with a 3inOne abutment, surgical cover cap, and abutment screw.					
3.5mm Implants 	Body Diameter x Length	Mount-free Mount-free implants are packaged without the 3inOne abutment	RBT Surface w/Laser-Lok	RBT Surface	HA Surface
	3.5mm x 9mm	PYLX3509	LPYR3509	PYR3509	PYH3509*
	3.5mm x 10.5mm	PYLX35105	LPYR35105	PYR35105	PYH35105*
	3.5mm x 12mm	PYLX3512	LPYR3512	PYR3512	PYH3512*
	3.5mm x 15mm	PYLX3515	LPYR3515	PYR3515	PYH3515*
4.0mm Implants 	4.0mm x 9mm	PGLX4009	LPGR4009	PGR4009	PGH4009*
	4.0mm x 10.5mm	PGLX40105	LPGR40105	PGR40105	PGH40105*
	4.0mm x 12mm	PGLX4012	LPGR4012	PGR4012	PGH4012*
	4.0mm x 15mm	PGLX4015	LPGR4015	PGR4015	PGH4015*
5.0mm Implants 	5.0mm x 9mm	PBLX5009	LPBR5009	PBR5009	PBH5009*
	5.0mm x 10.5mm	PBLX50105	LPBR50105	PBR50105	PBH50105*
	5.0mm x 12mm	PBLX5012	LPBR5012	PBR5012	PBH5012*
	5.0mm x 15mm	PBLX5015	LPBR5015	PBR5015	PBH5015*
6.0mm Implants 	6.0mm x 9mm	PBLX6009	LPBR6009	PBR6009	PBH6009*
	6.0mm x 10.5mm	PBLX60105	LPBR60105	PBR60105	PBH60105*
	6.0mm x 12mm	PBLX6012	LPBR6012	PBR6012	PBH6012*
	6.0mm x 15mm	PBLX6015	LPBR6015	PBR6015	PBH6015*

Not all products are available in all markets.

Surgical Cover Cap



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

For use during submerged surgical healing. Hand-tighten with the .050" (1.25mm) Hex Driver. Titanium Alloy. A surgical cover cap is included with each implant but can also be ordered separately.

* Effective June 30, 2012, HA-coated implants will no longer be manufactured. shop online at www.biohorizons.com

SINGLE-STAGE IMPLANTS

<p>All Single-stage implants come packaged with a 2mm healing abutment.</p>		<p>Surface Treatment Configuration:</p> 	<p>RBT with Laser-Lok</p> <p><i>RBT only configurations available in limited quantities. Please call for availability.</i></p> <p>RBT surface treatment</p>
<p>3.5mm Implant Body 3.5mm Prosthetic Platform</p> 	3.5mm x 7mm, 3.5mm platform	LSYR3507	SYR3507
	3.5mm x 9mm, 3.5mm platform	LSYR3509	SYR3509
	3.5mm x 10.5mm, 3.5mm platform	LSYR35105	SYR35105
	3.5mm x 12mm, 3.5mm platform	LSYR3512	SYR3512
	3.5mm x 15mm, 3.5mm platform	LSYR3515	Not available
<p>4.0mm Implant Body 3.5mm Prosthetic Platform</p> 	4.0mm x 7mm, 3.5mm platform	LSYR4007	SYR4007
	4.0mm x 9mm, 3.5mm platform	LSYR4009	SYR4009
	4.0mm x 10.5mm, 3.5mm platform	LSYR40105	SYR40105
	4.0mm x 12mm, 3.5mm platform	LSYR4012	SYR4012
	4.0mm x 15mm, 3.5mm platform	LSYR4015	Not available
<p>4.0mm Implant Body 4.5mm Prosthetic Platform</p> 	4.0mm x 7mm, 4.5mm platform	LSGR4007	SGR4007
	4.0mm x 9mm, 4.5mm platform	LSGR4009	SGR4009
	4.0mm x 10.5mm, 4.5mm platform	LSGR40105	SGR40105
	4.0mm x 12mm, 4.5mm platform	LSGR4012	SGR4012
	4.0mm x 15mm, 4.5mm platform	LSGR4015	Not available
<p>5.0mm Implant Body 4.5mm Prosthetic Platform</p> 	5.0mm x 7mm, 4.5mm platform	LSGR5007	SGR5007*
	5.0mm x 9mm, 4.5mm platform	LSGR5009	SGR5009*
	5.0mm x 10.5mm, 4.5mm platform	LSGR50105	SGR50105*
	5.0mm x 12mm, 4.5mm platform	LSGR5012	SGR5012*
	5.0mm x 15mm, 4.5mm platform	LSGR5015	Not available
<p>5.0mm Implant Body 5.7mm Prosthetic Platform</p> 	5.0mm x 7mm, 5.7mm platform	LSBR5007	SBR5007
	5.0mm x 9mm, 5.7mm platform	LSBR5009	SBR5009
	5.0mm x 10.5mm, 5.7mm platform	LSBR50105	SBR50105
	5.0mm x 12mm, 5.7mm platform	LSBR5012	SBR5012
	5.0mm x 15mm, 5.7mm platform	LSBR5015	Not available
<p>6.0mm Implant Body 5.7mm Prosthetic Platform</p> 	6.0mm x 7mm, 5.7mm platform	LSBR6007	SBR6007*
	6.0mm x 9mm, 5.7mm platform	LSBR6009	SBR6009*
	6.0mm x 10.5mm, 5.7mm platform	LSBR60105	SBR60105*
	6.0mm x 12mm, 5.7mm platform	LSBR6012	SBR6012*
	6.0mm x 15mm, 5.7mm platform	LSBR6015	Not available

*call for availability

shop online at www.biohorizons.com

Virtual Implant Placement (VIP)

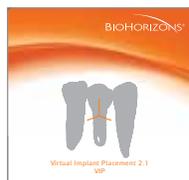
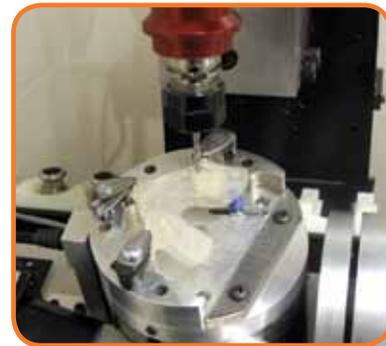
VIP was exclusively developed for clinicians who prefer an innovative and user-friendly treatment planning solution to help deliver a predictable surgical outcome. The integration of digital treatment planning for diagnosis and our Compu-Guide surgical templates for guided surgery gives you the confidence for a safe and effective procedure.

VIP BENEFITS

- Interactive 2D and 3D treatment planning
- Open implant platform designed for cross implant compatibility
- DICOM converter for instant file conversion



VIP virtual surgical plan transfers to Compu-Guide surgical template for implant position and orientation



VIP2.1 VIP 2.1 Software

Interactive 2D and 3D treatment planning software.
Includes (2) software licenses.



L0303 VIP Catalog & Surgical Manual

SURGICAL INSTRUMENTS

Internal / Single-stage Surgical Kit

122-800
Internal / Single-stage Surgical Kit
 Includes all instruments shown on pages 9-11
 except where indicated.

SST
Internal / Single-stage Tray & Lid
 without instruments



Individual Components



122-103
2.0mm Starter Drill



122-100
Drill Extender
*(adds 16mm to
 length of drill)*

- 122-12507** 2.5 x 7mm Depth Drill
- 122-12509** 2.5 x 9mm Depth Drill
- 122-125105** 2.5 x 10.5mm Depth Drill
- 122-12512** 2.5 x 12mm Depth Drill
- 122-12515** 2.5 x 15mm Depth Drill
- 122-225** 2.5mm Depth Drill (without Depth Stop)



- 122-230** 3.0mm Width Increasing Drill
- 122-232** 3.4mm Width Increasing Drill
- 122-237** 3.9mm Width Increasing Drill
- 122-242** 4.4mm Width Increasing Drill
- 122-247** 4.9mm Width Increasing Drill
- 122-252** 5.4mm Width Increasing Drill



**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*

Individual Components



- PT35** Internal / Single-stage 3.5mm Bone Tap
- PT40** Internal / Single-stage 4.0mm Bone Tap
- PT50** Internal / Single-stage 5.0mm Bone Tap
- PT60** Internal / Single-stage 6.0mm Bone Tap



- PCBD35** Internal 3.5mm Crestal Bone Drill
- PCBD40** Internal 4.0mm Crestal Bone Drill
- PCBD50** Internal 5.0mm Crestal Bone Drill
- PCBD60** Internal 6.0mm Crestal Bone Drill



- 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*



- 144-100** Straight Parallel Pins (2 per kit)
- 144-200** 20° Angled Parallel Pins (2 per kit)



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

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

SURGICAL INSTRUMENTS

Individual Components



130-000
Ratchet



144-300
Implant Spacer / Depth Probe



300-400
Hand Wrench*



135-351
.050" (1.25mm) Hex Driver



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.*

Additional Kit Components



- SYCD35** Single-stage 3.5mm Counter-sink Drill, 3.5mm platform
- SYCD40** Single-stage 4.0mm Counter-sink Drill, 3.5mm platform
- SGCD40** Single-stage 4.0mm Counter-sink Drill, 4.5mm platform
- SGCD50** Single-stage 5.0mm Counter-sink Drill, 4.5mm platform
- SBCD50** Single-stage 5.0mm Counter-sink Drill, 5.7mm platform
- SBCD60** Single-stage 6.0mm Counter-sink Drill, 5.7mm platform

Sold separately; not included in the 122-800 surgical kit.



- SYSTA** Simple Solutions 3.5mm Surgical Trial Abutment (2 per kit)
- SGSTA** Simple Solutions 4.5mm Surgical Trial Abutment (2 per kit)
- SBSTA** Simple Solutions 5.7mm Surgical Trial Abutment (2 per kit)

Sold separately; not included in the 122-800 surgical kit.

*instrument o-rings wear out over time. If an instrument is no longer held securely by its associated driver, order a replacement o-ring through Customer Care.

Extended Shank Depth Drills with stops



- 122-403** 2.0mm Starter Drill, Extended Shank
- 122-42507** 2.5 x 7mm Depth Drill, Extended Shank
- 122-42509** 2.5 x 9mm Depth Drill, Extended Shank
- 122-425105** 2.5 x 10.5mm Depth Drill, Extended Shank
- 122-42512** 2.5 x 12mm Depth Drill, Extended Shank
- 122-42515** 2.5 x 15mm Depth Drill, Extended Shank
- 122-425** 2.5mm Depth Drill, Extended Shank

Extended Shank Drills have the same depth marks and cutting geometry as our standard drills, but add 8mm of length to the shank.

Extended Shank Drills



- 122-430** 3.0mm Width Increasing Drill, Extended Shank
- 122-432** 3.4mm Width Increasing Drill, Extended Shank
- 122-437** 3.9mm Width Increasing Drill, Extended Shank
- 122-442** 4.4mm Width Increasing Drill, Extended Shank
- 122-447** 4.9mm Width Increasing Drill, Extended Shank
- 122-452** 5.4mm Width Increasing Drill, Extended Shank

Extended Shank Drills have the same depth marks and cutting geometry as our standard drills, but add 8mm of length to the shank.

Burs



- 122-110** 2.0mm Lindemann Bone Cutter
Side-cutting drill used to correct eccentric osteotomy preparations.
- 122-106** #6 Round Bur

Hex Drivers



- 135-351** .050" (1.25mm) One-piece Hex Driver*
- 135-451** .050" (1.25mm) One-piece Hex Driver, Long*
- 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 Hex Drivers, Long (134-450 and 135-451) are 5mm longer than the standard versions (134-350 and 135-351). *In early 2011, a running change was made to improve abutment screw retention and handling.

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.

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.

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.



PYTP 3.5mm Tissue Punch

PGTP 4.5mm Tissue Punch

PBTP 5.7mm Tissue Punch

Tissue Punches are used 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 3 platform diameters.

Tissue Punches



PYBP 3.5mm Bone Profiling Bur & Guide

PGBP 4.5mm Bone Profiling Bur & Guide

PBBP 5.7mm Bone Profiling Bur & Guide

Used at implant uncoverly to contour crestal bone for abutments when the implant is subcrestal. For use in latch-type reduction handpieces. 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. Comes in three sizes corresponding to the three internal prosthetic platforms.

Bone Profiling Burs



*instrument o-rings wear out over time. If an instrument is no longer held securely by its associated driver, order a replacement o-ring through Customer Care.



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 (ImplantMED) or premium (ElcoMED) 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

WH-00900103

ImplantMED SI-915 (S-NU Foot Pedal) 1.8m Cable, Blue Console

WH-15933100

ElcoMED SA-310 (with Documentation) 1.8m Cable

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

WH-04363600

Disposable Irrigation Tubing, 2.2m (Implantmed and ElcoMED SA-310) (box of 6)

WH-06338400

Irrigation Spike w/ Roller Clamp

WH-04757100

Irrigation Spray Clip for External and Internal Irrigation (set of 3)

WH-10940011

MD-400 Service-Oil F1

WH-02038200

Oil Spray Cap for MD-400 Service-Oil F1

WH-04035100

Pump Tube Complete (ElcoMED SA-200(C))

WH-04013900

Pump Tube Complete (ImplantMED and ElcoMED SA-310)

WH-06338500

Spare Irrigation Tube for Spike

WH-04035200

Spare Pump Tubes (ElcoMED SA-200(C)) (set of 3)

WH-04014000

Spare Pump Tubes (ImplantMED and ElcoMED SA-310) (set of 3)

WH-00929300

Spray Tubes (box of 10)

WH-04032600

Sterilization Motor Protector

WH-04019000

Tube Clamps (ImplantMED) (set of 5)

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-02139800

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.



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 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 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 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.

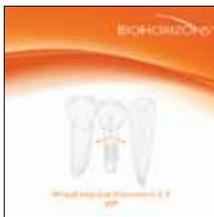
Indications

BioHorizons Internal & Single-stage implants are intended for use in the mandible or maxilla for use as artificial root structures for single tooth replacement or for fixed bridgework and dental retention.

BioHorizons Internal & Single-stage implants may be restored immediately

- 1) with a temporary prosthesis that is not in functional occlusion or
- 2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.

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**

SURGICAL PROTOCOLS



Implant with Cover Cap in a two-stage protocol.

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.



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



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

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



Internal 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



Single-stage 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.

IMPLANT SPACING CONSIDERATIONS

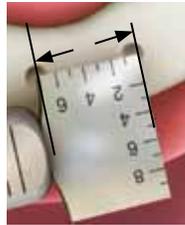
Implant Spacer / Depth Probe

Purpose: Multi-function instrument for intraoral measurements.

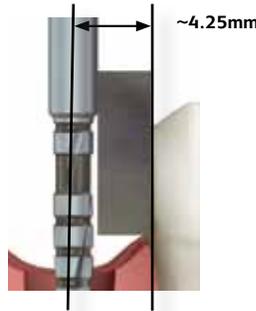
- Five centimeter graduated ruler on shaft



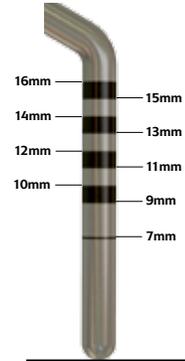
The rectangular end of the tool provides intraoral measurements.



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



The rectangular end against an existing crown places the osteotomy $\sim 4.25\text{mm}$ from the contact.



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

Internal Implant Spacing

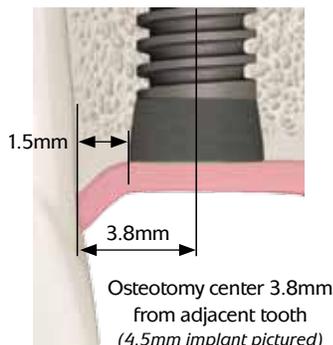


During implant placement, clinicians must apply their best judgment as to the appropriate spacing for individual patient conditions.

The osteotomy centerpoint required to maintain a 1.5mm implant-to-tooth spacing is derived using the following calculation:

$$\frac{1}{2} [\text{prosthetic platform diameter}] + 1.5\text{mm}$$

The measurements for the 3 Internal prosthetic platforms are shown below.



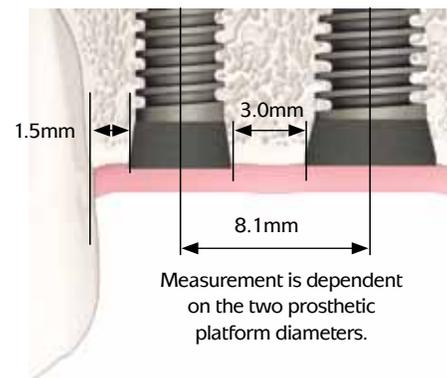
Osteotomy center 3.8mm from adjacent tooth (4.5mm implant pictured)

body diameter	osteotomy center from adjacent tooth
3.5mm	3.3mm
4.5mm	3.8mm
5.7mm	4.4mm

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:

$$\frac{1}{2} [\text{sum of 2 prosthetic platforms}] + 3.0\text{mm}$$

The table below lists the permutations.



Measurement is dependent on the two prosthetic platform diameters.

body diameter	3.5mm	4.5mm	5.7mm
3.5mm	6.5mm		
4.5mm	7.0mm	7.5mm	
5.7mm	7.6mm	8.1mm	8.7mm

Implant center to center

IMPLANT SPACING CONSIDERATIONS

Single-stage Implant Placement

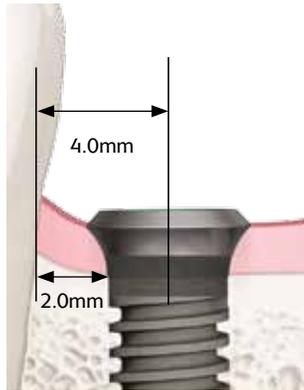


During implant placement, clinicians must apply their best judgment as to the appropriate spacing for individual patient conditions.

The osteotomy centerpoint required to maintain a 2.0mm implant-to-tooth spacing for Single-stage implants is derived using the following calculation:

$$\frac{1}{2} [\text{implant body diameter}] + 2.0\text{mm}$$

The figures below illustrate the measurements for the 4 implant body diameters.



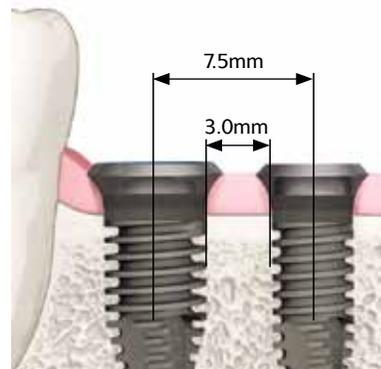
Osteotomy center 4.0mm from adjacent tooth
(4.0mm implant pictured)

body diameter	osteotomy center from adjacent tooth
3.5mm	3.8mm
4.0mm	4.0mm
5.0mm	4.5mm
6.0mm	5.0mm

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:

$$\frac{1}{2} [\text{sum of 2 implant body diameters}] + 3.0\text{mm}$$

The table below lists the different permutations.



Measurement is dependent on the two implant body diameters.
(3.5, 4.5 & 5.7mm implants pictured)

body diameter	3.5mm	4.0mm	5.0mm	6.0mm
3.5mm	6.5mm			
4.0mm	6.8mm	7.0mm		
5.0mm	7.3mm	7.5mm	8.0mm	
6.0mm	7.8mm	8.0mm	8.5mm	9.0mm

Implant center to center



Placement in Uneven Ridges

When placing the 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 & DRILL SEQUENCE

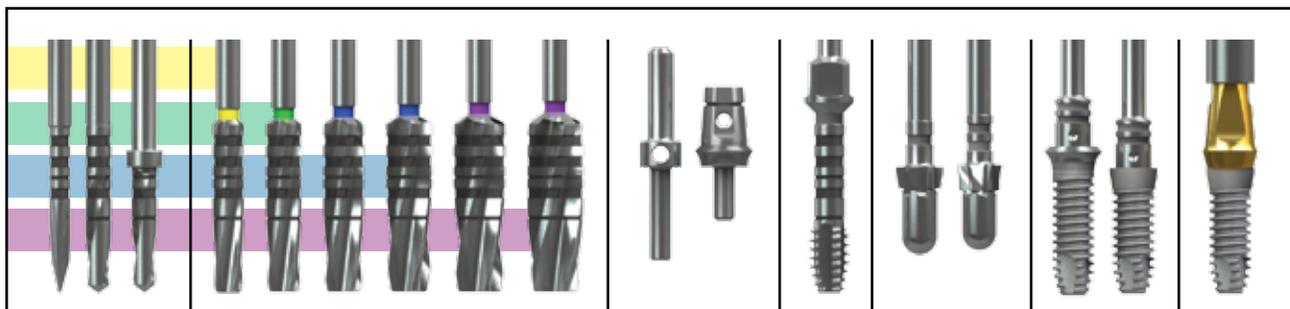
Surgical Kit Layout



The Internal / Single-stage 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.

Drill Sequence



Depth Drill Sequence

Width Increasing Drill Sequence

Depth Gauges

Bone Taps

Crestal Bone & Countersink Drills

Implant-level and/or Abutment-level Drivers

SURGICAL DRILL OVERVIEW

Drill Markings

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

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.

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 at biohorizons.com 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.

2.0mm Starter Drill



Purpose: Initiate osteotomy.

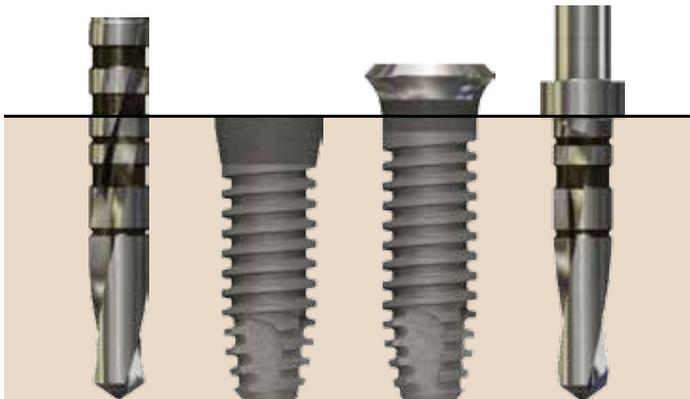
- Chisel-tip design eliminates "skating" on osseous crest
- Prepares site for Paralleling Pins
- Matte finish for increased visibility under operatory lights

2.5mm Depth Drill



Purpose: Set osteotomy depth.

- Efficient cutting drill design collects bone for autografting
- Matte finish for increased visibility under operatory 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
- 1 mm laser-etched line guides supracrestal implant placement

OSTEOTOMY MODIFICATION



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

Paralleling Pins



Purpose: Incrementally widens the osteotomy without creating excessive heat.

- 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.

Width Increasing Drills



Purpose: Evaluation of osteotomy position for Simple Solutions restoration.

- Represents either:
 - Internal implant with 5.5mm high / 1.8mm collar Abutment or
 - Single-stage implant with 5.5mm high Abutment
- Used following 2.0mm Starter Drill
- Shank is 5.0mm long and 2.0mm in diameter



Trial Abutments are used to assess final abutment position, margin height and chimney height. They approximate the intra-oral position of either a 5.5mm high / 1.8mm collar Internal Simple Solutions Abutment on an Internal implant or 5.5mm high Single-stage Simple Solutions Abutment on a Single-stage implant. 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.

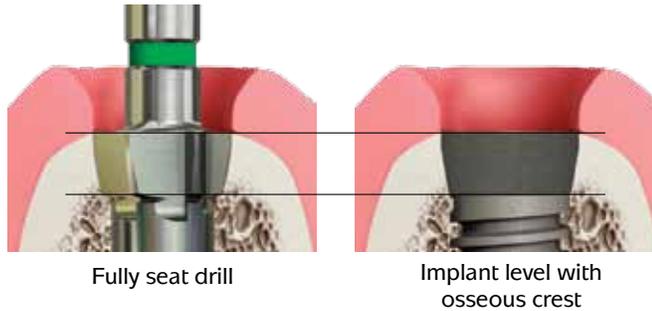
Simple Solutions Trial Abutments

Crestal Bone Drills (for Internal implants)



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

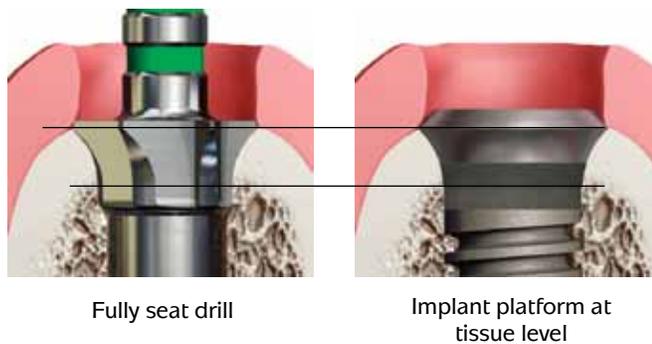


Countersink Drills (for Single-stage implants)



Purpose: Remove cortical bone at ridge crest to countersink Single-stage implants.

- 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



Implant Body **5.0mm**

Prosthetic Platform **4.5mm**

Counter-sink Drills are available (sold separately) 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. To fully countersink the Single-stage implants, the osteotomies need to be overdrilled by 1.8mm.

Each of the Single-stage Counter-sink Drills has a unique double color-code band representing the Implant Body/Prosthetic Platform combination. Be certain the Counter-sink Drill matches the Implant Body/Prosthetic Platform combination being placed.

FINAL BONE PREPARATION & DRIVERS

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 (for Internal implants)

Purpose: Engage the pre-mounted 3inOne Abutment on the Internal implant 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



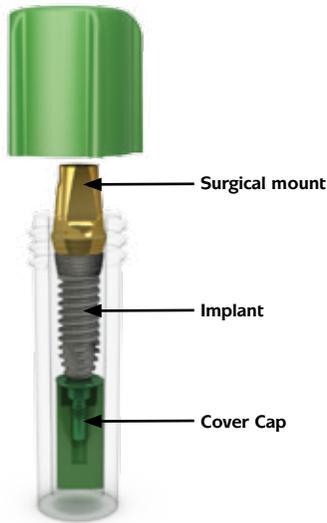
Implant-level Drivers

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

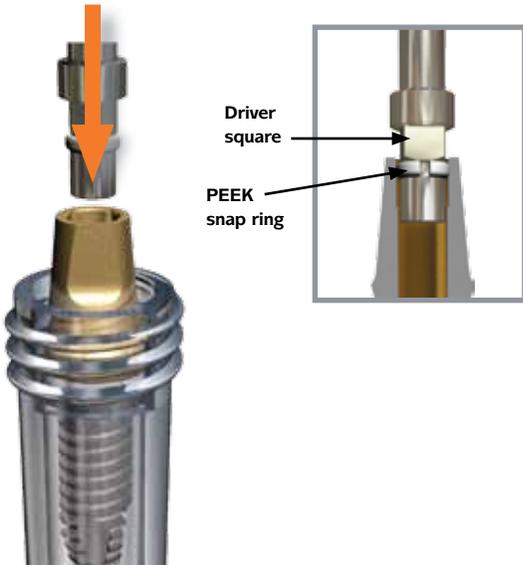
- May also be used following removal of the 3inOne Abutment
- Offers a narrower path of insertion than placing with a mount
- 30 rpm or less¹⁷



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.

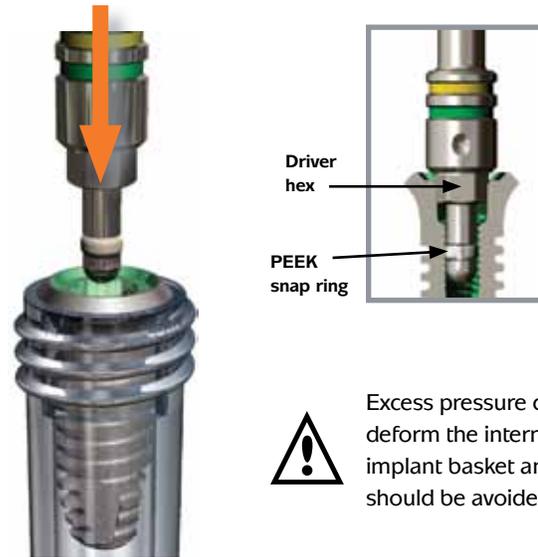


Engage the 3inOne Abutment with the PEEK snap ring of the Abutment-level driver. The driver square has no retentive feature and does not need to be engaged. The driver square will automatically engage in the osteotomy when the driver is slowly rotated under apical pressure.

Mount-free Transfer



The Cover Cap for the Internal mount-free is mounted in the vial cap.



Engage the implant with the PEEK snap ring of the Implant-level Driver. The hex of the driver has no retentive feature and does not need to be engaged. The driver hex will automatically engage in the osteotomy when the driver is slowly rotated under apical pressure.



Excess pressure can deform the internal implant basket and should be avoided.

ABUTMENT LEVEL PLACEMENT (INTERNAL IMPLANT)

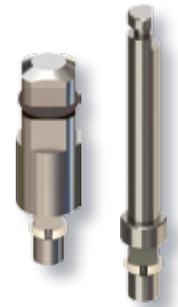


Place the apex of the implant into the osteotomy, apply firm apical pressure and begin rotating slowly (30 rpm or less is recommended)¹⁷. When the threads engage, allow the implant to feed without excessive pressure. If the handpiece is unable to fully seat the implant, remove the 3inOne and complete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

Implant Placement



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 (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.

Implant Placement

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



- Exclusive method for placing Single-stage implants
- May also be used with Internal implants
- Handpiece or manual insertion options
- 30 rpm or less¹⁷



Implant-level Drivers - Handpiece and Ratchet

Implant-level Drivers engage the implant's internal hex. 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.

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 dimples found on Implant-level Drivers are indexed to the internal hex flats and can be used to help achieve the correct hex orientation.



POST-OPERATIVE INSTRUCTIONS

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

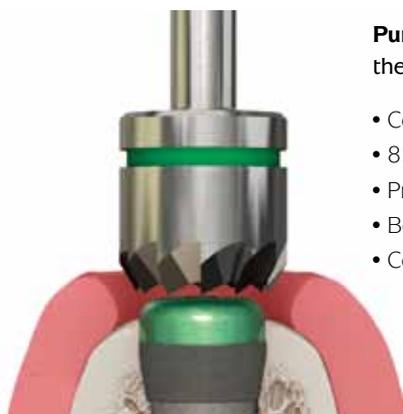
All BioHorizons Surgical Kits are provided non-sterile and must be cleaned and sterilized prior to use. Always remove instruments from packaging prior to sterilization, and remove and discard packaging materials used to stabilize and secure kits during shipment. Double-check all surgical instruments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

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 cap 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 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 (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.

SINGLE-STAGE IMPLANT HEALING PROTOCOLS

Cover cap/2mm Healing Abutments for Single-stage Protocol



Purpose: Protects Single-stage implant connection during healing or helps contour tissue when implant is countersunk.

- Comes packaged with every Single-stage implant
- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver
- Color-coded by prosthetic platform
- Encoded for easy intraoral identification, for example:
SG2 = Single-stage / Green (4.5mm) platform / 2mm High



4mm Healing Abutments for Single-stage Protocol

Purpose: Protects prosthetic platform & contours thick tissue or use when the Single-stage implant is countersunk

- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver
- Suture groove helps apically position tissue
- Color-coded by prosthetic platform
- Encoded for easy intraoral identification, for example:
SG4 = Single-stage / Green (4.5mm) platform / 4mm High



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.

Immediate Provisional Restorative Options

Temporary Abutments

Purpose: Easily modified for fabrication of cement or screw-retained provisional restorations. A Direct Coping Screw (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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References

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17. Root Form Surgery in the Edentulous Mandible: Stage I Implant Insertion. CE Misch. *Contemporary Implant Dentistry Second Edition*. Mosby: St. Louis, 1999. 347-369.

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.¹⁵

(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.

Treatment planning and clinical application of BioHorizons products are the responsibility of each individual clinician. BioHorizons strongly recommends completion of postgraduate dental implant education and adherence to the IFU that accompany each product. BioHorizons is not responsible for incidental or consequential damages or liability relating to use of our products alone or in combination with other products other than replacement or repair under our warranties.

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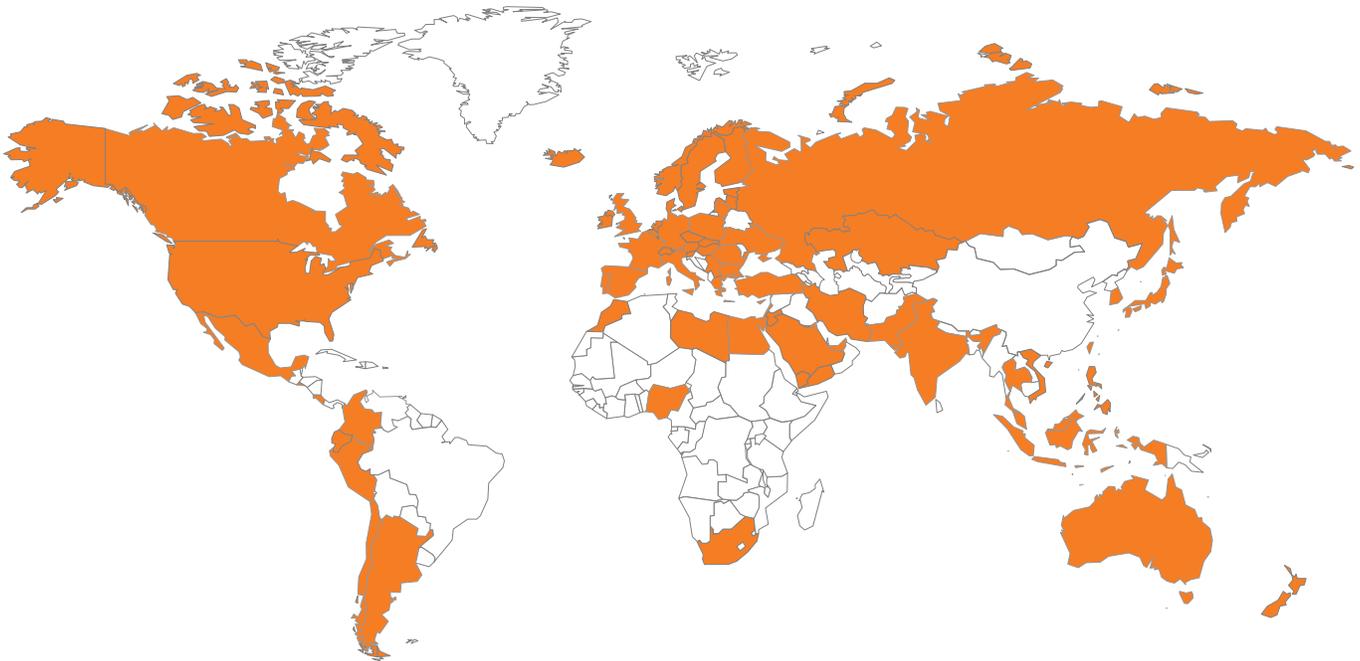
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