



Product Catalog and Technique Manual





ORDERING & WARRANTY INFORMATION

Product Support Specialist:					
cell phone:	fax:				
BioHorizons USA	Customer Care/Servicio al Cliente: 888-246-8338/205-967-7880				
BioHorizons Canada	Customer Care/Service à la Clientèle: 866-468-8338/905-944-1700				
BioHorizons Ibérica	Atención al Cliente: +34 91 713 10 84				

BioHorizons No Exceptions Warranty:

Our warranty policies are a tangible expression of our belief in the excellence and simplicity of our products, as well as our commitment to our customers. We will repair or replace any of our products if they fail or cause problems within the warranty period for any reason, without exception.

Lifetime Warranty on Implants and Prosthetics:

BioHorizons implants and prosthetic attachments carry a Lifetime Warranty. We will provide a replacement for any BioHorizons implant or prosthetic attachment if removal of that product is required for any reason, at any time.

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

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

(1) Instruments: The warranty on BioHorizons instruments extends for a period of one (1) year from the date of initial invoice. The instruments covered by this warranty include drivers, sinus lift components, implant site dilators and other BioHorizons tools used in the placement or restoration of our implants, with the exception of surgical drills and taps, which are specified below (2). Torque wrenches require recalibration every 12 months. Our Customer Care Department can provide information on where to send your wrenches for recalibration and service.

(2) Surgical Drills and Taps: The warranty on surgical drills and taps extends for a period of 90 days from the date of initial invoice. Surgical drills and taps should be replaced when they are worn, dull, corroded or in any way compromised. Smaller diameter drills, used more often than larger diameter drills, should be replaced with greater frequency. BioHorizons recommends the replacement of drills after 12 to 20 osteotomies.

Return Policy:

All returns of product require a Return Authorization Form, which can be acquired by calling Customer Care at 888-246-8338. Please include a copy of the Return Authorization Form with the product. Special regulations for tissue products - AlloDerm and AlloDerm GBR may not be exchanged or returned for credit. Grafton must be exchanged or returned within ten (10) days of receipt.

Product may be returned for full credit up to 60 days after the date of shipment provided: (1) it is returned to BioHorizons freight prepaid and (2) it is in its original un-opened package. Under no circumstances can BioHorizons accept product for return or exchange that has been used clinically. Product returned 61-120 days after shipment from BioHorizons will be assessed a restocking charge of 15%. Please contact your product support specialist for returns of product beyond 120 days from date of shipment.

BioHorizons strongly recommends completion of post-graduate dental implant education and strict adherence to the instructions for use (IFU) that accompany our products. Treatment planning and use of the products are solely your responsibility. 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. BioHorizons continually strives to improve its products and therefore reserves the right to improve, modify, change specifications or discontinue products at any time.

-1 - 8 8 8 - 2 4 6 - 8 3 3 8

TABLE OF CONTENTS

Ordering and warranty information BioHorizons Internal system overview	inside front cover 3-4
Product Catalog —	
Implants	5-6
Healing Abutments and emergence profile	7-8
Surgical kit and components	9-10
Abutment selection flowchart	11-12
Abutment dimensions	13-14
Cement-retained restorations	15-16
Custom-castable restorations	17-18
Screw-retained abutment-level restorations	19-20
Ball Abutment restorations	21-22
Ancillary surgical and prosthetic instruments	23-24
W&H surgical motors and handpieces	25-26
Education and marketing materials	27
Surgical Manual —————————————————————	
Icon legend	28-29
Surgical template	29-30
Surgical instruments	31-34
Osteotomy sequence	35-38
Implant packaging	39
Implant placement	39-40
Abutment removal/Cover Cap placement	41
Bone Profiler	42
Healing Abutment placement	42
Cleaning	43
Instructions for use	44
Post-operative Instructions	45
Impression Techniques ————————————————————————————————————	
Impression technique overview	46-47
Closed Tray (Indirect) Transfer Impression, implant level	48-50
Open Tray (Direct) Pick-up Impression, implant level	51-53
References	54



SYSTEM OVERVIEW



...the implant system that blends the time-proven biomechanical modified square-thread design with the advantages and security of an internal-hex connection.

A safe, strong connection.

The 1.5mm deep internal hex connection is enhanced by the use of Spiralock[®] screw technology; the same design used by NASA and in orthopedics to guard against screw-loosening in high load environments.¹

The connection forms an intimate mating of the abutment and implant for a tight biologic seal at this critical junction.

BioHorizons Internal implants and prosthetic components are color-coded by the diameter of the prosthetic platform to ensure confusion-free restorations.

Abutments and Abutment Screws utilize the standard .050" Hex Driver and are torqued to 30Ncm which eliminates the need for multiple drivers and wrenches.

Utilizes industry standard tooling: .050" hex and 30Ncm torque.

Biologic seal and leadin bevel at the implant/ abutment interface.

Precision machining and 1.5mm hex connection ensure correct abutment seating every time.

Spiralock[®] threadlocking internal geometry virtually eliminates screw loosening.





Free esthetic abutment with every implant.

Are you tired of paying *a la carte* for your abutments? With the patented $3inOne^{TM}$ Abutment, you don't have to.

Included free with each implant, it serves as a prepable titanium abutment, as well as a surgical mount and impression coping (when used with a ball-top screw). It features an esthetic margin profile and a gold-hued, titanium nitride coating for tissue esthetics. The natural taper allows for easy restoration with minimal modification.

Use of the *3inOne* abutment maximizes simplicity and value, while minimizing inventory requirements and cost. Providing the restoring dentist with the final abutment is a strong marketing tool for specialists looking to expand their practice.

<u>-1 - 8 8 8 - 2 4 6 - 8 3 3 8</u>

SYSTEM OVERVIEW

Surface treatment & Surface area. Quality & Quantity.

Surface treatment and bone-to-implant contact are important in promoting rapid osseointegration. Why then do most companies choose to put their surfaces on implants that, by design, limit the amount of surface area? BioHorizons' thread design increases surface area up to 150% over conventional v-thread designs, while also enhancing the bone response.²

A recent randomized, prospective animal study of various thread designs showed that square-thread implants had more bone-to-implant contact and higher reverse torque values than v-thread and reverse buttress thread implants at 12 weeks post-surgery evaluation.¹⁰ The study concluded that the square-thread design may be more effective for endosseous implants than alternative designs.

In vivo human and animal histological research on implants with the BioHorizons thread design indicates lamellar bone formation apposing the implants to be similar to that found adjacent to natural teeth.²⁻⁵ Healthy bone leads to healthy soft tissue and better esthetic results. The modified square-thread design is based on the principle that bone is strongest under compressive loading and weakest under shear loading. It has shown a 99.4% success rate in a 5-year, prospective, multi-clinic trial.⁶

Square threads transmit 10 times more compressive load to the bone than conventional v-threads, while minimizing destructive shear loads. This attribute has become increasingly important with the emergence of early and immediate load protocols.⁴⁻⁵

The titanium alloy used throughout the system is the strongest in the industry. It is 4 times stronger than commercially pure titanium, and 1.6 times stronger than Grade 4 Titanium.¹



Nomarsky microscopy showing bone apposition to the implant. Concentric lamellae of the forming osteons and interstitial lamellae are apparent.³



Photomicrograph of the implant bone interface of an immediately loaded maxillary posterior implant removed one year after function demonstrating more than 80% bone contact.⁴

Photograph courtesy of Dr. Marco Degidi and Dr. Adriano Piattelli

Two surface treatment options to address various conditions.



Resorbable Blast Texturing (RBT)

Unlike other systems that blast their implants with aluminum oxide, BioHorizons uses RBT technology to create the optimal surface texture (75µ Ra average) without the chance of leaving imbedded particles on the implant. The biocompatible calcium phosphate used in the blast process is dissolved during the passivation phase of manufacturing, leaving an ideal roughness profile on a pure titanium oxide surface.⁷

BioHorizons pioneered the use of RBT in 1997, and it has been proven to improve bone cell contact as compared to a machined titanium surface.⁸

HA coating and improved thread-form create an unbeatable combination for rapid integration, initial stability and long-term success. These factors are increasingly important when working in soft bone and/or areas high load.

Multiple clinical studies document the improved success rates of HA-coated implants in compromised bone.⁹



Hydroxylapatite (HA)



IMPLANT COLOR CODE LEGEND

BioHorizons Internal components have a prosthetic platform-specific color code for easy identification. Parts that are crosscompatible between platforms are not color-coded.







IMPLANTS

BioHorizons Internal Implants

STERILE R

Each implant is packaged with the 3inOne Abutment, Cover Cap and Abutment Screw. Choice of RBT or HA surface treatment.

		RBT Surface	HA Surface	Diameter and Length
		PYR3509	PYH3509	Ø3.5mm x 9mm
•		PYR35105	PYH35105	Ø3.5mm x 10.5mm
		PYR3512	PYH3512	Ø3.5mm x 12mm
		PYR3515	PYH3515	Ø3.5mm x 15mm
	10.0	PGR4009	PGH4009	Ø4.0mm x 9mm
		PGR40105	PGH40105	Ø4.0mm x 10.5mm
		PGR4012	PGH4012	Ø4.0mm x 12mm
	2.1	PGR4015	PGH4015	Ø4.0mm x 15mm
		PBR5009	PBH5009	Ø5.0mm x 9mm
		PBR50105	PBH50105	Ø5.0mm x 10.5mm
		PBR5012	PBH5012	Ø5.0mm x 12mm
		PBR5015	PBH5015	Ø5.0mm x 15mm
		PBR6009	PBH6009	Ø6.0mm x 9mm
		PBR60105	PBH60105	Ø6.0mm x 10.5mm
	the second	PBR6012	PBH6012	Ø6.0mm x 12mm
	200	PBR6015	PBH6015	Ø6.0mm x 15mm

Surgical Cover Cap



Low Profile - for use during submerged surgical healing. Packaged FREE with each implant system. Utilizes a .050" Hex Driver.









HEALING ABUTMENT LEGEND

Healing Abutments and Emergence Profile

Healing Abutments are used for tissue healing at second-stage uncovery, or as the transmucosal element for a single-stage procedure. The Suture Groove allows the surgeon to apically position the soft tissue flap and retain it in this position for improved esthetic results. Three factors should be considered when ordering Healing Abutments: **diameter, height and emergence profile**.

The **diameter** of the Healing Abutment must be the same as the prosthetic platform width of the corresponding implant, either Ø3.5mm, Ø4.5mm or Ø5.7mm.

The **height** of the Healing Abutment is typically chosen based upon the soft tissue thickness. Available heights are **1mm**, **3mm and 5mm**.

The **emergence profiles** offered are: **narrow**, **regular** and **wide**. They should be chosen based upon the desired emergence of the final restoration. For example: if the final restoration calls for a Wide Emergence Profile Abutment, the Healing Abutment and Impression Coping used should also be Wide Emergence. Following this protocol will make the seating of prosthetic components much easier by contouring the soft tissue away from the prosthetic platform. Custom Cast Abutments do not specify an emergence since the emergence will be determined by the contour of the final restoration.



HEALING ABUTMENTS

Healing Abutments



Available in three heights to accommodate various tissue thickness: 1mm, 3mm and 5mm. Emergence (Narrow, Regular or Wide) should be chosen based upon the desired emergence of the final restoration. Utilizes a .050" Hex Driver.



		PGNHA1	4.5mm Narrow Healing Abutment, 1mm Height
T	$\left(\frac{\mathbf{N}}{\langle 4.5 \rangle} \right)$	PGNHA3	4.5mm Narrow Healing Abutment, 3mm Height
1		PGNHA5	4.5mm Narrow Healing Abutment, 5mm Height
	R	PGRHA3	4.5mm Regular Healing Abutment, 3mm Height
Ť	4.5	PGRHA5	4.5mm Regular Healing Abutment, 5mm Height
			4 5mm Wide Healing Abutment, 3mm Height
T		r Gwinag	4.5mm Wide Healing Abuthent, 5mm Height
	(4.5)	PGWHA5	4.5mm Wide Healing Abutment, 5mm Height





5.7mm Narrow Healing Abutment, 1mm Height5.7mm Narrow Healing Abutment, 3mm Height5.7mm Narrow Healing Abutment, 5mm Height





PBRHA3 PBRHA5 5.7mm Regular Healing Abutment, 3mm Height5.7mm Regular Healing Abutment, 5mm Height



SURGICAL KIT & COMPONENTS



SURGICAL KIT & COMPONENTS



ABUTMENT SELECTION FLOWCHART



ABUTMENT SELECTION FLOWCHART



The Abutment Selection Flow Chart is provided to aid in the proper selection of the abutment(s) needed based on the final prosthetic option desired. Simply determine if the case is for a single tooth, multiple unit or overdenture restoration. Next, select the desired abutment(s) based on cement-retained or screw-retained fixation. For an overdenture prosthesis, select the desired abutment based on either a bar-retained or abutment-retained denture.



ABUTMENT DIMENSIONS



ABUTMENT DIMENSIONS









*Diameters of Impression Copings are .25mm greater than the associated abutment. The Ø4.5mm platform is shown here as an example. Height measurements are equal for all prosthetic platforms. The 3inOne abutment may be used with the Ball-top Screw as an indirect transfer coping with regular emergence.

BIOHORIZONS®

*parts shown not to scale

CEMENT-RETAINED RESTORATIONS

Abutments for Cer	nent-Retained Resto	Drations - Hexed STERLE R 30 Ncm
Indicated for single and multiple Abutment Screw (PXAS).	unit cement-retained restoration	s. All two-piece abutments are packaged with the
	PYNEA	3.5mm Narrow Emergence Abutment
	PGNEA	4.5mm Narrow Emergence Abutment
	PBNEA	5.7mm Narrow Emergence Abutment
	PYREA	3.5mm <i>3inOne</i> Abutment (Regular Emergence)
		4.5mm 3inOne Abutment (Regular Emergence)
	PBREA	5.7mm 3inOne Abutment (Regular Emergence)
	PYWEA PGWEA	3.5mm Wide Emergence Profile Abutment 4.5mm Wide Emergence Profile Abutment
	PYRAA PGRAA PBRAA	3.5mm Angled Abutment (Regular Emergence) 4.5mm Angled Abutment (Regular Emergence) 5.7mm Angled Abutment (Regular Emergence)



PXBT

May also be used to extend length of Indirect Transfer Copings by 3mm

all platforms





CEMENT-RETAINED RESTORATIONS



CUSTOM CASTABLE - HEXED



1 - 8 8 8 - 2 4 6 - 8

3

CUSTOM CASTABLE - NON-HEXED



SCREW-RETAINED ABUTMENT LEVEL



SCREW-RETAINED ABUTMENT LEVEL



BALL ABUTMENT RESTORATIONS





PYGBAA PBBAA 3.5/4.5mm Ball Abutment Analog 5.7mm Ball Abutment Analog

-1 - 8 8 8 - 2 4 6 - 8 3 3 8

BALL ABUTMENT RESTORATIONS

Ball Attachment System

The Ball Attachment system offers several advantages over traditional O-ring attachments. It requires less mesial/distal/ buccal/lingual space and offers four (4) different levels of retention. The retention inserts can be easily changed chairside.



O-Ring Attachment System

		J			
Standard O-ring	g attachment.				
			0	260-210	Clinical O-Ring Used for clinical applications. Silicone. 12 per package.
	260-100	O-Ring Attachment Set O-Ring encapsulator 2 Processing O-rings 2 Clinical O-rings	0	260-220	Processing O-Ring Used for lab processing. applications. Buna. 12 per package
			9	260-300	O-Ring Encapsulator Female receptacle processed into denture. Titanium. 2 per package.

BIOHORIZONS

ANCILLARY SURGICAL INSTRUMENTS

Extended Shank Drills

Extended Shank Drills are 3mm longer than our standard drills. They have the same depth marks and cutting geometry as our standard drills. They allow you to work next to long clinical crowns without having to use the drill extension. They are an optional purchase and are not included in the BioHorizons Internal Surgical Kit (PSKC).

	122-420	Ø2.0mm Depth Drill - Extended Shank
1	122-425	Ø2.5mm Depth Drill - Extended Shank
	122-430	Ø3.0mm Width Increasing Drill - Extended Shank
	122-432	Ø3.2mm Width Increasing Drill - Extended Shank
	122-437	Ø3.7mm Width Increasing Drill - Extended Shank
	122-442	Ø4.2mm Width Increasing Drill - Extended Shank
	122-447	Ø4.7mm Width Increasing Drill - Extended Shank
	122-452	Ø5.2mm Width Increasing Drill - Extended Shank

2.0mm Lindemann Bone Cutter

Side cutting drill used to correct eccentric osteotomy preparations.



Ø2.0mm Lindemann Bone Cutter

Tissue Punches

BioHorizons Tissue Punches are designed to be used in a latch-type handpiece and are used 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.



Bone Profiling Burs

Used at implant uncovery to contour crestal bone to accommodate 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 3 sizes corresponding to the 3 Internal prosthetic platforms.



Clean-out Tap Tool

Used to re-thread implants where the internal threads have become damaged. Requires a standard surgical Ratchet (130-000) or Hand Wrench (300-400) as a drive mechanism.



PXCT

BioHorizons Internal Implant Clean-out Tap Tool

-1 - 8 8 8 - 2 4 6 - 8 3 3 8

PROSTHETIC INSTRUMENTS

Implant Analog Handles

Used to hold abutments for chairside or laboratory preparation, these handles mimic the implant/analog hex geometry. Abutments are secured to the handle with the standard Abutment Screw (PXAS). Comes in two platform sizes: Ø3.5/4.5mm and Ø5.7mm.



PYGAH PBAH Ø3.5/4.5mm Platform Analog Handle Ø5.7mm Platform Analog Handle



ATCHET SPARE	HEX ADAPTERS		System Includes AS123 Hand Unit, Hand Wrench, 3 Torque Wrench, .050" Hex Driver, .050" Hex Long, Hex Adapters for Abutment for Screw Drive Extension and Sterilization Tray	30 Ncm x Driver, w, Square			
TORQUE WIENCH ESARE PDMA		300-070	300-070 Prosthetic Sterilization Tray Autoclavable tray for prosthetic instrumentation (included with the 320-000).				
-		300-100	AS123 Hand Unit Provides improved vision and easy access components in posterior regions of the mou Wrench and Drivers must be purchased se May also be purchased as part of the 320-0 Prosthetic Instrumentation System (see abo	to prosthetic uth. Hand parately. 000 Complete ove).			
-		300-430	30 Ncm Torque Wrench Used to deliver final torque to all prosthetic com	nponents.			
ľ	300-350 regular 300-351 long	.050" Hex E Used to drive a with the excep	Driver Regular and Long Il surgical and prosthetic components otion of the Abutment for Screw.	.050" Hex			
P	РХНА	Hex Adapte Required for pl by either Hand	Fr, Abutment for Screw acement of Abutment for Screw. May be driven Wrench, Torque Wrench or AS123 Hand Unit.	O Hex Adapter			
	300-400	Hand Wren Used on drive e Also fits individ	ch and of AS123 Hand Unit . ual Hex Drivers/Adapters and Bone Taps.				
			*produ	ucts shown not to scale.			



MOTORS

W&H ImplantMed 110 Starter Kit

The ImplantMed 110 is designed for use in dental implantology and provides the surgeon with a high quality power unit that is easy and safe to operate. Maximum motor speed is 40,000 rpm. The motor comes with the WS-75 20:1 handpiece, testing gauge, spray cap, irrigation spike and service oil.



WH-110

Re-order items:

WH-ST (10 PK) WH-110CLP (5 PK) WH-110PTWC WH-110RPT (3 PK) WH-110ISAWRC WH-110RC WH-110MC

W&H ImplantMed 110 Starter Kit

Green Single-Use Spray Tubes (10 pack) Set of Spray Tube Clamps (5 pack) Pump Tube (85mm) with Connectors Replacement Pump Tubes (85mm) (3 pack) Irrigation Spike Assembly with Roller Clamp Flow Regulating Roller Clamp Motor Cable - 1.8 meter

W&H ElcoMed SA-200 Professional Kit

The ElcoMed SA-200 combines power, performance and intelligence to support the surgeon in maxillofacial surgery, implantology, microsurgery and small bone surgery. Maximum motor speed is 50,000 rpm. The SA-200 also permits the storage of torque characteristics of a treatment stage, which can then be saved on a DOC card for archiving purposes. The kit also includes the WS-75 20:1 handpiece, testing gauge, spray cap, irrigation spike and service oil.



WH200

Re-order items:

WH-ST (10 PK) WH-CLP (10 PK) WH-200PTWC WH-200RPT (3 PK) WH-200INI WH-200DOC WH-200MC

W&H ElcoMed SA-200 Professional Kit

Green Single-Use Spray Tubes (10 pack) Set of Spray Tube Clamps (10 pack) Pump Tube (190mm) with Connectors Replacement Pump Tubes (190mm) (3 pack) INI Cards (3 pack) DOC Cards (3 pack) Motor Cable -1.8 meter

ElcoMed 100 - Legacy Re-order Items

WH-ST (10 PK) WH-CLP (10 PK) WH-100PTWC WH-100RPT (5 PK) WH-100MC Green Single-Use Spray Tubes (10 pack) Set of Spray Tube Clamps (10 pack) Pump Tube with Connectors (65mm) Replacement Pump Tubes (65mm) (5 pack) Motor Cable -1.8 meter

Universal W&H Re-order Items

WH-ST (10 PK) WH-ISA WH-ITWOS WH-MD400 WH-OSC WH-SP

Green Single-Use Spray Tubes (10 pack) Irrigation Spike Assembly (autoclavable) Irrigation Tubing w/o Spike (autoclavable) MD-400 Service Oil-F1 Oil Spray Cap Sterilization Plug for Motor Cable

-1 - 8 8 8 - 2 4 6 - 8 3 3 8

HANDPIECES



IMPORTANT NOTE: W&H motors and handpieces are distinguished by their precision craftsmanship and reliability and are covered by a 1-year manufacturer's warranty. Instructions for required cleaning and maintenance are outlined in each product's user manual, and adherence to these procedures is essential for proper function and longevity of the products. BioHorizons assumes no liability for the failure of, or damage to, motors and handpieces that are not properly maintained or used contrary to the instructions for use.

Please contact your product support specialist or Customer Care at 888-246-8338 (866-468-8338 in Canada) if you need additional information.

W&H ElcoMed Surgical Handpieces

W&H has designed a series of straight and contra-angle handpieces for maxillofacial surgery, implantology and microsurgery.

11 mm	WS-75	W&H 20:1 Contra-Angle Handpiece WS-75 E/KM Contra-Angle Handpiece with speed reduction ratio of 20:1 (2,500 rpm maximum). Equipped with both internal cooling & external cooling. Push- button bar release. Trapezoidal profile. Safe grip, particularly with gloves.
	WS-92	W&H 1:2.7 Contra-Angle Speed Increasing Handpiece 1:2.7 speed-increasing ratio - 135,000 rpm maximum. Contra-Angle Handpiece suitable for high speed preparation and tissue augmentation procedures. External irrigation port. Uses friction grip burs.
	S-11	W&H 1:1 Straight Surgical Handpiece 1:1 ratio - 50,000 rpm maximum. Suitable for bone harvesting, third molar extractions and osteoplasty. Easily dismantled for cleaning. Uses 45mm friction grip surgical burs (Ø2.35mm).
	S-12	W&H 1:2 Contra-Angle Surgical Handpiece 1:2 speed increasing ratio - 80,000 rpm maximum. Suitable for surgical procedures such as bone smoothing, third molar extractions and osteotomy site drilling. High precision bearings ensure that the unit runs vibration free. Uses friction grip surgical burs at least 65mm long (Ø2.35mm).

Hex Driver for Latch-Type Reduction Handpieces

Used with right angle latch connection handpieces for installation and removal of Cover Caps, Healing Abutments, Abutments and Abutment Screws.

134-350

.050" Handpiece Hex Driver

Bur Testing Gauge

Used 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 criteria are unfit for use, and may cause damage to the handpiece if used.



Bur Testing Gauge

EDUCATION & MARKETING



ML0118

BioHorizons Internal Prosthetic Manual

This guide walks the clinician and staff through impression making techniques and prosthetic/lab procedures with the BioHorizons Internal System. Step-by-step written instructions are coupled with detailed graphics to illustrate procedures and help identify the accompanying prosthetic and lab components.



Regeneration Specialty Catalog This catalog contains information on AlloDerm[®], Grafton DBM[®], MinerOss CCC,

the Bone Fixation Screw Kit and AutoTac[®] Titanium Tack System. Also shown are a wide range of bone and soft tissue grafting instruments including: Implant Site Dilators, SA-2 Osteotomes and other sinus grating instruments.



P4XIM

ML0203

BioHorizons Internal 4x Scale Model

This 4-times scale model includes the implant, Abutment Screw, Healing Abutment, Cover Cap, implant driver and Hex Driver. Excellent for demonstrating implant components to the patient.





ML0103

Radiographic Implant Template (overlay)

Designed to aid the clinician in the pre-operative determination of options for implant length and diameter. The clear overlay template shows all sizes of BioHorizons Internal system implants in 100% and 125% scale. Please refer to page 29-30 for detailed instructions for use.



Patient Education – Dental Implants... The Path Back to Your Smile.

This four-fold brochure helps the implant candidate understand the rationale and the advantages of implant therapy compared to traditional treatment methods. The message focuses on the positives of implants rather than attacking other treatment options.

-1 - 8 8 8 - 2 4 6 - 8 3 3 8

SURGICAL MANUAL

Surgical Manual - BioHorizons Internal

This Surgical Manual serves as a reference for use of the BioHorizons Internal system implants and surgical instrumentation. 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, and it does not replace clinical training or a clinician's best judgment about the needs of each patient. BioHorizons recommends appropriate training as a prerequisite for the placement of implants and associated treatment.



This surgical manual contains easy to follow icons to demonstrate the location of the surgical component being discussed. The location of the instrument is highlighted on the surgical tray icon so the location of that instrument can be found quickly and easily.



ICON LEGEND

Color Code Legend



In addition to the tray icons, this manual contains color coded dots that indicate which implant diameter uses the instrument being described. For example, the Starter Drill is used when placing all diameter implants; therefore, yellow (Ø3.5mm), green (Ø4mm), blue (Ø5mm) and purple (Ø6mm) dots are used in conjunction with the tray icon. The 5.2mm Width Increasing Drill is used only with 6.0mm implants; therefore, only a purple dot is shown.

Radiographic Template

Designed to aid the clinician in the pre-operative determination of options for implant length and diameter. The clear overlay template shows all sizes of BioHorizons Internal system implants in 100% and 125% scale. This template has several unique and important features:

- All implants are shown at 100% scale and 125% scale (for panoramic radiography). Be aware that panoramic radiography varies in magnification from 15% to 35%.
- 5mm circular representations are shown at 100% and 125% for the radiographic ball technique. This technique uses radiographic marking balls embedded in a plastic template prior to radiographic examination of the patient. These marking balls will be visible on the radiographic image.
- Measurements can be taken to determine the precise magnification factor of the radiograph and help the practitioner accurately determine the amount of available bone for implant placement. The following example shows the calculation of a distortion factor and the subsequent determination of available bone:
 - The radiographic marking ball has a known diameter of 5mm.
 - Assume the marking ball appears on the radiograph to have a diameter of 6mm.
 - The distortion factor is calculated as: $5 \div 6 = 0.833$.
 - Assume that the distance between the crest of the ridge and the superior aspect of the mandibular nerve canal appears on the radiograph to have a length of 15mm.
 - The actual distance between the crest of the ridge and the mandibular canal would be calculated as: 15mm x 0.833 = 12.5mm.

-1 - 8 8 8 - 2 4 6 - 8 3 3 8

SURGICAL TEMPLATE

BIOHORIZONS®					
BioHorizons Implant Systems, In One Perimeter Park South, Suite Birmingham, AL 35243	BioHorizons Implant Systems, Inc. One Perimeter Park South, Suite 230 South Birmingham, AL 35243 Radiographic Implant Template				
		9.0 mm	10.5 mm	12 mm	15 mm
100% Scale	3.5 mm				
Radiographic Ball 5.0 mm +	4.0 mm				
$ \begin{array}{c} \hline 15 \\ \hline 10 \\ \hline 5 \\ \hline 0 \end{array} $	5.0 mm				
	6.0 mm				
125% Scale	3.5 mm				
Radiographic Ball 5.0 mm +	4.0 mm		HUUR		
20 15 10	5.0 mm		HUNDErna		
	6.0 mm		ATTIC CONTRACTOR		Antonio

Always consider that a margin of safety should be factored into treatment planning when adjacent to a vital structure.

BIOHORIZONS®

SURGICAL INSTRUMENTS

Implant Spacer/Depth Probe







Use of the Implant Spacer/Depth Probe

The Implant Spacer/Depth Probe is a measurement instrument for osteotomy depth determination, implant spacing and general length determination. Diagram A indicates the relative positioning of the depth determination bands. Note that each band is 1mm in height and ranges from 9mm to 16mm.

The rectangular end of the device provides measurement markings for implant spacing and ridge width. Diagram B shows recommended implant-to-implant spacing for BioHorizons Internal implants using the Implant Spacer.

Ø5mm and Ø6mm Ø4mm Ø3.5mm

Recommended edge-to-edge implant spacing is approximately 3mm. The measurement should be taken from the widest diameter of the implant, which is the prosthetic platform for BioHorizons Internal implants. Therefore, the centerline-to-centerline distance for a Ø3.5mm, Ø4mm, Ø5mm and Ø6mm implant is approximately 6.5mm, 7.5mm and 8.7mm, respectively. The Ø5mm and Ø6mm implants share the same prosthetic platform. The measurement markings on the side of the rectangle can be used to measure available ridge width.

The recommended spacing between an implant and a natural tooth is 1.5mm to 2mm, measured from the contact of the tooth to the edge of the implant. Be careful of situations where the tooth root is beyond the contact region of the crown, as in angled or tipped teeth.

Diagram B

Paralleling Pins



Paralleling Pins (Force Direction Indicators)

Following the Ø2.0mm Depth Drill, the Paralleling Pins may be used to evaluate any minor changes needed to improve implant angulation and position. The Paralleling Pins are provided straight or with a 20° angle that corresponds to the angulation of the 20° angled abutments. The large end of the paralleling pin may be used again after the osteotomy is enlarged to Ø2.5mm.

Clinicians may wish to initiate all osteotomies with the Ø2.0 x 9mm Depth Drill, as this is the length of each side of the pin. After visual and radiographic verification of positioning is made, the osteotomy can be taken to depth with the appropriate Ø2.0mm Depth Drill.

Note:

The mid-section of each paralleling pin has a small pass-through hole. To avoid accidental dislodging and swallowing, it is recommended that silk suture be placed through the hole prior to use.

1 - 8 8 8 - 2 4 6 - 8 3 3 8

Design of BioHorizons surgical drills

BioHorizons surgical drills are high efficiency, low-chatter instruments made of surgical grade stainless steel. The drill series consists of a Starter Drill, Depth Drills (Ø2.0mm and Ø2.5mm diameter) and Width Increasing Drills (Ø3.0mm through Ø5.2mm diameter). The patent-pending system incorporates a series of dental burs that allows the doctor to drill into the bone to a pre-determined depth and width to create an osteotomy for receipt of the dental implant.

BioHorizons surgical twist drills are externally irrigated. This design allows for proper channeling of the irrigant to the base of the osteotomy while eliminating the possibility of irrigant restriction from blockage in an internal drill lumen. Externally irrigated drills are much easier to clean and provide a decreased risk of cross-contamination between patients.

Every drill (Starter Drill through Ø5.2mm diameter drill) is labeled with highly visible, dark contrast marks and grooves. These grooves are easier to see in surgery than flush surface marks when blood and tissue are present. Also, the glare of light used during surgery does not affect the visualization of these grooves when compared to other typical surface markings.

Each drill reference mark of the Depth Drills prepares the bone to receive an implant of corresponding length. The stated length of a BioHorizons Internal implant is measured from the apex of the implant up to the level of the prosthetic platform; therefore, drill to the 9mm depth mark to place a 9mm implant. Internal implants have 0.5mm polished collars. Placing an implant subcrestal (countersinking) requires that the surgeon drill to the next incremental 1mm marking.

Drilling Technique

It is recommended that **copious amounts of refrigerated sterile irrigant** be used in any osseous drilling procedure. With BioHorizons surgical drills, this irrigant must be applied externally and adjacent to the drill shaft. Many commercially available handpieces are equipped with an external irrigation port.

Drilling Speed

The speed of the drill may be adjusted in relation to the quality of the bone being prepared. Harder bone usually requires up to 2500 rpm to proceed without exerting excessive pressure. Intermittent pressure of 1 second on the bone and 1 to 2 seconds off the bone is recommended. Enough pressure should be used to proceed at least 2mm per second. If this is not achieved, new drills are indicated for each preparation. Note: Heat generation in bone is a function of both drill speed and pressure. The correct combination of speed and pressure will reduce the possibility of thermal necrosis of surrounding tissues.

Thread Forming

Thread forming (tapping) may be indicated in dense bone. Tap the bone at a maximum speed of 30 rpm. Note that the tap must engage the osteotomy and proceed at an axial rate of speed relative to the rotational speed (rpm) of the tap. Example: The tap will proceed slower into the osteotomy at a tap speed of 10 rpm versus 30 rpm. Please note that stripping of the thread form created in the osteotomy is more likely to occur at a higher rpm.



#6 Round Bur

#6 Round Bur (optional)

These burs are designed to prevent lateral perforations because they will "roll" away from the inner wall of the harder cortical plate and stay within the soft trabecular bone. The use of the #6 bur is optional and is primarily used for marking the implant recipient site and to determine spacing. It can also be used to stretch the initial osteotomy in any direction to improve final position prior to use of the surgical twist drills.





SURGICAL INSTRUMENTS

Depth Drills



Depth Drills

The Depth Drills are designed to increase the depth of the osteotomy. The drills are supplied in two diameters, Ø2.0mm and Ø2.5mm, with four depth gauging options. The cutting geometry of the drills is an optimized tri-fluted twist drill. The drill tip geometry is configured such that the drill has end-cutting capabilities. The Depth Drill is used after the Starter Drill to set the osteotomy depth.

No Depth-Stop Option: This drill has standard depth grooves ranging from 7mm to 15mm. The clinician must manually stop the drill at the desired depth based on the corresponding depth marks on the shaft of the drill. This drill is used if the prosthetic platform is submerged below the crest at final implant placement.

Depth-Stop Option: These Depth Drills have a circular ring set at a pre-determined distance along the length of the drill that acts as a "stop" that prevents the surgeon from drilling beyond a pre-determined depth. The depth stop is set to correspond with the length of the dental implant being placed (9mm, 10.5mm, 12mm and 15mm). The use of this drill allows the implant prosthetic platform to be placed flush with the crestal bone.

Width Increasing Drills





Width Increasing Drills

A series of drills follows the Depth Drills in order to increase the width of the osteotomy to correspond to the diameter of the dental implant being placed. These drills are the "*Width Increasing*" (WI) drills.

The WI drills have a tri-fluted twist, side-cutting geometry. The tip of the drill lacks the end-cutting geometry of the Depth Drill, thereby creating a "built-in" stop. This feature prevents the surgeon from increasing the osteotomy depth when subsequent drills are used in the drill series and reduces the need for the doctor to rely on the depth markings of each drill to reach the desired depth.

The drill diameters of the WI drills increase in small increments until the final desired osteotomy diameter is reached. By using this sequence of drills, the surgeon has better control over the angulation of the osteotomy. Furthermore, an incremental step in the drill sequence reduces excess heat and helps prevent thermal necrosis of the surrounding tissue.

SURGICAL INSTRUMENTS

Crestal Bone Drills





Crestal Bone Drill

The Crestal Bone Drill (CBD) is used to prepare the crestal bone for receipt of the implant crest module. The crest module is the area beneath the prosthetic platform and above the implant threaded area. *This drill is optional in less dense bone which also lacks a crestal bone ridge.*

There are three significant levels on the CBD. Level 1 is where the cutting geometry begins. Engaging the CBD in the bone to Level 2 opens up the osteotomy to accept the slightly wider crest module on the implants and allows the polished collar to be placed above the crest of the bone. Preparing the bone to Level 3 allows the implant to be placed with the prosthetic platform level with the crestal ridge. As shown in the recommended drilling sequence, the Crestal Bone Drills should be used at the following stages of osteotomy preparation:

Ø3.5mm Crestal Bone Drill: Ø4.0mm Crestal Bone Drill: Ø5.0mm Crestal Bone Drill: Ø6.0mm Crestal Bone Drill: Following the Ø3.0mm Depth Drill Following the Ø3.2mm Depth Drill Following the Ø4.2mm Depth Drill Following the Ø5.2mm Depth Drill



Bone Tap (Thread Former)





Ratchet &

Ratchet Extender

Hand Wrench & Ratchet Extender



Hand Wrench

The osteotomy should be tapped in dense bone. Dense bone typically requires that the full length of the osteotomy be prepared with the tap. The use of a Bone Tap is suggested in less dense bone when one (or two) sides of the osteotomy are in contact with a lateral cortical plate of bone.

Place the tip of the Bone Tap into the osteotomy, apply firm pressure and begin rotating slowly (30 rpm or less is recommended). When the threads engage, allow the thread former to feed without excessive pressure. To remove, switch the handpiece to the reverse mode and back out. *Do not pull on the Bone Tap*. The implant site may also be threaded by hand by attaching the Ratchet Extender and Hand Wrench or Ratchet to the tap. The Hand Wrench or Ratchet may also engage the thread former without the Ratchet Extender.





OSTEOTOMY STARTER SEQUENCE

IMPORTANT

Peri-operative oral rinses with a 0.12% Chlorhexidine Digluconate solution have been shown to significantly lower the incidence of post-implantation infectious complications.¹¹ 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. Drills that cannot advance 2mm per second in the osteotomy have become dull and should be replaced.

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





Center the Starter Drill in the desired area of the osteotomy and drill to the appropriate depth reference mark.





Ø2.0mm Depth Drill /

Using either the **No Depth-stop Option** or **Depth-stop Option drill** (described on page 33), drill to the appropriate depth as indicated by the reference marks or depthstop.

Note: The surgical kit is supplied with four different lengths of the *Depth-stop Option* Depth Drills (9mm, 10.5mm, 12mm and 15mm). Each drill has a positive stop that is specific to the length of the implant being placed.

1 - 8 8 8 - 2 4 6 - 8 3 3 8

OSTEOTOMY STARTER SEQUENCE

Paralleling Pins

Place the paralleling pin in the osteotomy (Ø2.0mm side) to ascertain the angulation of the osteotomy. A radiograph may be taken to help determine the osteotomy's proximity to anatomic landmarks. Adjustments may be made at this point with a Lindemann bur or the Depth Drills.

Starter Sequence 3



Ø2.5mm Depth Drill

Using either the **No Depth-stop Option** or **Depth-stop Option drill** (described on page 33), drill to the appropriate depth as indicated by the reference marks.

Note: The surgical kit is supplied with four different lengths of the *Depth-stop Option* Depth Drills (9mm, 10.5mm 12mm and 15mm). Each drill has a positive stop that is specific to the length of the implant being placed.

Optional: Use an implant site dilator of appropriate size or substitute the drill as a site dilator by pressing the drill to final depth without rotating.



Starter Sequence 4





36

Paralleling Pins

Place the paralleling pin in the osteotomy (Ø2.5mm side) to ascertain the angulation of the osteotomy. A radiograph may be taken to help determine the osteotomy's proximity to anatomic landmarks. Adjustments may be made at this point with a Lindemann bur or the Depth Drills.





5

Starter Sequence

OSTEOTOMY WIDENING SEQUENCE

Widening Sequence



2 Widening Sequence





37

Use Crestal Bone Drill for 4.0mm implant after the Ø3.2mm drill.

Follow with 4mm Bone Tap if desired.



Ø3.0mm Width Increasing Drill /

The Ø3.0mm Width Increasing Drill is used to increase the diameter of the osteotomy. The blunt tip on this drill will prevent it from increasing depth; therefore, the final osteotomy depth must be created with the Depth Drills. The blunt tip may not stop in poor quality bone; please exercise caution in D3 or D4 bone. Depth marks are included on the drills as a reference.

Optional: Use an implant site dilator of appropriate size or substitute the drill as a site dilator by pressing the drill to final depth without rotating.

Ø3.2mm Width Increasing Drill /

The Ø3.2mm Width Increasing Drill is used to increase the diameter of the osteotomy. The blunt tip on this drill will prevent it from increasing depth; therefore, the final osteotomy depth must be created with the Depth Drills. The blunt tip may not stop in poor quality bone; please exercise caution in D3 or D4 bone. Depth marks are included on the drills as a reference.

Optional: Use an implant site dilator of appropriate size or substitute the drill as a site dilator by pressing the drill to final depth without rotating.

Ø3.7mm Width Increasing Drill /

The Ø3.7mm Width Increasing Drill is used to increase the diameter of the osteotomy. The blunt tip on this drill will prevent it from increasing depth; therefore, the final osteotomy depth must be created with the Depth Drills. The blunt tip may not stop in poor quality bone; please exercise caution in D3 or D4 bone. Depth marks are included on the drills as a reference.

Optional: Use an implant site dilator of appropriate size or substitute the drill as a site dilator by pressing the drill to final depth without rotating.

3 Widening Sequence



1 - 8 8 8 - 2 4 6 - 8 3 3 8

OSTEOTOMY WIDENING SEQUENCE

Ø4.2mm Width Increasing Drill

Widening Sequence

The Ø4.2mm Width Increasing Drill is used to increase the diameter of the osteotomy. The blunt tip on this drill will prevent it from increasing depth; therefore, the final osteotomy depth must be created with the Depth Drills. The blunt tip may not stop in poor quality bone; please exercise caution in D3 or D4 bone. Depth marks are included on the drills as a reference.

Optional: Use an implant site dilator of appropriate size or substitute the drill as a site dilator by pressing the drill to final depth without rotating.



Use Crestal Bone Drill for 5.0mm implant after the Ø4.2mm drill.

Follow with 5mm Bone Tap if desired.

5

Ø4.7mm Width Increasing Drill

The Ø4.7mm Width Increasing Drill is used to increase the diameter of the osteotomy. The blunt tip on this drill will prevent it from increasing depth; therefore, the final osteotomy depth must be created with the Depth Drills. The blunt tip may not stop in poor quality bone; please exercise caution in D3 or D4 bone. Depth marks are included on the drills as a reference.

Optional: Use an implant site dilator of appropriate size or substitute the drill as a site dilator by pressing the drill to final depth without rotating.

Ø5.2mm Width Increasing Drill

The Ø5.2mm Width Increasing Drill is used to increase the diameter of the osteotomy. The blunt tip on this drill will prevent it from increasing depth; therefore, the final osteotomy depth must be created with the Depth Drills. The blunt tip may not stop in poor quality bone; please exercise caution in D3 or D4 bone. Depth marks are included on the drills as a reference.

Optional: Use an implant site dilator of appropriate size or substitute the drill as a site dilator by pressing the drill to final depth without rotating.

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Widening Sequence



Widening Sequence 6





Use Crestal Bone Drill for 6.0mm implant after the Ø5.2mm drill.

Follow with 6mm Bone Tap if desired.

IMPLANT PACKAGING

Implant Packaging



BioHorizons Internal implant packages have color-coded labels for easy identification of contents. Inner vial caps are also color-coded for easy reference.



Abutment emergence and prosthetic platform label

BioHorizons Internal implants are packaged in sterile blister trays and vials. When the lid of the tray is removed, the implant vial is exposed. The vial is then placed in the sterile field. The vial cap is removed by rotating it counter-clockwise. At this point, the implant and the patented **3inOne** Abutment are exposed. This **3inOne** Abutment is used to place the implant, eliminating the need to purchase a separate implant mount that has no additional value. Two different types of surgical placement adapters (handpiece or ratchet) are provided that interface with the **3inOne** Abutment to facilitate surgical placement.



Remove the inner vial from the outer packaging. The peel-and-stick label on the outer blister tray packaging should be placed in the patient's chart as a record of the device(s) used.

> Be certain to hold the inner vial upright when the cap is removed so the implant will not fall out of the vial.

Placement Options



Implant Placement with Handpiece

One of the four flat sides on the end of the surgical Handpiece Adapter is aligned with the flat side of the **3inOne** Abutment. Seat the adapter in the **3inOne** Abutment before the implant is removed from the inner vial. Do not touch the implant.

Using firm apical pressure, thread the implant into position at a rotational speed similar to the Bone Tap speed (less than 30 rpm is recommended). Paralleling Pins may be used in adjacent sites to guide the implant in at the correct angulation. Do not overtighten the implant in the osteotomy as osseous microfracture may occur. Too much pressure at the crest may also compromise final surgical results.

Note: If the final restoration will use an Angled Abutment, orient the implant with the abutment flat indexed to the facial/buccal. Doing so will properly align the Angled Abutment for the angulation correction. Failure to do so may require the use of a Custom Castable Abutment to make the required correction.

8 8 8 - 2 4 6 - 8 3 3 8

IMPLANT PLACEMENT

Placement with Ratchet

One of the four flat sides on the end of the Ratchet Adapter is aligned with the flat side of the *3inOne* Abutment. Seat the adapter in the *3inOne* Abutment before the implant is removed from the inner vial. *Do not touch the implant*.

Using firm apical pressure, thread the implant into position. Paralleling Pins may be used in adjacent sites to guide the implant in at the correct angulation. *Do not overtighten the implant in the osteotomy as osseous microfracture may occur.* Too much pressure at the crest may also compromise final surgical results.

Final implant seating via the Ratchet Adapter may be desired to gain a tactile sense of implant stability. If too much resistance is felt during insertion, the implant may be rotated clockwise three revolutions, then reversed one revolution counter-clockwise, until the implant is seated into place. The implant site may require tapping if too much resistance is felt.

Placement with Insertion Tool

The Insertion Tools are used for implant placement between teeth with long clinical crowns. They allow for a narrower path of insertion as compared to placement via the *3inOne* Abutment.

While the implant is still in the vial, the *3inOne* Abutment is removed from the implant. The Insertion Tool is then mated with the internal hex of the implant and lightly screwed into place. The implant can then be placed with the Hand Wrench and/or Ratchet.

The Insertion Tools may also be used to adjust the implant's rotational position after the removal of the **3inOne** Abutment. Simply mate the Insertion Tool with the internal hex of the implant and lightly screw into place. The implant can then be rotated using the Hand Wrench and/or Ratchet.

BIOHORIZONS





2

Placement Options



Placement with Hand Wrench

Placement Options 3



ABUTMENT REMOVAL/COVER CAP PLACEMENT

Implant Placement Level



The implant is advanced into the prepared site until the bottom of the polished collar is flush with the crestal ridge.

If there is concern that premature loading during the healing phase may occur, advance the implant into the site until the top of the prosthetic platform is flush with the crestal bone (refer to use of the CBD).

In dense bone, it may be possible to leave the prosthetic platform slightly higher than the crest of the osseous ridge.

3inOne Abutment Removal



The .050" Hex Driver is used for removal of the Abutment Screw. In less dense bone, or when the implant lacks initial stability, a hemostat or abutment holder should be used to grasp the outside of the abutment to provide counter-torque during the loosening of the Abutment Screw. The *3inOne* Abutment may be removed once the Abutment Screw has been completely loosened.

The **3inOne** Abutment and the Abutment Screw should be retained with the patient's chart. It can later be used as an impression post (when used with the Ball-top Screw) and as a temporary or final abutment for cement retention.

Cover Cap Placement



Following removal of the *3inOne* Abutment, the implant should be thoroughly irrigated to remove blood and other debris. When a submerged healing technique (two-stage) is desired, the low-profile surgical Cover Cap is used to seal the prosthetic platform of the implant. This Cover Cap, included with each implant, is unscrewed from its holder and inserted into the implant body via the .050" Hex Driver.

Do not overtighten the Cover Cap. The torque applied during the tightening process will be transferred to the surrounding bone and may cause movement of the implant in less dense bone. An antibacterial paste may be placed on the end of the Cover Cap to help seal the Cover Cap with the implant body and decrease the risk of bacterial growth within the implant body during the healing phase. Following placement of the Cover Cap, the surgical site should be irrigated and the soft tissue adapted in a normal surgical fashion.

Caution: Take precautions to prevent the Cover Cap from being aspirated by the patient.

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HEALING ABUTMENTS/POST-OP PROCEDURES

Bone Profilers



Bone Profiling Burs are designed to remove and contour excess bone and soft tissue from the area of the prosthetic platform prior to the seating of a healing or prosthetic abutment. There are three sizes of bone profiling burs, one for each of the three prosthetic platforms: Ø3.5mm, Ø4.5mm and Ø5.7mm. Their use requires the removal of the surgical Cover Cap from the implant and placement of the profiler guide (both use the .050" Hex Driver), which will help align the Bone Profiler and protect the implant from damage. The Profiler bur is used in a latch-type, reduction handpiece under copious amounts of sterile irrigation.

Bone Profilers and guides are not included in the surgical kit. Ordering information can be found on page 23.

Healing Abutment Placement

Healing Abutments are often used after initial bone healing in a two-stage surgical approach. They may also be used *in lieu* of a Cover Cap for a non-submerged healing (singlestage) approach. BioHorizons Internal Healing Abutments are specific to each of the three prosthetic platform diameters: Ø3.5mm, Ø4.5mm and Ø5.7mm. They come in three heights (1mm, 3mm and 5mm) and a choice of narrow, regular and wide emergence profiles.

A Healing Abutment should be selected so that it extends through the tissue approximately 1mm. The tissues may be approximated in the usual 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. An apically positioned flap technique can be easier to accomplish using the suture groove on the Healing Abutment (see diagram below).







C L E A N I N G

Surgical Kit Cleaning

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

Cleaning procedure for Surgical Tray and Instrumentation

- Disassemble the surgical kit and wash the tray using a broad spectrum cleaning or disinfecting agent such as Hu-Friedy Enzymax[®] (800-483-7433) or equivalent. Rinse the tray with water and dry thoroughly.
- 2. Place the instruments in a beaker of detergent solution and sonicate for 10 minutes. Rinse thoroughly.
- 3. Remove any visible debris or bone fragments with a soft bristle brush. Rinse thoroughly.
- 4. Rinse instruments with alcohol to remove any soap residue and minerals (important to help prevent corrosion).
- 5. Blot instruments with a towel and allow them to air dry completely.
- 6. Check latch-type burs with the bur testing gauge to verify fitness for future use (see facing page). Discard and replace unfit burs.
- 7. Return instruments to the appropriate location in the surgical tray.
- 8. Wrap the kit in a double layer of autoclave-approved paper.
- 9. Use one of three qualified steam sterilization cycles:
 - a. Pre-vacuum Steam: 132°C (270°F) for five minutes minimum.
 - b. Gravity Steam: 132°C (270°F) for thirty minutes minimum.
 - c. Gravity Steam: 121°C (250°F) for fifty minutes minimum.



Dry for 20 to 50 minutes as needed. Do not remove the surgical kit from the autoclave until the dry cycle is complete.

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

It is also recommended that proper testing, cleaning and calibration of sterilization equipment 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 proper sterilization technique for instrumentation is followed.

Lay out all the surgical instruments into the sterile field in the order of use prior to surgery. This assures a natural progression through the surgical sequence. The surgical kit is set up in this fashion.

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INSTRUCTIONS FOR USE

Bur Testing Gauge

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

Burs that fail either of these criteria are unfit for use and may become stuck in the handpiece if used. The gauge is included with all W&H starter packages, and may also be ordered from page 26.

Instructions For Use

Indications

BioHorizons dental implants may be used in the mandible and maxilla for use as an artificial root structure for single tooth replacement or as abutments for bridgework and denture retention.

Contraindications

BioHorizons dental implants should not be used in patients who have contraindicating systemic or uncontrolled local diseases such as blood dyscrasias, diabetes, hyperthyroidism, oral infections or malignancies, renal disease, uncontrolled hypertension, liver problems, leukemia, severe vascular heart disease, hepatitis, immunosuppressive disorder, pregnancy and/or collagen and bone diseases. Dental implants are contraindicated in patients where ridge dimensions are insufficient to accommodate proper implant placement without ridge augmentation. Relative contraindications may include habits such as tobacco use, alcohol consumption, poor oral hygiene, bruxism, nail biting, pencil biting and/or improper tongue habits depending on severity.

Warnings and Precautions

Implant surgery is a complex dental procedure. Appropriate training in proper technique is strongly recommended prior to implant use. Improper techniques can result in implant failure and/or loss of supportive bone.

Appropriate x-ray films should be utilized to determine if adequate bone is available, and to determine the location of important anatomical landmarks, such as the mandibular canal, maxillary sinuses and adjacent teeth.

Implants can break during function for a number of reasons including overloading due to improper occlusion, metal fatigue and/or overtightening of the implant during insertion. An adequate number of implants should be used to provide support and to distribute the load to the abutments. A certain percentage of implants may fail to achieve or maintain osseointegration, as demonstrated by mobility, and should be removed. Potential causes of abutment fracture include, but are not limited to: casting beyond a 30° angle, casting titanium above 2010°F, inadequate implant support when attached to periodontically compromised teeth, non-passive fit of superstructure, overloading due to improper occlusion, incomplete seating of a cemented abutment, too long a span of bridge and excessive cantilevering of pontics.

Peri-operative oral rinses with a 0.12% Chlorhexidine Digluconate solution have been shown to significantly lower the incidence of post-implantation infectious complications. (*The Influence of 0.12% Chlorhexidine Digluconate Rinses on the Incidence of Infectious Complications and Implant Success.* Lambert, Paul M., et al, J Oral Maxillofacial Surgery 55:25-30, 1997, Suppl 5.) A pre-operative 30-second rinse is recommended, followed by twice-daily rinses for two weeks following surgery.

Complications and Adverse Effects

The risks and complications with BioHorizons dental implants are similar to those of other dental implants and include, but are not limited to: (1) infection requiring revision of the dental implant; (2) nerve damage that could cause permanent weakness, numbness and/or pain; (3) allergic reaction(s) to the implant material; (4) histologic responses possibly involving macrophages and/or fibroblasts; (5) formation of fat emboli; (6) perforation of the maxillary sinus; (7) perforation of the labial and lingual plates; (8) breakage of the implant or abutment; (9) loosening of the implant requiring revision surgery; (10) loosening of the Abutment Screw and/or retaining screw; (11) bone loss possibly resulting in revision or removal.

Handling and Sterilization

The implants are supplied sterile and should be considered sterile unless the package has been opened or damaged. Using accepted sterile technique, remove from the package only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the products with powder-free gloves, and avoid contact with hard objects that may damage the surface of the implant. Surgical components and metal laboratory components can be cleaned and then re-sterilized using an appropriate autoclave cycle. Implants are single use only, and re-use should not be attempted. BioHorizons assumes no responsibility for attempted re-use or re-sterilization of dental implants.





POST-OPERATIVE INSTRUCTIONS

Post-Operative Instructions

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

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

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

Notes:

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IMPRESSION TECHNIQUE TYPES

Impression Techniques - BioHorizons Internal

Stone models made from impressions form the foundation for the restoration, and care must be taken ensure as accurate a transfer as possible. Doing so will prevent the loss of time and the expensive of re-works. There are **three types** of impression techniques utilized in implant dentistry:

Prepared Abutment Impression

An intra-oral impression is made of prepared abutment(s), similar to a standard crown & bridge impression.

Implant Level Impression

An intra-oral impression is made, transferring the emergence of the implant. The implant's location and angle are recorded; with or without the orientation of the internal hex.

Abutment for Screw Level Impression

An intra-oral impression is made recording the position of Abutments for Screw that have been placed onto the implants. Abutments for Screw location and angle are recorded for fabrication of a screw retained prosthesis. See the BioHorizons Internal Prosthetic Manual for details regarding Abutment Level impressions.







Impression types





IMPRESSION METHODS

There are **two methods** for making Implant Level and Abutment for Screw Level Impressions: (1) Closed Tray (Indirect) Transfer Technique or (2) Open Tray (Direct) Pick-up Technique.

Note: Prepared Abutment impressions are always made using the Closed Tray technique.

The method chosen is dependent on the treatment plan and the degree of accuracy needed to fabricate the final restoration. The Open Tray Technique is more accurate than the Closed Tray Technique, and is recommended in multiple unit restorations.

1 Impression Methods





Closed Tray (Indirect) Transfer /

Open Tray (Direct) Pick-up

This indirect impression technique records the soft tissue profile as well as the implant's location. The implant's internal hex orientation is transferred when using the *3inOne* Abutment with a Ball-top Screw or any of the Indirect, Hexed (Closed Tray) Copings. If the hex location is not needed for the prosthesis fabrication, the Direct Pick-up, Non-hexed (Open Tray) Coping may be used.

In this technique, the Indirect Transfer Coping remains in the mouth after the impression is removed from the mouth. The coping is then removed from the mouth and connected with the appropriate Implant Analog. The coping/analog assembly is then indexed (transferred) into its corresponding position in the impression. A working model is poured in dental stone, providing a replica of the implant's location in the patient's mouth.

Impression Methods





This impression technique records the soft tissue profile as well as the implant's location. The implant's internal hex orientation is transferred when using the Direct Pick-up Hexed (Open Tray) Copings. If the hex location is not needed for the prosthesis fabrication, the Direct Pick-up Non-Hexed (Open Tray) Copings are used.

In the open tray transfer technique, the Direct Pick-up Coping remains in the impression when it is removed from the mouth. For this technique, a custom tray or modified stock tray with a screw access hole in the area above the implant is required. The Direct Coping Screw that holds the Direct Pick-up Coping in place while the impression is made is removed through the access hole after the material sets. The impression is removed with the Direct Pick-up Coping embedded within the impression. The Implant Analog is connected to the embedded coping and a working model is poured in dental stone, providing a replica of the implant's location in the patient's mouth.

1 - 8 8 8 - 2 4 6 - 8 3 3 8

CLOSED TRAY INDIRECT TRANSFER

Implant Level Impression (Hexed)

Closed Tray, Indirect Transfer Technique

Remove Healing Abutment

Remove the Healing Abutment with the .050" Hex Driver. Make sure that the implant prosthetic platform is free of bone and soft tissue.

The emergence of the impression coping selected should match the emergence of the Healing Abutment and the intended final abutment (either Narrow, Regular or Wide). Custom Cast emergence will be determined by the lab prescription.

🐨 Helpful Hint

When placing impression copings on multiple implants, remove one Healing Abutment at a time, replacing it immediately with the impression coping. This prevents the possibility of soft tissue collapsing onto the implant. Work from the posterior to the anterior.

Place impression coping

Option A - Seat the *3inOne* Abutment and secure it with a Ball-top Screw (hand-tighten).

Option B - Seat the Indirect Transfer Coping and secure it with the included screw (hand-tighten).

If practical, orient the flat side of the abutment/coping to the facial for easier indexing.

Take a radiograph along the long axis of the implant to ensure the coping is fully seated.







CLOSED TRAY INDIRECT TRANSFER

3 Clinical



Block out screw access hole /

Block out the hex hole on top of the Ball-top Screw (**Option A**); or the screw access hole of the Indirect Transfer Coping (**Option B**) with a material of choice.

4 Clinical



Apply impression material

Syringe a light or medium-bodied impression material around the coping assembly and record a full-arch impression with a medium or heavy-bodied material.

Remove the coping assembly after the tray has been removed. Replace the Healing Abutment immediately to prevent soft tissue collapse.

Send to Lab

- Impression
- Impression coping, either:
- 3inOne/Ball-top Screw Combo, or
- Indirect Transfer Coping
- Abutment Screw (comes with 3inOne)
- Implant Analog
- Bite registration
- Opposing model or impression
- Shade

-1 - 8 8 8 - 2 4 6 - 8 3 3 8

CLOSED TRAY INDIRECT TRANSFER

Assemble analog

Option A - Assemble the *3inOne* Abutment with the appropriate diameter Implant Analog using the Ball-top Screw.

Option B - Assemble the Indirect Transfer Coping with the appropriate diameter Implant Analog using the included screw with the .050" Hex Driver.

Insert the coping assembly into the corresponding location in the impression, ensuring that the flat of the coping aligns with the corresponding indice in the impression.

Create soft tissue model

A soft tissue model material is recommended around the implant; verify analogs are seated properly and apply lubricant around the analogs where soft tissue needs to be added.



Lab

Fabricate stone model

Fabricate a working cast. Articulate according to normal laboratory procedures.





5

Option B

6

Lab

Option A

OPEN TRAY DIRECT TRANSFER

Implant Level Impression (Hexed and Non-hexed) Open Tray, Direct Pick-up Technique

IMPORTANT

Open Tray Direct Pick-up Impression Technique

The Direct Pick-up impression technique requires the use of a custom tray or modified stock tray with screw access holes over the area of the implants. The holes allow the long screws to protrude through the top of the tray. See the BioHorizons Internal Prosthetic Manual for custom tray fabrication. It is available through Customer Care (888-246-8338) or viewed in .pdf format at www.biohorizons.com.

1 Clinical



Remove the Healing Abutment with the .050" Hex Driver. Make sure that the implant prosthetic platform is free of bone and soft tissue.

The emergence of the impression coping selected should match the emergence of the Healing Abutment and the intended final abutment (either Narrow, Regular or Wide). Custom Cast abutment emergence will be determined by laboratory prescription.

F Helpful Hint

When placing impression copings on multiple implants, remove one Healing Abutment at a time, replacing it immediately with the selected impression coping. This prevents the possibility of soft tissue collapsing onto the implant. Work from the posterior to the anterior.

Place impression coping

Remove Healing Abutment





Place the appropriate diameter Direct Pick-up Coping (either hexed or non-hexed) on the implant body and retain with the included Direct Pick-up Coping Screw (hand-tighten).

These screws feature a knurled top to aid in manual insertion, as well as a .050" hex access hole for insertion with the Hex Driver.

Take a radiograph along the long axis of the implant to ensure the coping is fully seated.

1 - 8 8 8 - 2 4 6 - 8 3 3 8

OPEN TRAY DIRECT TRANSFER

Try in impression tray

Try in the impression tray to verify that the coping screw protrudes through the tray.

The custom tray is fabricated using a tray material of choice. A window is cut out of the tray over the area of the implant to allow clearance for the coping screw.

Alternatively, a stock impression tray may be modified to accommodate the coping screw which will protrude through the top of the tray.

Make an impression

Syringe a light or medium-bodied impression material around the coping assembly. Load the impression tray with a medium or heavy-bodied impression material and seat it in the mouth. Wipe excess impression material off the coping screw before it sets.

Remove coping screws

After the impression material has set, first remove the coping screw, and then remove the tray from the mouth. Verify that the impression material is completely adapted around the pick-up copings.

Replace the Healing Abutment immediately to prevent soft tissue collapse.

Send to Lab

- Impression with coping inside
- Coping screw
- Implant Analog
- Abutment and screw (if chosen)
- Bite registration
- Opposing model or impression

BIOHORIZONS

Shade









Clinical

Clinical

6 Lab

Assemble analog /



Assemble the appropriate diameter Implant Analog to the Direct Pick-up Coping with the coping screw.

A soft tissue model material is recommended around the implant; verify analogs are seated properly and apply lubricant around the analogs where soft tissue needs to be added.



Fabricate stone model /



53



Fabricate a working cast. Articulate according to normal laboratory procedures.

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