Pro Surgical System

Catalog & Surgical Manual

BIOHORIZONS®

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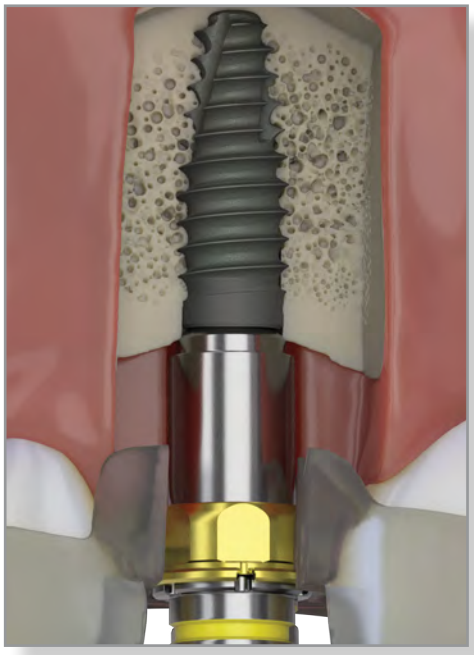
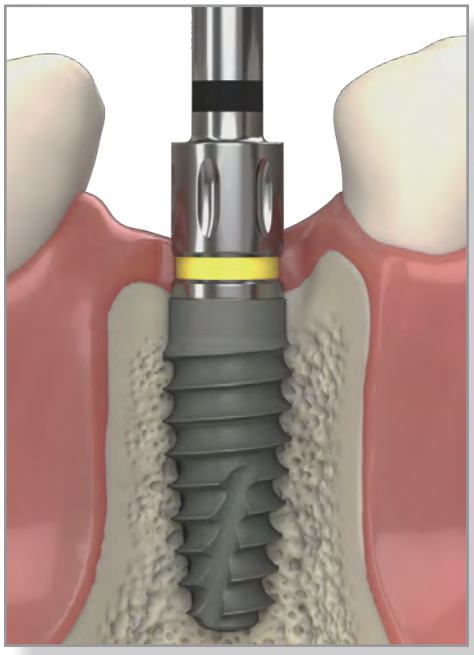
BioHorizons Pro Surgical System

The Pro surgical kit from BioHorizons offers predictability and flexibility in a single system. Guided implant placement can be performed with control and precision following a keyless drilling protocol. The same set of length specific drills can also be used for freehand placement, offering flexibility for treatment planning and for surgery.



keyless guided workflow

Fully guided implant placement provides control over the final implant position with the ease of keyless guided drilling



freehand workflow

Freehand protocol uses standard width-increasing drill protocol for traditional placement

innovative Guide Adapter*

The Guide Adapter integrates the flexibility of freehand surgical protocols with the control and precision of guided placement. When engaged with a standard Length Drill, the Guide Adapter converts a freehand drill into a keyless guided drill. This adaptability allows the Pro Surgical System to offer a single kit solution for both freehand and guided surgery.

perfect system for precise implant placement

The Pro Guided Surgery System can be used to place all diameters from 3.0mm to 5.8mm and all lengths from 9mm to 15mm of the highly successful Tapered Pro Conical, Tapered Pro, Tapered 3.0, Tapered Internal**, and Tapered Plus implants.

* Patent pending
**5.8mm Tapered Internal implants are not supported by the PRO4000 or PRO5000 kits.

Guided Surgery Process

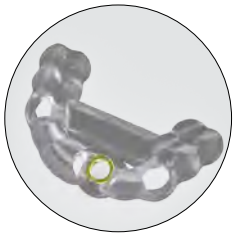
Surgical plan to surgical guide

1. Clinical step - CT scan appointment

Initial patient records and CT scan. CT scan protocols will vary depending on the guide manufacturer. Guide manufacturer details are available at https://biohorizons.com/Products/workflowpartners.

2. Clinical step - Treatment plan

Diagnose and treatment plan for guided surgery. Determine if adequate vertical space is available to accommodate the surgical guide and related components. Import CT scan data into the treatment planning software and design the case.



3. Guide manufacturer step - Guide fabrication

Guide manufacturer fabricates the surgical guide using the virtual treatment plan, BioHorizons Master Cylinders or pilot sleeves. A patient-specific surgical protocol is generated for the clinician to follow.

4. Clinical step - Guided surgery

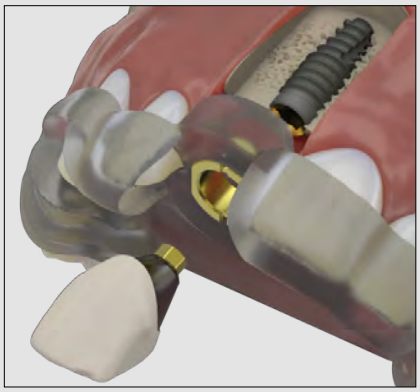
Clinician performs the procedure using the surgical guide and the BioHorizons guided surgery kit while following the surgical protocol.

Guided Restorative Solutions

by Vulcan and BioHorizons

Guided Restorative Solutions (GRS) combines the efficiency and predictability of guided surgery, with hybrid or titanium custom abutments. GRS conveniently delivers everything needed for a case, including BioHorizons implants.

Learn more: www.vulcandental.com



The surgical guide must be fabricated using BioHorizons manufactured Master Cylinders and pilot sleeves. Please contact your guide manufacturer for further information.

Pro Guided Surgery

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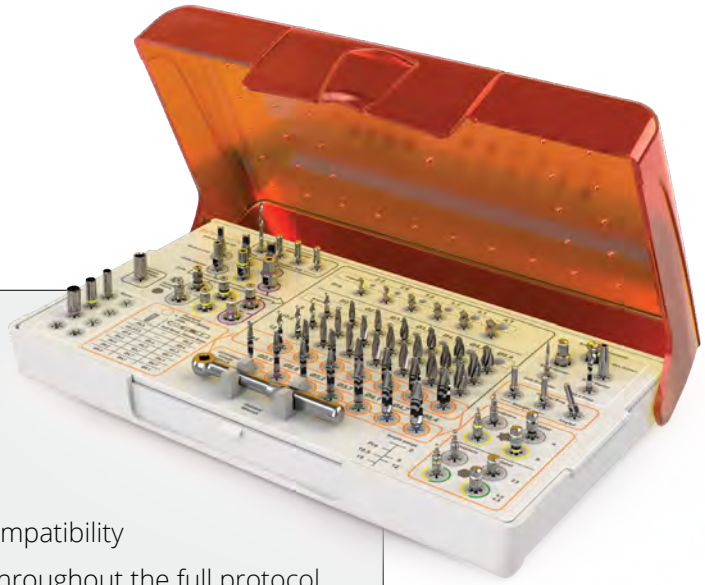


PRO5000 **Pro Surgical Kit**

Keyless guided surgery and freehand kit for BioHorizons Tapered Pro Conical and Tapered Internal Hex Implants.

features:

- keyless guided surgery solution
- supports guided and freehand surgical protocols
- spare slots for additional instrumentation
- color coded instruments for easy recognition of compatibility
- fully guided implant placement maintains control throughout the full protocol

PRO4000 **Pro Surgical Kit, Hex**

Keyless guided surgery and freehand kit for BioHorizons Tapered Internal Hex Implants only.

PRO4500 **Pro Surgical Tray (without instruments)**

Individual guided instruments

Bone Levelers

PROBLGY	Pro Bone Leveler, Grey
PROBLYL	Pro Bone Leveler, Yellow
PROBLPR	Pro Bone Leveler, Purple

Tissue Punches

PROTPGY	Pro Tissue Punch, Grey
PROTPYL	Pro Tissue Punch, Yellow
PROTPPR	Pro Tissue Punch, Purple

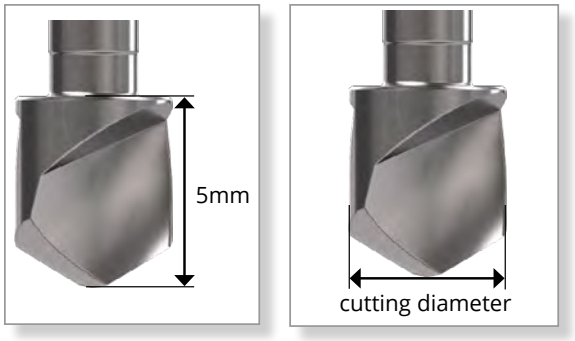
Pro Guided Surgery

Guided Drills

Pre Drills

The Pre Drills are designed to match the dense bone drill diameter for a given osteotomy sequence. This allows for the subsequent narrower drills to nest in the initial osteotomy, providing additional guidance during the drilling protocol.

Cutting Diameter	Ø 2.8mm	Ø 3.2mm	Ø 3.7mm	Ø 4.1mm	Ø 4.7mm	Ø 5.4mm
Pre Drills	**PROPRE25**	**PROPRE28**	**PROPRE32**	**PROPRE37**	**PROPRE41**	**PROPRE47**



Length Drills

Pro Guided Surgery uses standard Length Drills in conjunction with a Guide Adapter, following a depth increasing sequence. The patient-specific surgical protocol that accompanies the surgical guide will indicate which drill lengths and widths to use. 15mm Length Drills have a full set of depth specific laser-marks to support freehand use.

Cutting Diameter	Ø 2.5mm	Ø 2.8mm	Ø 3.2mm	Ø 3.7mm	Ø 4.1mm	Ø 4.7mm	Ø 5.4mm
9mm Drills	**PROLD2509**	**PROLD2809**	**PROLD3209**	**PROLD3709**	**PROLD4109**	**PROLD4709**	**PROLD5409**
10.5mm Drills	**PROLD2510**	**PROLD2810**	**PROLD3210**	**PROLD3710**	**PROLD4110**	**PROLD4710**	**PROLD5410**
12mm Drills	**PROLD2512**	**PROLD2812**	**PROLD3212**	**PROLD3712**	**PROLD4112**	**PROLD4712**	**PROLD5412**
15mm Drills	**PROLD2515**	**PROLD2815**	**PROLD3215**	**PROLD3715**	**PROLD4115**	**PROLD4715**	**PROLD5415**

Pro Guided Surgery

Guided Instruments

Guide Adapters

The Guide Adapter is designed to interface with a Master Cylinder for control and guidance while engaging with a standard Pre Drill or Length Drill. This assembly functions like a keyless guided drill. Drills can be interchanged with the Guide Adapter, instead of the handpiece, to incrementally deepen the osteotomy. The color coding on the Guide Adapter matches the compatible Master Cylinder.

PROGAGY	**Pro Guide Adapter, Grey**
PROGAYL	**Pro Guide Adapter, Yellow**
PROGAPR	**Pro Guide Adapter, Purple**

Pro Implant Drivers

Screw-retained Implant Drivers are used to pickup and seat implants when used with a 4mm Square Ratchet or 4mm Square Driver Converter. The driver is secured to the implant using the captured screw and can be released after implant placement. Use the integrated depth stop to seat the implants to the planned depth. Orient the implant connection using the notches as a visual reference. The color coding on the Implant Driver matches the compatible Master Cylinder.

Internal Hex Drivers

PROIDGY	**Hex Pro Guided Implant Driver, Grey***
PROIDYL	**Hex Pro Guided Implant Driver, Yellow***
PROIDPR	**Hex Pro Guided Implant Driver, Purple***

Conical Drivers

PROCDGY	**Conical Pro Guided Implant Driver, Grey***
PROCDYL	**Conical Pro Guided Implant Driver, Yellow***
PROCDPR	**Conical Pro Guided Implant Driver, Purple***

CGS-4SC	**4mm Square Drive Converter**

The Drive Converter allows the screw-retained drivers to be used with a handpiece.

* 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.

Pro Guided Surgery

Freehand Instruments

Extended Shank HD Drills

The Tapered HD drills feature highly efficient cutting flutes for crisp osteotomies in even the densest bone. Simplified drill markings correspond to the five Tapered Pro implant lengths. Extended Shank drills are 12mm longer than the 15mm Length Drills.

TSD4025HD	**2.5mm Extended Shank HD Drill**
TSD4028HD	**2.8mm Extended Shank HD Drill**
TSD4032HD	**3.2mm Extended Shank HD Drill**
TSD4037HD	**3.7mm Extended Shank HD Drill**
TSD4041HD	**4.1mm Extended Shank HD Drill**
TSD4047HD	**4.7mm Extended Shank HD Drill**
TSD4054HD	**5.4mm Extended Shank HD Drill**

features:

- cutting flutes designed for maximum efficiency
- non-reflective surface for high visibility
- simplified drill markings match each implant length
- compatible with Tapered Pro, Tapered PTG, Tapered Internal, Plus and Tissue Level
- creates 12-20 osteotomies depending on bone density
- recommended drill speed 1500-2000 rpm (2.5mm), 1000 rpm (all others)

Pilot Drills

122-015	**1.5mm Starter Drill**

The 1.5mm starter drill facilitates precise initiation of osteotomies and features a 10.5mm depth marking.

TSD2020HD	**Tapered HD Drill, 2.0mm**

The 2.0mm pilot drill uses end cutting geometry to efficiently set the depth of an osteotomy. The drill includes a full set of depth marks, matching the extended shank drills.

Pro Guided Surgery

Surgical Instruments

3.0mm Internal Hex Implant Drivers

Drivers are color-coded by prosthetic connection:
- 3.0mm platform - no color indicator

TP3IDHR	3.0mm Implant-level Driver, Handpiece, Regular
TP3IDRR	3.0mm Implant-level Driver, Ratchet, Regular*
TP3IDRL	3.0mm Implant-level Driver, Ratchet, Long* (sold separately)

3.5/4.5mm Internal Hex Implant Drivers

Drivers are color-coded by prosthetic connection:
- 3.5mm platform - yellow
- 4.5mm platform - green

TYGIDH	3.5/4.5mm HD Implant-level Driver, Handpiece
TYGIDR	3.5/4.5mm HD Implant-level Driver, Ratchet*

Conical Narrow Implant Drivers

CNIDH	Conical Narrow Implant-level Driver, Handpiece
CNIDR	Conical Narrow Implant-level Driver, Ratchet*
CNIDRL	Conical Narrow Implant-level Driver, Ratchet, Long*

Conical Regular Implant Drivers

CRIDH	Conical Regular Implant-level Driver, Handpiece
CRIDR	Conical Regular Implant-level Driver, Ratchet*

* 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.

Pro Guided Surgery

Ancillary Instruments

Guide Fixation

122-024	2.0 x 24mm CGS Pilot Drill
CGS-FP	CGS Fixation Pin (3 included with kit)

Master Cylinders

Interface between surgical guide and surgical instruments. Reference L02083 for compatibility specifications. Reference L02094 for Guide Fabrication Techniques.

PROMCGY-10	Pro Master Cylinder, Grey (pack of 10)
PROMCYL-10	Pro Master Cylinder, Yellow (pack of 10)
PROMCPR-10	Pro Master Cylinder, Purple (pack of 10)

300-205
4mm Square Drive Extender*

130-000
Ratchet

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

122-100
Drill Extender

144-100
Straight Parallel Pins
(2 per kit)

144-200
20° Angled Parallel Pins
(1 per kit)

144-230
30° Angled Parallel Pins
(sold separately)

* 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.

Pro Guided Surgery

Ancillary Instruments (sold separately)

Hand Wrench

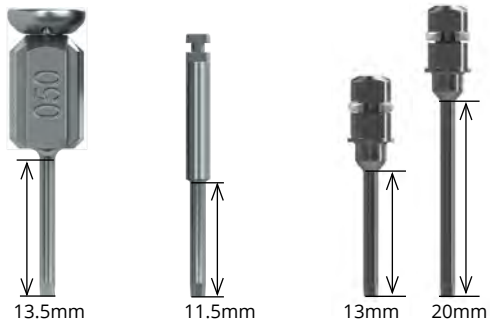
Allows for manual use of the screw-retained and ratchet drivers.

300-400	Hand Wrench

Implant mount

The implant mount provides additional surgical guide fixation. The mount is designed to pass through the surgical guide and screw into an implant that has already been placed; the thumb wheel is then tightened, fixating the guide in the patient's mouth.

CGS-IM	CGS Implant Mount



.050" (1.25mm) hex drivers

For installation and removal of cover caps, prosthetic and abutment screws.

135-451	Manual Hex Driver, Long
134-450	Handpiece Hex Driver, Long
300-351	4mm Square Hex Driver, Long*
300-354	4mm Square Hex Driver, Extra Long*

Torque wrench

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

C12374	Elos Adjustable Torque Wrench
C8521	Elos Replacement Bit, 4mm Square Driver
C8381	Elos Replacement Bit, Handpiece Driver

* 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.

Pro Guided Surgery

Ancillary Instruments (sold separately)

Burs

122-110	2.0mm Lindemann Bone Cutter

Side-cutting drill used to correct eccentric osteotomy preparations.

122-106	#6 Round Bur

Bone Profiling Burs

Use at implant uncovery to remove excess crestal bone for proper abutment seating. Screw the guide pin into the implant and align the profiling bur for precise bone removal. Match profiler & guide color to prosthetic connection.

TP3DBP	3.0mm Bone Profiling Bur & Guide
PYDBP	3.5mm Bone Profiling Bur & Guide
PGDBP	4.5mm Bone Profiling Bur & Guide

Multi-unit Bone Profiling Burs

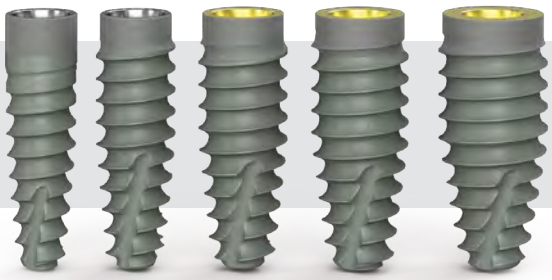
TP3MUBP	3.0mm Multi-unit Bone Profiler
PYMUBP	3.5mm Multi-unit Bone Profiler
PGMUBP	4.5mm Multi-unit Bone Profiler

Bone Profiler Guide Pins

TP3BPGP	3.0mm Bone Profiler Guide Pin (pack of 4)
PYBPGP	3.5mm Bone Profiler Guide Pin (pack of 4)

BioHorizons Tapered Implants

Color-coding for Tapered Pro Conical

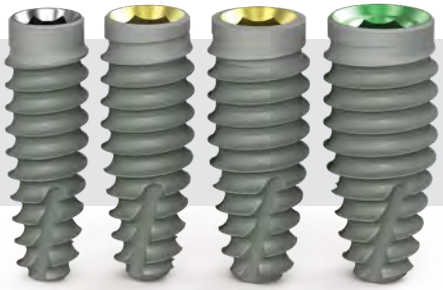


Tapered Pro Conical Implants

	3.3mm	3.8mm	4.2mm	4.6mm	5.2mm
9.0mm length	**CTA3309**	**CTA3809**	**CTA4209**	**CTA4609**	**CTA5209**
10.5mm length	**CTA3310**	**CTA3810**	**CTA4210**	**CTA4610**	**CTA5210**
12.0mm length	**CTA3312**	**CTA3812**	**CTA4212**	**CTA4612**	**CTA5212**
15.0mm length	**CTA3315**	**CTA3815**	**CTA4215**	**CTA4615**	**CTA5215**
18.0mm length	**CTA3318**	**CTA3818**	**CTA4218**	**CTA4618**	—
apical diameter	2.4mm	2.8mm	3.0mm	3.2mm	3.3mm
Laser-Lok zone	1.8mm	1.8mm	1.8mm	1.8mm	1.8mm
Implant Body					
Master Cylinder					
Guide Adapter					
Prosthetic Connection	 Narrow	 Narrow	 Regular	 Regular	 Regular
Implant Driver					

BioHorizons Tapered Implants

Color-coding for Tapered Pro

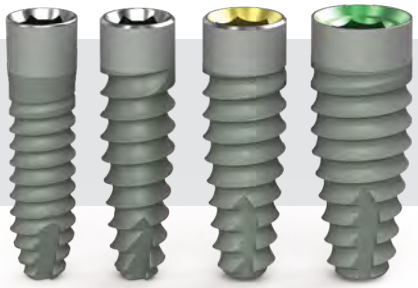


Tapered Pro Implants

	3.8mm	4.2mm	4.6mm	5.2mm
9.0mm length	**BTA3809**	**BTA4209**	**BTA4609**	**BTA5209**
10.5mm length	**BTA3810**	**BTA4210**	**BTA4610**	**BTA5210**
12.0mm length	**BTA3812**	**BTA4212**	**BTA4612**	**BTA5212**
15.0mm length	**BTA3815**	**BTA4215**	**BTA4615**	**BTA5215**
apical diameter	2.8mm	3.0mm	3.2mm	3.3mm
Laser-Lok zone	1.8mm	1.8mm	1.8mm	1.8mm
Implant Body				
Master Cylinder				
Guide Adapter				
Prosthetic Connection	 3.0mm	 3.5mm	 3.5mm	 4.5mm
Implant Driver				

BioHorizons Tapered Implants

Color-coding for Tapered Internal



Tapered Internal Implants

	3.0mm	3.4mm	3.8mm	4.6mm
9.0mm length	—	**TLX3409**	**TLX3809**	**TLX4609**
11.0mm length	**TLX3010**	**TLX3410**	**TLX3810**	**TLX4610**
13.0mm length	**TLX3012**	**TLX3412**	**TLX3812**	**TLX4612**
16.0mm length	**TLX3015**	**TLX3415**	**TLX3815**	**TLX4615**
apical diameter	2.0mm	2.4mm	2.8mm	3.1mm
Laser-Lok zone	2.1mm	1.8mm	1.8mm	1.8mm
Implant Body				
Master Cylinder				
Guide Adapter				
Prosthetic Connection	3.0mm	3.0mm	3.5mm	4.5mm
Implant Driver				

BioHorizons Tapered Implants

Color-coding for Tapered Plus

Tapered Plus Implants

	3.8mm	4.6mm	5.8mm
9.0mm length	**TLXP3809**	**TLXP4609**	**TLXP5809**
10.5mm length	**TLXP3810**	**TLXP4610**	**TLXP5810**
12.0mm length	**TLXP3812**	**TLXP4612**	**TLXP5812**
15.0mm length	**TLXP3815**	**TLXP4615**	**TLXP5815**
apical diameter	2.8mm	3.1mm	3.9mm
platform switch	0.4mm	0.5mm	0.6mm
Laser-Lok zone	1.8mm	1.8mm	1.8mm
Implant Body			
Master Cylinder			
Guide Adapter			
Prosthetic Connection	 3.0mm	 3.5mm	 4.5mm
Implant Driver			

Surgical Manual

Instructions for use

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

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

Before beginning any surgical procedure using the Pro Surgical Kit:

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

Indications

The Pro Surgical Kit is intended to facilitate the creation of an osteotomy for placement of BioHorizons implants using a surgical guide that incorporates BioHorizons manufactured Master Cylinders. The bone cutting instruments are intended for use in the mandible or maxilla for partially and fully edentulous arches.

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.[1] 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.[2]
  A Drill Usage 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.

Surgical Kit

Surgical kit instructions

Prior to use, clean and sterilize the surgical tray and instruments according to the Instructions for Use included with the kit. Study the kit layout, color-coding and iconography. Surgical assistants should be thoroughly familiar with all instruments and their uses prior to initiating the surgical procedure.

Fixation Pin instrumentation

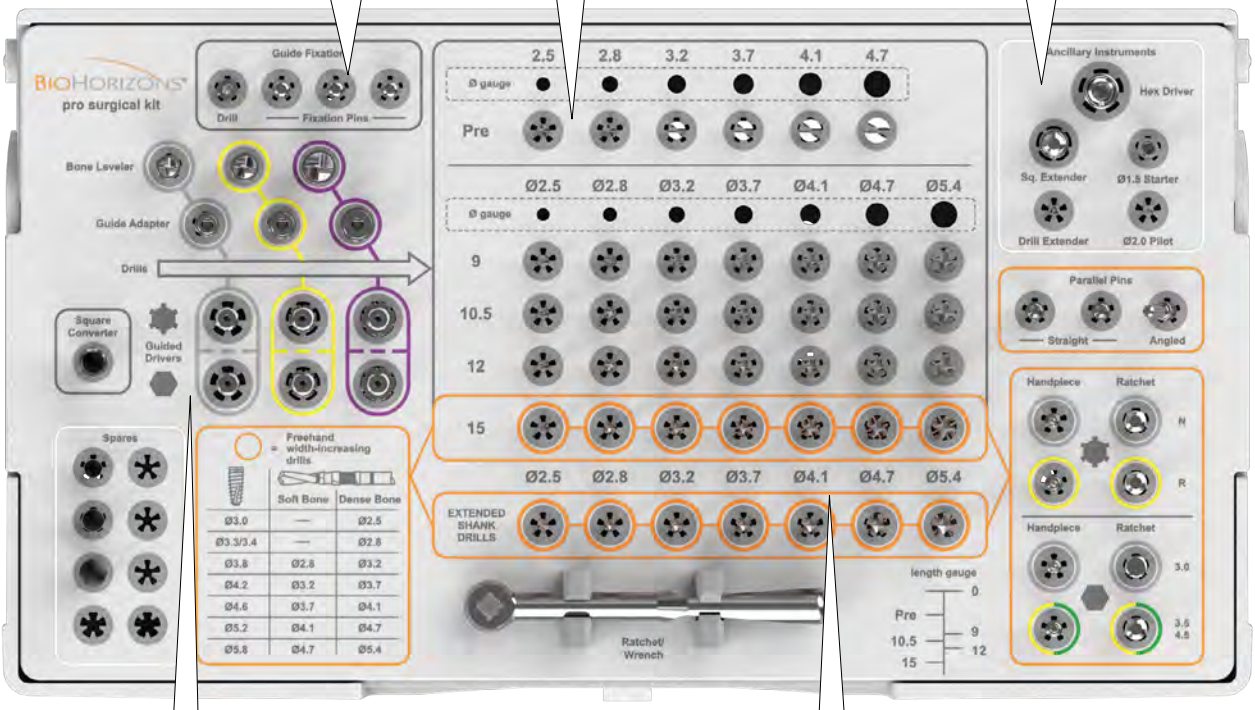
Fixation pins and a corresponding surgical drill are included in the kit for guide fixation during edentulous cases.

Drill bank

Length and diameter specific drills are included to support both depth and width increasing protocols.

Ancillary instruments

Ancillary instruments are included to offer greater flexibility for adjustments during drilling and placement.



Guided surgery components

Grey, Yellow, and Purple color-coded instruments are designed to interface with the Master Cylinders for guidance during use.

Freehand instruments

Instruments outlined in orange can be used for freehand placement of implants following a width-increasing protocol.

The kit includes features to help identify the primary dimensions of each drill in the kit. Diameter gauges are featured in the first row of each drill section to identify the diameter of drills stored in the corresponding column. A length gauge is listed along the bottom edge of the kit to specify the length of a drill, implant or laser-marks.

Guided Protocol–Master Cylinders

Master Cylinders

Patient anatomy and the virtual treatment plan determine the Master Cylinder to be used in the surgical guide. Three different Master Cylinder diameters are available.

	Height	Drill Guide Requirement	Implant Body Diameter
 PROMCGY	3mm	yes	3.0mm 3.3mm 3.4mm 3.8mm
 PROMCYL	3mm	yes	3.8mm 4.2mm 4.6mm
 PROMCPR	3mm	yes	4.6mm 5.2mm 5.8mm

Pilot Sleeves

Pilot sleeves are available as part of the CGS4000 surgical system. Reference L02028 for more information on instructions and planning.

Pilot Guide Technique

When using a pilot sleeve, advance the 2.0mm pilot drill without a Guide Adapter.

Once the initial osteotomy has been drilled, remove the surgical guide and proceed with the manufacturer's standard protocol for implant placement.

Reference L02028 for full instructions on Pilot Guide protocols.

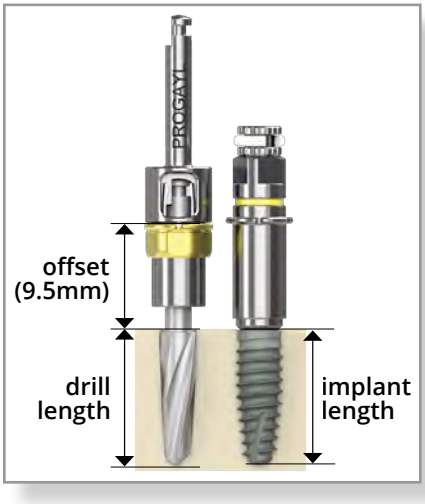
Guided Protocol–Drill Overview

Guided drill sequence

Guided drilling sequences for the Pro Surgical System kit use a depth increasing protocol due to the keyless drill design. For each supported implant diameter, the osteotomy is initiated at the undersized or soft bone diameter. The final diameter drill of the given implant length can be used as an optional drill for dense bone preparation.

Reference the surgical plan developed by the planning software or surgical guide manufacturer for specific instructions for each implant and protocol.

Implant Diameter		Master Cylinder	Tissue Punch	Bone Leveler	Guide Adapter	Pre Drill	Implant Length				Dense Bone Drill	Implant Driver
							9mm	10.5mm	12mm	15mm		
3.0mm 3.3mm 3.4mm 3.8mm												
3.8mm 4.2mm 4.6mm												
4.6mm 5.2mm 5.8mm												



Offset

Guided surgery workflows with the Pro Surgical System use a fixed 9.5mm offset for all implant lengths.

The Guide Adapter component is designed to ensure that each drill length is adequately controlled by the Master Cylinder. Drills should be interchanged with the Guide Adapter, instead of the handpiece, until the osteotomy is complete.

Guided Protocol–Surgical Plan

Drilling technique

Drilling Technique

Fully seat the drill assembly into the Master Cylinder. Ensure the drill has a resistance free path of insertion by pumping the drill assembly in-and-out of the guide prior to drilling.

Each Guide Adapter should be advanced as far as possible through the Master Cylinder prior to initiating drilling.

Use short, light strokes to progressively advance each drill to depth with minimal pressure on the drill. Profuse irrigation throughout the drilling sequence is necessary to provide lubrication and prevent overheating.

Use an in-and-out pumping action to help clear flutes of any bone debris. The drill should not be completely removed from Master Cylinders during pumping. When finally removing the drill assembly from the Master Cylinder, the drill should continue to rotate until it is fully disengaged from the guide.

Avoid applying lateral pressure to the Master Cylinder by ensuring the drill path is in line with the Master Cylinder.

Guide Design

When designing surgical guides for use with the Pro Surgical System, it is important to ensure that sufficient guide material is incorporated around the Master Cylinder to provide support during the surgical workflow.

When assembling the Pro Master Cylinders with the surgical guide, it is recommended to use medical device adhesive to help retain the Master Cylinder in the guide. The inclusion of glue or irrigation channels adjacent to the Master Cylinder is not recommended, as the removal of material can weaken the guide.

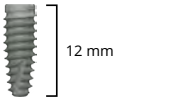
Guided Protocol–Surgical Plan

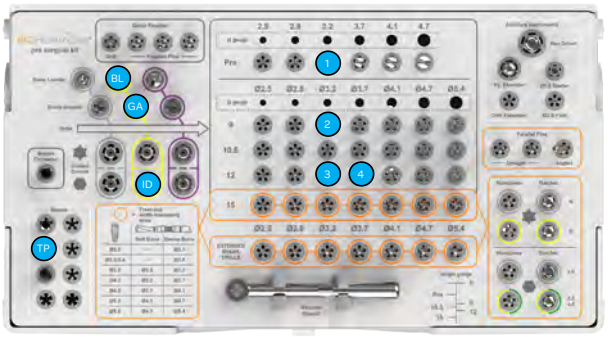
Drilling protocol

Pro Surgical System

Guided Surgical Protocol

BTA4212
Ø 4.2mm, L 12mm





Implant	Diameter(mm)	Length(mm)	Apical Diameter
BTA4212	4.2mm	12mm	2.87mm

Master Cylinder (MC)	Tissue Punch (TP)	Bone Leveler (BL)	Guide Adapter (GA)	Implant Driver (ID)
PROMCYL-10	PROTPYL	PROBLYL	PROGAYL	PROIDYL

Guided Length Drill

Required

Sequence	Legend	Part #	Drill Markings
Pre Drill	1	PROPRE32	PRE 3.2
Drill 1	2	PROLD3209	3.2 x 9
Drill 2	3	PROLD3212	3.2 x 12

Guided Dense Bone Drill

Optional

Sequence	Legend	Part #	Drill Markings
Drill 3	4	PROLD3712	3.7 x 12

Surgical Plan

A patient-specific surgical protocol is included with the surgical guide. The surgical protocol includes the recommended components to be used for each implant site. Verify the protocol corresponds to the submitted virtual treatment plan prior to surgery.

Clinician judgment must always supersede any recommendations in the surgical protocol and any BioHorizons Instructions for Use.

Guided Protocol–Surgical

Osteotomy development

Tissue Punch (optional)

Purpose: Remove soft tissue for a flapless procedure.

- 1,000 RPM

Bone Leveler

Purpose: Create a level site for the osteotomy and allow for guided engagement of subsequent drills.

- Insert the Bone Leveler through the Master Cylinder and use short, light strokes to advance until the depth stop rests on the Master Cylinder.
- 1,000 RPM
- For guided protocols only

Guide Adapter

Purpose: Interface with Pre Drills or Length Drills and Master Cylinders to provide guidance.

- Insert the individual Guide Adapter through the Master Cylinder and ensure there is proper clearance with soft tissue and bone.

Guided Protocol–Surgical

Osteotomy development

Pre Drill

Purpose: Use with the Guide Adapter to initiate the osteotomy.

- Insert the drill in the Master Cylinder and use short, light strokes to progressively advance the drill until the depth stop rests on the Master Cylinder.
- 1,500 - 2,000 RPM
- When engaging dense cortical bone, a narrower diameter Pre Drill can optionally be used to more gradually initiate the osteotomy.

Length Drills

Purpose: Use with the Guide Adapter to deepen the osteotomy, corresponding to implant length.

- 1,000 RPM

Length Drills - Dense Bone (optional)

Purpose: Use with the Guide Adapter to widen the osteotomy.

- 1,000 RPM

Guided Protocol–Surgical

Implant delivery

Implant Drivers are color-coded by the compatible Master Cylinder (grey, yellow, purple) for proper engagement with the guide and control during implant placement.

Reference the patient-specific surgical protocol for the required Implant Driver.

Mount-free Transfer

Engage the implant with screw-retained driver by inserting the driver into the implant platform and tightening the screw. The driver can then be picked up with a handpiece by using the converter (CGS-4SC) or manually using a ratchet.

The cover cap for the mount-free implant is mounted in the vial cap.

Guided Implant Delivery

A handpiece or ratchet can be used to place the implant through the Master Cylinder.

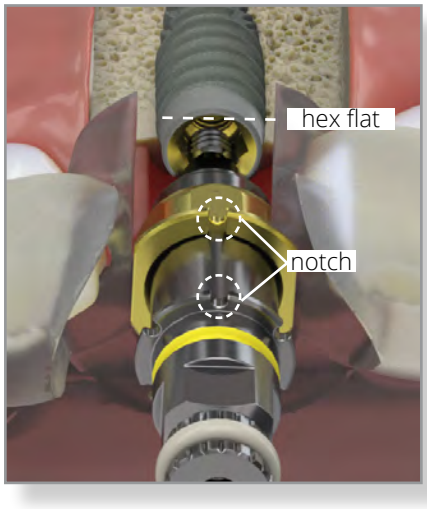
- Ensure the shaft of the Implant Driver is properly aligned with the Master Cylinder.
- Depth placement of the implant is controlled by the driver design.
- If using a ratchet, an extender may be required to avoid collision with adjacent anatomy.

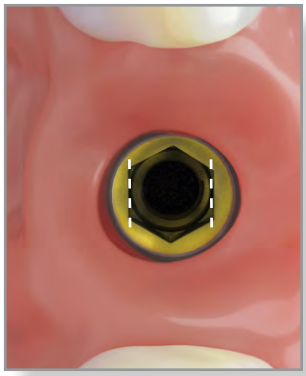
Guided Protocol–Surgical

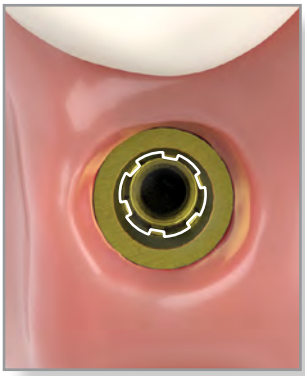
Implant delivery

Guided Implant Delivery

When seating the implant with a ratchet, use the corresponding notches on the driver and Master Cylinder to orient one internal hex flat or cam perpendicular to the implant angulation plane.







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.

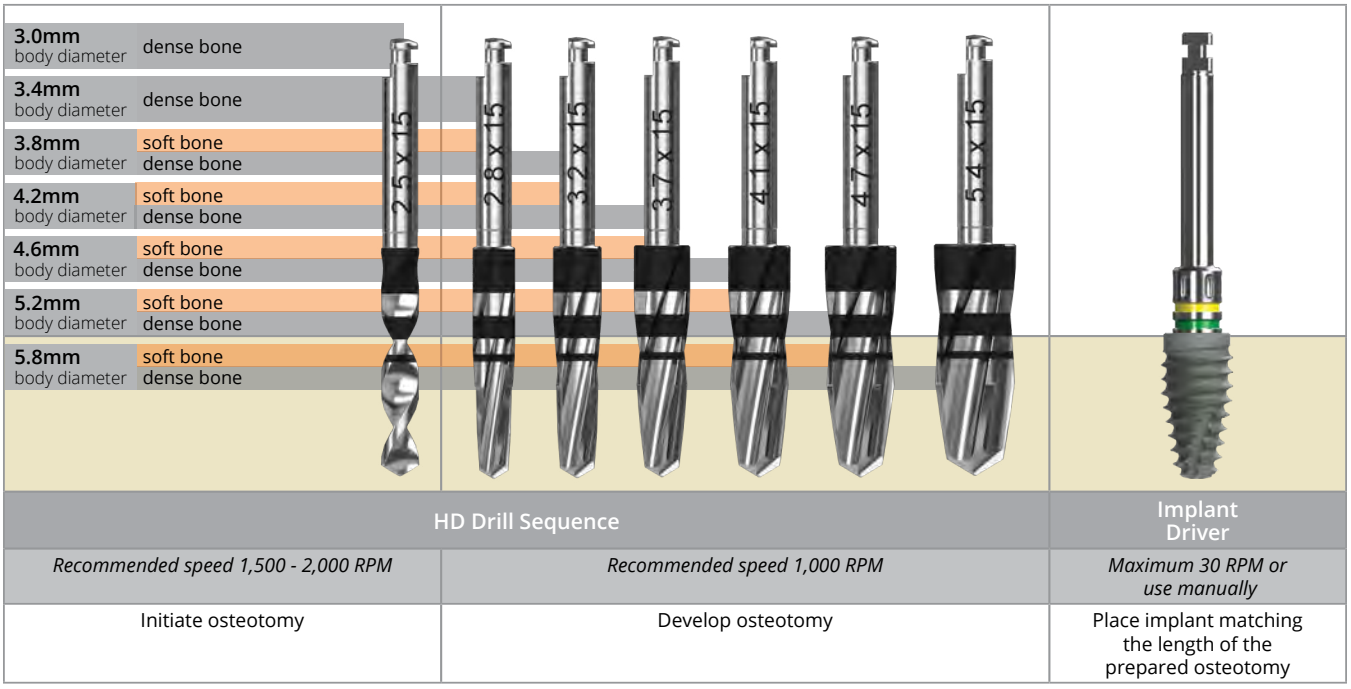
If a removable prosthesis is used during the initial healing phase, a soft liner material should be used to prevent pressure on the surgical site. Relieve the prosthesis over the implant site prior to the soft liner application. Periodically check the patient's soft tissue and bone healing using clinical 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.

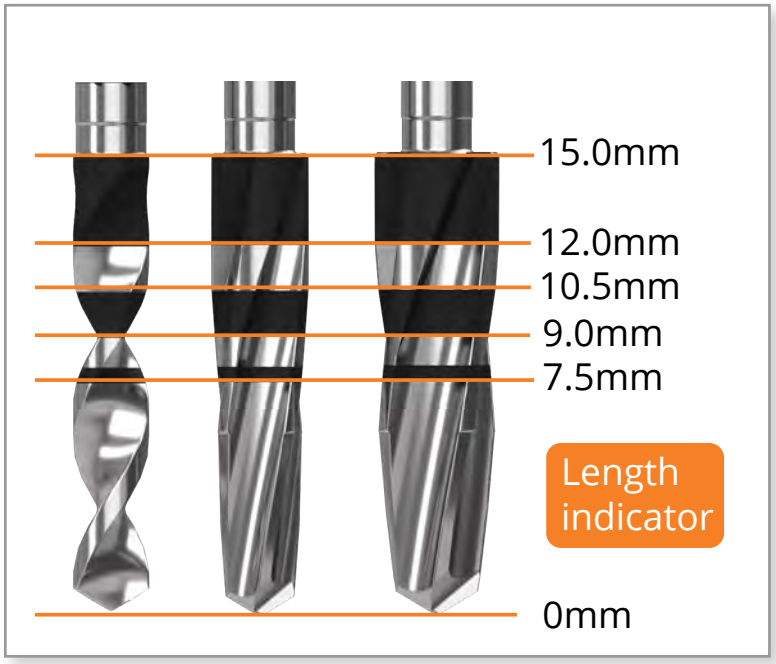
Freehand Protocol–Drill Overview

Drilling protocol

Freehand drill sequence



HD Drill Sequence		Implant Driver
Recommended speed 1,500 - 2,000 RPM	*Recommended speed 1,000 RPM*	*Maximum 30 RPM or use manually*
Initiate osteotomy	Develop osteotomy	Place implant matching the length of the prepared osteotomy



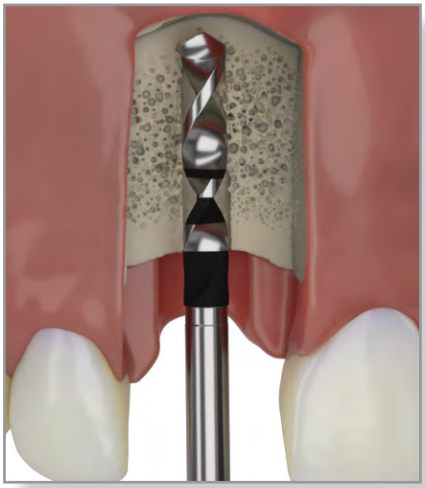
Drill Markings

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

Note: The depth marks are only applied to the 15mm length surgical drills and the extended shank drills. The markings on these drills are consistent throughout all drill diameters.

Freehand Protocol–Surgical

Osteotomy development



2.5 x 15mm Length Drill

Purpose: Initiate osteotomy.

- Efficient cutting drill design collects bone for autografting
- Matte finish for increased visibility under operatory lights
- 1,500 - 2,000 RPM

The 2.5mm extended shank drill can be used in cases where additional drill length is required.

If a narrower drill diameter is required to initiate the osteotomy, the 1.5mm and 2.0mm pilot drills can be used in place of the 2.5mm Length Drill

The 2.5mm Length Drill should not be used subsequently to the 1.5mm or 2.0mm pilot drills. Instead, progress to the 2.8mm Length Drill.

Parallel Pins

Purpose: Evaluate osteotomy position and angle.

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

Freehand Protocol–Surgical

Osteotomy development

15mm Length Drills

Purpose: Incrementally widen the osteotomy to reduce heat generation.

- Depth-marked for reference
- Efficient cutting drill design collects bone for autografting
- The drill tip has limited end cutting. However, the osteotomy depth can be increased with these drills.
- 1,000 RPM

Comparable diameter extended shank drill can be used in cases where additional drill length is required.

Implant Drivers

Purpose: Engage the implant's connection to drive implants into the osteotomy.

- Implant level drivers are color-coded by prosthetic connection:

  Internal Hex:

  - Gray = 3.0mm platform
  - Yellow/green = 3.5/4.5mm platform

  Conical:

  - Gray = Narrow platform
  - Yellow = Regular platform

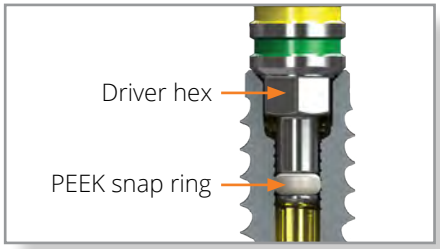
- 30 rpm or less[3]

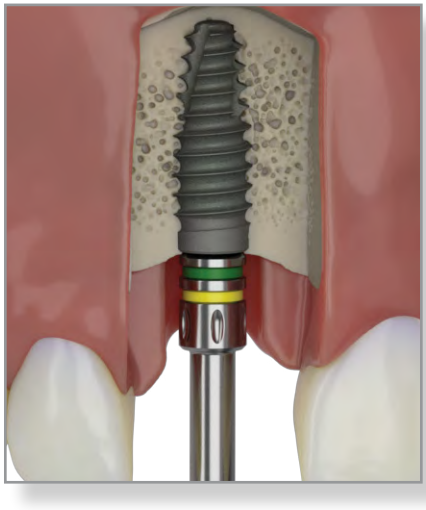
Freehand Protocol–Surgical

Implant delivery

Implant Pick-up

To pick-up the implant, align the driver hex with the implant connection and press firmly to engage the PEEK snap ring.

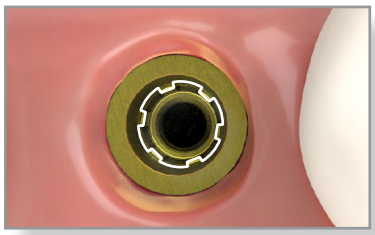




Implant Placement

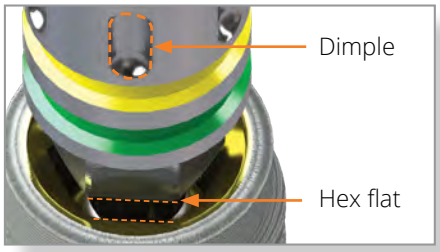
Place the apex of the implant into the osteotomy and begin rotating slowly.

⚠ If too much resistance is felt during insertion, reverse the implant to relieve pressure and re-insert into the osteotomy. If the dense bone drill was not used while preparing the osteotomy, remove the implant and revise the osteotomy with the final drill.



Connection Orientation

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

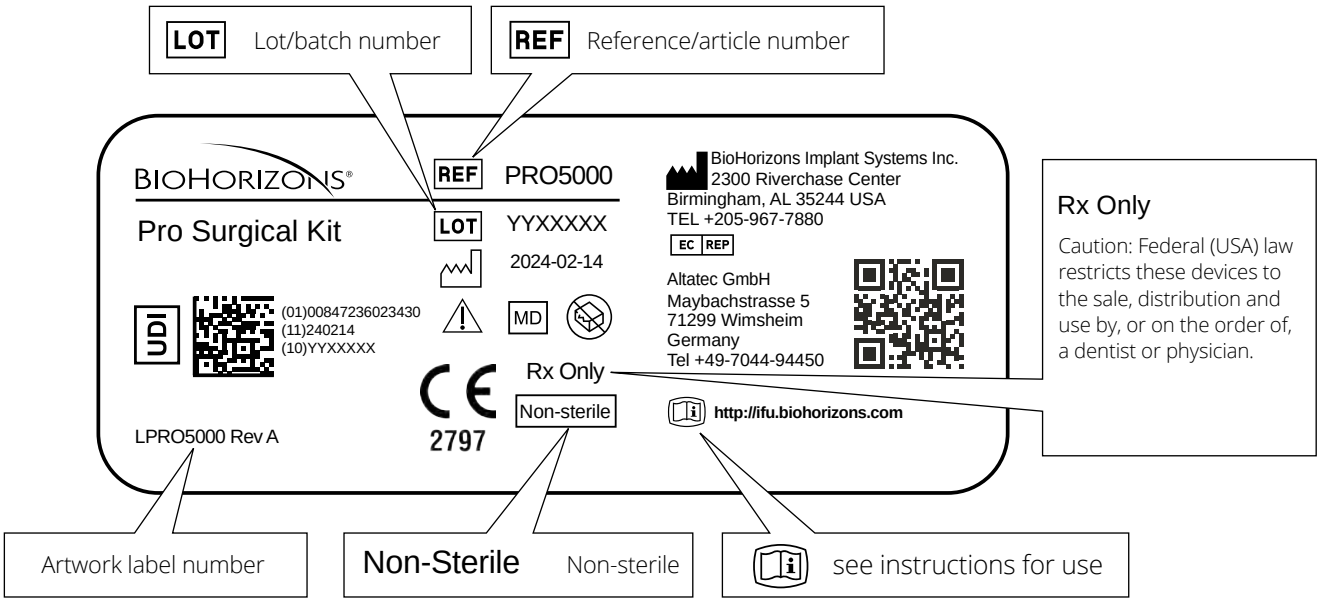


Icon Legend

Product Labeling

Symbol Descriptions for Product Labeling

The example labeling below is to demonstrate content and symbology, and may differ on individual product labeling.



Ordering, Warranty, Information & References

Territory Manager: _____

cell phone: _____

email and/or fax: _____

BioHorizons Lifetime Warranty on Implants and Prosthetics for Clinicians: 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 surgical drills, taps and other surgical and restorative instruments.

(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.[2]

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

Return Policy: Product returns require a Return Authorization Form, which may be acquired by contacting Customer Care or through the online store. The completed Return Authorization Form must 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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Validity: Upon its release, this literature supersedes all previously published versions.

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

Any images depicted in this literature are not to scale, nor are all products depicted. Product descriptions have been modified for presentation purposes. For complete product descriptions and additional information, visit store.biohorizons.com.

References

1. The influence of 0.12 percent chlorhexidine digluconate rinses on the incidence of infectious complications and implant success. Lambert PM, Morris HF, Ochi S. *J Oral Maxillofac Surg* 1997;55(12 supplement 5):25-30.

2. Heat production by 3 implant drill systems after repeated drilling and sterilization. Chacon GE, Bower DL, Larsen PE, McGlumphy EA, Beck FM. *J Oral Maxillofac Surg.* 2006 Feb;64(2):265-9.

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

Notes

Notes

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