Product Catalog & Manual 2007
One-piece 3.0/ Overdenture
ORDERING & WARRANTY INFORMATION

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 GmbH  
Kunden Service:  
+49 7661-909989-0

BioHorizons UK  
Customer Care:  
+44 8700 620 550

BioHorizons No Exceptions Lifetime Warranty on Implants and Prosthetics:
BioHorizons implants and prosthetic components carry a Lifetime Warranty. We will replace any BioHorizons implant or prosthetic component if removal of that product due to failure (excluding normal wear to overdenture attachments) is required for any reason, at any time.

Warranties on Instruments, Surgical Drills and Taps:
BioHorizons warranties instruments, surgical drills and taps 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. This includes all BioHorizons tools used in the placement or restoration of our implants, with the exception of surgical drills and taps (see below).

(2) Surgical Drills and Taps: Surgical drills and taps are covered by warranty 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. BioHorizons recommends the replacement of drills after 12 to 20 osteotomies.

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

Symbol descriptions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>LOT</td>
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<td>Reference/article number</td>
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<td>Sterile by gamma irradiation</td>
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<td>NON-STERILE</td>
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<td>Rx Only</td>
<td>Caution: Federal (USA) law restricts these devices by, or on the order of, a dentist or physician.</td>
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<td>②</td>
<td>Single use only</td>
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<td>!</td>
<td>Refer to Instructions for Use</td>
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<td>⌛</td>
<td>Use before expiration date</td>
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<tr>
<td>CE</td>
<td>BioHorizons products carry the CE mark and fulfill the requirements of the Medical Devices Directive 93/42/EEC</td>
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Disclaimer of Liability
BioHorizons dental implants may only be used in conjunction with the associated original components and instruments according to BioHorizons instructions for use. Use of any non-BioHorizons products in conjunction with BioHorizons implants will void any warranty or any other obligation, expressed or implied, of BioHorizons.

This literature serves as a reference for BioHorizons One-piece 3.0 and Overdenture implants, prosthetics and instrumentation. It is not intended to describe the methods or procedures for diagnosis, treatment planning, or placement of implants, nor does it replace clinical training or a clinician’s best judgment regarding the needs of each patient. BioHorizons recommends appropriate training as a prerequisite for the placement of implants and associated treatment.

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.
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The following color scheme is used to designate pages or sections of this literature featuring components and/or instruments dedicated to One-piece 3.0, Overdenture or both systems.

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### Product Ordering Information

- Surgical Kit and Instruments
- One-piece Implants and Accessories
- Overdenture Implants and Accessories
OVERDENTURE SYSTEM OVERVIEW

Bridging the Gap between “Minis” and Two-piece Implants

BioHorizons Overdenture implant system provides a long-term denture stabilization solution. Its cost and simplicity bring secure dentures within reach of many patients who cannot afford conventional treatment plans requiring bone grafts.

- **Maximum Strength - Minimum Profile.** Its one-piece, titanium alloy construction provides maximum strength, while its 3.0mm diameter allows placement in narrow ridges. The clinically proven modified-square-thread form and Resorbable Blast Texturing (RBT) surface maximize bone-to-implant contact and osseointegration.

- **Minimal Surgery - Maximum Simplicity.** Overdenture implants are placed using a single-stage protocol, with options for either flapped or flapless surgery. For simplicity, each implant comes packaged with the complete attachment system with options for three levels of retention.

BioHorizons Overdenture Specifications

- **Material:** Titanium Alloy – Ti-6Al-4V
- **Surfaces:** Resorbable Blast Texturing (RBT)
- **Diameter:** Ø3.0mm x 12mm, 15mm or 18mm
- **Collar Height:** 2mm or 4mm to address variable tissue thickness
- **Includes:** Complete Ball Attachment Set
- **Warranty:** Lifetime unconditional on Implant
Treatment Planning Considerations

Overdenture implants are designed to stabilize a tissue-supported denture, not to support the prosthesis by themselves. A well-fitting denture with good soft tissue support is essential. Placement of Overdenture implants is contraindicated where more than 30 degrees of divergence is necessary. Overdenture implants are NOT suited for transitional use due to the high degree of osseointegration that is achieved by the thread design and RBT surface treatment.

A flapped procedure is indicated whenever the amount of available bone or the proximity of critical anatomic landmarks is in question. Clinicians must assess each case to determine the appropriate number of implants necessary for successful treatment. Four implants are typically recommended for dense bone in the mandible. Five or more implants are indicated for softer bone in both the mandible and maxilla. Implant length (12, 15 or 18mm) should be chosen to make maximum use of available bone height. Implant collar height (2mm or 4mm) should be chosen so that the RBT portion of the implant is in bone and the ball-top is sitting above the soft tissue.

Overdenture implants must be carefully evaluated for stability before selecting an appropriate level of initial retention. Less retention, rather than more retention, is recommended for initial loading. Relief of the denture to avoid contact with the implants (with or without a soft liner material) in lieu of the attachments is recommended during the initial healing phase. It is recommended that the Ball Attachment Housings be processed into the denture only after rigid fixation or osseointegration of the implants has occurred.

The Overdenture Surgical Kit provides the necessary instruments for the ideal positioning and osteotomy preparation for Overdenture implants. BioHorizons strongly recommends the use of the Surgical Kit for the placement of Overdenture implants. Placement without the kit voids the implant’s Lifetime Warranty. Please refer to the Instructions for Use for further information on indications and contraindications of BioHorizons Overdenture implants.

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.

Clinical images courtesy of Dr. Michael Reddy and Dr. Michael McCracken, University of Alabama at Birmingham
Section 3: Overdenture Surgical Technique

Overdenture Drill Sequence
The recommended drilling sequence for the Overdenture Implant System is shown at the right. Clinicians may opt to omit an instrument when deemed appropriate due to variations in bone density or morphology.

Drilling should be done under a constant stream of sterile irrigation, with a drill speed of 850 to 2,500 rpm. A pumping motion should be employed to help prevent overheating the bone. BioHorizons recommends the replacement of drills after 12 to 20 osteotomies.

Soft Tissue Access
The Tissue Punch may be used to gain access to the site. A conventional flap may be created if visualization of the osseous morphology and anatomic landmarks is required. Maintain a safety margin of at least 1 mm from all vital anatomic structures.

A Radiographic Template (overlay) is provided that can assist the clinician in the preoperative determination of available bone for implant placement.

Osteotomy Initialization
The Alignment Drill is used to initiate the osteotomy to a depth of 5 mm. The cutting surface of the drill hub prepares the crestal bone to accept the stop geometry of the Depth Drill and the Trial Implant. The Alignment Drill has an aggressive cutting geometry to function well in dense cortical bone. Care must be taken to ensure that the drill does not over prepare the osteotomy to a greater depth than desired. See page 22 for details on drill dimensions.
Position and Angulation Verification
Trial Implants may be placed in the osteotomies to verify their position and angulation. A radiograph may be taken to evaluate the osteotomy’s proximity to adjacent anatomic structures. Soft tissue thickness can be assessed using the 2mm reference marks as shown below. The osteotomy’s position and angulation may be corrected using the side-cutting ability of the Alignment Drill.

Use the Trial Implant to mirror position and angulation for consecutive implant sites. The minimum recommended center-to-center spacing for Overdenture implants is 6mm. Implants must be placed in a relatively parallel fashion (15 degrees per implant; up to 30 degrees total relative divergence between two implants).

Depth Drills
The osteotomy depth is established using one of the three Ø2.0mm Depth Drills. Each Depth Drill has a fixed stop corresponding to one of the three implant lengths (either 12, 15 or 18mm). The fixed stop prevents the drill from preparing the osteotomy deeper than desired.

The 15mm and 18mm Depth Drills have additional depth marks for reference. See page 22 for details regarding drill dimensions.

Finishing Drill
The osteotomy is widened to Ø2.5mm using the Finishing Drill. Use of the Finishing Drill may not be necessary in softer (D3-D4) bone. It has depth marks at 12, 15 and 18 millimeters.

The Finishing Drill has a non-end-cutting geometry designed to help it stop at the depth determined by the previous Depth Drill. However, because variations in bone density may be encountered within the osteotomy, clinicians must observe the depth marks as the primary determinant of depth. See page 22 for details regarding drill dimensions.
**OVERDENTURE SURGICAL**

**Bone Tap**
The use of the Bone Tap is typically only required in sites where dense cortical bone (D1) is present. It is driven using a low-speed latch-type handpiece. The Bone Tap has depth marks at 12, 15 and 18mm. See page 22 for details regarding Bone Tap dimensions.

Place the tip of the Bone Tap into the osteotomy, apply firm apical pressure and begin rotating at 30 rpm or less in a clockwise direction. When the threads engage the bone, allow the tap to advance without excessive pressure. Remove the Bone Tap by reversing the Handpiece and allowing it to back out of the osteotomy. Do not pull on the Bone Tap to remove it from the site.

**Implant Pick-up**
Implant collar height (2mm or 4mm) should be chosen so that the RBT portion of the implant is in bone and the ball-top is sitting above the soft tissue. Hold the sterile vial in an upright fashion and remove the cap by rotating it in a counter-clockwise direction.

Engage the hexagon on the implant collar with the desired Adapter, either Handpiece or Ratchet. The Adapters have dimples to provide a visual index aligning with the hexagon. Align the dimple with one of the hex flats and push down gently to seat the implant into the adapter.

Do not touch the implant surface during the transfer.

**Implant Placement**
Thread the implant into the osteotomy at 30 rpm or less. The Ratchet Adapter may be used in lieu of the Handpiece Adapter when preferred; it will fit either the Hand Wrench or the Ratchet.

Overdenture implants are typically placed so that the ball portion sits completely above the soft tissue (as shown above). Take care not to overtorque the implant as bone stripping or pressure necrosis may occur.

The peel-and-stick labels on the blister tray should be placed in the patient's chart as a record of the device(s) used.
Initial Stabilization - Day of Placement
It is recommended that Overdenture implants be given adequate time to osseointegrate prior to full loading. Initial denture stability can be obtained through the soft lining of the transitional prosthesis (often the existing denture). Relieve the denture to avoid contact with the implants and line with soft reline material during the initial healing phase. It is recommended that the Ball Attachment Housings be processed into the denture only after osseointegration has occurred.

Place a transferable mark on top of each ball-top and seat the denture in the patient’s mouth to determine where the denture needs to be relieved. Create a trough in the denture that allows complete soft tissue support with no contact between the denture and the implants.

**Flapless Surgery** - A soft reline material may be placed in the trough described above to provide a transitional degree of retention prior to use of the Ball Attachments.

**Flapped Surgery** - A tissue conditioner should be used in lieu of soft reline material as it is less likely to irritate the sutured flap margins.

Place the Protective Disks or rubber dam material over the ball-tops, seat the denture and instruct the patient to bite in light centric occlusion until the soft liner or tissue conditioner cures. After the material has cured, remove the denture and fill any voids.

Patient recall should be scheduled with frequency to ensure the soft liner is replaced prior to losing function.
Relieve Denture to Accommodate Housings

When the existing denture is to be used for a chair-side pick-up of the Attachment Housings, it must be relieved to sit passively over the seated Housing assemblies. Mark the denture to note the position of the ball-tops as captured in the liner material. Remove the liner material from the denture.

Insert Black Positioning Inserts (BCIB) into the Attachment Housings (BCAHT) with the Insert Seating Tool (BCIST) as shown on page 20, and seat on the implant ball-tops.

Try in the denture over the seated Insert/Housing assemblies to determine if further relief is necessary for adequate clearance. 1.5mm to 2.0mm of clearance is suggested around and above each Housing for maximum retention in the denture base.

Vent holes should be made in the lingual surface of the denture to allow verification of housing/denture clearance, and permit excess acrylic to escape during the pick-up procedure.

Chairside Pick-up without Directional Rings

Place Rubber Dam material or the clear Protective Disk over each ball-top. Seat the Insert/Housing assemblies onto the implant ball-tops and rotate the housings to create a parallel path of draw. Block out any undercuts with wax or other appropriate material.

The Black Positioning Inserts must be used for chair-side pick-up procedures. The Yellow and Green Clinical Inserts may provide too much retention and cause the denture to become locked on to the implant ball-tops.
Optional - Chairside Pick-up with Directional Rings

Directional Rings (purchased separately, page 25) are placed to establish and maintain the Attachment Housings in parallel position during a chairside pick-up, or pick-up in the laboratory. The set contains rings of 7° and 14°, as well as a flat ring (0°) for use with relatively parallel implants.

A rubber dam may be used to protect the tissue if desired. Punch 3mm holes in the rubber dam material to accommodate each implant. This ensures the dam seats completely over the hex beneath the ball-top of the implants. The rubber dam should be placed prior to the seating of the Directional Rings and the Insert/Housing assemblies.

Seat the Directional Rings and the Insert/Housing assemblies onto the implant ball-tops. Rotate the Directional Rings to create a parallel path of draw. The Directional Rings serve a secondary function by blocking out potential undercuts, reducing the need to block out the area.

The Black Positioning Inserts must be used for chairside pick-up procedures. The Yellow and Green Clinical Inserts may provide too much retention and cause the denture to become locked on to the implant ball-tops.

Pick-up of the Housing Assemblies

Place a small amount of acrylic on the top of the Attachment Housings. Fill the relieved area of the denture base with acrylic and place the denture over the housings. Instruct the patient to bite in light centric occlusion. Remove the denture after the acrylic sets and fill in any voids around the housings and polish the denture base as required.

If desired, the Black Positioning Inserts may be left in the denture for a period of time as a transitional step between the soft reline and full retention of the Clinical Inserts. They provide limited retention, but do create a positive vertical stop and increase lateral stability.
Removal of Black Positioning Inserts

After the pick-up of the housing assemblies has been accomplished, remove the Positioning Inserts from the Attachment Housings with a spooned instrument and proceed with the insertion of the appropriate Clinical Insert and retention adjustment procedure.

Seating of Clinical Inserts

Clinical Inserts are available with four different retention levels. Overdenture implants are packaged with the two that offer the least retention (green and yellow).

Using the Insert Seating Tool (BCIST), seat the desired Clinical Insert into ONE Attachment Housing and try-in the denture. If retention is too great, adjust the retention with the Reamer (BCR) by inserting the tool in the insert and turning clockwise to reduce the retention. When appropriate retention is achieved, continue the same process with the next Insert/Housing.

The duration of Clinical Inserts in the mouth varies from prosthesis to prosthesis, depending on: number and arrangement of attachments/implants, prosthesis balance and other factors. It is recommended to replace the caps every 12 months. Patients should be instructed to contact the office immediately if they feel their retention becomes compromised between recalls.

Inserts must be replaced before they wear to the point that would allow the Overdenture implant’s ball-top to come in contact with the titanium Attachment Housing. Metal-to-metal contact will cause wear to ball-top, diminishing its retentive ability.

<table>
<thead>
<tr>
<th>Clinical Inserts</th>
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<tr>
<td><strong>Relative Retention</strong></td>
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<tr>
<td>Elastic</td>
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<tr>
<td>Included with Implant</td>
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</tbody>
</table>
Optional - Stone Model with Analogs Fabrication

Pick-up Housing Assemblies
Block out sutures, if present. Place the clear Protective Disk over each implant’s ball-top.

Place a Black Nylon Insert / Attachment Housing assembly on each ball-top and arrange in a path of parallel draw. Directional Rings may be used to help align the assemblies. Block out any undercuts with a material of choice.

Use a medium or heavy-bodied impression material to make a closed-tray, full-arch impression that picks up the Insert/Housing assemblies. Express a small amount of impression material around each assembly to ensure a good pick-up. Record opposing dentition if necessary.

Insert Analogs
After removing the impression, verify that an accurate pick-up was made. Insert the appropriate number of Ball Attachment Analogs (purchased separately, page 25) into the Insert/Housing assembly contained in the impression. Be certain that the Analogs are fully seated before pouring the stone.

Pour the Model / Pick up the Housings
After pouring the working cast, the Insert/Housing assemblies are retrieved from the impression. The Inserts/Housings can then be incorporated into a baseplate to create a stabilized wax occlusal rim following standard laboratory procedures.
160-300
One-piece/Overdenture Surgical Kit
Includes all the instruments shown below plus the cover (not shown).

122-104 Alignment Drill
144-400 Trial Implant (3 per kit)
122-52012 12mm Depth Drill (Ø2.0mm)
122-52015 15mm Depth Drill (Ø2.0mm)
122-52018 18mm Depth Drill (Ø2.0mm)
122-525 Finishing Drill (Ø2.5mm)
122-900 Bone Tap

122-200 Tissue Punch
122-100 Drill Extension

133-000 3.0 Handpiece Adapter
133-000OS Overdenture Handpiece Adapter

330-200 3.0 Ratchet Adapter
330-200OS Overdenture Ratchet Adapter

300-400 Hand Wrench
130-000 Ratchet

Surgical Kit and Components
The stated length is measured from the apex to the base of the machined collar. A Ball Attachment Set (MBAS) is provided with each implant at no additional cost. Titanium alloy (Ti-6Al-4V) with Resorbable Blast Texturing (RBT) surface.

### Overdenture Implants

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<th>Description</th>
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<td>3012OS2</td>
<td>Overdenture Implant 3.0mm x 12mm, 2mm collar</td>
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<td>3015OS2</td>
<td>Overdenture Implant 3.0mm x 15mm, 2mm collar</td>
</tr>
<tr>
<td>3018OS2</td>
<td>Overdenture Implant 3.0mm x 18mm, 2mm collar</td>
</tr>
<tr>
<td>3012OS4</td>
<td>Overdenture Implant 3.0mm x 12mm, 4mm collar</td>
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<tr>
<td>3015OS4</td>
<td>Overdenture Implant 3.0mm x 15mm, 4mm collar</td>
</tr>
<tr>
<td>3018OS4</td>
<td>Overdenture Implant 3.0mm x 18mm, 4mm collar</td>
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### Ball Attachment Set & Accessories

**MBAS**

Overdenture Ball Attachment Set

Packaged with each Overdenture implant. Includes:

- (1) Titanium Housing
- (3) Female Nylon Inserts - green (elastic retention), yellow (extra soft retention), black (lab processing)
- (1) Protective Disk (tissue protector for impression taking and chair-side denture pick-up)

**BCAH**

Attachment Housings – Titanium

For Resin pickup or Soldering. 2 per package.

**BCIB**

Black Nylon Insert

Lab Processing and Chair-side Denture Pick-up. 2 per package.

**BCIG**

Green Nylon Insert

Clinical use. 2 per package. Elastic Retention.

**BCIY**

Yellow Nylon Insert

Clinical use. 2 per package. Extra Soft Retention: 1.4lb / 525g
OVERDENTURE | ACCESSORIES

**Overdenture Accessories**

**BCIST**
- **Insert Seating Tool**
  - Used to seat nylon inserts in attachment housings.

**OSDR**
- **Directional Rings**
  - Used for obtaining parallelism.
  - Set of 3: 0º, 7º, and 14º rings
  - Color-coded, multiple-use titanium.

**BCR**
- **Reamer**
  - Used to adjust retention of nylon inserts.

**BCIP**
- **Pink Nylon Insert**
  - Clinical use. 2 per package.
  - Soft Retention: 2.3lb / 875g

**BCIW**
- **White Nylon Insert**
  - Clinical use. 2 per package.
  - Standard Retention: 3.3lb / 1250g

**BCAA**
- **Ball Attachment Analog**
  - Used for fabrication of model.

**BCIW**
- **Overdenture Patient Education Model**
  - Designed to aid the clinician in educating patients on the Overdenture System.
  - Features 4 Overdenture implants in a clear acrylic mandible and a lower denture with the incorporated attachment housings.

**L0110**
- **Radiographic Implant Template (overlay)**
  - Designed to aid the clinician in determining the available bone for implant placement. The clear overlay template shows all sizes of One-piece 3.0 and Overdenture implants in 100% and 125% scale.

**ML0114**
- **Patient Education – Denture Stabilization**
  - This brochure helps the implant candidate understand the rationale and the advantages of implant therapy compared to traditional treatment methods.
  - 50 brochures per package.

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References:

BioHorizons strongly recommends completion of postgraduate 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.

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