# Simple Solutions Technique Guide

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Simple Solutions Overview

Restorative Visit One

1. Seat Simple Solutions Abutment
2. Make closed-tray, pick-up impression
3. Seat Healing Cap

Laboratory Procedure

4. Seat Replica, pour stone model
5. Wax framework. Sprue, invest and cast
6. Verify framework fit. Apply veneer

Restorative Visit Two

7. Remove Healing Cap
8. Seat restoration. Check occlusion
9. Release patient
Simple Solutions restorations on BioHorizons implants allow clinicians to deliver cement-retained fixed prostheses in a minimal number of office visits. The innovative system allows identical restorative paths to be followed on three distinctly different implant designs; providing extraordinary flexibility to the entire implant team.

The pre-tapered abutments are designed to be restored without laboratory modification. Once the impression has been made, patients can wear a tooth-colored provisional Healing Cap over the abutment while the laboratory fabricates the final prosthesis.

Single-stage Simple Solutions restorations finish on the restorative shoulder of the implants (figure A, opposite). Therefore, Single-stage implants intended for Simple Solutions restorations should be placed with the restorative shoulder as close as possible to the desired position of the crown margin.

Internal and Tapered Internal Simple Solutions restorations finish on the restorative shoulder of the abutment. There are three options for transmucosal collar height: 0.8mm / 1.8mm / 2.8mm. The collar height should be selected to put the restorative shoulder as close as possible to the desired position of the crown margin (figure B, opposite).

In general, and regardless of the implant system, restorations in the esthetic zone will have subgingival margins; whereas non-esthetic posterior restorations might be at or above the gingival level for hygiene considerations.

Figure C on the opposite page represents a traditional cement-retained fixed crown restoration on a lab-modified abutment. The abutment height and margin position is adjusted on the stone model in the laboratory as required for each case. Please refer to either the Internal / Single-stage Product Catalog (ref. ML0115) or Tapered Internal Product Catalog (ref. ML0603) for information on these and other restorative options.
INTRODUCTION TO SIMPLE SOLUTIONS

Figure A. Single-stage Simple Solutions crowns finish on implant shoulder

Figure B. Internal Simple Solutions crowns finish on abutment shoulder

Figure C. Traditional crowns finish on a laboratory-defined abutment margin
Simple Solutions restorative components are designed to be intuitive and user-friendly. Each implant prosthetic platform and its corresponding components have a highly-visible matching color-code. The Abutments and Replicas are laser-marked either 4.0 or 5.5, reflecting their height in millimeters. Healing Abutments are also encoded with the platform information to aid in component selection before being removed.

**Abutment Height Selection**

The abutment height (either 4.0mm or 5.5mm) should be selected to ensure a minimum of 1.5mm of clearance on the occlusal aspect. This allows adequate space for the precious metal framework and veneer of a porcelain-fused-to-metal (PFM) prosthesis; or the required thickness of an all-ceramic restoration.

**Alternative Technique:** When 1.5mm of clearance cannot be obtained using the shortest (4.0mm high) Simple Solutions Abutment, a custom cast screw-retained or laboratory-modified cement-retained restoration may be indicated. These alternative protocols require an implant-level impression and a working stone cast with soft tissue material.

Please refer to the Internal / Single-stage Product Catalog (ref. ML0115) or Tapered Internal Product Catalog (ref. ML0603) for information on these and other restorative options.

**Simple Solutions Color-coding**

Simple Solutions restorative components are designed to be intuitive and user-friendly. Each implant prosthetic platform and its corresponding components have a highly-visible matching color-code. The Abutments and Replicas are laser-marked either 4.0 or 5.5, reflecting their height in millimeters. Healing Abutments are also encoded with the platform information to aid in component selection before being removed.
Complete Restorative Kits

Simple Solutions Restorative Kits contain all the laboratory components needed for fabrication of a cement-retained prosthesis: Abutment, Abutment Screw, Impression Cap, PEEK Healing Cap, Replica and Waxing Sleeves.

The innovative packaging has three separate compartments designed to be opened as needed by members of the implant team during the various restorative stages. Components are also sold individually, please refer to either the Internal / Single-stage Product Catalog (ref. ML0115) or Tapered Internal Product Catalog (ref. ML0603) for ordering information.
**INDIVIDUAL COMPONENTS**

### Single-stage Simple Solutions Abutments

*Used: with Single-stage implants*

- Match by prosthetic platform:
  - 3.5mm (yellow) / 4.5mm (green) / 5.7mm (blue)
- Select abutment height: 4.0mm / 5.5mm
- Designed to be restored without modification
- Standard .050” (1.25mm) Hex Driver / 30 Ncm Torque Wrench
- Titanium Alloy (Ti-6Al-4V)

### Internal Simple Solutions Abutments

*Used: with Internal and Tapered Internal implants*

- Match by prosthetic platform:
  - 3.5mm (yellow) / 4.5mm (green) / 5.7mm (blue)
- Select transmucosal collar height: 0.8mm / 1.8mm / 2.8mm; and
- Select abutment height: 4.0mm / 5.5mm
- Designed to be restored without modification
- Standard .050” (1.25mm) Hex Driver / 30 Ncm Torque Wrench
- Titanium Alloy (Ti-6Al-4V)

### Impression Caps

*Used: to make a closed-tray pick-up impression*

- Universal to Internal and Single-stage Simple Solutions Abutments
- Must match platform and height of the abutment
- Color-coded by prosthetic platform
- Retracts soft tissue away from the restorative shoulder
- Provides positive seat for indexing Replica in the impression
- Single-use only. Do not reuse or sterilize
INDIVIDUAL COMPONENTS

PEEK Healing Caps

**Used:** for provisionalization of Simple Solutions Abutments
- Universal to Internal and Single-stage Simple Solutions Abutments
- Must match platform and height of the Simple Solutions Abutment
- PEEK (PolyEtherEtherKetone) material
- Used as is, or with acrylic added for enhanced esthetics
- *In situ* use up to 30 days. Secure with temporary cement
- Single-use only. Do not reuse or sterilize

Replicas

**Represents:** the implant and abutment in the working cast
- Universal to Internal and Single-stage Simple Solutions Abutments
- Must match platform and height of the Simple Solutions Abutment
- Must not be confused with Implant Analogs
- Titanium Alloy (Ti-6Al-4V)

Waxing Sleeves

**Purpose:** burn-out coping to facilitate waxing of framework
- Universal to Internal and Single-stage Simple Solutions Abutments
- Must match platform of the Simple Solutions Abutment
- One height (7.0mm) for each prosthetic platform. Trim as necessary
- Single-unit Waxing Sleeve has internal anti-rotational features
- *See page 13 for an alternative method for coping fabrication*
FIRST RESTORATIVE VISIT

Please visit www.biohorizons.com/videos to view an animated step-by-step video of the Simple Solutions restorative procedure on both Single-stage and Internal/Tapered Internal Implants. The presentations are also available on the BioHorizons Animated Restorative Technique Guide (ref. MLV129, see page 20 for ordering information).

NOTE: Before beginning this or any restorative procedure with BioHorizons components please see pages 18-19 for important information on abutment screw/hex driver engagement and delivery of torque.

<table>
<thead>
<tr>
<th>Remove Healing Abutment</th>
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<tbody>
<tr>
<td>Remove the Healing Abutment using the .050” (1.25mm) Hex Driver. Any debris on the implant platform or restorative shoulder must be removed. Irrigate the internal aspect of the implant body/screw hole and thoroughly dry.</td>
</tr>
<tr>
<td>Single-stage implants: Verify the implant platform diameter by color-code and choose the corresponding Single-stage Simple Solutions Abutment with the desired height: 4.0mm or 5.5mm.</td>
</tr>
<tr>
<td>Internal / Tapered Internal implants: Verify the implant platform diameter by color-code and choose the corresponding Internal Simple Solutions Abutment with the desired collar height (0.8, 1.8 or 2.8mm) AND abutment height (4.0 or 5.5mm). Healing Abutments matched to the emergence and collar heights of Internal Simple Solutions Abutments are available. Please contact BioHorizons Customer Care for ordering information.</td>
</tr>
<tr>
<td><strong>ALTERNATIVE TECHNIQUE:</strong> Patients may present for restoration with an unmodified Simple Solutions Abutment with a provisional prosthesis in place (e.g. PEEK Healing Cap). If so, carefully remove the provisional using standard crown removal procedures and proceed with the impression procedure as described on page 9. If the provisional can be removed intact, it may be re-seated while the laboratory fabricates the final prosthesis. Otherwise, it will be necessary to seat a new Healing Cap or fabricate a new provisional.</td>
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<table>
<thead>
<tr>
<th>Deliver Simple Solutions Abutment</th>
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<tbody>
<tr>
<td>Seat the Simple Solutions Abutment and Abutment Screw using the .050” (1.25mm) Hex Driver (finger-tighten: 10-15 Ncm). Aligning one of the anti-rotation flats to the facial/buccal will aid component indexing and leave more room for porcelain on the facial of the prosthesis.</td>
</tr>
<tr>
<td>If the implant/abutment connection is obscured by tissue, radiographically verify complete abutment seating prior to torquing the Abutment Screw to 30Ncm using the .050” (1.25mm) Hex Driver and a calibrated Torque Wrench.</td>
</tr>
<tr>
<td>An Abutment Clamp may be used to apply counter-torque during the tightening procedure. Grasp the exterior of the abutment with the Clamp and hold it against the rotation of the wrench to shield the bone from excess stress.</td>
</tr>
<tr>
<td><strong>ALTERNATIVE TECHNIQUE:</strong> An intra-oral scan may be taken of the seated abutment if a Computer-assisted Design/Computer-assisted Machined (CAD/CAM) restoration is desired. See page 15 for more information.</td>
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Seat Impression Cap

Select an Impression Cap corresponding exactly to the prosthetic platform and abutment height. Failure to do so will result in a unusable impression. See page 11 for information on differentiating Impression Cap height.

Verify the abutment and restorative shoulder are dry and free of all debris. The Impression Cap will not seat properly unless all impediments are removed.

If a provisional prosthesis was in place prior to the impression procedure, remove all residual cement from the abutment and restorative shoulder, as well as material used to blockout the screw access channel prior to seating the Impression Cap.

Seat the Plastic Impression Cap on the Abutment being certain to align the internal flats of the Cap with the two flats on the abutment. The exterior ridges on the Cap are used as visual guides to help alignment. An internal ring snaps into the groove at the base of the abutment, holding it securely in place. A core pin within the Cap seats into the abutment screw access channel for stability.

Core pin within the Cap engages the screw access channel for added stability

Impression Cap snaps into circumferential groove

Ridges on the Cap align with the Abutment flats

A perceptible snap will be felt as the Cap becomes fully seated
Syringe a medium- or heavy-bodied elastomeric impression material around the Impression Cap. Record the full arch impression with the tray loaded with the same or heavier-bodied impression material. After the impression material has set, remove the tray with the incorporated Cap from the patient’s mouth. Verify complete adaptation of the impression material around the Cap.

Verify complete adaptation of the impression material around cap

Fill the screw access channel in the abutment with a resilient material of choice to prevent the ingress of cement into the screw hole.

Place a small amount of soft access cement around the inside margin of the Healing Cap and seat over the Abutment. Remove all excess cement from sulcus area. Check and modify occlusion to eliminate contacts.

Acrylic may be added to the Healing Cap to create a more esthetic provisional restoration. Score the exterior surface of the Cap to help create added surface area for a better mechanical bond.
LABORATORY PROCEDURE

Send Case to Lab

Send the Replica and Waxing Sleeves (contained in Simple Solutions Kit) with the impression to the dental laboratory for prosthesis fabrication. Be certain to send a bite registration, shade and the opposing model or impression.

Seat Replica

Seat the Replica in the impression, being certain to index the flats of the Replica to the flats of the Impression Cap. The Replica has a circumferential groove to engage the snap ring of the Impression Cap and hold it securely in place.

A soft tissue model material is always recommended around the Replica, and is essential whenever the crown margin will be subgingival. Verify proper Replica seating and apply lubricant where soft tissue model material is to be applied.

Impression Cap Height Differentiation

When Impression Caps of the same color (prosthetic platform) but different heights are present, visually inspect for the V-groove before seating Replicas. Presence of the groove on the core pin indicates 4.0mm Cap height; absence of the groove indicates 5.5mm height.

⚠️ Mismatching Impression Cap and Replica heights and/or color will result in an inaccurate, unusable working cast.
Use standard laboratory technique to fabricate the working cast with extra hard low-expansion dental stone.

⚠️ Soft tissue material (gingival mask) is always recommended, and is essential for subgingival crown margins.

Articulate according to standard laboratory procedures.

Alternative Technique: The working cast may be scanned by optical or touch-device methods if a Computer-assisted Design/Computer-assisted Machined (CAD/CAM) restoration is desired. See page 15 for more information.

Pour Working Cast

Select Waxing Sleeve

Select the appropriate Plastic Waxing Sleeve: either Crown (single-unit) or Bridge (multiple-unit) and reduce the height as needed. The Waxing Sleeves snap on to the Replicas in the same manner as the Impression Caps.

Technicians may opt to reduce or remove the snap feature from the Waxing Sleeves with the Casting Reamers (see page 14) prior to beginning the wax-up. This will make it easier to remove the coping from the Replica. If the retentive snap is removed, take care to ensure the Waxing Sleeve sits properly on the Replica throughout the waxing procedure.

The Waxing Sleeves for Crown are visually differentiated by exterior ridges and have internal anti-rotation flats to engage the replica flats. The Waxing Sleeves for Bridge have no anti-rotational feature, and therefore must not be used for single-units.

Alternative Technique: See the facing page for an alternative method for fabricating wax copings using Simple Solutions Replica Lab Tools.
Follow the alloy manufacturer’s recommendations for spruing. Do not use debubblizers or surfactants as they may leave a residue which can cause a rough internal surface on the casting because the plastic expands first before it starts to burn out. Failure to place the wax layer can result in fractures and/or breakdown of the investment yielding a poor casting.

Clean the interior portion of the coping with alcohol on a cotton swab to remove wax, dirt or oil residues.

**Replica Lab Tools (alternative technique)**

Technicians preferring to create copings without use of the Waxing Sleeves may wax directly to the Simple Solutions Replica Lab Tools. The double-ended tools (4.0mm platform / 5.5mm platform) precisely mimic the geometry of Simple Solutions Replicas including the anti-rotation flats, but WITHOUT the retentive snap feature. Castings made from copings fabricated on the Replica Lab Tools do not require use of the Casting Reamers as described on page 14.

Available for each of the three prosthetic platforms, please contact BioHorizons Customer Care for ordering information.

**Invest and Cast**

Follow the alloy manufacturer’s recommendations for spruing. Do not use debubblizers or surfactants as they may leave a residue which can cause a rough internal surface on the casting. Use a phosphate bonded investment and follow the manufacturer’s recommendations for a two stage burn-out.

**Rapid-fire burn-out techniques may cause fracturing in the investment during the process of burning out the plastic.**

Cast the coping or framework from a high noble alloy, following the manufacturer’s recommendations. After casting, remove as much of the investment as possible from the external surfaces of the casting with blasting media. Protect the internal aspect of the casting to prevent damage to the interface during divestment.

Remove the investment from the internal surfaces of the castings with a hydrofluoric acid substitute in an ultrasonic bath or a fiberglass brush. Glass beads may be used instead, but are not the preferred choice for accuracy.
The Waxing Sleeve’s snap ring is replicated in the casting, and must be removed prior to seating the casting on the model. Failure to do so will prevent proper seating of the casting. This step is not necessary if the snap feature was removed from the Waxing Sleeve prior to casting.

Casting Reamers are available for removing the snap feature of each of the three prosthetic platforms. Working under magnification, remove the snap feature with the cutting edge of the Reamer, taking care not to damage the margin of the casting. The Reamer features a built-in stop preventing removal of too much material.

**Biohorizons Casting Reamers are designed for use with noble or high-noble alloys; do not use with castings made of non-precious metals.**

**ALTERNATIVE TECHNIQUE:** Castings fabricated on Replica Lab Tools do not require use of the Casting Reamers because the snap feature is not replicated in the wax-up (see page 13).

1. Insert appropriate diameter Reamer into the casting.
2. Apply firm pressure and rotate several complete turns in a clockwise direction. Built-in stop prevents excessive removal of material.
3. Remove Reamer and verify passive fit on the Replica in working cast.

Snap feature must be removed for casting to seat properly.

Reamer will “bottom out” or stop when cutting is complete.
LABORATORY PROCEDURE

Veneer the Framework

Verify the fit of the casting on the working cast and/or return to the clinician for patient try-in. Following verification of fit, prepare the casting to receive the opaque layer according to routine laboratory procedures. Apply veneering material and finish according to manufacturer’s specification. Polish any metal margins as is routine. Return the finished prosthesis to clinician.

CAD/CAM Ceramic Restorations (alternative technique)

The following is a brief description of how Simple Solutions Abutments may be used in Computer-assisted Design/Computer-assisted Machined (CAD/CAM) restorations. Please consult a dental laboratory technician or other qualified source for detailed information.

The process is initiated by either an intraoral scan of the seated Abutment with a small handheld infrared camera, or by an optical or physical touch-device of the Replica in a stone cast at the laboratory. Follow procedures discussed earlier in this manual to seat the abutment in the patient and/or create the stone cast as required.

Information from the scan of either the Abutment or Replica will be entered into a computer program where it will be used by the clinician or technician to design a custom prosthesis. The retentive groove and the screw access channel on the Abutment or Replica must either be physically blocked-out before the scan or removed via the computer design program, to prevent these features from being replicated in the custom-milled prosthesis.

The design is then entered into an automated milling machine which mills a prosthetic framework out of solid ceramic. The framework can receive a layer of veneering material after milling, per standard laboratory procedures. Following processing, the fit and occlusion are verified and the prosthesis is bonded into place.
Sanitize the final restoration. Remove the Healing Cap or provisional prosthesis. Make sure the restorative shoulder and Abutment are free of all temporary cement. Re-torque the Abutment Screw to 30Ncm using a calibrated Torque Wrench and the .050" (1.25mm) Hex Driver.

Fill the access hole in the abutment with a resilient material of choice. This allows access to the Abutment Screw in the future if needed. Seat the prosthesis and confirm fit and contour. Check and modify occlusion if necessary.

Place a small amount of cement around the inside margin of the prosthesis. Soft-access cement may be used for future retrievability. Seat the prosthesis and remove all excess cement from sulcus area.

Roughing of the Simple Solutions Abutment surface will facilitate retention of the restoration when using soft cements, or where short abutment height requires additional surface area for permanent cementation.

Coarse rotary instruments can be utilized or surface micro-blasting with 50 micron aluminum oxide. Mounting the abutment the corresponding implant-level analog is recommended during micro-blasting to prevent damage to the implant/abutment interface.

Following seating of the restoration, take a radiograph for final prosthesis delivery records. The patient should be given complete oral hygiene instructions prior to release.
Modified Simple Solutions Abutments *(alternative technique)*

If a Simple Solutions Abutment requires modification, it will be necessary to make a Crown & Bridge-type of impression of the abutment. Simple Solutions Restorative Components cannot be used in these cases.

Block out the screw access hole of the abutment with a resilient material of choice. The use of retraction cord may be necessary to ensure the transfer of the margin of the restorative shoulder. Syringe light or medium-bodied impression material around abutment. Use medium or heavy-bodied impression material in the tray. Make a full-arch Crown & Bridge impression with the elastomeric impression material of choice.

Send the impression, an opposing model or impression and a bite registration to the laboratory for prosthesis fabrication. For chair-side provisional fabrication, lightly lubricate the modified abutments and use the technique and material of choice.

*Alternative Technique: An intra-oral scan may be taken of the seated abutment if a Computer-assisted Design/Computer-assisted Machined (CAD/CAM) restoration is desired. See page 15 for more information.*
Torque, as typically related to implant dentistry, is the measure of rotational force delivered to an abutment screw. The delivery of specific torque values to abutment screws helps control implant/abutment joint integrity during patient function. 30 Newton centimeters (Ncm) is the recommended torque value for the Abutment Screw (ref. PXAS) used to secure Simple Solutions Abutments.

Hand-tightening components (using a hex driver without a torque wrench) has been shown to deliver a torque value of about 13 Ncm; but the actual value varies widely by individual user. Therefore, the use of a calibrated torque wrench is recommended to ensure delivery of accurate torque values.1

Seat the abutment and hand-tighten the screw with a .050” (1.25mm) Hex Driver. Radiographically verify complete abutment seating whenever the implant/abutment connection is obscured (e.g. subgingival). Insert a .050” (1.25mm) Hex Driver into a calibrated 30 Ncm Torque Wrench in the “closed” position (see opposite page).

Engage the screw with the driver and apply firm apical pressure to ensure proper seating. Failure to fully engage the hex of the screw may cause stripping of the driver or the abutment screw (see opposite).

Turn the wrench slowly in a clockwise direction until the hinge “breaks”, which indicates the calibrated torque value has been delivered.


Use of an Abutment Clamp to provide counter-torque can protect the bone/implant interface from excessive shear force during torque delivery. The practice is particularly important in softer (D4) bone.

Grasp the abutment (see above) and hold it steady while the torque is being applied. This helps prevent the rotational force of the Torque Wrench from being transmitted to the bone/implant interface.

Please refer to either the Internal / Single-stage Product Catalog (ref. ML0115) or Tapered Internal Product Catalog (ref. ML0603) for ordering information.
**APPENDIX**

**Hex Driver / Abutment Screw Engagement**

The tips of BioHorizons Hex Drivers are slightly tapered to allow a friction-fit engagement of mating screws and components. The taper allows screws to be carried to the restorative site on the hex driver. However, while the taper enhances clinical utility, it requires the driver be engaged to the full depth of the hex hole before torque is applied. Failure to fully engage the hex may cause stripping of either the driver or the screw. A gloved finger may be placed on the top of the driver to provide apical pressure to keep the driver fully engaged.

Use of magnification may be required to verify the absence of foreign material in the hex hole. If a provisional prosthesis was in place prior to final torque delivery, remove all material used to blockout the screw access channel prior to seating the driver. A dental probe or similar instrument may be useful for removing impediments.

![Hex Driver / Abutment Screw Engagement Diagram](image)

**Autoclaving Hinge-type Torque Wrenches**

Autoclaving hinge-type Torque Wrenches in the “broken” position extends the period of time between required recalibration. Manually verify the wrench’s hinge mechanism is properly functioning prior to clinical application of torque. Please refer to the Instructions for Use accompanying Torque Wrenches for additional information.

![Autoclaving Hinge-type Torque Wrenches](image)

“Broken” position  
“Closed” position
Simple Solutions Support Material

**MLV129**
**Animated Restorative Technique Guide**
Guides the clinician and laboratory through impression making techniques and prosthetic/lab procedures with the BioHorizons Simple Solutions components.

**ML0115**
**Internal / Single-stage Product Catalog**
Complete ordering information for BioHorizons Internal and Single-stage implants, prosthetic components and ancillary instruments.

**ML0603**
**Tapered Internal Product Catalog**
Complete ordering information for BioHorizons Tapered Internal implants, prosthetic components and ancillary instruments.
**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 Simple Solutions prosthetic components used with BioHorizons Single-stage implants. 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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**Symbol descriptions for product labeling**

- **LOT**: Lot/batch number
- **REF**: Reference/article number
- **STERILE**: Sterile by gamma irradiation
- **NON-STERILE**: Non-sterile
- **Rx Only**: Caution: Federal (USA) law restricts these devices by, or on the order of, a dentist or physician.

- **Single use only**:  
- **Refer to Instructions for Use**:  
- **Use before expiration date**:  

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

**Prosthetic platform**

- Ø3.5mm Prosthetic Platform
- Ø4.5mm Prosthetic Platform
- Ø5.7mm Prosthetic Platform

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**ICON LEGEND**

Symbols for product labeling:

- **Lot/batch number**: LOT
- **Reference/article number**: REF
- **Sterile by gamma irradiation**: STERILE
- **Non-sterile**: NON-STERILE
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**Prosthetic platform**

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BioHorizons products are cleared for sale in the European Union under the EU Medical Device Directive 93/42/EEC. We are proud to be registered to ISO 13485:2003, the international quality management system standard for medical devices, which supports and maintains our product licences with Health Canada and in other markets around the globe.

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