IMPORTANT PRODUCT INFORMATION
FOR BIOMET 3I ABUTMENTS AND OTHER RESTORATIVE COMPONENTS

This document applies to all BIOMET 3I dental implant abutments and overdenture bar/frameworks.

Description: BIOMET 3I Dental Implant Abutments and Overdenture Bars and/or Frameworks are manufactured from biocompatible materials (including titanium, titanium alloy, gold alloy, ceramic and PEEK – polyether-ether-ketone). BIOMET 3I Implant Abutments may have various treatments such as titanium nitride and anodized surfaces and/or coatings. For specific product descriptions and net quantities, please refer to individual product labels.

Indications for Use: BIOMET 3I Dental Implant Abutments, Overdenture Bars and/or Frameworks are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially edentulous or edentulous patient. These are intended for use to support single- and multiple-tooth prostheses in the jaws. For compatibility of Bellatek™ Patient Specific Abutments, please refer to Table 1 below.

Contraindications: Do not use these components if the patient has a known hypersensitivity to titanium, titanium alloy, gold alloy, ceramic materials, or PEEK.

Storage and Handling: The components should be stored at room temperature. Refer to individual product labels and the Restorative Manual for special storage or handling conditions, if any.

Sterility: Some components are supplied sterile. Refer to individual product labels for sterilization information; all sterile products are labeled ‘STERILE’. All products sold sterile are for single use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened.

Instructions for BIOMET 3I Restorative Components Requiring Sterilization Before Use: Products provided non-sterile must be sterilized prior to use. Use a steam gravity sterilization method – minimum fifteen (15) minutes at a temperature of 270-275°F (132-135°C) or pre-vacuum sterilization method – minimum four (4) minutes (four pulses) at a temperature of 270-275°F (132-135°C). Drying times may vary according to load size.

BIOMET 3I recommends cold sterile solution processing as the preferred sterilization method for the Zinital™ Posts Ceramic Abutments and Bellatek Ceramic Patient Specific Abutments (EDA2).

Do not re-sterilize or autoclave components except where instructions are provided on the product label, the Restorative Manual, or in any additional product literature for the given component.

Warnings: Handling of small components inside the patients’ mouth carries a risk of ingestion and/or aspiration.

When restorative components are loaded beyond their capacity, breakage may occur. It is recommended that small diameter implants not be restored with angled abutments in the posterior region. It is recommended to be placed in the anterior region of the mouth.

PEEK components are intended for use to support single- or multiple-unit provisional prostheses in the mandible or maxilla for up to 180 days, at which time a definitive prosthesis should be inserted.

reuse of BIOMET 3I products that are labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

BIOMET 3I Dental Implant Abutments have not been evaluated for safety and compatibility in the Magnetic Resonance Imaging environment. BIOMET 3I Dental Implant Abutments have not been tested for heating or migration in the Magnetic Resonance Imaging environment.

Precautions: For safe and effective use of BIOMET 3I Dental Implant Abutments and other surgical and restorative dental accessories, these products or devices should only be used by trained professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures. Improper technique or loading can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and/or aspiration. Excessive forces applied to the dental implant should be avoided. Proper occlusion of the restoration should be evaluated and the patient’s parafunctional habits should be taken into consideration.

Potential Adverse Events: Potential adverse events associated with the use of restorative components may include:

• Infection or mucosal inflammation due to poor maintenance and cleaning of the components
• Excessive bone loss requiring intervention
• Implant or component failure
• Choking from aspiration of components

For detailed information on the specific procedure for the product being used, please refer to the individual product labels and/or the appropriate manual.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed dentist or physician.

Table 1 - Compatibility Chart for Patient Specific Abutments

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Implant</th>
<th>Platform (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomet 3I</td>
<td>Certain Osseotite, Nanosite</td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>Ex-Hex Osseotite, Nanosite</td>
<td>4.1</td>
</tr>
<tr>
<td>Internal Connection Nobel Replace Implant</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>Internal Connection Nobel Active Implant</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>Straumann</td>
<td>Straumann Bone Level Implant</td>
<td>4.1</td>
</tr>
</tbody>
</table>

*NOTE: The maximum angle of the EDA and EDAX abutments should not exceed 30°.