

## EN IMPORTANT PRODUCT INFORMATION

This document applies to all BIOMET 3i™ Restorative Products.

For detailed information on the specific procedure for the product you are using, please refer to the individual product labels or the appropriate manual on the BIOMET 3i website.

**Description:** BIOMET 3i Restorative Products are manufactured from biocompatible titanium, titanium alloy, gold, gold alloy, zirconium, stainless steel, polyetheretherketone (PEEK), cobalt chromium alloy, and polyoxymethylene (Delrin). Please refer to product Guidelines for Use/Surgical Manual for additional device information.

**Indications for Use:** BIOMET 3i Restorative Products are intended for use as an accessory to endosseous dental implants for placement in the maxilla and mandible.

Provisional Abutments are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. They are intended for use to support a prosthesis in the mandible or maxilla for up to 180 days during endosseous and gingival healing, and are for non occlusal loading of provisional restorations. The prosthesis will be either cement, mechanically or screw retained to the abutment system based on individual product design.

For compatibility of BellaTek Patient Specific Abutments, please refer to the compatibility table in accompanying document.

**Contraindications:** Placement of BIOMET 3i Restorative Products are precluded by known patient hypersensitivity to any of the materials listed in the Description Section of this document.

**Warnings:** Mishandling of small components inside the patient's mouth carries a risk of aspiration and/or swallowing. Fracture of a restoration may occur when an abutment is loaded beyond its functional capability. 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.

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.

**Sterility:** Some BIOMET 3i Restorative Products 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 "use by" date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Products provided non-sterile may need to be cleaned and sterilized prior to use. Please refer to the individual product labels or Restorative Manual for more information. For products provided non-sterile requiring sterilization prior to use, BIOMET 3i recommends the following sterilization parameters for wrapped items:

Steam gravity sterilization method (gravity-displacement cycle) - Minimum exposure of fifteen (15) minutes timing at a temperature of 270°-275°F (132-135°C)\* or

Pre-vacuum sterilization method (dynamic-air-removal cycle) - Minimum exposure of four (4) minutes, four (4) pulses timing at a temperature of 270°-275°F (132-135°C)\*

\*Post sterilization, devices should be thoroughly dried for 30 minutes. Please refer to the Surgical and Restorative Manual or package insert for the remaining care and cleaning instructions.

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












**MRI Statement:** BIOMET 3i Restorative Products have not been evaluated for safety, heating, migration, or compatibility in the Magnetic Resonance Imaging (MRI) environment.

**Precautions:** BIOMET 3i Restorative Products should only be used by trained professionals. The surgical and restorative techniques required to properly utilize these products are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration. Components made from PEEK material are intended for use for up to 180 days.

**Potential Adverse Events:** Potential adverse events associated with the use of restorative products may include: failure to integrate; loss of integration; dehiscence requiring bone grafting; Infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency; gingival hyperplasia; Excessive bone loss requiring intervention; fracture; and nerve injury.

**Storage and Handling:** BIOMET 3i Restorative Products should be stored at room temperature. Refer to the Surgical Manual for special storage or handling conditions.

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

 Date of Manufacture	 Use by date
 Catalogue number	 By prescription only
 Batch code	 Do not use if package is damaged
 Caution, consult accompanying documents	 Consult Instructions for Use
 Do not re-use	 Do not re-sterilize
 Sterilized using gamma irradiation	

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**EC REP**

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