INSTRUCTIONS FOR USE

This document applies to BIOMET 3i Certain BellaTek® Express and BellaTek® Flex Abutment 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.

eLabeling:
The Instructions for Use can be accessed online by visiting the website provided on the label. Additional translations are also available in electronic format for download.

Description:
The Certain BellaTek Express Abutment and BellaTek Flex Abutment are two-piece titanium-base type abutments. They are intended to be used with Biomet 3i Certain (Internal Hex) dental implants for single and multi-unit restorations. Certain BellaTek Express Abutment and BellaTek Flex Abutment are available in hexed (single-unit) and non-hexed (multi-unit) configurations. They are available in pre-defined platform diameters, emergence profiles and heights to accommodate varying patient anatomies. They are machined from Titanium Alloy Ti-6Al-4V ELI (ASTM F136). They are intended for single use only. The device is packaged in a sealed nylon bag and provided non-sterile.

Indications for Use:
Certain BellaTek Express and BellaTek Flex Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained.

All digitally designed superstructures and/or hybrid abutment crowns for use with Certain BellaTek Express or BellaTek Flex Abutments are intended to be sent to a Biomet 3i validated milling center for manufacture.

Directions for Use:
A superstructure design file is created by the clinician/lab technician and sent to a validated milling center. After the superstructure design file is received by a validated milling center, it is uploaded to the milling machine to mill the superstructure. All digitally designed superstructure and/or hybrid crowns for use with Certain BellaTek Express and BellaTek Flex Abutments are intended to be sent to a registered and listed Biomet 3i validated milling centers for milling. Visit www.zimmerbiometdental.com/vmc for a list of validated milling centers.

Design limitation parameters for the custom zirconia superstructure and/or hybrid crown are included in the following table:
<table>
<thead>
<tr>
<th>Description</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Height</td>
<td>4.7 mm</td>
<td>12.0 mm</td>
</tr>
<tr>
<td>Gingival Margin Diameter</td>
<td>3.8 mm</td>
<td>16.0 mm</td>
</tr>
<tr>
<td>Gingival Margin Height (Collar)</td>
<td>0.25 mm</td>
<td>6.0 mm</td>
</tr>
<tr>
<td>Total Height</td>
<td>5.3 mm</td>
<td>15.0 mm</td>
</tr>
<tr>
<td>Wall Thickness</td>
<td>0.15 mm</td>
<td>N/A*</td>
</tr>
</tbody>
</table>

*Feature maximum size is based on patient anatomy and clinician discretion.

Superstructure and/or hybrid crowns designed using CAD/CAM techniques must fulfill Biomet 3i allowable range of design parameters. The end-user should modify the ceramic top-half using hand tools, if necessary to ensure proper occlusion. These modifications should not change/exceed any of the dimensions outside of the design envelope as listed in the superstructure design parameters table above.

Biomet 3i recommends the use of Ivoclar Vivadent Multilink Hybrid Abutment Cement to affix the zirconia superstructure and/or hybrid crown to the Certain BellaTek Express and BellaTek Flex abutments.

Biomet 3i validated milling center must fabricate the digitally designed superstructures from zirconia conforming to ISO 13356:2015 and ISO 6872:2015.

**Contraindications:**
Placement of the Certain BellaTek Express and BellaTek Flex Abutments is precluded by known patient hypersensitivity to Titanium Alloy (Ti-6Al-4V ELI).

**Warnings:**
Mishandling of small components inside the patient’s mouth carries a risk of ingestion, aspiration and/or swallowing. 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.

**Precautions:**
Certain BellaTek Express and BellaTek Flex Abutment 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 fracture, screw loosening, ingestion and aspiration and/or swallowing.

**Potential Adverse Effects:**
Potential adverse events associated with the use of Certain BellaTek Express and BellaTek Flex Abutments may include: Infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency; gingival hyperplasia; excessive bone loss requiring intervention; ingestion, aspiration and/or swallowing and nerve injury.
Sterility and Shelf Life:
The Certain BellaTek Express and BellaTek Flex abutment, are packaged as a single use, non-sterile product and must be sterilized prior to use by a clinician. The end-user shall perform any modifications necessary for proper occlusion to the zirconia superstructure, cement it with Certain BellaTek Express or BellaTek Flex abutment, and then perform sterilization on the final cemented assembly. The recommended sterilization methods in accordance with ANSI/AAMI ST79 are gravity-displacement steam sterilization or pre-vacuum steam sterilization method using an FDA cleared sterilization wrap or pouch. The gravity-displacement steam sterilization method requires sterilization for minimum fifteen (15) minutes at a temperature of 132 °C/270 °F. Post gravity steam sterilization method, devices should follow a 30 minute dry time with a 30 minute cool down time. The pre-vacuum steam sterilization method requires sterilization for minimum four (4) minutes (4 pulses) at a temperature of 132 °C/270 °F. Post pre-vacuum sterilization method, devices should follow a 30 minute dry time with a 30 minute cool down time. Do not re-sterilize the Certain BellaTek Express and BellaTek Flex Abutment. Certain BellaTek Express and BellaTek Flex Abutment has no shelf life as it is supplied non-sterile.

Single Use:
Do not reuse Certain BellaTek Express and BellaTek Flex Abutments. Reuse of a single use device that has come in contact with blood, bone, tissue, body fluids or other contaminants may lead to patient or user injury.

Product Packaging:
Certain BellaTek Express and BellaTek Flex Abutments has been cleaned and packaged within an environmentally controlled room for convenience and immediate use. They are provided in a sealed nylon bag. The label on the packaging contains a lot number that should be recorded in the patient’s file to ensure complete traceability of the product.

Storage and Handling:
Certain BellaTek Express and BellaTek Flex Abutments should be stored at room temperature.

Magnetic Resonance Imaging (MRI) Safety Information:
Non-clinical testing has demonstrated the Certain BellaTek Express and BellaTek Flex Abutment are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
Under the scan conditions defined above, the BIOMET 3i Restorative Products are expected to produce a maximum temperature rise of less than 4º C at 3.0 T and 3º C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends radially up to 2.7 cm and 2.2 cm from the implant when imaged with a gradient echo-pulse sequence and 3.0 T and 1.5 T MRI systems, respectively.

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