INSTRUCTIONS FOR USE

This document applies to TSV™ BellaTek® Encode® Healing Abutments 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 TSV BellaTek Encode Healing Abutment is a two piece healing abutment designed to facilitate gingival tissue healing. It consists of an abutment and a retaining screw that are assembled together. Both components are machined from Titanium Alloy (Ti-6AL-4V ELI). The shelf life of the TSV BellaTek Encode Healing Abutment is 5 years from the date of manufacture and they are intended for single use only. The device is packaged in a sealed nylon bag and sold sterile. The device is sterilized using the gamma irradiation method. TSV BellaTek Encode Healing Abutments are compatible with the following implants:

<table>
<thead>
<tr>
<th>Implant System</th>
<th>Implant Diameter (mmD)</th>
<th>Implant Platform Diameter (mmD)</th>
<th>Implant Length (mmL)</th>
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</thead>
<tbody>
<tr>
<td>Tapered Screw-Vent®</td>
<td>3.7</td>
<td>3.5</td>
<td>8, 10, 11.5, 13,16</td>
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<td>4.1</td>
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<td>6.0</td>
<td>5.7</td>
<td>8, 10, 11.5, 13,16</td>
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<tr>
<td>Screw-Vent®</td>
<td>3.3</td>
<td>3.5</td>
<td>8,10,13,16</td>
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<td></td>
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<tr>
<td>Trabecular Metal™</td>
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</tr>
</tbody>
</table>

Indications for Use:
The TSV BellaTek Encode Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.

Contraindications:
Placement of the Encode 2-Piece Healing Abutment is precluded by 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, swallowing and/or choking. Fracture of a restoration may occur when an abutment is loaded beyond its functional capability. Potential overloading conditions may result in, or from, significant bone loss, deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing/clenching), loss or changes in dentition or functionality, improper casting procedures, inadequate prosthesis fit, and physical trauma. Additional treatment may be necessary when any of the above conditions are present to reduce the possibility of breakage. 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:**
TSV™ BellaTek® Encode® Healing Abutments 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, ingestion and aspiration and/or swallowing.

**Potential Adverse Effects:**
Potential adverse events associated with the use of TSV™ BellaTek® Encode® Healing Abutments 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; ingestion, aspiration and/or swallowing and nerve injury.

**Sterility and Shelf Life:**
The TSV™ BellaTek® Encode® Healing Abutments are supplied sterile and are for single use only. Do not re-sterilize the TSV™ BellaTek® Encode® Healing Abutments. All products sold sterile are for single-use before the “use by” date printed on the product label. The product expiration date is indicated by the hourglass symbol on the product label, followed by the year, month & day of expiration. Do not use sterile products if the packaging has been damaged or previously opened.

**Single Use:**
Do not reuse TSV™ BellaTek® Encode® Healing 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:**
TSV™ BellaTek® Encode® Healing Abutments have been cleaned, packaged within an environmentally controlled room, and sterilized for convenience and immediate use. The label on
the inner packaging contains a lot number that should be recorded in the patient’s file to ensure complete traceability of the product.

**Storage and Handling:**
TSV™ BellaTek® Encode® Healing Abutments should be stored at room temperature.

**Magnetic Resonance Imaging (MRI) Safety Information:**
Non-clinical testing has demonstrated the TSV™ BellaTek® Encode® Healing Abutments 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 4° C at 3.0 T and 3° 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.
**Disclaimer:**

This document is intended exclusively for dental professionals and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.