

## INSTRUCTIONS FOR USE

### ZIMMER® ZFX™ ABUTMENT FOR USE WITH ZIMMER IMPLANT SYSTEMS, ZIRCONIA

Before using a product placed on the market by Zimmer Dental or Biomet 3i, LLC ("Zimmer Biomet"), the operating surgeon/practitioner should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., technical product description, description of the surgical and restorative technique, catalog sheet, etc.) and fully comply with them. Zimmer Biomet is not liable for complications arising from the use of the device outside of its indicated uses.

#### Sterility

Abutments are sold non-sterile and are intended for single use. Sterilization is recommended prior to insertion in dental patients.

#### Precautions

Proper case planning is essential to the long-term success of both the prosthesis and the implant. Overload is one of the key contributors to implant failure particularly in the molar region where occlusal loads are typically the highest. Ensure the implant size and abutment angulation are appropriate for the occlusal load. Highly angled abutments should be avoided in the posterior region. Highly angled abutments (i.e. 30 degrees) should be used in the anterior region of the mouth due to potential excess load created in the pre-molar and molar region. Splinting should be considered where appropriate. Appropriate tightening of the screw is essential to prevent premature loosening. Bulk trimming of abutments should be performed outside the oral cavity to minimize any heat transfer to implant and supporting structures.

#### Product Compatibility

Detailed instructions over and above those contained in this instruction for use concerning the possible combinations product-specific risks, preparatory steps, indications and contraindications etc can be found in the description of the surgical technique in the technical description of the product or on the appropriate catalogue sheet. Zimmer Biomet also recommends attending the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the Zimmer Biomet representative in the various countries.

#### Description

The *Zimmer Zfx* Abutment in Zirconia for *Zimmer Tapered Screw-Vent*® Implant System is a zirconia post with an attached titanium ring that is unique for each patient. The abutment engages the internal hex of the implant and is secured with a separate retaining screw.

#### Labeling Identification



#### Design Guidelines

Abutments must be designed according to good dental practice and be appropriate for the clinical situation. All components must have sufficient volume and support to withstand anticipated loading requirements. Please reference the design parameters in the table below prior to designing an abutment.

Design Parameters		Range
Cuff Width/Diameter	3.5mm Platform	3.5-8.0 mm
	4.5mm Platform	4.5-8.0 mm
Cone Angle		0°-30°
Minimum Cone Height		3.0mm
Overall Height		3.5-12.0mm

#### Indications

The *Zimmer Zfx* Abutment in Zirconia for *Zimmer Tapered Screw-Vent* Implant System is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for single or multiple-unit restorations in anterior and pre-molar regions.

#### Contraindications

The zirconia abutment is contraindicated for use in the molar region. DO NOT AUTOCLAVE. Do not apply porcelain directly to the zirconia abutment.

#### Cleaning

Disassemble the abutment and screw. Rinse in cool to lukewarm water for two-and-one-half minutes. Place in an ultra sonic cleaner with an enzymatic detergent diluted with tap water per the manufacturer's guidelines. Sonicate for 10 minutes. Rinse with tap water for three minutes.

#### Sterilization

For zirconia abutments, disassemble the abutment and screw then perform dry heat sterilization at 160°C/320°F for 2 hours. **DO NOT AUTOCLAVE ZIRCONIA ABUTMENTS.**

### Preparing the Zirconia Abutment











Should modifications be necessary, coronal walls can be reduced to 0.5mm thickness. Do not prepare the hex or implant interface area. Only use burs manufactured for use on ceramics when modifying zirconia abutments.

### Procedure

- A. Remove the surgical cover screw, healing collar or temporary abutment from the implant using a 1.25mmD hex tool.
- B. Place the abutment on the implant. Rotate it sufficiently to engage the hex and ensure seating of the abutment. Once the abutment is in place, tighten the retaining screw with a 1.25mmD hex tool.
- C. If modifications are needed, mark areas of reduction and remove abutment to perform bulk trimming extra-orally. Do not prepare the abutment implant interface area. Re-insert abutment to original position and re-evaluate reduction.
- D. To achieve optimum torque, tighten the retaining screw to 30 Ncm with a calibrated prosthetic torque wrench. Following modification and reattachment, verify with periapical x-rays that the abutment is seated flush onto the implant.
- E. Block out the screw access hole with appropriate material.
- F. Cement final prosthesis in place. Remove excess cement. When cementing an all-ceramic crown to the zirconia abutment, be sure to use a cement recommended by the porcelain manufacturer for zirconia and follow the instructions as provided by the manufacturer of the cement.

### Changes in Performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications and precautions as well as to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g. looseness of the prosthesis, infection or exudate around the implant, pain or any other unusual symptoms that the patient has not been told to expect). If these conditions occur the patient should be instructed to see a trained dental professional immediately.

<u>Labeling Identification</u>	
	Symbol for Legal Manufacturer
	Symbol for Catalogue number
	Symbol for Batch code
	Symbol for Use by Prescription Only
	Consult Instructions for Use <a href="http://www.ifu.biomet3i.com">www.ifu.biomet3i.com</a>
	Symbol for Do not re-use
	Symbol for Non-sterile
	Symbol for Date of Manufacture
	Symbol for Do not use if package is damaged
	Symbol for Hexagon



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