INSTRUCTIONS FOR USE

ZIMMER® ZFX™ ABUTMENT
FOR ZIMMER TAPERED SCREW-VENT® IMPLANT SYSTEMS, TITANIUM

Before using a Zimmer Dental or Biomet 3i, LLC ("Zimmer Biomet") product, the operating surgeon/practitioner in charge should carefully study the indications, contraindications, recommendations, warnings and instructions, as well as all other product-specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) and fully comply with them. 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 appropriate representatives in the various countries. The manufacturer, the importer and the suppliers of Zimmer Biomet products are not liable for complications, injuries, the need for replacement procedures, implant failures, other negative effects or damages that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, use of expired products, patient anatomy, overloading, asepsis and so on. The operating surgeon is responsible for any such complications or other consequences. It is also the operating surgeon's responsibility to properly instruct and inform the patient on the functions, handling and necessary care of the product and on all known product and procedure risks.

Product Compatibility
Zimmer Zfx Abutments for *Zimmer Tapered Screw-Vent Implant System* in Titanium are compatible with the following implant systems.

Implant System	**Screw Tightening Torque**
Zimmer Trabecular Metal™ Dental Implant	30 Ncm
Zimmer Tapered Screw-Vent and *Screw-Vent*® Implants	30 Ncm

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Description
The *Zimmer Zfx* Abutment for *Zimmer Tapered Screw-Vent Implant System* is a titanium alloy post that is unique for each patient. The abutment engages the internal hex of the implant and is secured with a separate titanium retaining screw.

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.

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Design Parameters		**Range**
Minimum Margin Width		0.5mm
Cuff Width/ Diameter	3.5mm Platform	3.5-9.0mm
	4.5mm Platform	4.5-10.0mm
	5.7mm Platform	5.7-12.0mm
Maximum Cone Angle		30°
Minimum Cone Height		3.0mm
Overall Height		3.5-12.0mm

Indications
The *Zimmer Zfx* Abutment for *Zimmer Tapered Screw-Vent Implant System*, Internal Hex, Titanium is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for a single or multiple-unit restoration.

CONTRAINDICATIONS
The abutment is not to be used as a "cast-to" abutment. Zimmer Dental implants should not be placed if there is an insufficient volume of alveolar bone to minimally support the implant (minimum 1mm circumferential and 2mm apical). Implants placed in the maxilla should not perforate the sinus floor membrane. Poor bone quality, poor patient oral hygiene, heavy tobacco use, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction, and psychological instability may

contribute to lack of integration and/or subsequent implant failure. Severe bruxism, clenching, and overloading, may cause bone loss, screw loosening, component fracture, and/or implant failure. Exposure to radiation and chemotherapy may impact health of the implant. Dental implant patients should be instructed to consult with their physician prior to undergoing such treatment options.

Refer to the relevant Zimmer Dental implant system IFUs at ifu.zimmerdental.com for additional information.

WARNINGS
Surgical and restorative techniques required to place dental implants are highly specialized and complex procedures. Practitioners should attend courses of study to familiarize themselves with implantology techniques. Improper technique can cause bone loss, patient injury, pain and implant failure. Zimmer Dental implant systems are intended to be used only with Zimmer Dental specially designed bone drills and prosthetics. Implants placed at unsuitable angles relative to existing dentition or multiple implants placed at convergent/divergent manner can result in complex restorations that may overload implants, potentially leading to implant failure (including fracture). A thorough diagnostic work-up and use of x-rays and surgical templates are recommended to help ensure proper angulation and avoidance of certain anatomical features such as sinus membranes, adjacent teeth and craniofacial nerves.

Other relative warnings include steroid and anticoagulant treatment which may affect the surgical site, surrounding tissue, or patient's healing function. Exposure to long-term use of bisphosphonate drugs especially with chemotherapy may impact implant survival. Careful patient selection including consultation with the patient's physician is strongly recommended prior to implant treatment. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site and allow site to heal as though it were an atraumatic extraction. Due to the metal conductivity, electrosurgery around the implants and intraoral abutment preparations without irrigation could result in tissue damage, patient injury and implant failure.

Refer to the relevant Zimmer Dental implant system IFUs at ifu.zimmerdental.com for additional information.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Non-clinical testing has demonstrated that the evaluated *Zimmer Zfx* Abutment for *Zimmer Tapered Screw-Vent Implant System* is 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 and 3.0 Tesla (T)
- Maximum spatial gradient field of 3000 Gauss/cm (30 T/m).
- Maximum MR system reported, whole body average specific absorption rate (SAR) of less than 2 W/kg (Normal Operating Mode) or less than 4.0 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the *Zimmer Zfx* Abutment for *Zimmer Tapered Screw-Vent Implant System* is expected to produce a maximum temperature rise of less than 4°C after 15 minutes of continuous scanning.

Owing to the low magnetism and the small size of the implant, artifact during MRI is expected to extend less than 2cm beyond the implant.

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. Ensure the implant size and abutment angulation are appropriate for the occlusal load. Highly angulated abutments should be avoided.

Splinting should be considered where appropriate. Appropriate tightening of the screw is essential to prevent premature loosening.

Refer to the relevant Zimmer Dental implant system IFUs at ifu.zimmerdental.com for additional information.

Breakage
Implant and abutment fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. Potential overloading conditions may result from significant bone loss (e.g. >3mm), 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.

Changes in Performance
It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need 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).

Hygiene & Maintenance
Long-term implant health is directly related to the maintenance of oral hygiene. Potential implant candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following implant placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the implant(s). The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

Abutment Preparation
Major abutment reductions should be prepared outside the mouth. Minor abutment modifications may be performed intraorally with irrigation. To minimize heat generation, intermittent cutting using medium grit diamond burs under copious irrigation is recommended**.**

General Considerations

Control of biomechanical stresses is the key factor to long-term success of the prosthesis. Even after implant integration, imbalances in occlusal forces can lead to implant failure. Implant patients should be monitored post-operatively for screw loosening, periimplant bone loss and tooth wear as signs of occlusal overloading.

ADVERSE EFFECTS
The following complications may occur relative to implant placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, the need for additional surgery or removal, local and generalized allergic reaction, lack of integration, loss of bone, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

STERILITY
The *Zimmer Zfx* Abutment for *Zimmer Tapered Screw-Vent Implant System* is sold non-sterile. Sterilize product prior to use in patients. The *Zimmer Zfx* Abutment for *Zimmer Tapered Screw-Vent Implant System* is for single use only.

Single Use
Do not reuse the *Zimmer Zfx* Abutment for *Zimmer Tapered Screw-Vent Implant System*. 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. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

Product Packaging
The *Zimmer Zfx* Abutment for *Zimmer Tapered Screw-Vent Implant System* has been cleaned and packaged within an environmentally controlled room. It is provided in a sealed polybag. The label on the outer packaging contains a lot number that should be recorded in the patient's file to ensure complete traceability of the product. A patient chart label provided containing the lot number can also be placed in the patient file for traceability.

CLEANING/STERILIZATION INFORMATION
Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens. Clinically contaminated implants should not be cleaned and resterilized under any circumstances. Improper cleaning could lead to inadequate sterilization.

Cleaning
Use the following guidelines for cleaning products:

Rinse with cool-to-lukewarm drinkable, tap water for two-and-one-half minutes. For all parts place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Sonicate for 10 minutes. Rinse with drinkable, tap water for three minutes.

Sterilization
When sterilizing individual parts, parts should be placed in sterilization pouch prior to sterilization. The following validated sterilization parameters (method, time and temperature) are required to achieve a 10^{-6} sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table. Verify the calibration of your unit to ensure recommended temperatures are reached. To ensure autoclave is performing effectively, periodic use of biologic indicators should be considered. Chemiclave sterilization is NOT recommended for the *Zimmer Zfx* Abutment for *Zimmer Tapered Screw-Vent Implant System*. Store in the sterilization pouch until use.

Cycle Type	Temperature	Exposure Time	Dry Time
Gravity (steam)	132°C 270°F	15 minutes	20 minutes
Pre-vacuum (steam)	132°C 270°F	4 minutes	20 minutes
Pre-vacuum (steam)	134°C 273°F	3 minutes	20 minutes
Pre-vacuum (steam)	134°C 273°F	18 minutes	20 minutes
Dry Heat	160°C 320°F	120 minutes	for immediate use

TECHNIQUE INFORMATION

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 separate 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. The abutment removal tool may be necessary to remove the abutment from the implant. 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 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. Verify occlusion in centric and lateral excursions. Cement final prosthesis in place. Remove excess cement.

Labeling Identification			
	Symbol for Legal Manufacturer		
REF	Symbol for Catalogue number		
LOT	Symbol for Batch code		
Rx only	Symbol for Use by Prescription Only		
	Consult Instructions for Use www.ifu.biomet3i.com		
2	Symbol for Do not re-use		
NON STERILE	Symbol for Non-sterile		
	Symbol for Date of Manufacture		
	Symbol for Do not use if package is damaged		
	Symbol for Hexagon	MR	Symbol for MR Conditional

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