

Instruction Manual

Zfx™ GenTek™

Intraoral Scan Body

Version: 3/11.2019
Compiled at: 18.11.2019
Effective date: 18.11.2019
Replaces version: 2/09.2019
Page 1 of 2



Intended Use

The Zfx™ GenTek™ Intraoral Scan Body is intended to capture the location, angulation and connection orientation of the dental implant in the patient's mouth during the scanning period. The Zfx™ GenTek™ Intraoral Scan Body is available with a genuine connection for the following implant-level Zimmer Biomet Dental implant systems: Certain®, External Hex, TSV™/ Trabecular Metal™, and Eztec™. In addition, abutment level TiBases are available for the Zimmer Biomet Dental Low Profile and Tapered Abutment Systems. For specific dental implant compatibility, please refer to the information on the individual product label. Zfx™ GenTek™ Intraoral Scan Bodies are compatible with Zimmer Biomet Dental prosthetic tooling as outlined in the Zfx™ GenTek™ Components Catalog – please refer to the components catalog located on the Zfx website.

Device description

The Zfx™ GenTek™ Intraoral Scan Body is a two-piece post with a titanium alloy grade 5 ELI (TiAl6V4 ELI) base and a polyetheretherketone (PEEK) coronal section. The scan body engages the connection of the implant and is secured with an integrated screw. The Zfx™ GenTek™ Intraoral Scan Bodies, used in conjunction with the implant-level system, are available in two different heights per package, 4 mm and 7 mm. The Zfx™ GenTek™ Intraoral Scan Bodies used in conjunction with the abutment level tibases are available in one heights per package, the 7 mm.

Product life time

The scan bodies are multiple use with a product life time of 25 autoclave cycles. Product accuracy cannot be guaranteed when exceeding this number of autoclave cycles.

Cleaning and Sterilization

The Zfx™ GenTek™ Intraoral Scan Body is non-sterile. Prior to placement of the Zfx™ GenTek™ Intraoral Scan Body into the patient and prior to each use, the scan body must be cleaned and sterilized. Do not disassemble the scan body prior to cleaning and sterilization.

Cleaning

1. Rinse the Intraoral Scan Body/Restoration under running cold tap water for 2 minutes.
2. Hand wash instruments in a bath with demineralized water for 5 minutes. Remove debris with a soft brush where possible. Cavities should be rinsed with a syringe. This should be repeated until all debris is removed.
3. Clean the instruments in an ultrasonic bath at a frequency of at least 40 kHz for 20 minutes.
4. Rinse thoroughly with demineralized water for 1 min.

Sterilization

The recommended sterilization procedure is full cycle pre-vacuum steam sterilization at a temperature of 134°C (273.2°F) for 3 minutes, 4 pulse minimum or full cycle gravity steam sterilization at 134°C (273.2°F) for 3 minutes minimum. Scan body should not be used prior to 16 minutes after pre-vacuum steam sterilization and 30 minutes after gravity steam sterilization.



Note: Follow the loading instructions issued by the sterilizer manufacturer.

Intra Oral Scanning

- × Remove any provisional abutment, cover screw, healing abutment or similar from the implant upon which the scan body is intended to be placed.
- × Confirm that the selected scan body is the same size as the implant.
- × Ensure that the seating surface of the implant is clean, free of residue, bone, or soft tissue and is dry when mounting.
- × Affix the Zfx™ GenTek™ Intraoral Scan Body into the implant using a Zimmer Biomet Dental hex driver with a minimum of 5Ncm but no more than 15Ncm maximum torque. In cases with multiple scan bodies, it is important that they are seated with the same torque.
- × Proceed with scanning.



Warnings

- × Do not over-tighten the scan body (max torque 15 Ncm) as it can cause damage and lead to inaccurate scanning.
- × **DO NOT** acquire the bite scan with the scan body still in place. The scan body is not designed to withstand biting forces and should be discarded if a patient bites down on it.
- × As the scan body is a high precision tool, it may not be used while still warm from the autoclave, as the thermal expansion may lead to inaccurate scanning data.
- × Refer to the instruction for use of the scanner for details on the recommended protocol of the respective scanner.
- × The GenTek™ Intraoral Scan Body may only be used with a compatible digital library file installed in the design software.
- × The Zfx™ GenTek™ Intraoral Scan Body must only be used and handled by dental professionals who have approved training in dentistry.

Signs and symbols



Catalogue number



Batch code



Manufacturer



Non-sterile



Consult instructions for use
www.zfx-dental.com



Don't use if package
is damaged

Information on Manufacturer



Zfx GmbH
Kopernikusstraße 15
85221 Dachau
Germany

T +49 (0) 8131 / 33 244 - 0
F +49 (0) 8131 / 33 244 - 10
www.zfx-dental.com

Incident Reporting / Complaints:

Please send to qm@zfx-dental.com

