Adin Scan Bodies, Ti Bases and TMA Cementing Cone

INSTRUCTIONS FOR USE

Adin Scan Bodies

Product description

Scan Body and its Retaining Screw are products which are used for the digital acquisition of an implant position instead of an impression post to transmit the implant position and connection orientation to a 3D model, a Scan Body is required in the digital process, which can be optically acquired in an effective way along with the mouth situation. For this purpose, a titanium scan body product is mounted on an implant or laboratory analog with a Retaining Screw. The design of the Scan Body bottom portion is in line with the implant's specific platform or the Multi Unit (TMA-MU) abutment requirements and can only be screwed onto specific implant/TMA-MU platform with a certain diameter and connection.

Adin Scan Bodies are designed with optimal geometry and texture for the ViZ® Intra Oral Dental Scanner System (Manufactured by Adin Digital Ltd.).

Indications

The Scan Body is used to detect the exact position of the implant or TMA-MU in the mouth or in the stone model to transfer it in the correct position of a 3D model.

Contraindications

The Scan Bodies of each Platform can only be combined with the corresponding compatible platform. No inappropriate in connection geometry should be used. Any post-processing at the connection geometry to the implant may result in fitting inaccuracies prohibiting further use. Furthermore, the Scan Bodies may not be ground and their shape must not be changed, as this is essential to ensure an accurate scan result.

Scan Body's Compatibility

Adin's Scan Bodies are compatible with Adin Implant Systems: Touareg™, Touareg-S™, Touareg-OS™, Touareg CloseFit™, Swell™, Triple™ and Triple-OS™.

Implant System	Platform Connection	Compatible Scan Bodies
Touareg™ Touareg-S™ Touareg-OS™ Swell™ Triple™ *Triple-OS™	RS (Regular Standard Internal Hex)	RS0088 RS Scan Body 7mm
		RS0089 RS Scan Body 10mm
Touareg CloseFit™ UNP (Ultra Narrow Platform) 2.75mm	UNP (Conical Hex Connection)	UNP0088 UNP CloseFit™ Scan Body 7mm
		UNP0089 UNP CloseFit™ Scan Body 10mm
Touareg CloseFit™ NP (Narrow Platform) 3.0mm	NP (Conical Hex Connection)	NP0088 NP CloseFit™ Scan Body 7mm
		NP0089 NP CloseFit™ Scan Body 10mm
Touareg CloseFit™ RP (Regular Platform) 3.5mm	RP (Conical Hex Connection)	RP0088 RP CloseFit™ Scan Body 7mm
		RP0089 RP CloseFit™ Scan Body 10mm
Touareg CloseFit™ WP (Wide Platform) 4.3/5.0mm	WP (Conical Hex Connection)	WP0088 WP CloseFit™ Scan Body 7mm
		WP0089 WP CloseFit™ Scan Body 10mm
TMA (Trans-Mucosal Abutment Multi Unit)	TMA	TM0006 TMA Scan Body 6mm
		TM0009 TMA Scan Body 9mm

Scanning-step-by-step instructions for use

1. Choose the Scan Body according to the platform connection and desired height (see Table above).

2. Clean & Sterilize the Scan Body and its components prior to use according to the cleaning & sterilization instructions as seen in the Cleaning and Sterilization section below. The Scan Body is designed for up to 20 cycles of cleaning & sterilization only.

3. Before placing the Scan Body ensure that all components are clean, sterilized and in undamaged condition (neither scratches, deformations nor discolorations).

4. The retaining screw is a fixation screw in the Scan Body. Ensure that the screwdriver and the screw are correctly engaged in order to assure aspiration security.

5. Mount the suitable Scan Body onto the implant or the TMA-MU in the mouth of the patient or on the matching laboratory analog/replica in the stone model and screw it tight (15 Ncm) using the supplied retaining screw and a compatible screwdriver. In doing so, it is significant in which direction the flat side of the Scan Body points. It is recommended that the flat side of the Scan Body point to the buccal side.

6. The Scan Body is scannable without powder or scan spray with most of the Intra Oral scanners. Refer to the special instructions for use of your scanner.

7. Acquire the 3D surface topography situation with ViZ® Intra Oral Scanner or any other scanner of your choice.

Limitations on use and re-processing

- Maximum recommended number of uses: 20
- Maximum recommended number of cleaning & sterilization cycles: 20
- Scan Bodies should be visually inspected for signs of wear and tear (e.g. scratches, deformations or discolorations) prior to each reuse and discarded if necessary

Titanium Bases and TMA Cementing Cone

Product Description

A titanium base is used for the restorative supply of an implant. For this purpose, a superstructure is glued onto the titanium base, which can be individually adjusted in line with aesthetic and functional requirements. Depending on the superstructure design, the product glued to the titanium base can be used as the abutment or directly bolted crown. An Abutment Screw is also used for the definitive attachment to the implant.

The Ti Base product consists of two individual components: Titanium base and Abutment Screw.

The Ti Base is available for all Adin platforms and TMA-MU (as TMA Cementing Cone).

Adin's Ti Bases and TMA Cementing Cone are compatible with Adin Implant Systems: Touareg™, Touareg-S™, Touareg-OS™, Touareg CloseFit™, Swell™, Triple™ and Triple-OS™.

Implant System	Platform Connection	Compatible Component
Touareg™ Touareg-S™ Touareg-OS™ Swell™ Triple™ *Triple-OS™	RS (Regular Standard Internal Hex)	RS1404 - RS Ti Base Engaged
		RS1417 - RS Ti Base Angular Engaged
		RS1408 - RS Ti Base Non Engaged
Touareg CloseFit™ UNP (Ultra-Narrow Platform) 2.75mm	UNP (Conical Hex Connection)	UNP1704 - UNP CloseFit™ Ti Base Engaged
		UNP1717 - UNP CloseFit™ Ti Base Angular Engaged
		UNP1708 - UNP CloseFit™ Ti Base Non Engaged
Touareg CloseFit™ NP (Narrow Platform) 3.0mm	NP (Conical Hex Connection)	NP1004 - NP CloseFit™ Ti Base Engaged
		NP1017 - NP CloseFit™ Ti Base Angular Engaged
		NP1008 - NP CloseFit™ Ti Base Non Engaged
Touareg CloseFit™ RP (Regular Platform) 3.5mm	RP (Conical Hex Connection)	RP1204 - RP CloseFit™ Ti Base Engaged
		RP1217 - RP CloseFit™ Ti Base Angular Engaged
		RP1208 - RP CloseFit™ Ti Base Non Engaged
Touareg CloseFit™ WP (Wide Platform) 4.3/5.0mm	WP (Conical Hex Connection)	WP1304 WP CloseFit™ Ti Base Engaged
		WP1317 WP CloseFit™ Ti Base Angular Engaged
		WP1308 WP CloseFit™ Ti Base Non Engaged
TMA (Trans-Mucosal Abutment Multi Unit)	TMA	TM0010 TMA Cementing Cone

Intended use
Titanium base is intended for manufacturing a two-part restoration, comprising of Ti Base and superstructure (abutment or directly bolted crown).

Indications
Ti Bases are attached to an implant for the adhesion of superstructure (abutment or crown) made of Zirconium and/or metal alloys such as CoCr to restore function and aesthetics in the oral cavity.
Ti Bases are intended for single use only.
Do not reuse Ti Bases or TMA Cementing Cone. Reuse of these items, will lead to an increased risk for product failure as functionality cannot be guaranteed if these products are reused. In addition, there is an increased risk of contamination.

Contraindications
- Insufficient oral hygiene
- Insufficient space available
- Bruxism
- For restorations with angulation correction of more than 20° to the implant axis
- For individual tooth restorations with free end saddle
- For restorations whose length exceeds a ratio of 1:1.25 in comparison to the length of the implant
- Allergic or hypersensitive response to Ti-6Al-4 V alloy (titanium, aluminum, vanadium).

Processing the Ti Base in the Laboratory
The diameter of the Ti Base must not be reduced e.g. by grinding. Shortening the Ti Base is not permitted.
The contact surfaces of the Ti Base to the implant should not be sandblasted or otherwise processed. Only the surfaces of the Ti Base intended for gluing with a superstructure may be sandblasted (50µm aluminum oxide, max. 2.0 bar) and then cleaned (with alcohol or steam).
Use "PANAVIA ™ F 2.0" or "PANAVIA™ V5" or equal as an adhesive extra orally to connect the Ti Base and the sintered Zirconia superstructure. Other glues are required for attaching different materials. Observe the operating instructions for the material used.
1. For easier handling during the gluing process, it is recommended that the Ti Base be screwed into an implant analog or a polishing tool.
2. Cover the hex head of the abutment screw with wax.
3. Sand-blast the gluing surfaces of the Ti Base with 50 µm aluminum oxide and up to 2.0 bar and clean the surfaces with alcohol or steam.
4. Ensure that the superstructure can be fully slid onto the Ti Base.
(In case of cement retained restoration-send the parts to the dentist)

For Screw Retained Cases
5. Apply metal primer and glue to the Ti Base while observing the manufacturer specifications.
6. Push the sintered Zirconia (or any other material) superstructure in as far as it will go. Make sure it latches into the rotation and position stops.
7. Remove excess glue immediately. Make sure that there is no glue residue left in the screw channel.
8. Follow the recommendations of the glue manufacturer with regard to the final hardening of the glue.
9. Remove residue with a rubber polisher after hardening.

Processing the Ti Base or TMA Cementing Cone in the Dental Clinic by the Dentist

For Cement Retained Cases
1. The Ti Bases/TMA Cementing Cone and a compatible retaining screw are delivered in non-sterile condition.
2. Clean and Sterilize according to instructions provided in Cleaning and Sterilization section below.
3. Connect the Ti Bases to the Implant or TMA Cementing Cone to the TMA-MU and tighten the Retaining Screw according to the following table:

Recommended Torque (Ncm)

Prosthetic device	UNP	NP	RP	WP	RS
Ti-Base	25	35	35	35	35
TMA Cementing Cone	15	15	15	15	15

Caution: Don't exceed the recommended prosthetic tightening torque for abutment screws. Over tightening of abutment may lead to a screw fracture.

4. Apply metal primer and glue to the Ti Base/TMA Cementing Cone while observing the manufacturer specifications.
5. Push the superstructure; sintered Zirconia (or any other dental material) crown in as far as it will go. Make sure it latches into the rotation and position stops. Remove excess glue immediately. Make sure that there is no glue residue left in the Ti Base/TMA Cementing Cone chamfer.
6. Follow the recommendations of the glue manufacturer with regard to the final hardening of the glue.
7. Remove residue with a rubber polisher after hardening.

Cleaning and Sterilization instructions:

1. Point of Use
Adin's devices (i.e. Scan Bodies, Ti Bases and TMA Cementing Cone) are delivered non-sterile and must be cleaned and sterilized prior to first use and between subsequent uses (if applicable).
Remove contaminations (scan spray, saliva, blood, surgical residues etc.) directly after use.
Caution: Contamination that adheres on the Scan Body may cause corrosion and compromise the function of the device.

2. Preparation for decontamination
Disassemble the device and its screw. Clean, sterilize and store each component separately.

3. Cleaning
Prior to first use and after each use, proceed with the following cleaning procedure:
- As soon as possible after their use, rinse the device under running cold water and while keeping them immersed, brush thoroughly away from the body
- Place the instruments in an ultrasonic cleaner with neutral pH enzymatic detergent (e.g. deconex POWER ZYME), that was diluted per manufacturer's instructions and sonicate for 10 minutes
- Rinse the device with tap water for two minutes while brushing with a soft bristled brush to remove visible contamination / debris
- Clean the interior lumen (if applicable) with a thin wire to remove any remaining debris
- Inspect the devices visually to ensure that all visible contamination/debris have been removed and scrub as necessary

Warning: Cleaning in automated washer-disinfector is not recommended in order to maintain surface integrity for subsequent scanning.

4. Drying
- Dry the device using paper toweling or dry heat not exceeding 132°C/270°F.

5. Functional Testing, Inspection & Maintenance
- Visual inspection for cleanliness should be performed with magnifying glasses.
- If necessary perform reprocessing again until the device is visibly clean.

6. Packaging
- Wrap the device in a sterilization pouch to protect it from contact with contaminated instruments until sterilization by autoclave.

7. Sterilization
- Steam sterilize the device in an autoclave in a sterilization pouch for 4 min at 132°C/270°F, following with a 20 minutes drying cycle

Caution: Sterilization in Chemclave is not recommended.

8. Storage
- Store at room temperature.

For Scan Bodies:
- Take appropriate precautions to avoid recontamination prior to next use. Scan Bodies should be stored in sterilization pouches until next use to avoid recontamination according to pouch manufacturer instructions
- Disposable after the maximum recommended number of uses

Explanation of Pictograms

LOT Batch number
REF Catalogue number
Manufacturer
Date of manufacture
CAUTION
Do not re-use
Do not use if package is damaged
EC REP Authorised representative in the European Community
℞ ONLY CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician or dentist
NON STERILE Non-sterile
CE Marked

CE 0473

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