Instructions For Use: Osteon Ti Base Provisional Restoration – US

ART-038, Version 1.0 (Effective from 22/06/2023)

Indication for use:

The Osteon Ti Base Provisional Restoration is indicated for attachment to dental implant and/or abutments and act as a temporary solution in the treatment of fully edentulous jaws for the purpose of restoring chewing function. These devices are intended for short term use (up to 3 months) prior to final restoration installation.

Description:

Each provisional restoration, made for an individual patient as per the specifications provided by the prescribing health professional, is digitally designed using advanced computer aided design (CAD) system and produced in biocompatible materials, The device is to be retained with prosthetic screws.

The Ti Base Provisional Restorations are either designed and manufactured by Osteon and provided to clinicians, or the clinicians may order a Provisional Restoration Design Only and self-manufacture the product.

For 3rd Party (Clinician) Manufactured Ti Base Provisional Restorations:

The below information may not be applicable, and it is up to the Clinician to provide all the necessary information to the patient. It is responsibility of the Clinician to adequately manufacture the products including fabrication, prink processing, cementation, and cleaning etc. Clinicians should consult in advance with Osteon and procure the Ti Bases and screws recommended by Osteon for the installation of the product as any off-the-shelf Ti Base may not be compatible with the Osteon designed Ti Base Provisional Restoration.

Material:

For Osteon Manufactured Ti Base Provisionals, the Ti Bases provided are made of Titanium Alloys and Provisional Bridges are fabricated in either Arcylic (PMMA) or Compatible Dental Resins.

Contraindications:

Allergies to materials used, which may include any or all of the following: Titanium alloy (Titanium, Aluminium, Vanadium, N, C, H, Fe, O etc.), PMMA and dental resin. If any irritation occurs, please seek medical attention.

Patients with bruxism since an overload of the device may occur.

Cylinders are not to incorporate divergence that will cause the resulting angulation of any single construct to exceed the maximum angulation of the compatible multi-unit abutment system.

Warnings and Precautions:

Proper surgical procedures and restorative techniques are the responsibility of the dental professional. Each clinician must evaluate the appropriateness of the procedure used based on personal medical training and experience as applied to the patient case at hand. Clinicians are also responsible for informing patients on proper maintenance of the device post restoration after evaluating their underlying health conditions and oral parafunction.

It is responsibility of the clinician to ensure the patient do not wear the devices for periods longer than what is specified by the manufacturer.

Small components dropped/chipped in the patient's mouth could be swallowed or aspirated and therefore should be handled with care.

If any modifications are made to the Osteon Ti Base Provisional interface, the provisional may have a fitting issue. These products are made specifically for a patient. Re-use of the product for another patient should not be attempted. Osteon assumes no responsibility for attempted re-use of the device on another patient or defects that arise due to the modification (grinding, deburring, or otherwise retouching) of the device.

Potential causes of Osteon Ti Base Provisional fracture include but are not limited to non-passive fit of the provisional, overloading due to improper occlusion, overloading due to parafunction, incomplete seating of cemented abutments, and excessive cantilevering of pontics.

Divergence/Angulation: Cylinders are not to incorporate additional divergence that will cause the resulting angulation of any single construct to exceed the maximum angulation of the compatible multi-unit abutment system as stated in the Indications for Use of the Osteon Ti Base Provisional Restoration.

Disinfection:

Osteon products are supplied NON-STERILE and must be disinfected prior to their placement in the mouth. It is the responsibility of the clinician to disinfect the Osteon Ti Base Provisional Restorations. Disinfection can be carried out by using any medical grade disinfectant. Please follow instructions provided by the disinfectant manufacturer to adequately disinfect the Osteon Ti Base Provisional Restorations.

Specific Instruction For Use:

Refer to the biaxial card provided for suprastructures containing biaxial systems to identify their location. Biaxial driver and OEM (original equipment manufacturer) driver should be used with biaxial and straight screws respectively. The Biaxial screws should be secured with the torque specified on biaxial screw packaging. For straight systems, screws should be torqued as per implant/abutment OEM specifications.

Safety information:

Osteon products have not been evaluated for safety when exposed to electric, radiation and thermal energy and compatibility is unknown. Exposure to these energies may result in patient injury and adequate precautions should be taken.

Note: *Any serious incident(s) that has occurred in relation to the device shall be reported to Osteon and the competent authority having jurisdiction in the locale where the incident occurred.*

MRI Safety Information:

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the device, or ensuring the device is located outside the RF coil. A patient with the device can be scanned safely in an MR system under the following conditions:

Device Name:	Osteon Ti Base Provisional Restoration
Static Magnetic Field Strength (BO)	≤ 3.0 T
Maximum Spatial Field Gradient	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)

RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the device, or ensuring the device is located outside of the coil. Extremity T/R coil. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Labelling Symbols:

Labelling Symbols according to ISO 15223-1:2021	
Symbol	Description
	Manufacturer
	Date of manufacture
	Non-Sterile
	Consult electronic Instructions for Use (E-IFU)
	Fragile, handle with care
	Medical Device
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
	MR Conditional
	Catalogue number
	Serial Number
	Do not use if package is damaged
	Keep dry (before opening)
	Single patient (multiple use)

	Unique Device Identifier

Disposal:

For disposing product and packaging comply with applicable national waste disposal regulations in your country.

Contact Details:

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