Instructions For Use: Osteon Precision Milled Suprastructure - US

ART-008, Version 12.0 (Effective from 13/03/2024)

Indication for use:

The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) implants. Osteon Precision Milled Suprastructures is indicated for compatibility to the following abutment systems:

- Astra Tech Implant System® Multi Base Abutment EV, 4.8mm, max 30°
- BioHorizons Multi Unit Abutment, 4.8mm, max 30°
    - CONELOG® Implant System
- Biomet 3i Multi Unit Abutments, 4.8mm, max 30°
    - TSX™ Implants
    - Tapered Screw-Vent Implant
- DESS Dental Multi Unit Abutments, 3.4-5.7 mm, 0°
    - 3i OSSEOTITE®
    - Astra Tech OsseoSpeed™
    - Neodent Grand Morse
    - NobelReplace® Trilobe
    - NobelReplace® Conical
    - Nobel Brånemark System®
    - Straumann BLX Implants
- DESS Dental Multi Unit Abutments, Angled, 3.4-6.5 mm, max 30°
    - NobelActive® NobelParallel Conical
    - Straumann® Bone Level
    - Zimmer Screw Vent® and Tapered Screw-Vent®
- Dentium SuperLine® Abutments, 4.5-5.5 mm, max30°
- GENESIS ACTIVE™ Multi-Unit Abutments, 4.8mm, max 30°
- Implant Direct GPS® Angled Abutment, 5.0mm, max 30°
- KDG Abutments, 4.8mm, max 30°
- Keystone Multi Unit Abutment, 4.8mm, 0°
- Medentika Multi Unit Abutments, 4.8mm, max 30°
    - EV Series – Dentsply® Implants Astratech Osseospeed®
    - F Series – Nobel Biocare NobelActive® – NobelReplace® Conical
    - H Series – Biomet 3i Certain®
    - L Series – Straumann Bone Level
    - N Series – Straumann Soft tissue Level
    - R Series – Zimmer Dental Tapered Screwvent®
- Medentika Multi Unit Abutments, 4.8mm, 0°
    - E Series – Nobel Biocare Replace™ Select
    - I Series – Biomet 3i Osseotite®
    - K Series – Nobel Biocare™ Branemark
    - S Series – Astra Tech OsseoSpeed™
    - T Series – Dentsply Friadent® Frialit/Xive®
- MegaGen Multi Unit Abutments, 4.8mm, max 30°
    - Xpeed® AnyRidge® Internal Implant System
    - AnyOne® Internal Implant System
    - AnyRidge® Octa 1 Implant System
    - AnyOne® External Implant System
    - AnyRidge® Octa 1 Implant System
    - AnyOne® Internal Implant System
    - Rescue Internal Implant System
- MIS Multi-unit Abutments, 4.8mm
    - C1 Conical Connection Implant System, max 30°
    - V3 Conical Connection Implant System, max 30°
    - Internal Hex Implant System, max 30°
    - Conical Connection, max 30°
- Neodent GM Mini Conical Abutment, 4.8 mm, max 30°
- Nobel Biocare™ Brånemark Multi Unit Abutment, 4.8 mm, max 17°
- Nobel Biocare™ Multi Unit Abutment Plus, 4.8 mm, max 30°
- Nobel Biocare™ Multi Unit Abutment, 4.8 mm, max 30°
- Nobel Biocare™ Multi Unit Abutments for Straumann and Astra Tech System, 4.8 mm, max 30°
- Nobel Biocare™ Multi Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems, 4.8 mm, max 30°
- Nobel Biocare Xeal Abutments, 4.8 mm, max 30°
- OSSTEM Multi Unit Abutment, 4.8mm, max 30°
    - SS SA Fixture Implants
    - SA Implant System
    - ET US SSS Prosthetic System
- Paltop Multi Unit Abutment, 5.0 mm, max 17°
- Southern Compact Conical Abutments, 4.8 mm
    - MAX Implant System, 0°
    - Provata Implant System, max 30°
    - Deep Conical (DC) Implants, 0°
    - Piccolo Implants, 0°
    - External Hex Implants, max 30°
- Straumann® BLX Screw Retained Abutment, 4.6 mm, max 30°
- Straumann® Screw Retained Abutment, 4.6 mm, max 30°
- Zimmer Angled Tapered Abutments, 4.5 mm, max 30°

Description:

Each suprastructure, 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, precision milled (CAM) in biocompatible materials is compliant with the requirements of relevant Essential Principles. The device is to be retained on implants with screws.

Material:

Ti-6Al-4V (Grade 5) alloy as per ASTM F136, DIN EN ISO 22674 and DIN EN ISO 5832-3.

Contraindication:

Allergies to materials used, which may include any or all of the following: titanium (Ti), titanium alloy (Ti-6Al-4V: titanium, aluminium, vanadium, N, C, H, Fe, O).

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.
Small components dropped in the patient's mouth could be swallowed or aspirated and therefore should be handled with care.
If any modifications are made to the implant suprastructure interface, the suprastructure 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 suprastructure fracture include but are not limited to inadequate implant support when attached to periodontally compromised teeth, non-passive fit of suprastructure, overloading due to improper occlusion, 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 Precision Milled Suprastructure.

Sterilization:

Osteon products are supplied NON-STERILE and must be sterilized according to a validated method prior to use in the oral environment. The recommended sterilization cycle is standard prevacuum steam sterilization, exposure at 132°C (270°F) for 4 minutes (after sterilizer has reached indicated temperature) with a dry time of 45 minutes, using a sterilization pouch that is FDA-cleared for the indicated cycle.

Specific Instruction For Use:

Refer to the biaxial card provided for suprastructures containing biaxial systems to identify their precise 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 Precision Milled Suprastructure
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:

Australia:
Implant Solutions Pty Ltd (trading as Osteon Medical)
759-767 Springvale Rd, Mulgrave, VIC 3170, Australia
Contact:
customerservice.au@osteonmedical.com
+61 3 9264 0111

USA:
Osteon Medical North America
Suite 150, 175 Technology Drive, Irvine, CA
Contact:
customerservice.USA@osteonmedical.com
1-888-203-6180

US Agent
Keystone Dental Group
154 Middlesex Turnpike, Burlington, MA US 01803
NDeAngelo@keystonedental.com