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Instruction for use no:
T-20250623-IM,
Rev. B
March 2026

**Instructions for Use**
**Preat Ti Blank Abutments – Digital Dentistry Workflow**

**Mill Manufacturer: imes-icore® GmbH**

CAUTION: U.S. federal law restricts these devices to sale by or on the order of a licensed dentist or physician.

**Product Description**
Preat Abutments is a dental implant abutment system composed of dental abutments and screws intended to be placed into dental implants to provide support for prosthetic restorations.

This document will focus on the Titanium Blank dental abutment, which are used to fabricate patient-specific abutments using a validated CAD/CAM workflow, herein also referred to as Preat Milled Titanium Abutments. The Titanium Blanks are made of the biocompatible titanium alloy and have a pre-manufactured/pre-milled connection interface that corresponds directly to a pre-specified dental implant. The patient specific abutment is intended to be manufactured according to a digital dentistry workflow or at a Preat Validated Milling Center. Preat Milled Titanium Abutments are delivered non-sterile and the final restoration, including the corresponding Preat prosthetic screw, are intended to be sterilized at the dental clinic prior to placement within the patient.

**Commercial Off-The-Shelf (COTS) Software/Computer Specifications**
There are several COTS software detailed in the instructions below, and each supplier may recommend computer specifications for their product. Preat recommends users to follow these recommendations, which may be subject to change based on new releases of software. Ensure that the software manuals from each supplier are reviewed and followed prior to following this Digital Dentistry Workflow. Off-the-Shelf software updates will also be monitored, evaluated, and re-validated, as necessary, by Preat as they become available. These instructions will be updated to reflect the latest releases as validations are completed. It is recommended that users check the Preat website for updated Preat IFU documents prior to updating to new versions of any referenced software.

**Intended Use / Indications for Use**
Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed CAD/CAM customizations for Preat Abutments are intended to be sent to a Preat Validated Milling Center for manufacture or to be designed and manufactured according to a digital dentistry workflow. The digital dentistry workflow integrates multiple components of the digital dentistry workflow: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

Preat Abutments are compatible with the following third-party implant restorative platforms:

| Compatible Third-Party Implant Systems | Implant Body Diameter (mm) | Implant Platform Diameter (mm) |
|---|---|---|
| 3i OSSEOTITE® Certain® | 3.25 | 3.4 |
| | 4.0 | 4.1 |
| | 5.0 | 5.0 |
| | 6.0 | 6.0 |
| Astra Tech OsseoSpeed™ | 3.0 | 3.0 |
| | 3.5, 4.0 | 3.5/4.0 |
| | 4.5, 5.0 | 4.5/5.0 |
| Astra Tech OsseoSpeed™ Plus (OsseoSpeed™ EV) | 3.0 (3.0S) | 3.0 |
| | 3.6 (3.6S) | 3.6 |
| | 4.2 (4.2C, 4.2S) | 4.2 |
| | 4.8 (4.8C, 4.8S) | 4.8 |
| | 5.4 (5.4S) | 5.4 |
| BioHorizons® Tapered Internal | 3.0 | 3.0 |
| | 3.5 | 3.5 |
| | 4.0 | 4.5 |
| HIOSSEN ET III | 3.5 | Mini |
| | 4.0, 4.5, 5.0, 6.0, 7.0 | Regular |
| Implant Direct Legacy | 3.2 | 3.0 |
| | 3.7, 4.2 | 3.5 |
| | 4.7, 5.2 | 4.5 |
| | 5.7, 7.0 | 5.7 |
| Keystone PrimaConnex™ | 3.5 | 3.5 (SD) |
| | 4.1 | 4.1 (RD) |
| | 5.0 | 5.0 (WD) |
| MegaGen AnyRidge | 3.5, 4.0, 4.5, 5.0, 5.5 | 3.5 |
| Neodent® GM™ Helix | 3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0 | 3.0 |
| Neoss | 3.5, 4.0, 4.5, 5.0, 5.5 | 4.1 |
| Nobel Biocare™ NobelActive® | 3.0 | 3.0 |
| | 3.5 | NP |
| | 4.3, 5.0 | RP |
| Nobel Biocare™ NobelReplace® | 3.5 | NP |
| | 4.0, 4.3, 5.0 | RP |
| | 5.0 | WP |
| | 6.0 | 6.0 |
| Straumann™ BLX | 3.75, 4.0, 4.5 (RB) | RB |
| | 5.0, 5.5, 6.5 (WB) | WB |
| Straumann® Bone Level | 3.3 | NC |
| | 4.1, 4.8 | RC |
| Straumann® Tissue Level | 3.3, 4.1, 4.8 | RN |
| | 4.8, 6.5 | WN |
| Zimmer Screw-Vent®/ Tapered Screw-Vent® | 3.3, 3.7, 4.1 | 3.5 |
| | 4.7 | 4.5 |
| | 6.0 | 5.7 |

**Contraindications**

- Do not use Preat Abutments in patients with hypersensitivity to any material listed in the product description. Preat Abutments should not be used unless the dental implants are stable and there are no signs of infection or severe bone loss as this may contribute to lack of integration and/or subsequent implant failure.
- Dental implant patients should be instructed to consult with their physician prior to undergoing any major dental treatment options.

**Warnings**

- Products discussed in this IFU are for single use only. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury.
- Implant and tooth fractures can occur when applied loads exceed the normal functional design tolerances

of the components. Potential overloading conditions may result from deficiencies in implant or tooth 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), improper denture manufacture procedures, inadequate denture fit, physical trauma and bad implant placement.

- 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.
- Long-term health is directly related to the maintenance of oral hygiene. Following placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the prosthesis.
- Implant patients should be monitored for signs of peri-implant bone loss as signs of occlusal overloading.
- Use of any abutments device, scanners, milling units, tools and CAD/CAM software other than those specifically identified as compatible in these instructions, may result in fitment issues and/or damage to the dental restorations.

**Materials**

Preat Abutments and corresponding abutment screws are made from titanium alloy (Ti-6Al-4V ELI per ASTM F136).

**Milling Equipment Setup**

Details on installation and setup are below. Check with manufacturer for any updates to processes or revisions of manuals. Operating manuals and maintenance guides for the imes-icore GmbH Mills can be requested by contacting:

imes-icore GmbH
Phone: +49 (0) 6672 898-469
Email: service@imes-icore.de

**Details from "imes-icore CORiTEC® 350i series Operating manual Article Number 51100X X350" Below:**

- Utility Requirements
  - Requires AC 110-230 V power at 50-60 Hz, with a nominal current of 3 A.
  - Requires an air compressor with a constant output of 6.5-9 bar.
- Maintenance (see manual for specific steps and additional details)
  - Clean the machine regularly (Do not clean with compressed air).
  - imes-icore recommends the use of disposable wipes to clean cooling lubricant.
  - Plastic panels and surfaces must be cleaned with a damp cloth and a suitable cleaning product.
  - Extraction systems provided by imes-icore are to be used for vacuuming dry milling dust.
  - The workpiece holder must be cleaned before milling.
  - Tool holders (in the tool changer) and the length measuring probe must be clean of dust and chips.
  - Thoroughly clean the guide rails of the protective door
  - The machining spindle nose and tools must be cleaned.
  - Use the collet chuck maintenance kit to clean and maintain the collet chuck.
  - Fan filters must be removed, then cleaned or replaced once a week.
  - Clean the safety interlocking system of the protective door loader once a week.
  - Clean the zero-point clamping system (mount) after use.
  - Before every operation, check the pre-filter of the cooling lubricant tank for contaminants.
  - The cooling lubricant tank must be cleaned every two weeks.
  - The water separator must be checked daily.
  - Must replace any partially or completely failed internal LED strips.
  - For a detailed maintenance schedule, see CORiTEC 350i series Operating manual pages 140-143.
- Installation, qualification, and training of mill must be performed with imes-icore Technicians. For additional information on installation, see the CORiTEC 350i series Operating manual pages 69-84.

**CAD Software Setup (exocad®)**

Details on installation and setup are below. Check with manufacturer for any updates to processes or revisions of manuals. Operating manuals for exocad can be requested by contacting:

Operating manuals for exocad DentalCAD can be requested by contacting: www.exocad.com

Details from "exocad AbutmentCAD3.2_User_Manual_en, 2023-12-11" below:

- Minimum Computer Requirements
  - Processor – Quad-Core and 2.8Ghz
  - Memory (RAM) – 4GB
  - Video Card – Nvidia GTX or AMD Radeon series dedicated GPU with at least 1 GB graphics memory, OpenGL 4, DirectX 11.1, Shader Model 5 and a graphics driver dated August 2019 or newer.
  - Operating System – Windows 10 (21H2-22H2), Windows 11 (21H2-23H2)

After installation, setup, and training are complete with exocad, the library file may be imported by following the instructions detailed in the exocad user manual. Preat libraries must be installed prior to abutment design and can be downloaded from www.preat.com.

**CAD Software Setup (3Shape®)**

Details on installation and setup are below. Check with manufacturer for any updates to processes or revisions of manuals. Operating manuals for 3shape can be requested by contacting:

Operating manuals for 3Shape Dental System can be requested by contacting: www.3shape.com

Details from "3Shape Dental System User Manual DS-2.20.1.0-A-EN 88.1" below:

- Minimum Computer Requirements
  - Processor – Intel Core i5 Gen 10 or higher
  - Memory (RAM) – 8GB
  - Video Card – 512MB NVIDIA GeForce or NVIDIA Quadrop DirectX 11 or later
  - Operating System – Windows 8.1 Home (64-bit), Windows 10 Home (64-bit)

After installation, setup, and training are complete with 3shape, the library file may be imported by following the instructions detailed in 3shape user manual. Preat libraries must be installed prior to abutment design and can be downloaded from www.preat.com.

**Magnetic Resonance (MR) Safety Information**

MR Conditional


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 dental implant abutment or ensuring the implant abutment is located outside of the RF coil.
A patient with this device can be scanned safely in an MR system under the following conditions:

| | |
|---|---|
| **Device Name** | Preat Abutments |
| **Static Magnetic Field Strength ($B_0$)** | ≤ 3.0T |
| **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 implant, or ensuring the implant is located outside of the coil.<br>Extremity T/R coils permitted.<br>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 |

A patient card is available for download at https://www.preat.com/ifu.

**Precautions**

- Preat Prosthetic Components and accessories should only be used for their intended purpose by individuals with training and experience specific to their clinically accepted application. Preat Corporation, Inc. is not liable for damages resulting from treatment outside of its control. It is the responsibility of the licensed clinician or laboratory technician to determine the appropriate treatment protocols and device selection. Preat devices should only be used for dental procedures with the implant systems they were designed for.
- Ensure that the implant angle corrections are appropriate for the occlusal load.
- General rules for restorative dental treatment, occupational safety, and accident prevention must be applied during the use of this product.
- Prior to restorative treatment, ensure that the required components, and instruments, and ancillary materials are complete, functional, and available in the correct quantities. If the indications and intended usage are not clearly specified, treatment should be suspended until these considerations have been clarified. Inspect all components prior to use. Do not use any component that is damaged.
- Components and accessories used intraorally should be secured to prevent aspiration or ingestion.

**Cleaning & Sterilization**

All components and instruments are supplied NON-STERILE, and prior to clinical use, the final finished abutment, abutment screw, components, and instruments must be sterilized by the end user.

The recommended cleaning and sterilization process is shown below. Sterilization wrap shall be FDA cleared for the indicated sterilizer type.

**Manual Cleaning Procedure**

| | |
|---|---|
| **1** | Transfer tongs and vessels used to contain the detergent solution or rinse will be appropriately cleaned and rinsed with at least 70% isopropanol (IPA) prior to use. Thoroughly wet the vessels and instruments with IPA and allow to air dry. Do not use cellulose-based IPA wipes. |
| **2** | Rinse the devices under running cold utility (tap) water to remove gross soil.<br>○ A soft bristle M16 style brush can be used in the aid for cleaning |
| **3** | Prepare a detergent bath using an enzymatic detergent (such as Enzol) at the manufacturer's recommendation using utility (tap) water. |
| **4** | Fully immerse the device in detergent and allow them to dwell per the detergent's instructions.<br>○ While the devices are immersed use a soft bristled M16 style brush to brush the surface of the devices to remove visible soil. |
| **5** | Prepare a new detergent bath using an enzymatic (such as Enzol) at the manufacturer's recommendation using utility (tap) water in an ultrasonic unit. |
| **6** | Sonicate the devices in new detergent solution for 10 minutes at 40-45 kHz. When handling the wet devices, do not touch the devices with gloves. Use IPA-rinsed transfer instruments only. |
| **7** | Remove the devices from the detergent solution and place in critical water (such as RO/DI). |
| **8** | Sonicate the devices for 10 minutes at 40-45 kHz. |
| **9** | Remove the devices from the rinse solution and place in fresh RO/DI water. |
| **10** | Sonicate the devices for 10 minutes at 40-45 kHz. |
| **11** | Repeat Steps 8 and 9 for a minimum of three complete rinse cycles. Continue rinse steps if residue is visibly present. Continue rinse steps if residue is visibly present. |
| **12** | Remove the devices and place in a clean vessel. Immerse with 99% IPA. Soak the devices for 5-10 minutes. |
| **13** | Remove the devices from the IPA rinse and place on Kimwipes or a previously IPA cleaned metal surface. Allow to fully dry prior to handling with gloves or packaging. Check any inner lumens for remaining liquid and allow for further drying if needed. |

**Steam Sterilization Parameters**

| **Sterilizer Type:** | **Pre-vacuum** |
|---|---|
| **Preconditioning Pulses:** | 4 |
| **Temperature:** | 132°C |
| **Full Cycle Exposure Time:** | 04 minutes |
| **Dry Time:** | 20 minutes |

The cycle has been validated by the overkill method to a sterility assurance level (SAL) of $10^{-6}$ according to ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices* and ISO 14937 *Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*.

Local specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the Sterilization Parameter's table however, only the above methods were tested. Verify the calibration of your unit to ensure recommended temperatures are not exceeded. To ensure autoclave is performing effectively, periodic use of biological indicators should be considered. Chemclave sterilization is NOT recommended. Excessive and long-term exposure to water or moisture in the atmosphere could result in discoloration of metals and in some instances, rust.

**Digital Dentistry Workflow**

All digitally designed CAD/CAM customizations for Preat Abutments are intended to be sent to a Preat validated Milling Center for manufacture or to be designed and manufactured according to a digital dentistry workflow. The digital dentistry workflow integrates multiple components of the digital dentistry workflow: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, milling machine and associated tooling and accessories as detailed below.

**Figure 1**: Validated workflow for Preat Milled Titanium Abutments.

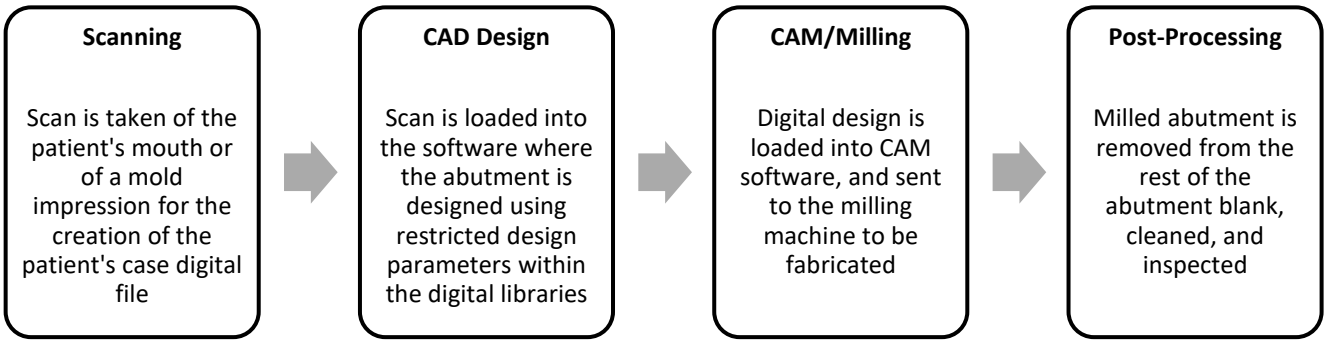


**Table 1**: Validated Equipment

| | | |
|---|---|---|
| **Step 1: Scanning** | **Option 1A:** Intraoral Scanner<br>(device must be registered with FDA, product code NOF or KZN) | |
| | **Option 1B:** Laboratory / Desktop Scanner<br>(device must be registered with FDA, product code NOF or KZN) | |
| **Step 2: Abutment Design (Approved design software)** | **Option 2A:** 3Shape - Version DS 20.1.2<br>Preat Library: 3Shape_ALL_PREAT (versions 2 through 6) | |
| | **Option 2B:** exocad - Version 3.2 Elefsina Engine build 8820<br>Preat Library: ALL_PREAT-implant (versions 2 through 6) | |
| **Step 3: Manufacturing (Approved milling machine and milling variables)** | **Mill Machine MFG and Model(s)** | CORiTEC® 350i |
| | **CAM Software Version** | hyperDENT V9.4.4_7.5.5.2150 |
| | **CAM Template File (dbconfig)** | dbconfig_Preat_imes_350i_Rev01 |
| | **Machine Tooling** | 526029 3006 imes-icore T1 - 3.0mm Diameter Ballnose for Ti<br>526029 2006 imes-icore T2 - 2.0mm Diameter Ballnose for Ti<br>526029 1006 imes-icore T3 - 1.0mm Diameter Ballnose for Ti |
| **Step 4: Post Processing** | Rotary Tool<br>Polishing Lathe<br>Ultrasonic Cleaner<br>Detergents/Cleaning Agents | |

**Step 1: Scanning**

- Detect the precise implant position using a compatible scan body and intraoral or desktop scanner. The scanner must be FDA registered (product code NOF or KZN).
- Follow the scanning software instructions for proper scanning sequences using the appropriate scan body object in the Preat Choice digital library
- Note that scan bodies are specific to implant diameters and use the appropriate scan body for the implant placed. Preat scan bodies are single use only. Discard the scan body and replace if fit becomes loose within the implant analog or patient's implant.

**Step 2: Abutment Design**

- Import library file and select the appropriate implant platform from the library. Preat libraries must be installed prior to abutment design and can be downloaded from https://www.preat.com/
- Import the digital scan file from the scanner into the design software.

| Design (CAD) Software |
|---|
| 3Shape® Dental System (Version DS 20.1.2) (www.3shape.com) |
| Exocad® DentalCAD (Version 3.2 Elefsina Engine build 8820) (www.exocad.com) |

See **Table 1 – Validated Equipment** for additional information on required software and equipment needed for this process.

- Preat Milled Titanium Abutments design parameters listed below:
- Design the abutment within the specified design parameters. Preat libraries have built-in limitations that prevent/warn the user from modifying outside those ranges.

| **Third-Party Compatible Implant System[1]** | **Prosthetic Platform Diameter (mm)** | **Min Gingival Height (mm)** | **Max Gingival Height (mm)** | **Min Wall Thickness (mm)** | **Max Post Correction Angle (°)** | **Min PH (mm)** | **Max PH (mm)** |
|---|---|---|---|---|---|---|---|
| 3i OSSEOTITE® Certain® | 3.4, 4.1, 5.0, 6.0 | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Astra Tech OsseoSpeed™ | 3.0 | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Astra Tech OsseoSpeed™ | 3.5/4.0, 4.5/5.0 | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Astra Tech® Osseospeed Plus (Osseospeed EV) | 3.0, 3.6, 4.2, 4.8, 5.4 | 0.5 | 3 | 0.5 | 0 | 4 | 12 |
| BioHorizons Tapered Internal | 3.0, 3.5, 4.5 | 0.5 | * | 0.5 | 30 | 4 | 12 |
| HIOSSEN ET III | Mini, Regular | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Implant Direct Legacy | 3.0, 3.5, 4.5, 5.7 | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Keystone Prima Connex™ | 3.5 (SD), 4.1 (RD), 5.0 (WD) | 0.5 | * | 0.5 | 30 | 4 | 12 |
| MegaGen AnyRidge | 3.5 | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Neodent® GM™ Helix | 3.0 | 0.9 | * | 0.5 | 30 | 4 | 12 |
| Neoss | 4.1 | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Nobel Biocare™ NobelActive® | 3.0 | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Nobel Biocare™ NobelActive® | NP, RP | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Nobel Biocare™ Nobel Replace™ | NP, RP, WP, 6.0 | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Straumann™ BLX | 2.9 (RB/WB), 2.9 (WB) | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Straumann® Bone Level | NC, RC | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Straumann® Tissue Level | RN, | 0.5 | * | 0.5 | 30 | 4 | 12 |
| Zimmer Screw-Vent®/ Tapered Screw-Vent® | 3.5, 4.5, 5.7 | 0.5 | * | 0.5 | 30 | 4 | 12 |

[1] See Trademark section

Gingival height limits for all abutment connection types notated by "*" above:

| Post Angulation | *Max Gingival Height |
|---|---|
| 0-17° | 6mm |
| 17.1-19° | 5mm |
| 19.1-21° | 4mm |
| 21.1-25° | 3mm |
| 25.1-30° | 2mm |

**Step 3: Manufacturing**

- Once design files are created, abutments may be milled, using the milling manufacturer Instructions for Use using the validated workflow. The pathway detailed in **Table 1** specifies the validated pathway's CAM Software Version, CAM Template File Revisions, Mill Machine (Manufacturer and Model), and the associated Machine Tooling. It is critical to ensure that each of these items match the equipment being used. Ensure that all equipment used is following requirements detailed in the milling manufacturer's instructions for use.
- The Validated Equipment Workflow detailed in this IFU requires the use of this equipment to ensure products are manufactured within specification. Ensure that all equipment is maintained according to the manufacturer's instructions, and all software revisions are accurate. All validated equipment used to manufacture all digitally designed CAD/CAM customizations is detailed in the table below, please contact Preat with any questions.
  - For all hardware and Operating Systems (OS) questions for any of the equipment/software below, see the corresponding operating manual and/or contact the corresponding manufacturer for further details..
  - All necessary CAM Template Files can be obtained at: https://www.preat.com

**Step 4: Post-Processing**

All post-processing shall be completed per the milling machine manufacturer's instructions for sprue removal. If no sprue removal instructions are provided by milling machine manufacturer, please refer to the steps outlined below:

- Using a high-speed hand piece and cutting bur to separate the abutment from the holder. After separation, use a polishing disk/bur to remove any rough edges around the sprue location.
- Clean the abutment according to the instructions provided in the Sterility section of this document.
- Visually inspect finished abutments with adequate lighting. Ensure that the abutments are clean and free of oils, and debris.
- Visually inspect the implant-abutment connection of the abutment to ensure no damage occurred during the milling machine processing.

**Final Restoration**

The final restoration which is placed over the customized abutment is manufactured outside of the regulatory aspects of the abutment manufacturing. It may be produced at a dental laboratory following traditional or CAD/CAM methods.

**Deliver the Final Restoration**

- Sterilize Preat Milled Titanium Abutments according to the procedure detailed above.
- Seat the titanium abutment or screw-retained hybrid restoration completely into the implant, making sure that the anti-rotational features of the connection interface are fully engaged, and the contours of the sculpted emergence profile are esthetically oriented.
- Insert the Preat Titanium Prosthetic Screw (provided) into the screw access hole and hand-tighten using the appropriate driver. It is strongly recommended that a radiograph of the connection site be taken to confirm complete seating of the abutment or hybrid restoration before proceeding.
- Using the appropriate driver in conjunction with a properly metered torque wrench, tighten the abutment or hybrid restoration to the implant manufacturer's recommended torque value (see "Torque Values" below).
- Fill the screw access hole with cotton, Teflon tape, gutta-percha, or other suitable material.
- If the restoration is of a screw-retained hybrid design, cover the screw access hole with flowable composite, and cure. Otherwise, follow applicable cementation procedures to affix the definitive restoration to the abutment.

**Torque Values**

Preat Prosthetic Components designed to support a provisional or final prosthesis should be affixed to the implant and tightened using a properly metered torque wrench to the value recommended by the implant manufacturer, as indicated in the table below. The application of torque in excess of the manufacturer's recommended value may result

in fracture of the implant fixture or retaining screw. Insufficient application of torque may result in screw loosening or inadequate component attachment.

| **Third-Party Compatible Implant System and Platform Sizes (mm or name)[1]** | | **Third-Party Manufacturer's Recommended Torque (Ncm) for Titanium Abutment/ Screw** |
|---|---|---|
| 3i OSSEOTITE® Certain® | 3.4, 4.1, 5.0, 6.0 | 20 Ncm |
| Astra Tech OsseoSpeed™ | 3.0<br>3.5/4.0<br>4.5/5.0 | 15 Ncm<br>20 Ncm<br>25 Ncm |
| Astra Tech OsseoSpeed™ Plus (OsseoSpeed™ EV) | 3.0, 3.6, 4.2, 4.8, 5.4 | 25Ncm |
| BioHorizons Tapered Internal | 3.0, 3.5, 4.5 | 30 Ncm |
| HIOSSEN ET III | Mini<br>Standard | 20 Ncm<br>30 Ncm |
| Implant Direct Legacy | 3.0<br>3.5, 4.5, 5.7 | 20 Ncm<br>30 Ncm |
| Keystone PrimaConnex™ | 3.5, 4.1, 5.0 | 30 Ncm |
| MegaGen AnyRidge | 3.5 | 30 Ncm |
| Neodent® Helix GM™ | 3.0 | 20 Ncm |
| Neoss | 4.1 | 32 Ncm |
| Nobel Biocare™ NobelActive® | 3.0<br>NP, RP, WP | 15 Ncm<br>35 Ncm |
| Nobel Biocare Nobel Replace® | NP, RP, WP, 6.0 | 35 Ncm |
| Straumann™ BLX | RB/WB, WB | 35 Ncm |
| Straumann® Bone Level | NC, RC | 35 Ncm |
| Straumann® Tissue Level | RN, WN | 35 Ncm |
| Zimmer Screw-Vent®/ Tapered Screw-Vent® | 3.5, 4.5, 5.7 | 30 Ncm |

[1] See Trademark section

**Labelling Information**

| Symbol | Title of Symbol (Reference Number) | Description |
|---|---|---|
|  | Manufacturer | Indicates the medical device manufacturer. |
|  | Date of manufacture | Indicates the date when the medical device was manufactured. |
|  | Catalog Number | Indicates the manufacturer's catalog number so that the medical device can be identified. |
|  | Batch Code | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|  | Quantity | Indicates the number of unit per package. |
|  | Prescription Only | This symbol indicates U.S. Federal Law restricts this device to sale by or on the order of a physician |
|  | Consult instructions for use or consult electronic instructions for use | Indicates the need for the user to consult the instructions for use. |
|  | Non-Sterile | Indicates a medical device that has not been subjected to a sterilization process. |
|  | Do not re-use | Indicates a medical device that is intended for one single use only. |
|  | Do not use if package is damaged and consult instructions for use | Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use additional information. |
|  | MR Conditional | Indicates that a medical device presents no known hazards in a specific MR environment under specific device and MR scanner conditions. |

**Policy / Warranty**

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