
Instructions for Use and Restorative Manual

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| **Preat®**<br>**Abutments** | **Preat Corporation**<br>**2625 Skyway Dr. Suite B**<br>**Santa Maria, CA 93455 USA**<br>**1-800-232-7732**<br>www.preat.com | REF<br>LOT<br>QTY |
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## Preat Corporation Prosthetic Components

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# Restorative Considerations

## Scope

This manual outlines the appropriate procedures for using Preat® Prosthetic Components in the process of restoring endosseous dental implants with a common range of prosthetic solutions, such as single- or multiple-unit crowns and bridges (cementable or screw-retained), fixed-removable full-arch prostheses, or attachments for securing removable implant overdentures.

The procedures and guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant restorative dentistry and are not intended to be a substitute for formal clinical or laboratory training. Preat Prosthetic Components and accessories should only be used 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. Responsibility rests with the provider.

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

## 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. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Bases or Titanium Blanks are to be sent to a Preat validated milling center for manufacture.

## Compatible Third-Party Implant Systems

Preat Prosthetic Components manufactured by Preat Corporation are compatible with the following third-party implant restorative platforms:

| Compatible Third-Party Implant Systems[1] | 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 |

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| | | |
|---|---|---|
| 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 |
| | 5.5 | WP |
| 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 |

**NOTE:** The availability of a particular type of prosthetic component varies by implant system, and may be limited by geographical territory. The platform-specific compatibility of each component is indicated on the individual product label. For a complete product listing, please refer to the **Preat Prosthetic Components Product Catalog**, or contact a Preat sales representative.

## Contraindications

Do not use Preat Components in patients with hypersensitivity to any material listed in the product description. For product-specific contraindications, please refer to the individual product information sections contained within this restorative manual.

Preat Abutments should not be used unless the dental implants are stable and there are no signs of infection or severe bone loss. Poor bone quality, poor patient oral hygiene, heavy tobacco use, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction, and psychological instability may contribute to lack of integration and/or subsequent implant failure. Severe bruxism, clenching, and overloading may cause bone loss, screw loosening, component fracture, and/or

implant failure. Exposure to radiation and chemotherapy may impact the health of the implant. Dental implant patients should be instructed to consult with their physician prior to undergoing such treatment options.

## Precautions

Proper case planning is essential to the long-term success of both the prostheses and the implants. Overload is one of the key contributors to implant failure. Ensure that the implant angle corrections are appropriate for the occlusal load.

Preat Prosthetic Components may only be used for their intended purpose, in accordance with general rules for restorative dental treatment, occupational safety, and accident prevention. The improper technique associated with the use of these devices may result in adverse effects, including but not limited to implant fracture or failure, loss of supporting bone, restoration fracture or failure, and compromised oral function. 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.

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.

**Breakage**

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, and physical trauma.

**Changes in Performance**

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 (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

**Hygiene and Maintenance**

Long-term health is directly related to the maintenance of oral hygiene. Potential candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the prosthesis. The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

**General Considerations**

Control of biomechanical stresses is the key factor to long-term success of the prosthesis. Even after implant integration, imbalances in occlusal forces can lead to implant failure. Implant patients should be

monitored for signs of peri-implant bone loss and excessive attachment wear as signs of occlusal overloading.

**Single Use**

Preat abutments and components 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. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

## 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 a Preat Abutments 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 preat.com.

## Sterility

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>o 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>o 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:** | 30 minutes |
| **Test Article Configuration:** | Test articles individually double pouched and placed on edge in sterilizer |

| | |
|---|---|
| **Sterilizer Type:** | **Gravity** |
| **Preconditioning Pulses:** | N/A |
| **Temperature:** | 121°C |
| **Full Cycle Exposure Time:** | 30 minutes |
| **Dry Time:** | 30 minutes |
| **Test Article Configuration:** | Test articles individually double pouched and placed on edge in sterilizer |

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 or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table however, only the above methods were tested. Verify the calibration of your unit to ensure recommended temperatures are not being 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.

## Materials

All Preat Abutments and Abutment Screws are made from titanium alloy (Ti-6Al-4V):

- Preat Temporary Abutments/ Verification Cylinders
- Preat Esthetic Abutments
- Preat Multi-Unit Abutments
- Preat Clix Ball Abutments
- Preat O-Ring Abutments
- Preat Titanium Base Abutments
- Preat Titanium Blank Abutments
- Preat Titanium Screws
- Preat Healing Abutments

Preat Transfer Copings (Class I accessories) are also made from titanium alloy (Ti-6Al-4V).

## Residual Risk

- Fracture
- Infection
- Adverse Local Tissue Reaction
- Tissue Inflammation
- Internal Trauma
- Toothache/ Pain
- Excessive Wear

## Storage and Handling

Preat Prosthetic Components should be stored in a dry location at room temperature, in their original packaging. Visually inspect all products to ensure seals and contents are intact prior to use. For product-specific handling instructions, please refer to the individual product labels.

## Prosthetic Component Types

Preat Corporation offers an extensive line of prosthetic components under the Preat brand name:

- Transfer Copings (Class I accessories)
- Preat Temporary Abutments/ Verification Cylinders
- Preat Esthetic Abutments
- Preat Multi-Unit Abutments
- Preat Clix Ball Abutments
- Preat O-Ring Abutments
- Preat Titanium Base Abutments
- Preat Titanium Blank Abutments
- Preat Titanium Screws
- Preat Healing Abutments

## Restorative Protocols

With the exception of system-specific drivers (please refer to the "Driver Selection" section below), the restorative protocols outlined in this manual are system independent. Unless otherwise noted, the same techniques apply regardless of which implant system is being used. While every attempt has been made to document appropriate restorative procedures, it is the responsibility of the clinician to be familiar with any protocols that may govern use of a specific implant system as determined or recommended by the system manufacturer.

## Driver Selection

For clinical convenience, Preat Prosthetic Components are designed to be compatible with the restorative instrumentation of the specified implant system. This means that the clinician can expect to use the implant manufacturer's recommended drivers to engage the female connection feature of any Preat prosthetic component, as follows:

| Third-Party Implant System[1] | Require Driver | Compatible Preat Drivers |
|---|---|---|
| 3i OSSEOTITE® Certain® | 0.048" Hex Driver | 9000035<br>9000065<br>9000075 |
| Astra Tech OsseoSpeed™ | 0.050" Hex Driver | 9000034<br>9000064<br>9000074 |
| Astra Tech® OsseoSpeed™ Plus (OsseoSpeed™ EV) | 0.050" Hex Driver | 9000034<br>9000064<br>9000074 |
| BioHorizons Tapered Internal | 0.050" Hex Driver | 9000034<br>9000064<br>9000074 |
| HIOSSEN ET III | 0.048" Hex Driver | 9000035<br>9000065<br>9000075 |

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| | | |
|---|---|---|
| Implant Direct Legacy | 0.050” Hex Driver | 9000034<br>9000064<br>9000074 |
| Keystone PrimaConnex™ | Square Driver | N/A |
| MegaGen AnyRidge | 0.048” Hex Driver | 9000035<br>9000065<br>9000075 |
| Neodent® Helix GM™ | Neo Screwdriver | N/A |
| Neoss | 0.050” Hex Driver | 9000034<br>9000064<br>9000074 |
| Nobel Biocare NobelActive® | Unigrip ™ Hex Driver | 9000033<br>9000063<br>9000073 |
| Nobel Biocare Nobel Replace® | Unigrip ™ Hex Driver | 9000033<br>9000063<br>9000073 |
| Straumann™ BLX | SCS (Screw Carrying System) Driver | 9000032<br>9000072<br>9000072 |
| Straumann® Bone Level | SCS (Screw Carrying System) Driver | 9000032<br>9000072<br>9000072 |
| Straumann® Tissue Level | SCS (Screw Carrying System) Driver | 9000032<br>9000072<br>9000072 |
| Zimmer Dental Screw-Vent® / Tapered Screw-Vent® | 0.050” Hex Driver | 9000034<br>9000064<br>9000074 |

## 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)** | | | | |
|---|---|---|---|---|---|
| | **Healing/ Temporary Abutment** | **Titanium Abutment / Screw** | **Multi-Unit Abutment / Screw** | **Multi-Unit Prosthetic Screw** | **Clix Ball/ O-Ring Abutment** |
| 3i OSSEOTITE® Certain®<br>3.4, 4.1, 5.0, 6.0 | 15 Ncm | 20 Ncm | 20 Ncm | 15 Ncm | 30 Ncm |
| Astra Tech OsseoSpeed™ 3.0<br>3.5/4.0<br>4.5/5.0 | 15 Ncm<br>15 Ncm<br>15 Ncm | 15 Ncm<br>20 Ncm<br>25 Ncm | 20 Ncm<br>20 Ncm<br>25 Ncm | 15 Ncm<br>15 Ncm<br>15 Ncm | 30 Ncm<br>30 Ncm<br>30 Ncm |

| | | | | | |
|---|---|---|---|---|---|
| Astra Tech OsseoSpeed™ Plus (OsseoSpeed™ EV) 3.0, 3.6, 4.2, 4.8, 5.4 | 15 Ncm | 25Ncm | 25Ncm | 15 Ncm | N/A |
| BioHorizons Tapered Internal 3.0, 3.5, 4.5 | 15 Ncm | 30 Ncm | 20 Ncm | 15 Ncm | 30 Ncm |
| HIOSSEN ET III Mini<br>Standard | 15 Ncm<br>15 Ncm | 20 Ncm<br>30 Ncm | 20 Ncm<br>30 Ncm | 15 Ncm<br>15 Ncm | 30 Ncm<br>30 Ncm |
| Implant Direct Legacy 3.0<br>3.5, 4.5, 5.7 | 15 Ncm<br>15 Ncm | 20 Ncm<br>30 Ncm | 20 Ncm<br>30 Ncm | 15 Ncm<br>15 Ncm | 30 Ncm |
| Keystone PrimaConnex™ 3.5, 4.1, 5.0 | 15 Ncm | 30 Ncm | 30 Ncm | 15 Ncm | N/A |
| MegaGen AnyRidge 3.5 | 15 Ncm | 30 Ncm | 30 Ncm | 15 Ncm | 30 Ncm |
| Neodent® Helix GM™ 3.0 | 15 Ncm | 20 Ncm | 20 Ncm | 15 Ncm | N/A |
| Neoss 4.1 | 15 Ncm | 32 Ncm | 32 Ncm | 15 Ncm | 30 Ncm |
| Nobel Biocare™ NobelActive® 3.0<br>NP, RP, WP | 15 Ncm<br>15 Ncm | 15 Ncm<br>35 Ncm | 15 Ncm<br>35 Ncm | 15 Ncm<br>15 Ncm | N/A<br>30 Ncm |
| Nobel Biocare Nobel Replace® NP, RP, WP, 6.0 | 15 Ncm | 35 Ncm | 35 Ncm | 15 Ncm | 30 Ncm |
| Straumann™ BLX RB/WB, WB | 15 Ncm | 35 Ncm | 35 Ncm | 15 Ncm | N/A |
| Straumann® Bone Level NC, RC | 15 Ncm | 35 Ncm | 35 Ncm | 15 Ncm | 30 Ncm |
| Straumann® Tissue Level RN, WN | 15 Ncm | 35 Ncm | 35 Ncm | 15 Ncm | 30 Ncm |
| Zimmer Screw-Vent®/ Tapered Screw-Vent® 3.5, 4.5, 5.7 | 15 Ncm | 30 Ncm | 30 Ncm | 15 Ncm | 30 Ncm |

## Preat® Transfer Coping

**Product Description**

Preat® Transfer Copings are used to transmit the position, angulation, and connection feature orientation of seated implants when captured in an elastomeric impression. Impressions may be taken with either the indirect or direct technique, depending on the clinician's preference and chairside conditions. Transfer copings are precisely machined from titanium alloy and attached to the implant fixture by a titanium screw or guide pin. Each transfer coping is specific to the restorative platform of the seated implant, as well as the impression technique and desired emergence profile. Transfer copings are Class I accessories.

*Closed-tray* transfer copings are for use when employing an indirect impression technique. *Open-tray* transfer copings are for use when using a direct impression technique. It is important to use the appropriate transfer coping for the impression technique employed. Using a closed-tray transfer coping with an open tray will result in an unreliable impression, as the lack of undercuts on the closed tray coping do not impress a vertical stop for repositioning the coping without the surface of a closed tray.

Closed Tray
(Indirect Technique)

Open Tray
(Direct Technique)

Each closed-tray Preat Transfer Coping comes packaged with a retaining screw (Preat® Closed Tray Transfer Screw) compatible with the restorative instrumentation of the specified implant system. Do not use an open-tray transfer screw or guide pin with a closed-tray transfer coping, as the dissimilar screw lengths will allow the coping to slide along the screw shaft in an unpredictable manner.

Each open-tray Preat Transfer Coping comes packaged with a retaining screw (Preat® Open Tray Transfer Screw) and a provisional screw (Preat® Guide Pin) compatible with the restorative instrumentation of the specified implant system. The guide pin should be used throughout the impression process, while the open-tray transfer screw should only be utilized to affix the appropriate implant analog prior to delivery to the laboratory technician.

Open Tray Screw

Guide Pin

Each open-tray Preat Transfer Coping also comes packaged with a length of rigid plastic tubing to serve as a blockout during the impression procedure.

Preat® Transfer Copings are supplied NON-STERILE, and prior to clinical use, must be sterilized by the end user.

**Contraindications**
Preat Transfer Copings should not be used for digital impressions captured with an intraoral scanner.

**Closed Tray Impression Procedure**
**Select a Closed Tray Transfer Coping**

1) Verify adequate primary stability of the implant before seating any Preat Closed Tray Transfer Coping.
2) Select the appropriate Preat Closed Tray Transfer Coping based on the implant system, platform size, and impression technique to be used.

**Place the Closed Tray Transfer Coping**

1) Ensure gingival tissue is sufficiently withdrawn from the implant access site in order to avoid pinching.

2) Seat the Preat Closed Tray Transfer Coping onto the implant fixture so the anti-rotational features of the connection engage. Hand-tighten into place using the Preat Closed Tray Transfer Coping Screw (provided).

**NOTE:** It is recommended that a radiograph be taken of the implant-coping connection to confirm the transfer coping is completely seated before proceeding.

**Capture the Impression**

1) Follow documentation for the chosen impression material to take a full-arch elastomeric impression.
2) Once the impression material has set within the closed tray, remove the tray from the patient's ridge. The Preat Closed Tray Transfer Coping will remain connected to the seated implant.

**Record Implant Placement**

1) Unscrew the Preat Closed Tray Transfer Coping from the seated implant and remove. Mount a corresponding implant analog on the closed-tray transfer coping and fasten with the same closed-tray transfer coping screw.
2) Reposition the closed-tray transfer coping into its corresponding depression in the impression tray and press firmly to engage. The implant analog should protrude from the impression.
3) Proceed with the fabrication of a stone model using standard laboratory techniques. Upon separation, the implant analog is a part of the master cast, replicating the position of the implant seated in the oral cavity.

**Open Tray Impression Procedure**

**Select an Open Tray Transfer Coping**

1) Verify adequate primary stability of the implant before seating any Preat Open Tray Transfer Coping.
2) Select the appropriate Preat Open Tray Transfer Coping based on the implant system, platform size, and impression technique to be used.

**Place the Open Tray Transfer Coping**

1) Ensure gingival tissue is sufficiently withdrawn from the implant access site in order to avoid pinching.
2) Seat the Preat Open Tray Transfer Coping onto the implant fixture so the anti-rotational features of the connection engage. Hand-tighten into place using the Preat Guide Pin (provided).
3) Slide the blockout tube (provided) over the guide pin, making sure it rests firmly on the occlusal end of the open-tray transfer coping.

**Prepare the Impression Tray**

Using a custom tray, prepare a hole in the tray that will align with the Preat Open Tray Transfer Coping and the protruding Preat Guide Pin when the impression is taken.

**NOTE:** It is recommended that a radiograph be taken of the implant-coping connection site to confirm the transfer coping is completely seated before proceeding.

**Capture the Impression**

1) Follow documentation for the chosen impression material to take a full-arch elastomeric impression.

2) Once the impression material has set within the open tray, remove the blockout tube to expose the protruding guide pin.
3) With the tray still in place on the ridge, unscrew and remove the guide pin from the Preat Open Tray Transfer Coping.
4) Remove the tray from the patient's ridge. The open-tray transfer coping should be captured by the impression material.

**Record Implant Placement**

1) Mount a corresponding implant analog on the Preat Open Tray Transfer Coping captured within the impression. Fasten using the Preat Open Tray Transfer Coping Screw (provided), making sure to maintain a hold on the analog rather than the impression tray, so as not to rotate the transfer coping in the impression material.
2) Proceed with the fabrication of a stone model using standard laboratory techniques. Upon separation, the implant analog is a part of the master cast, replicating the position of the implant seated in the oral cavity.

## Preat® Temporary Abutment/ Verification Cylinder

**Product Description**

Preat® Temporary Abutments and Preat® Bite Verification Cylinders are indicated for the fabrication of temporary screw-retained restorations. Provisional restorations can be made chairside using any standard fabrication technique (e.g., vacuum-formed sheet, prefabricated crown/bridge form, etc.). Temporary abutments and bite verification cylinders are precisely machined from titanium alloy and attached to the implant fixture (or implant analog) by a titanium screw or provisional guide pin. Each temporary abutment or bite verification cylinder is specific to the restorative platform of the seated implant.

*Engaging* temporary abutments are indicated for single-unit restorations to prevent rotation of the provisional crown. *Non-engaging* temporary abutments are indicated for multi-unit bridges, and therefore avoid the unnecessary anti-rotational implant connection feature to allow for a passive path of insertion.

Engaging

Non-Engaging

Each Preat Temporary Abutment or Preat Bite Verification Cylinder is packaged with a separate provisional screw (Preat® Guide Pin) and separate retaining screw (Preat® Titanium Screw) compatible with the restorative instrumentation of the specified implant system. The guide pin should be used throughout the fabrication process. The titanium screw should only be utilized to retain the finished provisional.

Guide Pin

Titanium Screw

Preat® Temporary Abutments and Preat® Bite Verification Cylinders are supplied NON-STERILE, and prior to clinical use, must be sterilized by the end user.

**Contraindications**

Preat Temporary Abutments and Preat Bite Verification Cylinders are not intended for applications exceeding 180 days during endosseous and gingival healing.

The following conditions would contraindicate use of Preat Temporary Abutments / Verification Cylinders:

- Less than 4.0 mm abutment height
- Use on implants placed in any orientation other than vertical. No post angle correction is allowed with Preat Temporary Abutment/Verification Cylinders.

**Temporary Abutment Placement Procedure**

**Select a Temporary Abutment or Bite Verification Cylinder**

1) Verify adequate primary stability of the implant before seating any Preat Temporary Abutment or Preat Bite Verification Cylinder.
2) Select the appropriate Preat Temporary Abutment or Preat Bite Verification Cylinder based on the implant system, platform size, and type of provisional restoration to be fabricated.

**Place the Temporary Abutment or Bite Verification Cylinder**

1) Modify the Preat Temporary Abutment or Preat Bite Verification Cylinder as needed by means of hand-milling prior to seating.
   **NOTE**: *If the Abutment/Cylinder post is modified, at least 4 mm in height must be preserved.*
2) Sterilize Preat Temporary Abutment or Preat Bite Verification Cylinder according to the procedure detailed above.
3) Seat the base of the Preat Temporary Abutment against the exposed implant platform (or imp lant analog, if the provisional is being fabricated on a model). If engaging, align the anti-rotational connection feature of the abutment with the internal cavity of the seated implant (or implant analog).
4) Using the Preat Guide Pin packaged with the Preat Temporary Abutment or Preat Bite Verification Cylinder, hand-tighten the abutment into place against the implant (or implant analog).
5) Block out any undercuts on adjacent teeth. Failure to do so may result in the provisional becoming locked in during reline.
6) Prepare the provisional crown or bridge form by drilling a hole through the mold directly above the seated implant (or implant analog).

**Fabricate the Provisional Restoration**

1) Fill the plastic crown or bridge form with composite resin, acrylic, or other temporary crown-and-bridge material. Care must be taken to confine temporary crown-and-bridge material to the restoration space only.
2) Place the plastic mold onto the ridge or model. The guide pin should protrude through the hole previously drilled into the mold. Apply vertical pressure to the mold and confirm that it is firmly seated on all guide teeth.
3) While maintaining pressure, follow curing procedures for the chosen crown-and-bridge material.
4) Once the crown-and-bridge material is properly cured, remove the screw.

5) Remove the mold and provisional restoration from the ridge together. The Preat Temporary Abutments or Preat Bite Verification Cylinders should be captured within the restoration.
6) Remove the restoration from the mold and make adjustments as needed.

**Place the Provisional Restoration**

1) Reseat the provisional restoration onto the ridge. Utilize radiography to verify complete seating, if clinically appropriate.
2) Locate the Preat Titanium Screw that came packaged with the Preat Temporary Abutment or Preat Bite Verification Cylinder.
3) Select the appropriate driver based on the implant system being utilized (see "Driver Selection"). Using the selected driver, advance threaded delivery of the titanium screw until fully seated, in order to secure the temporary abutment or bite verification cylinder to the implant.
4) Using the appropriate torque wrench, tighten the titanium screw to the implant manufacturer's recommended value for a temporary restoration (see "Torque Values").
5) Fill the screw access hole with cotton, Teflon tape, gutta-percha, or other suitable material.
6) Seal the screw access hole with temporary veneering material.

## Preat® Titanium Esthetic Abutments

**Product Description**

Preat® Titanium Esthetic Abutments are prefabricated, screw-retained intraoral abutments intended to be connected directly to an endosseous implant for retention of a cemented dental prosthesis. They may be indicated for single- and multiple-tooth restorations. Titanium esthetic abutments are precisely machined from titanium alloy and attached to the implant fixture with a titanium screw. Unlike the circular emergence profile of standard stock abutments, esthetic abutments are manufactured with a tapered emergence profile for more natural-looking contouring of the soft tissue at the implant site. Each esthetic abutment is specific to the restorative platform of the seated implant, and anatomically designed for the connection site's region on the ridge. Angled abutment bodies, produced with a 15-degree slope of one hemisphere to compensate for an undesirable path of insertion resulting from excessive implant angulation, are available.

Each Preat Titanium Esthetic Abutment is packaged with a separate retaining screw (Preat® Titanium Screw) compatible with the restorative instrumentation of the specified implant system.

Titanium Screw

**Contraindications**

The following conditions would contraindicate use of Preat Titanium Esthetic Abutments:

- Wall thickness less than 0.5 mm
- Gingival margin diameter less than 0.5 mm wider than the implant
- Less than 0.5 mm margin height
- Less than 4.0 mm abutment height

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

**Restorative Procedure with Titanium Esthetic Abutments**

**Capture Implant Placement**
Take an implant-level impression utilizing the preferred technique (direct, indirect, or intraoral scan). Submit the impression to the laboratory.

**Laboratory — Fabricate the Restoration**
1) Follow pouring procedures for the appropriate die stone to produce a working model and articulate with a bite registration.
2) Select the appropriate Preat Titanium Esthetic Abutment based on the system, platform size, location, angulation, and occlusal clearance of the implant seated in the patient's mouth.
3) Seat the abutment completely into the implant analog on the working model, 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. For angled abutments, the tapered side should be oriented nearest vertical along the same plane as the implant.
4) Insert the Preat Titanium Screw (provided) into the abutment's screw access hole and hand-tighten using the appropriate driver.
5) Fabricate the restoration using conventional casting or CAD/CAM techniques. Veneer as necessary. If a screw-retained hybrid restoration is indicated, lute the ceramic crown to the titanium abutment.

**Deliver the Final Restoration**
1) Seat the titanium esthetic 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. For angled abutments, the tapered side should be oriented nearest vertical along the same plane as the implant.
2) Insert the Preat Titanium 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.
3) 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"). Fill the screw access hole with cotton, Teflon tape, gutta-percha, or other suitable material.
   Follow applicable cementation procedures to affix the definitive restoration to the abutment. Or, if the restoration is of a screw-retained hybrid design, cover the screw access hole with flowable composite, and cure.

## Preat® Multi-Unit Abutment

**Product Description**
Preat® Multi-Unit Abutments are screw-retained intraoral abutments intended to be connected directly to endosseous implants in partially or fully edentulous patients for the retention of cast or milled bar overdentures. For implant-supported prostheses, six or more implants are recommended in the maxilla, four or more in the mandible. If clinical conditions dictate fewer implants, an implant-retained, tissue-supported prosthesis is indicated. Multi-unit abutments are precisely machined from titanium alloy, and are available with a variety of collar heights to achieve optimal emergence from shallow or deep gingival wells.

*Straight* multi-unit abutments lack any anti-rotational features at the implant-abutment interface. The apical portion of a straight multi-unit abutment is threaded for integration with the internal cavity of a seated implant. For abutment delivery, the occlusal surface features a male hex head compatible with the multi-unit driver recommended by the implant manufacturer.
*Angled* multi-unit abutments of 17 degrees and 30 degree enable clinicians to compensate for the divergence of seated implants or to otherwise accommodate an angled path of insertion. Angled multi-unit abutments feature an anti-rotational connection interface specific to the matching implant platform, and are attached to the implant fixture with an angled multi-unit abutment screw.
Both straight and angled multi-unit abutments feature a female connection port at the coronal apex, to allow for the attachment of a screw-retained or fixed-removable dental prosthesis with a multi-unit restorative screw (Preat® Prosthetic Screw).

Straight 17° Angle 30° Angle

Each angled Preat Multi-Unit Abutment is packaged with a separate retaining screw (Preat® Angled Multi-Unit Abutment Screw) compatible with the restorative instrumentation of the specified implant system.

Angled Multi-Unit Abutment Screw

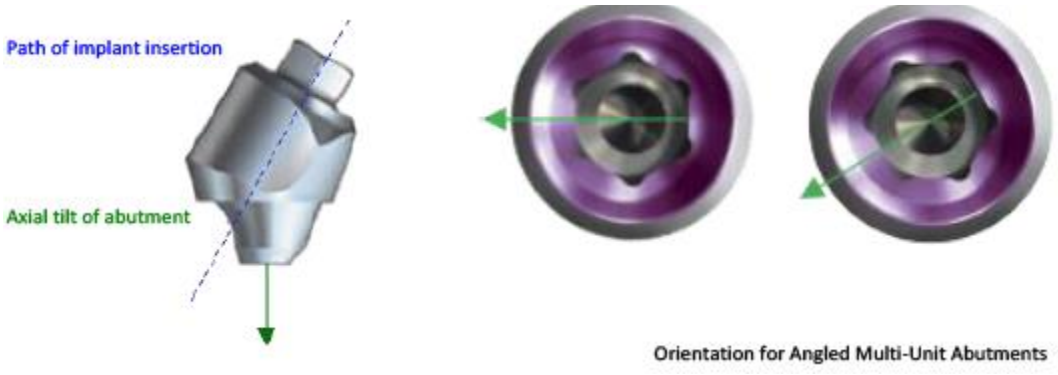
Preat® Multi-Unit Abutments are supplied NON-STERILE, and prior to clinical use, must be sterilized by the end user.

**Contraindications**
The following conditions would contraindicate use of Preat Multi-Unit Abutments:

- Greater than 32 degrees divergence from parallel for a splinted restoration when using 17-degree angled multi-unit abutments

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

**Implant Orientation**
The axial tilt of a Preat Angled Multi-Unit Abutment (angular divergence from path of insertion) is designed and manufactured to lie along a *plane* of the implant connection geometry, as opposed to a corner or junction. To maximize the angle-correcting attributes of the multi-unit abutment, be sure to rotate the implant upon final seating so that one side of the internal connection geometry (flat or lobe) is oriented to serve as the base of angulation, in accordance with the restorative treatment plan.




Orientation for Angled Multi-Unit Abutments

NOTE: Some implant manufacturers may offer implant drivers marked to facilitate proper orientation of implants upon final seating. These markings may not apply to the ideal implant orientation for angled multi-unit abutments. Proper treatment planning is essential to restorative success.

**Restorative Procedure with Multi-Unit Abutments**

**Place the Multi-Unit Abutment**

1) Select the appropriate Preat Multi-Unit Abutment based on platform size, endosseous implant angle and depth of the soft-tissue well. The margin should be 1 to 2 mm supragingival.
2) Remove the lid from the aseptic vial and retrieve the abutment by lifting the plastic abutment carrier straight out.
3) Sterilize Preat Multi-Unit Abutment Cylinder according to the procedure in detailed above.

For Straight Abutments:

1) Using the plastic carrier, seat the abutment into the implant and hand-tighten. Remove the plastic carrier by pulling the apex of the carrier toward the facial. It is strongly recommended that a radiograph of the connection site be taken to confirm complete seating of the abutment before proceeding.
2) Using the appropriate driver in conjunction with a properly metered torque wrench, tighten the multi-unit abutment to the implant manufacturer's recommended torque value (see "Torque Values").

For Angled Abutments:

3) Using the plastic carrier, seat the abutment into the implant until the anti-rotational features of the connection interface are engaged. Lift and rotate as necessary to orient the angle in the required direction.
4) Hand-tighten the Preat Angled Multi-Unit Abutment Screw using the appropriate driver (see "Driver Selection" section above). Twist the plastic carrier counterclockwise to remove. It is strongly recommended that a radiograph of the connection site be taken to confirm complete seating of the abutment before proceeding.

5) Using the appropriate driver in conjunction with a properly metered torque wrench, tighten the multi-unit abutment to the implant manufacturer's recommended torque value (see "Torque Values").

**Delayed Loading of Multi-Unit Abutments**

1) If the initial stability of the seated implant is insufficient for loading, cover each Preat Multi- Unit Abutment with a Preat Multi-Unit Temporary Healing Cap and hand-tighten with the Preat Prosthetic Screw provided, using the appropriate driver. Do not overtighten.
2) Using the patient's existing denture or other prosthesis, relieve the area directly above the placement of each temporary healing cap until the denture rests on the ridge.
3) Follow procedures to reline the denture over the temporary healing caps, using soft reline material only. The temporized denture can be used during a healing phase until the implants obtain sufficient load-bearing stability.

**Closed Tray (Indirect) Impression Procedure for Multi-Unit Abutments**

1) Ensure gingival tissue is sufficiently withdrawn to avoid pinching.
2) Twist a Preat Closed Tray Multi-Unit Impression Coping onto each multi-unit abutment until fully seated. Hand-tighten only. Overtightening may result in loosening of the multi-unit abutments when the copings are removed.
3) Follow documentation for the chosen impression material to take a full-arch elastomeric impression.
4) Once the impression material has set within the closed tray, remove the tray from the patient's ridge. Each closed tray multi-unit impression coping will remain connected to its corresponding abutment.
5) Unscrew each closed tray multi-unit impression coping from its corresponding multi-unit abutment and remove. Twist each closed tray impression coping onto a Preat Multi-Unit Abutment Analog and hand-tighten.
6) Reposition each closed tray multi-unit impression coping into its corresponding depression in the impression tray and press firmly to engage. The multi-unit abutment analogs should protrude from the impression.
7) Proceed with the fabrication of a stone model using standard laboratory techniques. Upon separation, the multi-unit abutment analogs are a part of the master cast replicating the position of each multi-unit abutment in the oral cavity.

**Open Tray (Direct) Impression Procedure for Multi-Unit Abutments**

1) Ensure gingival tissue is sufficiently withdrawn to avoid pinching.
2) Seat a Preat Open Tray Multi-Unit Impression Coping onto each multi-unit abutment.
3) Slide the Preat Guide Pin (provided with each Preat Open Tray Multi-Unit Impression Coping) into the impression coping. Turn the guide pin clockwise to hand-tighten. Overtightening may result in loosening of the multi-unit abutment when the guide pin is removed.
4) Follow documentation for the chosen impression material to take a full-arch elastomeric impression.
5) Once the impression material has set within the open tray, unscrew and remove the guide pin with the tray still in place on the arch.
6) Remove the tray from the patient's ridge. The open tray multi-unit impression copings should be captured by the impression material.
7) Mount a Preat Multi-Unit Abutment Analog onto each open tray multi-unit impression coping captured within the impression, and refasten using the guide pin.

8) Proceed with the fabrication of a stone model using standard laboratory techniques. Upon separation, the multi-unit abutment analogs are a part of the master cast replicating the position of each multi-unit abutment in the oral cavity.

**Temporize with Multi-Unit Abutments**

1) Sterilize Preat Multi-Unit Titanium Temporary Cylinder according to the instructions detailed above.
2) Seat a Preat Multi-Unit Titanium Temporary onto each multi-unit abutment and hand- tighten the Preat Prosthetic Screw (provided) using the appropriate driver (see "Driver Selection").
3) Using an existing denture or other prosthesis, place a hole in the position directly above the placement of each multi-unit titanium temporary. The holes should puncture all the way through the prosthesis.
4) Resting the denture on the ridge with the titanium temporaries protruding from the apex, carefully fill the hole around each titanium temporary with acrylic, flowable composite, or other material suitable for securing the temporary to the denture. Follow procedures to cure the material, being careful to keep the temporary's screw access channel free of adhesive.
5) Remove the prosthetic screw from each titanium temporary and remove the denture. The temporaries should be captured within the denture.
6) Modify the denture as necessary. Grind any protruding titanium from the upper side of the denture. Fill any voids around the base of each titanium temporary on the underside of the denture with acrylic, flowable composite, or other suitable material, and cure.
7) Reseat the temporary denture onto the ridge and replace the prosthetic screw into the multi-unit titanium temporaries. Using the appropriate driver in conjunction with a properly metered torque wrench, tighten the prosthetic screws to 15 Ncm.
8) Fill the screw access channels with gutta-percha, silicone, or other suitable temporary material.

**Take the Occlusal Rim Bite Registration**

1) Remove the occlusal rim from the working cast by twisting and removing the guide pins straight up through the access holes.
2) Seat the record base onto the multi-unit abutments on the patient's ridge. Hand-tighten the record base and occlusal rim fixture to the abutments with the prosthetic screws, using the appropriate driver.

**NOTE:** The alignment procedure may require multiple insertions and removals of the occlusal rim. At least two screws should be fastened during registration to ensure proper fit.

3) Using a heated Bard Parker knife, index the midline and smile line with a notch across the facial aspect of each occlusal rim.
4) Modify extraorally as needed with a heated Bard Parker knife to set the vertical dimension of occlusion.
5) Using a heated Bard Parker knife, cut a shallow triangular notch into the occlusal surface of each occlusal rim's posterior regions. If the patient is completely edentulous, be sure the notches in the maxillary and mandibular occlusal rims are slightly offset for successful indexing of the bite registration.
6) With the occlusal rim securely fastened by the prosthetic screws, syringe sufficient elastomeric bite registration material onto the rim and create the bite registration.

7) Remove the occlusal rim from the patient's mouth. Replace and fasten to the working cast with the guide pins, and return the working cast, occlusal rims, and bite registration to the laboratory.

NOTE: If desired, measurement and luting of the bar segments can be performed intraorally, and a stone working model produced from the luted bar by connecting Preat Multi-Unit Abutment Analogs to the luted bar copings.

**Try-in the Bar**

1) Confirm that the multi-unit abutments seated on the endosseous implants are tightened to the implant manufacturer's recommended torque value (see "Torque Values").
2) Seat the bar onto the multi-unit abutments. Hand-tighten a Preat Prosthetic Screw into either distal-most abutment.
3) Examine the other abutments to confirm no separation or lifting of the bar has resulted from tightening the first. Proceed to hand-tighten each abutment in turn, starting from the distal and moving forward, alternating between sides of the ridge.

If a passive fit is achieved:

4) Remove the prosthetic screws and return the bar to the laboratory for fabrication of the final prosthesis.

If a passive fit is *not* achieved:

5) Determine the two connection points between which the bar ceases to fit passively.
6) Remove the prosthetic screws and remove the bar from the patient's mouth.
7) Using a high-speed disc bur, cut through the bar at the point where the bar ceases to fit passively.
8) Reseat the bar sections into the patient's mouth and hand-tighten with prosthetic screws.
9) Apply auto polymerizing resin liberally to the separation point between the sections, and allow to set in the new configuration.
10) Remove and return the modified bar to the lab for fabrication.

**Laboratory — Prepare the Final Prosthesis for Bar Retention**

Follow procedures to process and finish the denture with the chosen bar attachments integrated.

**Deliver the Final Restoration**

1) Remove any temporary prosthesis.
2) Confirm that each multi-unit abutment is tightened to the implant manufacturer's recommended torque value (see "Torque Values").

For screw-retained, fixed removable prosthesis:

3) Line the prosthesis onto the abutments. Beginning with the midmost screw access channel, hand-tighten a Preat Prosthetic Screw into the multi-unit abutment. Repeat for each abutment, working outward and alternating left to right.
4) Confirm appropriate seating. With the same middle-out, left-to-right technique, tighten each prosthetic screw to 15 Ncm.
5) Check comfort and occlusion, and make any necessary adjustments.

6) Fill each screw access channel with gutta-percha, silicone, or other suitable temporary material.

For attachment-retained removable prosthesis:

7) Follow procedures to seat the attachment component onto each multi-unit abutment. Tighten to the manufacturer's recommended torque value (see "Torque Values").
8) Line the prosthesis onto the attachment components and snap into place. Check comfort and occlusion, and make any necessary adjustments.

# Preat® Clix-Ball Abutments

**DESCRIPTION**

Implant Abutment: Universal rotational, resilient attachment for endosseous implants in the mandible or maxilla in order to restore masticatory function. The attachment system allows for the prosthesis to be removed and replaced by the patient.

**INDICATIONS**

Implant Abutment: Clix Ball Abutment System is designed for use with overdentures or partial dentures, retained in whole or in part by endosseous implants in the mandible or maxilla.

**CONTRAINDICATIONS**

Implant Abutment: Not appropriate where a totally rigid connection is required. Use of a single implant with divergence of greater than 30 degrees from vertical is not recommended. Patients undergoing Chemotherapy or Radiation. Patients that use smokeless Tobacco. Patients with moderate to severe bone loss.

**WARNINGS AND PRECAUTIONS**

Product from damaged packaging must not be used on patients. In the event that the packaging is damaged, the damaged packaging with the product must be returned to the manufacturer and a replacement will be provided only if damage to packaging is caused by product shipment.

If the Clix Ball Abutment is subjected to inappropriate loading conditions, there may be a potential risk of metal fatigue. Patient evaluation including the determination of the general health, oral hygiene habits and status, motivation toward good dental care, and anatomic acceptability prior to the placement of the implant attachments as part of restorative process is critical. Thorough evaluation of the patient's medical status and health history is mandatory.

The use of each of this abutment system requires that the clinician be thoroughly familiar with the product and the method for its use and application. The clinician must also use reasonable judgment in deciding when and where to use the product. Treatment planning is vital to the success of the implant and prosthesis.

**SINGLE-USE DEVICES**

The Clix Ball Abutment components and tools are single use devices. Single-Use devices must not be reused or re-sterilized.

**PROSTHETIC PROCEDURES**

Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate Clix Ball Abutment based on the type of implant and diameter being used. It is imperative that all bone and soft tissue be removed from the superior aspect of the implant body to guarantee complete seating of the Abutment. Using a calibrated torque wrench, tighten the Clix Ball Abutment to the manufacturer's recommended torque value (see "Torque Values").

**Warning:**

Use of higher torque values than recommended above could cause a fracture of the Clix Ball Abutment.

Impression and Stone Model Fabrication: Indirect Technique: With the Clix Ball Abutment torqued in place, proceed by taking an impression. Remove the tray and insert an Analog into each intaglio of the Clix Ball Abutment. Capture the abutment position in stone using standard methods for fabricating a laboratory stone model.

**Prosthesis Fabrication**: Seat the Clix Ball Housings with White Females on each of the abutments. Fabricate the prosthesis using standard laboratory techniques. When delivering the prosthesis, use the lowest retentive level, White Female to begin with and increase the retention if needed.

Denture Cap Pickup Technique (Optional): Place rubber dam and Block Out Spacer around each Abutment and press down.

Seat the Clix Ball Housings with White Females on each of the Abutments. Secure the Clix Housings to the prosthesis using auto-polymerizing or light cure acrylic or composite resin pickup technique.

**NOTE**: Excessive occlusal pressure during the setting time may cause tissue recoil against the denture base and could contribute to dislodging and premature wear of the Clix Females.

**NOTE: Clix Attachment may not be included in the abutment. The attachment consists of the following Replacement Females, Housing, Ancillary Processing parts (i.e., analogs, black out spacer, etc) and Tools. Attachment is sold separately.**

**Prosthesis Delivery**

Once the fit of the prosthesis is verified, instruct the patient in the path of insertion. Have the patient insert and remove the prosthesis several times.

**HEALING PHASE**

For delayed loading protocols: Relieve the denture to ensure the Abutments are not in contact with any denture acrylic. A soft liner may be added to the denture to ensure patient comfort during the healing phase.

**PATIENT CARE**

Good oral hygiene is vital to attachment success. The patient should be made aware of the following:

The Clix Ball Abutments must be thoroughly cleaned each day to prevent plaque build-up and the patient should use a soft nylon bristle or end-tufted toothbrush with a non-abrasive toothpaste to clean the Abutments. The coarse particles in abrasive toothpaste may scratch the surfaces of the Abutments and cause plaque accumulation. The Clix Females are made of a soft plastic material (polypropylene) to allow the Overdentures to be removed/replaced regularly. Plastic materials are subject to wear as part of normal use and may require replacement. Bruxism wears the Clix Ball Abutments and may reduce the longevity of the Clix Females. Patients should be instructed to maintain routine follow-up visits for hygiene and attachment function evaluation. Abutments must be re-tightened at follow-up visits to the torque specifications outlined above. Failure to re-tighten Abutments could lead to screw loosening and Abutment fracture. Follow-up visits are recommended at 6 month intervals.

**Inserting and Removing the Overdentures**

The patient should be instructed on how to properly insert the Overdenture. The patient should make sure they can feel that it is positioned over the Abutments prior to applying pressure. The patient should use both hands and press down one each side and firmly snap the Overdenture into place.

**CAUTION :** THE PATIENT MUST NOT BITE their Overdentures into place as this force will result in improper wear of the Abutments, including the Clix Females in the Overdenture. Remove the Overdenture by placing the thumbs under the edges of the Overdenture flanges and pulling each side upward/downward simultaneously. Use of the tongue may aid in removal. Once removed, a thorough cleaning is recommended.

Cleaning your Implant Retained Denture: Instruct the patient to follow the protocol below to ensure the longevity of their Overdenture. Fill a washing basin with some warm water to prevent fracture of the Overdenture. Apply non-abrasive toothpaste onto the soft bristle toothbrush and thoroughly clean every surface of the Overdenture. Each night, remove Overdenture and immerse in a cup of plain water.

**Further Information**: Traditional restorative protocols should be followed to process the attachments into the patient's Overdenture. Standard Overdenture care and maintenance should be followed in order to ensure the longevity of the restoration.

## Preat® O-Ring Abutments

**DESCRIPTION:**

Implant Abutment: Universal rotational, resilient attachment for endosseous implants in the mandible or maxilla in order to restore masticatory function. The attachment system allows for the prosthesis to be removed and replaced by the patient.

**INDICATIONS**:

Implant Abutment: O-Ring Abutment System is designed for use with overdentures or partial dentures, retained in whole or in part by endosseous implants in the mandible or maxilla.

**CONTRAINDICATIONS:**

Implant Abutment: Not appropriate where a totally rigid connection is required. Use of a single implant with divergence of greater than 20 degrees from vertical is not recommended. Patients undergoing Chemotherapy or Radiation. Patients that use smokeless Tobacco. Patients with moderate to severe bone loss.

**PROSTHETIC PROCEDURES:**

Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate O-Ring Abutment based on the type of implant and diameter being used. It is imperative that all bone and soft tissue be removed from the superior aspect of the implant body to guarantee complete seating of the abutment. Using a calibrated torque wrench, tighten the O-Ring Abutment to the manufacturer's recommended torque value (see "Torque Values").

**Warning:** Use of higher torque values than recommended above could cause a fracture of the O-Ring Abutment.

**Impression and Stone Model Fabrication:** Indirect Technique: With the O-Ring Abutment torqued in place, proceed by taking an impression. Remove the tray and insert an Analog into each intaglio of the O-Ring Abutment. Capture the abutment position in stone using standard methods for fabricating a laboratory stone model.

**Prosthesis Fabrication:** Seat the O-Ring Housings with Processing O-Ring on each of the abutments. Fabricate the prosthesis using standard laboratory techniques. When delivering the prosthesis, use the Black or White O-Ring.

O-Ring Housing Pickup Technique (Optional): Seat the O-Ring Housings with Processing O-Rings on each of the Abutments. Secure the O-Ring Housings to the prosthesis using auto-polymerizing or light cure acrylic or composite resin pickup technique. When delivering the prosthesis, use the Black or White O-Ring.

**NOTE:** Excessive occlusal pressure during the setting time may cause tissue recoil against the denture base and could contribute to dislodging and premature wear of the O-Rings.

**Note: O-Ring attachment are not included in the abutment. The attachment consists of the following O-Rings, Housing, Ancillary Processing Parts (i.e. analogs, processing O-Ring, etc.), and Tools. Attachment are sold separately.**

Prosthesis Delivery: Once the fit of the prosthesis is verified, instruct the patient in the path of insertion. Have the patient insert and remove the prosthesis several times.

**HEALING PHASE:** For delayed loading protocols: Relieve the denture to ensure the Abutments are not in contact with any denture acrylic. A soft liner may be added to the denture to ensure patient comfort during the healing phase.

**PATIENT CARE:** Good oral hygiene is vital to attachment success. The patient should be made aware of the following:

The O-Ring Abutments must be thoroughly cleaned each day to prevent plaque build-up and the patient should use a soft nylon bristle or end-tufted toothbrush with a non-abrasive toothpaste to clean the Abutments. The coarse particles in abrasive toothpaste may scratch the surfaces of the Abutments and cause plaque accumulation. The O-Rings are made of a soft plastic material (polypropylene) to allow the Overdentures to be removed/replaced regularly. Plastic materials are subject to wear as part of normal use and may require replacement. Bruxism wears the O-Ring Abutments and may reduce the longevity of the O-Rings. Patients should be instructed to maintain routine follow-up visits for hygiene and attachment function evaluation. Abutments must be re-tightened at follow-up visits to the torque specifications outlined above. Failure to re-tighten Abutments could lead to screw loosening and Abutment fracture. Follow-up visits are recommended at 6 month intervals.

**Inserting and Removing the Overdentures:** The patient should be instructed on how to properly insert the Overdenture. The patient should make sure they can feel that it is positioned over the Abutments prior to applying pressure. The patient should use both hands and press down one each side and firmly snap the Overdenture into place.

**CAUTION:** THE PATIENT MUST NOT BITE their Overdentures into place as this force will result in improper wear of the Abutments, including the O-Rings in the Overdenture. Remove the Overdenture by placing the thumbs under the edges of the Overdenture flanges and pulling each side upward/downward simultaneously. Use of the tongue may aid in removal. Once removed, a thorough cleaning is recommended.

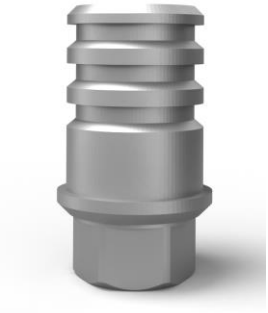
**Cleaning your Implant Retained Denture:** Instruct the patient to follow the protocol below to ensure the longevity of their Overdenture. Fill a washing basin with some warm water to prevent fracture of the Overdenture. Apply non-abrasive toothpaste onto the soft bristle toothbrush and thoroughly clean every surface of the Overdenture. Each night, remove Overdenture and immerse in a cup of plain water.

**Further Information:** Traditional restorative protocols should be followed to process the attachments into the patient's Overdenture. Standard Overdenture care and maintenance should be followed in order to ensure the longevity of the restoration.

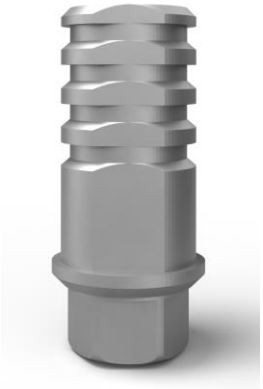
## Preat® Titanium Base & ASC Titanium Base Abutment

Preat Titanium Base & ASC Titanium Base Abutments support prosthetic restorations prepared in a dental laboratory.

Preat Titanium Base is available in heights of 4.5mm and 6mm. Selection of height is based on Interocclusal space.



Titaium Base X 4.5mm



Titanium Base x 6mm

Preat ASC X 9mm Titanium Base may be adjusted to heights of 7mm and 5mm. The heights are marked on Titanium Base.


ASC X 9mm Titanium Base. May be adjusted to 7mm and 5mm.

**NOTE**: *If the Abutment post is modified, at least 4 mm in height must be preserved.*

Preat ASC and ASC X 9mm Titanium Bases allow the screw channel to be adjusted up to 30 Degrees.


The design parameters for the zirconia mesostructure of CAD/CAM Titanium Base customized abutments are:

| Min Gingival Height (mm) | Max Gingival Height (mm) | Min Gingival Diameter (mm) | Max Gingival Diameter (mm) | Min Wall Thickness (mm) | Maximum Post Correction Angle° | Min Post Height (mm) | Max Post Height (mm) | Abutment Height (mm) |
|---|---|---|---|---|---|---|---|---|
| 0 | 5 | 4 | 7.6 | 0.5 | 0 | 4 | 12 | 15 |

All zirconia superstructures are for straight abutments only.
All digitally designed zirconia superstructures are to be sent to a Preat validated milling center for manufacture.
The recommended cement for bonding the superstructure to the titanium base is **Ivoclar Multilink® Abutment Cement.**

## Preat® Titanium Blank Abutment

Preat Titanium Blank Abutments are designed for custom abutment fabrication by a CAD/CAM process. All patient-specific custom abutment fabrication is by prescription on the order of the clinician. Pre-milled Blank Abutments are made of titanium alloy (Ti-6Al-4V).

The design parameters for the CAD/CAM Titanium Blank custom abutment are:

| Third-Party Compatible Implant System[1] | Preat Abutment Prosthetic Platform Diameter (mm) | Min Gingival Height (mm) | Max Gingival Height (mm) | Gingival Diameter (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 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| **Astra Tech OsseoSpeed™** | **3.0, 3.5/4.0, 4.5/5.0** | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Astra Tech OsseoSpeed™ Plus (OsseoSpeed™ EV) | 3.0, 3.6, 4.2, 4.8, 5.4 | 0.5 | 3 | 3.3 | 0.5 | 0 | 4 | 12 |
| BioHorizons Tapered Internal | 3.0, 3.5, 4.5 | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |

[1] All product names, logos, and brands are property of their respective owners. All company, product and service names are for identification purposes only. Use of these third-party names, logos, and brands does not imply, nor should it be understood as, any indication that the respective third-party brand owners have endorsed or sponsored, or are otherwise affiliated with or connected to, Preat or Preat's goods or services.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| HIOSSEN ET III | Mini, Standard | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Implant Direct Legacy | 3.0, 3.5, 4.5, 5.7 | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Keystone Prima Connex™ | 3.5, 4.1, 5.0 | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| MegaGen AnyRidge | 3.5 | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Neodent® GM™ Helix | 3.0 | 0.9 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Neoss | 4.1 | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Nobel Biocare™ NobelActive® | 3.0, NP, RP | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Nobel Biocare™ NobelReplace® | NP, RP, WP, 6.0 | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Straumann™ BLX | 2.9 (RB/WB), 2.9 (WB) | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Straumann® Bone Level | NC, RC | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Straumann® Tissue Level | RN, WN | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |
| Zimmer Screw-Vent®/ Tapered Screw-Vent® | 3.5, 4.5, 5.7 | 0.5 | * See below | 3.3 | 0.5 | * See below | 4 | 12 |

Correction angle and gingival height limits for all abutment connection types notated by "*" above:

- $\leq$ 2mm gingival height must have $\leq$ 30° correction angle.
- $\leq$ 3mm gingival height must have $\leq$ 25° correction angle.
- $\leq$ 4mm gingival height must have $\leq$ 21° correction angle.
- $\leq$ 5mm gingival height must have $\leq$ 19° correction angle.
- $\leq$ 6mm gingival height must have $\leq$ 17° correction angle.

All digitally designed abutments for use with Preat Titanium Blank are to be sent to a Preat validated milling center for manufacture.

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

**Product Description**

Preat® Titanium Abutments are prefabricated, screw-retained intraoral abutments intended to be connected directly to an endosseous implant for retention of a cemented dental prosthesis. They may be indicated for single- and multiple-tooth restorations. Titanium abutments are precisely machined from titanium alloy and attached to the implant fixture with a titanium screw. For use in any region of the mouth, they contain a standard, circular emergence profile and straight abutment body. Each abutment is specific to the restorative platform of the seated implant.

Each Preat Titanium Abutment is packaged with a separate retaining screw (Preat® Titanium Screw) compatible with the restorative instrumentation of the specified implant system.

Titanium Screw

Preat® Titanium Base, ASC Base Abutments, and Titanium Blank Abutments are supplied NON-STERILE, and prior to clinical use, must be sterilized by the end user.

## Restorative Procedure with CAD/CAM Abutments

**Contraindications**
The following conditions would contraindicate use of CAD/CAM Abutments:

- Wall thickness less than 0.5 mm
- Gingival margin diameter less than 0.5 mm wider than the implant
- Less than 0.5 mm margin height
- Less than 4.0 mm abutment height

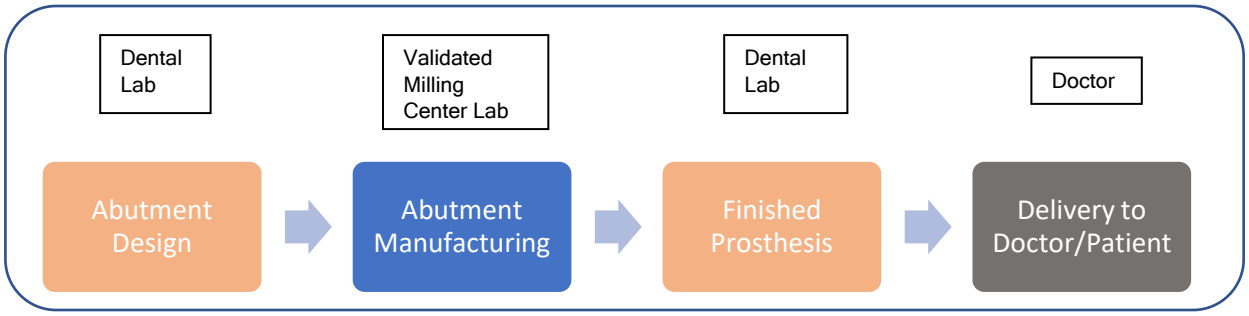
**CAD/CAM Abutment Workflow**

**Digital Workflow**
Titanium base and titanium blank abutments are intended to be customized by means of CAD/CAM technology. Customization of the top portion of the abutments is be performed by a Preat validated milling facility. ***Customization or modification of the implant/abutment interface is not permitted.***

Abutments are to be designed using an FDA 510(k) cleared abutment design software program such as the following:

- 3Shape Abutment Design (K200100)
- 3Shape Abutment Designer (K151455)
- Exocad AbutmentCAD (K193352)

Preat validated abutment design parameter libraries are available for each of the above programs and must be used in conjunction with the design of the abutment. These design parameter libraries provide design parameter constraints which are enforced by the above software program.



**Abutment Design Process**

***Digital Scan***

The stone model must be digitally scanned with the appropriate *Preat Abutments* scan body. Follow the scanning software instructions for proper scanning sequences of the scan body object. Note that scan bodies are specific to implant diameters and use the appropriate scan body for the implant placed. Scan bodies are single use only. Discard the scan body and replace if fit becomes loose within the implant analog.

***Alternative workflow with Traditional Impression - Capture Implant Placement***

Take an implant-level impression utilizing the preferred technique (direct, indirect, or intraoral scan). Submit the impression to a validated Preat milling center.

***CAD Design***

The *Preat Abutments* library for selected abutment design software program above must be installed prior to abutment design. Follow the software program's Instructions for Use for the design sequence and process. Abutment design parameters such as gingival height, post correction angle and wall thickness are limited to within specific ranges within the library and cannot be modified outside of those ranges due to regulatory requirements. Abutment design parameters for Titanium Base and Titanium Blank abutments are detailed above.

Once abutment design is complete, forward the design file to one of the Preat validated milling centers for final manufacturing.

**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**

1) Sterilize Preat® Titanium Base, ASC Base Abutments, and Titanium Blank Abutments Cylinder according to the procedure detailed above.
2) 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.
3) Insert the Preat Titanium 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.
4) 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").
5) Fill the screw access hole with cotton, Teflon tape, gutta-percha, or other suitable material.
6) 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.

# Preat® Titanium Screw/Guide Pin

**Product Description**

Preat® Titanium Screws and Preat® Guide Pins are threaded fasteners used to attach implant prosthetic components to dental implant fixtures or implant analogs on a temporary or long-term basis. Each screw or guide pin is precisely machined from titanium alloy and is specific to the system or the restorative platform of the seated implant. The occlusal surface of the screw or guide pin contains a female instrumentation port compatible with the restorative driver recommended by the implant manufacturer.

*Titanium screws* are generally reserved for the long-term retention of a finished provisional or definitive restoration in the oral environment. A screw used to attach prosthetic components to an implant analog in a working model during laboratory fabrication processes should be replaced with a new screw upon final delivery of the definitive restoration. *Guide pins* are reserved for provisional applications, to attach prosthetic components to an implant analog captured in a working model during laboratory fabrication processes, or, after sterilization, to attach a Preat® Open Tray Transfer Coping to an endosseous dental implant during an open-tray (direct) impression procedure.

Titanium Screw
(retaining screw)

Guide Pin

Preat® Titanium Screws and Preat® Guide Pins are supplied NON-STERILE, and prior to clinical use, must be sterilized by the end user.

**Contraindications**

Preat Guide Pins are not intended for use in the oral environment, except to temporarily attach a Preat® Open Tray Transfer Coping to an endosseous dental implant during an open-tray (direct) impression procedure.

**Attachment Procedure**

**Select a Screw or Guide Pin**

Select the appropriate Preat Titanium Screw or Preat Guide Pin based on the intended application, as well as the system of the implant or implant analog to which the restorative component will be attached. For implant systems that utilize platform-specific screws, consideration must also be given to the size of the restorative platform.

**Attach the Restorative Component**

1) Properly seat the restorative component against the implant fixture or implant analog to which it will be attached.

2) Insert the Preat Titanium Screw or Preat Guide Pin through the screw access hole of the restorative component and into the internal connection cavity of the implant fixture or implant analog. Make sure the screw or guide pin enters at the same angle as the implant or analog to avoid potential damage that may result from cross-threading.
3) Rotate the screw or guide pin clockwise until engaged with the internal threads of the implant/analog connection cavity.
4) Select the appropriate driver based on the implant system being utilized (see "Driver Selection"). Using the selected driver in conjunction with a properly metered torque wrench, advance threaded delivery of the screw or guide pin until the restorative component is fully seated against the implant/analog platform. Hand-tighten only, if indicated. Otherwise, tighten to the implant manufacturer's recommended torque value (see "Torque Values").
5) Verify complete seating of the restorative component against the implant/analog platform. Utilize radiography to do so, if clinically appropriate.

**Retrieval Procedure**

**Detach the Restorative Component**

1) If applicable, remove any overlying restoration or other material preventing access to the head of the Preat Titanium Screw or Preat Guide Pin.
2) Select the appropriate driver based on the implant system being utilized (see "Driver Selection"). Insert the driver into the screw access hole to engage the female instrumentation port of the screw or guide pin.
3) Rotate the screw or guide pin counter-clockwise until completely disengaged from the internal threads of the implant/analog connection cavity.
4) Carefully remove both the screw or guide pin and the restorative component as it is loosened from the implant/analog platform.

## Preat® Healing Abutments

**Description:**

Healing abutments are pre-manufactured dental implant abutments that can be directly connected to the endosseous dental implant to support the healing of the surrounding soft tissue.

**Intended Use/Intended Purpose:**

They are intended to be temporarily connected to an endosseous dental implant or implant abutment to support the healing of the surrounding soft tissue. Healing abutments are indicated for use for up to 180 days.

**Indications:**

Healing abutments are indicated for endosseous dental implants in the maxilla or mandible to support the single tooth to full arch denture procedures.

**Contraindications:**

It is contraindicated to use healing abutments in:

- Patients who are medically unfit for an oral surgical procedure.

- Patients in whom adequate sizes, numbers, or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium)

**Intended Users and Patient Groups:**

- Healing abutments are to be used by dental health care professionals.
- Healing abutments are to be used in patients subject to dental implant treatment

**Handling Procedure for Healing Abutments and Slim Healing Abutments:**

1. Select appropriate abutment and check occlusal clearance.

2. Connect the abutment to implant and hand-tighten using a dedicated screwdriver. It is recommended to verify the final abutment seating using radiographic imaging.

**Caution**: Never exceed recommended tightening torque for the screw. Verify manufactures' recommended torque values before tightening. Overtightening of the abutment may lead to a screw fracture.

3. If removal of the abutment is needed, untighten it using a dedicated screwdriver.

**Additional product information may be obtained by visiting our website at www.preat.com or calling our office at (800) 232-7732.**

**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. |