KeystoneDentalGroup

# Paltop

## Prosthetic Manual

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# 1.1 Introduction

This manual outlines the appropriate procedures for utilizing the Paltop Dental Implant System 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. Keystone Dental Group is not liable for damages resulting from treatment outside of its control. Responsibility rests with the provider.

CAUTION: US Federal law restricts the sale of this device to, or on the order of, a licensed dentist or physician.

DISCLAIMER:  Some products are not available for sale in all markets including the USA.

Paltop disclaims any liability for the performance, outcomes, or complications of Paltop Dental Implant Systems products when used in conjunction with non-original Paltop components. For detailed information on compatible component combinations and the prescribed workflows for each implant platform, please consult the Paltop Catalog.

# 1.2 Characteristics

The Paltop Dental Implant System includes implants, abutments, and associated surgical tools/instruments, restorative, and dental laboratory components.
Paltop Dental implants are surgically inserted into the upper and/or lower jawbone and serve as a replacement tooth root, which provides a stable foundation for a restoration.

Paltop implants are made of biocompatible TI-6AL-4V ELI and have a large grit sandblasted, acid-etched surface in various lengths and diameters. The Paltop dental implants have either an internal hexagonal or conical connection and indexing hex feature, which are intended for single use.

Each implant is accompanied by a standard cover screw. There are no medicinal substances or human blood derivatives found in Paltop Implant Systems implants, abutments, and associated surgical, restorative, and dental laboratory components.

The Paltop Dental Implant System implants are available in the following sizes:

| System Name | Connection | Platform | Ø (mm) | Length (mm) | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 6 | 8 | 10 | 11.5 | 13 | 16 |
| Paltop Dental Implant System | Internal Hex | NP (Narrow) | 3.0 | | | X | X | X | X |
| | | | 3.25 | | | X | X | X | X |
| | | SP (Standard) | 3.75 | | X | X | X | X | X |
| | | | 4.2 | X | X | X | X | X | X |
| | | | 5.0 | X | X | X | X | X | X |
| | | WP (Wide) | 6.0 | X | X | X | X | X | X |
| | Conical | | 3.25 | | | X | X | X | X |
| | | | 3.75 | | X | X | X | X | X |
| | | | 4.2 | X | X | X | X | X | X |
| | | | 5.0 | X | X | X | X | X | X |

Paltop dental prosthetics are made of biocompatible TI 6AL 4V ELI, Gold parts (Au60%Pt19%Pd20%), or PEEK (Polyetheretherketone).

Paltop Dental Prosthetic components are part of the Paltop Dental Implant System and are pre-manufactured components compatible with Paltop dental implants. They are intended to be used as an aid in prosthetic rehabilitation. Paltop dental prosthetic components comprise abutments and associated prosthetic parts. Paltop Prosthetic Abutments are designed to engage directly with compatible Paltop Dental implants, providing a secure and stable connection that supports appropriate clinical outcomes, temporary or long-term, in line with the components' intended use. The components also interface with corresponding prosthetic screws, forming part of the complete restorative system assembly.

Paltop Dental Prosthetic components are single use. Reuse of the device is not allowed as it may cause microbial contamination and loss of performance.

# 1.3 Indications for Use

| System Name | Connection | Platform | Ø (mm) | Length (mm) | Indications for Use |
|---|---|---|---|---|---|
| Paltop Dental Implant System | Internal Hex | Standard and Wide | 3.75-6.0 | 8.0-16.0 | The Paltop dental implant system Internal Hex Standard and Wide Platforms implants (implant diameters 3.75 and above and lengths 8mm and above) as well as Conical Connection implants (implant diameters 3.75 and above and lengths 8mm and above), are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop dental implant system is indicated also for immediate loading in extraction sockets, when good primary stability is achieved and with appropriate occlusal loading. |
| | Conical | Conical | 3.75-5.0 | 8.0-16.0 | |
| | Internal Hex | Narrow | 3.0-3.25 | 10.0-16.0 | The Paltop Narrow Implant (Internal Hex and Conical Connections, for implant diameters 3.25 and below and lengths 10mm and above) is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the interdental spaces are limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Narrow Implant is indicated also for immediate loading in extraction sockets, when good primary stability is achieved and with appropriate occlusal loading. |
| | Conical | Conical | 3.25 | 10.0-16.0 | |
| | Internal Hex | Standard and Wide | 4.2-6.0 | 6.0 | Paltop Short Implants (Internal Hex and Conical Connections) are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw as an artificial root structure for single tooth replacement or for fixed bridgework to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Paltop Short Implants are indicated to be used only with straight abutments and are for delayed loading only. |
| | Conical | Conical | 4.2-5.0 | 6.0 | |

Paltop Dental Prosthetics are pre-manufactured components intended for prosthetic rehabilitation in conjunction with endosseous dental implants. These components are designed for either direct connection to the dental implant (e.g., abutments) or indirect connection (e.g., associated prosthetic parts).

**Patient Population**

Implant placement is recommended only for patients who have completed jawbone growth, ranging from adolescents to the elderly population.

**Contraindications**

The Paltop Dental Implant System is contraindicated for patients:

- Who are medically unfit for dental implant procedures
- Who are allergic or hypersensitive to any of the raw materials listed above.
- In whom adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads, unless an augmentation procedure can be considered.
- The Paltop Dental Implant System is relatively contraindicated for patients: With unfinished cranial growth with incomplete tooth eruption.
- Less than 1 year post head and neck radiation therapy.
- With uncontrolled Diabetes
- Taking systemic bisphosphonate medication (‡2 yr)

- With renal osteodystrophia
- With Osteoporosis
- Having different conditions and medications interfere with an uncomplicated wound healing and place the patient at higher risk for implant failure, e.g., alcoholism, smoking ‡20 cig/d tobacco users and drug abuse
- With poor oral hygiene,
- With poor oral habits e.g. bruxism clenching

**Warnings General**

- The guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry and are not intended to substitute for formal clinical or laboratory training. These devices should only be used by dental clinicians with training and experience specific to their clinically accepted application.
- Dental implant surgery and restoration are not without risks. It is the obligation of the clinician to inform the patient about risks associated with these procedures.
- Pre-operative evaluation of the patient is necessary to determine factors that may either cause risk to the
- patient or affect the healing process of the bone and/or soft tissue.
- Care should be taken that the patient does not swallow or aspirate components. It is recommended to use a throat pack to prevent swallowing or aspiration of small parts during the surgical and restorative phases.
- Product may not be effective in patients with any of the following conditions: chronic bleeding problems, psychological impairment, metabolic bone or connective tissue diseases, treatment with corticosteroids, tobacco usage, diabetes (uncontrolled), treatment with chemotherapeutic agents, chronic renal disease, poor oral hygiene, bruxism, or alcoholism.
- It is important that the clinician uses an appropriate number, and diameter of implants to provide adequate support and properly distribute load between abutments, to minimize the potential for implant failure or fracture.
- It is strongly recommended that Paltop implants be used with dedicated Paltop surgical instruments and prosthetic components. Utilizing components not precisely engineered for optimal compatibility may result in mechanical failure of instruments, tissue damage, or unsatisfactory aesthetic outcomes. To ensure optimal functionality and long-term success, practitioners are advised to consult the official Paltop Catalog for detailed information regarding compatible component combinations and the prescribed workflows specific to each implant platform.
- Implant mobility, bone loss, or chronic infection may result in implant failure.
- Implants should not be used if their surface is damaged.
- Single-use devices shall not be reused. Reuse of device may lead to infection of tissue, infectious diseases, and/or failure of the device to perform as intended.
- Restorative components are intended for single use only.
- Do not alter implants.
- Use caution when handling drills as the tips of these devices are sharp.
- It is recommended that the PEEK Concave Temporary Abutment and temporary restorations be kept out of occlusion and excursive movements.
- The use of electro-surgical instruments or lasers around metallic implants and their abutments may cause electric and/or heat conductivity.
- Do not use if the package is damaged.
- Temporary abutments are not intended for angular correction and are not intended to be cast.

**Warnings specific to Paltop 3.0mm and 3.25mm Internal Hex and 3.25mm Conical Connection Narrow Implants:**

- The Ø 3.0 and Ø 3.25mm Narrow implants are not recommended for posterior placement and/ or in areas of poor bone quality.
- Narrow diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

**Warnings 6.0 mm length Short implants (internal hex and conical connections):**

- Short 6.0 mm length implants are not to be immediately loaded.
- Because of the reduced surface area for anchorage in the bone, Paltop Short 6mm implants should be used with caution because they present greater risks to failures compared to standard implants and are recommended for the following situations:
- As an additional implant together with longer implants to support implant-borne restorations.
- As an auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible.

When a short implant is the treatment of choice perform a two-stage surgical approach, splinting of implants, and placement of the widest possible implant. For Paltop Short 6mm implants, clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes in the implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. Allow longer periods for osseointegration in both the maxillae & mandible jaw compared to longer dental implants.

- Paltop Short 6mm implants should not be placed in patients who demonstrate untreated occlusal parafunction, such as bruxism or clenching.

**Precautions General**

- Determine local anatomy and suitability of the available bone prior to implant placement. Adequate radiographs, direct palpation, and visual inspection of the implant site are necessary prior to treatment.
- Product should only be used by surgical or restorative clinicians who have had appropriate education and training. Improper techniques can contribute to implant failure and/or bone loss.
- Collaboration between the surgeon, restorative dentist, and dental laboratory technician is essential for a successful implant treatment plan.
- Products which are provided sterile and are modified by the end-user, must be cleaned and re-sterilized after any modification are made, or any procedures used which may compromise the sterility of the device, prior to use in the patient.
- Pre-operative hard tissue or soft tissue deficits not identified may yield a compromised result or unfavorable implant angulation.
- Clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length.
- Special attention should be given to patients who have localized or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, uncontrolled diabetes, oral-facial radiotherapy, steroid therapy, infections in the neighboring bone).
- If the implant shows mobility, it should be removed.
- If the implant shows bone loss, it should be evaluated.
- Do not use damaged or worn instruments.
- Products are intended for use only in the applications defined in the Paltop Dental Implant System Surgical and/or Prosthetic Manual.

**Procedural Precautions**

- All implant drilling and placement procedures should be done at speeds recommended in the Paltop Dental Implant System Surgical Manual.
- All drills must be sharp and sterile prior to use. Paltop Dental recommends a maximum of 20 uses and sterilization cycles for Surgical tools/instruments, or prior to that if cutting efficiency declines.
- All drilling should be done using intermittent drilling action with minimal pressure and continuous irrigation using ample chilled sterile saline.
- Do not open sterile packaging until the correct implant size has been determined and the operative site has been prepared.
- It is recommended to have a replacement implant on hand.

- Mandatory precautions for surgery should be properly evaluated such as asepsis.
- Failure to recognize actual lengths of step/twist drills relative to radiographic measurements or drilling beyond the depth intended can result in permanent injury to vital structures, potentially resulting in permanent numbness to the lower lip and chin or leading to hemorrhage in the floor of the mouth.
- Excessive insertion torque may cause damage to the implant, implant connection and surrounding bone.
- Clean and dry the inside of the internal connection of the implant before hand- tightening the Healing Cap or Cover Screw.
- Application of excessive force to the implant area should be avoided, especially during the healing period.
- After implant surgery, the clinician should evaluate patient bone quality and implant stability to determine when implants may be loaded.
- Proper occlusion should be evaluated, and restorations should have a passive fit to the abutments.

**Adverse Effects**

Immediately after insertion of dental implants, activities that demand considerable physical exertion should be avoided. Risks and complications with product are similar to those of other dental implant systems and include, but are not limited to:

- Infection
- Persistent pain, numbness, or paresthesia
- Lack of osseointegration, mobility of implant
- Loss of implant
- Implant fracture
- Perforation of the maxillary sinus
- Perforation of the labial and/or lingual plates
- Loosening of the abutment screw
- Bone loss
- Local soft tissue degeneration

It is recommended that the dental personnel brief the patients to abstain from smoking, drink fluids through a straw, and maintenance of dental hygiene.

Residual risks associated with the Paltop dental implant system may result in harms that include procedural delays, infection, damage to adjacent anatomical structures, or circumstances that require an additional surgical procedure due to failure of the implant or undesired surgical outcomes.

**Adverse Events**

- To help ensure a successful treatment we recommend informing the patient of the precautions to be taken for a regular follow up after implant treatment and how to maintain good oral hygiene protocol.
- In the case of a serious incident, for a patient/user/third party, please contact Keystone/Paltop Dental.
- In the European Union and in countries with a similar regulatory regime (Regulation 2017/745/EU on Medical Devices), if a serious incident has occurred during the use of this device or as a result of its use, please report it to Paltop Inc. and the competent authority of the Member State in which the user and/or patient is established.
- Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.
- Risks and complications with product are similar to those of other dental implant systems and include but are not limited to:
    - Infection
    - Persistent pain, numbness, or paresthesia
    - Lack of osseointegration, mobility of implant
    - Loss of implant
    - Implant fracture
    - Perforation of the maxillary sinus

- Perforation of the labial and/or lingual plates
- Loosening of the abutment screw.

**Product Sterility**

Some Paltop Dental Implant System abutments are sterilized using gamma sterilization and are delivered sterile. These products are intended for single use before the "use by" date printed on the product label. The sterile packaging must not be opened until immediately prior to insertion. The intact sterile packaging protects the gamma-sterilized abutment from outside influences, if stored correctly, ensures sterility up to the expiration date. Sterile abutments with damaged sterile packaging must not be used due to risk of contamination. Resterilization can cause risk or harm to the patient. Paltop Dental does not accept any responsibility for resterilization of products supplied sterile. Some Paltop branded system components are supplied non-sterile. Refer to individual product labels for sterilization information. Products provided non-sterile for use in a clinical environment need to be cleaned and sterilized prior to use.

Prosthetic components placed in the patient's mouth must be sterile prior to use. For sterilization instructions, including Ti 6AI-4V ELI and Zirconia components, refer to the Cleaning and Sterilization section.

**Clinical Benefits**

- Enable replacement of missing teeth, thus restoring function, aesthetics, comfort, and phonetics.
- Offer restorative solutions without requiring traditional fixed or removable treatment work to replace missing teeth.
- Offer a long-term solution for tooth replacement*.
- Stimulate the bone and maintain its dimension in edentulous sites in a manner similar to healthy natural teeth.
- A decreased risk of caries and endodontic problems of adjacent teeth.
- *For short 6mm length implants, as an auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible.
- 
- Clinical Procedures
- Modification of abutments should be performed using appropriate tools. Use copious water irrigation if adjustments are performed intra-orally.
- Prior to placement, inspect the implant-abutment interface. Damage to the interface can lead to improper seating Do not grind the interface area.
- Fasten the abutment with the provided screw using a recommended torque value listed in the Torque Value Reference Table. In the event that the abutment has been seated and removed a number of times, it is recommended to use a new abutment screw while placing the final abutment at the time of delivery.
- After cementing the prosthesis on the abutment, excess cement should be removed immediately.

**Storage and Handling**

Product must be stored in its original, sterile (if applicable) packaging under dry, room temperature conditions, out of direct sunlight. The tools/instruments should be stored individually in a protective tray. There are no additional storage and handling conditions for Paltop Dental Implant System implants, abutments, and associated surgical, restorative, and dental laboratory components.

**Disposal**

After use, devices may be disinfected and thrown in a designated bin for biohazard waste (follow local regulations and environmental requirements).

Paltop Dental Implant System components are not represented to be "pyrogen-free", and makes no claims regarding the absence of pyrogens in the products.

**Treatment Planning**

Successful treatment requires the coordinated efforts of the implant surgeon, restorative dentist, and dental

technician. A presurgical treatment option discussion between these individuals help to determine the appropriate restorative strategy, and adds balance between the surgical, aesthetic, and phonetic objectives and function of the final prosthesis.

This coordinated approach ensures that treatment is complete, there is no omission of important technical considerations (such as the use of a surgical guide for implant positioning), and that the biomechanics of the final prosthesis are maintained.

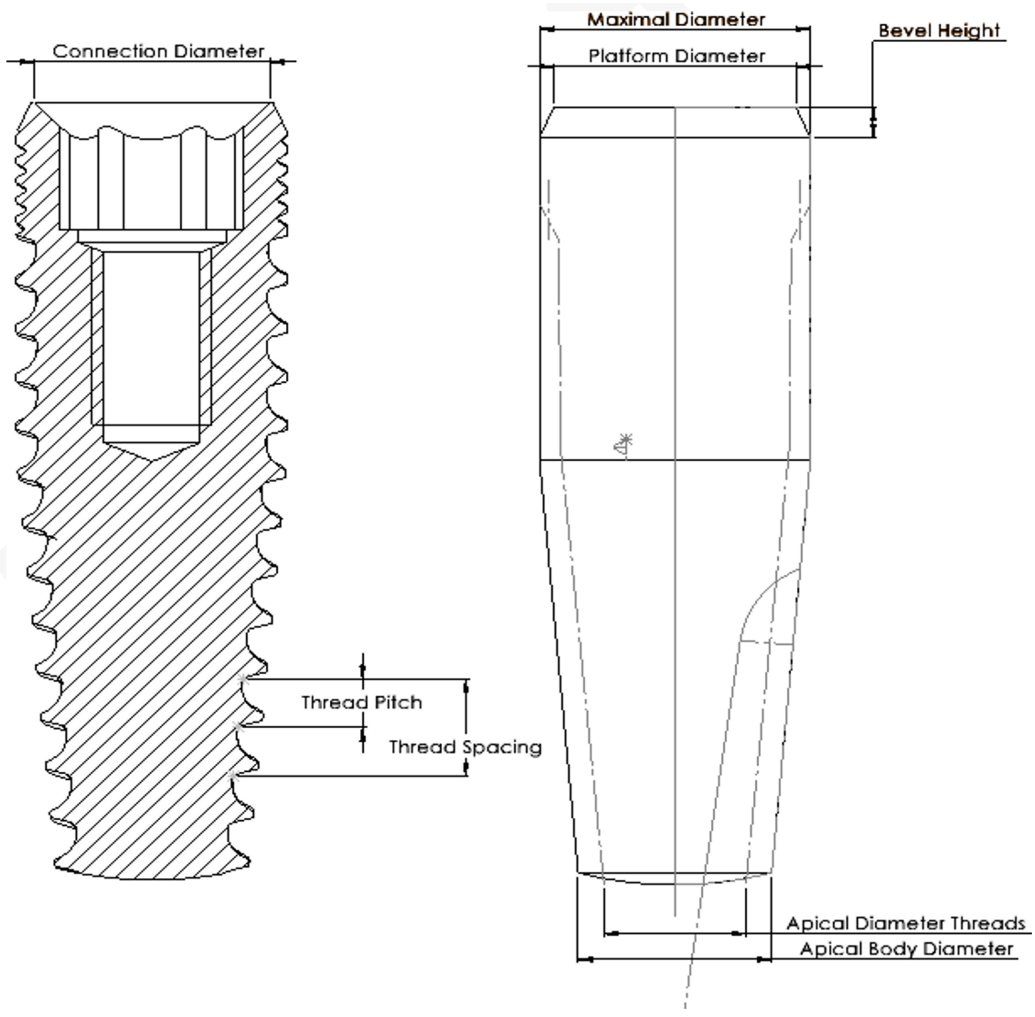
**Diagnostic Casts**

Mounted study casts and a diagnostic wax-up are the foundation for determining correct implant location. The implant surgeon, restoring dentist, and dental technician should work together to produce diagnostic wax-ups.

# 1.4 Connection

**Internal Hex Connection**
The internal hex connection features an internal hexagon index in the lower portion of the connection just below the 90° tapered section, which is used to correctly orientate the prosthetic abutments when working at implant level. This connection is consistent with all implant diameters.

All implants are available in lengths of 6mm, 8mm, 10mm, 11.5mm, 13mm, and 16mm.



| Internal Hex Ø3.0 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 3.1 mm | | | | | |
| **Platform Diameter** | 3.0 mm | | | | | |
| **Connection Diameter** | 3.0 mm | | | | | |
| **Bevel Height** | 0.0 mm | | | | | |
| **Apical Diameter** | 2.4 mm | | | | | |

| Internal Hex Ø3.25 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 3.25 mm | | | | | |
| **Platform Diameter** | 3.25 mm | | | | | |
| **Connection Diameter** | 3.0 mm | | | | | |
| **Bevel Height** | 0.0 mm | | | | | |
| **Apical Diameter** | 2.5 mm (Advanced, PAI, PAI$^{TC}$)<br>2.4mm (Advanced+, Dynamic) | | | | | |

| Internal Hex Ø3.75 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 3.75 mm | | | | | |
| **Platform Diameter** | 3.75 mm | | | | | |
| **Connection Diameter** | 3.70 mm | | | | | |
| **Bevel Height** | 0.00 mm | | | | | |
| **Apical Diameter** | 2.75 mm (Advanced)<br>2.70 mm (Advanced+, Dynamic)<br>2.99 mm (PAI)<br>2.67 mm (PAI$^{TC}$) | | | | | |

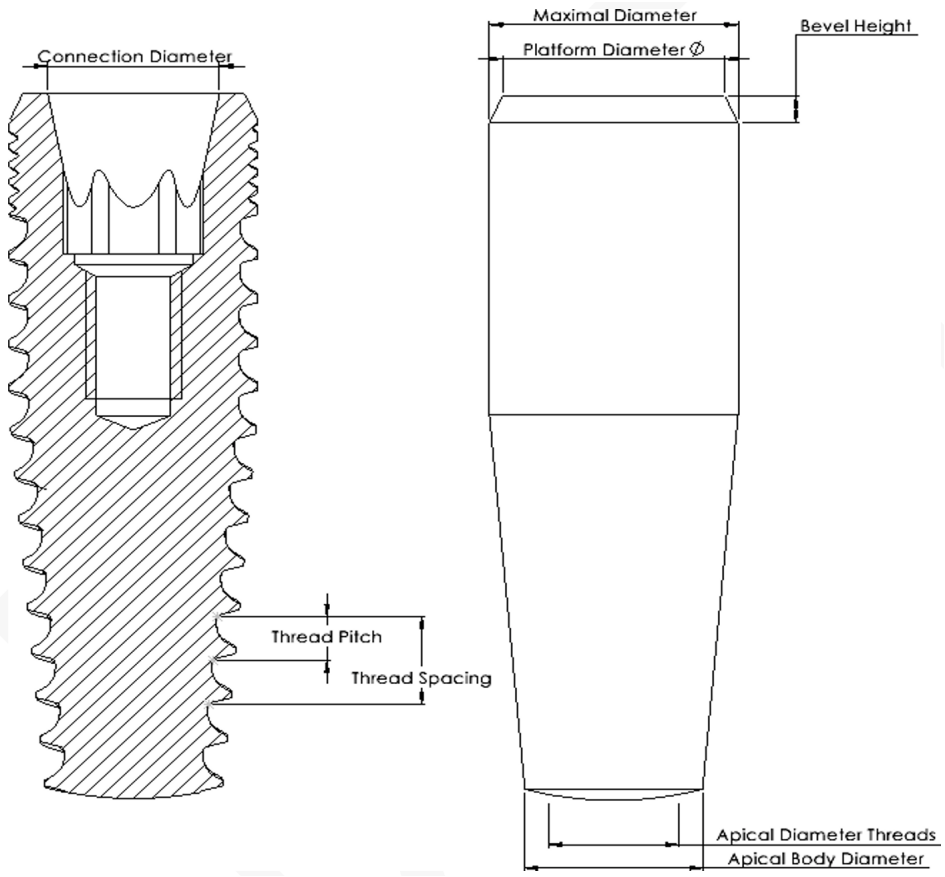
| Internal Hex Ø4.2 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 4.2 mm | | | | | |
| **Platform Diameter** | 3.75 mm | | | | | |
| **Connection Diameter** | 3.70 mm | | | | | |
| **Bevel Height** | 0.5 mm | | | | | |
| **Apical Diameter** | 3.6 mm<br>3.1 mm | (Advanced, PAI, PAI$^{TC}$)<br>(Advanced+, Dynamic) | | | | |
| | | 3.1 mm (Advanced, PAI$^{TC}$)<br>3.0 mm (Advanced+, Dynamic)<br>3.4 mm (PAI) | | | | |

| Internal Hex Ø5.0 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 5.0 mm | | | | | |
| **Platform Diameter** | 3.75 mm | | | | | |
| **Connection Diameter** | 3.7 mm | | | | | |
| **Bevel Height** | 0.5 mm | | | | | |
| **Apical Diameter** | 3.75 mm<br>4.40 mm | (Advanced, Advanced+, Dynamic)<br>(PAI, PAI$^{TC}$) | | | | |
| | | 3.75 mm (Advanced)<br>3.65 mm (Advanced+, Dynamic)<br>4.2 mm (PAI)<br>3.9 mm (PAI$^{TC}$) | | | | |

| Internal Hex Ø6.0 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 6.0 mm | | | | | |
| **Platform Diameter** | 6.0 mm | | | | | |
| **Connection Diameter** | 4.5 mm | | | | | |
| **Bevel Height** | 0.0 mm | | | | | |
| **Apical Diameter** | 4.45 mm<br>5.40 mm | (Advanced, Advanced+, Dynamic)<br>(PAI, PAI$^{TC}$) | | | | |
| | | 4.6 mm (Advanced, Advanced+, Dynamic)<br>5.2 mm (PAI)<br>4.9 mm (PAI$^{TC}$) | | | | |

## Conical Connection

The conical connection features an internal hexagon index in the lower portion of the connection just below the 22° tapered section, which is used to correctly orientate the prosthetic abutments when working at implant level. This connection is consistent with all implant diameters. All implants are available in lengths of 6mm, 8mm, 10mm, 11.5mm, 13mm, and 16mm.



| Conical Ø3.25 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 3.25 mm | | | | | |
| **Platform Diameter** | 3.25 mm | | | | | |
| **Connection Diameter** | 3.0 mm | | | | | |
| **Bevel Height** | 0.0 mm | | | | | |
| **Apical Diameter** | 2.4 mm | | | | | |

| Conical Ø3.75 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 3.75 mm | | | | | |
| **Platform Diameter** | 3.75 mm | | | | | |
| **Connection Diameter** | 3.0 mm | | | | | |
| **Bevel Height** | 0.0 mm | | | | | |
| **Apical Diameter** | 2.7 mm | | | | | |

| Conical Ø4.2 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 4.2 mm | | | | | |
| **Platform Diameter** | 3.75 mm | | | | | |
| **Connection Diameter** | 3.0 mm | | | | | |
| **Bevel Height** | 0.5 mm | | | | | |
| **Apical Diameter** | 3.1 mm | 3.0 mm | | | | |

| Conical Ø5.0 mm | | | | | | |
|---|---|---|---|---|---|---|
| **Length** | 6.0 mm | 8.0 mm | 10 mm | 11.5 mm | 13 mm | 16 mm |
| **Maximum Outside Diameter** | 5.0 mm | | | | | |
| **Platform Diameter** | 3.75 mm | | | | | |
| **Connection Diameter** | 3.0 mm | | | | | |
| **Bevel Height** | 0.5 mm | | | | | |
| **Apical Diameter** | 3.73 mm | 3.65 mm | | | | |

# 2.1 Prosthetic Components

**Introduction**

The restorative protocols outlined in this manual are system independent. 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 system as determined or recommended by the system manufacturer.

There are several ways to rehabilitate patients using dental implants. To make this procedure easier, a dental implant prosthesis can be classified according to:

- Placement: implant level or abutment level.
- The retention type: cement-retained, screw-retained, or overdenture.
- Single tooth or multi-unit restorations.

**Considerations**

Paltop Dental Prosthetic components are part of the Paltop Dental Implant System and are pre-manufactured components compatible with Paltop dental implants. They are intended to be used as an aid in prosthetic rehabilitation. Paltop dental prosthetic components comprise abutments and associated prosthetic parts.

Paltop Prosthetic Abutments are designed to engage directly with compatible Paltop Dental implants, providing a secure and stable connection that supports appropriate clinical outcomes, temporary or long-term, in line with the component's intended use. The components also interface with corresponding prosthetic screws, forming part of the complete restorative system assembly.

Paltop Dental Prosthetic components are classified as Implantable devices and surgically invasive with either short-term or long-term duration.

- Temporary Abutments containing PEEK are recommended for use for up to 30 days.
- It is recommended that the PEEK Concave Temporary Abutment be kept out of occlusion and excursive movements.
- Titanium Temporary Abutments and Titanium Temporary Cylinders for Single-Unit or Multi-Unit Abutments are temporary solutions acceptable for longer-term use and are recommended for use for up to 90 days. Any modification must maintain a post height of at least 5 mm.
- The Single-Unit or Multi-Unit Titanium Temporary Cylinder may not be used for angle correction.
- Single-Unit and Multi-Unit Abutments are only to be used in combination with their corresponding prosthetic components and screws.
- Immediate Temporary Abutment PEEK Cap, used with the Titanium Immediate Temporary Abutment, are not intended for angle correction and are only to be used with implants placed in a straight manner.
- The Temporary PEEK Abutment Cap/Sleeve, Immediate (used with the Temporary Abutment Immediate), is not intended for angular correction and are only to be used with implants placed in a straight manner.
- Straight abutments are only to be used with implants placed in a straight manner.
- The maximum divergence angle for the Paltop NP angulated abutments is limited by the 20° test for each implant/abutment construct.
- The maximum divergence angle for the Paltop SP/WP angulated abutments is limited by the 30° test for each implant/abutment construct.

# 2.2 Considerations

**Indications for Use**

Once the abutment type is chosen, other factors also need to be determined, as each abutment has a different transmucosal height, shape, and angle. The main considerations of abutment selection:

- Interocclusal space, height, and diameter.
- Transmucosal height (gingival).
- Biological space (distance between the abutment and the bone crest).
- If there is a need for angle correction (15°, 17°, 20°, 25°, or 30° options) of the implant with the abutment or if it is parallel to adjacent abutments.

Abutments are placed during the following healing phases:

- During a surgical procedure, soon after the placement of the implant (immediate loading).
- Immediate restoration of Paltop Dental Implant System
- In the healed soft-tissue site (after removal of healing abutments or temporary crowns).
- After the removal of the cover screws (straight to final abutment for abutment level impression).

The Paltop Dental Implant System allows, within the scope of indications, immediate restoration in single tooth gaps and in an edentulous or partially dentate jaw. Good primary stability and an appropriate occlusal load are essential. Two or more adjacent implants should be prosthetically joined to spread the occlusal load.

**Healing Caps**

Healing Caps are prefabricated, one-piece prosthetic components made from Ti 6Al- 4V ELI and are packaged sterile. Healing Caps are intended to connect directly to the endosseous dental implant and may be delivered immediately (single-stage protocol) or after an initial healing period (two-stage protocol), depending upon implant stability, and may be placed in lieu of a Cover Screw (provided with the implant).

**Configurations**

Healing Caps are available in two different geometric designs, concave or straight. Select the appropriate Healing Cap based on the soft-tissue depth and desired emergence profile. The chart below defines the recommended Healing Caps in concave and flared designs.

| Implant Diameter | Platform | Concave or straight | Prosthetic Diameter | Heights |
|---|---|---|---|---|
| Ø 3.0<br>Ø 3.25 | NP | Concave | Ø 3.0 | 1.0, 2.0, 3.0, 4.0, and 5.0 mm |
| | | | Ø 4.0 | 1.0, 2.0, 3.0, 4.0, 5.0, 6.0 and 7.0 mm |
| | | Straight | Ø 4.0 | 2.0, 3.0, and 5.0 mm |
| Ø 3.75<br>Ø 4.2<br>Ø 5.0 | SP | Concave | Ø 4.5 | 1.0, 2.0, 3.0, 4.0, 5.0, 6.0 and 7.0 mm |
| | | | Ø 5.5 | 1.0, 2.0, 3.0, 4.0, and 5.0 mm |
| | | | Ø 6.5 | 3.0, 4.0, and 5.0 mm |
| | | Straight | Ø 4.5 | 2.0, 3.0, and 5.0 mm |
| | | | Ø 5.5 | 2.0, 3.0, and 5.0 mm |
| Ø 6.0 | WP | Concave | Ø 6.5 | 2.0, 4.0, and 6.0 mm |
| | | Straight | Ø 6.5 | 2.0, 4.0, and 6.0 mm |
| Ø 3.25<br>Ø 3.75<br>Ø 4.2<br>Ø 5.0 | Conical | Concave | Ø 4.5 | 2.0, 3.0, 4.0, 5.0 and 7.0 mm |
| | | | Ø 6.0 | 2.0, 3.0, 4.0, 5.0 and 7.0 mm |
| | | Straight | Ø 3.0 | 2.0 mm |
| | | | Ø 4.5 | 2.0, 3.0, and 5.0 mm |

**Technical Considerations**

- Before seating a Healing Cap, verify adequate primary stability or osseointegration of the implant. Ensure the Healing Cap is properly seated by ensuring no soft tissue is impeding.
- Select the appropriate Healing Cap based on the platform size, soft-tissue depth, and desired emergence profile.
- Tighten screw in accordance with the Torque Value Reference Table.

**Healing Cap Placement Procedure**

1. Insert the Healing Cap clockwise into the implant until fully seated. Be sure to enter at the same angle as the implant angle to avoid potential damage to internal threads.
2. Using the Ø 1.25 hex driver, rotate the Healing Cap in a clockwise direction until fully seated on the implant platform.
3. Verify complete seating of the Healing Cap. It is recommended to utilize radiography to assess correct seating.

**Closure of the Flap**

- The selection of the proper Healing Cap is dependent upon several biological factors, such as tissue height, desired final crown size, contour position in arch, occlusal clearance, and available space mesial and distal. Once the final Healing Cap is selected, always communicate the implant diameter and selected Healing Cap emergence profile and height to the restoring doctor or dental laboratory to facilitate the proper final abutment selection.
- If a soft-tissue flap has been reflected to facilitate implant placement, adapt the soft tissue tightly around the seated Healing Cap and suture it tension free into place.

# 2.3 Torque Ratchet/Wrench with Bending Beam

**Torque Procedure**

- Paltop Dental implants are designed to support a provisional or final prosthesis that should be affixed to the implant and tightened using a properly metered torque ratchet to the recommended torque value. The application of torque higher than 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.
- Finger tightens abutment with the hand driver.
- Insert the proper torque tip into the torque ratchet.
- Make sure before torquing that the arrow is facing in a clockwise direction.
- Slide the teardrop to the proper desired torque based on the Torque Value Reference Table.
- To verify the correct torque, you must view the scale from directly above the needle.

**Torque Ratchet with Bending Beam**

The Torque Ratchet with Bending Beam is a manual reusable ratchet used to confirm that the correct torque is applied during manual tightening of prosthetic abutments and screws. The Torque Ratchet with Bending Beam can be connected to a prosthetic screwdriver utilizing a torque ratchet adapter that is inserted into the torque ratchet the torque level is reached when the tear drop lever arm is pulled to a specific value on the shaft of the torque ratchet.


For prosthetic components that require a torque value which ends in a unit of 5 (example 25), the tear drop lever arm should be located between the 20 Ncm and 30 Ncm marks on the shaft as shown above.

Do not exceed the recommended maximum prosthetic torque for the abutment screw or prosthetic screw (see table below). Overtightening of abutment may lead to screw fracture.

**NOTE:** See Torque Ratchet with Bending Beam Instructions for Use for further information about care and use of the torque ratchet.

# 2.4 Abutment Screw Attachment Procedure

**Abutment Screw Product Description**

Abutment screws are manufactured out of Ti 6AI-4V ELI. They are used to attach implant prosthetic components to dental implant fixtures on a temporary or long-term basis. Abutment Screws are packaged together with each abutment. Screws packaged together with abutments are provided sterile when the abutment is sterile, and non-sterile when the abutment is packaged non-sterile. See sterility on the product label. Screws are also available as a standalone replacement part and sold non-sterile. Non-sterile components should be cleaned and sterilized according to the cleaning and sterilization procedures mentioned in the cleaning and sterilization sections prior to being placed in the patient's mouth's

**Abutment Screw Attachment Procedure**

- All abutment screws are placed using a 1.25mm hex key/driver.
- The drivers are available in multiple length configurations.
- Properly seat the restorative component into the implant/analog fixture utilizing the appropriate hex key/driver.
- Verify complete seating of the restorative component, utilizing radiography, if clinically appropriate.
- Tighten screw in accordance with Torque Value Reference Table.
- Protect the screw head with suitable material for easy retrieval, if necessary.

**Abutment Screw Retrieval Procedure**

- If applicable, remove any overlying restoration or other material protecting the access to the head of the abutment screw.
- Using the appropriate screwdriver and torque ratchet in reverse, disengage screw from the implant by rotating in a counterclockwise motion until completely disengaged from the internal threads of the implant/analog connection cavity.
- Carefully remove both the screw and the restorative component as it is loosened from the Ïmplant/analog platform

# Torque Value Reference Table

| Prosthetic Component | Torque (Ncm) |
|---|---|
| Healing Cap*<br>Multi-Unit/Single-Unit Abutment Healing Caps*<br>PEEK Temporary Abutments**, NP/SP<br>Temporary Abutment, Immediate**<br>Cover Screw*<br>Impression Coping Screw | 15 |
| Multi-Unit Prosthetic Screw | 20 |
| Titanium Temporary Abutments** NP<br>Angulation Corrective System Screw | 25 |
| Titanium Temporary Abutments** SP/WP/Conical<br>Straight Multi- Unit Abutments<br>Single-Unit Abutments<br>Paltop Equator Abutments<br>Ball Abutments<br>Abutment Screw, NP/SP/WP/Conical (for Titanium/Gold Abutment)<br>Multi-Unit Abutment Screw for Angulated | 30 |

* Recommended not to exceed 20 Ncm

** Clinician should use best clinical judgment when lowering the recommended torque value for any temporary abutment/cylinder placed at time the of implant placement.

NOTE: It is recommended that the PEEK Concave Temporary Abutment and temporary restorations be kept out of occlusion and excursive movements.

# 3.1 Cement Retained

**Restoration**

Cement-retained implant restorations are very similar to traditional crown and bridge restorations. An abutment is prepared and is screwed onto the implant. The screw access hole is protected for retrieval of the abutment, if necessary. The restoration is cemented to the prepared abutment.

**Intended Applications**

- Single tooth or multiple-unit implant restorations.
- Fully or partially edentulous arch.
- All tooth positions.

**Advantages**

- Use of conventional crown and bridge techniques.
- Maintaining optimum occlusal integrity by the intact occlusal surface of the cement- retained restoration.
- Flexibility to achieve optimal aesthetics.

**Disadvantages**

- Difficulty in retrieving the restoration, if necessary.

# 3.2 Screw-Retained

**Restoration**

Screw-retained restorations are indicated when inter-arch space is limited and/or a screw- retained restoration is planned. In this application, the abutment and restoration are all one piece, seated on the implant, and retained by a screw that enters through the occlusal surface of the prosthesis. It is recommended to block the screw channel. This prevents food entering and damage to the head of the screw.

**Intended Applications**

- Single tooth or multiple-unit implant restorations.
- Fixed-detachable (hybrid-type) restorations.
- Fully or partially edentulous arch.
- All tooth positions.

**Advantages**

- Ease of retrievability for hygiene maintenance.
- Minimal inter-arch space is required.
- Flexibility to achieve optimal aesthetics.

**Disadvantages**

- Splinted restorations on implants with divergent angles greater than 10°.
- Screw holes for wider implants may be highly unaesthetic.

# 3.3 Bar or Implant-Retained

Screw-retained restorations are also used for bar-supported and/or implant-supported overdenture cases. The denture is retained by a bar with attachments or fixed directly to the bar and screwed to the implants or multi-unit abutments (i.e., fixed-detachable or hybrid types).

NOTE: An implant-retained, tissue-supported prosthesis is indicated when there are fewer than four implants in the mandible and fewer than six in the maxilla.

**Intended Applications**

- Multiple-unit restorations.
- Areas where extensive bone loss has occurred.
- Excessive interocclusal space.
- Fully edentulous patients in the maxilla or mandible.

**Advantages**

- Bar-Supported Overdenture: Easier to remove by patient. Easier hygiene maintenance by patient.
- Implant-Supported Overdenture: Fixed (not removable) by patient. “Natural Teeth” feeling.

**Disadvantages**

- Interocclusal space between the maxilla and mandible is limited.

**Number of Implants**

- In the mandible, four to six implants are recommended for an implant-supported/bar- retained prosthesis.
- In the maxilla, six to ten implants are recommended for an implant-supported/bar- retained prosthesis.

# 4.1 Types and Techniques

**Implant Level**

The Healing Cap is removed, and an impression coping is placed on the implant. An impression is taken to transfer the position, angle, contour of the tissue, and depth of the implant.

**Impression Copings**

Impression Copings are used to transmit the position, angulation, and orientation of the connection of seated implants when captured in an elastomeric impression. Impressions may be taken with either indirect or direct technique, depending on the clinician's preference and chairside conditions. Impression Copings are precisely machined from TI- 6AL-4V ELI and attached to the implant fixture by a TI-6AL-4V ELI screw. Each Impression Coping is specific to the restorative platform of the seated implant, as well as the impression technique and desired emergence profile. Impression copings are provided sterile with their corresponding screw. When an impression coping screw is provided as a replacement part, it is provided non-sterile.

**Contraindications**

Impression Copings should not be used for digital impressions captured with an intraoral scanner.

**Open Tray (Direct) Pick-Up Impression Coping**

This technique requires use of an impression coping and a screw. The open tray impression coping transfers the position of the internal hex or the internal hex below the conical connection, angle of the implant, concave contours of the tissue, and depth of the implant in the osteotomy. Open tray impression copings are recommended for use when an impression is made of multiple divergent implants or impression across the arch.

**Closed Tray (Indirect) Pick-Up Impression Coping**

This technique requires use of an impression coping and a screw. The closed tray impression coping transfers the position of the internal hex or internal hex below the conical connection, angle of the implant, concave contours of the tissue, and depth of the implant in the osteotomy. Closed tray impression copings are ideal for use in limited inter-arch space.

**Abutment Level**

The Healing Cap is removed, and an unprepared abutment is seated on the implant in the patient's mouth. When allowed, an abutment is modified in the mouth using copious amounts of irrigation. The abutment screw is tightened to the recommended torque, the screw access channel is blocked out. An impression is then taken with the prepared abutment in place.

# 4.2 Open Tray (Direct)

**Procedure**

1. The Concave or Straight Healing Cap is removed utilizing the Ø 1.25 hex key/driver in counter clockwise direction.

2. The impression coping is positioned into the implant connection and fully seated utilizing the Ø 1.25 hex key/ driver. A material of choice is placed into the screw access hole of the impression coping screw to protect the screw access hole and preserve the integrity of the impression.

   **NOTE:** Take a radiograph to verify the proper fit between the impression post and the implant.

3. A light or medium body impression material is injected around the implant/impression coping junction at the gingival aspect. Then, the customized impression tray is filled with heavy body impression material and fully seated to take the impression.

4. Once the impression material is completely set, the impression tray can be removed leaving the impression coping still attached to the implant. The impression coping can now be removed, and an analog is attached to the impression coping and transferred back into the impression. The impression coping must be completely seated with the correct orientation, preferably under magnification. The Healing Cap is placed onto the implant, or a temporary crown is fabricated and seated. The impression with the impression coping/ analog assembly is sent to the laboratory, including an impression of the opposing arch, proper jaw relation record, and shade, if needed.

5. Once the dental stone has fully set, remove the impression tray and the copings from the cast. At this time, abutment choices are finalized, and the restoration is fabricated.

# 4.3 Closed Tray (Indirect)

**Procedure**

1. The Concave or Straight Healing Cap is removed utilizing the Ø 1.25 hex key/driver.

2. The impression coping is positioned into the implant connection and fully seated utilizing the Ø 1.25 hex key/ driver. A material of choice is placed into the screw access hole of the impression coping screw to protect the screw access hole and preserve the integrity of the impression.

**NOTE:** Take a radiograph to verify the proper fit between the impression post and the implant.

3. A light or medium body impression material is injected around the implant/impression coping junction at the gingival aspect. Then, the customized impression tray is filled with heavy body impression material and fully seated to take the impression.

4. Once the impression material is completely set, the impression tray can be removed leaving the impression coping still attached to the implant. The impression coping can now be removed, and an analog is attached to the impression coping and transferred back into the impression. The impression coping must be completely seated with the correct orientation, preferably under magnification. The Healing Cap is placed onto the implant, or a temporary crown is fabricated and seated. The impression with the impression coping/ analog assembly is sent to the laboratory, including an impression of the opposing arch, proper jaw relation record, and shade, if needed.

5. Once the dental stone has fully set, remove the impression tray and the copings from the cast. At this time, abutment choices are finalized, and the restoration is fabricated.

# 4.4 Cast Fabrication

**Implant Analog**

Implant Analogs, made of Ti- 6Al-4V ELI, are diameter-specific replicas of dental implants, used in a working model to represent the location and platform orientation of a seated implant. They are provided non-sterile and intended for single use only.

Contraindication: Implant Analogs are not intended for use in the oral cavity.

**Procedure**

1. Once the impression, bite, opposing model, shade, and instructions have been received by the dental laboratory, inspect the impression for accuracy.

2. Please refer to the Impression Types and Techniques, Open Tray (Direct) or Closed Tray (Indirect) Technique for attachment of implant analog, if the clinician did not attach the analog prior to sending the case to the laboratory.

3. Fabricate the master cast using standard procedure and a minimal expansion/high hardness dental stone. A gingival mask should always be used to ensure the proper emergence profile of the restoration through the soft tissue. Fix the bite and mount the maxilla and mandible casts on the articulator.

# 5.1 Temporization Options

**Temporization**

Paltop Dental offers three types of temporary abutments for chairside or lab- fabricated temporary restorations. The options are designed to prepare the soft tissue for permanent restoration throughout the healing process. Please note: Products which are provided sterile and are modified by the end-user, must be cleaned and re-sterilized after any modifications are made, or any procedures used which may compromise the sterility of the device, prior to use in the patient.

**PEEK Concave Temporary Abutment**

An aesthetic tooth-colored material for short-term, single-unit temporary restorations. Intended to be in the mouth for up to 30 days. It is recommended that the PEEK Concave Temporary Abutment be kept out of occlusion and excursive movements. PEEK Temporary Abutments are provided sterile. PEEK Temporary Abutments should not be modified.

**Titanium Temporary Abutment**

A titanium base composed of Ti-6Al-4V ELI that tooth-colored acrylic is mechanically bonded to in order to create a temporary screw-retained restoration. Intended to support single or multiple units for all implant sizes. Intended to be in the mouth for up to 90 days. Temporary Abutments are provided sterile. If modified, these abutments should be cleaned and sterilized according to procedures in the cleaning and sterilization sections.

**Titanium Temporary Abutment, Immediate**

Mechanical grooves of the PEEK Cap assist with the mechanical retention of acrylic or composite for the preparation of an immediate cement-retained crown. Intended to be in the mouth for up to 30 days. The Titanium component is made of Ti-6Al-4V ELI and the cap is composed of PEEK. Titanium Temporary Abutment, Immediate Abutments are provided sterile. Titanium Temporary Abutment, Immediate Abutments are intended for single-unit restorations. Temporary Abutments are provided sterile. Temporary PEEK Abutment Cap, Immediate may not be modified. If the titanium temporary immediate abutment is modified, it should be cleaned and sterilized according to procedures in the cleaning and sterilization sections.

# 5.2 Temporization Types

**Screw-Retained**

A PEEK or premanufactured titanium alloy abutment connected directly to an implant to support a screw-retained single tooth or multi-unit temporary prosthesis.

- PEEK Concave Temporary Abutment
- Titanium Temporary Abutment

**Cement-Retained**

A premanufactured abutment directly connected to the implant and composed of two parts, a PEEK coping with grooves for retention of an acrylic temporary restoration and a titanium alloy non- engaging base, indicated for a single tooth cement-retained temporary restoration.

- Titanium Temporary Abutment, Immediate

# 5.3 Temporization Abutment

**Intended Applications**

- Cement-retained or Screw-retained restorations.
- Single tooth or multiple units, partial and full edentulous restorations.
- All tooth positions

**Technical Considerations**

- Not intended for angle correction.
- Titanium Temporary Abutments are recommended for use for up to 90 days.
- PEEK Concave Temporary Abutment recommended use up to 30 days and be kept out of occlusion and excursive movements.
- Titanium Temporary Immediate Abutments are recommended for use for up to 30 days.
- Recommended screw tightening in accordance with the Torque Value Reference Table.
- For cleaning and sterilization procedures, please refer to Cleaning and Sterilization Sections.
- Recommended to choose a gingival cuff height that is no more than 1.5 mm to 2.0 mm below the soft tissue margin.
- Titanium Temporary Immediate Abutments and Titanium Temporary Abutments require a minimum of 5 mm post height.
- Titanium Temporary Immediate Abutments are not recommended in cases that require angle correction.
- Titanium Temporary Immediate Abutments do not engage the anti-rotation feature of the connection.
- It is not recommended to modify the wall thickness and height of the PEEK Cap or titanium post.

If modifying the Titanium Temporary Abutment, follow the following parameters:

- Maximum Post Height above Gingival Cuff 10 mm
- Minimum Post Height above Gingival Cuff 5 mm
- Minimum Wall Thickness (above the cuff) No change permitted
- Abutment Post Correction Angle 0° (No change permitted)

- Engaging used for single teeth only
- Do not exceed the recommended torque of the abutment screw as this may lead to failure of the screw or implant fracture.
- A minimum of 5mm of the grooved cylinder is required for adequate retention of the overlying temporary material.
- Engaging Titanium Temporary Abutments are intended for single-unit restorations to prevent rotation of the provisional crown.
- Non-engaging Titanium Temporary Abutments are intended for multi-unit bridges, the anti-rotational implant connection feature facilitates a passive path of insertion. The non-engaging temporary abutments must not be used for single tooth restorations.
- Each Titanium Temporary Abutment is packaged with a separate screw compatible with the restorative platform of the specified implant system.

**Procedure for Screw-Retained Temporary Restoration**

Verify adequate primary stability of the implant. Select the appropriate temporization procedure and abutment of choice based on available mesiodistal/interocclusal space. The emergence profile is in multiple cuff heights.

1. Using the master cast, place a denture tooth in the edentulous area and then fabricate a vacuum-formed stent, using .020 stent material. If a temporary shell crown is used, select the crown that will fit within the confines of the edentulous space.

2. Place the Titanium Temporary Abutment or PEEK Concave Temporary Abutment using the appropriate screw packaged with the abutment and the Ø 1.25 hex key/ driver.

   NOTE: The PEEK Concave Temporary Abutment is not recommended for modification.

3. Modify the Titanium Temporary Abutment as necessary to allow adequate space for acrylic between stent and abutment, preserving a minimum of 5 mm post height and maintaining wall thickness.

   If using the PEEK Temporary Abutment, roughen the abutment portion, above the cuff, to mechanically bond the acrylic of choice.

   If using a shell crown for screw-retained restorations, prepare a screw access hole on the lingual portion after bonding the acrylic.

4. Block out the abutment screw access hole and any undercuts on adjacent teeth to prevent acrylic from flowing inside the abutment or locking onto adjacent teeth. Use an abutment apron to protect the concave area of the cylinder and prevent attachment of the reline material.

5. Place the temporary acrylic material of choice into the stent or the shell crown and place the stent or crown over the abutment and adjacent teeth. Follow the manufacturer's recommendations for curing times.

6. Remove the stent and separate it from the acrylic temporary abutment.

7. Remove the temporary restoration using the Ø 1.25 hex key/driver. The abutment should be securely captured within the restoration. Add/adjust acrylic for optimum emergence and contour through the tissue, while keeping the bite out of occlusion and excursive movements. Highly polish and steam clean the temporary restoration per instructions in Instructions for Use.

8. Proceed with final insertion using the Ø 1.25 hex key/driver attached to the Torque Ratchet with Bending Beam. Recommend screw tightening in accordance with the Torque Value Reference Table.

   NOTE: Fill the screw access hole with a suitable material to protect the screw head and facilitate easy removal when needed. Seal the top of the screw access hole with temporary veneering material.

**Procedure for Cement-Retained Temporary Restoration**

1. Place the Titanium Temporary Immediate Abutment utilizing the Titanium Temporary Abutment, Immediate hex driver and tighten to recommended torque found in the torque values.

2. Place the Titanium Temporary Immediate PEEK Cap and evaluate that it is fully seated. The PEEK Cap should fit flush with the top of the abutment post. Evaluate occlusal clearance as it is not recommended to modify the abutment post. The abutment is a non-engaging abutment and should be torqued at the time of placement.

3. Fabricate a chairside temporary crown using traditional chairside techniques. Ensure the acrylic or composite material

flows inside the grooves of the PEEK Cap.

NOTE: Acrylic does not bond to the PEEK Cap. Therefore, if used, follow PEEK manufacturer's Instructions for Use for proper application of acrylic or composite material to the PEEK Cap.

4. The acrylic or composite should have a fluid consistency to engage the grooves of the sleeve to ensure good mechanical retention and attachment to the PEEK Cap.

   After attachment of the temporary crown to the PEEK Cap, remove the crown and connected PEEK Cap. Then complete the cervical anatomy by adding acrylic or composite using standard chairside techniques.

5. Polish the crown margin in preparation for cementation. Steam clean before insertion into the mouth.

6. Out of the mouth on a secondary abutment, cement the temporary crown with a temporary cement of choice and connected PEEK Cap to the post of the abutment. Remove excess cement, then seat the temporary restoration in the mouth. Once the crown is placed in the mouth, remove any excess cement. Check the occlusion and excursive movements to avoid contact with opposing teeth.

# 6.1 Titanium Straight/Angulated Abutment

**Description**

Titanium Abutments are prefabricated, intraoral abutments intended to be connected directly to an endosseous implant for retention of a cement retained dental prosthesis. They are intended for single- and multiple-tooth restorations. Titanium abutments are precisely machined from Ti- 6Al-4V ELI and attached to the implant fixture with a titanium screw. For use in any region of the mouth, they contain either a standard flared or concave emergence profile and straight or angulated abutment body available in a selection of gingival height options. Each abutment is specific to the restorative platform of the seated implant. Titanium Straight and Angulated Abutments are provided sterile. Screws packaged together with abutments are provided sterile. Screws are also available as a standalone replacement part and sold non-sterile. Non-sterile components should be cleaned and sterilized according to the cleaning and sterilization procedures mentioned in the cleaning and sterilization sections prior to being placed in the patient's mouth.

Each abutment is packaged with a separate Abutment Screw that requires a Ø 1.25 hex key/driver.

**Intended Applications**

- Cement-retained single tooth or multiple-unit restorations.
- All tooth positions.

**Configurations**

- Straight, 15°, 20° and 25° angulated designs.
- Multiple cuff heights from 1.0-5.0 mm for different platforms/implant connections.
- Different emergence profiles of Ø 3.5- Ø 6.5.

**Technical Considerations**

- A minimum interocclusal distance of 4.5 mm plus the restoration thickness is required between the implant prosthetic table and the occlusal plane.

**Procedural Methods**

A. Chairside preparation of a Titanium Abutment, see section Chairside Preparation and Temporization by the Clinician.

B. An implant level impression is taken. The dental technician prepares the abutment and sends the abutment and final restoration back to the clinician. See the following section on Lab Preparation of the Titanium Abutment.

**Clinical Section**

It is recommended to modify outside the mouth, however if an intraoral abutment modification is necessary, use copious amounts of irrigation to eliminate excessive heat buildup in the surrounding bone and/or tissue that may compromise the osseointegration of the implant.

NOTE: Modification should not be below the cuff. Minimal modifications above the cuff may be needed depending on inter-occlusal space. The cuff can be lowered as needed to place the margin subgingival but that should be the only thing modified other than the height or angle.

**A. Chairside Preparation and Temporization by the Clinician**

When selecting the proper Titanium Abutment cuff height, measure the tissue depth from the top of the implant to the height of the soft tissue on the buccal.

**NOTE:** For aesthetics, the final margin of the Straight or Angulated Abutment should be 1.0–1.5 mm below tissue height.

1. Place the Titanium Abutment using the Ø 1.25 hex key/driver. Determine if reduction in the height of the abutment and/or the cuff is required. Mark the abutment for the required vertical reduction and gingival contour.

2. Remove and modify the abutment using carbide burs, cut-off disks, or heatless stone wheels. A diamond bur may be used to define the margins. Create a mark to indicate the buccal surface to assist in orientation of the abutment in the mouth.

   TIP: To improve abutment stability while adjusting the fit, attach an implant analog to the abutment.

3. Using a Ø 1.25 hex key/driver latch tip, ratchet adapter, and torque ratchet, seat the Titanium Abutment and apply torque as defined in the Torque Value Reference Table to the Abutment Screw.

4. Take a radiograph to verify that the abutment is completely seated.

5. Place a resilient removable material into the screw access hole to protect the abutment screw.

6. Conventional impression techniques are used for the final restoration. Always take a full-arch impression. If the margin is subgingival, retraction cord or injectable retraction material may be necessary to expose the prepared margin.

7. Prepare a temporary restoration to support the soft tissues based on the contours of the adjacent teeth. Cement the temporary restoration with material of choice.

**Laboratory Section – Fabrication of the Restoration**

1. Construct and wax the coping/metal framework following conventional crown and bridge procedures. It is recommended that the bucco-lingual dimension of the implant final restoration be narrower than that of natural dentition and that occlusion should be in group function.

2. Sprue, invest, and cast following conventional crown and bridge techniques.

3. Divest and finish the coping/metal framework using conventional crown and bridge techniques.

4. Apply porcelain application following conventional laboratory procedures.

5. Disinfect and return the final restoration on the master model to the clinician for final insertion.

**Clinical Section – Final Insertion**

**CAUTION:** Laboratory modified abutments need to be cleaned and sterilized prior to final insertion.

1. The crown is placed, and occlusion and aesthetics are evaluated and adjusted as necessary.

   NOTE: It is recommended that the screw access hole be blocked out to protect the screw. At this point, the crown is cemented onto the Titanium Straight or Angulated Abutment. All excess cement must be meticulously removed, and the occlusion evaluated once more. The patient is then provided with oral hygiene instructions and a recall appointment is recommended.

**B. Lab Preparation of the Titanium Abutme**nt

1. Fabricate the master cast using standard procedure and a minimal expansion/high hardness dental stone. A gingival mask should always be used to ensure the proper emergence profile of the crown. Fix the bite and mount the maxilla and mandible casts on the articulator.

2. When selecting the proper Titanium Abutment cuff height, measure the tissue depth from the top of the implant analog to the height of the soft tissue on the buccal.

   **NOTE:** For aesthetics, the final margin of the Titanium Abutment should be 1.0–1.5 mm below tissue height on the buccal.

3. Place the Titanium Abutment using the laboratory screw and the Ø 1.25 hex key/driver.

   **NOTE:** For single-unit cases, it is recommended to mark the buccal of the abutment with a bur mark to assist the clinician with orientation in the mouth.

   **NOTE:** The laboratory may fabricate a "positioning jig" using a pattern resin material. Using the positioning jig, the clinician can transfer the abutment from the master model to the mouth, simplifying the abutment seating procedure.

4. After preparation is complete, block out the top of the screw access hole to prevent wax from flowing into the area during fabrication of the restoration.

5. Construct and wax the coping/metal framework following conventional crown and bridge techniques.

6. Sprue, invest, and cast following conventional crown and bridge techniques.

7. Divest and finish the coping/metal framework using conventional crown and bridge techniques.

   **NOTE:** If a multi-unit restoration was requested by the clinician, confirm a passive fit of multi-unit restorations. An intraoral metal try-in is recommended.

8. If there is no metal framework fitting assessment, proceed to the Porcelain Application Section and follow standard laboratory procedures.

9. If metal framework fitting is requested, return to the clinician for traditional clinical procedures for try-in of framework.

**Clinical Section – Metal Framework Fitting Assessment**

1. Remove the metal framework from the master model. Clean and sterilize metal framework and abutments before placement in the mouth. Note the orientation marks on the model and on the Titanium Abutments placed by the dental technician.

2. Place the Titanium Abutments in the patient's mouth. Verify that the position of the orientation mark is towards the buccal or with a verification jig, if provided. Use the Ø 1.25 hex key/driver and the laboratory screw to hand tighten the abutments.

3. Take a radiograph to verify that the abutments are completely seated.

4. Seat the coping/metal framework and verify that the framework fits passively and completely over the Titanium Abutments.

   **NOTE:** If the framework binds as it is seated or does not go completely down to the margin of the abutments, then the bridge must be cut, orientated in the mouth, and returned to the laboratory for soldering/laser welding. It may be possible to use an indicating spray or paste to determine if the internal aspect of the bridge can be modified to allow the bridge to seat.

5. Reseat the sections in the mouth and lute the sections of the framework together using a pattern resin material. Once the material has set according to the manufacturer's specifications:

   A.Return the metal framework to the laboratory to be soldered/laser welded and returned for a second framework fit assessment.

   B. Pick up the luted together framework in a secondary full-arch impression.

6. Return the impression to the laboratory for soldering/laser welding and porcelain application.

7. If try-in of the metal framework over the abutments, passive seating, and accurate margins are verified, the framework may be removed along with the Titanium Abutments and returned to the laboratory.

**Laboratory – Porcelain Application**

Proceed with porcelain application following standard laboratory procedures.

**Clinical – Final Insertion**

**CAUTION:** Laboratory-modified abutments need to be cleaned and sterilized prior to final insertion.

**Procedure**

1. After the Healing Cap or temporary crown is removed, the Titanium Abutment is seated onto the implant. The Abutment Screw with a Ø 1.25 hex key/driver is placed and hand tightened. A radiograph is taken to ensure proper seating of the abutment. At this point, the Ø 1.25 hex key/ driver and ratchet adapter are inserted into the torque ratchet and the Abutment Screw is tightened.

2. The crown is placed. Occlusion and aesthetics are evaluated and adjusted as necessary.

**NOTE:** It is recommended that the screw access hole be blocked out to protect the screw. At this point, the crown is cemented onto the Titanium Abutment. All excess cement must be meticulously removed, and the occlusion evaluated once more. The patient is then provided with oral hygiene instructions and a recall appointment is recommended.

# 6.2 Gold Base Castable Abutment

**Description**

The Gold Castable abutments are available in Engaging or non-engaging castable abutments that combine a precision-machined interface with the convenience of a castable plastic sleeve. The Gold Base Castable Abutments are recommended for fabrication of a customized abutment for both screw and cement retained restorations. Provided non-sterile with abutment screw.

**Intended Applications**

- Cement or Screw-retained single or multiple unit restorations.
- All tooth positions.
- Partial and full edentulous restorations

**Configurations**

- Plastic sleeve for wax and cast techniques
- Engaging or non-engaging

**Technical Considerations**

- A minimal inter-occlusal distance of 4.5 mm is required between the implant prosthetic table and the top of the abutment screw when seated.
- Maximum angle corrections up to 25° based on platform
- Castable Abutments are packaged non-sterile

**Laboratory Procedure**

Laboratory Model Fabrication See Section 4.4.

**Crown/Metal Framework Procedure**

1. Pour the soft tissue material around the implant analog. When the material has set, pour a stone master model.

2. Place the Gold Base Castable Abutment on the laboratory cast.

3. Determine the modifications needed to provide adequate clearance for adjacent and opposing dentition.

4. Add wax and/or acrylic burnout resin to the abutment to contour the abutment into the appropriate dimensions. Extend a small amount of wax onto the gold base to ensure a smooth junction between the base and the plastic sleeve.

5. Sprue, invest and cast following conventional crown and bridge techniques. See the Gold Base Castable package insert for technical data on casting and melting temperatures.

   **NOTE:** A chemical divestment material is recommended to preserve the implant/ abutment interface. When divesting and casting, it is important not to sandblast the implant/abutment interface. Doing so could result in a poor fit between the abutment and implant.

6. Confirm fit of the abutments on the master cast. The soft tissue material can be removed to verify an accurate fit of the custom abutment to the implant analog on the model. Polish any part of the abutment that will be exposed in the soft tissue.

   NOTE: When polishing the abutment collar, attach an implant analog to protect the implant/abutment interface.

7. Construct a wax coping/metal framework following conventional crown and bridge procedures.

8. Sprue, invest and cast following conventional crown and bridge techniques.

9. Divest and finish the coping/metal framework using conventional crown and bridge techniques.

   NOTE: If requested, the coping/metal framework may now be returned to the dentist for metal try-in.

10. If there is no metal framework try-in, proceed to section Porcelain Application following standard laboratory procedures. Return the final restoration on the master model to the clinician.

**Clinical Section**

**Metal Framework Try-in**

1. Remove the metal framework from the master model. Before placement in the mouth, note the orientation marks on the model and on the Gold Base Castable abutments placed by the dental technician.

2. Place the Gold Base Castable abutments in the patient's mouth. Verify that the position of the orientation mark is towards the buccal.

3. Use the Ø1.25 hex driver and the abutment screw to hand tighten the abutments in the mouth.

4. Take a radiograph to verify that the abutments are completely seated.

5. Seat the coping/metal framework and verify that the framework fits passively and completely over the Gold Base Castable abutments.

   **NOTE:** If the framework binds during seating or does not go completely down to the margin of the abutment(s), then the bridge must be sectioned, orientated in the mouth, and returned to the laboratory for soldering/laser welding.

6. Reseat the sections in the mouth and lute the sections of the framework together using a pattern resin material. Once the material has set to the manufacturer's specifications:

   Return the metal framework to the laboratory to be soldered/laser welded and returned for a second framework fitting.

   **OR**

   Pick up the luted framework in a secondary full arch impression. Return the impression to the laboratory for soldering/laser welding and porcelain application.

7. If the metal framework fit passively and completely, it can be removed along with the Gold Base Castable abutments and returned to the laboratory.

## Laboratory Section

### Porcelain Application

Proceed with porcelain application following conventional laboratory procedures.

## Clinical Section

### Final Insertion

Prior to final insertion non-sterile abutments need to be cleaned and sterilized.

1. After the healing cap or temporary crown is removed, the final crown is secured to the implant by an abutment screw with Ø1.25 hex driver. Then a radiograph is taken to ensure proper seating of the restoration. Using a Ø1.25 hex driver, Ratchet Adapter, and Torque Ratchet, seat the abutment and tighten final abutment screw in accordance with Torque Value Reference Table.

   A radiograph is taken to ensure proper seating of the abutment. At this point, the Ø1.25 hex driver and ratchet/latch adapter are inserted into the Torque Ratchet and the final abutment screw is tightened.

2. The crown is placed, occlusion and aesthetics are evaluated and adjusted as necessary. It is recommended that the screw access hole be blocked out to protect the screw. At this point, the crown is cemented onto the Abutment.

   All excess cement must be meticulously removed, and the occlusion evaluated once more the patient is then provided with oral hygiene instructions and a recall appointment is recommended.

# 6.3 Single-Unit Abutment System

**Description**

Single-Unit Abutments are prosthetic components directly connected to endosseous dental implants and intended to provide support and retention for single-unit screw-retained restorations. Since this is a nonengaging abutment, it must be torqued down correctly to prevent loosening. The Single unit abutment is not suitable for excessively large molar teeth with increased height or large occlusal surface.

Single-Unit abutments and Interface copings are not intended to be modified. Single-Unit abutments are only to be used with implants placed in a straight manner. Single-Unit abutments are only to be used in combination with the corresponding subject interface coping or temporary cylinder. The minimum post height above the gingival collar is 5mm when combined with an interface coping or cylinder. Temporary Titanium Cylinders are intended to be used for up to 90 days. Choose the appropriate height of the Single-Unit abutment, according to the measured mucosa height. For aesthetic results, it is recommended to place the cuff of the abutment 1.0-1.5mm sub- gingival.

A premanufactured titanium alloy Ti-6Al-4V ELI abutment directly connected to the implant for use for a screw-retained single-unit restoration. The Fully castable Single-Unit Abutment and material is a white acetal (POM H Delrin 150). Depending on the chosen loading protocol, the Single-Unit Abutment can be connected to the implant at time of surgery or after one-stage/ two-stage healing protocols. Provided sterile.

**Intended Applications**

- Screw-retained single unit restorations.
- All tooth positions.
- Partial edentulous restorations.

**Configurations**

- Single-Unit Abutment is non-engaging.
- All accessories are engaging.
- Cuff heights 1.0mm – 5.0mm.

**Technical Considerations**

- A minimal inter-occlusal distance of 5.0mm is required between the implant prosthetic table and the top of the abutment screw when seated.
- Not recommended for angle corrections
- Ø1.25 hex driver is needed to tighten final abutment screw in accordance with Torque Value Reference Table.
- Single-Unit Abutments, Single-Unit Healing Caps, Temporary Cylinders, and Single-Unit Impression Copings are packaged Sterile
- Fully Castable Single-Unit Abutments and Single-Unit Interface Copings are packaged non-sterile

## Clinical Section

### Placement of Single-Unit Abutment

1. Select the appropriate Single-Unit Abutment based on platform size, implant angle, and depth of the soft tissue (cuff height). The margin of the Single-Unit Abutment should be at gingival level or slightly below.
2. Remove the Single-Unit Abutment from the sterile blister packaging. To maintain the sterility of the Single-Unit Abutment, be careful to handle only by the blister packaging.
3. Seat the Titanium Straight Single-Unit Abutment into the implant and hand-tighten with Ø1.25 hex driver. A radiograph is recommended of the connection site be taken to confirm complete seating of the abutment before proceeding.
4. Once confirmed, utilizing the Ø1.25 hex driver in conjunction with a properly metered torque wrench, tighten the Single-Unit Abutment to the recommended torque value.

### Closed Tray (Indirect) Impression Procedure

1. Utilizing the Single-Unit Impression Coping 

2. Twist a Closed Tray Single-Unit Impression Coping onto the Single-Unit Abutment until fully seated. Hand-tighten only. Overtightening may result in loosening of the Single-Unit Abutments when the coping is removed.

   Verify with an x-ray if subgingival impression coping is fully seated.

3. Follow user instructions & documentation for the chosen impression material to take a full-arch Medium/Heavy body polyvinylsiloxane impression.

4. Once the impression material has set within the closed tray, remove the tray from the patient's jaw. The Closed Tray Single-Unit Impression Coping will remain connected to its corresponding abutment.

5. Examine the impression, use disinfectant & rinse in soapy water to remove residual matter. Dry the impression material using low air pressure.

6. Unscrew Closed Tray Single-Unit Impression Coping from Single-Unit Abutment. Attach Closed Tray Single-Unit Impression Coping onto the Single-Unit Abutment Analog and hand-tighten.

7. Reposition the Closed Tray Single-Unit Impression Coping into the depression in the impression material and press firmly to engage. The Single-Unit Analog should protrude from the impression & be stable.

### Temporization of the Single-Unit Abutment

1. Seat a Titanium Single-Unit Cylinder onto the Single-Unit Abutment and hand- tighten the Prosthetic Screw utilizing the Ø1.25 hex driver.

2. Take a temporary crown, place a hole in the position directly above the placement of the Titanium Single-Unit Cylinder. The hole should allow the temporary cylinder to pass all the way through the temporary crown. Mark the portion of the cylinder that protrudes through the crown may be shortened by hand-milling providing that the minimum cylinder height is no less than 5 mm.

3. Remove the Titanium Single-Unit Cylinder and screw. Modify the height, clean, and sterilize the modified cylinder and screw following the procedure listed above. Reseat the Titanium Single-Unit Cylinder into the mouth and secure with screw.

4. Block out the screw access hole to protect the screw during fabrication of temporary restoration. Carefully add some acrylic, flowable composite, or other suitable material inside the prefabricated crown and seat onto the Titanium Single-Unit Cylinder. Allow material to set based on manufactures curing procedures.

5. Remove the prosthetic screw from the Titanium Single-Unit Cylinder with crown attached. The Titanium Single-Unit Cylinder should be captured within the crown.

6. Modify the temporary crown as necessary. Grind any protruding titanium from the upper side of the crown. Fill any voids around the base of the Titanium Single-Unit Cylinder on the underside of the crown with acrylic, flowable composite, or other suitable material, and cure.

7. Reseat the temporary crown and replace the prosthetic screw into the Single-Unit Titanium Cylinder. Using the Ø1.25 hex driver in conjunction with a properly metered torque wrench, tighten the prosthetic screws to recommended torque. Verify temporary restoration is fully seated.

8. Fill the screw access channel with gutta-percha, silicone, or other suitable temporary material.

   NOTE: If temporization is not desired, a healing cap can be placed during the restorative phase.

**Open Tray (Direct) Impression Procedure**

1. Ensure gingival tissue is sufficiently withdrawn to avoid pinching.

2. Seat an Open Tray Single-Unit Impression Coping onto the Single-Unit Abutment.

3. Place the Open Tray Single-Unit Impression Coping Screw into the Open Tray Single- Unit Impression Coping. Turn it clockwise to hand- tighten. Overtightening may result in loosening of the Single-Unit Abutment when the screw is removed.

   Verify with an x-ray if subgingival impression coping is fully seated.

4. Follow user instructions & documentation for the chosen impression material to take a full-arch medium/heavy bodied polyvinylsiloxane impression.

5. Following manufacturer's recommended setting times, once the impression material has set within the impression tray, unscrew, and remove the screw with the tray still in place on the arch.

6. Remove the tray from the patient's mouth. The Open Tray Single-Unit Impression Copings should be captured by the impression material.

7. Examine the impression, use disinfectant & rinse in soapy water to remove residual matter. Dry the impression material using low air pressure.

8. Mount a Single-Unit Analog onto each Open Tray Single-Unit Impression Coping captured within the impression and refasten using the Open Tray screw by entering it through the top of the impression and fasten it to the Single-Unit Abutment Analog inside the impression. Send impression and components to the dental laboratory with opposing impression, shade, and bite.

**Laboratory Section**

**Crown/Metal Framework Procedure**

1. If subgingival, ensure to inject soft tissue material around the Single-Unit Abutment Analog prior to pouring the cast. Proceed with the fabrication of a stone model using standard laboratory techniques. Upon separation, the Single-Unit Analog is a part of the master cast replicating the position of the Single-Unit Abutment in the oral cavity.

2. Place the Engaging Castable Abutment on the laboratory cast.

3. The Engaging Castable Abutment should be reduced to a point where it is slightly out of occlusion. Add wax and/or acrylic resin to the sleeve to contour the abutment into the appropriate dimensions.

4. Sprue, invest and cast following conventional crown and bridge techniques. See the Engaging Castable Abutment package insert for technical data on casting and melting temperatures.

5. Confirm fit of the screw-retained restoration on the laboratory cast. The soft tissue material can be removed to verify an accurate fit of the framework to the implant analog on the model. Polish any part of the abutment/frame that will be exposed in the soft tissue. When polishing the abutment collar, attach an implant analog to protect the implant/ abutment interface.

   A chemical divestment material is recommended to preserve the implant/abutment interface. When divesting and casting, it is important not to sandblast the implant/ abutment interface. Doing so could result in a poor fit between the abutment and implant.

**Clinical Section**

**Crown/Metal Framework Procedure**

1. Place the screw-retained metal restoration in the mouth. Verify the fit between the restoration and implant and abutment interface.

2. If subgingival, verify seating with an x-ray. Once verified remove metal screw-retained casting and return to the laboratory for porcelain addition. Replace healing cap or temporary restoration.

**Laboratory Section**

**Porcelain Procedure**

1. Apply an opaque layer to the coping/metal framework. Apply a porcelain application following conventional laboratory procedures. Polish any exposed metal with a gold polishing paste.

When polishing the abutment and the implant collar, attach an implant analog to protect the implant/abutment interface.

**Caution:** Do not sandblast the pre-machined surface of the metal framework.

**Clinical Section**

**Final Procedure**

Prior to final insertion non-sterile abutments need to be cleaned and sterilized

1. After the healing cap or temporary crown is removed, the final crown is secured to the implant by a final abutment screw with Ø1.25 hex driver. Then a radiograph is taken to ensure proper seating of the restoration. Using a Ø1.25 hex driver, Ratchet Adapter, and torque ratchet, seat the abutment and tighten abutment screw in accordance with Torque Value Reference Table.

2. The crown is placed, occlusion and aesthetics are evaluated and adjusted as necessary.

3. It is recommended that the screw access hole be blocked out to protect the screw. At this point, the crown is cemented onto the Titanium Abutment.

4. All excess cement must be meticulously removed, and the occlusion evaluated once more the patient is then provided with oral hygiene instructions and a recall appointment is recommended.

**Digital Process**

**Clinical Section**

**Digital Scan Procedure**

**Note:** In some cases, it may be necessary to scan the emergence profile to provide the lab with the soft tissue contours.

1. Remove the healing cap or temporary restoration and scan the emergence profile immediately.

2. Seat the single-unit scan body utilizing the Ø1.25 hex driver to the Single-Unit abutment. It is recommended to place the point/dot of scan body towards the facial for easy identification in the software. The scan body has a unique geometry that allows easy and accurate scanning and is suitable for both intra-oral and laboratory scanning. A titanium base ensures a precise fit into the connection, while the PEEK top allows visibility of the component in the oral surface scan.

3. Check for proper seating to prevent any rotational or vertical displacement. Hand-tighten to 15Ncm.

4. Take peri-apical x-ray to verify seating prior to recording the intra-oral scan.

5. Scan the top of the scan body and all sides to make sure you have captured the scan body completely.

6. Scan the full jaw, scan antagonist, scan the bite.

7. Replace the healing cap or temporary restoration.

8. Send all files to the dental laboratory.

**Laboratory Section**

**Digital Model**

1. Upload scans from the clinician to your preferred prosthetic software (3shape Dental System, Exocad, Dental Wings).

2. Utilizing the Single-Unit DIM Analog, create your digital model.

3. Design the Single-Unit screw-retained crown utilizing the Single-Unit Titanium, Interface coping.

4. Use the Single-Unit Titanium Interface Coping to design the final restoration.

5. Manufacture the crown following the instructions for use of the material and manufacturing equipment.

6. Once the restoration is completed, prior to cementing the crown restoration place the Single-Unit Titanium Interface.

7. Coping in the digital model and evaluate the restoration for correct anatomical contours contact points and occlusion.

8. If clinician recommends the dental laboratory lute the Zirconia restoration to the Single-Unit Titanium Interface Coping. The crown is then luted to the interface utilizing an approved luting material for Zirconia or full feldspathic porcelain (follow manufacturer's instructions for luting).

9. Return screw-retained restoration with final abutment screw to the clinician.

**Clinical Section**

**Seating of Final Screw-Retained Restoration**

1. Carefully remove the healing cap or temporary crown.

2. Verify the Single-Unit abutment is stable and torqued to 35Ncm.

3. If the Zirconia was not luted to the Single-Unit Titanium Interface Coping, seat the Single-Unit Titanium Interface Coping and seat the screw-retained restoration over the coping.

4. Check aesthetics, fit, occlusion and comfort.

5. Following clinical approval, the crown is then luted to the interface using an approved luting material for Zirconia or full feldspathic porcelain (follow manufacturer's instructions for luting).

6. Tighten the prosthetic screw by hand, take clinical x-ray to verify correct seating.

7. Final delivery of the crown the prosthetic screw should be torqued to the recommended torque value.

8. Close the screw access hole to protect the head of the prosthetic screw & then fill the screw access channel with an appropriate composite flow in accordance with the crown color shading.

# 6.4 Paltop Straight/Angulated Multi-Unit Abutment

Description

Multi-Unit Abutments are precision manufactured abutments made of Ti6Al4V ELI designed for a removable or fixed implant supported prosthesis of partially or fully edentulous arches. The Fully Castable Multi-Unit Abutments, and Snap on Closed Tray Impression coping is manufactured from White Acetal (POM H Delrin 150) and the Multi- Unit Scan body is a PEEK (Polyaryletherketone) with a Ti6AL4V ELI screw. These abutments are available in both straight (non- engaging, one-piece) and angulated (engaging, 17° and 30°) alternatives with a wide selection of cuff heights to match the thickness of soft tissue. The Angulated Multi- Unit Abutments (AMUA) come with a premounted positioning tool for simplified abutment seating, Multi-Unit Screw for Metal Guide. It also serves as a visual guide for checking correct abutment angulation. The use of Multi-Unit Abutments can correct restorative challenges and is recommended when creating a full-arch prosthesis to provide a passive fit and positive seat for the prosthesis. The Multi-Unit Abutments are available in a Standard Platform (SP), Narrow Platform, Conical Connection, and Wide Platform (WP). The accessories are also available to fit Standard Platform (SP), Narrow Platform, Conical Connection, and Wide Platform (WP). The workflow follows traditional laboratory techniques and may follow either an immediate loading protocol or loading following the completion of initial osseointegration of the underlying implants. Multi-Unit Abutments are provided Sterile. Angulated Multi-Unit Abutments are provided with a screw and guide.

Intended Applications

- Multiple-unit fixed or removable implant-supported prosthetics.
- Simplified prosthetic access for diverging implant angles.
- All tooth positions.
- Engaging and non-engaging connections.

Technical Considerations

- Multi-Unit Abutments are not intended to be modified.
- Multi-Unit Titanium Cylinders are to be hand milled to height and must maintain at least a 5 mm post height. If modification is needed, follow the Cleaning/Sterilization procedure prior to placement in the patient's mouth.
- Straight Multi-Unit Abutments are only to be used with implants placed in a straight manner.
- No angle correction is allowed as part of the Multi-Unit Temporary Sleeve. If angle correction is necessary, it must come from the Multi-Unit Abutment base. Select the appropriate Multi-Unit Abutment for the case.
- Temporary Titanium Cylinders used with multi-unit abutments are intended to be used for up to 90 days.
- Multi-Unit Abutments, Multi-Unit Healing Caps, Temporary Cylinders, and Multi-Unit Impression Copings are packaged Sterile
- Fully Castable Multi-Unit Abutments, Stand-Alone Screws/Guides, Plastic Snap-On Closed Tray Impression Coping, and Multi-Unit Interface Copings are packaged non-sterile
- For contraindications, see Contraindications section above.

### Straight Multi-Unit Abutments

Available in different cuff heights to accommodate different soft tissue heights. Select and place appropriate abutment. Use plastic holder to facilitate the insertion. It is recommended to verify the final abutment selection and seating using radiographic imaging. Remove the plastic holder and tighten the abutment to the recommended torque using the proper Multi-Unit Abutment Driver.

### Angulated Multi-Unit Abutments

Available in different cuff heights to accommodate different soft tissue heights and angle corrections. Select and place appropriate abutment. Use the positioning tool to facilitate a proper position, as there are several positions possible based on the implant connection and the abutment angulation. It is recommended to verify the final abutment selection and seating using radiographic imaging. Tighten the abutment using the proper Multi-Unit Abutment Driver.

### Straight/Angulated Multi-Unit Abutment Process

Remove the Healing Cap, if placed. Measure the tissue depth from the top of the implant to the top of the soft tissue at its highest point. It is recommended to select a Multi-Unit Abutment with a cuff height which is 1.0 mm subgingival. Select the abutment platform and angulation needed for proper positioning to create a passive prosthesis.

| Platform | Straight Cuff Heights | 17° Cuff Heights | 30° Cuff Heights |
|---|---|---|---|
| Narrow Platform (NP) | 1.0, 2.0, 3.0, 4.0, 5.0 mm | 3.0, 4.5 mm | |
| Standard Platform (SP) | 1.0, 2.0, 3.0, 4.0, 5.0 mm | 2.5, 3.25, 4.0 mm | 3.5, 4.5 mm |
| Wide Platform (WP) | 1.0, 2.0, 3.0, 4.0 mm | 3.0 mm | |
| Conical | 1.0, 2.0, 3.0, 4.0, 5.0 mm | 3.0, 4.5 mm | 4.0 mm |

### Titanium Angulated Multi-Unit Abutment

1. Use the Multi-Unit Screw Guide (which comes attached to the angulated Multi Unit) to seat the Titanium Angulated Multi-Unit Abutment into the implant until the anti-rotational features of the connection interface are engaged. Lift and rotate as necessary to orient the angle of the MUA in the required prosthetic orientation.

2. Hand-tighten the Angled Multi-Unit Screw Using a Paltop driver. To remove the metal handle, twist the metal handle counterclockwise. It is strongly recommended that a radiograph of the connection site be taken to confirm complete seating of the abutment on the implant connection before proceeding.

3. Using the appropriate driver in conjunction with a properly metered torque wrench, tighten the Multi-Unit Angulated Abutment to the recommended torque value (see "Torque Values Chart"). Unscrew the Multi-Unit Screw Guide from the Angulated Multi-Unit.

### Bar-Retained (Removable) Implant-Supported Prosthesis

For implant-supported prostheses, it is recommended to place a minimum of six or more implants in the maxilla, and a minimum of four or more in the mandible. Implant-retained dentures are removable by the patient. This prosthesis resembles a conventional removable denture but does not rest on the patient's gum tissue. This prosthesis rests completely on the implants and is held securely in place by a variety of attachments options.

### Fixed (Hybrid) Implant-Supported Prosthesis

Hybrid Prosthesis or Fixed-Detachable Prosthesis is a combination of an implant-supported overdenture and an implant-supported fixed bridge. Four to six implants are usually used, and the prosthesis is screwed onto Multi-Unit Abutments. The prosthesis is removable by the clinician and cannot be removed by the patient.

**Immediate Temporization Titanium Temporary Sleeves**

Titanium Multi-Unit Cylinder are prefabricated prosthetic components manufactured from Ti 6AL-4V ELI, available in two heights of 10 and 15mm. The Titanium Multi-Unit Cylinders seat directly onto the Multi-Unit Abutments using a Multi-Unit Prosthetic Screw. They are intended for use to support multiple-unit screw-retained temporary prostheses in the maxilla or mandible. The circumferential mechanical retention grooves of the Titanium Multi-Unit Cylinders enable mechanical bonding of a temporary prosthesis.

**Titanium Multi-Unit Cylinder H10mm**

**Titanium Multi-Unit Cylinder H15mm**

**Intended Application**

- During endosseous and gingival healing when following an immediate loading protocol.
- Following initial osseointegration, when using a second-stage protocol, for the fabrication of a temporary screw-retained prosthesis.

**NOTE:** Products which are provided non-sterile and/or modified by the end-user or any procedures used which may compromise the sterility of the device must be cleaned and sterilized after any modifications are made prior to use in the patient

1. If the initial stability of the seated implant is insufficient for loading, cover each Multi- Unit Abutment with a Multi-Unit Healing Cap and tighten (see "Torque Values Chart" table below) with the Multi-Unit Healing Cap Screw provided, using the appropriate driver. Do not overtighten.

2. If the implants have reached adequate primary stability, it may be possible to utilize the patient's existing denture or other prosthesis, relieve the area directly above the placement of each multi-unit healing cap until the denture rests on the jaw In the case of denture reline it is recommended to use the tapered healing cap, this will reduce the occlusal pressure from the relined denture.

3. Follow procedures to reline the denture over the Multi-Unit Healing Caps, using soft reline material only. The temporized denture can be used during a multi-unit healing phase until implants obtain sufficient load-bearing stability.

**Clinical Section**

1. Seat the Titanium Multi-Unit Cylinder onto the Multi-Unit Abutments and hand tighten the Multi- Unit Prosthetic Screws utilizing the Ø 1.25 hex driver.

2. Take the temporary prosthesis and place holes in the positions directly above the placement of the Titanium Multi-Unit Cylinders. The holes should allow the temporary sleeves to pass all the way through the temporary prosthesis. If the cylinder interferes with the opposing arch, mark the portion of the sleeve that protrudes through the prosthesis to the desired length. The Titanium Multi-Unit Cylinder may be shortened by hand- milling providing that the minimum sleeve height is no less than 5 mm.

3. Remove the Titanium Multi-Unit Cylinder and Multi-Unit Prosthetic Screws. Modify the height, clean, and sterilize the modified sleeves and screws. Reseat the Titanium Multi-Unit Cylinders into the mouth and secure with the Multi-Unit Prosthetic Screws.

4. Block out the screw access holes to protect the screws during fabrication of the temporary restoration. Carefully add some acrylic, flowable composite, or other suitable material, inside the prefabricated prosthesis and seat onto the Titanium Multi-Unit Cylinders. Allow the material to set based on manufacturer's curing procedures.

5. Remove the Laboratory Prosthetic Screws from the Titanium Multi-Unit Cylinders.

6. Modify the temporary restoration as necessary. Grind any protruding titanium from the upper side of the prosthesis. Fill

any voids around the base of the Titanium Multi-Unit Cylinders on the underside of the prosthesis with acrylic, flowable composite, or other suitable material, and cure.

7. Reseat the temporary restoration and place the Multi-Unit Prosthetic Screws into the Titanium Multi-Unit Cylinders. Using the Ø 1.25 hex driver in conjunction with a properly metered torque wrench, tighten the multi-unit prosthetic screws to recommended screw torque in accordance with the Torque Value Reference Table. Verify that the temporary restoration is fully seated.

8. Fill the screw access channel with a suitable temporary material.

**Closed-Tray Impression Procedure (Indirect Transfer)**

1. Remove the Healing Caps or temporary prosthesis using the Ø 1.25 hex driver.

2. Ensure gingival tissue is sufficiently withdrawn to avoid pinching.

3. Twist the appropriate Closed-Tray Multi-Unit Impression Coping onto the Multi- Unit Abutment until fully seated. Hand tighten only.

   **NOTE:** Overtightening may result in loosening of the Multi-Unit Abutments when the impression copings are removed.

4. A heavy-bodied impression material is injected around the impression coping. Then, fill the custom tray with impression material and fully seat over the impression coping, capturing the soft tissue and ridge (lower arch) or palate (upper arch).

5. Once the impression material has set within the closed tray, remove the tray from the patient's mouth. Each Closed-Tray Multi-Unit Impression C o p i n g will remain connected to its corresponding abutment.

6. Unscrew each Closed-Tray Multi-Unit Impression Coping from its corresponding Multi-Unit Abutment.

7. Seat the Healing Caps or temporary prosthesis.

8. Attach each Closed-Tray Impression Post onto the appropriate Multi-Unit Abutment Analog and hand tighten.

9. Gently clean the housing of the Closed Tray Impression Coping to ensure there is no residue/saliva. Reposition each Closed-Tray Multi-Unit Impression Coping into its corresponding depression in the impression material and press firmly into place.

10. Send the impression and counter model to the laboratory.

**Open-Tray Impression Procedure (Direct Transfer)**

1. Remove the Healing Abutments or temporary prosthesis using the Ø 1.25 hex driver.

2. Ensure gingival tissue is sufficiently withdrawn to avoid pinching.

3. Seat the appropriate Open-Tray Multi-Unit Impression Coping onto each Multi-Unit Abutment.

4. Slide the appropriate Open-Tray Impression Coping Screw into the Open-Tray Multi- Unit Impression Coping. Utilizing the Ø 1.25 hex driver, hand tighten the Impression Coping Screw.

   NOTE: Overtightening may result in loosening of the Multi-Unit Abutment when the screw is removed.

5. A heavy bodied impression material is injected around each Impression Coping. Then fill the custom tray with

impression material and fully seat over the impression post capturing the soft tissue and vestibule. Ensure that the Open-Tray Impression Post Long Screw protrudes through the hole in the tray.

6. Once the impression material has set within the tray, unscrew and remove the Long Screws utilizing the Ø 1.25 hex driver with the tray still in place on the mouth.

7. Remove the tray from the patient's mouth. The Open-Tray Multi-Unit Impression Copings should be captured by the impression material.

8. Mount the appropriate abutment analog onto each Open-Tray Multi-Unit Impression Coping captured within the impression and refasten using the Open-Tray Impression Coping Screw.

9. Send the impression to the laboratory.

**Laboratory Section – Laboratory Cast Fabrication**

For impressions captured with the closed-tray (indirect) technique, ensure that the Closed- Tray Multi-Unit Impression Copings are placed appropriately within the impression. Ensure each captured Closed-Tray Multi-Unit Impression Coping is fully seated on the Multi-Unit Abutment Analog, and that there is no movement of the analog.

**NOTE:** If movement is observed, a new impression is required.

For impressions captured with the open-tray (direct) technique, unscrew and remove the Long Screws from the underside of the impression tray before separating the model from the impression.

Fabricate 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.

**Creation of the Verification Index — Titanium Temporary Sleeves**

NOTE: Products which are provided non-sterile and/or modified by the end-user, or any procedures used which may compromise the sterility of the device, must be cleaned and sterilized after any modifications are made prior to use in the patient.

1. Seat a Multi-Unit Titanium Temporary Cylinder onto each analog with the Laboratory

2. Intertwine dental floss around the middle of the Multi-Unit Titanium Temporary Cylinder.

3. Apply a pattern resin or a light-cured material to the area the dental floss was attached to and lute the impression copings or cylinders together.

4. Section the pattern resin between the impression copings or cylinders. Mark the impression copings or cylinders for mid-facial orientation and number.

5. Send the verification index and the Prosthetic Screws to the restorative clinician. A passive fit intraorally will confirm that an accurate final impression has been achieved.

**Clinical Section – Verification Index Confirmation**

1. Place the individual verification indexes on the Multi-Unit Abutments according to the numbering and mid-facial orientation.

2. Hand tighten utilizing a Multi-Unit Prosthetic Screw and the Ø 1.25 hex driver.

3. Confirm that the Titanium Multi-Unit Cylinder sit passively and completely on their respective abutments.

4. Lute using pattern resin, or light-cured composite, each Titanium Multi-Unit Cylinder until all cylinders are attached. Remove the verification index and send it to the laboratory.

**Laboratory Section – Fabrication of a Record Base and Occlusal Rim**

1. Place the verification index on the Multi-Unit Abutment Analogs.

2. Hand tighten, either of the distal-most screws into the Multi-Unit Abutment Analog, using the Ø 1.25 hex driver. Confirm that the remaining sleeves sit passively and completely on their respective abutments.

   **NOTE:** If any of the sleeves do not fully seat on an analog, the analog must be removed from the model and reoriented.

3. Fasten each of the remaining sleeves, beginning with the distal and working forward by alternating sides. Hand tighten only.

4. If a passive fit is achieved, an accurate transfer has been recorded. The verification index will act as the framework for the record base.

5. Following normal lab procedures, create a record base material to form and cure the base around the index framework. Be sure the material conforms fully to the contours of the edentulous arch. The base should fit tightly around the Titanium Multi-Unit Cylinders. Follow procedures to build a wax occlusal rim on top of the record base. Send the record base/occlusal rim fixture to the restorative clinician while still fastened to the working cast.

**Clinical Section – Verification of Occlusal Rim and Bite Registration**

1. Remove the occlusal rim from the working cast, utilizing the Ø 1.25 hex driver. Seat the record base onto the Multi-Unit Abutments. Hand tighten the record base and occlusal rim fixture to the Multi-Unit Abutments with the Multi-Unit Prosthetic Screws, using the Ø 1.25 hex driver.

   **NOTE:** At least two screws should be fastened during registration to ensure proper fit.

2. Use standard prosthodontic techniques for tooth selection and positioning. Index the midline and smile line across the facial aspect of the occlusal rim. Syringe sufficient elastomeric bite registration material onto the rim and create the bite registration against the opposing dentition.

3. Remove the occlusal rim from the patient's mouth. Replace and fasten to the working cast with the Multi-Unit Prosthetic Screws. Then return the working cast, occlusal rim, shade, counter model, and bite registration to the laboratory.

**Laboratory Section – Articulation and Denture Wax Try-in**

Mount the working model with the opposing model on an articulator. Follow normal laboratory and clinical procedures for denture wax-up techniques.

**Clinical Section – Denture Try-in and Verification**

1. Seat the wax try-in onto the Multi-Unit Abutments and hand tighten the Screws, utilizing the Ø 1.25 hex driver.

2. Modify as needed to obtain the desired aesthetics, phonetics, and occlusion.

3. Remove the wax try-in and return the approved wax try-in to the laboratory.

**Laboratory Section – Fabrication of the Final Prosthesis**

1. Index the facial contours of the final wax set-up with putty or plaster matrix. This will provide a guide for bar positioning and attachment placement. Using the wax try-in as the template, follow laboratory procedures to create the final prosthesis.

   **NOTE:** If the prosthesis will be bar-retained, the bar should be fabricated concurrently with the prosthesis to ensure proper fit and adequate retention. Confirm that each Multi-Unit Abutment is tightened to the recommended torque value (see "Torque Values Chart" ).

2. Remove the wax try-in from the working model. Fabricate a screw-retained bar for the prosthesis following traditional methods.

**Clinical Section – Try-in of Bar and Denture Wax-up for Verification**

1. Seat the bar and denture wax try-in onto the Multi-Unit Abutments. Hand tighten utilizing the Ø 1.25 hex driver and Multi-Unit Prosthetic Screw into a distal-most abutment. Examine the other abutments to confirm no separation or lifting of the bar has resulted from tightening the first screw.

2. Place the next Multi- Unit Prosthetic Screw and 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:

Remove the Multi- Unit Prosthetic Screws and return the bar to the laboratory for fabrication of the final prosthesis.

If a passive fit is not achieved:

Determine the two connection points between which the bar ceases to fit passively. The bar must be cut, orientated in the mouth, and returned to the laboratory for soldering/ laser welding.

A. Remove the Multi- Unit Prosthetic Screws and remove the bar from the patient's mouth. Remove the denture wax try-in.

B. Using a high-speed disc bur, cut through the bar at the point where the bar ceases to fit passively. Reseat the bar sections into the patient's mouth and hand tighten the Multi-Unit Prosthetic Screws.

C. Apply auto-polymerizing resin liberally to the separation point between the sections and allow it to set in the new configuration.

D. Remove and return the modified bar to the lab for solder/laser welding and new wax try-in.

**NOTE:** If a passive fit was not achieved, repeat steps 1–3 under Bar and Denture Wax-up for Verification Section set-up until passive fit is achieved.

**Laboratory Section – Process Final Prosthesis**

Follow procedures to process and finish the denture with the chosen bar design integrated. Deliver the final restoration to the clinician.

**Clinical Section – Delivery of Final Prosthesis**

1. Remove any temporary prosthesis.

2. Confirm that each Multi-Unit Abutment is tightened to the recommended torque value found in the Torque Value

Reference Table.

3. Align the prosthesis onto the Multi-Unit Abutments. Beginning with the midmost screw access channel, hand tighten the Multi-Unit Abutment Prosthetic Screw into the Multi-Unit outward and alternating between sides of the ridge.
4. Confirm appropriate seating. With the same middle-out, left-to-right technique, tighten each prosthetic screw to the recommended torque value found in the Torque Value Reference Table.

5. Check comfort and occlusion and make any necessary adjustments.

6. Fill each screw access channel with a suitable temporary material.

**NOTE:** The patient is then provided with oral hygiene instructions, and a recall appointment is recommended.

**Traditional Laboratory Procedure for screw retained Zirconia Hybrid Prosthesis**

**Create the Verification Index- Multi-Unit Interface Coping**

1. Seat a Multi-Unit Interface Coping onto each analog captured in the stone working model and hand-tighten with a screw using the appropriate driver.

2. Lute two adjacent copings together at the non-tapered coronal aspect with light-cure composite resin or auto polymerizing acrylic resin.

3. Once cured, separate the resin connections with a high-speed disc bur or Bard Parker knife. Repeat for each pair of adjacent copings.

4. Once all copings are sectioned, confirm all screws are hand-tightened and lute all sections together by adding a small amount of resin to each separation point.

5. Remove the screws and the verification index. Send the verification index and the prosthetic screws included with the Multi-Unit Interface Coping to the restorative dentist.

**Clinic – Confirm a Passive Fit with the Verification Index**

1. Intra Oral – Place the verification index on the Multi-Unit Abutments.

2. Hand-tighten either of the distal-most copings into the Multi-Unit Abutment using a prosthetic screw and the appropriate driver. Confirm that the remaining copings sit passively and completely on their respective abutments.

3. Fasten each of the remaining copings, beginning with the distal and working forward by alternating sides. Hand-tighten only.

4. If a passive fit is achieved, an accurate transfer has been recorded. Remove the verification index.

**Laboratory — Fabricate a Rigid Base (using traditional laboratory techniques) and Occlusal Rim**

1. Re-attach the verification index to the working model with a hand-tightened screw for each coping. The verification index will act as the framework for the rigid base.

2. The rigid base form must conform fully to the contours of the edentulous arch. The base should fit tightly around the protruding impression coping screw and fill in any gaps between the framework and the jaw.

3. Follow procedures to build a wax occlusal rim on top of the rigid base.

4. Send the screw retrained occlusal rim to the dentist, still fastened to the working cast.

**Clinic Take the Occlusal Rim Bite Registration**

1. Remove the occlusal rim from the working cast by twisting and removing the screws straight up through the access holes.
2. Seat the occlusal rim onto the Multi-Unit Abutments on the patient's jaw. Hand-tighten the occlusal rim 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 extra orally 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 impression coping screws, and return the working cast, occlusal rims, and bite registration to the laboratory.

**Laboratory — Fabricate the Wax Try-In**

Articulate the models with the aid of the contoured occlusal rims follow procedures to mount the wax try-in denture teeth onto the screw retained occlusal rim.

**Clinic Try-in the Restoration**

1. Seat the wax try-in onto the Multi-Unit Abutments on the patient's jaw and hand-tighten with the prosthetic screws.
2. Modify as needed to obtain the desired esthetics, phonetics, and occlusion.
3. Remove the wax try-in and return the approved apparatus to the laboratory.

**Laboratory — Fabricate the Final Prosthesis**

1. Follow plaster or silicone casting procedures to fabricate a matrix of the approved wax try-in.
2. Using the wax try-in as the template, follow traditional laboratory procedures to create the final prosthesis.

**Clinic Deliver the Final Restoration**

1. Remove any temporary prosthesis.
2. Clean and sterilize the final prosthesis according to the validated cleaning and sterilization procedures above.
3. Confirm that each Multi-Unit Abutment is tightened to the recommended torque value (see "Torque Values Chart" table 9 below).

**CAD/CAM Restorative Procedure- Screw Retained Restorations on Multi-Unit Abutments**

**Clinical Procedure:**

**Digital Scan Procedure**

1. Remove the healing caps or temporary restoration and evaluate the soft tissue.

2. Ensure the Multi-Unit Abutments are torqued to the recommended torque value found in the Torque Value Reference Table.

3. Seat the Multi-unit scan body utilizing the Ø1.25 hex driver to the Multi-Unit abutment. It is recommended to place the point/dot of scan body towards the facial for easy identification in the software. The scan body has a unique geometry that allows easy and accurate scanning and is suitable for both intra-oral and laboratory scanning. A titanium base ensures a precise fit into the connection, while the PEEK top allows visibility of the component in the oral surface scan.

4. Check for proper seating to prevent any rotational or vertical displacement. Hand-tighten to 15Ncm.

5. Take peri-apical x-ray to verify seating prior to recording the intra-oral scan.

6. Scan the top of the scan body and all sides to make sure you have captured the scan body completely and the adjacent tissue.

7. Scan the full jaw, scan antagonist, scan the bite.

8. Replace the healing caps or temporary restoration.

9. Send all the scans to the dental laboratory.

**Laboratory Procedure:**
**Digital Model**

1. Upload scans from the clinician to your preferred prosthetic software (3shape Dental System, Exocad, Dental Wings).

2. Utilizing the Multi-Unit DIM Analog, create your digital model.

   **NOTE:** If a 3D printed temporary restoration is fabricated skip to next Clinical Procedure: Evaluation of 3D printed temporary restoration. If no try-in was requested proceed to Laboratory Procedure: Fabrication of Final Prosthesis

3. A 3D printed temporary restoration can be fabricated at this time for evaluation of final prosthetic design by doctor and patient.

**Clinical Procedure:**
**Evaluation of 3D printed Temporary Restoration**

1. Remove the healing caps or temporary restoration and evaluate the soft tissue.

2. Seat the 3D printed try in onto the Multi-Unit Abutments and hand tighten with the prosthetic screws.

3. Modify as needed to obtain the desired aesthetics, phonetics, and occlusion.

4. Remove the 3D printed try in and return the approved apparatus to the laboratory.

5. Replace the healing caps or temporary restoration.

**Laboratory Procedure:**
**Fabrication of Final Prosthesis**

1. Design the Multi-Unit screw-retained restoration utilizing the Multi-Unit Titanium, Interface coping.

2. Manufacture the zirconia restoration following the instructions for use of the material and manufacturing equipment.

3. Once the screw-retained restoration is completed, prior to cementing the screw-retained restoration, place the Multi-Unit Titanium Interface Coping in the digital model, seat and evaluate the screw-retained restoration for correct anatomical contours contact points and occlusion.

4. If clinician recommends the dental laboratory lute the Zirconia restoration to the Multi-Unit Titanium Interface Coping. The screw-retained restoration is then luted to the interface coping utilizing an approved luting material for Zirconia or full feldspathic porcelain (follow manufacturer's instructions for luting).

5. Return screw-retained restoration with final abutment screw to the clinician.

**Clinical Procedure:**
**Seating of Final Screw-Retained Restoration**

1. Carefully remove the healing caps or temporary restoration.

2. Verify the Multi-Unit abutments are stable and torqued to recommended torque value found in the Torque Value Reference Table.

3. Clean and sterilize the final prosthesis according to the validated cleaning and sterilization.

4. If the Zirconia was not luted to the Multi-Unit Titanium Interface Coping, seat the Multi-Unit Titanium Interface Copings and seat the screw-retained restoration over the copings.

5. Check aesthetics, fit, occlusion and comfort.

6. Following clinical approval, the screw retained restoration is then luted to the interface using an approved luting material for Zirconia or full feldspathic porcelain (follow manufacturer's instructions for luting).

7. Confirm appropriate seating prior to adding the final prosthetic screws. Tighten the prosthetic screw by hand from left to right, take clinical x-ray to verify correct seating.

8. Check for comfort, aesthetics, phonetics, and occlusion.

9. On final delivery of the restoration, the prosthetic screw should be torqued to the recommended torque value found in the Torque Value Reference Table.

10. Close the screw access hole to protect the head of the prosthetic screw & then fill the screw access channel with an appropriate composite flow in accordance with the crown color shading.

CAD/ CAM Restorative Procedure – Premium Multi-Unit Abutments
Refer to: Osteon Precision Milled Superstructure Prosthetic Manual

https://www.osteonmedical.com/downloads

# 6.5 Ball Abutment System

Description

Ball Abutments are premanufactured dental implant abutments made of Ti6Al4V ELI that directly connect to an implant used to retain an overdenture. The Ball Abutment threads directly into the implant and the denture cap is processed into the denture base by either a chairside method or at the dental laboratory. The Nylon retentive Inserts offer varying degrees of retention to stabilize the denture. The Ball Abutment is provided sterile.

Intended Applications

- The Ball Abutment System is an attachment mechanism designed for fully edentulous jaws retaining a tissue- supported overdenture. Indicated for patients with excessive bone and soft tissue loss, with compromised manual dexterity or phonetic concerns.
- Allows for mis-angulations up to 30° between implants.
- Ball Abutments should not be used for single tooth restorations
- Ball abutments are designed to accommodate a path of insertion divergence of up to 20° per implant, with no more than 40° of divergence between implants

Configurations

- Ball height 1.7mm
- Ball diameters 2.5mm
- Spherical shaped abutment fitting into a metal housing

Technical Considerations

- A minimal inter-occlusal distance of 12.0 mm - 15.0mm is required between the implant prosthetic table and the top of the denture when seated.
- Ø1.25 hex driver is needed to tighten Ball Abutment in accordance with Torque Value Reference Table.
- In patients whom adequate sizes, number of desired positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Refer to the ball abutment accessories IFU from Rhein 83: https://www.rhein83.com/en/instructions-for-use/

**Clinical Procedure:**

**Placement of Ball Abutment**

1. Before abutment seating, remove the healing cap and register the mucosal height for proper selection of the permanent abutment. The appropriate height of the ball abutment is measured from the highest point of the soft tissue margin putting the ball section 1.5mm above the soft tissue.
2. Attach the Ball Abutment to the Ø 1.25 hex driver. Connect the driver with the Torque Ratchet and tighten the abutment to the recommended torque in accordance with Torque Value Reference Table.
3. Take the abutment-level impression in a standard or customized impression tray with a polyvinylsiloxane medium/heavy bodied impression material. Remove the impression once the impression material has set. Verify that the impression is correct and send it to the laboratory.

**Laboratory Procedure:**

**Model Fabrication and Wax Rim**

1. Place the Ball Abutment Analog firmly into the impression. Fabricate a master model with the ball analog and high-quality stone material.
2. Determine a common path of insertion for the ball attachment-retained overdenture. Construct a baseplate incorporating the metal case and nylon insert for stability. Cure the female part into the acrylic. Use a burr to remove excess acrylic then polish the overdenture base.
3. Fabricate the baseplate and wax rim on the cast for bite registration.

**Clinical Procedure:**

**Secure Wax-Rim**

Secure the occlusal rim to the Ball Abutments. Use standard prosthodontic techniques for tooth selection and positioning.

**Laboratory Procedure:**

**Denture Set-up**

Follow normal laboratory and clinical procedures for denture wax-up techniques.

**Clinical Procedure:**

**Denture Set-up Try-in**

Place the wax denture into the mouth and verify aesthetics, phonetics, and occlusion. Make any necessary adjustments.

**Laboratory Procedure:**

**Processing Denture**

1. Process the denture using normal laboratory procedures. Place a block-out material over the head of each Ball Abutment Analog onto the model.
2. Complete the processing and polishing of the final denture. Return the completed denture to the clinician.

**Clinical Procedure:**

**Final Denture Insertion**

1. Seat the denture with the metal case and the nylon insert still in place to gauge initial retention. If the retention is acceptable, the nylon insert may be worn clinically for a period of time determined by the clinician. This will allow time to make necessary adjustments to the denture if required.
2. When the patient is ready for final retention inserts, remove the nylon inserts and place the insert of choice into the metal base, Check and adjust the final fit of the overdenture. Make corrections to the occlusion relation as needed.
3. Refer to IFU of Rhein 83 for ball abutment retentive caps.

# 6.6 LOCATOR® Abutment System

**Description**

**LOCATOR® Abutment System**

LOCATOR® Abutments removable attachment system are premanufacture titanium alloy abutments used with two or more implants as the attachment mechanism between the implants and the patient's denture for attachment retained overdenture restorations. The LOCATOR® Abutment threads directly into the implant and the denture cap is processed into the denture base by either a chairside method or at the dental laboratory. The Nylon retentive inserts offer varying degrees of retention to stabilize the denture.

For procedure refer to: Zest Dental Technique Manuals found at www.zestdent.com

# 6.7 Paltop Equator Abutment System

**Paltop Equator Abutments Product Description**
The Paltop Equator offers a vertical profile of 2.1 mm and diameter of 4.5 mm. This system offers multiple solutions for overdenture treatment planning when vertical space limitations are a consideration. The Prefabricated titanium abutments offer cuff heights from 0.5 mm to 6 mm.

Female caps are retained by means of a stainless-steel housing ranging in four levels of retention, making it easy to process at the dental laboratory or chairside in the dental office. A complete line of OT Equator accessories and tools are also available. Impression coping, analog, core tool, stainless steel housing & assorted retentive caps.

Paltop Equator Abutments are made of Ti6Al4V ELI with TIN Coating. Available in different tissue heights. The Paltop Equator has a 2.5mm half sphere which provides retention anchoring to the removable denture by using a specific retentive cap which is inserted into a stainless-steel housing. The stainless-steel housing is fixated into the removable denture using self-cure acrylic. Refer to the instructions for use of the retentive caps for further usage

**Material Composition:**
- Equator Abutments: Ti6Al4V ELI + TIN Coating
- Paltop Equator Abutments – Sterile
- Accessories- non-sterile

Usage:
Intended to be screwed into osseointegrated dental implants in the maxilla or mandible to support a direct attachment with elastic retention to anchor a removable denture. All prosthetic components in this system are intended for single- use. The core tool is reusable and should be sterilized before reuse.

**Contraindications**
- For contraindications, see general contraindications above.

**Clinical Procedure:**
1. Screw in the Paltop Equator into the implant using the equator core tool.

2. Insert the equator core tool into the Paltop equator head and tighten it into the implant.

3. Unscrew and re-screw 2 or 3 times to allow for adaptation of the threads.

4. Tighten with manual torque ratchet to 30-35 N-cm

Additional instructions on how to use the OT Equator accessory components, please refer to the OT Equator Rhein 83 IFU.
https://www.rhein83.com/en/instructions-for-use/

# 7.1 Paltop Solutions

**Digital Workflow**

Titanium base and titanium blank abutments are intended to be customized by means of CAD/CAM technology.

**NOTE:** 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 Abutment CAD (K193352)

Paltop Dental 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.

**Digital Abutments**

Tibase Round, Anterior Tibase Round, ACS, and pre-milled Titanium Blank are titanium alloy Ti 6Al-4V ELI abutments that directly connect to the implant for use with a screw-retained or cement-retained single or splinted multiple unit restorations.

**Restorative Options**

| Restorative Abutment | Cuff Heights | Titanium Base Post Height |
|---|---|---|
| TiBase Round | 0.5 mm, 1.0 mm, 2.0 mm, 3.0 mm | 4.0 mm, 6.0 mm |
| TiBase Anterior Round | 0.5 mm, 2.0 mm, 3.0 mm | 6.0 mm |
| Angle Corrective System (ACS) | 1.0 mm, 3.0 mm | 4.0 mm |
| Pre-milled Blanks | NA | 20 mm* |

***For specific height of blanks check specific manufacturer's heights**

# 7.2 Paltop Digital Procedures

**Clinical Section – Scanning and Impression Techniques**

**Scan Abutment**

The scan abutment is made of Ti 6Al-4V ELI and PEEK. The scan body is 4.5 mm in diameter and can be used intraorally or in the laboratory with a desktop scanner. The scan abutment is tightened following the recommended torque found in the Torque Value Reference Table. The scan body is used on an implant and/or abutment to transfer the position following scanning for use in the procedure.

Scan Abutments should not be used when:

- The peek top of the Scan Abutment is damaged.
- The connection of the Scan Abutment is damaged
- The implants to be scanned are not stable (fully Osseointegrated)

**Digital Impressions – Intraoral**

An implant/abutment level digital impression is taken by the restorative clinician using an intraoral scanner and a scan abutment. It is important to use the correct scan abutment and follow the scanning strategy for the planned restorative procedure.

**Conventional Impressions – Model Scanning**

The restorative clinician takes a conventional impression and sends the case to a dental laboratory. The dental technician scans the model to make a digital workflow for restoration fabrication. It is important to use the correct scan abutment and follow the manufacturer's model scanning instructions for the planned restorative procedure.

**Laboratory Section – Digital Procedure**

1. Download the Abutment Design libraries from http://keystonedental.com/pages/digital-libraries appropriate for the geography. There are two types of abutment design software available: 3Shape® and exocad. Follow the software program's Instructions for Use for the design sequence and process. The libraries are used when designing restorations for a Zirconia Hybrid screw-retained restoration or a custom titanium abutment for a cement-retained restoration. These libraries contain all needed parts to design and manufacture the restoration.
2. The file that is created during the digital impression is imported into the downloaded design software that will be used by the technician to design the restoration. The crown may also be designed at this time depending on the desired workflow.

If fabrication is for a screw-retained Zirconia Hybrid restoration utilizing a TiBase, or Angulated Corrective System (ACS):
The design parameters for the zirconia superstructures are to be designed according to Paltop specific ranges within the library and cannot be modified outside of those ranges due to regulatory requirements. This includes minimal wall thickness, post height, and angulations specified in the software, as detailed below.

**Abutment Requirements**

| | | |
|---|---|---|
| Minimum Zirconia Thickness | Min. 0.4 mm | ---------- |
| Screw Channel Angulation | --------- | Max 20° |
| Gingival Margin Diameter Limit | Min. 4.0 mm | Max. 12 mm |
| Gingival Margin Height Limit | Min. 1.0 mm | Max. 5 mm |
| Abutment Height Limit | Min. 4.75 mm | Max. 15 mm |
| Abutment Post Height Limit | Min. 4.0 mm | Max. 15 mm |
| Abutment Angulation Limit | Min. 0° | Max. 30° |

Since there are titanium bases that include a Gingival Height dimension, the design parameters of the zirconia portion must be limited so that the overall maximum Gingival Height dimension is not exceeded. Given that all titanium base abutments have at least a 1 mm gingival height component, the following table illustrates the zirconia gingival height design parameter restrictions for the given titanium base gingival height.

| Titanium Base Gingival Height | Min. Zirconia Gingival (Cuff) Height | Max. Zirconia Gingival (Cuff) Height | Min. Zirconia Wall Thickness | Max Post Correction Angle | Min. Zirconia Post Height | Max Zirconia Post Height |
|---|---|---|---|---|---|---|
| 1.0 mm | 0.0 mm | 4.0 mm | 0.45 mm | 30° | 4.0 mm | 12 mm |
| 2.0 mm | 0.0 mm | 3.0 mm | 0.45 mm | 30° | 4.0 mm | 12 mm |
| 3.0 mm | 0.0 mm | 2.0 mm | 0.45 mm | 30° | 4.0 mm | 12 mm |

1. Design the zirconia screw-retained crown on a TiBase or Agle Corrective Abutment. It is recommended to review the design with the clinician. If design requires an Angle Corrective Abutment, the screw access channel allows the screw access hole to be optimally positioned an angle correction maximum of 20°, improving the aesthetics.

2. Once the abutment design is confirmed and approved, the file is sent to a milling machine for manufacturing at a validated milling center. After the milling is complete, inspect the restoration to ensure that it matches the original design.

3. Place the TiBase or Angle corrective Abutment using a Laboratory Abutment Screw into an implant analog in the model. Evaluate contacts, modify occlusion if needed, and prepare for cementation following the manufacturer's Instructions for Use. Create an abutment jig for the clinician for ease of seating.

TiBase and Angle Corrective Abutment corresponding zirconia superstructure are provided to the clinician either with the superstructure cemented to the abutment by the milling center or the dental laboratory, or separately for the clinician to bond together chairside, using the cement recommended in the labeling (Multilink Hybrid Abutment Cement (Ivoclar Vivadent AG)).

**Clinical Section – Digital Procedure**

1. Sterilize components returned from the laboratory.

2. Remove the Healing Abutment or temporary restoration, seat the validated milling center fabricated TiBase (Hybrid) abutment and restoration utilizing the specific Laboratory Abutment Screw using the appropriate driver.

3. Place the restoration utilizing an abutment jig if provided, on the abutment and evaluate contact, occlusion, and color.

4. Seat the validated milling center fabricated TiBase (Hybrid) abutment restoration in the mouth with the Final Abutment Screw and torque to the recommend value found in the Torque Value Reference Table. Fill the screw access channel with a suitable material.

**Laboratory Section – Digital Procedure**

If fabrication is for a Titanium custom abutment with cement-retained restoration utilizing a pre-milled Titanium Blank:

The design parameters for premilled Titanium Blanks are to be designed according to Paltop specific ranges within the library and cannot be modified outside of those ranges due to regulatory requirements. This includes wall thickness, post height, and angulation specified in the software, as detailed below.

| | | |
|---|---|---|
| Minimum Thickness | Min.0.550 mm | |
| Gingival Margin Diameter Limit (0.5 mm above gingival margin, SP and WP) | Min. 4.0 mm | |
| Gingival Margin Diameter Limit (0.5 mm above gingival margin, NP and Conical) | Min. 3.0 mm | |
| Gingival Margin Height Limit | Min. 0.5 mm | Max. 3.0 mm |
| Abutment Height Limit | Min. 5.5 mm | Max. 12 mm |
| Abutment Post Height Limit (for Single-Unit Restoration, above gingival height, SP and WP) | | Max. 7.0 mm |
| Abutment Post Height (for Single-Unit Restoration, above gingival height, NP and Conical) | | Max. 6.5 mm |
| Abutment Angulation Limit (SP and WP) | Min. 0° | Max. 25° |
| Abutment Angulation Limit (NP and Conical) | Min. 0° | Max. 20° |

1. Design the custom titanium abutment in the design software. It is recommended to review the design with the clinician.

2. Once the abutment design is confirmed and approved, the file is sent to a validated milling center for manufacture. After the milling is complete, inspect the abutment to ensure that it matches the original design.

3. Place the custom abutment on the stone model or digital model and complete the crown, following routine laboratory procedures. To ensure the correct position when the restoration is delivered, create an abutment jig.

**Clinical Section – Digital Procedure**

1. Sterilize components returned from the laboratory.

2. Remove the Healing Abutment or temporary restoration.

3. Place the titanium custom abutment, using the Final Abutment Screw together with the Ø 1.25 hex driver and torque to the recommend value found in the Torque Value Reference Table. Fill the screw access channel with a suitable material.

4. Seat the restoration with the abutment jig, if provided. Check occlusal contact with adjacent teeth. Make corrections, if needed. Cement the final restoration on the abutment. Cementation technique should be adapted to the restoration and according to the instructions from the manufacturer. Carefully remove all excess cement.

# 8.1 Cleaning

**Cleaning Instructions for Paltop Metal Prosthetic Devices, Tools, and Surgical Instruments**

- Prosthetic devices provided non-sterile should be cleaned and sterilized prior to use. Prosthetic devices which are provided sterile and are modified by the end-user must be cleaned after any modifications are made, or any procedures used which may compromise the sterility of the device, prior to use in the patient.

- Tools/Instruments which are not supplied sterile must be cleaned and sterilized prior to first use. All tools/instruments must be cleaned and sterilized after each use based on established procedures. Proper tool/instrument care is an important part of successful implant dentistry. All tools/instruments were developed for sterilization by autoclave. Automated washers should not be used as it may reduce the life of the instruments.

- Use of personal protective equipment as recommended by cleaning agent supplier (minimum water impermeable protection gown, gloves, face and eye shield), is recommended.

**Cleaning of the devices is performed in the dental clinic according to the following parameters:**

- Tools/Instruments inside a kit should be removed from the tray using dental tweezers.
- Surgical kit trays should be picked up and all tools/instruments should be removed from the bottom of the kit.
- Used tools/instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva and tissue residue.
- Multiple-part tools/instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue on devices must be removed with a soft brush.
- Devices should be inspected, cleaned separately, and discarded if damaged.
- Devices should be placed in an ultrasonic bath with an enzymatic solution, approved and appropriate for dental use (for example, PowerZyme, Deconex 50FF). Refer to the Instructions for Use (IFUs) of the cleaning agents to ensure the appropriate and effective utilization of each material.
- Wash the devices in an ultrasonic device according to the device's instructions, for 15 minutes.
- Clean the plastic parts, the kit, the tray, including the grommets, with soap (for example, 18%, st-moritz) and water and wash well with running water and dry.
- Remove the devices from the ultrasonic bath at the end of the cycle and wash with running water.
- Use a soft brush to remove any residue from the devices and wash again with running water and dry.

# 8.2 Sterilization

**Sterilization for Paltop Metal Prosthetic Devices, Tools, and Surgical Instruments**

- Devices may be delivered sterile or non-sterile. Please see indication on device package prior to use.
- Devices placed in the patient's mouth must be sterile prior to use. Use of non-sterile device may lead to infection of tissues or infectious diseases.
- Sterilization of non-sterile packaged devices, or prosthetic devices which are provided sterile and are modified by the end-user or laboratory, must be re- sterilized after any modifications are made, or any procedures used which may compromise the sterility of the device, prior to use in the patient.
- As validated according to the ISO standard 17665-1:2006, sterilization of these non-sterile metal devices should be performed in the dental clinic setting by steam autoclave sterilization according to the following parameters:

| | | |
|---|---|---|
| Sterilization Method | Steam, Gravity Displacement | Steam, Pre-vacuum method (Dynamic Air Removal) |
| Temperature | 273°F (134°C) | 273°F (134°C) |
| Cycle Time | 10 minutes | 3 minutes |
| Dry Time | 30 minutes | 16 minutes |
| Packaging | 510(k)-cleared sterilization pouch | 510(k)-cleared sterilization pouch |
| Sterility Assurance Level | $\leq 10^{-6}$ | $\leq 10^{-6}$ |
| Chamber Pressure | up to 2.3 bars (34 psi) | ~296 KPa |
| Load Configuration | Coldest spot in the chamber, near the door. The autoclave may be loaded up to the maximal load, as determined by the autoclave manufacturer. | Coldest spot in the chamber, near the door. The autoclave may be loaded up to the maximal load, as determined by the autoclave manufacturer. |

- Follow the autoclave manufacturer's instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the tools/instruments being sterilized including the internal surface and tubes channels. Allow tool/instrument to air cool to room temperature before use.
- Products labeled as sterile should be considered sterile until the indicated "use by" date on the label unless the package has been opened or damaged. Never use products if the "Use by" date has expired.
- After sterilization, place the device in a dry and dark place such as a closed cupboard or drawer. Follow the instructions of manufacturer of the sterilization pouches regarding storage conditions and expiration date of sterilized goods.

## Sterilization Guide

| Description – Abutments | Sterilization Procedure |
|---|---|
| Custom Abutment Solutions* | See reference table found in Sterilization Section |
| Cover Screws (when provided stand-alone) | |
| Abutment Screws (when provided stand-alone) | |
| Plastic Snap On Impression Coping | |
| Multi-Unit/Single-Unit Interface Copings | |
| Castable Abutments | |
| Healing Caps<br>Multi-Unit/Single-Unit Abutment Healing Caps<br>Impression Copings<br>Immediate Temporary Abutments and PEEK Cap<br>Titanium Temporary Abutments | Delivered Sterile: |
| PEEK Temporary Abutments<br>Titanium Abutments | |
| Titanium Multi-Unit Abutments<br>Titanium Straight Ball Abutments | |
| Titanium Straight Single-Unit Abutments<br>Titanium Multi-Unit/Single-Unit Cylinder | |

- For instruments see reference table found in Sterilization Section.*It is recommended that non-sterile abutments from the dental laboratory or milling center be sterilized according to sterilization procedures listed above prior to final insertion.
- Sterilization is required if modified.

# 9.1 MRI Safety Information

**For MR patient safety card please visit:**
**KeystoneDental.com/pages/mr**


**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 implant, or ensuring the implant is located outside of the RF coil.

A patient with a Paltop Dental Implant System device made of Ti6Al4V
ELI, Gold,  or PEEK can be scanned safely in an MR system under the following conditions:

**MRI Safety Information - MR Conditional**

| Device Name | Paltop Dental Implant System |
|---|---|
| Static Magnetic Field Strength (B0) | ≤ 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. |

# 9.2 Symbol Definitions

| Symbol Definitions | |
|---|---|
|  | Catalog number |
|  | Batch Code |
|  | Medical Device |
|  | Caution, consult accompanying documents |
|  | Do not reuse |
|  | Non-Sterile |
|  | Single Sterile Barrier System |
|  | Do not use if package is damaged |
|  | Sterilized using irradiation |
|  | By Prescription Only |
|  | Use by date |
|  | Do not resterilize |
|  | Manufacturer |
|  | Date of Manufacturer |
|  | MR Conditional |
|  | Keep away from sunlight |
|  | Consult Instructions for Use |
|  | Authorized representative in the European Union |
|  | Unique device identifier |

The SSCP can be accessed in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI of Paltop products, which can be found: https://ec.europa.eu/tools/eudamed. If EUDAMED is not active, the SSCP will be made available upon request, contact Paltop at: customersupport@keystonedental.com

The most up to date revision of this manual can be found at the Keystone Dental website www.KeystoneDental.com, in the dedicated section.

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The Summary of Safety Clinical Performance Report (SSCP) is available upon request, contact Paltop at: customersupport@keystonedental.com

For MR patient safety card please visit KeystoneDental.com/pages/mr

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