Resource Document

KeystoneDentalGroup

Prosthetic
Manual

GENESIS™
ACTIVE

GENESIS
A KeystoneDentalGroup Brand

1 Surgery

1.1
GENESIS ACTIVE™

Introduction

This manual outlines the appropriate procedures for using the GENESIS ACTIVE™ 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, a licensed dentist or physician.

1.2
Characteristics

Indications for Use

The GENESIS ACTIVE™ Implant System is intended for use in single-stage or two-stage surgical procedures for replacing single or multiple missing teeth in partially or fully edentulous mandibles and/or maxillae. The GENESIS ACTIVE™ Implant System supports single or multiple-unit restorations to re-establish patient chewing function and aesthetics. GENESIS ACTIVE™ implants are intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established, and appropriate occlusal loading is applied. All digitally designed custom abutments for use with GENESIS ACTIVE™ Implant System implants are to be sent to a Keystone Dental validated milling center for manufacture.

Contraindications

- Patients with uncontrolled or severe cases of hyper- thyroidism, diabetes, malignancies, renal disease, liver problems, hypertension, leukemia, severe vascular heart disease, hepatitis, immunosuppres- sive disorders, collagen and bone diseases, or other serious illnesses.
- Patients with titanium and titanium alloy allergies.
- Patients with alveolar ridge dimensions that are not sufficient to accommodate and sustain proper implant placement.
- Patients with systemic, local oral, or respiratory infection
- For PEEK components: patients who are hypersensitive or allergic to PEEK (polyether ether ketone).

Local Contraindications

- Cases where adequate numbers of implants could not be placed to achieve full functional support for a prosthesis.
- Cases when the implant has not reached acceptable primary stability.

Warnings

- 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.
- Care should be taken that the patient does not swallow or aspirate components. It is recommended to use a rubber dam to prevent swallowing or aspiration of small parts during the surgical and restorative phases.
- Implant failure or fracture can occur during routine function.
- The use of electro-surgical instruments or lasers around metallic implants and their abutments may cause electric and/or heat conductivity.
- Implant mobility, bone loss, or chronic infection may result in implant failure.
- 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.
- It is recommended that the PEEK Concave Temporary Abutment be kept out of occlusion and excursive movements.
- Small-diameter implants and angled abutments are not recommended in the posterior region of the mouth.

Precautions

- Product should only be used by surgical or restorative clinicians who have had appropriate education and training. Improper technique can contribute to implant failure and/or bone loss.
- Products are intended for use only in the applications defined in the GENESIS ACTIVE™ Implant System Surgical and/or Prosthetic Manual.

Product Sterility

Some Keystone Dental 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. Do not use if packaging is damaged. Sterile unmodified abutments must not be sterilized. Sterilization may cause risk or harm to the patient. Keystone Dental does not accept any responsibility for sterilized unmodified abutments or components.

Some Keystone-branded system components are supplied non-sterile. Refer to individual product labels for sterilization information. Products provided non-sterile may need to be cleaned and sterilized prior to use.

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

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 fitting. Do not process the interface area.
- Fasten the abutment with the provided screw using a recommended torque value listed in the Torque Value Reference Table.
- 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. There are no additional storage and handling conditions for GENESIS ACTIVE™ Implant System implants, abutments, and associated surgical, restorative, and dental laboratory components.

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.

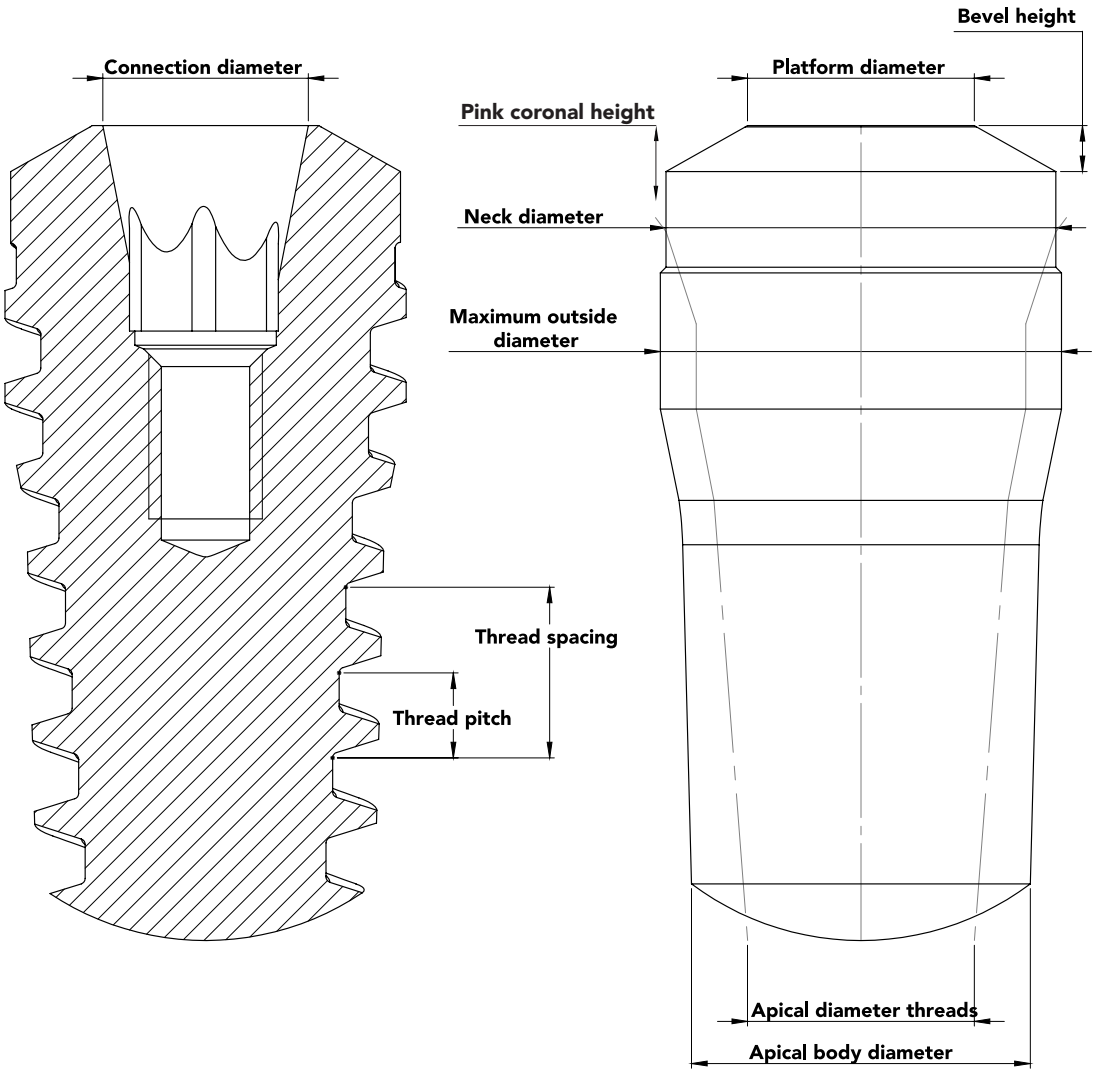
Surgical Guides

A surgical guide is used to indicate practical boundaries for the placement of implants and may prevent them from being placed too buccal/lingually or mesial/distally. This prosthetic-driven process helps to ensure functional placement of implants and aesthetic results. The implant surgeon should communicate to the dental technician any conditions that may affect guide design (e.g., the type of incision that will be used, expected reflection of tissue, etc.). The designed surgical guide provides, information relating to ideal tooth shape, tooth support options (cemented or screw-retained), and supporting bone structures that may have been lost.

1.3
Connection

Characteristics

The GENESIS ACTIVE™ 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 8.5 mm, 10 mm, 11.5 mm, 13 mm, and 16 mm, except for the Ø 3.5 mm which is not offered in 8.5 mm length and 16 mm length in Ø 5.5.



GENESIS ACTIVE™ Ø 3.5 mm				
Length	10 mm	11.5 mm	13 mm	16 mm
Maximum Outside Diameter	3.8 mm			
Neck Diameter	3.5 mm			
Platform Diameter	3.20 mm			
Connection Diameter	2.90 mm			
Bevel Height	0.65 mm			
Pink Coronal Length	1.00 mm			
Apical Diameter	2.92 mm			

GENESIS ACTIVE™ Ø 3.8 mm					
Length	8.5 mm	10 mm	11.5 mm	13 mm	16 mm
Maximum Outside Diameter	4.10 mm			4.0 mm	
Neck Diameter	3.8 mm				
Platform Diameter	3.20 mm				
Connection Diameter	2.90 mm				
Bevel Height	0.65 mm				
Pink Coronal Length	1.00 mm				
Apical Diameter	3.20 mm				

GENESIS ACTIVE™ Ø 4.5 mm					
Length	8.5 mm	10 mm	11.5 mm	13 mm	16 mm
Maximum Outside Diameter	4.7 mm				4.6 mm
Neck Diameter	4.5 mm				
Platform Diameter	3.20 mm				
Connection Diameter	2.90 mm				
Bevel Height	0.65 mm				
Pink Coronal Length	1.00 mm				
Apical Diameter	3.77 mm				

GENESIS ACTIVE™ Ø 5.5 mm				
Length	8.5 mm	10 mm	11.5 mm	13 mm
Maximum Outside Diameter	5.7 mm			
Neck Diameter	5.5 mm			
Platform Diameter	3.20 mm			
Connection Diameter	2.90 mm			
Bevel Height	0.65 mm			
Pink Coronal Length	1.00 mm			
Apical Diameter	4.8 mm			4.4 mm

2 Portfolio

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

GENESIS ACTIVE™ prosthetics are prefabricated components to be directly connected to the endosseous dental implant and are intended as an aid in prosthetic rehabilitation. Prosthetic components are single use. Reuse of the device may cause microbial contamination and loss of performance.

- 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 are recommended for use for up to 90 days.
- If modified for patient occlusion, the cylinder (post) of a TiPink Temporary Abutment must maintain a post height of at least 4 mm.
- 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 TiPink Immediate Temporary Abutment, are not intended for angle correction and are only to be used with implants placed in a straight manner.
- If modified for patient occlusion, the Multi-Unit Temporary Abutment must maintain a post height of at least 4 mm and may not be used for angle correction.

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 (17°, 20°, 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).
- 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).

Healing Abutments

Healing Abutments are prefabricated, one-piece prosthetic components made from Ti 6Al-4V ELI and are packaged sterile. Healing Abutments 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 Abutments are available in two different geometric designs, concave or flared. The impression post geometry follows the diameter of the healing abutment concave or flare shape. Select the appropriate Healing Abutment based on the soft-tissue depth and desired emergence profile. The chart below defines the recommended Healing Abutments in concave and flared designs.

Implant Diameter	Concave or Flared	Prosthetic Diameter	Heights
Ø 3.5	Concave or Flared	Ø 3.5/Ø 4.5	1.0, 2.0, 3.0, 4.0, 5.0, 6.0 and 7.0 mm
Ø 3.8	Concave or Flared	Ø 4.5	1.0, 2.0, 3.0, 4.0, 5.0, 6.0 and 7.0 mm
Ø 4.5	Concave or Flared	Ø 4.5/ Ø 6.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0 and 7.0 mm
Ø 5.5	Concave or Flared	Ø 6.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0 and 7.0 mm

Technical Considerations

- Before seating a Healing Abutment, verify adequate primary stability of the implant.
- Select the appropriate Healing Abutment based on the platform size, soft-tissue depth, and desired emergence profile.
- Tighten screw in accordance with the Torque Value Reference Table.

Healing Abutment Placement Procedure

1. Insert the Healing Abutment 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 Abutment in a clockwise direction until fully seated on the implant platform.
3. Verify complete seating of the Healing Abutment. It is recommended to utilize radiography to assess correct seating.

Closure of the Flap

- The selection of the proper Healing Abutment 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 Abutment is selected, always communicate the implant diameter and selected Healing Abutment 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 Abutment and suture it tension free into place.

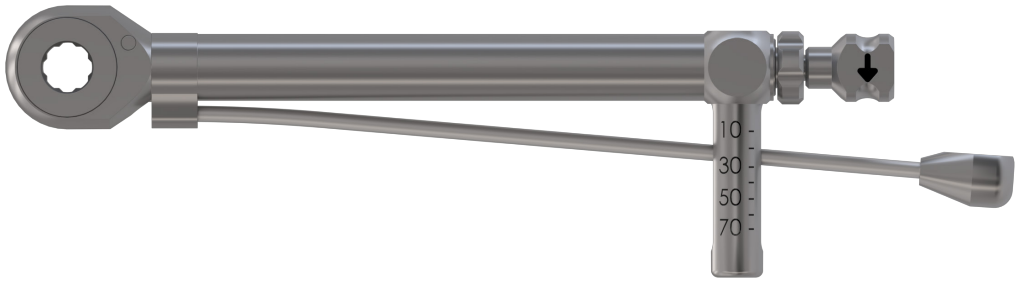
2.3
Bending Beam Torque Wrench

Torque Procedure

- GENESIS ACTIVE™ implants are designed to support a provisional or final prosthesis that should be affixed to the implant and tightened using a properly metered torque wrench 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 wrench.
- 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.

Bending Beam Torque Wrench

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



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

NOTE: See Bending Beam Torque Wrench Instructions for Use for further information about care and use of the torque wrench.

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. Throughout the try-in phase in the dental laboratory, it is recommended to use a lab screw. The lab screw is used to attach prosthetic components to an implant analog in a working model during laboratory fabrication process of the final prosthesis. The Final Abutment Screw is used only when seating the final prosthesis after all occlusal and inter-proximal adjustments are complete. All Final Abutment Screws are packaged together with each abutment and available in packs of 5 as needed. The laboratory screw is also available individually and in packs of 5.

Abutment Screw Attachment Procedure

Select the appropriate abutment screw based on the type of abutment selected to which the restorative component will be attached. The list below identifies the screw and driver needed.

Final Abutment Screw – Ø 1.25 Hex Driver
Torx® Screw – Torx® Ball Screwdriver
DIM Analog Screw – Ø 1.25 Hex Driver
Laboratory Screw – Ø 1.25 Hex Driver
Laboratory Screw (for ANGLEBase® or ELLIPTIBase®) - Torx® Ball Screwdriver
Prosthetic Screw (MUA) – Ø 1.25 Hex Driver
TiPink Immediate Temporary Abutment – Titanium Temporary Abutment, Immediate, Hex Driver
Straight Multi-unit Abutment (RP) – Straight Multi-Unit Abutment Driver (RP)
Angled Multi-unit Abutment (RP) – Angled Multi-Unit Abutment Driver (RP)
Straight Multi-unit Abutment (WP) – Straight Multi-Unit Abutment Driver (WP)

- The drivers are available in multiple length configurations.
- Properly seat the restorative component into the implant/analog fixture utilizing the appropriate 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 wrench in reverse, disengage screw from the implant by rotating in a counterclockwise motion.

Torque Value Reference Table

Prosthetic Component	Torque (Ncm)
Cover Screw, Healing Abutment* Multi-Unit Abutment Healing Caps* Intra-Oral Scan Abutments* PEEK Temporary Abutments** Multi-Unit Prosthetic Screw, RP/WP Multi-Unit Prosthetic Lab Screw, RP Laboratory Screws	15
Impression Post TiPink Immediate Temporary Abutment**	20
TiPink Temporary Abutment** Torx® Screw for ANGLEBase® & ELIPTIBase® Straight & Angulated Multi-unit Abutment Titanium Blanks, C-Base® Abutments TiBase Abutments TiPink Aesthetic Abutments (Straight & 20° Angled) Final Abutment Screws	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 be kept out of occlusion and excursive movements.

3 Options

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 of 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.

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
Implant or Bar-Retained

Overdenture Restoration

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 Impressions

4.1
Types and Techniques

Implant Level

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

Open Tray (Direct) Pick-Up Impression Post

This technique requires use of an impression post body and a long screw. The open tray impression post transfers the position of 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 posts are recommended for use when an impression is made of multiple divergent implants or impression across the arch.

Closed Tray (Indirect) Pick-Up Impression Post

This technique requires use of an impression post body and a short screw. The closed tray impression post transfers the position of the 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 posts are ideal for use in limited inter-arch space.

Abutment Level

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

4.2
Open Tray (Direct)

Procedure

1. The Concave or Flared Healing Abutment is removed utilizing the Ø 1.25 hex driver.

2. The impression post is positioned into the implant connection and can be fully seated with the Ø 1.25 hex driver.

NOTE: A radiograph is recommended 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 post junction at the gingival aspect. Then, the impression tray is filled with medium/heavy body impression material and fully seated to take the impression. It is recommended to expose the head of the long screw during the impression phase to prevent impression material from obstructing removal of the screw once the impression has set to manufacturer's specification.

4. Once the impression material has set, the long screw of the impression post is loosened and the impression with the impression post is removed from the mouth. An analog is then attached to the impression post/analog assembly and hand tightened. The Healing Abutment is placed onto the implant, or a temporary crown is fabricated and seated. The impression is sent to the laboratory, including an impression of the opposing arch and a proper jaw relation record, and shade, if needed.

5. Once the dental stone has fully set, remove the impression tray and the impression post 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 Flared Healing Abutment is removed utilizing the Ø 1.25 hex driver.

2. The impression post is positioned into the implant connection and fully seated utilizing the Ø 1.25 hex driver. A material of choice is placed into the screw access hole of the impression post short 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 post junction at the gingival aspect. Then, the customized impression tray is filled with heavy body impression material and fully seated to take the impression.

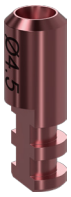
4. Once the impression material is completely set, the impression tray can be removed leaving the impression post still attached to the implant. The impression post can now be removed, and an analog is attached to the impression post and transferred back into the impression. The impression post must be completely seated with the correct orientation, preferably under magnification. The Healing Abutment is placed onto the implant, or a temporary crown is fabricated and seated. The impression with the impression post/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 posts 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.



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.

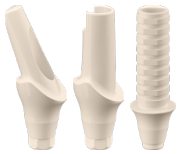
5 Temporization

5.1
Temporization Options

Temporization

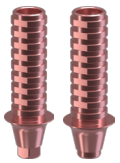
GENESIS ACTIVE™ offers three types of temporary abutments for chairside or lab-fabricated temporary restorations. The options are designed to prepare the soft tissue for permanent restoration throughout the healing process.

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.

TiPink Temporary Abutment



A titanium base 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.

TiPink Immediate Temporary Abutment

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.

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
TiPink 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 single tooth or multi-unit cement-retained temporary restoration.

TiPink Immediate Temporary Abutment

5.3
Temporary 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.
- TiPink Temporary Abutment recommended use up to 90 days.
- PEEK Concave Temporary Abutment recommended use up to 30 days.
- TiPink Immediate Temporary Abutment recommended use up to 30 days.
- Recommended that the PEEK Concave Temporary Abutment be kept out of occlusion and excursive movements.
- Recommended screw tightening in accordance with the Torque Value Reference Table.
- For cleaning and sterilization procedures, please refer to Cleaning and Sterilization Process.
- Recommended to choose a gingival cuff height that is no more than 1.5 mm to 2.0 mm below the soft tissue margin.
- TiPink Immediate Temporary Abutment requires a minimum of 4 mm post height.
- TiPink Immediate Temporary Abutment is not recommended in cases that require angle correction.
- TiPink Temporary Abutment does 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.

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 concave in diameters of Ø 3.5, Ø 4.5, and Ø 6.0 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 TiPink Temporary Abutment or PEEK Concave Temporary Abutment using the appropriate screw packaged with the abutment and the Ø 1.25 hex driver.

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

3. Modify the TiPink Temporary Abutment as necessary to allow adequate space for acrylic between stent and abutment, preserving a minimum of 4 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 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 driver attached to the Bending Beam Torque Wrench. 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 TiPink Immediate Temporary Abutment using the Titanium Temporary Abutment, Immediate, Hex Driver for Ratchet to the Immediate Temporary Abutment Screw.

2. Place the 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 Restoration

6.1
TiPink Straight/Angled Abutment

Description

TiPink Abutments are pre-machined abutments made of Ti 6Al-4V ELI with anatomical margins designed to follow gingival contours. The abutments are anodized pink. Modification below the cuff is not recommended to retain the pink anodization below the cuff. The cone shape of the the abutment has a patented microroughened surface to aid in retention of cement to the abutment.

Each abutment is packaged with a separate Final Abutment Screw that requires a Ø 1.25 hex driver. It is recommended to use a laboratory screw during the fabrication/try-in phase of the restoration. The Final Abutment Screw should only be used when the restoration is finalized and ready for final placement in the mouth.

Intended Applications

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

Configurations

- Straight and 20° angled designs with microroughened surface.
- Multiple cuff heights from 1.0–5.0 mm.
- Concave emergence profiles of Ø 3.5, Ø 4.5, and Ø 6.0.

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 TiPink 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

When 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.

A. Chairside Preparation and Temporization by the Clinician

When selecting the proper TiPink 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 Angled Abutment should be 1.0–1.5 mm below tissue height.

1. Place the TiPink Abutment using the laboratory screw and the Ø 1.25 hex 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.

   NOTE: Minimal modifications are recommended to the microroughened surface and below the cuff.

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

3. Using a Ø 1.25 hex driver latch tip, ratchet adapter, and torque ratchet, seat the TiPink Abutment and apply torque as defined in the Torque Value Reference Table to the Final 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 TiPink Straight or Angled 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 Abutment

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 TiPink 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 TiPink Abutment should be 1.0–1.5 mm below tissue height on the buccal.

3. Place the TiPink Abutment using the laboratory screw and the Ø 1.25 hex 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 TiPink Abutments placed by the dental technician.

2. Place the TiPink 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.

3. Use the Ø 1.25 hex driver and the laboratory screw to hand tighten the abutments.

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 TiPink 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.

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 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.

   OR

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

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 TiPink 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

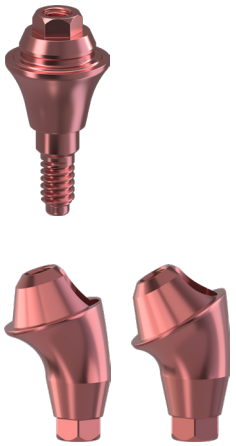
1. After the Healing Abutment or temporary crown is removed, the TiPink Abutment is seated onto the implant. The Final Abutment Screw with a Ø 1.25 hex driver is placed and hand tightened. A radiograph is taken to ensure proper seating of the abutment. At this point, the Ø 1.25 hex driver latch tip and 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.

   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 TiPink 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
Straight/Angled Multi-Unit Abutment

Screw-Retained



Multi-Unit Abutments (MUA) are designed for a removable or fixed implant supported prosthesis of partially or fully edentulous arches, such as the Keystone Arch treatment concept. These abutments are available in both straight (non-engaging, one-piece) and angled (engaging, 17° and 30°) alternatives with a wide selection of cuff heights to match the thickness of soft tissue. The Angled Multi-Unit Abutments (AMUA) come with a premounted positioning tool for simplified abutment seating. 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 Regular Platform (RP) and Wide Platform (WP). The accessories are also available to fit both RP and WP platforms.

Intended Applications

- Multiple-unit fixed or removable implant-supported prosthetics.
- Simplified prosthetic access for diverging implant angles.
- Industry-standard abutment prosthetic table.
- All tooth positions.
- Engaging and Non-Engaging connections.
- Transition from prosthetic table of implant through the soft tissue.
- 30° Angled MUA are not recommended for Ø 3.5 mm Implants.

Technical Considerations

- Multi-Unit Abutments and ANGLEBase® or TiBase are not intended to be modified.
- Multi-Unit Titanium Temporary Sleeves are to be handmilled to height and must maintain at least a 4 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.
- WP Multi-Unit Abutments are not intended to be used with the Nexus iOS System.

Contraindications

- Placement of the Multi-Unit Abutments on narrow Ø 3.5 mm implants placed exceeding 25° from vertical.
- Limited interocclusal space.

Bar-Retained (Removable) Implant-Supported Prosthesis

This type of prosthesis is supported by a minimum of four implants on Multi-Unit Abutments in the maxilla or 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.

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.

Angled 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/Angled Multi-Unit Abutment Process

Remove the Healing Abutment, 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 RP or WP abutment platform and angulation needed for proper positioning to create a passive prosthesis.

Regular Platform (RP) **Available Cuff Heights**	**Wide Platform (WP)** **Available Cuff Heights**
Straight – 1.0, 2.0, 3.0, 4.0, 5.0 mm	Straight – 1.0, 2.0, 3.0, 4.0, 5.0 mm
17° - 3.0, 4.5 mm	17° - 3.0, 4.5 mm
30° - 4.0, 5.0 mm	

Immediate Temporization Titanium Temporary Sleeves

Multi-Unit Titanium Temporary Sleeves are prefabricated prosthetic components manufactured from Ti 6AL-4V ELI, available in two heights of 10 and 15mm. The Titanium Temporary Sleeves seat directly onto the Multi-Unit Abutments using a Laboratory Prosthetic Screw until final seating, then utilize the Final 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 Multi-Unit Temporary Titanium Sleeves enable mechanical bonding of a temporary prosthesis.

Regular Platform (RP)	**Wide Platform (WP)**
Regular Multi-Unit Titanium Temporary Sleeves	Wide Multi-Unit Titanium Temporary Sleeves
Regular Laboratory Prosthetic Screws	Wide Laboratory Prosthetic Screws
Regular Final Prosthetic Screws	Wide Final Prosthetic Screws

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.

Clinical Section

1. Seat the Multi-Unit Titanium Temporary Sleeves onto the Multi-Unit Abutments and hand tighten the Laboratory 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 Multi-Unit Titanium Temporary Sleeves. The holes should allow the temporary sleeves to pass all the way through the temporary prosthesis. If the sleeve interferes with the opposing arch, mark the portion of the sleeve that protrudes through the prosthesis to the desired length. The Titanium Temporary Sleeve may be shortened by hand-milling providing that the minimum sleeve height is no less than 5 mm.

3. Remove the Multi-Unit Titanium Temporary Sleeves and Laboratory Prosthetic Screws. Modify the height, clean, and sterilize the modified sleeves and screws. Reseat the Multi-Unit Titanium Temporary Sleeves into the mouth and secure with the Laboratory 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 Multi-Unit Titanium Temporary Sleeves. Allow the material to set based on manufacturer's curing procedures.

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

with the prosthesis attached. The Multi-Unit Titanium Temporary Sleeves should be captured within the prosthesis.

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 Multi-Unit Titanium Temporary Sleeves on the underside of the prosthesis with acrylic, flowable composite, or other suitable material, and cure.

7. Reseat the temporary restoration and place the Final Prosthetic Screws into the Multi-Unit Titanium Temporary Sleeves. Using the Ø 1.25 hex driver in conjunction with a properly metered torque wrench, tighten the 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 Abutments 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 Post 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 posts are removed.

4. A heavy-bodied impression material is injected around the impression post. Then, fill the custom tray with impression material and fully seat over the impression post, 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 Post will remain connected to its corresponding abutment.

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

7. Seat the Healing Abutments 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 Post to ensure there is no residue/saliva. Reposition each Closed-Tray Multi-Unit Impression Post 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 Post onto each Multi-Unit Abutment.

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

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

5. A heavy bodied impression material is injected around each Impression Post. 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 Posts should be captured by the impression material.

8. Mount the appropriate abutment analog onto each Open-Tray Multi-Unit Impression Post captured within the impression and refasten using the Open-Tray Impression Post Long 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 Posts are placed appropriately within the impression. Ensure each captured Closed-Tray Multi-Unit Impression Post 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 Sleeve onto each analog with the Laboratory Prosthetic Screw and hand tighten utilizing the Ø 1.25 hex driver.

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

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

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

5. Send the verification index and the Laboratory 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 using a Laboratory Prosthetic Screw and the Ø 1.25 hex driver.

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

4. Lute using pattern resin, or light-cured composite, each Multi-Unit Titanium Temporary Sleeve until all sleeves are attached. Remove the verification index and send 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 Multi-Unit Titanium Temporary Sleeves. 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 Laboratory 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 Laboratory 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 Laboratory Prosthetic 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.

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 Laboratory 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 Laboratory 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 Laboratory 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 Laboratory 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 Laboratory 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 Final Prosthetic Screw into the Multi-Unit Abutment, utilizing the Ø 1.25 hex driver. Repeat for each abutment, working

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.

CAD/CAM Restorative Procedure – Multi-Unit Abutments

Refer to: Osteon Precision Milled Superstructure Prosthetic Manual

https://www.osteonmedical.com/downloads

7 Digital

7.1
Solutions

Digital Workflow

Titanium base and titanium blank abutments are intended to be customized by means of CAD/CAM technology. Customization above the implant/abutment interface is be performed by a Keystone Dental validated milling facility.

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)

Keystone 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, C-Base®, ANGLEBase®, ELLIPTIBase®, 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.

All digitally designed custom abutments listed below for use with Keystone Dental implants are to be sent to a Keystone Dental validated milling center for manufacture. See http://keystonedental.com/pages/validated-milling-centers for the most updated list of validated milling centers.

Restorative Options	Titanium Base Post Height	Surface Treatment (Above Cuff)
TiBase	4.2 mm	SelectGrip® Surface
C-Base®	4.68 mm	SelectGrip® Surface
ANGLEBase®	3.0 mm	SelectGrip® Surface
ELLIPTIBase®	3.0 mm	SelectGrip® Surface
Pre-milled Titanium Blank	20 mm	None

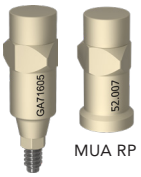
7.2
Procedure

Clinical Section – Scanning and Impression Techniques

Scan Body

The scan body is made of Ti 6Al-4V ELI with a non-reflective surface or glare. The scan body is 10 mm in total length from the implant connection and is 4 mm in diameter and can be used intraorally or in the laboratory with desktop scanner. It has a fixed internal screw, and the scan body 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.

Digital Impressions – Intraoral



MUA RP

An implant/abutment level digital impression is taken by the restorative clinician using an intraoral scanner and a scan body. It is important to use the correct scan body 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 Keystone Dental validated milling center. The dental technician scans the model to make a digital workflow for restoration fabrication. It is important to use the correct scan body 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, C-Base®, ANGLEBase®, or ELLIPTIBase®:

The design parameters for the zirconia superstructures are to be designed according to Keystone Dental 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 (REQUIRED FOR LIBRARIES used in the US MARKET)		
Minimum Zirconia Thickness	Min. 0.45 mm	
Screw Channel Angulation*		Max. 25°
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°

*ANGLEBase® Abutment

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. It is recommended to review the design with the clinician. If design requires an ANGLEBase® or ELLIPTIBase®, the screw access channel allows the screw access hole to be optimally positioned an angle correction maximum of 25° with a 360° radius ANGLEBase® and/or 20° ELLIPTIBase®, 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 C-Base® 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, ANGLEBase® and ELLIPTIBase® and 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)). The Select Grip® Surface of the TiBase and its height should not be modified (e.g. by grinding). To aid in cement adhesion we recommend that the TiBase, ANGLEBase® and ELLIPTIBase® be thoroughly cleaned before cementation as well as the ceramic surface of superstructure that is in contact with the SelectGrip® surface.

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 Keystone Dental 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.

ABUTMENT REQUIREMENTS (REQUIRED FOR LIBRARIES used in the US MARKET)		
Minimum Thickness	Min. 0.55 mm	
Gingival Margin Diameter Limit	Min. 4.0 mm	Max. 12 mm
Gingival Margin Height Limit	Min. 0.5 mm	Max. 5.0 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°

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 correct position when the restoration is delivered, create an abutment jig.

NOTE: The TiBase and 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. To aid in cement adhesion, we recommend that the TiBase be thoroughly cleaned before cementation. The ceramic surface of the superstructure in the cementing zone should be sandblasted and cleaned.

NOTE: For SelectGrip®, the diameter of the TiBase and its height should not be reduced (e.g., by grinding).

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 Sterilization

8.1
Sterilization

Cleaning and Sterilization Procedure

Components which are provided sterile, then modified by the end user, must be cleaned and sterilized prior seating in the patient's mouth, based on established procedures. Proper tool care is an important part of successful implant dentistry. Automated washers should not be used, as they may reduce the life of the tools.

Pre-Cleaning

- Used tools should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva, and tissue residue.
- Multiple-part instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue on instruments must be removed with a soft brush.
- Instruments should be inspected, cleaned separately, and discarded if damaged.

Principle Cleaning

- Best results are achieved if prosthetic tools are cleaned by material type.
- Rinse and brush under free-flowing tap water.
- Soak in enzymatic solution in an ultrasonic cleaner for at least five minutes following manufacturer's instructions.
- Rinse under free-flowing distilled water.
- Completely dry and inspect abutment for integrity and flaws.
- 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.
- Tools and non-sterile or modified abutments with their corresponding screws must be sterilized by the clinician prior to placement in a surgical site.

Sterilization

Sterilization of non-sterile components is performed in the dental clinic setting by steam autoclave sterilization as detailed in the Instructions for Use according to the following parameters.

Sterilization Method	Steam, Pre-vacuum method
Preconditioning Pulses	4
Cycle Time	275°F (135°C) for 3 minutes
Dry Time	16 minutes
Packaging	510(k)-cleared sterilization pouch
Sterility Assurance Level	$\leq 10^{-6}$

Sterilization Guide – GENESIS ACTIVE™ Abutments	
Description - Abutments	Sterilization Procedure
Custom Abutments, ANGLEBase® & ELLIPTIBase®, Premills, C-Base® All Prosthetic Tools	See reference table found in Sterilization section
Cover Screws	Delivered Sterile: Sterilization required if modified
Healing Abutments	
Multi-Unit Abutment Healing Caps	
Impression Posts	
TiPink Immediate Temporary Abutments	
Titanium Temporary Abutments	
TiPink Aesthetic Abutments (Straight & 20° Angled)	
Straight and Angled Multi-Unit Abutments	
Abutment Screws in sterile package	
Abutment Screws in sterile package	

*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.

Warning

The guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry and are not intended to be a substitute for formal clinical or laboratory training. These devices should only be used by individuals with training and experience specific to their clinically accepted application.

WARNING: MR Conditional Labeling has not been reviewed or approved by Health Canada. 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 Keystone Dental Implant System device can be scanned safely in an MR

MRI Safety Information - MR Conditional

Device Name	Keystone 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. Extremity T/R coils permitted. 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.

Sterilization Guide – GENESIS ACTIVE™ Abutments

Description - Abutments	Sterilization Procedure
Custom Abutments, ANGLEBase® & ELLIPTIBase®, Premills, C-Base® All Prosthetic Tools	See reference table found in Sterilization Section
Cover Screws Healing Abutments Multi-Unit Abutment Healing Caps Impression Posts TiPink Immediate Temporary Abutments Titanium Temporary Abutments TiPink Aesthetic Abutments (Straight & 20° Angled) Straight and Angled Multi-Unit Abutments Abutment Screws in sterile package	Delivered Sterile: Sterilization required if modified.

Torque Value Reference Table

Prosthetic Component	**Torque (Ncm)**
Cover Screw, Healing Abutment* Multi-Unit Abutment Healing Caps* Intra-Oral Scan Abutments* PEEK Temporary Abutments** Multi-Unit Prosthetic Screw, RP/WP Multi-Unit Prosthetic Lab Screw, RP Laboratory Screws	15
Impression Post TiPink Immediate Temporary Abutment**	20
TiPink Temporary Abutment** Torx® Screw for ANGLEBase® & ELIPTIBase® Straight & Angulated Multi-unit Abutment Titanium Blanks, C-Base® Abutments TiBase Abutments TiPink Aesthetic Abutments (Straight & 20° Angled) Final Abutment Screws	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 of implant placement.

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

Symbol Definitions

REF	Catalog number
LOT	Batch Code
MD	Medical Device
	Caution, consult accompanying documents
	Do not reuse
NON STERILE	Non-Sterile
	Single Sterile Barrier System
	Do not use if package is damaged
STERILE R	Sterilized using gamma radiation
Rx only	By Prescription Only
	Use by date
	Do not resterilize
	Manufacturer
	Date of Manufacturer
MR	MR Conditional
	Keep away from sunlight
	Consult Instructions for Use

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

Notes

Notes

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100064-EN01 REV B - 04/2024