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Keystone Dental
GENESIS ACTIVE™
Implant System

Keystone Dental GENESIS ACTIVE™ Implants

1. Description

1.1 The GENESIS ACTIVE™ Implant System includes implants, abutments, and associated surgical, restorative, and dental laboratory components. GENESIS ACTIVE™ 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. NOTE: See GENESIS ACTIVE™ Catalog or Prosthetic Manual for listing of implant and prosthetic compatibility information.

1.2 GENESIS ACTIVE™ implants are a screw shaped implant manufactured from a biocompatible Grade 4 titanium and are available in various diameters and lengths. All GENESIS ACTIVE™ implants have an internal geometry with a conical and indexing feature. The implants have a patented macro-, micro-, and nano topography with a unique BioSpark™ surface, which is hydrophilic and enriched with calcium and phosphorous ions. The implant collar is moderately-roughened and has a unique patented AnaTite™ surface with a pink color for enhanced aesthetics. There are no medicinal substances or human blood derivatives found in GENESIS ACTIVE™ Implant System implants, abutments, and associated surgical, restorative, and dental laboratory components.

1.3 GENESIS ACTIVE™ twist drills and final tapered drills are made of stainless steel and should be used with GENESIS ACTIVE™ implants.

1.4 Many of the GENESIS ACTIVE™ abutments are manufactured from Ti 6Al-4V ELI titanium. Some abutments have an AnaTite™ pink surface and others may have additional patented micro roughened surface technology. Other GENESIS ACTIVE™ prosthetic or laboratory components are made from Ti 6Al-4V ELI titanium, POM (polyoxymethylene), and/or PEEK.

1.5 Abutments are intended for fixed restorations and utilize a Ti 6Al-4V ELI titanium screw for attachment to the implant or abutment. Refer to the Torque Value Reference Table for recommended torque values depending on type of screw delivered with the abutment.

1.6 The GENESIS ACTIVE™ Implant System has implants ranging from Ø3.5 to Ø 5.5 mm in diameter with one prosthetic platform. Healing and final abutments fit all diameter implants.

2. Indications for Use

2.1 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.

2.2 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.

3. Patient Population

3.1 Implant placement is recommended only for patients who have completed jawbone growth.

4. Directions for Use

4.1 The implantation drilling sequence procedure should be performed under aseptic conditions using only sterile GENESIS ACTIVE™ Implant System surgical instruments. A drilling protocol with copious irrigation is recommended for implant placement in the surgical site. The use of the GENESIS ACTIVE™ Implant System Surgical Manual and surgical instruments are recommended to aid in implant placement.

4.2 Following site preparation, attach the surgical ratchet and/or handpiece adapter to the implant driver. To maintain the sterility of the implant, remove the implant and screw from the vial as follows. The implant is packaged in an outer vial with shrink wrap. This outer vial holds an inner sleeve/cap with the implant and cover screw. The surgical assistant opens the outer vial and removes the vial cap, without touching the inner sleeve/cap and tips the contents into the sterile field. The clinician holds the sterile inner sleeve/cap to remove the implant and cover screw with the appropriate sterile drivers.

4.3 Thread the implant into the prepared site in a clockwise direction, seating the implant at bone level, as indicated in the Surgical Manual. Place the cover screw*/healing abutment onto the implant and hand tighten. Close and suture the tissue. Refer to the GENESIS ACTIVE™ Implant System Surgical Manual for additional information on implantation. *All implants are provided with a cover screw found in the cap of the implant vial.

NOTE: Refer to the GENESIS ACTIVE™ Implant System Prosthetic Manual for detailed explanation of restorative procedures. Available upon request from Keystone Dental.

5. Contraindications

5.1 Patients with uncontrolled or severe cases of hyper-thyroidism, diabetes, malignancies, renal disease, liver problems, hypertension, leukemia, severe vascular heart disease, hepatitis, immunosuppressive disorders, collagen and bone diseases, or other serious illnesses.

5.2 Patients with titanium allergies.

5.3 Patients with alveolar ridge dimensions that are not sufficient to accommodate and sustain proper implant placement.

5.4 Patients with systemic, local oral, or respiratory infection.

5.5 For PEEK components: patients who are hypersensitive or allergic to PEEK (polyetheretherketone).

6. Warnings

6.1 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.

6.2 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.

6.3 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.

6.4 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, certain cardiac and vascular diseases, tobacco usage, diabetes (uncontrolled), treatment with chemotherapeutic agents, chronic renal disease, poor oral hygiene, bruxism, or alcoholism.

6.5 Implant failure or fracture can occur during routine function.

6.6 It is important that the clinician use an appropriate number, length, and diameter of implants to provide adequate support and properly distribute load between abutments, to minimize the potential for implant failure or fracture.

6.7 The use of electro-surgical instruments or lasers around metallic implants and their abutments may cause electric and/or heat conductivity.

6.8 Implant mobility, bone loss, or chronic infection may result in implant failure.

6.9 Implants should not be used if their surface is damaged.

6.10 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.

6.11 Restorative components are intended for single use only.

6.12 Do not alter implants.

6.13 Use caution when handling drills as the tips of these devices are sharp.

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

6.15 The Ø 3.5 mm implant is not recommended for posterior placement and/or in areas of poor bone quality. A clinical evaluation and care should be taken when placing small diameter implants in immediate function. It is recommended to achieve an appropriate insertion torque when good primary stability is established, and appropriate occlusal loading is applied.

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

7. Precautions

7.1 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.

7.2 Proper clinical and radiographic evaluation of the patient should be performed prior to implant placement.

7.3 Determine local anatomy and suitability of the available bone prior to plant placement. Adequate radiographs, direct palpation, and visual inspection of the implant site are necessary prior to treatment.

7.4 Products are intended for use only in the applications defined in the GENESIS ACTIVE™ Implant System Surgical and/or Prosthetic Manual.

8. Procedural Precautions

NOTE: Refer to the GENESIS ACTIVE™ Implant System Surgical and/or Prosthetic Manuals*, as applicable, for detailed explanations of procedures.

8.1 All implant drilling and placement procedures should be done at speeds recommended in the GENESIS ACTIVE™ Implant System Surgical Manual.

8.2 Drilling procedures require the use of specifically designed GENESIS ACTIVE™ instruments.

8.3 All drills must be sharp prior to use. Keystone Dental recommends a maximum of 20 uses and sterilization cycles.

8.4 All drilling should be done using intermittent drilling action with minimal pressure and continuous irrigation using ample chilled sterile saline.

8.5 Do not open sterile packaging until the correct implant size has been determined and the operative site has been prepared.

8.6 Excessive insertion torque above 100 Ncm can cause damage to the implant and surrounding bone.

8.7 Clean and dry the inside of the internal connection of the implant before hand- tightening the Healing Abutment or Cover Screw.

8.8 Application of excessive force to the implant area should be avoided, especially during the healing period.

8.9 After implant surgery, the clinician should evaluate patient bone quality and implant stability to determine when implants may be loaded.

8.10 Proper occlusion should be evaluated, and restorations should have passive fit to the abutments.

9. Adverse Effects

9.1 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

In the case of a serious incident, for a patient, user, or third party, please contact Keystone Dental.

10. Sterility

10.1 GENESIS ACTIVE™ Implant System implants and some 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.

10.2 Do not use if packaging is damaged. Sterile implants and unmodified abutments must not be resterilized. Resterilization can cause risk or harm to the patient. Keystone Dental does not accept any responsibility for resterilized implants, unmodified abutments, or components.

10.3 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.

11. Cleaning Instructions

11.1 Instruments must be cleaned and sterilized prior to first and after each use based on established procedures. Proper instrument care is an important part of successful implant dentistry. Automated washers should not be used as it may reduce the life of the instruments.

12. Pre-Cleaning

12.1 Used tools should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva, and tissue residue.

12.2 Multiple-part instruments must be disassembled prior to cleaning and sterilization.

12.3 Internal debris/residue on instruments must be removed with a soft brush.

12.4 Instruments should be inspected, cleaned separately, and discarded if damaged.

12.5 Used surgical trays must be cleaned with a suitable disinfectant.

13. Principle Cleaning

13.1 Best results are achieved if prosthetic tools are cleaned by material type.

13.2 Rinse and brush under free-flowing tap water.

13.3 Soak in enzymatic solution in an ultrasonic cleaner for at least 5 minutes following manufacturer's instructions.

13.4 Rinse under free-flowing distilled water.

13.5 Completely dry and inspect for integrity and flaws.

13.6 Trays must be cleaned, disinfected, and dried thoroughly.

14. Sterilization

14.1 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	273°F (134°C) for 4 minutes
Dry Time	40 minutes
Packaging	510(k)-cleared sterilization pouch
Sterility Assurance Level	$\leq 10^{-6}$

*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.

14.2 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.

14.3 Instruments and non-sterile or modified abutments with their corresponding screws must be sterilized by the clinician prior to placement in a surgical site. Instructions are provided in the Genesis ACTIVE Implant System Surgical and Prosthetic Manuals.

15. MRI Safety Information - MR Conditional

WARNING: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

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.

15.1 A patient with a Keystone Dental Implant System device can be scanned safely in an MR system under the following conditions:

16. Storage and Handling

16.1 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.

17. Bending Beam Torque Wrench

17.1 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 tear drop lever arm is pulled to a specific value on the shaft of the torque wrench.

17.2 For prosthetic components that require a torque value which ends in a unit of 5 (example 25 Ncm displayed) the tear drop 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 IFU for further information about care and use of the torque wrench.

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

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.

U.S. Patent Nos. 7,249,949, 5,996,779, 6,142,296, 7,740,481

Symbol Defintions

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