Keystone Genesis

INSTRUCTIONS FOR USE

Keystone Dental Genesis Implant System™

DESCRIPTION

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

Genesis implants are manufactured from Grade 4 titanium, have a tapered or straight cylindrical design with an internal indexing connection, and are available in various platform diameters and lengths. The implants have a macro-, micro- and nano-topography with a unique BioSpark™ surface, which is hydrophilic and enriched with calcium and phosphorous ions. The implant collar is micro-roughened and has a unique AnaTite™ surface with a pink color for enhanced esthetics.

The majority of Genesis abutments are manufactured from Grade 5 titanium and have an AnaTite™ surface. Other Genesis abutments are made from Grade 5 titanium/plastic or gold alloy/plastic. Abutments intended for fixed restorations utilize a Grade 5 titanium screw for attachment to the implant. Genesis abutments and associated restorative components are manufactured in a variety of sizes and configurations to be compatible with the implant platforms.

INDICATIONS FOR USE

The Genesis Implant System is intended for use in single-stage or two-stage surgical procedures in all types of bone in partially or fully edentulous mandibles and maxillae. The Genesis Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis 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.

DIRECTIONS FOR USE

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

Following site preparation, attach the surgical ratchet and/or handpiece adapter to the implant driver. Thread the implant into the prepared site in a clockwise direction, seating the implant at the crest of the ridge. Place the cover screw/healing abutment onto the implant and hand tighten. Close and suture the tissue flap. Refer to the Genesis Implant System Surgical Manual* for additional information on implantation.

*Note: Refer to the Genesis Implant System Prosthetic Manual for detailed explanation of restorative procedures.**

CONTRAINDICATIONS

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

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.
- Pre-operative evaluation of the patient is necessary to determine factors that may either cause risk to the patient or affect the healing process of the bone and/or soft tissue.
- Care should be taken that the patient does not swallow or aspirate components.
- 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.
- Implant failure or fracture can occur during routine function.
- It is important that the clinician use an appropriate number, length and diameter of implants in order to provide adequate support and properly distribute load between abutments, to minimize the potential for implant failure or fracture.
- 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.
- Implants should not be used if their surface is damaged.
- Implants are provided sterile and are intended for single use only. Under no circumstances should re-sterilization and/or re-use be attempted.
- Restorative components are intended for single use only.
- Do not alter implants.

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.
- Proper clinical and radiographic evaluation of the patient should be performed prior to implant placement.
- Determine local anatomy and suitability of the available bone prior to implant placement. Adequate radiographs, direct palpation, and visual inspection of the implant site are necessary prior to treatment.
- Products are intended for use only in the applications defined in the Genesis Implant System Surgical Manual* and Prosthetic Manual.*

PROCEDURAL PRECAUTIONS

*Note: Refer to the Genesis Implant System Surgical and/or Prosthetic Manuals, as applicable, for detailed explanations of procedures.**

- All implant drilling, tapping and placement procedures should be done at speedsrecommended in the Genesis Implant System Surgical Manual.*
- Drilling and tapping procedures require the use of specifically designed Genesis instruments.
- All drills and taps must be sharp prior to use. Keystone Dental recommends a maximum of 20 uses and sterilization cycles.
- All drilling should be done using intermittent drilling action with minimal pressure and continuous irrigation using ample chilled sterile saline.
- Do not open sterile packaging until the correct implant size has been determined and the operative site has been prepared.
- Excessive insertion torque can cause damage to the implant and surrounding bone.
- Clean and dry the inside of the internal connection of the implant before hand-tightening the healing screw.
- Application of excessive force to the implant area should be avoided, especially during the healing period.
- After implant surgery, the clinician should evaluate patient bone quality and implant stability to determine when implants may be loaded.
- Proper occlusion should be evaluated, and restorations should have passive fit to the abutments.

PACKAGING

- This package contains one dental implant. Product is intended for single use only.
- This package contains labels to place on the patient's dental record to facilitate product traceability.

STERILITY

- 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.
- Sterile products are gamma sterilized. Re-sterilization and/or re-use must not be attempted.
- Prior to use, instruments, abutments and screws must be sterilized by the clinician when they will be placed in a surgical site. Instructions are provided in the Genesis Implant System Surgical and Prosthetic Manuals.*

ADVERSE EFFECTS

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 paraesthesia
- Lack of osseointegration, mobility 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

STORAGE AND HANDLING

Product must be stored in its original, sterile (if applicable) packaging under dry, room temperature conditions.

CAUTION

Federal (U.S.A.) law restricts the sale of this device to, or on the order of, a licensed clinician.

SYMBOL DEFINITIONS

Caution, consult accompanying documents		Manufacturer	
Catalogue number	REF	Batch code	LOT
Use by		Do not reuse	
Sterilized using irradiation	STERILE R	Prescription only	Rx only
CE marking of conformity with Notified Body identification number	CE 0086	Authorized Representative in the European Community	EC REP
Peel			

** Supplied with initial shipment, or available at www.keystonedental.com or by contacting Keystone Dental, Inc. at the following:*

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EC REP

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

100000-EN01 Rev D-L 10/2012