INSTRUCTIONS FOR USE

This document applies to the Keystone Dental, Inc. line of dental implants, abutments and associated surgical, restorative and dental laboratory components.

For detailed information on a specific product and procedure, please refer to the individual product catalog, packaging labels and/or the appropriate manual.

DESCRIPTION
Keystone Dental, Inc. manufactures dental implants from biocompatible titanium and restorative components from titanium, titanium alloy, gold alloy and a variety of polymers. The "cast-to" gold abutments are made from a specific gold alloy so that dental technicians can cast precious and semi-precious metals onto these components.

For specific product descriptions refer to individual product packaging labels.

INDICATIONS
The I-HEXMRT™ and TILOBEMAXX® Implant Systems are intended for implantation in the maxillary or mandibular molar region where sufficient bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. The I-HEXMRT™ and TILOBEMAXX® implants provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

CONTRAINDICATIONS
Contraindications include: (1) cases where the remaining jaw bone is too diminished to allow implant installation, (2) patients allergic or hypersensitive to chemical ingredients of the following materials including but not limited to: titanium, titanium alloy, stainless steel, (3) patients with insufficient mental health precluding patient cooperation, (4) patients who abuse drugs or alcohol, (5) patients who have conditions such as but not limited to myocardial infarct within the last year, oral infections, or malignancies, (6) patients who have uncontrolled diabetes or blood disorders.

WARNINGS
For the safe and effective use of dental implants, it is strongly suggested that specialized training be undertaken, including hands on training to learn proper technique, biomechanical requirements and radiographic evaluations. THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING. Responsibility for proper patient selection, adequate training, experience in the placement of implants, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure and/or loss of supporting bone. Keystone Dental, Inc. will not accept liability for damage caused by improper implant treatment.

MRI SAFETY INFORMATION
The I-HEXMRT™ and TILOBEMAXX® dental implants, abutments, and other prosthetic components have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the these devices in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury or device malfunction.

STERILITY
Keystone Dental implants and some abutments are sterilized using gamma irradiation and are delivered sterile. These products are intended for single use prior to the expiration 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 implants and abutments must not be resterilized. Resterilization can cause risk or harm to the patient. Keystone Dental does not accept responsibility for resterilized implants or abutments. Some Keystone Dental products are provided non-sterile. Refer to individual product labels for sterility information. Products delivered non-sterile may need to be cleaned and sterilized according to the directions in the Surgical Manual prior to use.

In order to maintain the sterility of the products, remove the implant and screw from the vial following the instructions in the Surgical Manual. 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.

SURGICAL AND PROSTHETIC PROCEDURES
For detailed information of the surgical and prosthetic procedures refer to the SURGICAL and PROSTHETIC MANUALS.

PRE-CLEANING
- Used instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva and tissue residue.
- Used surgical trays including grommets must be cleaned with suitable disinfectants.
- Multiple-part instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue of 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 surgical instruments are cleaned by material type.
- Instruments and trays can be cleaned and disinfected by hand, followed by an ultrasonic bath with a detergent appropriate for surgical instruments.
- Instruments and trays must be rinsed and dried thoroughly.
- Automated washers should not be used as it may reduce the life of the instruments.

STERILIZATION
Instruments and tray should be autoclaved at:
- Steam Sterilization Gravity Cycle: 134˚C (~273°F) 20 minute exposure / 40-minute dry time.
- Steam Sterilization Pre-Vacuum Cycle: 134°C (~273°F) 4-minute exposure /40-minute dry time. The drying cycle (minimum 40 minutes) must be followed to avoid instrument corrosion. Instruments should be place in the tray and wrapped in sterilization paper or sterilization packs featuring indicating tape and date of sterilization.

DRILLS
- Replacement of reusable drills after 20 uses or sterilizations is recommended to ensure optimal performance
- Do not re-sterilize single use drills

PROCEDURAL PRECAUTIONS
- Thorough screening of prospective implant candidates must be performed.
- A systematic and coordinated plan delineating the responsibilities of each member of the team should be developed and followed.
- An evaluation of implant patients should include the following steps: Elicit and record a comprehensive medical and dental history and consider the relevance of that information to the individual case.
- Visual inspection as well as panoramic and apical radiographs is essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone. Lateral cephalometric radiographs and tomograms may also be beneficial.

During the planning phase, it is important to determine if the available bone dimensions are adequate for implant placement and to confirm that the available occlusal space is sufficient to accommodate the proposed abutment and final restoration. Minimizing the trauma to the host tissue increases the potential for successful osseointegration. Electro-surgery should not be attempted around metal implants, as they are conductive.

The I-HEXMRT™ Implant is not intended to be used with angled abutments or to provide an angle/ divergence correction.

Do not reuse Implants, Cover screws, Temporary Abutments and Abutments. These are single-use products.

POTENTIAL ADVERSE EFFECTS
Dental implant therapy has normal contraindications and risks that are extensively documented in the dental implant literature.

POSTPLACEMENT PROCEDURES
The following considerations should be reviewed prior to the restorative phase:
- Quantity, quality and health of soft and hard tissues
- Implant stability
- Implant position and abutment selection
- Occlusal analysis
- Oral hygiene assessment

STORAGE AND HANDLING
Devices should be stored at room temperature. Refer to the individual product packaging label and the corresponding manual for special handling instructions.

For Technical Assistance or additional product literature, please contact:

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STERILE R — Sterilized using Gamma Irradiation

Caution, consult accompanying documents

Do not reuse

Do not use if the package is damaged

℞ Only

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