beforehand. Preoperative medication along with antibiotics maybe prescribed depending on the medical condition of the patient & extent of the surgery may be prescribed along with consultation of the patient physician.

13.5 At Surgery:

- All instruments should be sterile & the surgery needs to be carried out in aseptic conditions. Because of the small sizes of the instruments, implants & components, care should be taken so as the patient does not accidently swallow them. Patient's vitals must be checked prior to surgery such as temperature, BP, sugar, pulse etc. The patient should be asked to gargle with povidone iodine, & the mouth extra orally should be wiped with the same.
- Adequate anesthesia should be ensured so as to carry out the surgery without any discomfort to the patient. The patient should be evaluated for any previous history of anesthesia.
- After the implant placement the primary stability achieved, the bone quality & the operator's decision/preference will determine when the implants will be loaded.
- Dental Implants come with peel & stick labels including all the relevant data related to the implant. They should be used to maintain long terms records of the patient.

13.6 After Surgery

- To ensure long term successful treatment outcome the patient should be asked for regular follow ups to check for osseointegration via visual evaluation as well as radiographic images. Patient should be educated to maintain a meticulous oral hygiene for good prognosis.

13.7 Prosthetic Phase:

- Post healing phase the patient is evaluated for stability of the implants & if the implant has osseointegrated the final restoration is fabricated. The occlusion adjustments are done prior to discharging the patient to prevent any overloading.

13.8 Follow up:

- Periodic follow-ups should be done to check any required occlusal adjustment & to check the oral hygiene status of the patient.

Radiographic evaluation is also recommended.

13.9 Drill Sequence:

- Follow proper surgical protocol & handle the sterile items with caution.
- During the drilling procedure use of copious irrigation is recommended to avoid overheating to prevent the damage to hard & soft tissue.
- Use normal saline during drilling. Raise and lower drill to distribute normal saline solution and to rinse bone tissue during drilling.
- Make sure that drill is attached firmly to the contra angle hand piece with 20:1 reduction.
- With i-Fix ZE-Series surgical drills prepare a hole 1 mm deeper than the end of the applicable implant (keep into consideration while selecting length of Implant).
- Use the Z depth indicators to determine the length of the Zygoma implant to be placed. Copious irrigation of the sinus is recommended prior to implant placement.
- Implant should be placed until the implant apex engages in the zygomatic bone
- Assess implant position taking into account anatomical landmarks such as the maxillary sinus neighbouring tooth and roots, bone substance and implant orientation.
- When placing multiple implants, ensure an appropriate distance is maintained between implants and/or natural teeth.
- Use sufficient cooling using normal saline during drilling.
- The drill carries a laser marking to measure the appropriate depth to which drilling should be carried out.
- Drills must be replaced when cutting performance becomes lower.
- Use drill extensions if the contra angle head interferes with neighbouring teeth, or if the length of the shank is insufficient.
- Before use, check that the drill is firmly attached to the drill extension

13.10 Site Preparation:

The site preparation depends upon the size of the dental implant used and the actual site where the dental implant is to the placed. The site preparation for the Dental implant 4.60 x 45.0 mm is given below, Doctors need to modify this procedure according to the actual case and actual implant size.

Procedure steps:

1. Drill a punch cut with lance drill
   a. @1200rpm.
   b. Drill an osteotomy in the cortical bone for initial punch.

2. Drill an osteotomy with tapered drill Ø2.4
   c. @1000rpm.
   d. Drill the implant site to the predetermined length.
   e. Repeat the procedure with Ø2.4
   f. @600-800 rpm.

3. Drill a hole with tapered drill Ø2.8 and then with Ø3.2
   g. Drill the implant site to the predetermined depth.
   h. Confirm the direction and inclination by inserting the thick end of the paralleling pin.
   i. @600-800 rpm.

13.11 Implant and Cover Screw Placement

Implant Placement:

- Place the implant at speeds of 25 rpm with torque up to 50Ncm.
- Start with a low torque depending on bone condition with gradual increase of torque, Once the insertion torque reaches 40 to 50 Ncm, the Z Handle may be utilized to manually tighten the implant to the proper insertion depth.
- Confirm the correct insertion angle and Continue insertion through the sinus until the implant apex engages in the zygomatic bone.
- Caution: Drill an osteotomy with smaller diameter drill, if the bone is soft.
- Drill an osteotomy with a larger diameter drill, if overall bone structure is hard.

Cover screw placement

- Insert the hex driver into the Torque Wrench.
- Insert and hold the end of the hex driver into the groove at the center of the cover screw.
- Press the head of the hex driver into the opening at the center of the cover screw.
- Insert the hex driver straight.
- Confirm that the screw drive is being held firmly.
- Always make sure that the interior of the implant contains no residues of any dental or other materials. If necessary, clean and dry appropriately.
- Insert the cover screw into the implant and gently tighten.

14.0 Complications related with surgery:

- The intraoperative complications related with surgery are:
- Haemorrhages
- Neurosensory alterations
- Damage to teeth adjacent to the implant

15.0 Technical Complications:

- They are denoted by mechanical damage of implants, Implant components and supra structure.
- Implant fracture
- Abutment fracture
- Abutment screw fracture
- Prosthetic/occlusal screw fracture
- Fracture/deformation of superstructure framework
- Fracture/deformation of superstructure veneering material
- Loss of retention of superstructure
- Loss of occlusal screw-hole restoration
- Abutment screw loosening
- Prosthetic screw loosening

16.0 How Supplied:

Sterile: This device is sterilized with Gamma Radiation and is non-pyrogenic. It is intended for single use only. Do not resterilize. Do not use the device if the package is opened or damaged.
Content: One (1) i-Fix ZE-Series Dental Implan with cover screw and One (1) Instruction for use.
Storage: Store in a dry, dark and cool place.

17.0 Recommended Instruments/Components to be used with i-Fix ZE-Series Dental Implant

- It is recommended to use instruments/components of Kamal Encon Industries Limited with i-Fix ZE-Series Dental Implant. This recommendation is based on the fact that the instruments/ components provided by Kamal Encon Industries Limited is compatible with i-Fix ZE-Series Dental Implant and the use of this instruments/components would enhance the device performance & clinical outcome.
- Recommended Instruments/Components provided by Kamal Encon Industries Limited are Implant Analogue, Impression Copping. Healing Abutment, Cemented Abutment, Shoulder Abutment, Angular Abutment, Temporary Abutment, UCLA, Ball Abutment, Ti Base Abutment, Pre-Milled Bar, H-Scan Body, Locator Abutment, Abutment Screw, Prosthetic Screw MUA, Abutment Screw MUA, Multi-unit Abutment, Healing Cap MUA & Surgical Kit.

Note: Apart from i-Fix ZE-Series Dental Implant with cover screw, all the instruments / components are supply non-sterile. Customer/User need to perform sterilization of these instruments/components prior to use.

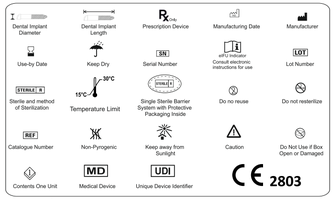
Cleaning Procedure:

- Rinse instruments in cool to lukewarm water for 2.5minutes.
- For drills use the wire to remove any debris from the irrigation channel.
- Sonicate the instruments/components for 10 minutes in an ultrasonic cleaner with a pH-neutral enzymatic detergent diluted with tap water as per the manufacturer's instructions.
- Rinse the instruments with tap water for 3 minutes. Inspect the instruments for signs of wear, damage, or unrecognizable colour identification and replace the instruments/components in case of any visible anomaly.
- **Sterilization:** After cleaning, carry out sterilization for 15 minutes at 121°C in autoclave.

18.0 Disclaimer of Warranty and Limitation of Remedy:

- Practitioners must have knowledge of dental implantology and the handling of the Dental Implant System in order to use products safely and properly in accordance with these instructions for use. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine if the device is suited to the individual patient's situation.
- There is no express or implied warranty, including without limitation any implied warranty of merchantability or fitness for a particular purpose, on Kamal Encon Industries Limited product(s) described here. Under no circumstances shall Kamal Encon Industries Limited be liable for any direct, incidental, or consequential damages other than as expressly provided by specific law. No person has the authority to bind Kamal Encon Industries Limited to any representation or warranty except as specifically set forth herein.
- Descriptions or specifications in Kamal Encon Industries Limited printed matter is meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties.
- Reuse of the device is strictly prohibited, consequences of such events are out of Kamal Encon Industries Limited Scope.

Symbol used in labeling:



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Mfg. Lic. No.: MFG/MD/2019/000057
Gamma Sterilization under
Mfg. Lic. No. MFG/MD/2023/000177

i-Fix® POWERING SMILES
DENTAL IMPLANT
ZE-SERIES

Kamal

Instructions For Use of Dental Implant

1.0 Product Description:

A dental implant is a surgical component that interfaces with the bone of the jaw or skull to support a dental prosthetics such as a crown, bridge, denture, facial prosthetics or to act as an orthodontic anchor. The basis for modern dental implants is a biologic process called osseointegration, in which material such as titanium form an intimate bond to bone. The implant fixture is first placed so that it is likely to osseointegrate, then a dental prosthetic is added. A variable amount of healing time is required for osseointegration before either the dental prosthetic (a tooth, bridge or denture) is attached to the implant or an abutment is places which will hold a dental prosthetic. The intended purpose of the implants is to replace the missing tooth root and thus provide a foundation for the prosthesis.

2.0 Intended use:

Dental implants intended to be used in the upper jaw bone for anchoring or supporting tooth replacement to restore chewing function and aesthetic oral rehabilitation of edentulous and partially dentate patients.

3.0 Indication:

Dental implant restoration range from single tooth to fixed removable, full dental arch overdenture applications to restore chewing function. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early as delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants can be placed with immediate function on single tooth &/or multiple tooth application when good primary stability achieved and kept off occlusion.

4.0 Intended Users:

The product shall only be used by Professional and Registered periodontist/ doctors trained and experienced maxillofacial surgeon or oral surgeon.

5.0 Specification of the device:

Generic Name	Dental Implants & prosthetics
Brand Name(s)	*i-Fix* **ZE-Series Dental Implant**
Description	Titanium Dental Implants having modified Threads, External Hex connection and Unique Surface Topography, sterile packed in blister with cover Screw.
Diameters (in mm):	4.3, 4.6
Lengths (in mm):	30.0, 35.0, 40.0, 42.5, 45.0, 47.5, 50.0, 52.5, 55.0, 57.5 60.0, 62.5
Primary Packing	Each Implant along with cover screw (only two piece) is packed in blister sealed with Tyvek lied whereas each single Prosthetics is packed in an aluminum pouch and labelled.
Secondary Packing	Each sterile single unit packed in laminated cardboard box.
Method of Sterilization	Gamma Radiation sterilization.
Expiry Date	60 months from the date of sterilization.
Storage condition	Store in dry, dark and cool place.

5.1 Product Components

Following are the key components of Dental Implant.

A. Implant Fixture/body
B. Cover Screw

A. Implant Fixture/body:

- The implant fixture is a root form implant, designed to use for vertical column of bone, similar to the root of a natural tooth. It prosthodontic abutment, to allow implant placement under the soft tissue during the initial bone healing.
- The macroscopic body design demonstrates a solid screw type tapered profile, which enables them to be threaded into the bone and which can enhance initial bone fixation.
- The thread geometry is Reverse Buttress type profile.

Implant Fixture Design:

- **Tapered design** is chosen over a parallel design as
  → It allows the placement of implant without encroaching vital anatomical structures like the sinus, adjacent roots and anatomical fossae.
  → The tapered design allows the self- tapping property.
  → The design is compatible with tapered drills and the design allows proper placement in the apico-coronal direction in-spite of an error of over-preparation with the initial drills and therefore, is suitable for use by beginners.
  → The rounded end prevents damage to vital structures like inferior alveolar nerve even if the implant is placed in close vicinity or pressing against it.

- **Threaded** implant design has been chosen, as:
  → The surface area is increased.
  → The primary stability is increased with the mechanical interlocking and therefore immediate or early loading options are possible.
  → The use of a threaded design is better for less experienced operators as the osteotomy preparation has a slightly larger margin for error in comparison to non-threaded press fit implants.

B. Cover Screw:

- The cover screw is placed over the implant after removal of the abutment, to protect the internal surfaces from bone and tissue invagination during the healing period.
- After an implant is placed, the internal components are covered with a cover screw. A cover screw is flush with the surface of the dental implant, and is designed to be completely covered by mucosa. After an integration period, a second surgery is required to reflect the mucosa and place a healing abutment.

Cover Screw Specification:

- Material: T-6Al-4V alloy, ASTM F136

6.0 The Intended Patient Population

The patients or individuals, who required prosthetic tooth restoration by mean of dental implant. Children above age 14, adult men and women and aged population.

7.0 Medical Condition to be diagnosed/treated

Partial/Complete edentulism

8.0 Patient Selection Criteria

8.1 Patient Inclusion Criteria

- Partial or completely edentulous maxilla.
- Adequate oral hygiene
- No active periodontal disease at the time of selection
- No active pathology at the intended implant site or the adjoining sites.
- Sufficient bone volume at the proposed bone site, as assessed by clinical and radiological examination
- Edentulous span opposed by natural dentition or prosthetic restoration
- Patient willing to undergo the procedure.
- Compliant patient with reasonable expectations

8.2 Patient Exclusion Criteria

- Systemic diseases that contraindicate surgery or compromise the prognosis according to criteria given by American society of Anaesthesiologists
- History of radiation therapy
- Patients on intra venous bisphosphonates medication or on oral bisphosphonates for greater than 3 years or with concomitant steroids.
- History and clinical evidence of parafunctional habits like bruxism and clenching.
- Habitual Smoker, Alcohol or drug abuse.
- Unfavorable skeletal inter-maxillary relation which includes severe Class II and Class III Malocclusion.
- Unfavorable crown-height space less than 7 mm which would preclude cementable prosthesis.
- Reduced mouth opening compromising the access to the area
- Active Occluso-muscular – Temporomandibular conditions.
- Pregnant Woman

9.0 Contraindications:

Dental Implant are contraindicated for following patients:

- who are medically unfit for an oral surgical procedure.
- with inadequate bone volume unless an augmentation procedure can be considered.
- in whom adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually para-functional loads.
- who are allergic or hypersensitive to commercially pure titanium grade 4 and grade 1, titanium alloy Ti-6Al-4V (titanium, aluminium, vanadium), stainless steel.

10.0 Precautions

- The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures.
- Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration.
- When the clinician has determined adequate primary stability is achieved, immediate functional loading can be considered.
- The following should be taken into consideration when placing dental implants: bone quality, oral hygiene, and medical conditions such as blood disorders or uncontrolled hormonal conditions.
- The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's bone density at the time of the surgical procedure.
- Proper occlusion should be evaluated on the implant restoration to avoid excessive force during the healing period on the implant.
- It is recommended that implants less than 4mm diameter NOT be placed in the posterior regions.
- Sterility: All dental implants are supplied sterile and are labelled "STERILE". All sterile STERILE are for single-use before the expiration date printed on the product label.
- Do not use products if the packaging has been damaged or previously opened.
- Do not re-sterilize.

11.0 Warnings:

- Excessive bone loss or breakage of a dental implant may occur when an implant is load bearing capacity.
- Physiological and anatomical conditions may affect the performance of dental implants.
- Forcing the implant into the osteotomy deeper than the depth established by the drills can result in damage to the implant, driver, or osteotomy.
- For short implants, clinicians should closely monitor patients for any of the conditions: peri-implant bone loss, changes to the implant's response to percussion or radiographic changes in bone-to implant contact along the implant's length.
- If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal.
- While selecting short implants, the clinician should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. In addition, the clinician should allow longer periods for osseointegration and avoid immediate loading.

- **MR Safety Information:**

MR Conditional: Non-clinical testing has demonstrated that dental implants are MR conditional. A patient with the dental implant can be safely scanned in an MR system meeting the following conditions:

→ Static magnetic field of 1.5 Tesla and 3.0 Tesla only
→ Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).
→ Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 2 W/Kg (Normal Operating Mode) or 4 W/Kg (First Level Controlled Mode).

Under the scan conditions defined before, the dental implant is expected to produce a maximum temperature rise of 4.1°C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends approximately 30mm from the dental implant when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.
Removable restorations should be taken out prior to scanning, as is done for watched, jewellery etc.
Should there be no MR symbol on the product label, please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration levels into account.

12.0 Potential Adverse effects

Potential adverse events associated with the use of dental implants may include: failure to integrate, loss of integration, dehiscence requiring bone grafting, perforation of the maxillary sinus, inferior border, lingual plate, labial plate, inferior alveolar canal, or gingiva, infection as reported by abscess, fistula, suppuration, inflammation, or radiolucency, persistent pain, numbness, paraesthesia, hyperplasia, excessive bone loss requiring intervention, implant breakage or fracture, systemic infection, nerve injury, and aspiration.

13.0 Surgical Procedure:

13.1 Direction for Use

- Proper surgical procedures and techniques are the responsibility of the medical professional. Each dentist must evaluate the appropriateness of the procedure used based on personal medical training and experience as applied to the patient case at hand. We strongly recommend sound knowledge of dental implants, prosthetics & the related surgical & prosthetic procedures as well as strict adherence to the instructions and procedures for use that accompany Dental Implant.

13.2 Preparation for Surgery.

- Careful clinical & radiographic analysis of the patient has to be done prior to the surgery to assess the psychological status of the patient & their ability to undergo the surgical procedure.
- Special attention has to be given to patients who have localized or systemic factors which can affect the healing of the soft/hard tissue, osseointegration or the prognosis of the implant. Factors such as immunocompromised patients, diabetic, uncontrolled hypertension, smoking, poor oral hygiene, cardiac insufficiency, malignancies, recent myocardial infections, bone pathologies, osteoradionecrosis, infection in adjacent site, allergy or hypersensitivity to certain materials, are to be considered prior to surgery.
- Special caution for patients receiving bisphosphonate therapy.
- In bruxism or traumatic occlusion, underlying cause should be treated prior to planning any implant procedure.
- In general implant & prosthetic planning should accommodate the patients' individual condition.

13.3 Examination:

- A proper extraoral & intraoral examination is a prerequisite for any surgical procedure in the oral cavity. Preoperative hard & soft tissue deficits lead to a compromised esthetic result or incorrect angulations. The patient should be thoroughly investigated & examined for any medical or dental history along with any drug allergy or contraindication. History of any prior anesthetic event should be recorded. The patient should also be counselled regarding the pre surgical, surgical & post-surgical procedures & precautions to be taken. The patient should be motivated to maintain a good oral hygiene, be compliant with all the instructions & be regular with follow up appointments.
- Radiographic evaluations should be done which include the standard Panoramic radiographs, periapical radiographs as well as whenever possible addition imaging modalities like CBCT should be done & recorded. Models of the jaws should be fabricated & the jaw relation should be recorded. While planning the neighbouring teeth & structure as well as anatomical landmarks such as vein nerves, maxillary sinus etc. should be considered. The dimensions of the bone available should be recorded by the above mentioned modalities.

13.4 Before Surgery:

- Implants should be selected prior to the surgery after careful evaluation of the available bone & estimation of the dimensions available. i-Fix ZE-Series implants are available in a variety of length & diameters giving the dentist a wide range to choose from according to the clinical scenario. Augmentation of the bone if required also has to be planned