loss requiring intervention, implant breakage or fracture, systemic infection, nerve injury, and aspiration.

Complications related with surgery:

- The intraoperative complications related with surgery are:
- Hemorrhages
- Neurosensory alterations
- Damage to teeth adjacent to the implant
- Intraoperative Mandibular fracture

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

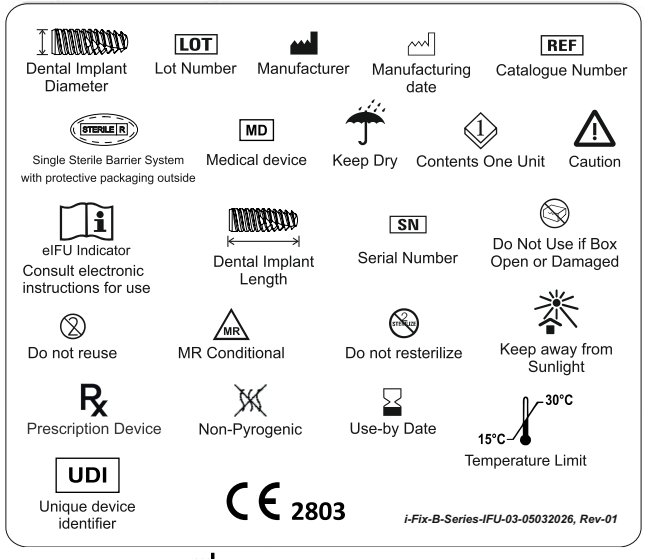
How Supplied:

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.
Contents: One (1) B-Series Dental Implant with Cover Screw & One (1) Instruction for Use
Storage: Store in a dry, dark and cool place.

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.
- Kamal Encon Industries Limited will not be responsible for any direct, incidental, or consequential damages resulting from reuse of the product.

20.0 Symbols 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

B-SERIES

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 prosthesis such as a crown, bridge, denture, facial prosthesis 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 of Device:

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

3.0 Indications:

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 Device:

i-FIX B-Series Dental Implant	
Generic Name	Dental Implants & Prosthesis
Description	Titanium Dental Implants having modified Threads, Conical connection and Unique Surface Topography. The sterile product packed in Aluminum pouch with cover Screw.
Dental Implant Material	Titanium Ti-6Al-4V Alloy
Diameters (in mm):	2.75, 3.00, 3.50, 4.00, 4.50, 5.00, 5.50, 6.00, 6.50 (± 0.02 mm Tolerance)
Lengths (in mm):	6.00, 6.50, 7.00, 7.50, 8.00, 8.50, 9.00, 9.50, 10.00, 10.50, 11.00, 11.50, 12.00, 12.50, 13.00, 13.50, 14.00, 14.50, 15.00 (± 0.05 mm Tolerance)
Primary Packing	Each single unit packed in Plastic Vial & then in in Aluminum pouch.
Secondary Packing	Each sterile single unit packed in laminated cardboard box.
Method of Sterilization	Gamma Radiation sterilization.
Storage condition	Store in a dry, dark and cool place.

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 or mandible
- 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 Anesthesiologists
- 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

Contraindications:
Dental Implants are contraindicated for following patients:
- Who are medically unfit for oral surgical procedure
- With inadequate bone volume unless an augmentation procedure can be considered
- In whom adequate sizes, number or desirable position of implants are not reliable to achieve safe support of functional or eventually para-functional loads
- Who are allergic or hypersensitive to commercially pure titanium, titanium alloy Ti-6Al-4V ELI (titanium, aluminum & vanadium) & Stainless steel.

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.

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 is 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, jewelry 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.

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, paresthesia, hyperplasia, excessive bone