IMPLANT SYSTEM

Instructions for Use

℞ ITL **Dental** biocompatible titanium alloy Implants, abutments, healing caps and screws are to be placed in the mouth only by licensed dentists, doctors and/or operators trained in the use and placement of dental implants in a clinical environment. Patients shoud be told of possible rejection due to allergic reaction to the implants themselves, and/or those with HA or surface coating, if applicable. Implants come packaged with a 3-in-One abutment premounted. 3-in-One abutments are for single patient use only. This abutment may be used as: (1) an implant mount; (2) a closed tray transfer and (3) a temporary or final abutment. "Peel and stick" labels supplied on the implant package contain important product information and should be applied to the patient's record in the event future reference is necessary.

Disclaimer of Liability: The users of implant products must determine whether or not a particular product is suitable for the patient application and circumstance. ITL Dental disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages arising out of or in conjunction with any errors in professional judgement or practice in the use of the products. Users are advised and obliged to study the latest news and developments in implant dentistry and to review www.itldental.com for any updates to products, specifications or to report product concerns. ITL Dental has no control over the use of its products which are the responsibility of the user. ITL Dental assumes no liability whatsoever for damage arising thereof if the user chooses the wrong dental implants for the patient(s) and/or causes clinical harm.

1] **Indications For Use:** The purpose of dental implantation is for use in the mandible or maxilla for use as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The implants may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion (2) when splinted together as an artificial root structure for multiple tooth replace-ment of mandibular incisiors, or *(3) for full arch restorations when 4 or more implants are splinted together rigidly*. The implants may be placed in immedidate function when good primary stability has been achieved and with appropriate occlusal loading. **Clinical Benefits:** The clinical benefit of dental implants is to replace missing or damaged teeth to improve the mastication of the patient and preserve bone loss.

2] Contraindications: Include but are not limited to: biological hypersensitivity and/or an allergic reaction to the material (titanium alloy,) HA coating and/or surface treatment, uncontrolled diabetes, clotting disorders, anticoagu-lant therapy, metabolic bone disease, chemotherapy or radiation therapy, chron-ic periodontal inflammation, insufficient soft tissue coverage, metabolic or sys-temic disorders associated with wound and/or bone healing, use of pharmaceu-ticals that inhibit or alter natural bone remodeling, any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene. Relative contraindica-tions may include habits such as tobacco use, alcohol consumption, poor oral hygiene, bruxism, nail biting, pencil biting and improper tongue habits depend-ing on severity.

3] **Oral Contraindications** Include but are not limited to: uncontrolled parafunctional habits (e.g. bruxing, clenching, gnawing), insufficient bone volume, insufficient inter-arch space, intraoral infection, poor or non-compliant patient oral hygiene.

4] **Sterile Packaging:** [STERILE R] (2) Implants and included materials are sold sterile by gamma radiation. All products sold sterile are for single-use before the "use by" date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Due to con-tamination concerns, ITL Dental will not accept the contents for return. Products to be disposed of must be treated and decontaminated as dental surgery waste in compliance with the relevant regulations.

Products provided non-sterile may need to be cleaned and sterilized prior to use.

Sterilization Cycle:

Reference	Type	Time/Temperature	Minimum Dry Time
ANSI/AAMI	GRAVITY	15 Minutes at 132°C	30 Minutes
TIR12:2010	STEAM	(270°F)	

ITL Dental takes no responsibility for re-sterilized dental implants regardless of the individual performing the re-sterilization or the method used for re-sterilization. Re-sterilization could result in surgical rejection and/or post-operative infection.

5] **Handling:** Implants must be stored in a dry place, at room temperature, in their original packaging. Dental implants are provided in sterile vials affixed to fixture mounts. The plastic cap attached to the fixture mount is intended to be used to transport the implant to the prepared surgical site. Do not handle implant surfaces directly. Users are advised to visually inspect the package to insure seals and contents are intact and in their original packaging prior to use.

6] **Shelf-Life:** Dental Implants are considered sterile for five years from the date of initial sterilization. Expiration dates are noted on the implant label.

7] **Surgical Techniques for Implant Placement:**

- *Pre-operative Treatment Planning: During the pre-operative stage, availability of bone volume at the desired implant site must be determined. must be determined. Appropriate radiography should be used to determine bone availability, optimal implant location and to avoid structures such as the mandibular canal, maxillary sinuses and adjacent teeth.*
- *Electro surgery: Due to the conductive nature of metallic implants, electro surgery is contraindicated.*
- *Surgical Site Preparation: Follow the corresponding drill sequence for bone preparation.*

Implant D	3.2	3.7	4.2
Pilot Drill	x	x	x
2.3/2.0	x	x	x
2.8/2.3	x	x	x
3.4/2.8		x	x
3.8/3.4			x
4.4/3.8			
4.8/4.4			
5.4/4.8			

Implant D	4.7	5.2	5.7
Pilot Drill	x	x	x
2.3/2.0	x	x	x
2.8/2.3	x	x	x
3.4/2.8	x	x	x
3.8/3.4	x	x	x
4.4/3.8	x	x	x
4.8/4.4		x	x
5.4/4.8			x

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- *Delete last drill for soft bone preparation.*
- *Patient information: Implant information should be maintained in the patient's chart.*
- *Open outer packaging: Peel back chevron package and remove inner vial.*
- *Remove from inner Packaging: Implants are packaged in a sterile plastic inner vial suspended from a fixture mount for ease of insertion.*

Pull contents out of inner vial with powder-free sterile gloved fingers by pulling upward on the plastic cap. Carry implant assembly to the implant osteotomy and begin threading the implant assembly by turning the plastic cap in a clockwise direction until the implant is stabilized. Avoid contact with the surface of the implant that will be in contact with bone.

- *Implant Insertion: Continue inserting the implant using appropriate instrumentation.Rotate until the implant is fully seated into the osteotomy with the roughened surface level with the crest of the bone. To remove the fixture mount, use a .050 (1.27mm) hex driver to unthread the retaining screw.*
- *Cover Screw: Use the .050 (1.27mm) hex driver to engage the cover screw found in the top of the plastic cap.*
- *Fixture Mount/Abutment: The fixture mount can be shortened to serve as a final abutment. Using a carborundum disc, separate the colored square from the tapered abutment portion of the fixture mount and attach the abutment to the implant using appropriate torque.*
- *Post-operative Care: It is recommended that patients use a suitable mouth rinse and perform regular oral hygiene following surgery.*
- *Healing Time: Implants are usually allowed to heal for a period of two to four months prior to being restored depending upon bone quality and type or any compromising medical condition.*
- *Residual Risks, Side Effects, Interactions, and Complications: Complications associated with dental implants included, but are not limited to: temporary pain, swelling, speech impediments, and gingival infections. Longer term could be paresthesia, dyesthesia, loss of bone, infections, problem with aesthetics, nerve damage, exfoliation, hyperplasia and eczema..*

MRI Compatibility: ITL Dental's implants, abutments, and healing caps are manufactured of titanium alloy which are paramagnetic and MRI conditional, based on literature and non-clinical testing and unlikely to interfere with patient safety. Magnetic dispacement of components of the ITL Dental implants have been shown in scientific articles to be less than the force exerted on the device by gravity, and RF heating leads to a maximum temperature rise below the heat-pain threshold of 8C-10C, not taking into account the cooling effect of surrounding tissue and blood flow. Note: As there are a variety of MRI scanners available on the market, ITL Dental cannot make any predictions regarding the safety of behavior of our implants therefore patients should consult with their physician and imaging technician prior to undergoing an MRI procedure.

Important: Please report to ITL Dental and appropriate government agency, any serious incident that occurs regarding usage of any devices associated to the dental implant system.

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