

IMPLANT

Instructions for Use

WARNING: R_X ONLY Implants are to be placed only by dentists, doctors or operators trained in the use and placement of dental implants. Dental implants to be used by prescription only.

Disclaimer of Liability: The users of implant products must determine whether or not a particular product is suitable for a particular 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 Dental 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.

1] **Indications For Use:** The ITL Dental implant is indicated for single tooth replacement of mandibular, central, and lateral incisors and maxillary lateral incisors. It is also indicated for multiple tooth replacements or denture stabilization. It is also indicated for the support and retention of fixed single or multiple tooth dental prosthesis. The implant is indicated for the support and retention of bar overdentures or as a terminal or intermediary attachment for screw retained fixed bridgework.

2] **Contraindications:** Include but are not limited to: hypersensitivity and/or an allergic reaction to the material (titanium alloy,) uncontrolled diabetes, clotting disorders, anticoagulant therapy, metabolic bone disease, chemotherapy or radiation therapy, chronic periodontal inflammation, insufficient soft tissue coverage, metabolic or systemic disorders associated with wound and/or bone healing, use of pharmaceuticals that inhibit or alter natural bone remodeling, any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene.

3] **Oral Contraindications:** Include but are not limited to: uncontrolled parafunctional habits (e.g. bruxing, clenching, gnawing), insufficient height and/or width of bone, 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. Implants are intended for single-use only. ITL Dental takes no responsibility whatsoever for resterilized dental implants regardless of the individual performing the resterilization or the method used for resterilization. Resterilization could result in surgical rejection and/or post-operative infection. If original packaging is compromised or seal broken, ITL Dental will not accept the contents for return.

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-height and width 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

- *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 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.*
- *Instructions:*  Users are advised to consult packaged instructions for use for assistance.
- *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: While it is up to the clinician to determine a patient's suitability for MRI imaging, ITL Dental's implants are made from titanium, a paramagnetic material that is not affected by the magnetic field of an MRI.*

Manufactured by:

ITL Dental
31 Peters Canyon
Irvine, CA 92606 USA
www.itldental.com

EU Representative:

EUCEREP
Roald Dahllaan 33,
5629MC Eindhoven,
The Netherlands

