Instructions for Use

Warning
The following instructions alone are not sufficient to allow for immediate use of the IMTEC OSI MDI Implant System. Knowledge of dental implantology and instruction in the handling of the IMTEC OSI MDI Implant System provided by a clinician with relevant experience are always recommended.

Disclaimer of Liability
This product is part of the IMTEC OSI MDI Implant System and may only be used in conjunction with the corresponding original components and instruments according to IMTEC Corporation instructions and recommendations. Use of products and tools made by third parties detracts from the efficient functioning of the MDI Implant System and void any warranty or other obligation, expressed or implied by IMTEC Corporation. Advice on the use of our products is provided verbally, in writing, by electronic media or in demonstrations. It does not relieve the user of IMTEC products of the responsibility of determining whether any product is suitable for the intended purpose, indications and procedures. Unintended use of this product is not within the control of IMTEC Corporation. It is the responsibility of the user. All liability for loss or damage attributable to the use of this product is excluded. Within the framework of the Conditions at Sale and Delivery of IMTEC Corporation, we warrant the quality of the MDI Implant System.

Availability
Some items in the MDI Implant System may not be available in all countries.

Description
IMTEC OSI MDI Implant System is a root form endosseuous dental implant with a gingival collar. It is fabricated from biocompatible titanium alloy, Grade 5 (Ti6Al4V) per ASTM F136. MDI implants are available in lengths of 10 to 18 mm and diameters of 3.0mm, 3.5mm, 4.0mm and 4.5mm. The surface is treated with resorbable blast media, which is sandblasted, acid etched to increase the surface area. Inclusive in the MDI Implant System are metal housings, o-rings, prosthetic and laboratory components and surgical and prosthetic instrumentation for the placement and restoration of MDI implants. Metal housings, laboratory components and instrumentation are fabricated from titanium alloy, stainless steel and a variety of polymers.

Figure 1
30XX-MOB (shown)
35XX-MOB (shown)
40XX-MOB
45XX-MOB

Indications
- The OSI O-Ball Abutment implant is a self-tapping titanium threaded screw indicated for long term intra-bony fixation of upper and lower dentures in edentulous cases. These devices will permit immediate splinting and ability and short-term fixation of failing crown and bridge installations, for full or partial edentulism. They can be used in the anterior regions of the maxillary and mandibular arches and are indicated for immediate loading when there is good primary stability and appropriate occlusal load. 510K Summary – K110548

Contraindications
IMTEC OSI MDI implant should not be placed if there is insufficient alveolar bone width and height to surround the implant. The implant should not be immediately loaded unless a minimum of 35 Ncm of resistance is met upon insertion. A minimum of .5 mm of bone wall thickness is necessary to ensure optimal performance. Possible additional contraindications are:
- serious internal medical problems
- bone metabolism disturbances
- uncontrolled bleeding disorders
- inadequate wound healing capacity
- poor oral hygiene
- poor general state of health
- maxillary and mandibular growth not completed (Ex: Pediatric patients)
- uncooperative, unmotivated patient
- drug or alcohol abuse
- psychosis
- prolonged therapy-resistant functional disorders
- xerostomia
- weakened immune system
- illness requiring periodic use of steroids
- titanium allergy
- uncontrollable endocrine disorders
- inadequate bone to achieve desired outcome

Relative Contraindications
- previously irradiated bone
- diabetes mellitus
- anticoagulation drugs
- hemorrhagic diatheses
- bruxism
- parafunctional habits
- unfavorable anatomic bone conditions
- tobacco abuse
- excessive alcohol use
- uncontrolled periodontitis
- temporomandibular joint disorders
- treatable pathologic diseases of the jaw and changes in the oral mucosa
- inadequate oral hygiene

Local Contraindications
- inadequate bone volume and/or quality
- local root remnants
- patients where adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.

Principles of Treatment Planning
The surgical part of implant treatment must be preceded by a comprehensive patient evaluation, preoperative diagnostics and therapy planning. Poor patient selection or Inadequate treatment planning may cause implant failure as well as case failure.

General Precautions
1. One hundred percent implant success can never be guaranteed. Patient motivation is a key factor in achieving success with any implant.
2. Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulation.

Warning: MAGNETIC RESONANCE IMAGING (MRI)
The MDI implant has not been evaluated for safety and compatibility in the MRI environment. The MDI implant has not been tested for heating or migration in the MRI environment.

Precautions Pre-surgery
1. A careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient.
2. Special attention should be given to patients who have localized or systemic factors that could interfere with the healing process of either bone or soft tissues or the osseointegration process (e.g., cigarette smoking, uncontrolled diabetes, oral-facial radiotherapy, steroid therapy, infections in the neighboring bone and excessive alcohol consumption).
3. In general, implant placement and prosthetic design must accommodate individual patient conditions.
4. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Precautions at Surgery
1. Proper handling and use of instruments and components is essential.
2. Drivers, instruments and other components should be sterilized prior to use (See "Sterility & Packaging).
3. Inspect instruments and components prior to use for deterioration. Worn instruments and drivers may cause damage to the implant which can impede implant advancement, strip abutment or lock driver onto implant.

4. Lack of adequate bone quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, and/or after osseointegration is initially achieved.
5. Besides routine precautions for any surgery, one must proceed with caution when drilling in the jawbone and one must avoid damage to nerves and vessels by referring to anatomical knowledge, preoperative radiographs and CT scans.
   Warning: Failure to recognize actual lengths of drills relative to radiographic measurements or drilling beyond the depth intended can result in permanent injury to nerves or other vital structures, potentially resulting in permanent numbness to the lower lip and chin or leading to hemorrhage in the floor of the mouth.
   Caution: A clinician should drill no closer than 1mm to any anatomical structure.
6. Caution should be exercised when selecting implants with lengths greater than 15 mm. longer implants are best suited for bicortical stability placed in Type III or Type IV bone regions. Implants longer than 15 mm are sometimes required to meet bicortical stabilization.
7. Take all provisions necessary to avoid patient ingestion and/or aspiration of components and instruments.

Warning: Side-effects & Interactions, Complications

Possible complications following insertion of dental implants are:

Temporary symptoms

- pain
- swelling
- phonetic difficulties
- gingivitis

More persistent symptoms

- chronic pain in connection with implant
- permanent paresthesia
- dysesthesia
- loss of maxillary/mandibular ridge bone
- localized or systemic infection
- unfavorably affected adjacent teeth
- irreversible damage to adjacent teeth
- fractures of the implant, jaw, bone or prosthesis
- esthetic problems
- nerve damage
- loss of soft tissue volume
- hyperplasia

Adverse events

- Loss of bone due to peri-implantitis, local or systemic infection.
- Biologic or mechanical failures including implant mobility, fatigue fracture of implants, bent or broken implants.
- Failure to osseointegrate.
- Perforation of maxillary sinus, inferior alveolar canal, lingual artery and other boney and/or soft tissue.
- Labial or lingual plate fractures.
- Nerve damage such as parasthesia or hypersthesia.

Necessary: Dental personnel should provide patient education regarding complications and adverse events as well as preventative maintenance such as abstinence from smoking, avoiding excessive alcohol and practicing good dental hygiene.

Surgical Procedures

1. Implant length and diameter should be selected according to radiological examination prior to surgery.
2. Place implants at least 7 mm mesial from the mental foramina and a minimum of 5 mm between each implant to allow for metal housings. Consideration of sinuses should be made for maxillary cases.
3. The entire implant should be surrounded by at least 1 mm of bone and implant threads should engage bone for the whole length of the implant threads.
4. Take an occlusal bite registration prior to anesthetic.
5. Mark entry points for each implant on the patient's tissue with a surgical marker.
6. Follow standard aseptic guidelines to prep the patient. Infiltrate each entry site buccal/lingual with appropriate anesthetic.
   Warning: An inferior alveolar nerve block is not recommended. It is important the patient has the ability to acknowledge implant infringement on the mental foramina.
7. Use a tissue punch to remove gingiva to the cortical bone.
8. For mobile mucosa, a tissue punch approximately .5mm smaller than diameter of implant is recommended.
9. Using a 1.2 mm Surgical Drill, lightly pump up and down over the entry point until the cortical plate is penetrated.
10. Proceed with the appropriate drill according to the "Recommended Drilling Sequence" (Figure 2 & Figure 3) to create a pilot hole for implant placement.

Figure 2
Recommended Drilling Sequence for 3.0 and 3.5 mm MDI

Bone Type	Implant	Tissue Punch	Marking Drill	Drill 1.2mm	Drill 1.5mm	Drill 2.5mm
Type – II	3.0mm	2.5mm	X		X	X
Type – III	3.0mm	2.5mm	X	X		X
Type – II	3.5mm	3.0mm	X		X	
Type – III	3.5mm	3.0mm	X	X		X

Figure 3
Recommended Drilling Sequence for 4.0 and 4.5 mm

Bone Type	Implant	Tissue Punch	Marking Drill	Drill 1.2mm	Drill 1.5mm	Drill 2.5mm
Type – II	4.0mm	3.0mm	X		X	X
Type – III	4.0mm	3.0mm	X	X		X
Type – II	4.5mm	3.0mm	X		X	X
Type – III	4.5mm	3.0mm	X	X		X

MDIAs a general rule, the depth should not exceed one-third to one-half the threaded length of the chosen MDI. The desired depth is the minimal amount that allows one to begin the auto-advancement of the implant into bone.
NOTE: Type IV (extremely soft bone) is not recommended for implant placement.

11. Bone quality needs to be considered when drilling.
    Caution: Drilling must proceed with high speed, 1200 to 1500 rpm with external irrigation using sterile saline.
12. After drilling pilot hole use sterile gloves to firmly grasp the implant carrier included with the implant prior to opening the pouch. Holding the implant carrier secure, open the implant packaging and transfer the implant directly from the packaging into the pilot hole using the implant carrier.
13. Applying light pressure, turn the implant carrier clockwise with downward pressure until the implant is securely seated in the pilot hole. Remove implant carrier.
14. Position the operator's fingers supportively under the patient's jaw, the thumb over the top of the Continuous Feedback Torque Wrench applying downward force upon the axis of the implant.
15. Using a 1/4 turn rotation with 2 to 3 second pause will reduce the frictional heat that may be detrimental to the health of the bone. This pause allows the bone to expand during advancement of the implant.
16. Final depth of the implant should meet a resistance of **35 Ncm** or greater **not to exceed 45 Ncm.**
    Caution: Avoid maximum torque when placing the implant as this increases the chance of necrosis of bone. Overtorqueing an implant may cause damage to the implant and fracture or necrosis of the bone site.
17. The ideal placement allows the abutment head to protrude from the gingival soft tissue at its full length. The smooth collar should be embedded in the gingiva with no threaded portions visible.
18. Placing implants at angles greater than 25° will result in being unable to place the o-ball into the metal housing in the denture. Parallel implants improve engagement of the metal housings which lessens wear on the system.
19. Caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.
    Warning: Over angulation of biting forces on the implant could fracture implant at the bone level.
20. Repeat procedure for each implant.

Prosthetic Procedure

1. Use an acrylic bur to relieve the denture where there is sufficient clearance for the selected metal housing.
2. Cut the appropriately sized **Blockout Shim** and place over the o-ball head of implant. Continue to slide the shim down over the square portion of the implant. **IMPORTANT:** The metal housing must not interfere with the denture when patient bites firmly. Test the denture intra-orally to confirm seating of the denture while in centric relation.
3. The metal housing must snap on o-ball head and still easily rotate with the blockout shim attached.

4. Apply petroleum jelly to all areas of the denture to be protected from bonding of **JUELL Cure** material. Follow reline material instructions.
5. Fill the relieved area of the denture with **JUELL Cure - Hard** reline material. If not using metal housings, then reline the denture with **JUELL Cure -Soft** over the implants.
6. Place the denture back in the patient's mouth and instruct patient to close bite gently. **IMPORTANT:** If blockout shim is not in place, the denture may be more difficult to remove or lock-on completely.
7. Allow 7 to 9 minutes for **JUELL Cure - Hard** to fully cure.
8. Remove, clean, trim flash and fill acrylic voids with reline material.
9. Finish denture borders, remove flash material and polish to a high luster.

Warning: Always use Blockout shims during any soft or hard reline or pickup procedure to avoid locking denture onto the implants. If sutures are used during implant placement, a rubber dam should be used for reline procedure instead of blockout shims.

10. Inform patient of post-op and maintenance instructions.

NOTE: Occasional adjustments to the patient's denture maybe required in cases of bone resorption or general wear to avoid overloading implants.

Replacing Metal Housing O-rings

1. Use a dental explorer to remove worn o-ring from metal housing.
2. Insert an o-ring into the metal housing and push into place with a ball burnisher.

Sterility & Packaging

IMTEC OSI MDI mini dental implants are delivered sterile. The intact sterile packaging protects the gamma-sterilized implant from outside influences and, if stored correctly (see "Storage and Use" section), ensure sterility up the expiration date. Do not open sterile packaging until implant is ready for immediate insertion.

Warning: Implants with damaged sterile packaging must not be used due to the risk of contamination. It is recommended to have a replacement on hand. Do not re-sterilize or re-use implants. Do not use implants after sterilization expiration date.

- Tissue punches, drills and implants are for single use only.
- Do not re-sterilize, re-use or autoclave products labeled "**SINGLE USE ONLY**".
- Instruments are provided non-sterile and should be sterilized prior to use according to their IFU.
- Clean and sterilize non-disposable instruments according to their IFU.

Storage & Use

- When removing the implant from the sterile packaging, the rules of asepsis must be observed.
- Store sterilized devices in a dry and dust-free environment.
- Sterilization can only be preserved if devices remain packaged, impermeable to microorganisms, following a validated process.
- Do not use implant after sterilization expiration date.
- Keep sterile and non-sterile products separate.
- This device should be observed for deterioration. In the event of a defect, return to IMTEC Corporation. Do not use.
- Only use sterile powder-free gloves to avoid contaminating the product.
- The titanium alloy used to manufacture StarVent implants is not magnetic and thus should be acceptable for MRI procedures. However, it is important that patients advise the medical professional about the presence of dental implants prior to imaging to ensure compatibility with the MRI equipment and to address potential artifacts, depending on the area of imaging.

Customer Information

No person is authorized to provide information which deviates from the information within this document.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

Warranty

IMTEC Corporation warrants this product to be free of defects for a period of one (1) year from the purchase date. At its option, IMTEC will replace or refund the purchase price of this device, to the original purchaser, for returned items due to defects in material and workmanship. If a defect is found in a product, the product should not be used. This warranty covers only the cost of the product, and not clinical and professional fees associated with the use of the product.

Limitation of Liability

IMTEC Corporation is not liable for any damage due to changes made to the product by the user. It is the manufacturer's intention that the product be utilized in a manner that has been submitted to the appropriate governing regulatory bodies. The user is responsible for determining the suitability of the product for its intended application.

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Labeling Identification	
	Symbol for Legal Manufacturer
	Symbol for Catalog Number
	Symbol for Lot Number
 Do Not Reuse	Symbol for Do not re-use
	Symbol for Sterile product
	Symbol for Expiry date