EN Instructions For Use

MIS Implants

Users must be licensed dentists/physicians, trained in implant dentistry and should be familiar with MIS Implant Systems.

INDICATIONS FOR USE

MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.30mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.

INTENDED USE

MIS implants are intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.

DEVICE DESCRIPTION

The MIS Implant Systems are designed for replacing one or more missing teeth in patients to restore chewing function and/or aesthetics. The patient target groups are persons with adult jaws to whom none of the contraindications apply that are related to dental implantations. MIS implants are self-tapping, root form, two-piece, screw-type dental implants made of titanium alloy. In addition, MIS non-circular implants feature flat surfaces at the neck area of the implant. MIS dental implants are manufactured from biocompatible titanium alloy, 90% Ti, 6% Al, 4% V per the ASTM F136 standard, with a sand-blasted and acid-etched surface.

MIS wet packed (CLEAR) implants: the MIS surface is preserved super-hydrophilic by storage in NaCl solution. It is recommended to use MIS CLEAR implants within 15 minutes upon their removal from the liquid package.

MIS Implants are delivered with the following sterile components inside their package:

- MIS C1 implants are provided with a cover screw, final drill and plastic temporary abutment.
- MIS V3 implants are provided with a cover screw and final drill.
- MIS SEVEN implants are provided with a cover screw and final drill.
- MIS M4 implants are provided with a cover screw.
- MIS LANCE implants are provided with a cover screw and mount/ transgingival abutment.
  - The mount is assembled to the implant by a prosthetic screw.
  - The implant is removed from the package and placed in the osteotomy using the mount.
  - The mount can be further used as an impression coping or a transgingival abutment, or it can be removed from the implant.

For the IFU of the components provided with the implants, please see:

- Cover screws: MP-UIHCS
- Plastic temporary abutment: MP-UITEM
- Transgingival abutment: MP-UICPK

The IFU's can be found at https://ec.europa.eu/tools/eudamed

Component	Sterilization	Materials	Torque(Ncm)
Abutments	Non sterile	Ti6Al4V ELI	30-35
Cover screw	Sterile	Ti6Al4V ELI	15-20
Healing cap	Sterile	Ti6Al4V ELI	20-25
Temporary cylinders	Non sterile	Ti6Al4V ELI	20-25
Gold-plastic cylinders	Non sterile	Gold/POM	20-25
Impression coping	Non sterile	Ti6Al4V ELI	20-25

A summary of the safety and clinical performance (SSCP) for the implantable products of the MIS Implant Systems can be found under https://www.mis-implants.com.

STERILIZATION

MIS implant package contents are sterilized by gamma irradiation.

IMPORTANT

MIS implants are to be used in combination with cover screws, healing caps, standard abutments, including up to 25° angulated abutments and additional abutments for prosthetic reconstruction. It is highly recommended to use only original MIS prosthetic parts with MIS implants. Using prosthetic parts which are specifically produced for MIS implants, ensures maximum compatibility and accuracy. The use of incompatible components may cause fitting issues, reduction of fatigue strength, damage to the implant, and may also impair the long-term success of the implant-supported prosthesis. The use of a compatible MIS Surgical Kit is recommended. Dental professionals should follow acceptable placement and loading protocols, and should ensure achievement of good primary stability and appropriate occlusal loading when an immediate loading procedure is considered. During the preoperative 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 blood vessels, nerves, the mandibular canal, maxillary sinuses, soft tissue spaces and adjacent teeth. Recommended implant insertion torque: 35-60Ncm. Avoid excessive force when placing the implant into the osteotomy.

CONTRAINDICATIONS

Dental surgeons performing dental implant placement procedures must have the knowledge and capability to evaluate the patient's general health status, as well as the patient's local clinical condition, and decide based on their own sound judgment whether the benefits of the planned procedure outweigh the risks of performing it.

All contraindications prevalent in oral surgery, apply in cases of an implant placement procedure. The practitioner is obligated to obtain the patient's complete and up-to-date general health condition, including any medication taken, and to consult the patient's physician regarding the possible effects of undergoing the surgical procedure while using these medications. In cases where there is a need to discontinue using certain medication before the surgical procedure, it is highly advised to consult with the patient's physician and obtain their agreement.

1. Patients with active osteolytic lesion, an inflammatory or infectious process in the implant site.
2. Patients who are unable to understand the proposed surgical procedure and give a written, conscious consent for the treatment.
3. Known hypersensitivity, or past allergic reaction to component or material which is intended to be used.
4. Patients who are unstable hemodynamically and are at risk for uncontrolled bleeding due to surgical procedure. This pertains to both medical conditions like hemophilia, and for patients under treatment with anticoagulant medications like aspirin, clopidogrel (Plavix), warfarin (coumadin), and NOAC.
5. Patients who have a chronic health condition that is unstable and/ or uncontrolled at the time of planning the implant placement. This includes patients with unstable and/or uncontrolled diabetes, unstable and/or uncontrolled cardiac conditions, unstable and/or uncontrolled blood pressure values, unstable and/or uncontrolled epileptic seizures, unstable and/or uncontrolled respiratory and lung diseases, unstable and/or uncontrolled kidney diseases that may present with abnormal laboratory values for BUN, creatinine or serum calcium, unstable and/or uncontrolled parathyroid function, unstable and/or uncontrolled osteoporotic condition, patients with organ transplant with unstable and/or uncontrolled status, patients with unstable and/or uncontrolled psychiatric disease. In addition, any other chronic medical condition which is in unstable and/or uncontrolled status at the time planned for the implant placement procedure.
6. Patients who have been diagnosed and/or are being treated for neoplasms and/or cancerous diseases, and are exposed to chemotherapy treatments, radiation treatments or biological treatments for the illness.
7. Patients suffering from different genetic hereditary syndromes that affect the integrity of connective tissues and wound healing, like Ehler-Danlos syndrome.
8. Conditions, diseases, medications or treatments which severely compromise the immune system and healing process, such as continual usage of corticosteroids.
9. Patients treated with medications from the bisphosphates group, either in high dosage for bone metastases, or for different conditions of osteoporosis may suffer from post treatment bone necrosis. The use of these medications must be stopped prior to the surgical procedure. An endocrinology consultation is mandatory.
10. Recent myocardial infarction (< 3 months)
11. Recent cerebrovascular accident.
12. Recent cardiac-valvular prosthesis placement.
13. Hemorrhagic diathesis.
14. Immunosuppression.
15. Active treatment of malignancy.
16. Severe liver dysfunction.
17. Florid infection.
18. Drug abuse.
19. Psychiatric illness.
20. Intravenous bisphosphonate use.

RISKS

Implant placement procedure is a surgical procedure performed in the oral cavity, and as such, the patient is exposed to all the risks of intraoral surgical procedures. Patients must be informed of all potential risks and provide a conscious, written consent for the procedure.

- Intraoperative risks: events which may occur during the surgical procedure (disregarding their probability and severity): local anesthetic complications, bleeding including uncontrolled perforation of the nasal and maxillary sinus, perforation of soft tissue spaces, nerve injuries, perforation of bone plates, perforation of adjacent teeth, difficulties with stabilization of the implant in its osteotomy, components in the patient's mouth may be swallowed or aspirated, immediate implant dislocation in the maxillary sinus, perforation of the maxillary sinus, mandibular base, lingual plate and the inferior alveolar canal, immediate fracture of the jaw bone .
- Short term post-operative risks (disregarding their probability and severity): pain, speech difficulties, intra oral and/or extra oral swelling, local and/or systemic infection, nerve injuries, acute sinus congestion and inflammation, penetration of an implant to body cavities or anatomical structures that requires a surgical procedure in order to remove it (such as penetration of an implant into the sinus cavity), necrosis due to inadequate cooling or excessive torque, suture dehiscence or hematoma.
- Long term post-operative risks (disregarding their probability and severity): irreparable nerve damage, chronic sinus congestion and inflammation, infectious endocarditis in susceptible individuals, delayed implant dislocation into the maxillary sinus, delayed fracture of the jaw bone, delayed loosening after ingrowth/implant loss due to insufficient osseointegration, implant breakage, peri-implantitis, periodontal problems due to inadequate width of attached soft tissue, esthetic or functional complications.
- Allergic or hypersensitivity reactions to materials used.
- Bone loss as a result of peri-implantitis or mechanical overload.
- Fracture or damage of implants , healing components, prosthetic components or prosthesis.

Implant placement is a common surgical procedure, which has been vastly documented as reliable, with predictable and high success rates. Nonetheless, there are cases where the dental implant doesn't integrate with the surrounding bone and must be removed and replaced. The probability of these occurrences, according to existing dental literature, may be up to 5% in the general, healthy population.

There are several, known conditions which may compromise the immediate and long-term success of implant placement:

1. Cigarette smoking. Cigarette smoking affects short and long-term success and survival rates of dental implants. It is highly advised to quit smoking prior to implant therapy.
2. Uncontrolled diabetes or other metabolic illness. It is highly recommended to insure the best achievable blood sugar levels while performing implant therapy.
3. Uncontrolled and/or untreated periodontal disease. It is highly recommended to undergo anti-infective periodontal treatment and to ensure low (as-possible) levels of infection and inflammation in the surrounding periodontal tissues prior to implant therapy.
4. Patient's self-performed oral hygiene habits and professional periodontal maintenance. Meticulous patient oral hygiene of the tissues surrounding the dental implants increases the probability of long-term success rates of dental implants. It is advisable to place a patient undergoing implant therapy on a maintenance and recall program.
5. Local anatomical conditions which impair the possibility of achieving primary stability for the implant (e.g. bone deficiency, low bone density).
6. Local anatomical conditions that pose an eminent risk of damaging important anatomical structures (e.g. nerves, blood vessels, sinus, teeth etc.).

IMPORTANT WARNING

- Lack of adequate training of the practitioner is a major risk factor for the success of the implant procedure, and may endanger patient health. Therefore, no implantation shall be performed without prior adequate training by a certified institute.
- Use of MIS 18 & 20mm implants requires extra caution in proximity with anatomical structures.
- MIS implant systems have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the MIS implant systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Small diameter implants and angled abutments are not recommended for the posterior region.
- Inform us and your competent authority in the case of notice of life threatening incidents or a severe deterioration in health status related to one of our products.

PRECAUTIONS

- MIS wet packed (CLEAR) implants: prior to opening the implant's primary outer tube package, please verify that the implant in the inner tube is immersed in fluid.
- Improper patient selection/analysis or failure to comply with the step-by-step instructions can lead to failed osseointegration or loss of osseointegration.
- Fracture or damage of implants, healing components, prosthetic components or prosthesis requiring removal and replacement of an implant may occur due to unfavorable loading conditions.

Mastication forces and restoration design must therefore be evaluated carefully.

- Routine implant treatment is not recommended until the end of the jaw bone growth and for pregnant women.
- Bone quality and quantity, local infections, disturbed initial healing or premature loading are all factors, which may influence implant survival. Successful healing and osseointegration may be negatively affected by the following factors:
  - Inflammations (e.g. periodontitis), tumors, abscess or cysts in the jaw area.
  - Insufficient height and/or width of bone.
  - Insufficient soft tissue coverage.
  - History of therapeutic radiation in the area.
  - Autoimmune diseases.
  - Uncontrolled para-functional habits (e.g. bruxism)
  - Inadequate oral hygiene.
  - Alcohol abuse.

CAUTIONS

- Do not use MIS implants if the package is damaged, after expiration of the sterilization date or if the seal of the external tube is damaged or missing.
- Do not use additional components supplied in the implants package if the package is damaged or after expiration of the sterilization date.
- For products packed in a pouch: Check for the existence of package defects such as tears; visually inspect the sealed area of the pouch for completeness and uniformity, or unsealed areas such as channels.
- The implant and other sterile components inside the implants package are supplied for one time use. DO NOT RE-STERILIZE and do not reuse implant and additional components packed with the implants. Reuse Prohibition: MIS strictly specifies that dental implants and additional components in the implants package are for single use only, and should never be reused. Reuse can cause infections, bone resorption, hard and soft tissue damage and/or implant failure. Implant success and osseointegration was found to be directly related to the cleanliness of the implant surface, lack of any biological or other contaminants on the surface and level of sterility.
- Use of implant may require preoperative antibiotic prophylaxis.
- No additional surface treatment should be carried out on MIS implants.
- The implant must be stored in its original packaging, protected from direct sunlight and at room temperature to maintain package integrity.
- Do not exceed the maximum drilling speed. Ensure sufficient irrigation of the drill. Minimizing trauma to the bone and surrounding tissue enhances the potential successful osseointegration.

INSTRUCTIONS FOR OPENING DOUBLE TUBE CONTAINING AN IMPLANT

1. Open the outer tube by turning the cap counter-clockwise. Drop the sterile inner tube into the sterile field.
2. To expose the implant, hold the inner tube facing up. Rotate and pull to open the cap.
3. Connect a sterile matching insertion tool to a contra-angle (for motor insertion tools) or a ratchet (for manual insertion tools). Use the assembly to lift the implant from the inner tube.
4. A cover screw is supplied in the inner tube cap. For removing, lift it with a sterile screwdriver.

INSTRUCTIONS FOR OPENING A STERILE POUCH CONTAINING A FINAL DRILL

1. Hold the pouch with the ISO shank of the drill facing up.
2. Tear the pouch at the lower opening cuts to open the pouch.
3. In order to prevent surface contamination of the drill blades, hold the drill still in the pouch, connect the contra-angle to the ISO shank of the drill.
4. Lift the drill from the pouch by pulling the contra-angle up.
5. Discard the pouch.

DISPOSAL

For disposal of the packaging and components, comply with the currently applicable national waste disposal regulations in your country.

LIMITED WARRANTY

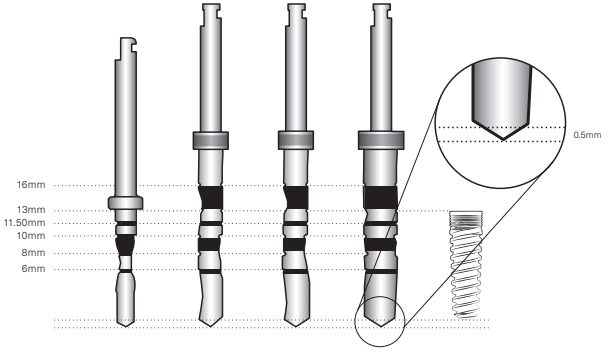
In case of implant failure, MIS undertakes to replace such implant unit, free of charge, subject to the following conditions: A written notice of such failure is submitted to MIS, no later than within 6 months of first sign indicating such failure, accompanied by a follow-up report in a form issued by MIS, the relevant X-Ray and the failed implant. This is the complete warranty for the implant by MIS, setting forth specific drug treatments indicated for implantation.

For further details about the indications and handling of MIS dental implant systems, please refer to MIS literature; (catalog, user guide, research, etc.).

KEY TO CODES USED

MD	Medical device	LOT	Batch code
	Single sterile barrier system	REF	Catalog number
	For instructions for use and symbols glossary refer to: http://ifu.mis-implants.com		Manufacturer
	Do not reuse		Date of manufacture
STERILE R	Sterilized using gamma irradiation		Keep away from sunlight
NON STERILE	Do not resterilize		Do not use if package is damaged
	Use by date		Caution, consult accompanying documents
	Importer	Rx only	Caution: U.S. federal law restricts this device for sale by or on the order of a dental professional.

GEOMETRICAL DIFFERENCE BETWEEN THE DRILL TIP AND THE IMPLANT



MIS IMPLANTS RECOMMENDED DRILLING SEQUENCE

MIS C1

RPM	Type of Bone*	Implant Diameter			
		Ø3.30	Ø3.75	Ø4.20	Ø5
1200-1500	-	Marking Drill			
900-1200		Pilot Drill Ø2.40			
500-700		-	Step Drill Ø3		
400-700		-	-	Step Drill Ø3.50	
400-600		-	-	-	Step Drill Ø4
200-400	1&2	Final Drill			

MIS V3

RPM	Type of Bone	Implant Diameter			
		Ø3.30	Ø3.90	Ø4.30	Ø5
1200-1500	-	Marking Drill			
900-1200		Pilot Drill Ø2.40			
500-700		-	Step Drill Ø3		
400-700		-	-	Step Drill Ø3.50	
400-600		-	-	-	Step Drill Ø4
200-400	1&2	Full Length Final Drill			
200-400	3&4	Half Length Final Drill			

MIS SEVEN

RPM	Type of Bone*	Implant Diameter				
		Ø3.30	Ø3.75	Ø4.20	Ø5	Ø6
1200-1500	-	Marking Drill				
900-1200		Pilot Drill Ø2.40				
500-700		-	Twist Drill Ø2.80			
400-700		-	-	Twist Drill Ø3.20		
400-600		-	-	-	Twist Drill Ø4	
300-500		-	-	-	-	Twist Drill Ø4.50
300-500		-	-	-	-	Twist Drill Ø5
200-400	1&2	Final Drill				
200-400	3&4	N/A	Countersink			

MIS M4

RPM	Type of Bone*	Implant Diameter				
		Ø3.30	Ø3.75	Ø4.20	Ø5	Ø6
1200-1500	-	Marking Drill				
900-1200		Pilot Drill Ø2.40				
500-700		Twist Drill Ø2.80				
400-700		-	Twist Drill Ø3.20			
400-600		-	-	Twist Drill Ø3.80		
300-500		-	-	-	Twist Drill Ø4.50	
300-500		-	-	-	-	Twist Drill Ø5
300-500		-	-	-	-	Twist Drill Ø5.50
200-400	3&4	Countersink				

MIS LANCE (External)

RPM	Type of Bone*	Implant Diameter			
		Ø3.30	Ø3.75	Ø4.20	Ø5
1200-1500	-	Marking Drill			
900-1200		Pilot Drill Ø2.40			
500-700		Conical Drill Ø3.10			
400-700		-	Conical Drill Ø3.65		
400-600		-	-	Conical Drill Ø4.10	
400-600		-	-	-	Conical Drill Ø4.90
200-500	3&4	Countersink			

* Bone type: Type 3&4 = Soft bone. Type 1&2 = Hard bone.

MIS Implants Technologies Ltd.
P.O.Box 7, Bar Lev Industrial Park,
2015600, Israel
Website: www.mis-implants.com

CE 0483

Dentsply Sirona Europe GmbH
Sirona Straße 1,
5071 Wals bei Salzburg, Austria