msdi

Implants Instructions for Use

This document applies to MSDI Dental Implants (Alef, Til, Conix).
All MSDI products are intended to be used by appropriate trained and licensed professionals.
A warned and formed practitioner to implantable technics should always perform MSDI Dental Implant system placement. The absence of practitioner's adequate training induces a major risk for the success rate of dental implants and can even compromise the state of general health of the patient

Indication for use:
MSDI Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support or prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.
It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

A summary of the safety and clinical performance (SSCP) for MSDI Dental implants can be found at: msdi-dental.com/report/sccp.

Description:
MSDI Dental Implant system is a high-technology system which uses the properties of self-tapping implants.
MSDI implants manufactures dental implants and restorative components from biocompatible titanium alloy 6AL4VELI.
MSDI implants' connection is internal hexagonal connection (Alef, Til) or internal conical connection (Conix). To ensure compatibility, only MSDI abutments and tools should be used in conjugation with MSDI implants.
For specific product description, please refer to individual product packaging labels.

All systems (Alef, Til, Conix) are intended for surgical restorative applications for placement in the bone of the upper and lower jaw, to provide support for prosthetic devices, such as artificial teeth.
All 3 systems make use of the very same basic design consisting of full-body, threaded, self-tapping Titanium implants.
All 3 are surface-treated to increase bone-implant interface, and hence facilitate osseointegration.

The Alef is more suitable to soft bone due to: the conical outer shape, the 2.4mm x 2 starts pitch (2.4mm depth in every round), the aggressive self-tapping feature and the trapeze thread profile.

The Conix Implant system is a high-technology system which uses the properties of self-tapping implants.
The connection is internal conical connection. To ensure compatibility, only MSDI Conical system abutments and tools should be used in conjugation with Conix implants.
Conix implants design consisting of full-body, threaded with micro rings at the cortical bone area, self-tapping Titanium implants.
The Conix is suitable to soft and dense bone due to: the conical outer shape, the 2.0mm x 2 starts pitch, the aggressive self-tapping feature and the Special trapeze with radius thread profile.

The Til Implant system is a Slim Platform, high-technology system which uses the properties of self-tapping implants.
The connection is internal hex connection (2.1mm with 90 Deg chamfer). To ensure compatibility, only MSDI Slim system abutments and tools should be used in conjugation with Til implants.
Til implants design consisting of full-body, threaded with micro rings at the cortical bone area, self-tapping Titanium implants for narrow area where ever you can't use the regular platform implants because of clinical limitations.
The Til is suitable to soft and dense bone due to: the narrow conical outer shape, the 2.1mm x 2 starts pitch, the aggressive self-tapping feature and the Special trapeze thread profile.

Contraindications:
General contraindication to oral surgery and jaws are applicable in case of dental implantation.
Applicable contraindications also include:
- The patients handled by radiotherapy or subjected to diverse immunosuppressive therapy. These treatments could be responsible in the reduction of the success rate of dental implants
- For bisphosphonate therapy and implant surgery, the duration, route, and the dosage of the medication, as well as the type of bisphosphonate are reported to play an important role in potential bisphosphonaterelated osteonecrosis of the jaws.
- The consumption of oral biphosphonates by patients who suffer from osteoporosis seems to be a partial contraindication for the treatment with dental implants and the patient must
- Understand the necessity of a longer follow-up period so as to detect any sign of bone chemical necrosis
- Risk is increased if the case of patients receiving treatment with ciclosporin, azathioprine or similar, corticoids or hormonal therapy, in this case it is an absolute contraindication.

The patients suffering from diabetes, cardiac and lung diseases also are to be watched. Dental implants will not be either placed in patients whose implanted site are under osteolytic, inflammatory or infectious activity.

Additional Contraindications:
- The consumption of tobacco seems to be a factor associated with the increase in the loss of dental implants; failure rate around 2.5 times higher in patients who smoke are reported.
- Processes, diseases or care compromising the therapeutic capacity (low motivation of the patient, psychiatric disorders preventing the patient from understanding and from interiorizing the necessity of implant placement, unrealistic expectations of the patient, impossible prosthetic reconstruction).
- Incapacity of the patient to manage his oral hygiene.
- Hypersensitivity of the patient in the specific components of the implant.

Secondary Effects:
The risks associated to this surgical operation can be divided into four categories:
1. Immediate risks related to the anaesthesia and the surgery procedure.
2. Risks related to psychological or psychiatric problems
3. Long-term medical complication
4. Permanent impact of the implant on the patient health

Among these possible risks, it is possible to indicate: drilled by the nasal cavity and by the maxillary sine, the local and systematic infection due to a breakthrough in the cavities of mild parts, reached by the nerve.
Temporary phenomena resulting from the insertion of the implant such as: pain, swelling, speech disorders and inflammation of the gums.
The following long-term problems can also appear: damaged nerve, local or systemic bacterial infection, infectious endocarditis in sensitive or post-transplantation individuals.
The incorrect placement of an implant can damage the natural set of teeth.

Warnings:
- MSDI Dental Implant system is used in association with specific related prosthetic parts manufactured by MSDI.
- These prosthetic parts must not be substituted by references not manufactured by MSDI.
- Any use of prosthetic material and/or ancillary not validated by MSDI pull de facto the loss of the manufacturer's guarantee.
- Invasive and implantable parts of the MSDI system are single-use devices and must not be reused. Any re-use of a single-use device induces a significant risk of infection for the user and the patient and a loss of the mechanical properties of the implants and the prosthetic parts. Re-use of implants may cause cross-contamination, infection and implant failure.
- All the implants are provided sterile. Do not re-sterilize implants. Re-sterilization of implants may cause cross-contamination, infection and implant failure.
- MSDI Implants 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 MSDI Implants 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 of the mouth.

Packaging:
- MSDI Dental Implant system is provided sterile (gamma sterilization) in unit package. A witness label affixed on the packaging indicates the actual passage of implants in irradiation. The sterility is guaranteed 5 years (from the date of sterilization).
- Only an intact packaging guarantees the sterility of the products. Do not use implants with damaged or prematurely opened package.
- Every packaging, besides the product reference, contains self-stick labels resuming all the specifications of the implant (cat number, lot number, sterilization, use by date, etc.) which are to be affixed on the patient file.
- Implants must be stored in a clean, dry, fresh and appropriate place.
- MSDI dental implants are single-use devices. Never reuse an extracted and/or rejected implant. The re-use and/or the re-sterilization of any implant can be at the origin of infectious disorders of the user and the patient.
- If tampering or damage exists contact your MSDI Representative.

Instruction for opening the implant package:
MSDI implants are delivered in sterile, sealed containers.

The implant is packaged in a tube placed inside a carton box. Open the carton box and take out the implant tube. Carefully open the tube by turning the cap counter-clockwise removing the implant from the sleeve, by gripping the implant driver.
The cover screw, located in the white cap, can be removed with a screwdriver by turning gently counter-clockwise.

After removal from its container place the implant on a sterile surface / tray, in order to maintain its sterility.

Patient Information:
The practitioner must inform the patient that the safety and/or the durability of the placement of an MSDI Dental Implant system are function of its activity and of the respect for the advice, which will have been given.
The practitioner will inform the patient of the potential unwanted effects consecutive to the dental implant placement (osseous split, infection, pains, bruise, oedema, temporary or permanent nerve damage, bleeding, oral drought, sinusitis). Patient's informed consent must be obtained before surgery.
It is recommended to inform patients that presence of implants should be reported to practitioners prior to MRI testing.

After dental implant placement, the patient will have to inform the practitioner of any sensation or modification appearing at the level of the implant.

Procedural Precautions:
All components must be checked before use.
The presence of the bone and its capacity to support the implant must be estimated from radiographies of the zone of implantation, according to the current techniques for the realization of false teeth.

Also it is necessary to study very carefully the location of blood vessels, maxillary sine, nasal cavity, cavities in mild parts, as well as their relation in the zone of setting-up.

Surgical Procedure:
1. Open the implant and cover screw case onto a sterile surface.
2. Disinfect the implant site
3. Marking the bone according to the planning of the established intervention
4. Preliminary drilling before the implant insertion: the insertion of the implant has to respect a surgical protocol including a sequence of drilling adapted to the clinical case and to the osseous criteria of the patient.
5. Insertion of the implant: do not exceed strength of 60N during the insertion of the implant
6. Screwing of the cover screw supplied with the implant or of a healing cap.

Caution: Federal law restricts this device to sale by or on the order of a dentist.

Explanation of Symbols:

	Use by date
REF	Catalogue reference
LOT	Lot number
	Do not re-use
	Caution, consult Accompanying documents
CE	Ce mark
	Manufacturer
	Date of manufacture
	Do not use if package is damaged
2 STERILIZE	Do not resterilize
UDI	Unique device identifier
MD	Medical devices
	Keep dry
	Keep away from sunlight
EC REP	Authorized representative in the european community
Rx Only	Caution: us federal law restricts this devices to sale by or on the order of a physician or dentist
STERILE R	Sterilized using gamma irradiation
	Single sterile barrier system

CE 0483

Manufacturer:
Medical Systems and Devices International Ltd.
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P.O Box 25414, Israel
Tel: 972-54-932-0515
E-mail: Omri@msdi-ltd.com

EC REP **Authorized Representative:**
MedNet EC-REP IIb GmbH,
Borkstrasse 10, 48163 Münster,
Germany

Recommended Surgical steps:

Alef:

Drill		ø2.00	ø2.50	ø2.80	ø3.20	ø3.65	ø4.20	ø5.20
Drill speed (rpm)		900-1200	900-1000	800-1000	500-700	400-700	400-600	400-600
Implant ø3.50	Soft Bone	○	○					
	Hard Bone	●	●	●	●*			
Implant ø3.75	Soft Bone	○	○	○				
	Hard Bone	●	●	●	●*			
Implant ø4.20	Soft Bone	○	○	○	○*			
	Hard Bone	●	●	●	●	●*		
Implant ø5.00	Soft Bone	○	○	○	○	○*		
	Hard Bone	●	●	●	●	●	●*	
Implant ø6.00	Soft Bone	○	○	○	○	○	○	
	Hard Bone	●	●	●	●	●	●	●

Til:

Drill		ø2.00	ø2.50	ø2.80
Drill speed (rpm)		900-1200	900-1000	800-1000
Implant ø3.00	Soft Bone	○		
	Hard Bone	●	●*	
Implant ø3.30	Soft Bone	○	○	
	Hard Bone	●	●	●*

Conix:

Drill		ø2.00	ø2.50	ø2.80	ø3.20	ø3.65	ø4.20
Drill speed (rpm)		900-1200	900-1000	800-1000	500-700	400-700	400-600
Implant ø3.50	Soft Bone	○	○	○*			
	Hard Bone	●	●	●	●*		
Implant ø4.30	Soft Bone	○	○	○	○		
	Hard Bone	●	●	●	●	●*	
Implant ø5.00	Soft Bone	○	○	○	○	○	
	Hard Bone	●	●	●	●	●	●*

* Drill through cortical plate only and up to 2/3 of drill length

** All measurements are in mm

*** The recommended drill protocol procedure should not replace the dentist's / surgeon's judgment.

IFU-IMP-EU Rev 09, Nov 2023