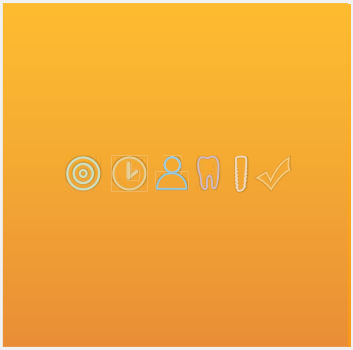
MP-U048 Rev1

MIS Implants Technologies Ltd.
www.mis-implants.com

MIS's Quality System complies with international quality standards: ISO 13485:2003 - Quality Management System for Medical Devices, ISO 9001: 2008 – Quality Management System and CE Directive for Medical Devices 93/42/EEC. MIS's products are cleared for marketing in the USA and CE approved.

User Manual

Always dedicated to the development of innovative products and technologies, MIS' scientists and engineers conduct continuous laboratory and field studies in collaboration with prestigious universities and dental research institutes. SEVEN is the innovative result of an extensive research and development process, offering a unique combination of surgical and restorative benefits.



Questions, comments or requests will be addressed promptly by contacting MIS specialists directly through our e-mailing address: service@mis-implants.com. MIS' website can be accessed at www.mis-implants.com. This online site highlights current products and reflects all new discoveries and developments.

Note: This User Manual is for educational use only.

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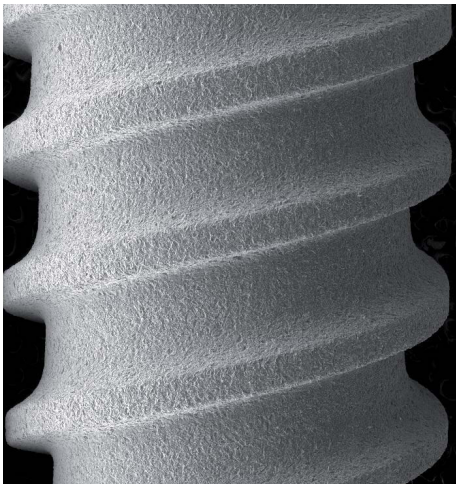


Overview.

Overview
Introduction

MIS is a dynamic production company. It develops and manufactures a comprehensive range of dental implants that provide long-lasting successful solutions to partial and complete edentulism. MIS Implant systems combine several advantageous elements in order to achieve high primary stability and successful osseointegration. These include: choice of raw material, macrostructure, microstructure and surface treatment. This chapter presents these factors and others that are a part of the implants' manufacturing process. MIS upholds its high standards, through comprehensive quality assurance evaluations throughout the whole process.

MIS' established surface is the result of a combination of sand-blasting and acid etching. The surface is constantly being monitored by large series of tests that are carried out in house, and in some of the world's best-known research institutions. These include:

- Mechanical tests
- XPS Analysis
- Roughness analysis
- Surface analysis
- SEM evauations
- Cytotoxicity tests
- Sterility validations
- Torque removal values
- Histology

Overview
Raw Material

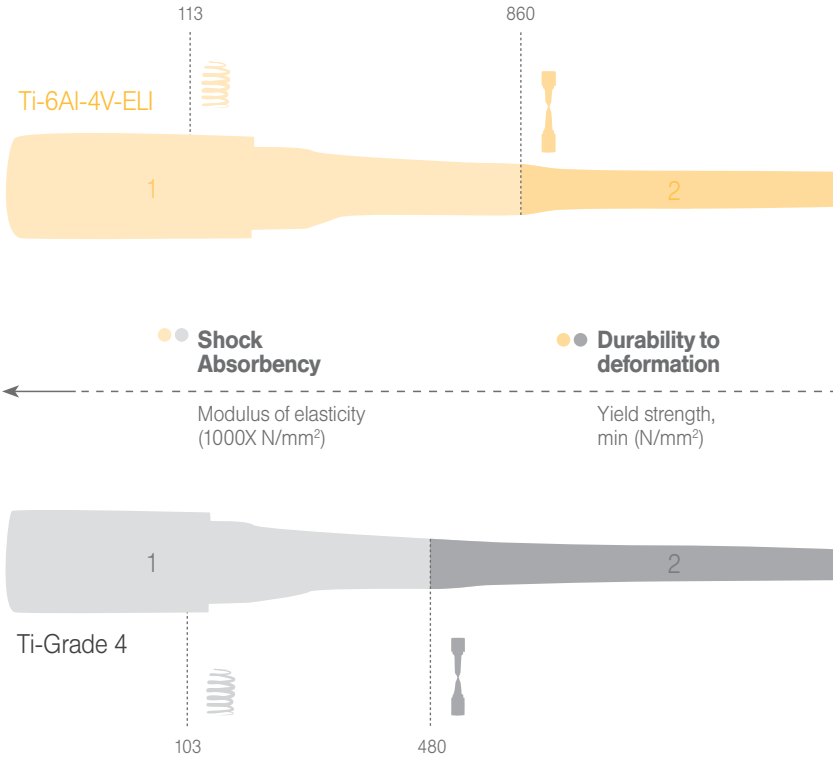
- Biocompatible
- Safe
- Long term proven clinical success
- Superior mechanical properties

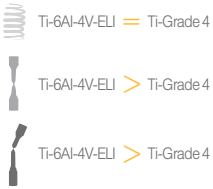
MIS implants are made of Ti-6Al-4V ELI alloy, which is the higher purity version of Ti-6Al-4V. This alloy combines excellent biocompatibility, superior mechanical properties, high fatigue strength and low modulus of elasticity, compared to Titanium grade 4.

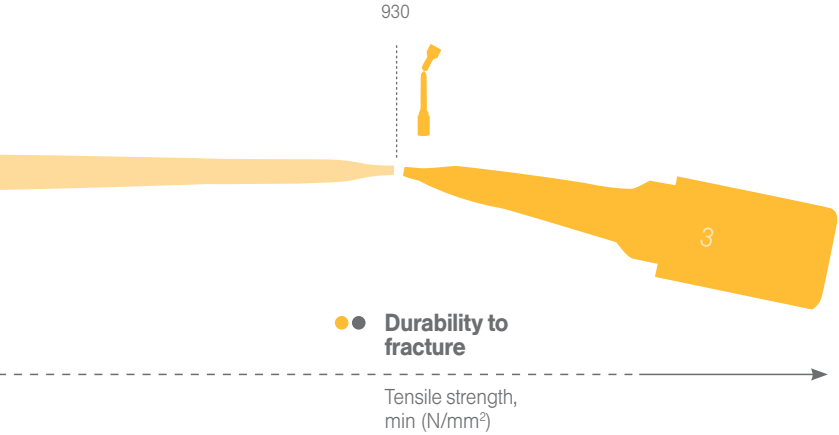
For these reasons, Ti-6Al-4V ELI is the material of choice for many medical and dental applications. Just like other Titanium alloys used in dental implantology, biocompatibility is derived from a thin titanium oxide (TiO_2) layer covering the surface. Therefore bone cells cannot differentiates between the different titanium grades. This layer also prevents leaking of metallic ions from the alloy, making it safe for long term use.

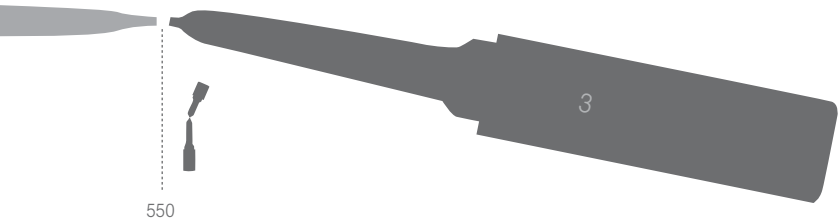
Mechanical Properties

Raw Material




Ti-6Al-4V-ELI = Ti-Grade 4
Ti-6Al-4V-ELI > Ti-Grade 4
Ti-6Al-4V-ELI > Ti-Grade 4


930
3
Durability to fracture
Tensile strength, min (N/mm²)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550

Overview

Manufacturing process

Structure (Raw Material)

MIS Surface Treatment

Sandblasting

Acid Etching

The combination of the two methods induces macro and microstructure that is optimal for osseointegtration.

Roughness (Macro & Micro)

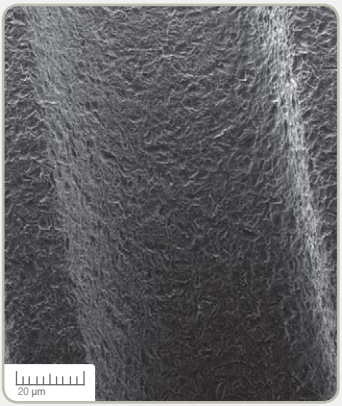
The result of sand blasting and acid etching is a significant increase in surface area. The roughened surface Improves bone adhesion, as well as the proliferation and differentiation of osteoblasts.

Overview

Implant Surface

Osseointegration is defined as the attachment of bone to dental implants, and is the critical factor related to the long term success of dental implants. It is determined by the material of which the impant is made, and by the morphology and chemical composition of its surface.

SEM image of 2 SEVEN implants



SEM image of the implant surface

Macrostructure

The geometric design of the body and thread profile of the implant act to increase primary stability and to distribute forces from the implant to the surrounding bone.

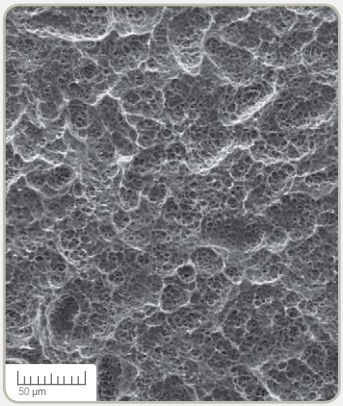
Micro and nano- structure

All MIS' implants are sand blasted and acid etched. This surface treatment increases the implant's surface area, creating both micro and nano-structures, while eliminating various surface contaminations.

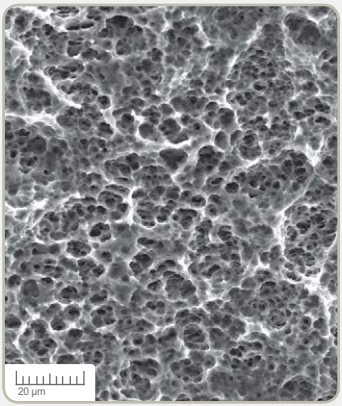
Sand-blasted and acid etched surfaces have been substantially proven to maximize the BIC (Bone to Implant Contact), achieving immediate and long lasting osseointegration.

Surface composition

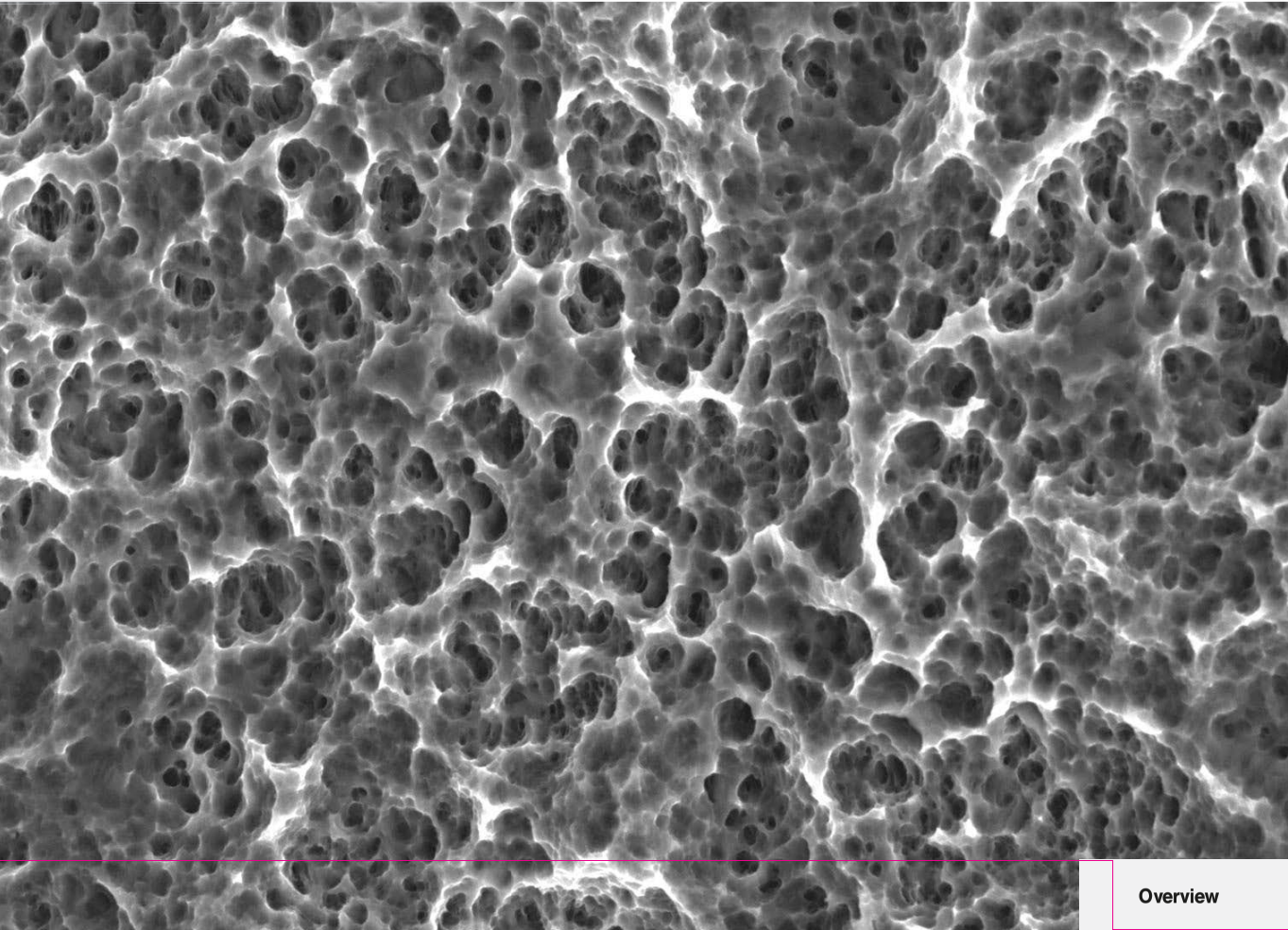
MIS' implant's outer surface consists of a thin layer of pure titanium oxide (TiO2). Acid etching and packaging processes are performed in a controled environment clean room to ensure their purity and quality. Implants are being inspected daily by a scanning electron microscopy (SEM) and routinely by X-ray photoelectron spectroscopy (XPS) to ensure that implants are free of contaminations.



SEM image of the implant surface showing the micro-structure

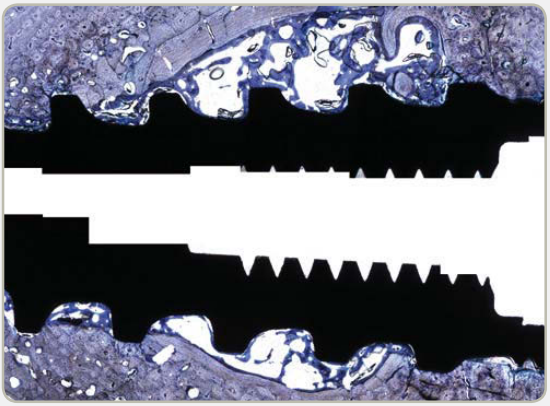


SEM image of the implant surface showing the nano-structure



Overview
Histology

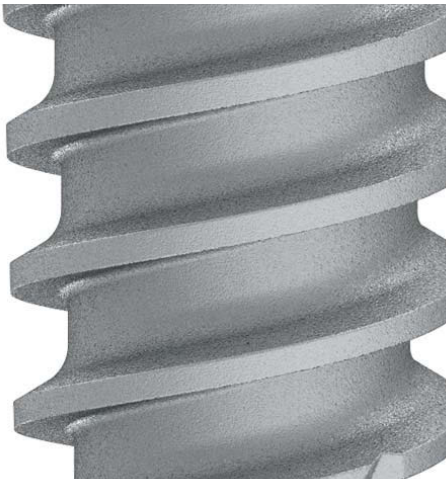
Histologic section of a SEVEN implant, 5 weeks after placement. Courtesy of Paulo G. Coelho, DDS, PhD, NYU College of Dentistry.



Curtsey of Paulo G. Coelho, DDS, PhD, NYU.

Overview
Hydrophilicity

Current literature demonstrates a link between improved bone healing and early osseointegration and specific surface features. MIS' surface treatment is based on a combination of sandblasting and acid etching. This combination ensures surface purity and its hydrophilic properties . The images present liquid "climbing" upwards on the surface exhibiting MIS' surface characteristics.



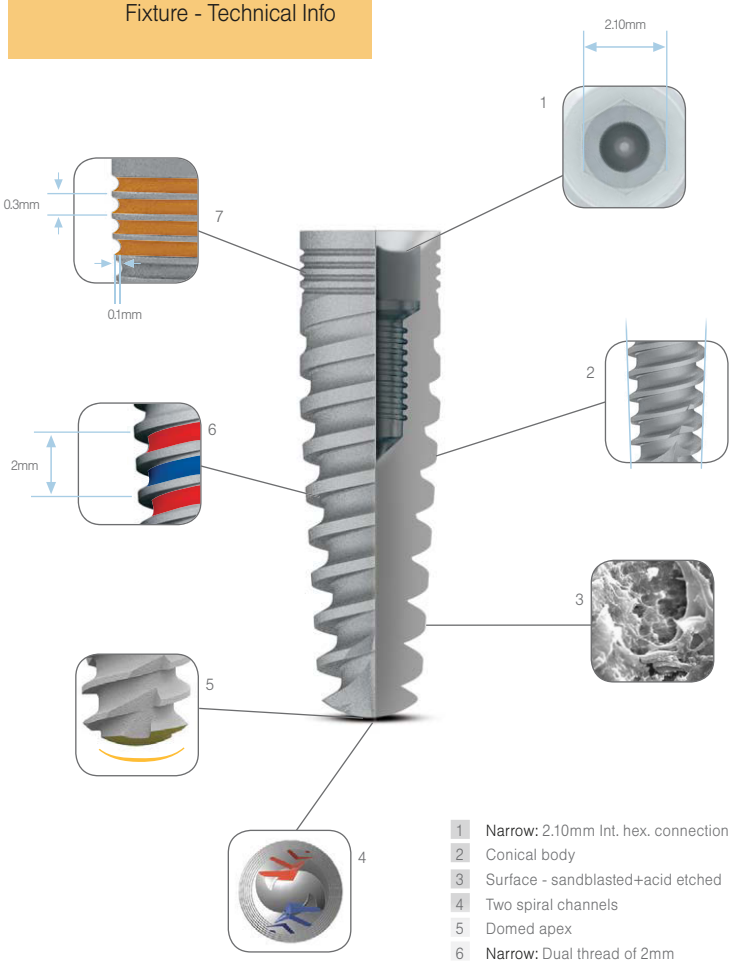
Implants.

SEVEN
Introduction

The MIS self-tapping SEVEN implants are specially designed for use in a wide range of bone types and placement protocols. Their geometric design includes dual threads, three spiral channels stemming from the apex, micro rings on the implant neck and a changing thread thickness along the implant. All MIS SEVEN implants are supplied with a single use final drill, to ensure best performence.

SEVEN | NARROW

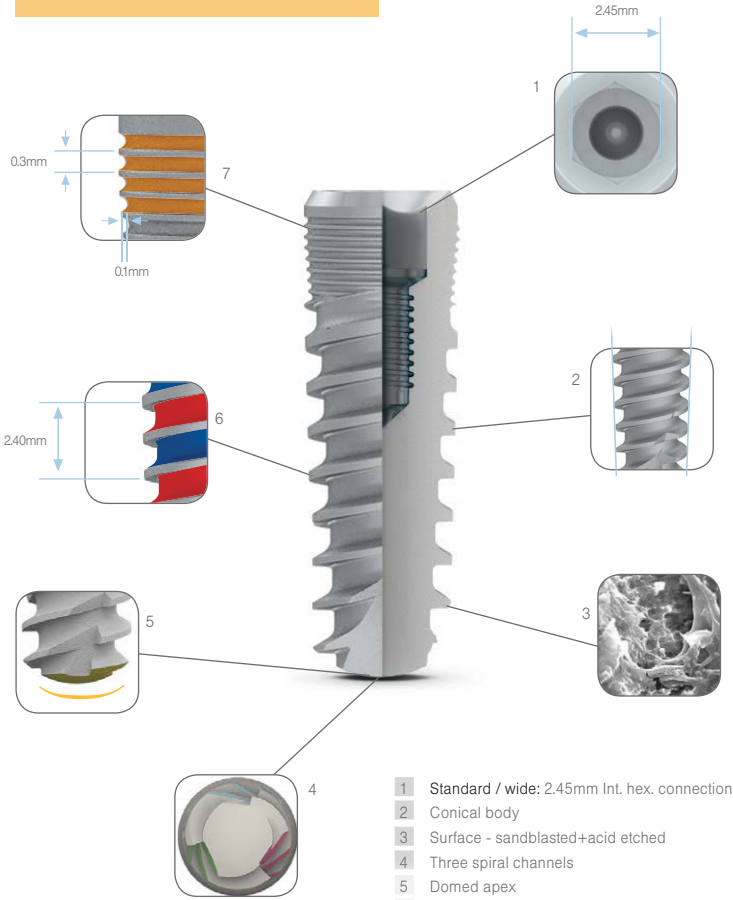
Fixture - Technical Info



1. Narrow: 2.10mm Int. hex. connection
2. Conical body
3. Surface - sandblasted+acid etched
4. Two spiral channels
5. Domed apex
6. Narrow: Dual thread of 2mm
7. Micro-rings (0.1x0.3mm)

SEVEN STANDARD WIDE

Fixture - Technical Info



1. **Standard / wide:** 2.45mm Int. hex. connection
2. Conical body
3. Surface - sandblasted+acid etched
4. Three spiral channels
5. Domed apex
6. **Standard / wide:** Dual thread of 2.40mm
7. Micro-rings (0.1x0.3mm)

SEVEN
Features

Features

- The SEVEN implant is designed to suit a wide range of bone types and bone augmentation procedures.
- A specially designed drill ensures short and safe drilling procedures.
- A double thread of 2.40mm increases the implant's insertion speed.
- Self-tapping capability.
- Three spiral channels for improved integration.
- The micro-rings (0.1x0.3mm) on the implant's neck reduce the shear stress in the crest zone.
- Differential thread thickness (0.15-0.4 mm) improves bone compression.
- The SEVEN implants are available in 3.30, 3.75, 4.20, 5 and 6mm diameters and 6, 8, 10, 11.50, 13 and 16mm lengths.

Successful

The SEVEN implant has a high success rate as a result of its advanced geometric design and new surface morphology.

Versatile

SEVEN is designed for implantation in a wide range of bone types and bone augmentation procedures.

Simple

A specially designed final drill is supplied with every implant, allowing a short and safe drilling procedure.

Efficient

The large thread design and self drilling capability enable secure and fast implant insertion.

Primary Stability

A change in thread thickness and depth locks the implant in the surrounding bone, ensuring smooth insertion and mild bone compression, resulting in high immediate stability.

Minimal Bone Resorption

A combination of MIS's successful and trusted surface treatment, combined with microrings at the neck of the implant ensure minimal bone resorption.

SEVEN
Implant Range

Length	6mm	8mm	10mm	11.50mm	13mm	16mm
Type						
Ø3.30mm Screw type implant narrow platform			MF7-10330 	MF7-11330 	MF7-13330 	MF7-16330 
Ø3.75mm Screw type implant standard platform		MF7-08375 	MF7-10375 	MF7-11375 	MF7-13375 	MF7-16375 
Ø4.20mm Screw type implant standard platform	MF7-06420 	MF7-08420 	MF7-10420 	MF7-11420 	MF7-13420 	MF7-16420 
Ø5mm Screw type implant wide platform	MF7-06500 	MF7-08500 	MF7-10500 	MF7-11500 	MF7-13500 	MF7-16500 
Ø6mm Screw type implant wide platform	MF7-06600 	MF7-08600 	MF7-10600 	MF7-11600 	MF7-13600 	

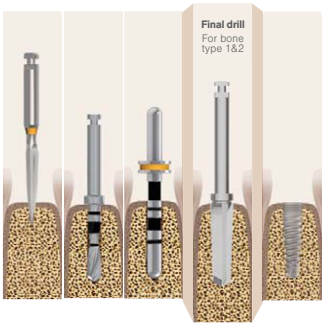
* Each SEVEN implant is supplied with a cover screw and a final drill.

SEVEN
Ø3.30mm / Ø3.75mm Procedure

* Recommended insertion torque: 35-60 Ncm.

Ø3.30mm Implant Procedure

Drilling Speed (RPM)	1200-1500	900-1200		200-400	15-25
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø2.20 Ø3.20	Ø3.30



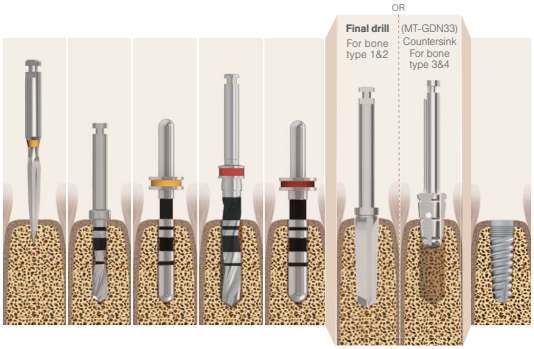
Do not use the final drill for bone type 3&4

The drilling sequence is demonstrated by a 13mm implant.

Procedure recommended by MIS cannot replace the judgment and professional experience of the surgeon.

Ø3.75mm Implant Procedure

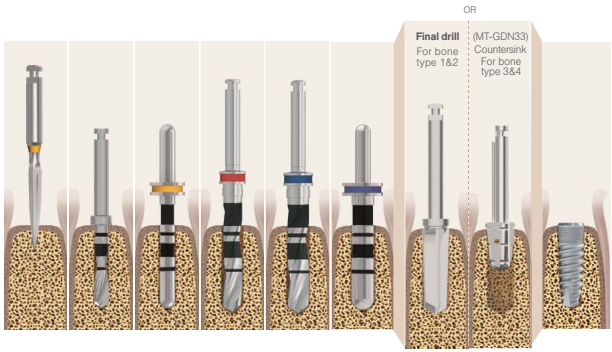
1200-1500	900-1200		500-700		200-400	200-500	15-25
Ø1.90	Ø2.40	Ø2.40	Ø2.80	Ø2.80	Ø2.80 Ø3.60	Ø3.75	Ø3.75



* Recommended insertion torque: 35-60 Ncm.

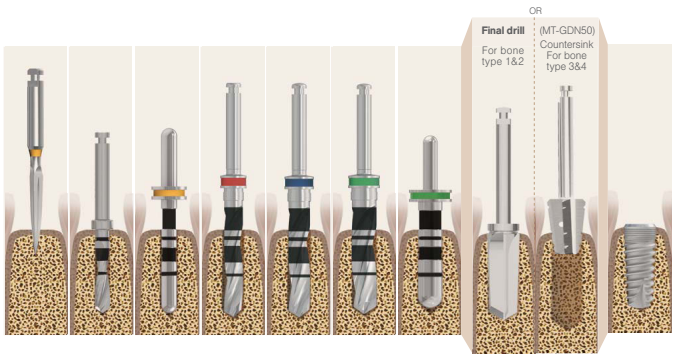
Ø4.20mm Implant Procedure

Drilling Speed (RPM)	1200-1500	900-1200		500-700	400-700		200-400	200-500	15-25
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø2.80	Ø3.20	Ø3.20	Ø3.30 Ø4.10	Ø3.30 Ø4.20	Ø4.20



Ø5mm Implant Procedure

1200-1500	900-1200		500-700	400-700	400-600		200-400	200-500	15-25
Ø1.90	Ø2.40	Ø2.40	Ø2.80	Ø3.20	Ø4	Ø4	Ø4.10 Ø4.90	Ø5	Ø5

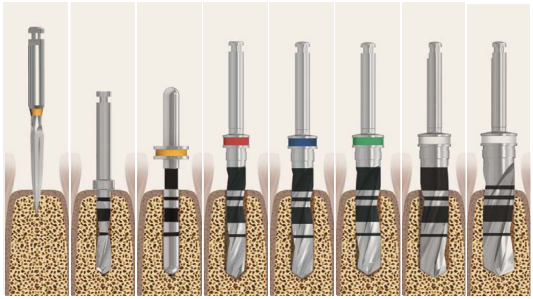


SEVEN
Ø6mm Procedure

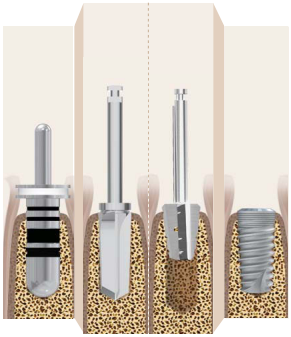
* Recommended insertion torque: 35-60 Ncm.

Ø6mm Implant Procedure

Drilling Speed (RPM)	1200-1500	900-1200		500-700	400-700	400-600	300-500	300-500
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø2.80	Ø3.20	Ø4	Ø4.50	Ø5



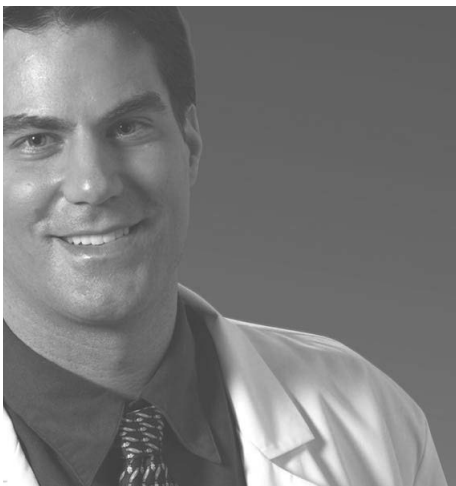
200-400	200-500	15-25
Ø5.10 Ø5.90	Ø6	Ø6
Ø5		



Do not use the final drill for bone type 3&4

The drilling sequence is demonstrated by a 13mm implant.

Procedure recommended by MIS cannot replace the judgment and professional experience of the surgeon.



Surgical Procedures.

For MIS Implants

Surgical Procedures

Indications and Contraindications

Indications

Adequate bone is needed to support the implant with width and height being the primary dimensions of concern. The amount of available bone should be evaluated based on accepted imaging and radiological techniques, used in implant dentistry.

In addition, a very careful evaluation has to be made as to the location of vital blood vessels, nerves, maxillary sinus, soft tissue spaces, and their relation to the site planned for implant placement.

Contraindications

All contraindications associated with elective surgery should be considered.

These include, but are not limited to:

- Metabolic bone diseases
- Blood and clotting disorders
- Medications affecting clotting or bone turnover
- Significant vascular or anatomic factors at the implant site
- Treatments, medications, or disorders that interfere with bone biology or wound healing.
- Hypersensitivity or known allergy to any components of the implants or their suprastructures.

Other Contraindications

Poor patient motivation.

Psychiatric disorders that interfere with patient understanding and compliance with the necessary procedure.

Unrealistic patient expectations.

Unattainable prosthodontic reconstruction.

Inability of patient to manage oral hygiene.

Risks

Risks associated with the surgical procedure fall into four broad categories:

1. Immediate anesthetic and surgical risks.
2. Psychological and psychiatric risks.
3. Medical threats to long-term retention.
4. Long-term deleterious effects of implants on health.

The risks may include:

Inadvertent perforation of the nasal a maxillary sinus, local and systemic infections, perforation into soft tissue spaces, rupture of primary blood vessels and nerve injury.

Temporary conditions that might result from implant placement may include pain and swelling, speech difficulties and haemorrhage.

Long term complications may include (but not limited to) nerve injuries and presistant local or systemic infections. Special care and attention needs to be given to susceptible ndividuals with compromised immune system due to medications, systemic conditions or those who underwent body part replacements.

Important Warning

Practitioner's lack of adaquate training, knowledge and experience are considered major risk factors to the patient's health and to the implant's success. Therefore, no implant placement procedure sholud be performed without prior training by a certified institution.

Surgical Procedures

Step by Step Protocol

The surgical manual is designed to provide an overview of the pre-surgical and the surgical procedures applicable to the SEVEN implant range. Successful implant placement procedures are the result of a large range of factors. This step by step protocol aims to ensure that significant factors are not overlooked.

Step 1.
Patient Selection and Medical History
(General medical history)

Patients must be carefully assessed for their ability to safely undergo surgical procedures. Medical history should be evaluated to ensure that patients are not put at risk. Certain medical conditions are considered either absolute or relative contra-indications for surgery. These may (but not limited) relate to the following conditions: patients who are either taking or took medications for the treatment of osteoporosis; immunodeficiency or immunosuppressive treatments; malignancies; head and neck radiation; poorly controlled diabetes or other hormonal disorders; bleeding disorders or anticoagulant therapy; recent myocardial infarction, severe cardiac insufficiency and valve pathology; general bone diseases; hypersensitivity or known allergy to specific relevant materials; psychiatric or personality disorders that limit or interfere with patients' understanding and compliance. Please be aware of the fact that updates based on current medical literature may include or exclude certain conditions.

Step 2.
Dental Conditions and Oral Hygiene

A complete and thorough intraoral examination must be performed and recorded. This must include an evaluation of the dentition, oral hygiene, smoking, habits, attitude to oral health, and any other relevant information. Implant procedures should not be performed on patients with active osteolitic conditions, active periodontal disease or infectious areas at the implant site. Extreme bruxing and clenching should be taken into consideration.

Step 3.
Radiographs and Imaging

Diagnosis and treatment planning for implant placement require the use of different types of radiographs and imaging technologies. Panoramic radiographs are considered standard pre-surgery radiographs, however additional imaging modalities such as CT (Computerized Tomography), Tomography and periapical radiographs may be required.

It should be emphasized that certain countries require specific radiographs to be taken before, during and after surgery. It is the obligation of the surgeon to ensure that all required documentation is available and recorded before and after surgery. Vertical and horizontal dimensions of implant sites should be measured and charted. The anatomical relationships of neighboring teeth and proximity to anatomical structures such as the mandibular canal, maxillary sinus and base of the nose must be evaluated. Bone inclination and shape should also be taken into account. Surgical guides with radioopaqe markers are recommended. These, coupled with computerized tomographic radiographs can later be altered to be use as computer based surgical guides.

Step 4.
Treatment Plan
(Patient cooperation)

Based on patients needs, alternative treatment plans should be considered and discussed. The chosen treatment plan should result in a sequence of actions related to initial preparations, surgical phase and a restorative phase.

Surgical Procedures

Step by Step Protocol

Step 5A.
Implant Selection

SEVEN implants feature a range of diameters and lengths. It is recommended that wide platform implants are used in the premolar and molar areas, while standard platform implants are used in the anterior areas. Specific analysis of available bone and distance from vital structures at each proposed site may lead to the choice of specific implant length and diameter; however, current augmentation procedures may allow the use of longer or wider implants.

Step 5B.
Surgical Phase

Surgery should be performed under strict infection control conditions. Preoperative medications and/or antibiotics may be required based on patients condition and the extent of surgery, and should be decided upon by the operating surgeon. Other monitoring measures, including blood-pressure and pulse measurements should also be considered. Emergency resuscitation apparatus should be available. Each MIS implant comes with labels including all relevant data related to the implant. It is critical that one is kept as part of the patient's record for future reference.

Warnings: SEVEN implants are supplied in a sealed and sterilized package. Implants should never be reused, and implants whose sterility is compromised should not be used. Implants should not be used later than the specific expiration date printed on their package. Implant placement should be performed in accordance with acceptable placement and loading protocols. MIS' recommended procedures are described in pages 20-43. However, it should be emphasized that procedures recommended

by MIS cannot replace the judgment and professional experience of the surgeon. The sale of MIS implants is restricted by law to licensed dentists only. Implant placement procedures should only be performed by trained and licensed dentists. Initial planning is of the utmost importance. As this is a prosthetic driven procedure, it is advisable that the restorative dentists be involved at the planning and the surgical phases as active participants when making decisions affecting the choice of implant type and the three dimensional positioning of the implant.

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24

Step 6.
Osseointegration phase

According to currently accepted loading protocols, implants should not be loaded earlier than 12 weeks after placement. Osseointegration is evaluated clinically and based on up-to-date radiographs.

Step 7.
Restorative phase

SEVEN implants can support different types of final restorations. Following the solution specified in the treatment plan, the final restoration is fabricated based on accepted restorative protocols. Special attention should be given to ensure correct occlusal adjustment, in order to prevent overloads on the implant supported restorations. MIS superstructures and components must be used with all MIS implants.

Step 8.
Follow-up

Annual follow-up evaluations including radiographs are required. Special attention should be put on oral hygiene and habits, occlusion adjustments and thee stability of the prosthesis.


FD
Ø3.75
Ø4.20
Ø5
Ø6
EXTENDER
long
SE MiS EN

Surgical Kits.

The Surgical Kit

Surgical Kit Description

Comprising all required tools for SEVEN implants placement procedures, the new SEVEN innovative surgical kit is designed to enhance simplicity and safety. The kit introduces a novel circular ergonomic design that follows the surgical drilling sequence. The kit includes a set of length based pilot drills for a worry-free procedure and color coded visual cues for both implant diameters and restorative platforms.

MK-EI48, Advanced Surgical Kit for SEVEN implant system with external irrigation drills

Please note:

The surgical kit is made of medically approved materials.

The surgical kit can be fully sterilized using an autoclave at a temperature that does not exceed 134°C (273°F).

The surgical kit is small in size, and therefore easy to store.

The modular trays represent the optimal solution in terms of cleaning, decontamination and sterilization due to the absence of hidden surfaces.

The steam flow is optimized through the built-in vents.

Warning
Avoid damage!

Temperatures higher than 150°C may cause damage. Radel, steel and silicone components may support repeated exposures to temperatures up to 180°C, but the lifetime of the trays may be shortened.

The use of inappropriate chemical agents may cause damage to the trays and to the instruments. Please handle them with care to avoid breakage. Never use broken trays or instruments.

Do not open the box while still hot after sterilization.

Cleaning Procedure

Stainless steel instruments should be cleaned and sterilized with materials that are specifically indicated for these materials. To avoid damage, please refrain from using:

▪ Cleaning and disinfection agents containing high rates of chlorine ▪ Cleaning or disinfection agents containing oxalic acid.

In order to prevent damage to instruments that are color coded, please refrain from using:

▪ Detergents and cleaning agents containing high rates of the aforementioned chemicals ▪ Extremely high temperature during cleaning and sterilization.

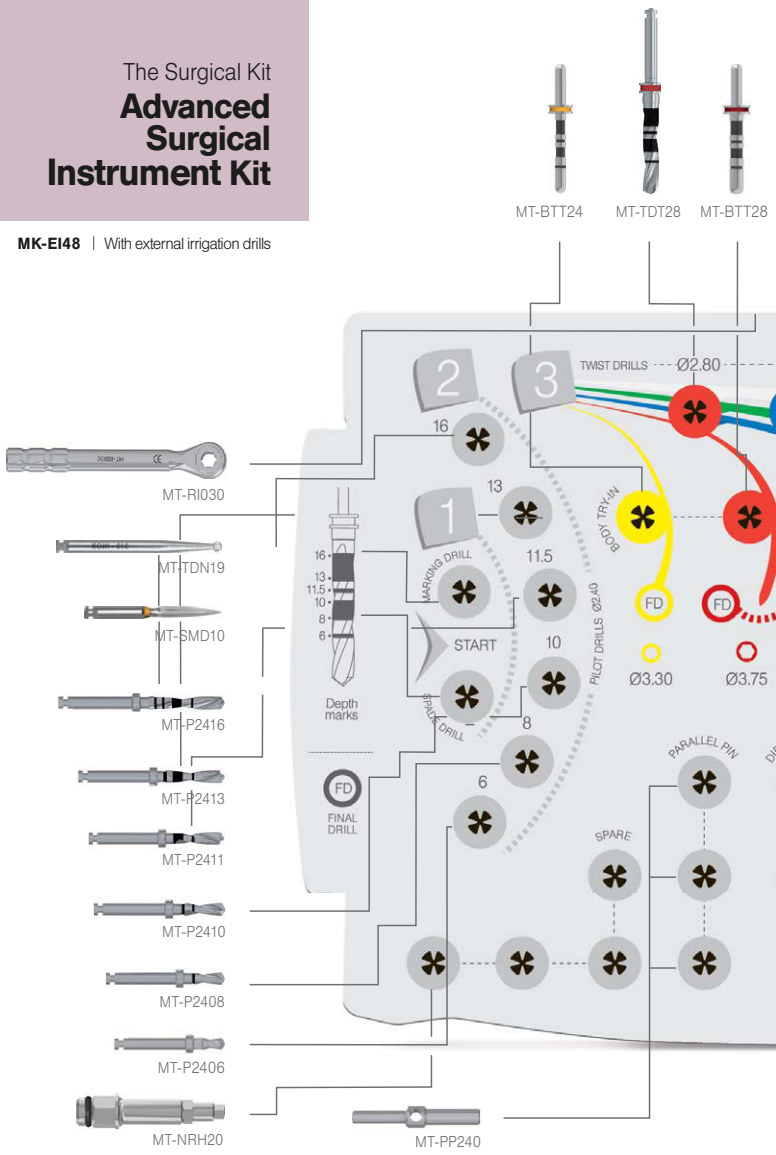
Please Note:

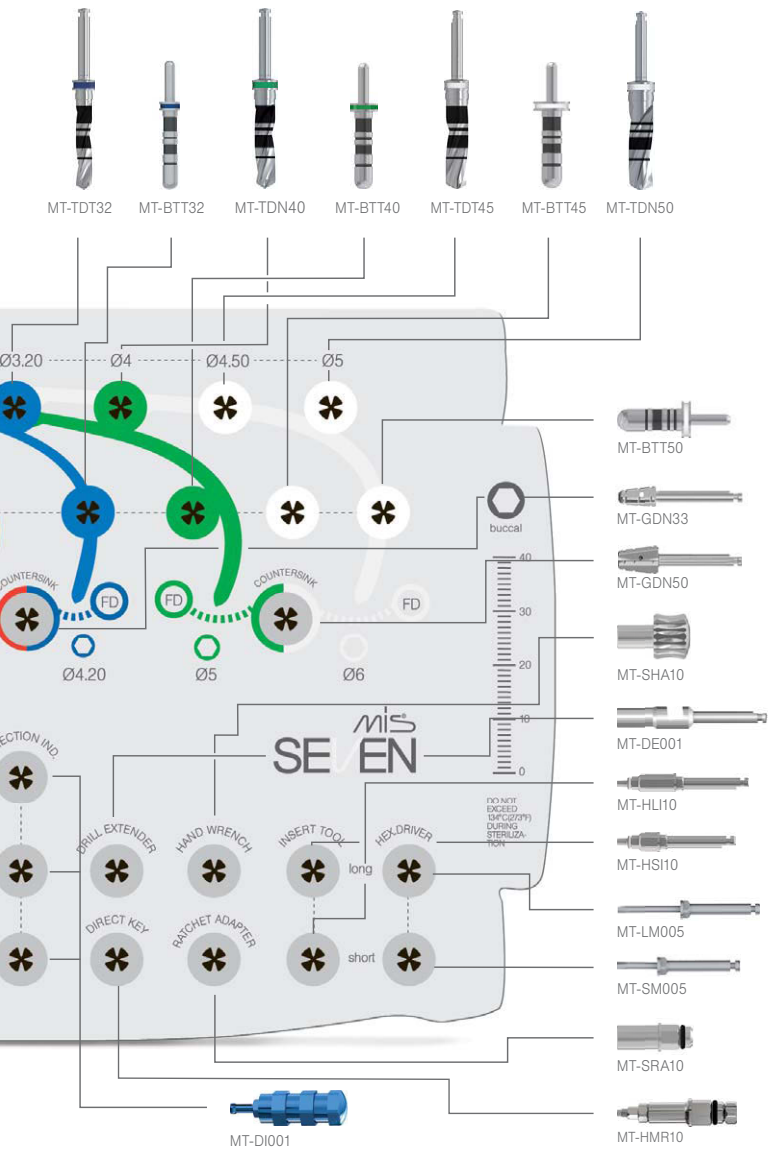
▪ Please conduct a visual inspection of the instruments prior to each use. Do not use faulty and dull instruments. Clean and disinfect such instrument separately ▪ Do not allow traces/ residue (blood, secretion, tissue residue) to dry on the instruments. Always soak in disinfecting fluid immediately after use ▪ Use only stainless steel dedicated detergents and strictly follow usage instructions ▪ Rinse instruments thoroughly with water to remove any remaining disinfectants or cleaning agents ▪ Do not store instruments that are damp or wet ▪ Use only nylon bristle brushes to clean instruments. Clean the cavities and hollow spaces thoroughly ▪ The use of an ultrasonic bath is highly recommended ▪ Do not clean/ disinfect instruments made of different materials together ▪ To prevent damage, do not allow sharp instruments to touch other instruments during cleaning. ▪ After mechanical or manual cleaning, all surgical appliances must be sterilized in an autoclave, at 134°C (273°F), a pressure of ≈315 Kpa during 6 minutes or for pre-vacuum autoclave at 132°C (270°F) during 4 minutes. Do not exceed 134°C. Never use dry sterilizers ▪ Inspect for corrosion after sterilization.

The Surgical Kit

Advanced Surgical Instrument Kit

MK-EI48 | With external irrigation drills

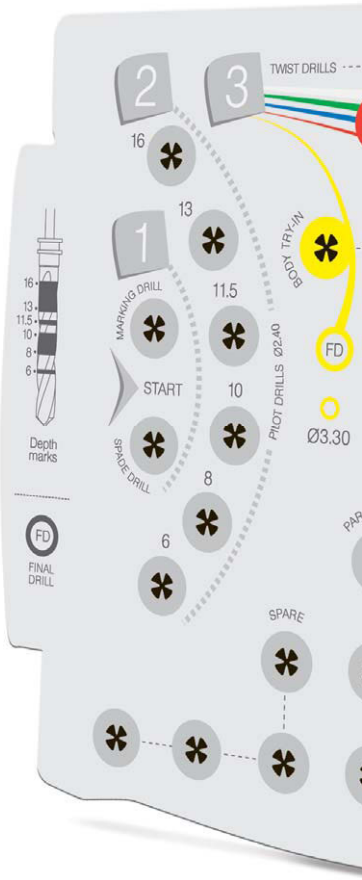



MT-TDT32
MT-BTT32
MT-TDN40
MT-BTT40
MT-TDT45
MT-BTT45
MT-TDN50
Ø3.20
Ø4
Ø4.50
Ø5
buccal
COUNTERSINK
FD
Ø4.20
Ø5
Ø6
40
30
20
10
0
SE mis EN
DRILL EXTENDER
HAND WRENCH
INSERT TOOL
HEX-DRIVER
long
DIRECT KEY
RATCHET ADAPTER
short
MT-BTT50
MT-GDN33
MT-GDN50
MT-SHA10
MT-DE001
MT-HLI10
MT-HSI10
MT-LM005
MT-SM005
MT-SRA10
MT-HMR10
MT-DI001

The Surgical Kit

Kit Contents

SEVEN Surgical Kit includes tools that are designed especially for the step by step placement process. Correct preparation of the implant site ensures efficient and accurate installation and high primary stability.



Ø2.80
Ø3.20
Ø4
Ø4.50
Ø5
FD
COUNTERSINK
FD
FD
COUNTERSINK
FD
Ø3.75
Ø4.20
Ø5
Ø6
buccal
40
30
20
10
0
DO NOT EXCEED 134°C (273°F) DURING STERILIZA-TION.
ALLEL PIN
DIRECTION IND.
DRILL EXTENDER
HAND WRENCH
INSERT TOOL
HEX.DRIVER
long
DIRECT KEY
RATCHET ADAPTER
short
mis
SEVEN

The Surgical Kit

Kit Contents

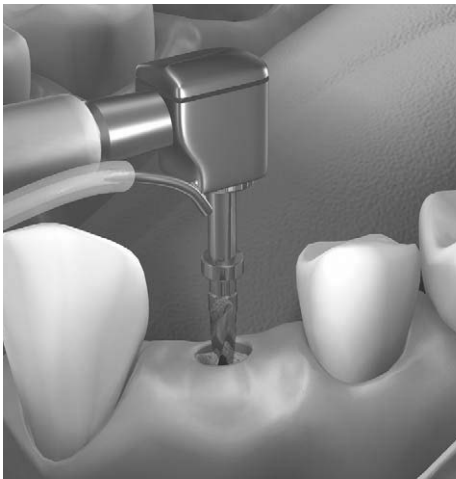
		Dimensions	Material
	**MT-P2406** | Pilot drill with built in stopper	Ø2.40 length 21.8mm	Stainless steel
	**MT-P2408** | Pilot drill with built in stopper	Ø2.40 length 23.8mm	Stainless steel
	**MT-P2410** | Pilot drill with built in stopper	Ø2.40 length 25.8mm	Stainless steel
	**MT-P2411** | Pilot drill with built in stopper	Ø2.40 length 27.3mm	Stainless steel
	**MT-P2413** | Pilot drill with built in stopper	Ø2.40 length 28.8mm	Stainless steel
	**MT-P2416** | Pilot drill with built in stopper	Ø2.40 length 31.8mm	Stainless steel
	**MT-BTT24** | Body try in Ø2.40mm for tapered impl. procedure	Ø2.40 length 28.5mm	Stainless steel
	**MT-BTT28** | Body try in Ø2.80mm for tapered impl. procedure	Ø2.80 length 28.5mm	Stainless steel
	**MT-BTT32** | Body try in Ø3.20mm for tapered impl. procedure	Ø3.20 length 28.5mm	Stainless steel
	**MT-BTT40** | Body try in Ø4mm for tapered impl. procedure	Ø4 length 28.5mm	Stainless steel
	**MT-BTT45** | Body try in Ø4.50mm for tapered impl. procedure	Ø4.50mm length 28.5mm	Stainless steel
	**MT-BTT50** | Body try in Ø5mm for tapered impl. procedure	Ø5mm length 25.5mm	Stainless steel

The Surgical Kit

Kit Contents

		Dimensions	Material
	**MT-TDT28** | Twist drill 2.80mm external irrigation	Ø2.80mm length 37.5mm	Stainless steel
	**MT-TDT32** | Twist drill 3.20mm external irrigation	Ø3.20mm length 37.5mm	Stainless steel
	**MT-TDN40** | Twist drill 4mm external irrigation	Ø4mm length 38.2mm	Stainless steel
	**MT-TDT45** | Twist drill 4.50mm external irrigation	Ø4.50mm length 38.2mm	Stainless steel
	**MT-TDN50** | Twist drill 5mm external irrigation	Ø5mm length 38.2mm	Stainless steel
	**MT-SMD10** | Spade marking drill	length 27.5mm	Stainless steel
	MT-TDN19 | Marking drill Ø1.90mm external irrigation	Ø1.90mm length 34mm	Stainless steel
	**MT-SHA10** | Hand wrench square connection	length 15.5mm	Stainless steel
	**MT-NRH20** | Hex. ratchet long adapter for int. hex. connection, NP	length 25mm	Stainless steel

		Dimensions	Material
	**MT-LM005** | Long motor adapter for 0.05" hex.	length 29mm	Stainless steel
	**MT-SM005** | Short motor adapter for 0.05" hex	length 24mm	Stainless steel
	**MT-DE001** | Drill extender	length 28.85mm	Stainless steel
	**MT-PP240** | Parallel pin Ø2.40mm for tapered impl. procedure	Ø2.40/ Ø3mm	Titanium
	**MT-DI001** | Implant Direction Indicator	length 17mm	Stainless steel
	**MT-HSI10** | Short insertion tool, int. hex. connection	length 24.4mm	Stainless steel
	**MT-HLI10** | Long insertion tool, int. hex. Connection	length 28.2mm	Stainless steel
	**MT-SRA10** | Square connection to ratchet adapter	length 15.5mm	Stainless steel
	**MT-HMR10** | Long direct hand and ratchet hex. key	length 25mm	Stainless steel
	**MT-GDN33** | Countersink for standard platform implant system	Ø3.75mm/ Ø4.20mm length 26mm	Stainless steel
	**MT-GDN50** | Countersink for wide platform implant system	Ø3.75mm/ Ø4.20mm length 26mm	Stainless steel
	**MT-RI030** | Ratchet wrench	length 75mm	Stainless steel



Drills.

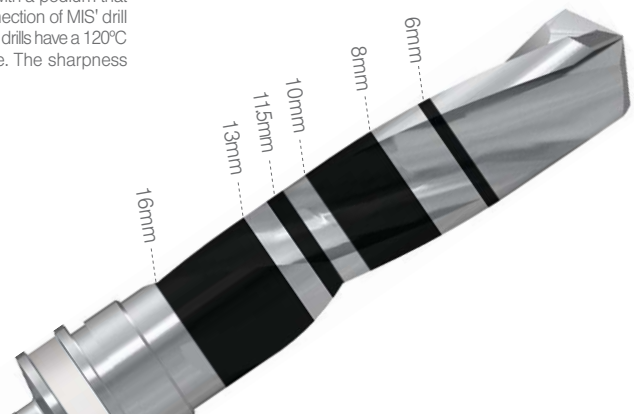
Drills

Using MIS Drills

Implant placement procedures require the use of several drills with different diameters and characteristics. MIS offers drills with internal and external irrigation, as well as conical and ceramic drills. Most MIS drills are marked for depth control and are color coded for immediate identification of drill diameter.

Features

MIS drills are designed to be used with all MIS implants. The drills are available with or without internal irrigation. Short drills are also available for each diameter. All drills are color coded. The drills are maked for depths of 6, 8, 10, 11.5, 13 and 16mm, and are equipped with a podium that allows the connection of MIS' drill stoppers. All MIS drills have a 120ºC cutting degree. The sharpness and high quality of the drills allow for up to 30 uses. Careful use of sharp drills will ensure atraumatic drilling procedures, and minimal heat generation.



Drill Stopper

MIS offers drill stoppers to enable simple and accurate depth control.

The SEVEN Drill stopper kits (MK-SDS06, MK-SDS08, MK-SDS10, MK-SDS11, MK-SDS13) are a series of kits, each used for one specific implant length: 6, 8, 10, 11.5 or 13mm.

For users who mostly use 3.75 or 4.2 implants, MIS offers a single assorted kit - the SEVEN Drill Stoppers Kit Standard Platform (MK-BS001) kit, which include all stoppers required for safe placement of standard platform implants.

SEVEN Drill Stoppers Kit

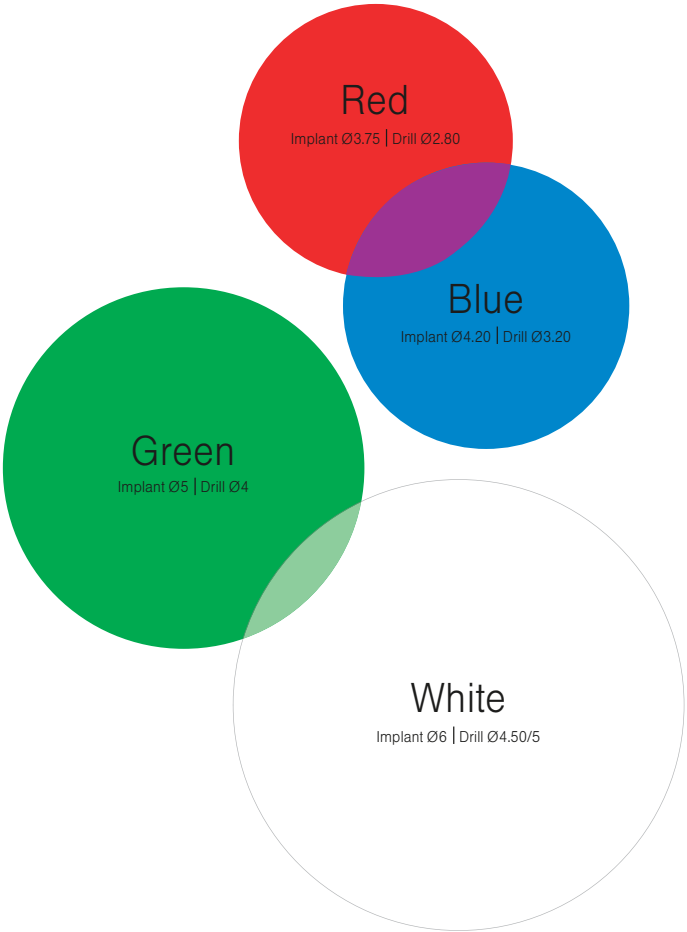
SEVEN Drill Stoppers Kit Standard Platform (MK-BS001)

	Implant	Length
Ø2.80mm 	Ø2.80mm	37.5mm
Ø3.20mm 	Ø3.20mm	37.5mm
Ø4mm 	Ø4mm	38.2mm
Ø4.50mm 	Ø4.50mm	38.2mm
Ø5mm 	Ø5mm	38.2mm

Drills

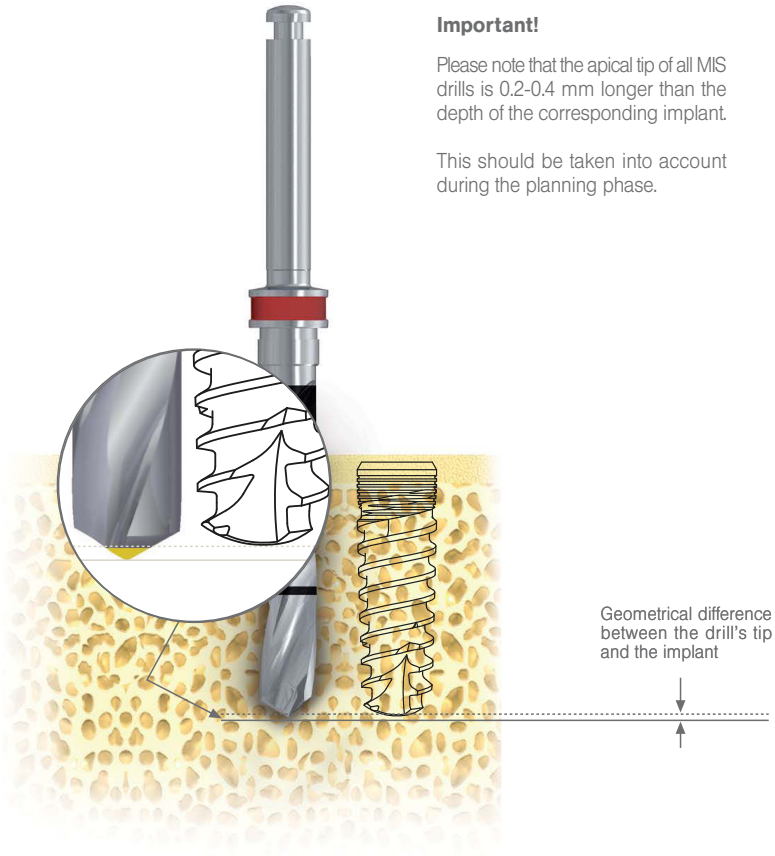
Color Code

Color-code is used for easy identification of drills or implants diameters as follows:



Drills

Drill Indications



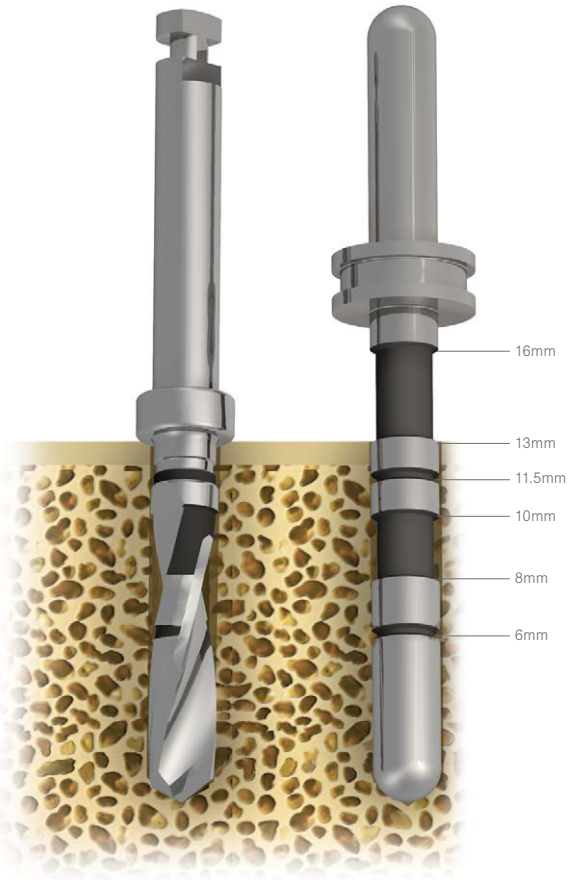
Important!

Please note that the apical tip of all MIS drills is 0.2-0.4 mm longer than the depth of the corresponding implant.

This should be taken into account during the planning phase.

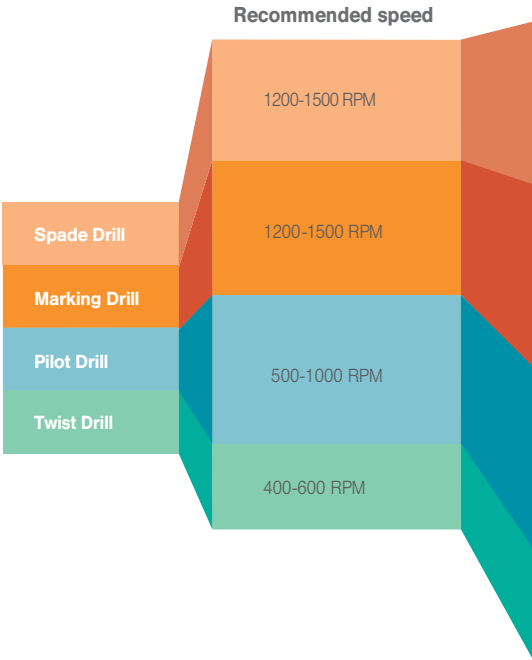
Depth verification

Depth verification can be done by the use of Body Try-In tools (MT-BTTx). Their laser markings correspond to these on the drills and allow safe and easy way to ensure that the required depth was achieved.



Drills

Drill Indications



Length & diameter	Aim of use
The Spade drill has a diameter of Ø1.9mm and a sharp tip. The Spade Drill is 27.5mm in length and made of stainless steel.	The spade drill is used to mark a reference point for further drills. It is especially useful in immediate placement procedure.
The Marking drill supplied is 34mm in length and 1.90mm in diameter.	The Marking drill is used for creating a reference point in the center of the ridge, and to mark the drilling location for further drilling.
SEVEN pilot drills comes in five different lengths 6, 8, 10, 11.5, 13 and 16mm and are equipped with a stopper to simplify the drilling procedure.	Pilot drills are the first invasive drills used for the preparation of a fixture site. The Pilot drills are length specific to ensure precise drilling depth.
Twist drills come in a variety of diameters and lengths.	Twist drills are used to widen the osteotomy. They are NOT length specific, and have laser markings for 6, 8, 10, 11.5, 13 and 16 mm implants. The use of stoppers is highly recommended while using Twist drills.

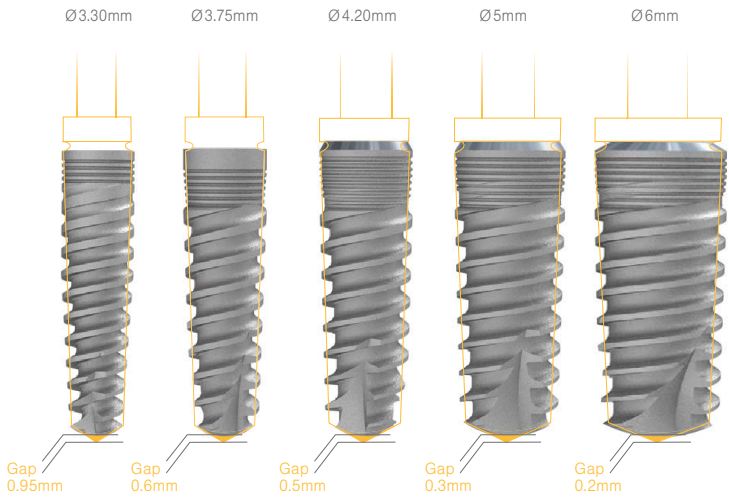
SEVEN
Final Drill

Final Drill for implant diameters

SEVEN
Special Final Drill

A specially designed final drill is recommended for use in bone types 1 and 2 for 6, 8, 10, 11.50, 13 and 16mm SEVEN implants in order to prevent pressure on the implant's neck. The special final drill is supplied with every implant, allowing a short and safe drilling procedure. The recommended drilling speed is 200-400 Rpm.

Implants and drills measurements



Drills

Drilling into Hard Bone

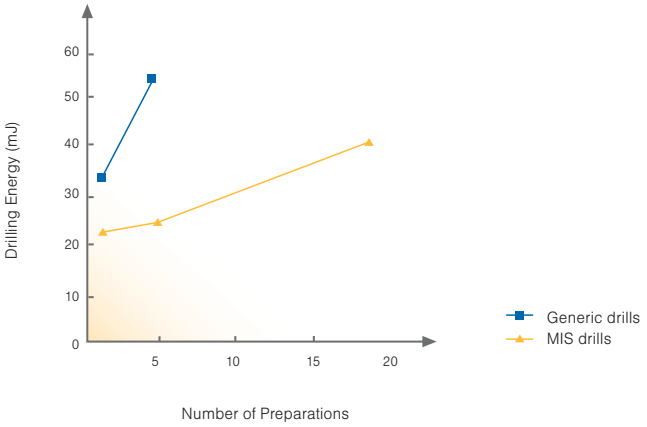
When drilling into hard bone, extra care should be exercised to prevent overheating. Therefore, lower speeds and higher torques should be used. In addition, to prevent extensive pressure on the bone or the need of extremely high insertion torque, it is highly recommended to use the appropriate countersink drills at the end of the drilling procedure.

Countersink (MT-GDN33, MT-GDN50)

A Countersink drill is used to widen the entrance area of the osteotomy, to prevent extensive pressure on the implant's neck. Depth marks of 3.75 and 4.20mm appear on the Standard platform Countersink drill (MT-GDN33), and 5 and 6mm marks appear on the wide platform Countersink drill (MT-GDN50). The recommended drilling speed is 200-500 RPM.

Drills

Drill Cutting Capability



Test conditions:

Pilot drill
Drill speed: 600 RPM
Drill feed: 0.04 mm/rev

Test bench- force transducer: obtained by DC motor controlled by a displacement potentiometric transducer

Conclusion

MIS's stainless steel drills, due to their design, present greater endurance and drilling efficacy.

Drills

Ceramic Drills

Ceramic drills feature reduced vibration, pleasant smooth operation and continuous substance removal.

The MIS Ceramic drills are made of a high performance mixture of zirconium dioxide (zirconia) and aluminum oxide(alumina) ceramics. The mixture of these two materials provides MIS Ceramic drills with an above-average bending strength of 2,000 MPa. In comparison, the bending strength of zirconium oxide ceramic, used in the manufacturing of root posts is 1,200 Mpa.

Advantages: Metal-free, biocompatible, corrosion-free

	MT-CRD21 Marking Drill	**MT-CRD20** Pilot Drill	**MT-CRD28** Twist Drill
Dimensions:	Ø2.10mm length 28.5mm	Ø2mm length 33.5mm	Ø2.80mm length 35mm
Material:	Zirconia- alumina ceramic	Zirconia- alumina ceramic	Zirconia- alumina ceramic

Drills

Drills Maintenance

Correct and careful maintenance of MIS drills is extremely important. Damage to drill tips can cause significant impairment of drill function. The following are detailed instructions for proper maintenance.

Instructions for Maintenance of Drills Prior to First Use

Stage 1: Cleaning and Rinsing - Drills should be dipped in appropriate detergent, rinsed, and dried. The use of an ultasonic bath is highly recommended.

Stage 2: Sterilization - Drills should be sterilized in an autoclave at 134˚C (273˚F), a pressure of ≈315 Kpa during 6 minutes or for pre-vacuum autoclave at 132°C (270°F) during 4 minutes. Do not exceed 134°C.

Stage 3: During Use - Drills should be soaked in a sterile saline solution until the cleaning stage.

Instructions for Cleaning and Storage of Drills After Use

Stage 1: Cleaning - Drills should be brushed with detergent to remove any remaining blood or tissue.

Stage 2: Ultrasonic Cleaning - Drills should be cleaned in an ultrasonic bath with appropriate detergent. Note: during ultrasonic cleaning, contact between drills should be avoided.

Stage 3: Rinsing - Drills should be rinsed under running water and dried.

Stage 4: Sterilization - Drills should be sterilized in an autoclave at 134˚C (273˚F), a pressure of ≈315 Kpa during 6 minutes or for pre-vacuum autoclave at 132°C (270°F) during 4 minutes. Do not exceed 134˚C.

Stage 5: Storage/Use - Store kits in a cool and controlled environment. Please note that sterilization may expire after a certain time, so if kits are stored for a prolonged period of time, resterilize them prior to use.

Recommendations

- Cutting tools should be used for a maximum of 30 drillings.
- Distilled water should be used in order to avoid surface stains.


NI

Surgical and Prosthetic Tools.

Surgical Tools
Specialized Surgical Tools

Ratchet wrench
MT-RI030

The ratchet wrench can be used for tightening or loosening screws and for implant placement.

- The device is not sterile.
- Cleaning and sterilization are required prior to first use.

Torque wrench
MT-RI040

Features

The Torque wrench is designed for tightening or loosening screws and for implant insertion. It also ensures the optimal transmission of force during implant insertion.

The Torque scale ranges from 15-45 Ncm at manufacture time, with an accuracy of plus or minus 5%. The scale on the opposite side can be used as reverse torque.

The maximal load, as indicated by the scale on the wrench body, should not be exceeded. Applying an overload that exceeds the maximum torque value may affect torque accuracy and could cause breakage or other damages.

User Instructions

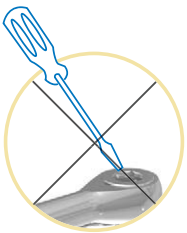
1. Connect the torque wrench **A** to the desired key.
2. Connect the key to an implant or to a screw.
3. While placing one hand on the axis of rotation **A**, and while exerting finger pressure on the handle **B**, turn the torque wrench slowly in a clockwise direction **C** until the desired torque is reached.

Ratchet &
Torque wrench

Instruments Maintenance

Maintenance

- Perform a visual and functional inspection of the instrument prior to sterilization. Especially look for: damage to instrument, corrosion, debris or stains and ensure that all moving components are working properly.
- Dispose of damaged instruments.



Do not attempt to dismantle the ratchet

Clean thoroughly immediately after use

Material

- Stainless steel

Sterilization

- The device is delivered not sterile.
- The device must be sterilized before use by autoclave, at 134˚C (273˚F), a pressure of ≈315 Kpa during 6 minutes or for pre-vacuum autoclave at 132°C (270°F) during 4 minutes. Do not exceed 134°C.

Cleaning and Disinfection

- Clean instrument with running water to remove any blood or tissue immediately after use.
- Immerse instrument in an approved cleaning/ disinfecting solution.
- Use of an ultrasonic cleaner is highly recommended.
- DO NOT USE agents containing high concentration of chlorine or agents containing oxalic acid.
- Use distilled water to prevent water stains.

Surgical Tools

Specialized Surgical Tools

Torque wrench
MT-RI050

Description of the torque wrench

The torque wrench with adjustable force is a dental device used to tighten or loosen screws, prosthesis components and implants. It is a precision instrument that can be disassembled and that is supplied non sterile. To ensure that it functions perfectly every time, the torque wrench must be disassembled, disinfected, cleaned, greased and sterilised after each use, according to the instructions for use. It is highly recommended to read instructions for use prior to handling. The handling and the use of the product are carried out without direct control from our side and remain under responsibility of the user. The user is liable for any possible damage that could occur. Before each use, in order to guarantee high torque precision, the device must be checked upon its functioning. This instrument is not a measuring device.

Use

By turning the torque adjustment screw, the torque wrench can be set to the desired torque value. To set the torque value correctly, the torque adjustment screw must be turned clockwise to reach the required torque value and set to the exact line marking. Ensure that the line on the handle is in straight alignment with the line on the torque adjustment screw. In order to change from a higher to a lower torque value, one must screw two turns under the desired torque value, then screw clockwise again to the exact line marking. Ratchet mode can be set by turning the torque adjustment screw to the lock (🔒) marking. The word 'IN' on the cover (3), shows the position of the wrench that is used for tightening, the word 'OUT' indicate the position used of loosing screws.

Lubrication

"Instrument Lubricant" approved USDA H1

Precision of new device

± 3,5 Ncm with total confidence of 95%

Recommendations

This instrument must not be used for any applications other than those listed in the section "Description of the torque wrench" or with equipment that could damage the intended use of the device. The persons in charge for the use and maintenance of this dental instrument should monitor any deterioration of the tightening, ratchet and torque mechanism of the device and, in the event of a defect, return the wrench to the supplier. During assembly, it is essential not to mix the various components belonging to different torque wrenches because the components are not interchangeable. If a component is lost, please return the whole instrument immediately to your retailer for repair. Components cannot be sold separately. Do not store the wrench with the spring compressed but with the torque set to its minimum. This device must not be sterilised in the packaging provided by the manufacturer.

Cleaning the torque wrench

When used in situations that do lead to operative residues (blood, secretions, tissue remnants), the torque wrench must be disassembled completely and placed in a suitable bath of disinfection in accordance with the recommendations of the manufacturer. This operation facilitates cleaning because dry residues cause corrosion. After cleaning, thoroughly rinse the parts with water and use a nylon brush to rub internal and external surfaces of the various parts of the torque wrench. During the cleaning process, avoid all contact between each part of the torque wrench.

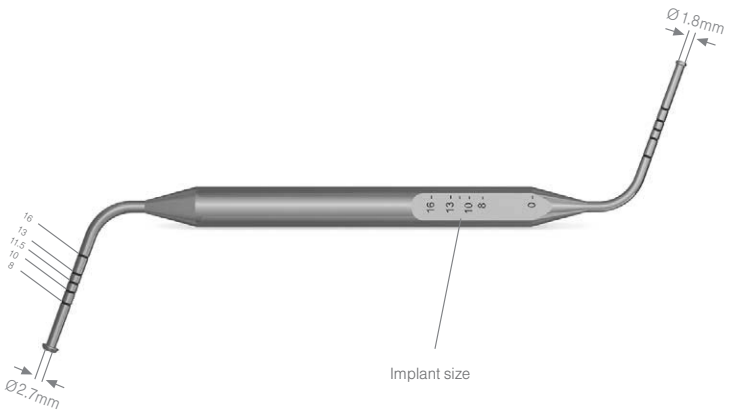
Sterilization

The instrument must undergo a sterilization with steam at 134 °C/ 273°F during 18 minutes. Before sterilization, the torque wrench must be completely assembled. Sterilise the key according to cycles of sterilization recommended by the manufacturer of the autoclave. We recommend the use of devices equipped with a vacuum pump (type B) to decrease the risk of formation of air pockets. This recommendation is particularly important for hollow instruments and guarantees a perfect drying. We advise against the use of a hot air steriliser because it can lead to ageing of the spring and subsequently bring about a change of the torque value.

Surgical Tools

Specialized Surgical Tools

Implant site depth probe
MT-BTI10



Features

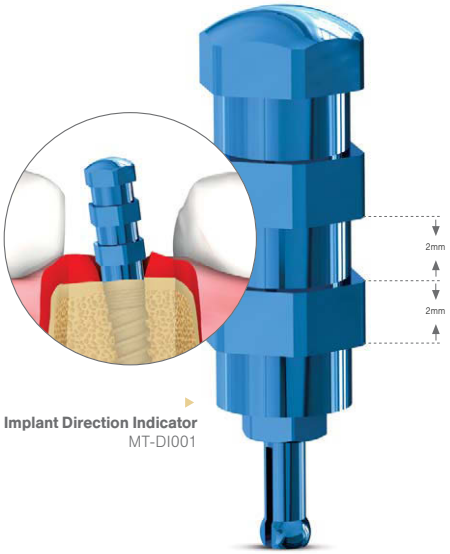
The probe enables quick and easy measurements and examination of a prepared implant site, at each step of the procedure.

Marked depths: 8, 10, 11.5, 13 and 16mm. The depth probe includes an apical flat section to ensure accurate placement within the ossteotomy.

Dimensions: Ø 1.80 / Ø 2.70mm. Total length: 100mm.

Implant Direction Indicator MT-DI001

This surgical instrument reveals the condition of a particular implant by showing the implant direction. The implant indicator is connected directly to the implant and shows the direction of the implant. The implant indicator contains groove marks indicating gingival heights (each groove mark indicates 2mm of gingival height).

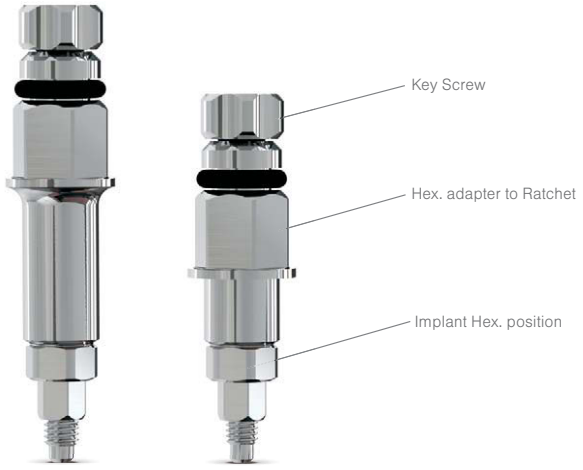


Implant Direction Indicator
MT-DI001

Surgical Tools

Specialized Surgical Tools

MIS provides a key designed specifically for the extraction of mountless standard or wide implants, placed in very soft bone or in sinus lift procedures. The key can be manipulated manually or with a ratchet. The connection between the key and the implant is facilitated by means of a screw that attaches to the thread of the implant. This allows for a firm connection between implant and key and for a safe and simple implant extraction.



MT-HMR10

MT-HMR05

The key consists of two parts: the body and the screw. The key is composed of stainless steel. It is recommended to dismantle the two key parts (body and screw) before sterilization.

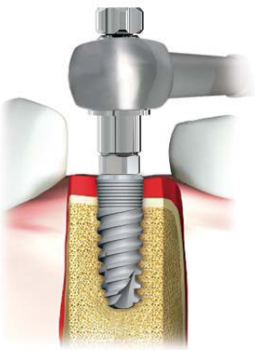
Direct Hand And Ratchet Hex Key
MT-HMR05 / MT-HMR10

Step
1.

By Hand

Tightening the screw to the implant

Step
2.



By Ratchet

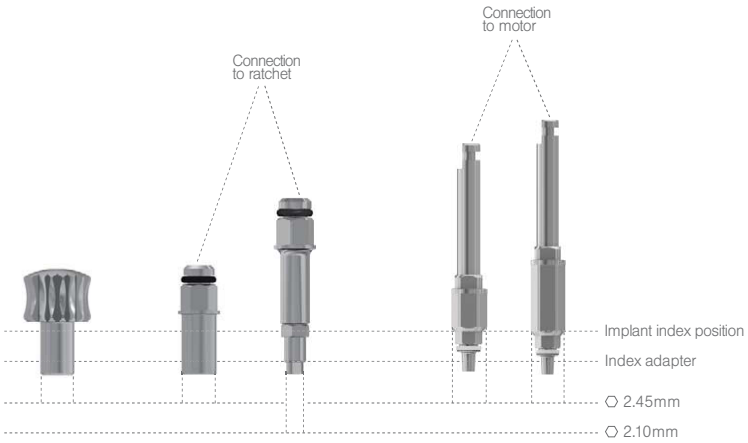
Ratchet connected to top of the key in order to pull implant

Surgical Tools

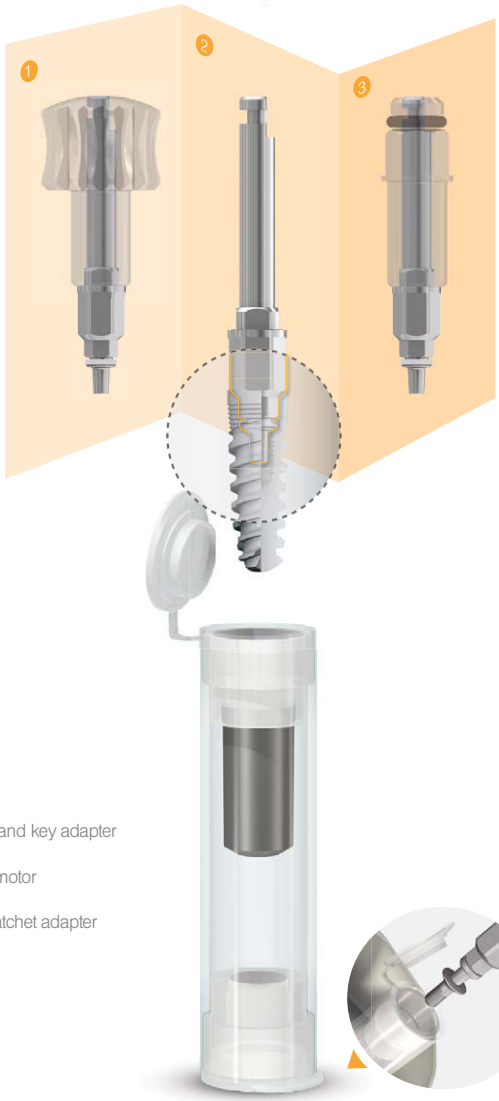
Specialized Surgical Tools

Standard platform insertion tools

In order to simplify procedures, a long and a short insertion tools are available. The 3 in 1 concept is based on the ability to connect each insertion tool to either a manual wrench or a motor.



Insertion Options.



1. Insertion tool in hand key adapter
2. Insertion tool for motor
3. Insertion tool in ratchet adapter

The same concept is applicable for wide platform tools.

Prosthetic Tools

Specialized Prosthetic Tools

The Friction fit abutment assembly contents
MT-IE172/ MT-IE161

The friction fit extractors (MT-IE171 standard/wide and the MT-IE161 narrow) are specifically designed to separate the friction fit abutments from the implant. The extractors are color coded, Blue for standard abutments and Yellow for narrow abutments.

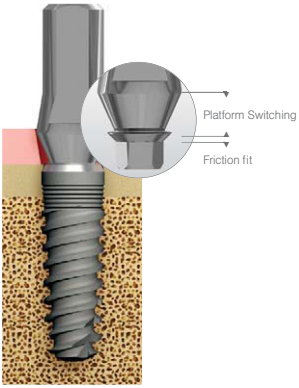
Int. connection abutment extractor
MT-IE172

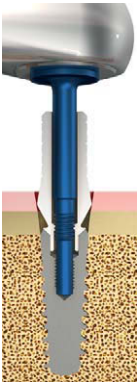
Int. connection abutment extractor, NP
MT-IE161

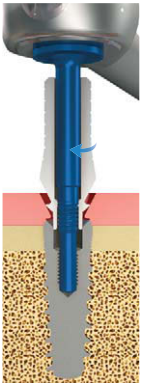
Extractor key

The extractor key is the extractor of friction fit abutments from the implants. Axis force activated on implant axis, take out the abutment from the implant.

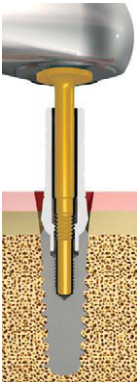
For standard / wide implants

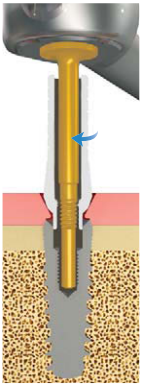



1.


2.

For narrow implants


1.


2.

Prosthetic Tools

Specialized Prosthetic Tools

SOS Broken Screw Kit
MT-TF172 / MT-RT001/ MT-HW001

The SOS Broken Screw Kit was designed to facilitate the removal of a broken screw.

SOS Broken Screw Kit
MK-0041

SOS Tools.

Thread Former
MT-TF172

Retriever
MT-RT001

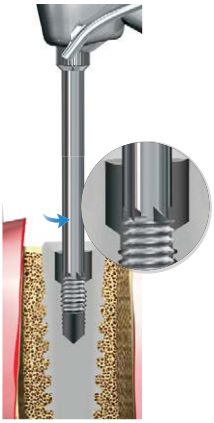
Hand Wrench
MT-HW001

Instructions for use:

1.

A. Connect the retriever to a micromotor.

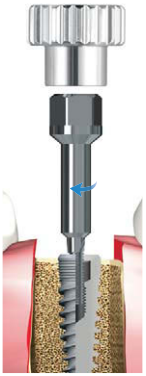
B. Adjust the micromotor to low speed (15-25 RPM), max torque and in reverse mode.



2.

A. Apply mild pressure with the retriever on the top of the broken screw.

B. While maintaining the pressure, activate the motor. This action should release the screw. If the screw is still not released, apply intermittent pressure on the screw.



3.

If internal threads are damaged:

A. The thread former has to be used carefully.

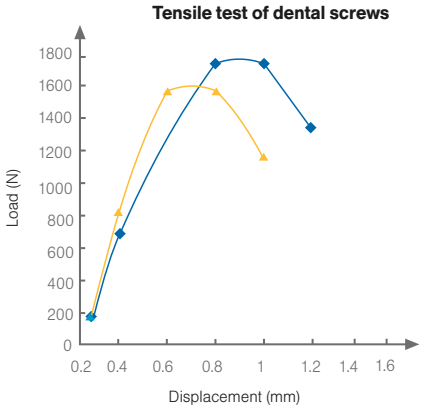
B. Be sure to align the thread former parallel to the long axis of the implant.

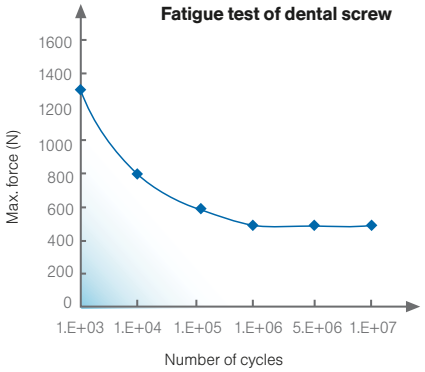
C. Always start by using a hand wrench. Apply gentle but firm force while turning the thread former in a clockwise direction. Release the pressure at the end of each complete turn by turning it 30° in a revere direction, and repeat the action as needed.

D. In instances where greater torque is needed, a ratchet may be used.

Surgical Tools

Screw Tests





Test conditions:

20 screws M2 of titanium grade 5
Loading frequency 30Hz

Test results indicate that the fatigue limit of the tested screws is 530N and that the screws will not break even after 5 million cycles.

Maintenance

The wide variety of MIS surgical tools requires careful maintenance:

Instrument maintenance:

MIS' surgical instruments are delivered non-sterile, unless indicated otherwise.

Disinfection

- Immerse instruments immediately after use.
- Use approved agents only.
- Observe manufacturer's recommendations regarding concentration/time/material compatibility.
- Detergents and cleaning agents containing high rates of the aforementioned chemicals.
- Extremely high temperature during cleaning and sterilization of the product.

Cleaning

Remove all residues.
Use an ultrasonic bath.
Use anticorrosive cleaning agent.
Thoroughly rinse away cleaning and disinfecting agents with running water.
Use distilled water to prevent water spots.

Drying

Allow instruments to dry, prior to sterilization.

Examination

Perform a visual inspection.
Dispose of damaged instruments.

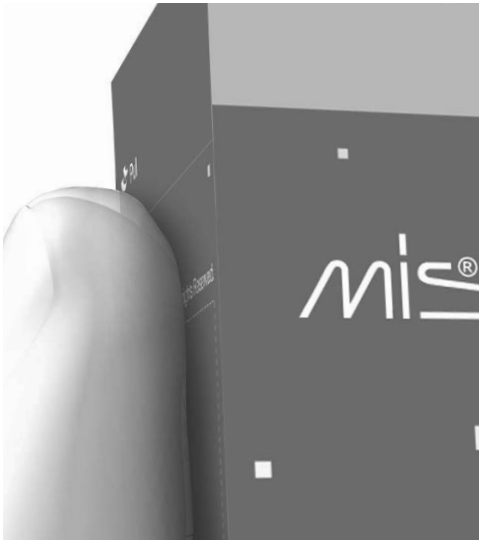
Check for:
Broken or dull drill blades
Bent instruments
Corrosion

Sterilization

Surgical instruments must be sterilized before use by autoclave, at 134°C (273°F), a pressure of ≈315 Kpa during 6 minutes or for pre-vacuum autoclave at 132°C (270°F) during 4 minutes. Do not exceed 134°C.

Storage

Store in a dry, dust-proof area. Keep instruments separated from chemicals. Resterilize prior to use, if instruments were stored for a prolonged period of time.



Packaging.

Packaging

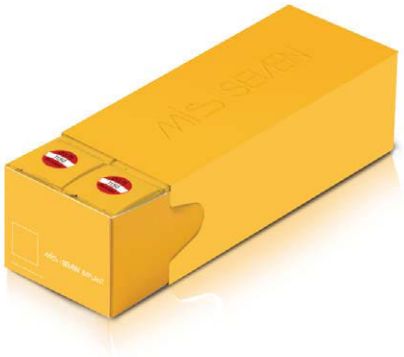
Implant Packaging

MIS' innovative packaging system is designed for simple and easy use. All of our implant's boxes feature distinctive colors, large typeface, clear data labels and a pull tab for quick opening. The square shaped boxes allow for compact, space saving storage.

Implant package

The individual implant package

Each SEVEN implant comes with a large range of sterilized components for any clinical scenario. Following the "Make It Simple" philosophy, MIS is proud to be the first to include a sterile single use final drill with every SEVEN implant, to ensure safe and precise surgical procedure.



10 Implants Package

A convenient 10 implant package is available. The drawer-like box is ideal for storage in drawers or cabinets for easy identification of implant's type, diameter and length.

Insertion of the adaptor

Cover screw

Implant

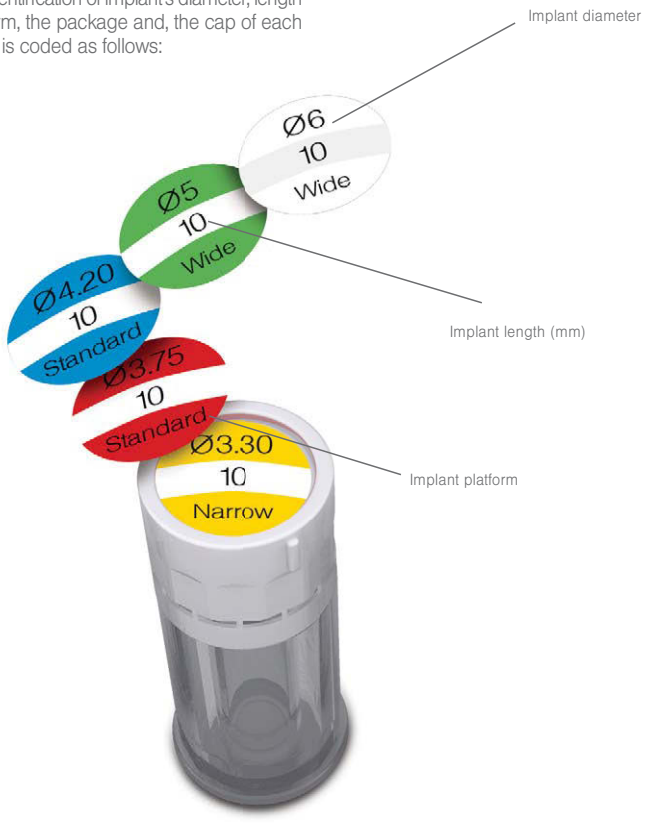
Double container system

To ensure that implants are sterile, and to prevent surface contamination, each implant is stored in a Titanium sleeve within an internal plastic tube. This tube is held in a larger sealed outer tube, marked with all relevant information. The inner tube is therefore sterile, and can be dropped to the surgical field whenever needed.

Packaging

Implant Identification Codes

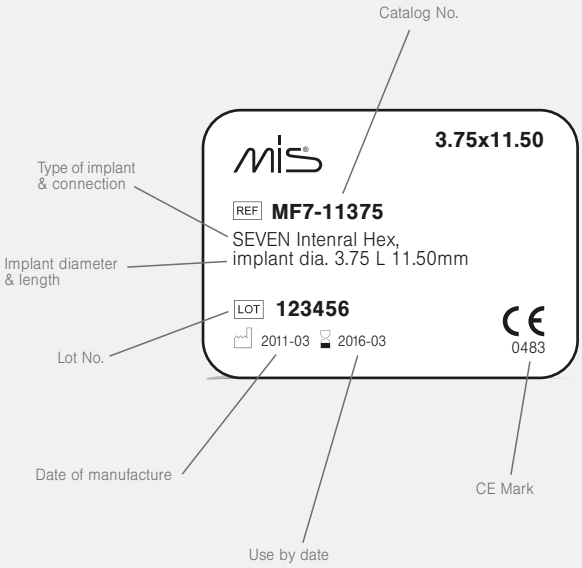
For easy identification of implant's diameter, length and platform, the package and, the cap of each outer tube is coded as follows:



Packaging

Implant Data Label

Each package contains three data labels, including all the required information related to the implant. The following image illustrates the label and its content:



Packaging

Implant Package Handling

Make sure using physical and visual examination that the implant is of the right type and dimensions for the specific procedure for each patient.

Fig. 1

Open the box by pressing on the marked dotted line, and remove the outer tube from the box.

Fig. 2

Open the outer tube by pressing down on the lid and turning the tube counter clockwise. Drop the sterile inner tube into the sterile field.

Packaging

Implant Package Handling

Fig. 3

The implants is held by the titanium sleeve. To expose the implant - hold the tube with the titanium sleeve facing up and open the upper cap. Open the tube's cap on the end containing the implant.

Fig. 4

The data labels should be used within the medical chart.

Use one of the following three options to remove the implant from the inner tube:

Fig. 6A

A contra-angle hand piece

Fig. 6B

Rachet

Fig. 6C

Rachet

Packaging
Implant Package Handling

Fig. 6D
A hand wrench

Fig. 6D
A hand wrench

Fig. 7

Commence implantation procedure

Fig. 8

Open the other end of the smaller tube. Remove the cover screw from the other side of the inner tube using the MT-LM005 key

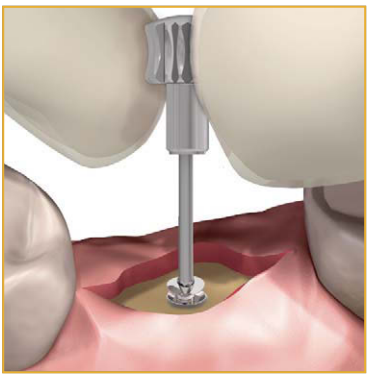
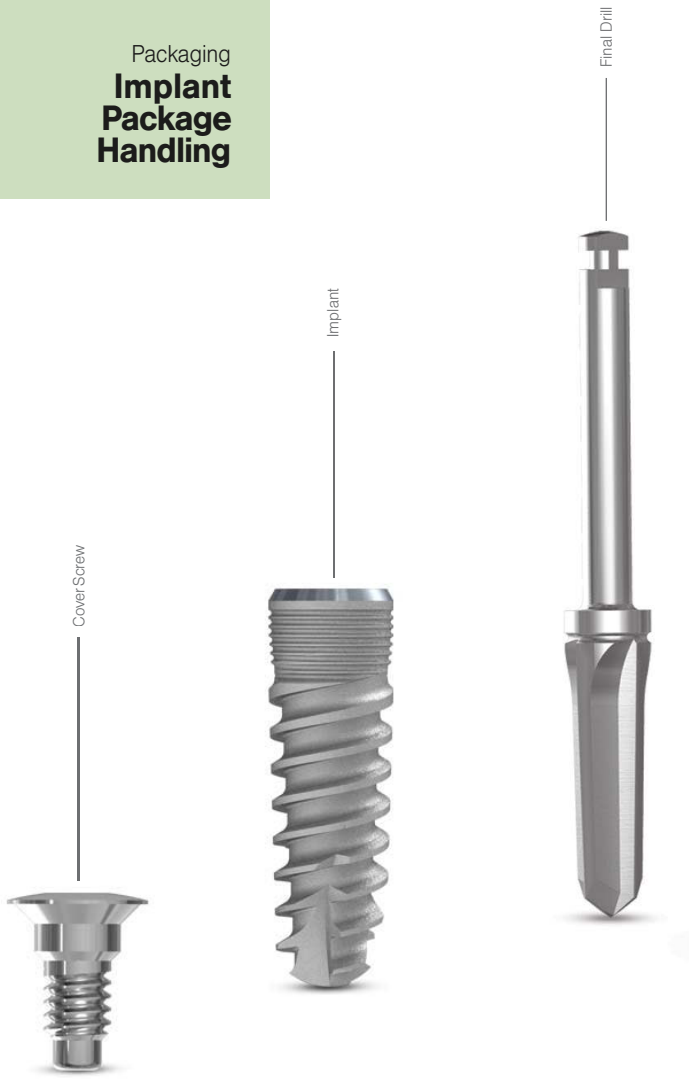


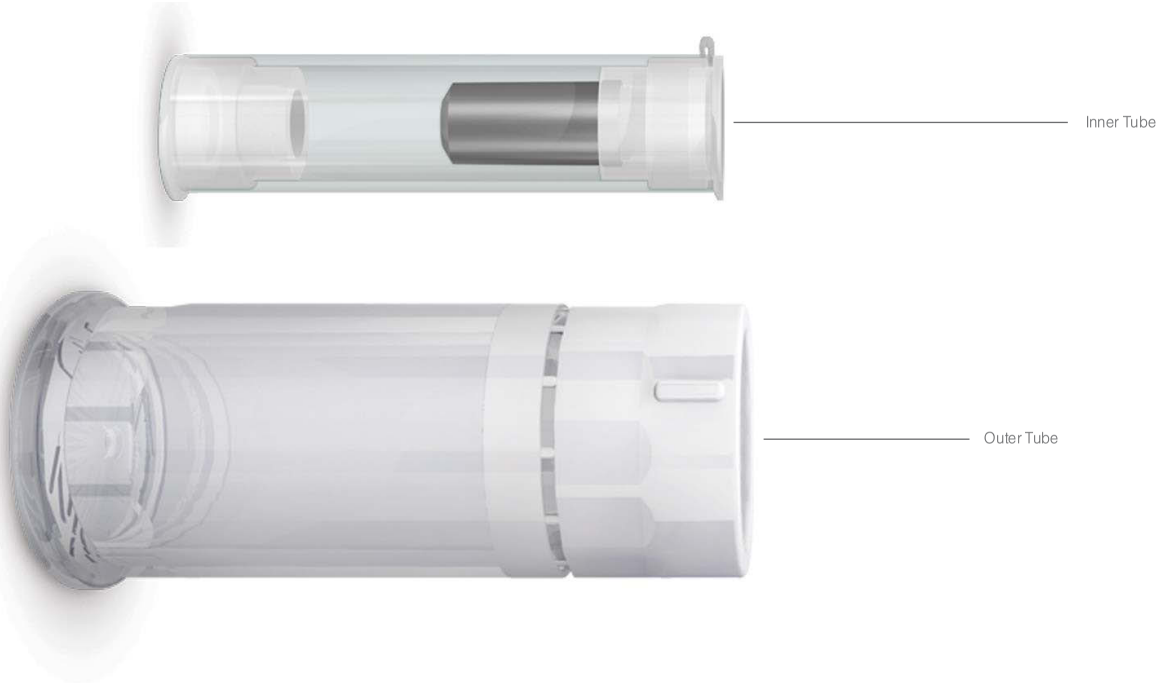
Fig. 9

Attach the cover screw to the implant using the MT-LM005 key

Packaging

Implant Package Handling





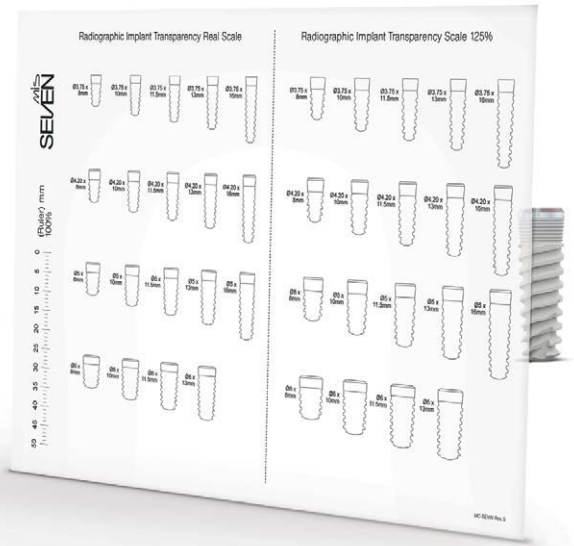
Packaging

Planning Transparency

MIS offers a planning transparency, illustrating the full SEVEN implant range. It includes two sets of images: one in real size, and the other at a magnification of 125%, relevant for use with panoramic radiographs that include a similar inherent magnification. In addition, the transparency includes a real size ruller.

By planing the appropriate section of the transparency on a radiograph, a clinician can choose the best fitting implant diameter and length, as part of the planning process.

The transparency available for SEVEN implants is: Cat No. **MC-SEVIN**



Symbols

Key to the symbols on labels and instruction leaflets:

LOT Batch code	Manufacturer
REF Catalog number	Do not resterilize
For single use only	Do not use if package is damaged
Attention, see instructions for use	EC REP Authorised representative in the European community
Date of manufacture	Use by
STERILE R Sterilized using gamma irradiation