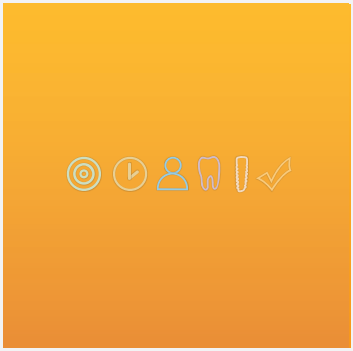
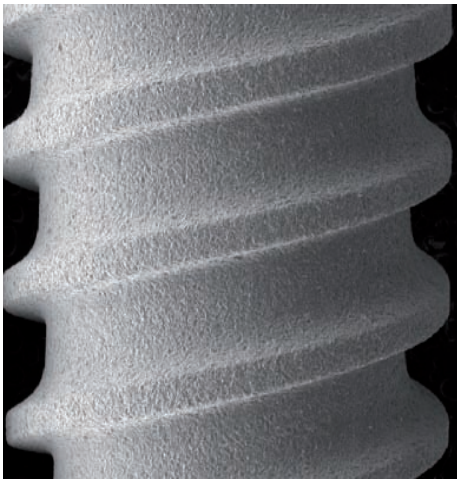
User Manual

MIS scientists and engineers are continually seeking superior materials, technologies and procedures with the aim of developing quality products designed to make implant dentistry effective, safe and simple. The SEVEN implant system is one such breakthrough. With over ten years' proven clinical experience, the SEVEN has become one of the world's best-selling implants, providing a unique combination of surgical and restorative benefits.



The MIS 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 products are cleared for marketing in the USA and CE approved.



Overview.

Overview
Introduction

MIS is a dynamic, state-of-the-art production company, developing and manufacturing a comprehensive range of dental implants designed to provide long-lasting successful solutions to partial and complete edentulous conditions. MIS implant systems combine several advantageous elements such as choice of raw materials, macro-structure, micro-structure and surface treatments, in order to achieve high primary stability and successful osseointegration.

MIS upholds high quality standards by conducting comprehensive quality assurance evaluations throughout the entire production process. MIS uses a clinically proven implant surface treatment technology that combines sand-blasting and acid-etching to increase surface area, creating both micro and nano-structures and eliminating surface contaminants. The implant surface is continuously monitored by a comprehensive series of tests, conducted both in-house and by internationally recognized research institutes.
Tests include:

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

Overview
Raw Material

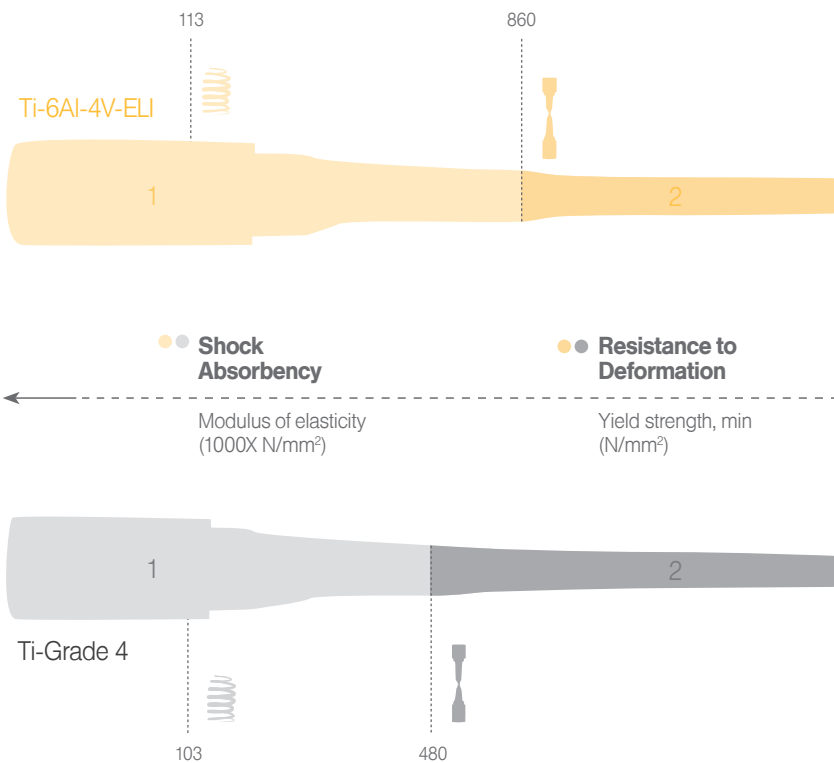
- Biocompatible
- Safe
- Long-term proven clinical success
- Superior mechanical properties

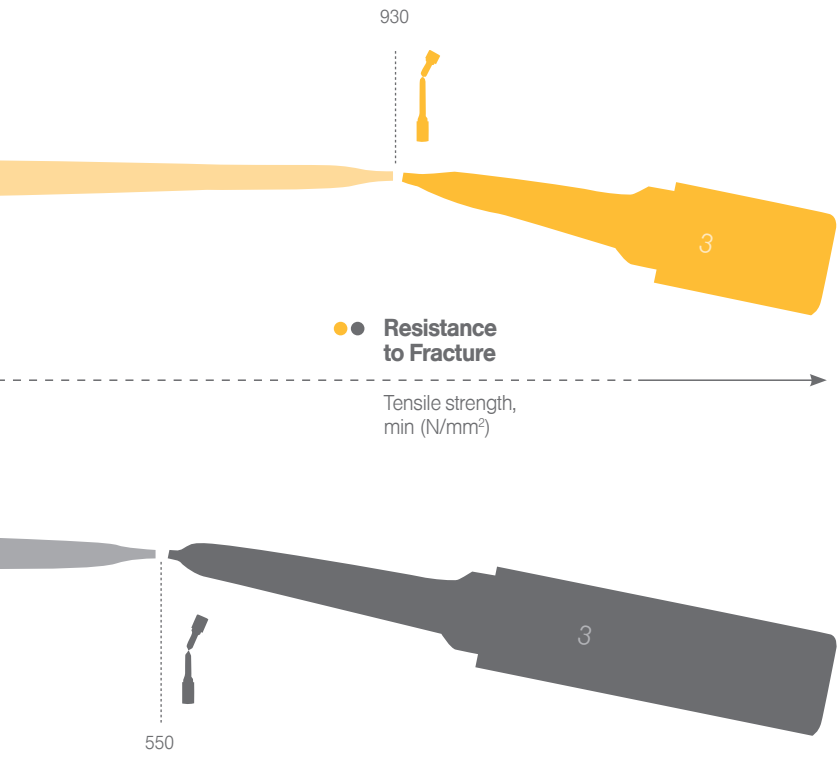
All MIS implants are made from Ti-6Al-4V ELI (Grade 23), the higher purity version of Ti-6Al-4V. This specific type of alloy combines biocompatibility, excellent fatigue strength and low elastic modulus. These benefits make Ti-6Al-4V ELI mechanically superior to titanium grade 4 and the ultimate dental and medical titanium grade.

Ti-6Al-4V has been in use for over 25 years, and is the raw material most commonly used in the production of dental implants.

Similar to commercially pure titanium (Grades 1-4), the outer surface of all MIS implants are comprised of a thin layer of pure titanium oxide (TiO_2). In this way, bone cells cannot differentiate between the different titanium grades. The TiO_2 layer also prevents metallic ions leaking from the alloy, for safe 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
Resistance
to Fracture
Tensile strength,
min (N/mm²)
3
550

Overview

Manufacturing Process

Structure (Raw Material)

MIS Surface Treatment

Sand-Blasting

Acid-Etching

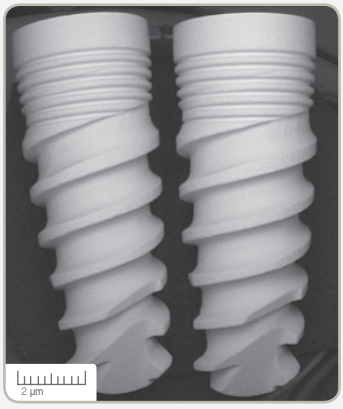
Roughness (Macro and Nano Structures)

The combination of sand-blasting and acid-etching induces macro and nano-structures that significantly increase surface area of the implant body for optimal osseointegration. The roughened surface improves bone adhesion, as well as the proliferation and differentiation of osteoblasts.

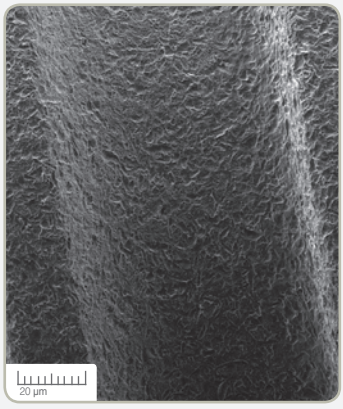
Overview

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. Osseointegration is determined by both the raw material of the implant, morphology and surface chemical composition.



SEM image of two SEVEN implants



SEM image of the implant surface

Macro-structure

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

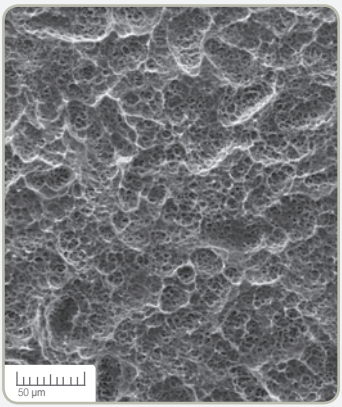
All MIS implants are sand-blasted and acid-etched. This surface treatment increases the implant surface area, creating both micro and nano-structures, while eliminating various surface contaminants.

MIS is one of only a handful of companies worldwide using electron microscopy on a daily basis for implant quality inspection.

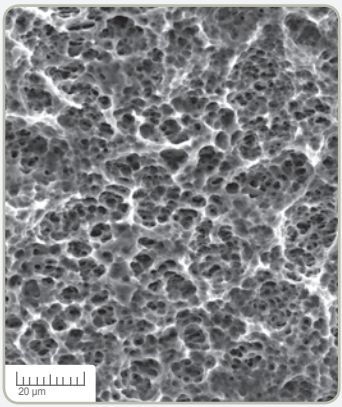
Sand-blasted and acid-etched surfaces have been substantially proven to maximize the BIC (Bone-to-Implant Contact), achieving immediate and long-lasting osseointegration.

Surface composition

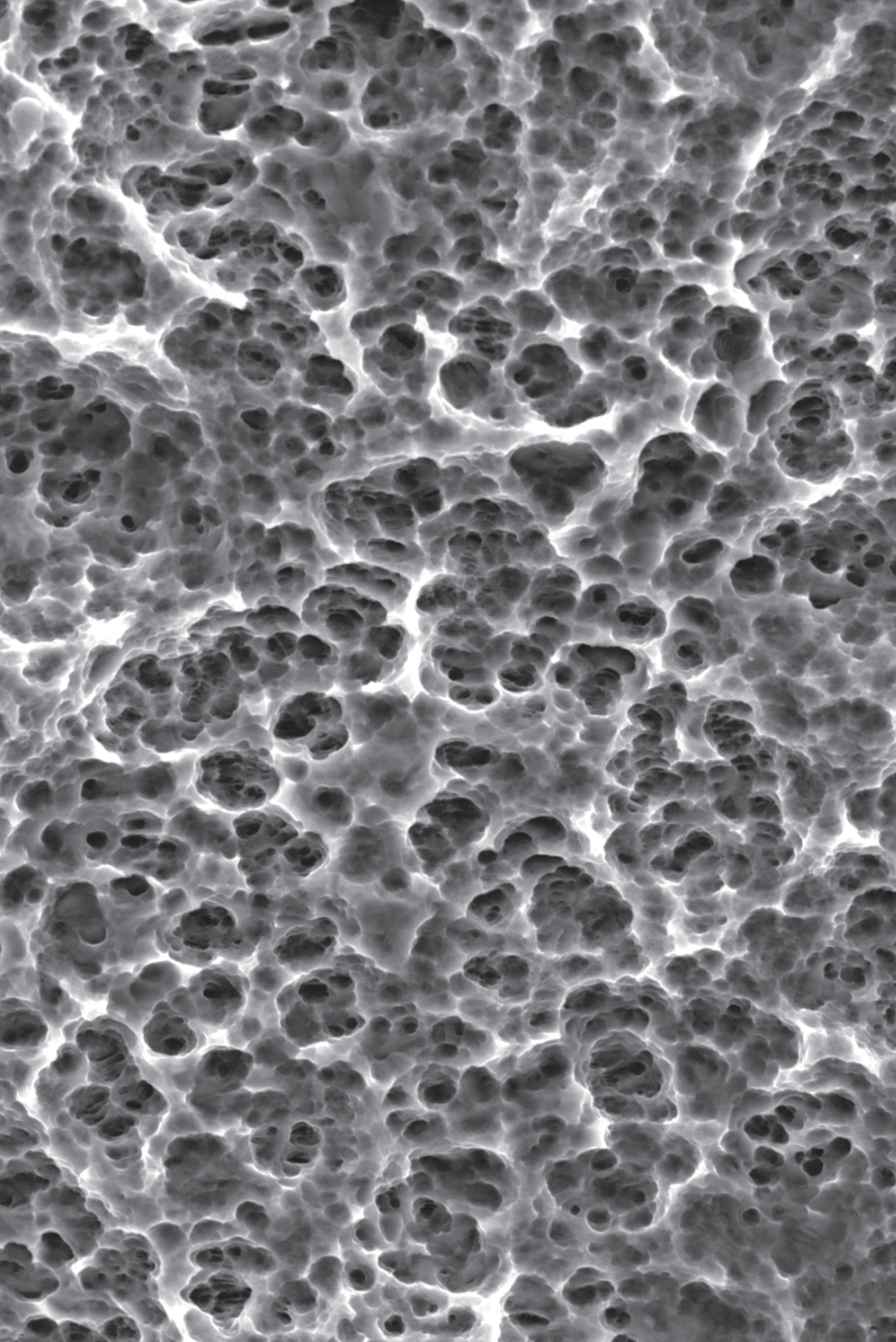
The outer surface of MIS implants, consist of a thin layer of pure titanium oxide (TiO2). Acid-etching and packaging processes are performed in a controlled environment clean-room to ensure purity and quality. Implants are inspected by electron microscope (SEM) scan and X-ray photoelectron spectroscopy (XPS), to ensure implants are free of contaminants.



SEM image of the implant surface showing the micro-structure

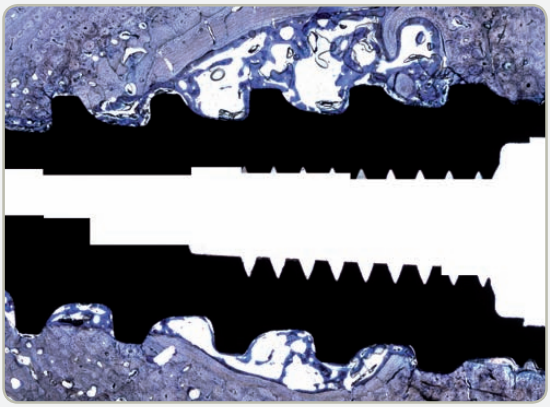


SEM image of the implant surface showing the nano-structure



Overview
Histology

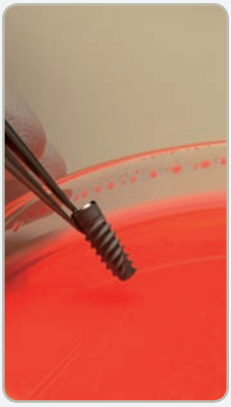
Histologic section of a SEVEN implant, 5 weeks after placement. Courtesy of Paulo G. Coelho, DDS, PhD, NYU College of Dentistry.

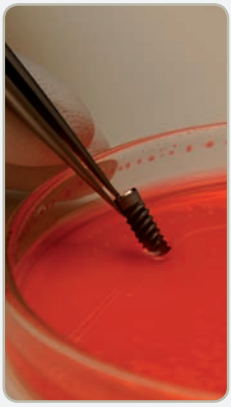


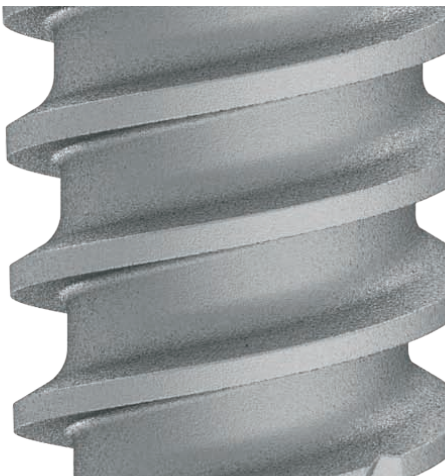
Courtesy of Paulo G. Coelho, DDS, PhD, NYU.

Overview
Hydrophilicity

Current literature demonstrates a linkage between improved bone healing and early osseointegration with the hydrophilicity of surface. MIS implant surface treatment combines sand-blasting and acid-etching. This combination ensures surface purity and hydrophilic properties. The images demonstrate liquid "climbing" upwards on the implant surface.





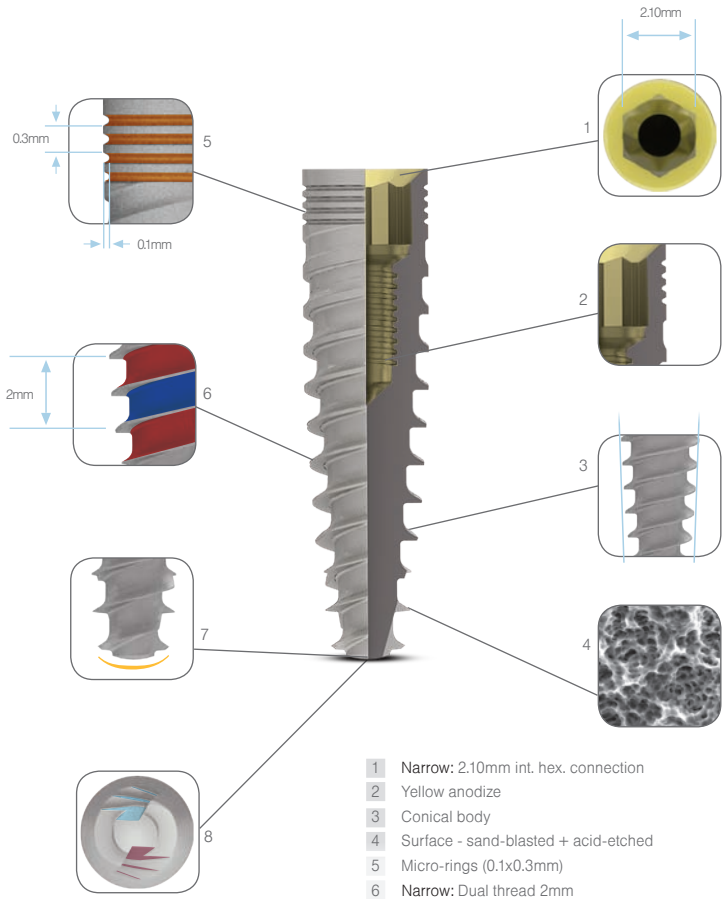


Implants.

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, spiral channels stemming from the apex, micro-rings on the implant neck and a variable thread thickness along the implant. All MIS SEVEN implants are supplied with a single use final drill, to ensure a sterile and consistently sharp blade for cutting bone walls to support the implant.

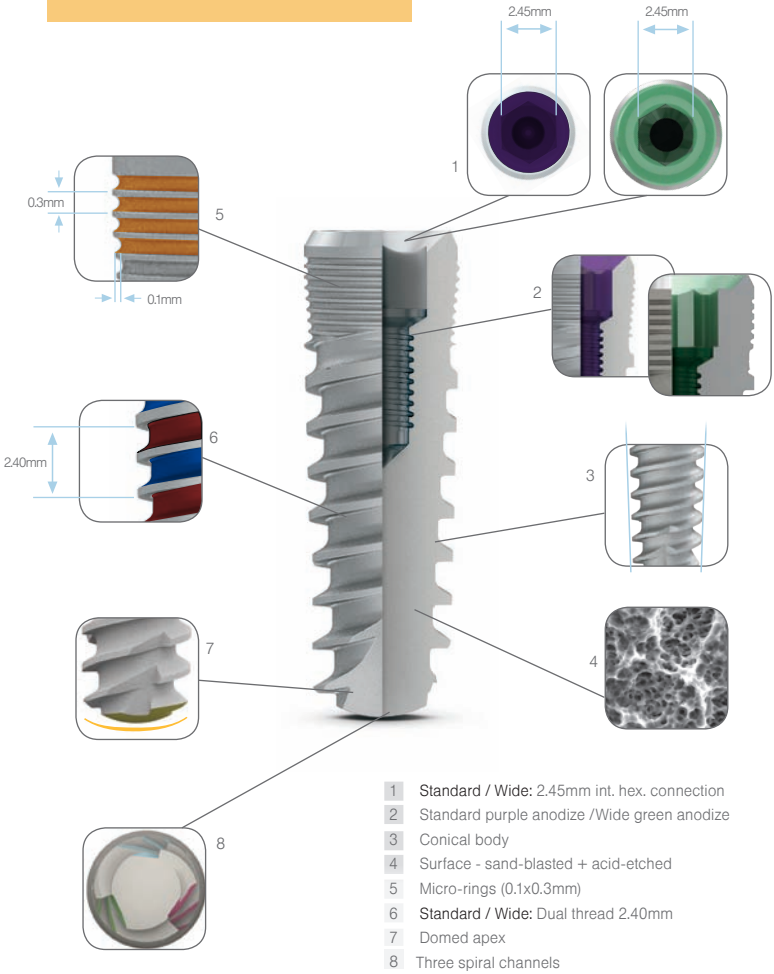
SEVEN | NARROW
Fixture - Technical Info



1. Narrow: 2.10mm int. hex. connection
2. Yellow anodize
3. Conical body
4. Surface - sand-blasted + acid-etched
5. Micro-rings (0.1x0.3mm)
6. Narrow: Dual thread 2mm
7. Domed apex
8. Two spiral channels

SEVEN STANDARD WIDE

Fixture - Technical Info



1 **Standard / Wide:** 2.45mm int. hex. connection
2 Standard purple anodize /Wide green anodize
3 Conical body
4 Surface - sand-blasted + acid-etched
5 Micro-rings (0.1x0.3mm)
6 **Standard / Wide:** Dual thread 2.40mm
7 Domed apex
8 Three spiral channels

SEVEN
Features

Features

- The SEVEN implant is designed to suit a wide range of bone types and bone augmentation procedures.
- Specially designed final drill ensures shorter, safer drilling procedures.
- A double thread of 2.40mm increases implant insertion speed.
- Self-tapping capability.
- Three spiral channels for improved integration.
- The micro-rings (0.1x0.3mm) on the implant neck reduce stress in the crestal zone.
- Differential thread thickness (0.15-0.4 mm) reduces bone compression.
- 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 well-established surface morphology.

Versatile

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

Simple

Designed for a simpler and safer drilling procedure, every SEVEN implant is packed with a sterile, single-use final drill.

Efficient

The large thread design and self-tapping capability enables secure and fast implant insertion.

Primary Stability

Tapered thread thickness and depth, locks implant into the surrounding bone, to ensure smooth insertion and mild bone compression, resulting in high immediate stability.

Minimal Bone Resorption

The unique MIS surface treatment combined with micro-rings at the implant neck, ensure minimal bone resorption.

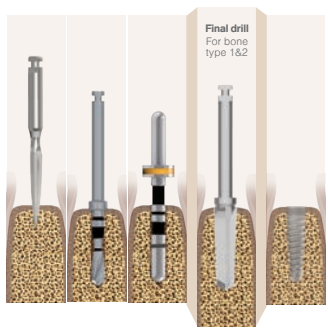
SEVEN
Implant Range

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.

* Recommended insertion torque: 35-60 Ncm.

Ø3.30mm Implant Procedure

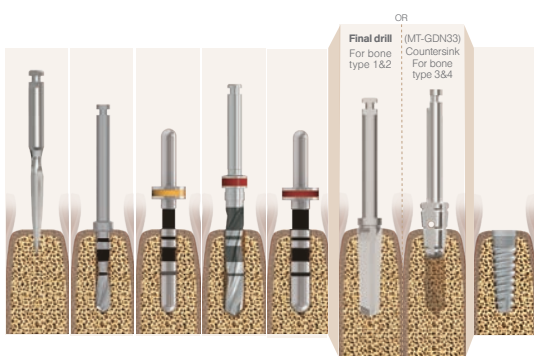


Do not use the final drill for bone type 3&4.

The drilling sequence is demonstrated by a 13mm implant.

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

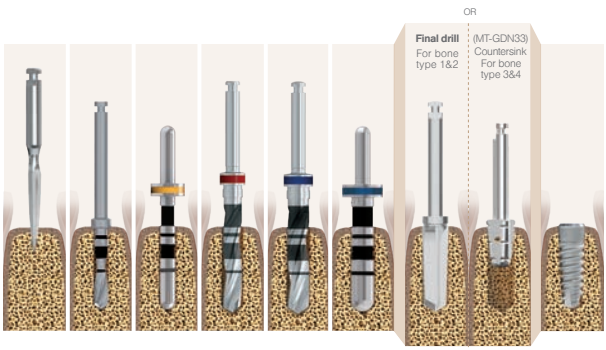
Ø3.75mm Implant Procedure



* Recommended insertion torque: 35-60 Ncm.

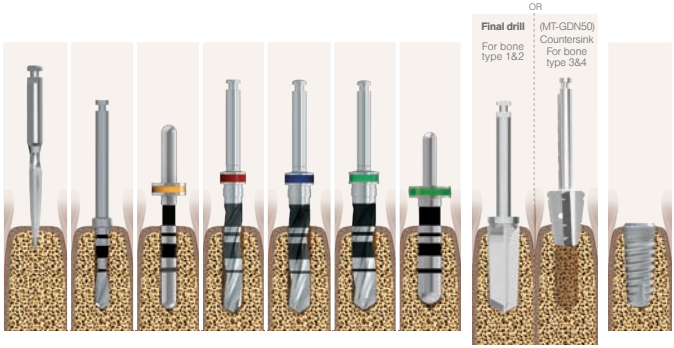
Ø4.20mm Implant Procedure

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

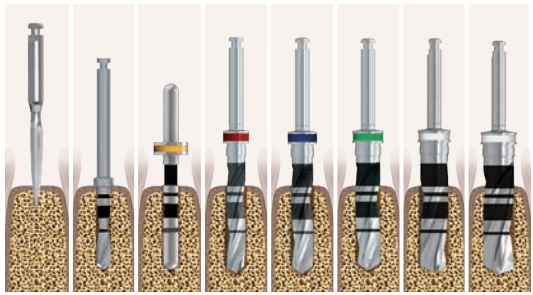


SEVEN
Ø6mm Procedure

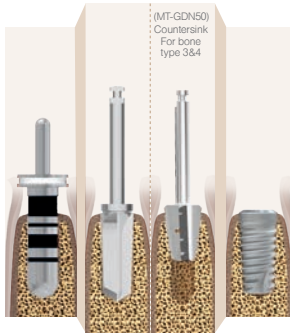
* Recommended insertion torque: 35-60 Ncm.

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 & 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 superstructures

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 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 are not limited to) nerve injuries and persistant local or systemic infections. Special care and attention needs to be given to susceptible individuals with compromised immune systems 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 should 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 wide 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 involve (but are not limited 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 in advance. 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 used as computer-based surgical guides.

Step 4.
Treatment Plan
(Patient cooperation)

Based on patient's 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 the patient's 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 the label 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 the package. Implant placement should be performed in accordance with acceptable placement and loading protocols. Recommended MIS procedures are described on 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.

12
24

Step 6.
Osseointegration Phase

Current literature supports multiple loading options. Dentist should decide when to load implants based on specific parameters, related to their individual case.

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 emphasis should be put on oral hygiene and habits, occlusion adjustments and the stability of the prosthesis.


FD
Ø4,20
Ø5
Ø6
SE
MIS
EN

Surgical Kit.

The Surgical Kit

Surgical Kit Description

The SEVEN surgical kit comprises a complete range of drills and tools required for SEVEN implant placement procedures. It features a convenient ergonomic layout that follows the surgical drilling sequence, and includes a set of length-based pilot drills for a smoother more accurate procedure. Kit components are color-coded for immediate identification of diameters for both implants 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 134°C (273°F) for 6 minutes. Do not exceed 134°C.

The surgical kit is compact and easy to store.

Tray can be removed from the box for easy cleaning and sterilization.

Steam flow is optimized through built-in vents.

Warning

Avoid damage!

Temperatures higher than 150°C may cause damage. Radel, steel and silicone components may support repeated exposure to temperatures up to 180°C, however tray-life may be reduced.

The use of cleaning or disinfecting agents containing high rates of chlorine or oxalic acid may cause damage to the trays and to the instruments. Please handle 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.

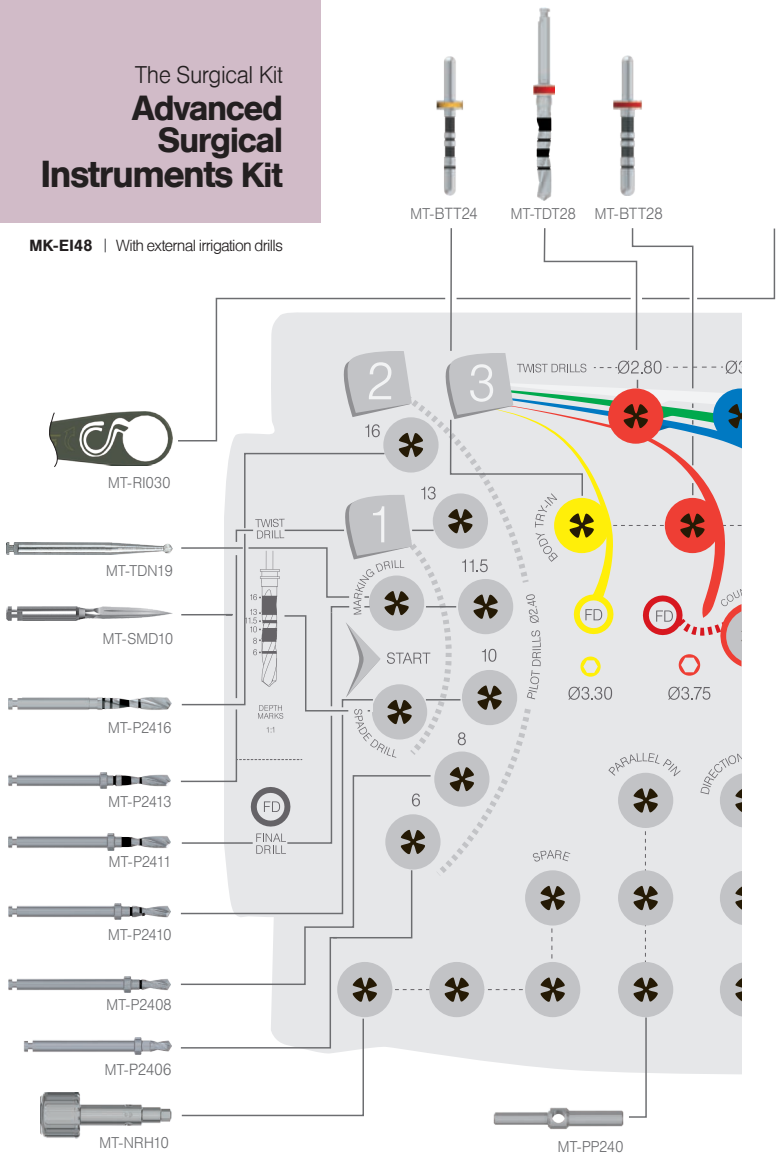
Please Note:

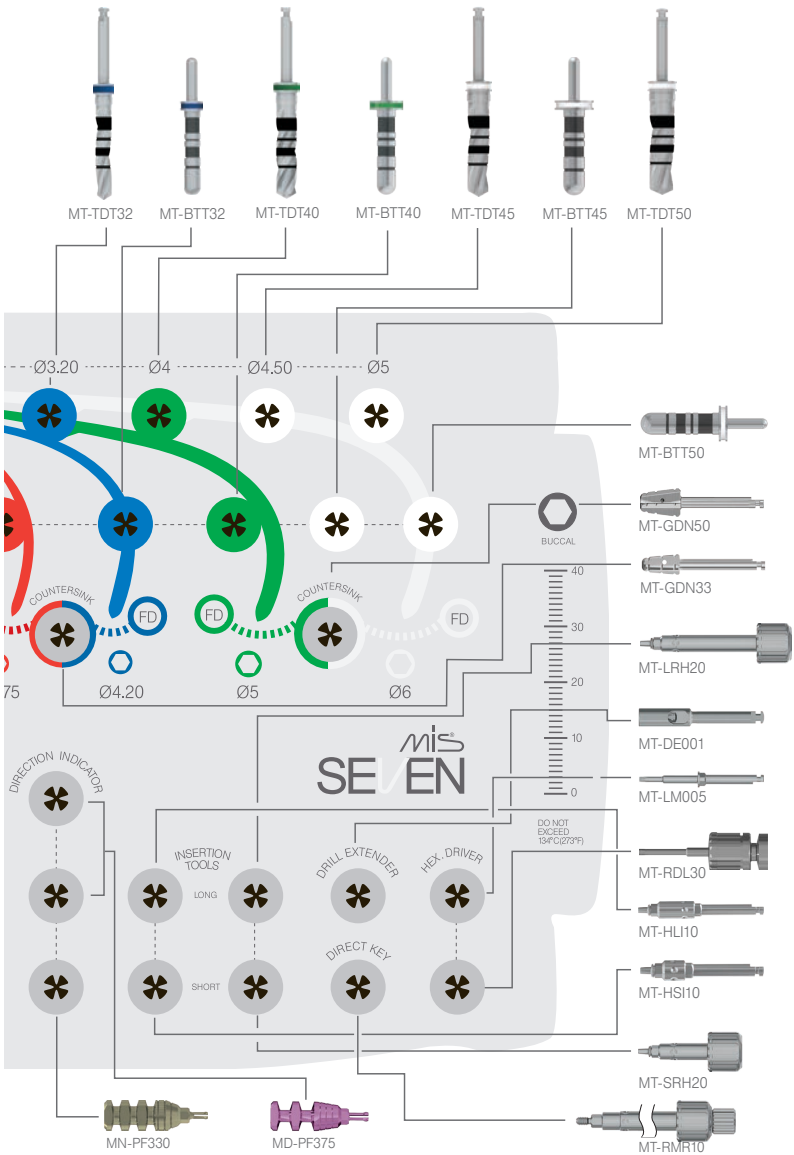
▪ Conduct a visual inspection of the instruments prior to each use. Do not use faulty and dull instruments. Clean and disinfect each instrument separately ▪ Do not allow traces/ residue (blood, secretion, tissue residue) to dry on the instruments. Always soak in disinfecting fluid immediately after use ▪ 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 instruments must be sterilized in an autoclave, at 134˚C (273˚F). Do not exceed 134°C. Never use dry sterilizers ▪ Inspect for corrosion after sterilization.

The Surgical Kit

Advanced Surgical Instruments Kit

MK-EI48 | With external irrigation drills




MT-TDT32
MT-BTT32
MT-TDT40
MT-BTT40
MT-TDT45
MT-BTT45
MT-TDT50
Ø3.20
Ø4
Ø4.50
Ø5
COUNTERSINK
FD
COUNTERSINK
FD
FD
75
Ø4.20
Ø5
Ø6
BUCCAL
40
30
20
10
0
DIRECTION INDICATOR
INSERTION TOOLS
LONG
SHORT
DRILL EXTENDER
HEX. DRIVER
DIRECT KEY
DO NOT EXCEED 134°C(273°F)
MT-BTT50
MT-GDN50
MT-GDN33
MT-LRH20
MT-DE001
MT-LM005
MT-RDL30
MT-HLI10
MT-HSI10
MT-SRH20
MT-RMR10
MN-PF330
MD-PF375

The Surgical Kit

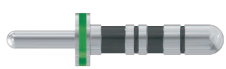
Kit Contents

The SEVEN Surgical Kit contains tools specifically designed for a step-by-step placement process. Correct preparation of the implant site ensures efficient and accurate placement and high primary stability.


Ø3.20
Ø4
Ø4.50
Ø5
FD
COUNTERSINK
Ø3.75
Ø4.20
Ø5
Ø6
BUCCAL
40
30
20
10
0
DO NOT EXCEED 134°C (272°F)
SE mis EN
DIRECTION INDICATOR
INSERTION TOOLS
LONG
SHORT
DRILL EXTENDER
HEX. DRIVER
DIRECT KEY

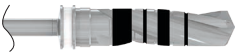
The Surgical Kit

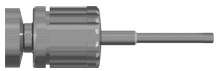
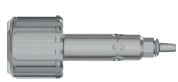
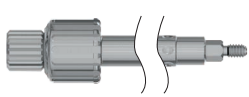
Kit Contents

		Dimensions	Material
	**MT-P2406** | Pilot drill with built in stopper Ø2.40 height 6mm	Ø2.40mm Length 31.8mm	Stainless steel
	**MT-P2408** | Pilot drill with built in stopper Ø2.40 height 8mm	Ø2.40mm Length 31.8mm	Stainless steel
	**MT-P2410** | Pilot drill with built in stopper Ø2.40 height 10mm	Ø2.40mm Length 31.8mm	Stainless steel
	**MT-P2411** | Pilot drill with built in stopper Ø2.40 height 11.5mm	Ø2.40mm Length 31.8mm	Stainless steel
	**MT-P2413** | Pilot drill with built in stopper Ø2.40 height 13mm	Ø2.40mm Length 31.8mm	Stainless steel
	**MT-P2416** | Pilot drill Ø2.40 height 16mm	Ø2.40mm Length 37.5mm	Stainless steel
	**MT-BTT24** | Body try-in Ø2.40mm for tapered impl. procedure	Ø2.40mm Length 28.5mm	Stainless steel
	**MT-BTT28** | Body try-in Ø2.80mm for tapered impl. procedure	Ø2.80mm Length 28.5mm	Stainless steel
	**MT-BTT32** | Body try-in Ø3.20mm for tapered impl. procedure	Ø3.20mm Length 28.5mm	Stainless steel
	**MT-BTT40** | Body try-in Ø4mm for tapered impl. procedure	Ø4mm 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
	**MT-TDT28** | Twist drill 2.80mm external irrigation	Ø2.80mm Length 37.5mm	Stainless steel

The Surgical Kit

Kit Contents

		Dimensions	Material
	**MT-TDT32** | Twist drill 3.20mm external irrigation	Ø3.20mm Length 37.5mm	Stainless steel
	**MT-TDT40** | 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-TDT50** | 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-LRH20** | Long insertion tool for int. hex. connection	Length 32.3mm	Stainless steel
	**MT-NRH10** | Long ratchet adapter for int. hex. connection, NP	Length 24.5mm	Stainless steel
	**MT-LM005** | Long motor adapter for 0.05" hex.	Length 30mm	Stainless steel

		Dimensions	Material
	**MT-RDL30** | Long hex . drive 0.05 inch	Length 23.5mm	Stainless steel
	**MT-DE001** | Drill extender	Length 24mm	Stainless steel
	**MT-PP240** | Parallel pin Ø2.40mm for tapered impl. procedure	Ø2.40/ Ø3mm / Length 24mm	Stainless steel
	**MN-PF330** | Direct press fit for closed tray NP	Length 16.7mm	Titanium
	**MD-PF375** | Direct press fit for closed tray	Length 16.3mm	Titanium
	**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-SRH20** | Short insertion tool for int. hex. connection	Length 22.30mm	Stainless steel
	**MT-RMR10** | Long direct hand and ratchet key	Length 38.50mm	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 84mm	

Drills.

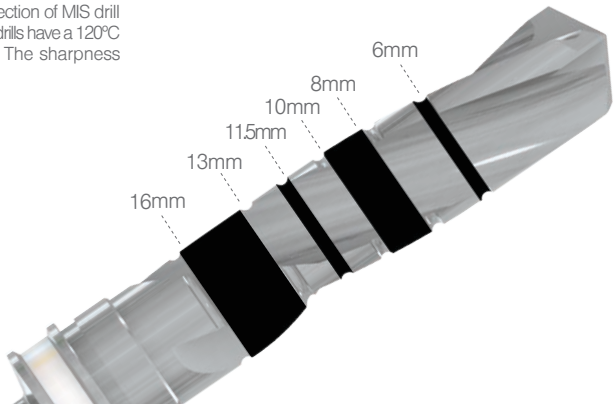
Drills

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. Drills are available with or without internal irrigation. Short drills are also available for each diameter. All drills are color-coded. The drills are marked 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 120°C 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 Stoppers

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 most commonly used implant lengths 3.75 or 4.2, MIS offers a single assorted kit - the SEVEN drill stoppers kit Standard platform (MK- BS001), which includes all stoppers required for safe placement of Standard platform implants.

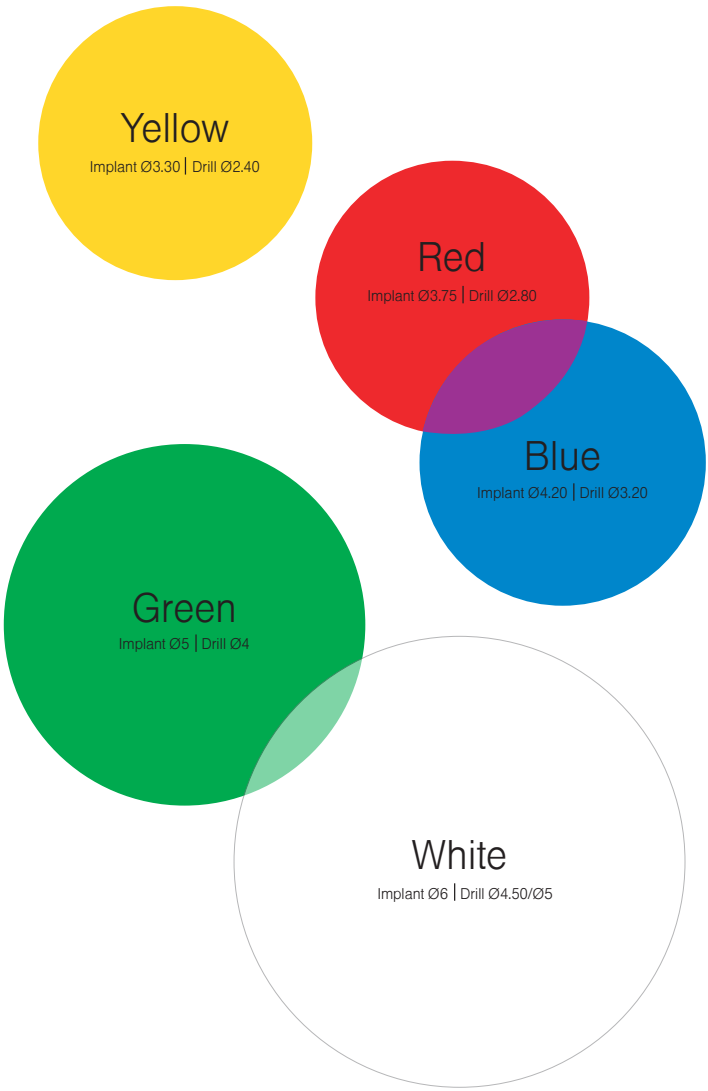
SEVEN Depth-based Drill Stoppers Kits:
(MK-SDS06, MK-SDS08, MK-SDS10, MK-SDS11, MK-SDS13)

SEVEN Drill Stoppers Kit Standard Platform:
(MK-BS001)

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

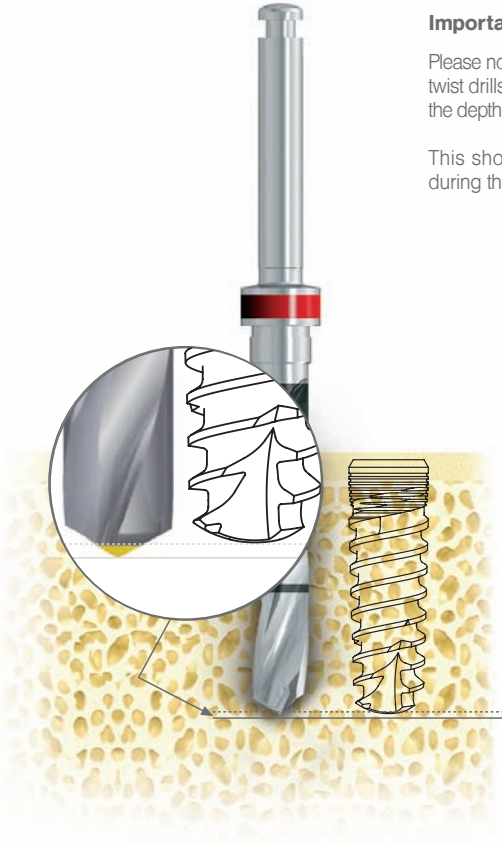
Drills
Color Code

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



Drills

Drill Indications



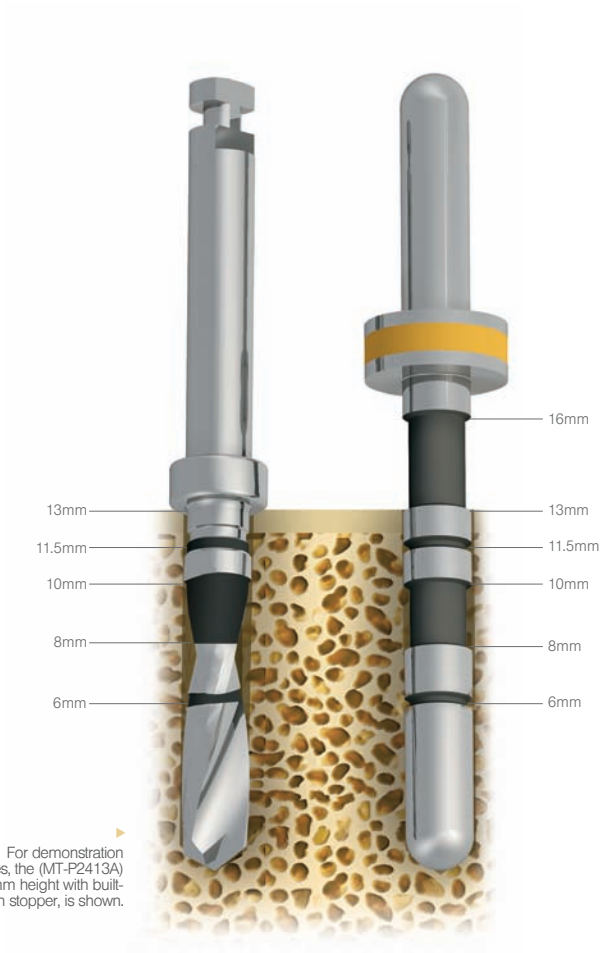
Important!

Please note that the apical tip of all MIS twist drills is up to 0.5mm longer than the depth of the corresponding implant.

This should be taken into account during the planning phase.

Depth Verification

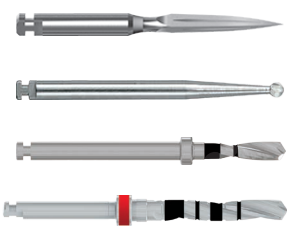
Depth verification can be made by the use of body try-in tools (MT-BTTxx). The laser markings correspond to those on the drills and allow a safe, easy way to ensure the required depth is achieved.

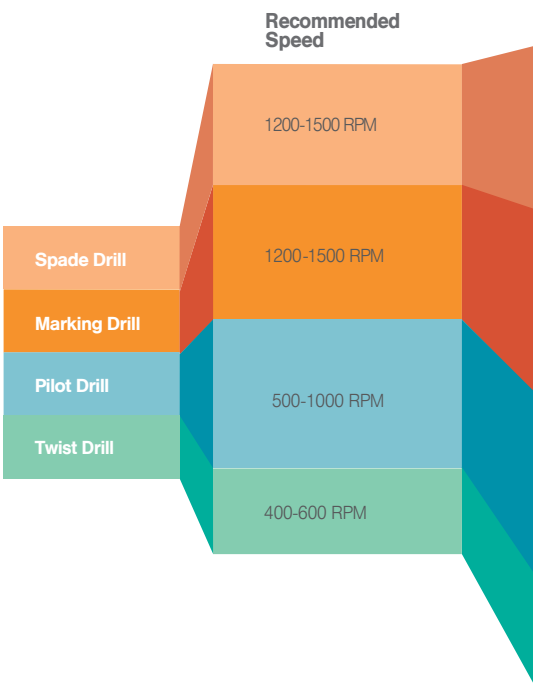


For demonstration purposes, the (MT-P2413A) drill 13mm height with built-in stopper, is shown.

Drills

Drills Overview





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 procedures.
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 come in six 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 when using twist drills.

SEVEN
Final Drills

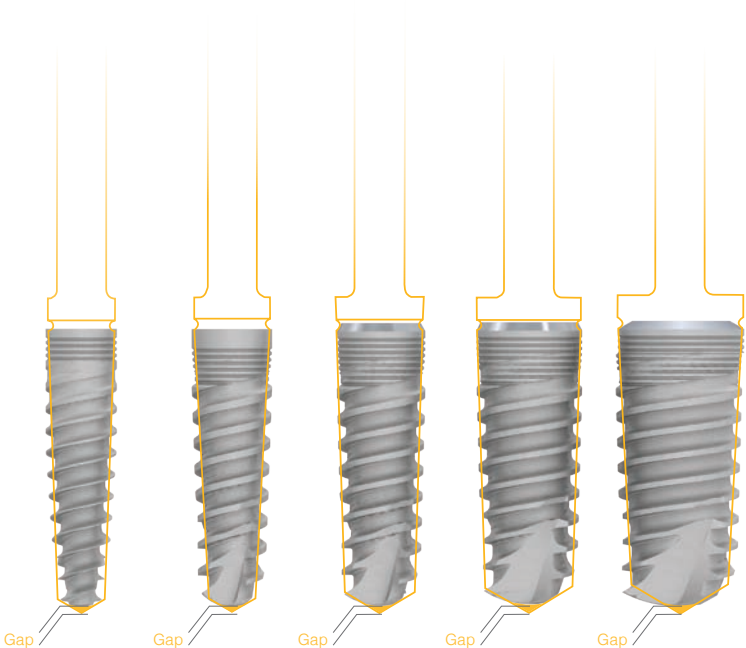
Final Drill for implant diameters

Ø3.30	Ø3.75	Ø4.20	Ø5	Ø6

SEVEN

Special Final Drill

The specially designed single-use 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 neck. The special final drill is supplied with every implant, allowing for a shorter, safer drilling procedure. Recommended drilling speed is 200-400 Rpm.

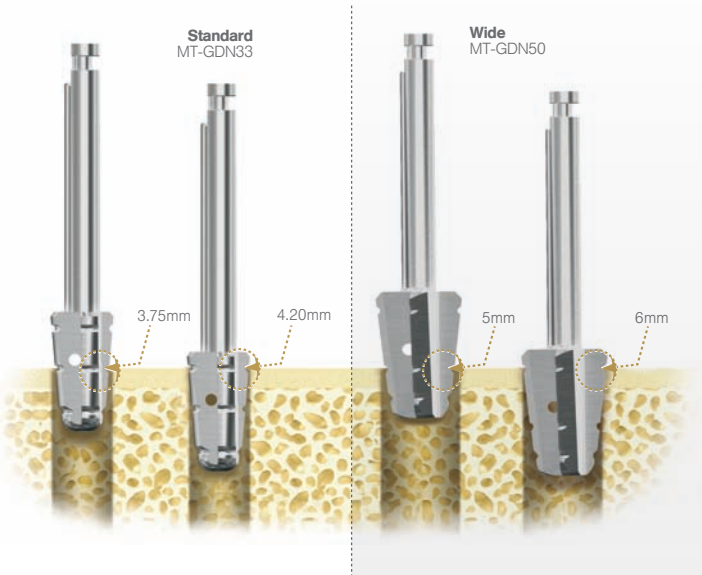


Drills

Countersink Drills

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 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). Recommended drilling speed is 200-500 RPM.



Drills

Ceramic Drills

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

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

Dimensions: Ø2.10mm Length 28.5mm

Material: Zirconia-alumina ceramic

MT-CRD20
Pilot Drill

Dimensions: Ø2mm Length 33.5mm

Material: Zirconia-alumina ceramic

MT-CRD28
Twist Drill

Dimensions: Ø2.80mm Length 35mm

Material: Zirconia-alumina ceramic

Drills

Drill 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) for 6 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) for 6 minutes. Do not exceed 134°C.

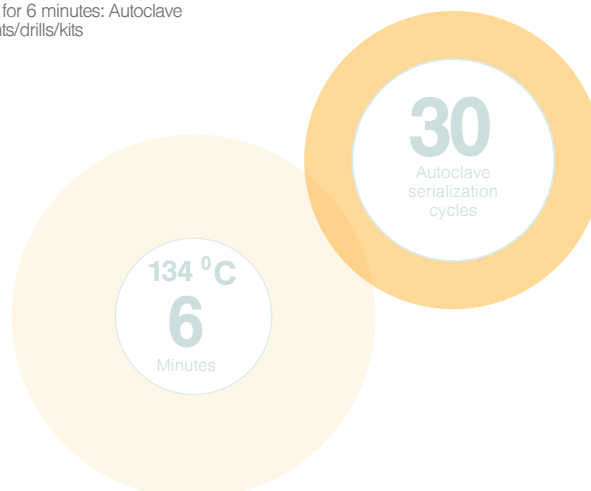
Stage 5: Storage/Use - Store kits in a cool and controlled environment. Please note that sterilization may expire after a certain time. If kits have been stored for a prolonged period resterilize them before use.

Drills

Drill Maintenance

Recommendations

- Cutting tools should be used for a maximum of 30 uses.
- Distilled water should be used in order to avoid surface stains.
- 134°C (273°F) for 6 minutes: Autoclave for Instruments/drills/kits

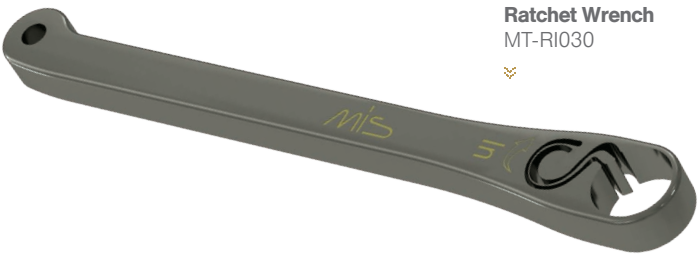


Surgical & Prosthetic Tools.

Ratchet

Mono-Block Ratchet Wrench

The new ratchet is a mono-block instrument with a unique mechanism that simplifies use and cleaning. To prevent damage to the mechanism, it is critical that the ratchet is used only with keys and adapters that are specifically designed for it. The ratchet wrench can be used for implant placement and tightening or loosening screws.



Ratchet Wrench
MT-RI030

Warnings

It should be emphasised that MIS recommends the use of a torque controlled driver whenever possible.

The ratchet wrench MT-RI030 may transfer torque levels that do not correlate to the recommendations specified for implant placement or screw fastening.

Excess loads may result in damage to implants, components, screws, the wrench itself and even to the bone-to-implant interface.

Instrument Maintenance

- The device is not sterile.
- Cleaning and sterilization are required prior to first use.
- Clean instrument with running water to remove any blood or tissue immediately after use.

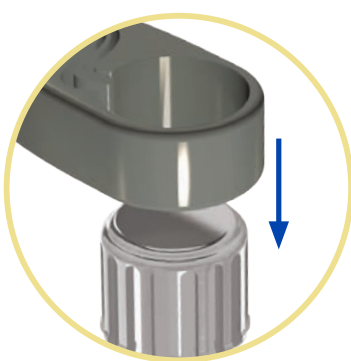
Cleaning and Disinfection:

- Immerse instrument in an approved cleaning/disinfecting solution.
- Use of an ultrasonic cleaner is highly recommended.
- DO NOT USE agents containing high concentrations of chlorine or agents containing oxalic acid.
- Use distilled water to prevent water stains.

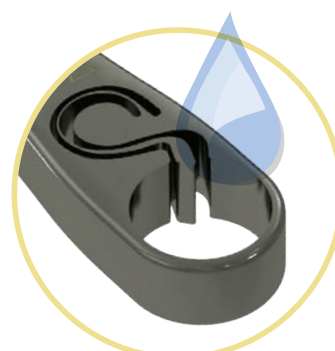
Sterilization

- All dental instruments must be sterilized prior to each use.
- The device is delivered non-sterile.
- Before use, the device must be sterilized by autoclave, at 134°C (273°F) for 6 minutes. Do not exceed 134°C.

User Instructions



Store the ratchet on its own, not attached to any tools.

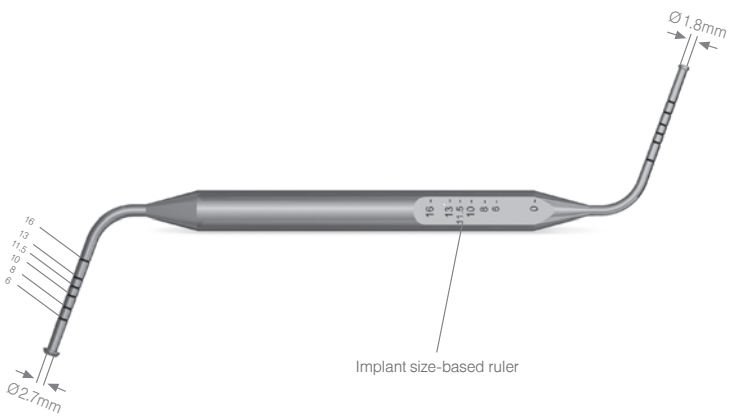


Clean thoroughly immediately after use.

Surgical Tools

Implant Site Depth Probe

Implant Site Depth Probe
MT-BTI10



Features

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

Marked depths: 6, 8, 10, 11.5, 13 and 16mm. The depth probe includes an apical flat section to ensure accurate placement within the ossteotomy.

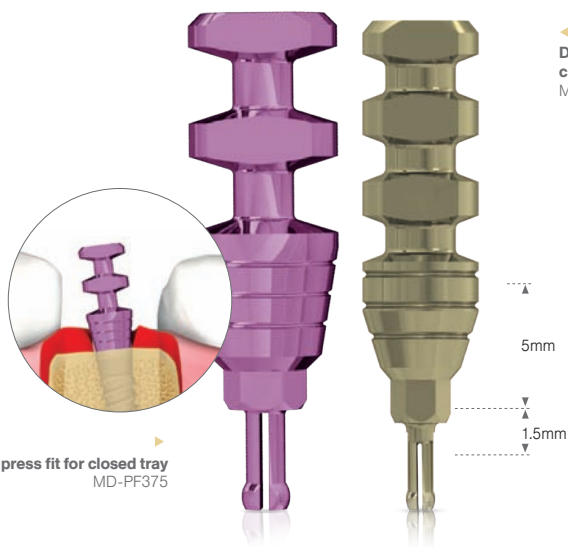
Dimensions: Ø1.80/Ø2.70mm. Total length: 100mm.

Surgical Tools

Implant Direction Indicator

Implant Direction Indicator MD-PF375/ MN-PF330

The Direction Indicator is connected directly to the implant. This surgical instrument enables the visualization of the 3D position of a particular implant. The implant indicator features groove marks indicating gingival heights (each groove mark indicates 1mm of gingival height). The round cavities at the upper section of the tool represent the position of the anti-rotational index within the implant.



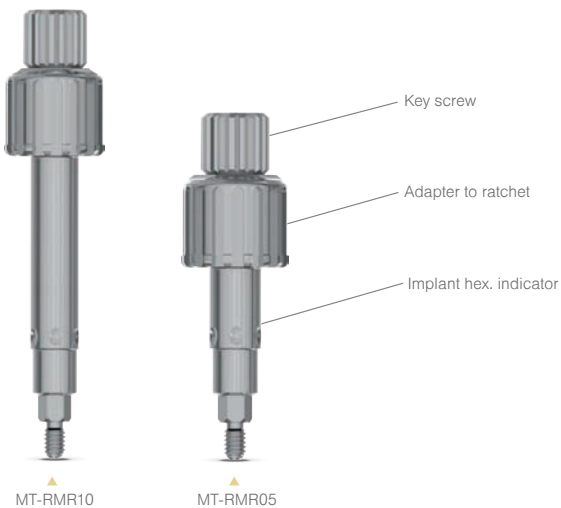
Direct press fit for closed tray NP
MN-PF330

Direct press fit for closed tray
MD-PF375

Surgical Tools

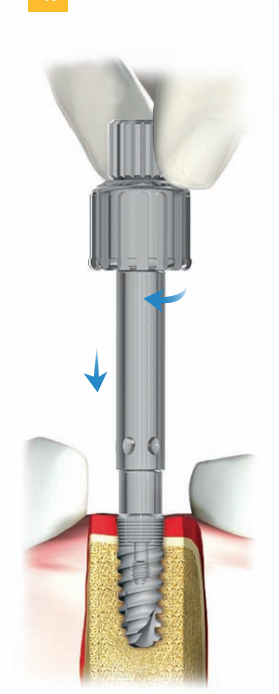
Implant Extraction Keys

The Implant Extraction Keys are designed for the extraction of mountless Standard or Wide platform implants, and can be used manually or with a ratchet. Each key consists of two components: the body, which includes a standard hex. and a key screw, that passes through the body to allow a firm connection between implant and key; for a safe and simple implant extraction. It is recommended to dismantle both components (key body and screw), prior to cleaning and sterilization.



Direct Hand and Ratchet Hex. Key
MT-RMR05 / MT-RMR10

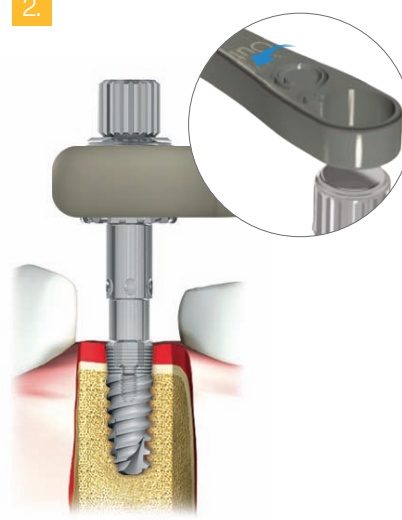
Step
1.



By Hand

Tightening the screw to the implant

Step
2.



By Ratchet

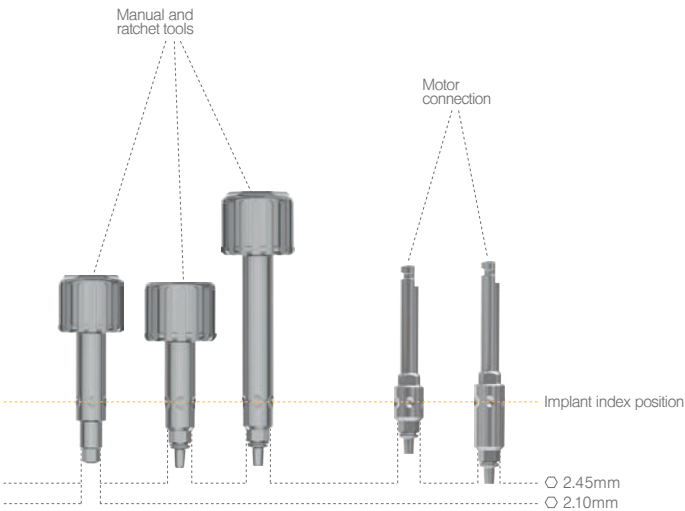
Ratchet is connected to top of the key in order to extract the implant.

Surgical Tools

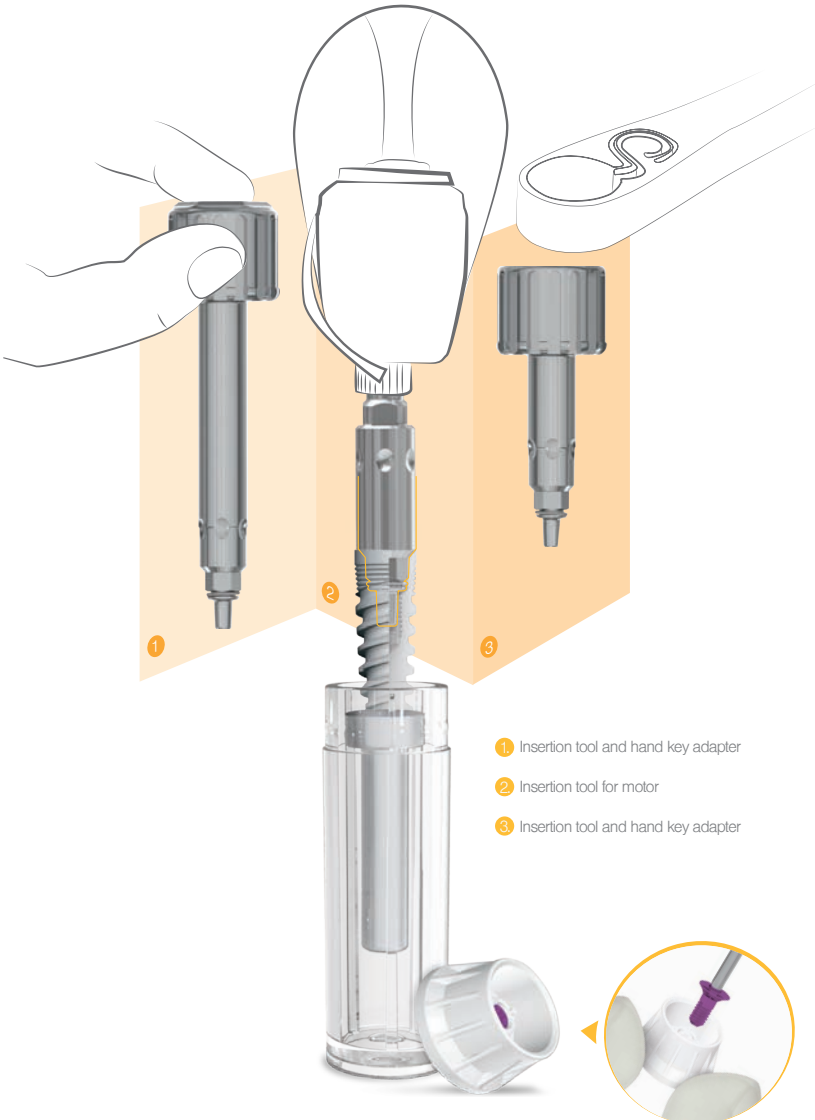
Specialized Surgical Tools

SEVEN Insertion Tools

Insertion tools are available in short and long versions, for manual, ratchet or motor options.



Insertion Options



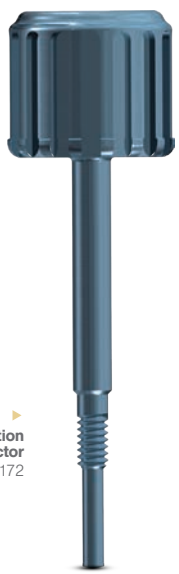
1. Insertion tool and hand key adapter
2. Insertion tool for motor
3. Insertion tool and hand key adapter

Prosthetic Tools

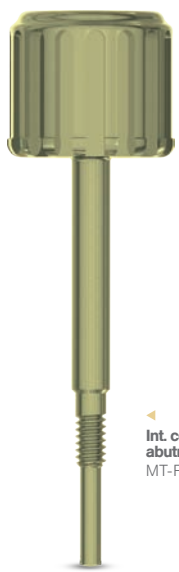
Friction Fit Extractor

Friction Fit
MT-RE172/ MT-RE160

The friction fit extractors are designed to separate the friction fit abutments from the implant. The extractors are color-coded, blue for Standard/Wide abutments and yellow for Narrow abutments.



Int. connection abutment extractor
MT-RE172

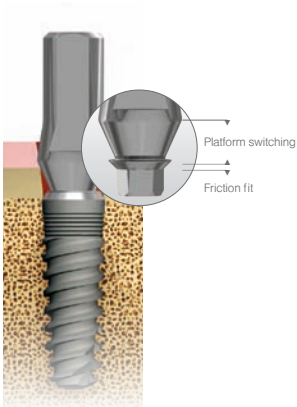


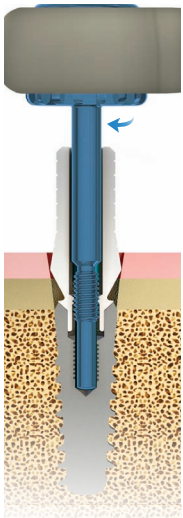
Int. connection abutment extractor, NP
MT-RE160

Mode of Action

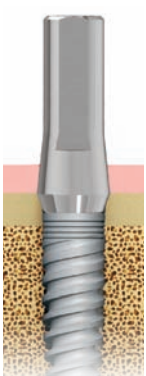
The Extractor Key applies vertical load parallel to the long axis of the implant. Thus it can release a "locked" abutment from an implant.

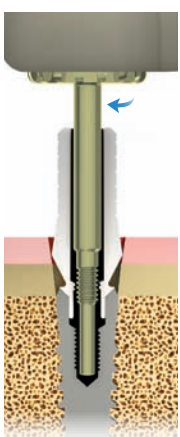
For Standard / Wide Implants





For Narrow Implants





Prosthetic Tools

SOS Broken Screw Kit

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 from within an implant.

SOS Broken Screw Kit
MK-0041

SOS Tools

Thread Former
MT-TF172

Retriever
MT-RT001

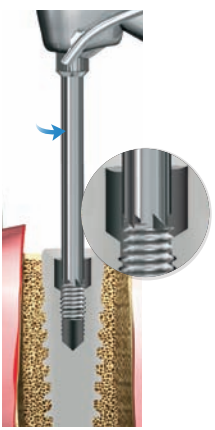
Hand Wrench
MT-HW001

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 to the top of the broken screw.

B. While maintaining 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. Use the thread former with care.

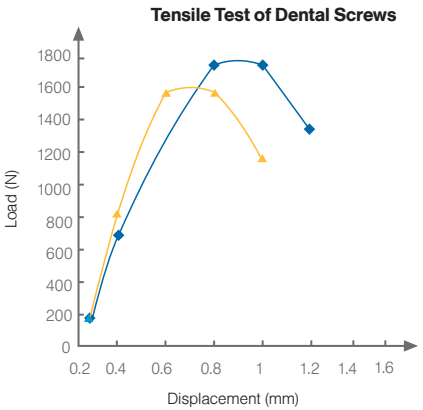
B. Be sure to align the thread former parallel to the long axis of the implant.

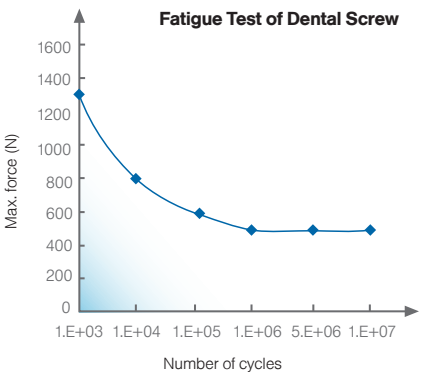
C. Always start by using a hand wrench. Apply gentle but firm force while turning the thread former in a clockwise direction. Release the pressure at the end of each complete turn by turning it 30' in a reverse direction, and repeat the action as needed.

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 require 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.
- Verify that detergents and cleaning agents don't contain oxalic acid and high rates of chlorine.
- Avoid 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 kit must be sterilized before use by autoclave, at 134°C (273°F) for 6 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 have been stored for a prolonged period of time.


mis®
Pu

Packaging.

Packaging

Implant Packaging

The MIS packaging system is designed for simple and easy use. All implant boxes feature distinctive colors, large typeface, clear data labels and a pull tab for quick opening. Box dimensions are designed for compact, space-saving storage.

Implant package

Individual Implant Package

Following our "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 a safe and precise surgical procedure.

10 Implant Package

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

Implants are packed without a mount, for ease of use and a faster placement procedure.

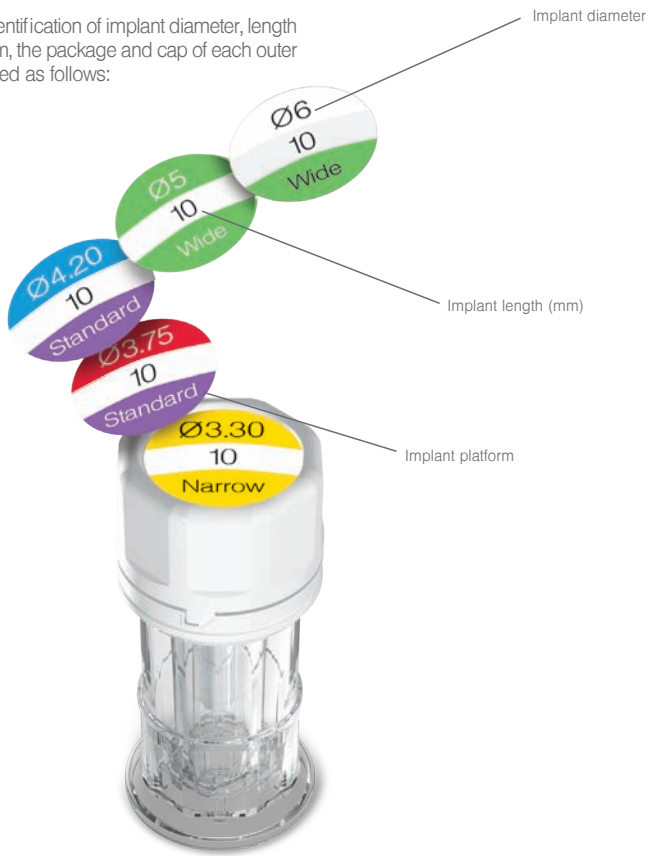
Double Container Sealing System

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 brought into the sterile surgical field whenever needed.

Packaging

Implant Identification Codes

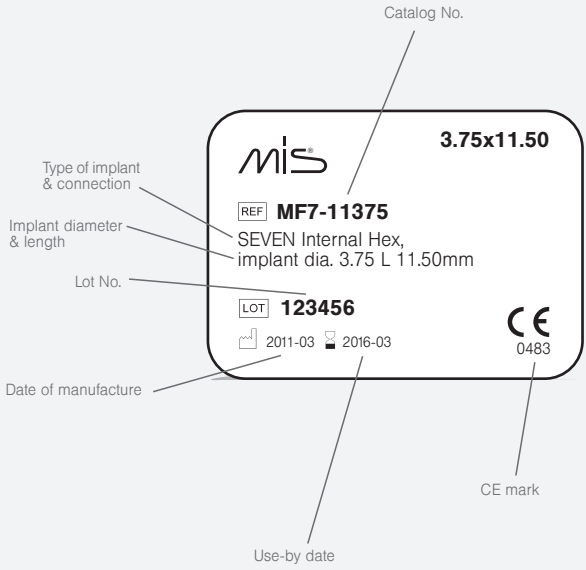
For easy identification of implant diameter, length and platform, the package and cap of each outer tube is coded as follows:



Packaging

Implant Data Label

Each package contains three data labels, which include all required information relevant to the implant. The following image illustrates the label and its contents:



Packaging

Implant Package Handling

Both physical and visual inspection of the implant package is required prior to use. This ensures that the correct implant model and dimensions are being used for the selected site.

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 turning the cap counter-clockwise. Drop the sterile inner tube into the sterile field.

Fig. 3

The implant is held by the titanium sleeve. To expose the implant - hold the tube with the titanium sleeve facing up. Rotate and pull to open the upper cap.

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

Fig. 4

Contra-angle hand piece

Packaging

Implant Package Handling

Fig. 5
Ratchet

Fig. 6
Implant extractor

Fig. 7

Remove the cover screw from the inner tube cap using the key.

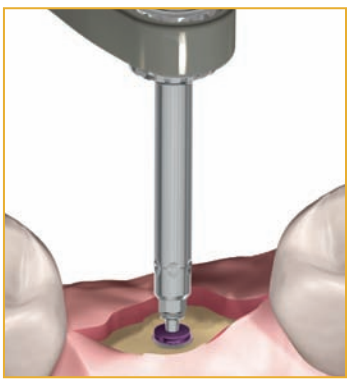


Fig. 8

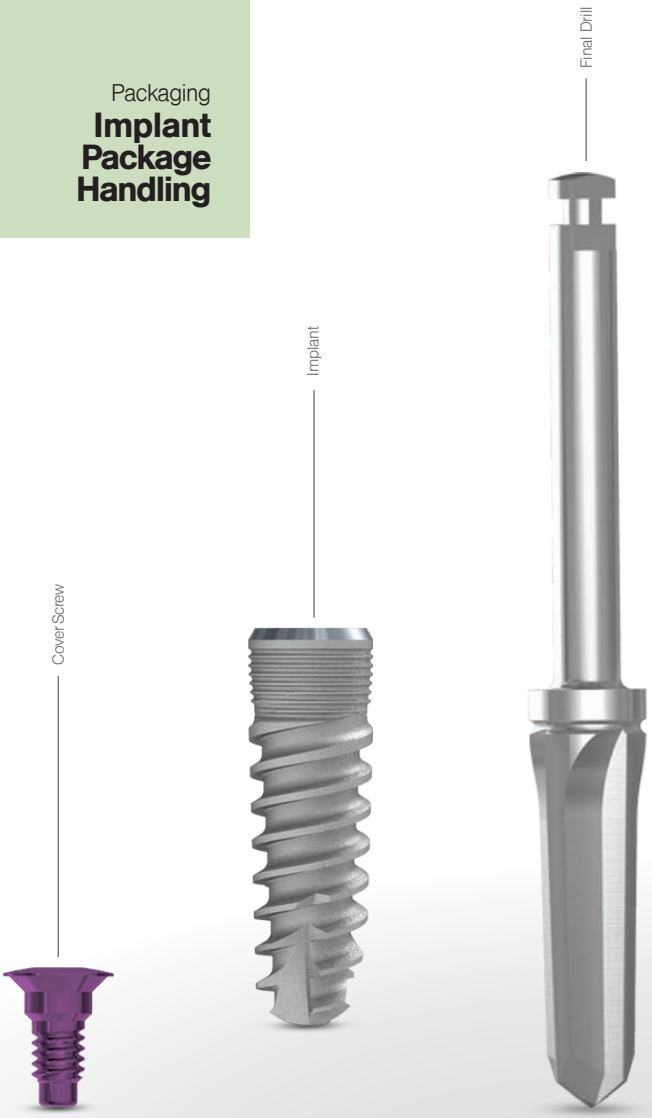
Begin tightening the screw.

Fig. 9

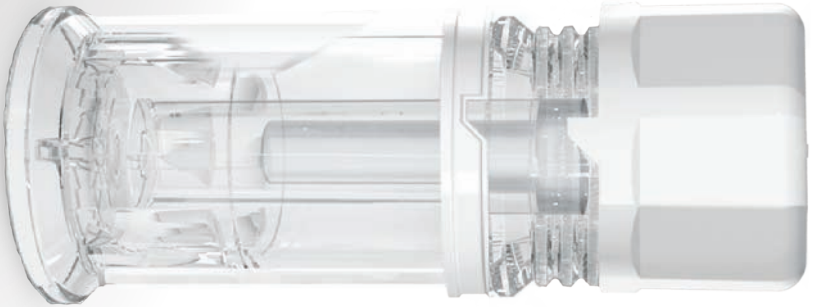
The data labels should be placed in the medical chart.

Packaging

Implant Package Handling



Inner Tube



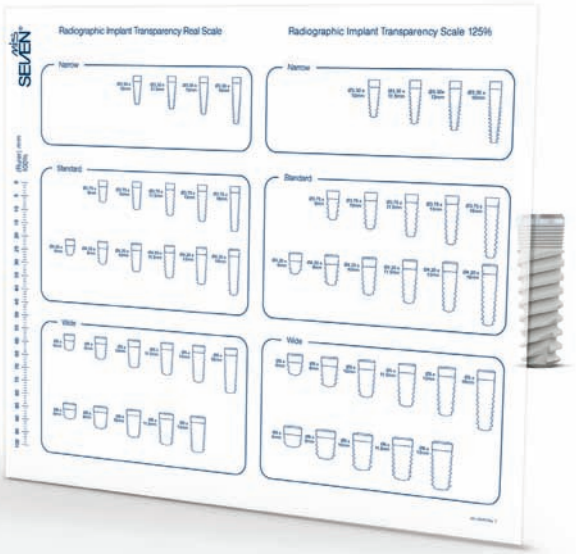
Outer Tube

Planning Transparency

MIS offers a planning transparency, illustrating the full SEVEN implant range. It includes two sets of images: one actual size 1:1, and the other at a magnification of 125%; for use with panoramic radiographs that include a similar inherent magnification. In addition, the transparency includes a 1:1 ruler.

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

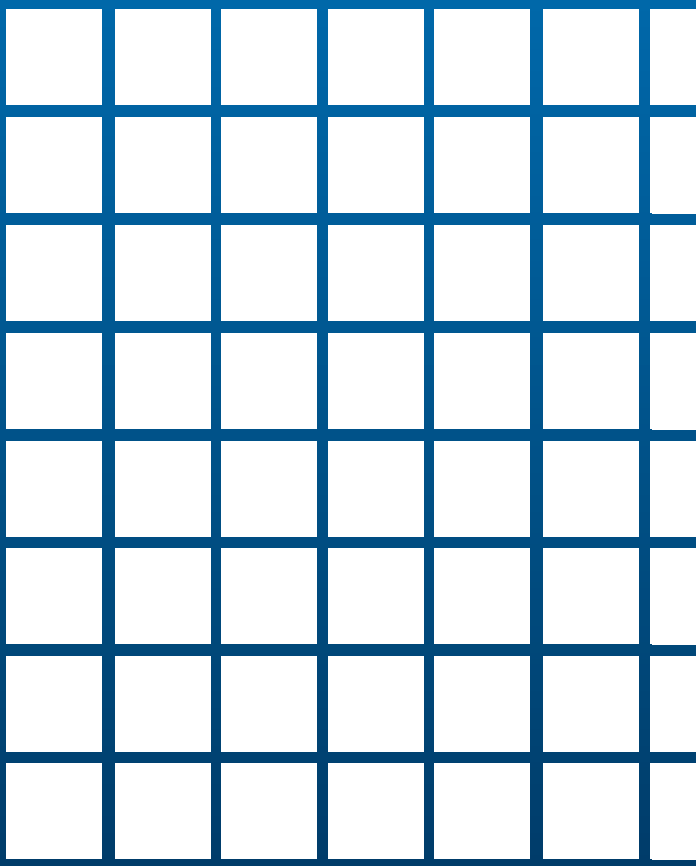
Cat No. **MC-SEVEN**

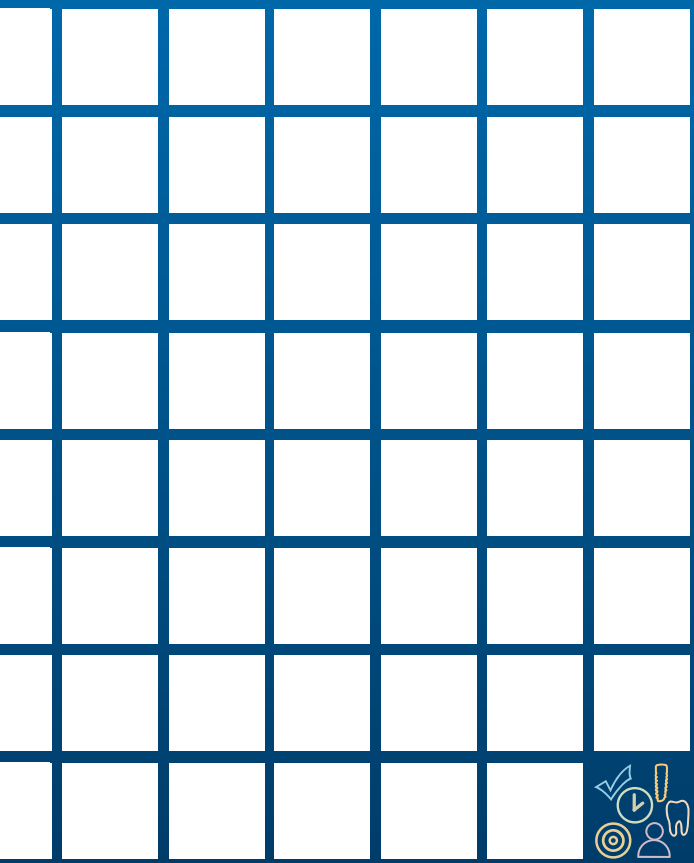


Symbols

Key to symbols that appear 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 date
STERILE R	Sterilized using gamma irradiation		





MPUI048 Rev. 4 May 2015

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

The MIS 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 products are cleared for marketing in the USA and CE approved.