MIS®

# User Manual

The V3 implant system is the outcome of an exceptionally high-level R&D process that has resulted in an implant that is simple, easy-to-use and offers enhanced functionality and performance. The V3 conical connection implant features built-in design characteristics that provide biological benefits for hard and soft tissue and promotes esthetic results.


Questions, comments or requests will be addressed promptly by contacting MIS specialists directly through our e-mailing address: service@mis-implants.com. The MIS website may 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 purposes only.

MIS Quality System complies with international quality standards: ISO 13485:2003 – Quality Management System for Medical Devices, ISO 9001: 2015 – Quality Management System and Medical Device Directive 93/42/EEC. MIS products are CE marked.

# Overview


8. Introduction
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13. Implant Surface
16. Histology
17. Hydrophilicity

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. The unique MIS implant surface treatment 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 tests
- Removal torque values
- Histology
- Packaging integrity test

Overview

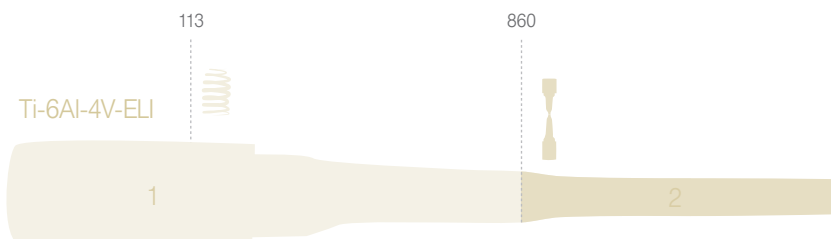
# Raw Material

- 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.

Similar to commercially pure titanium (Grades 1-4), the outer surface of all MIS implants is comprised of a thin layer of pure titanium dioxide ($TiO_2$). 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

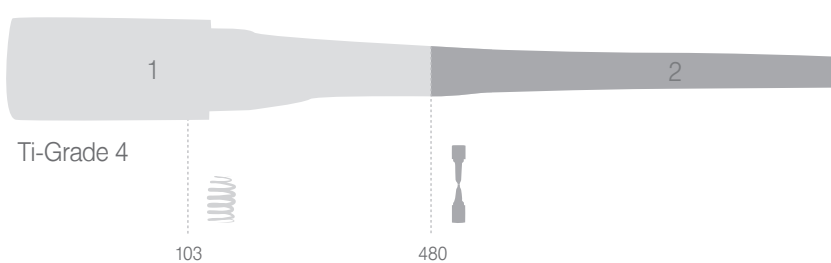


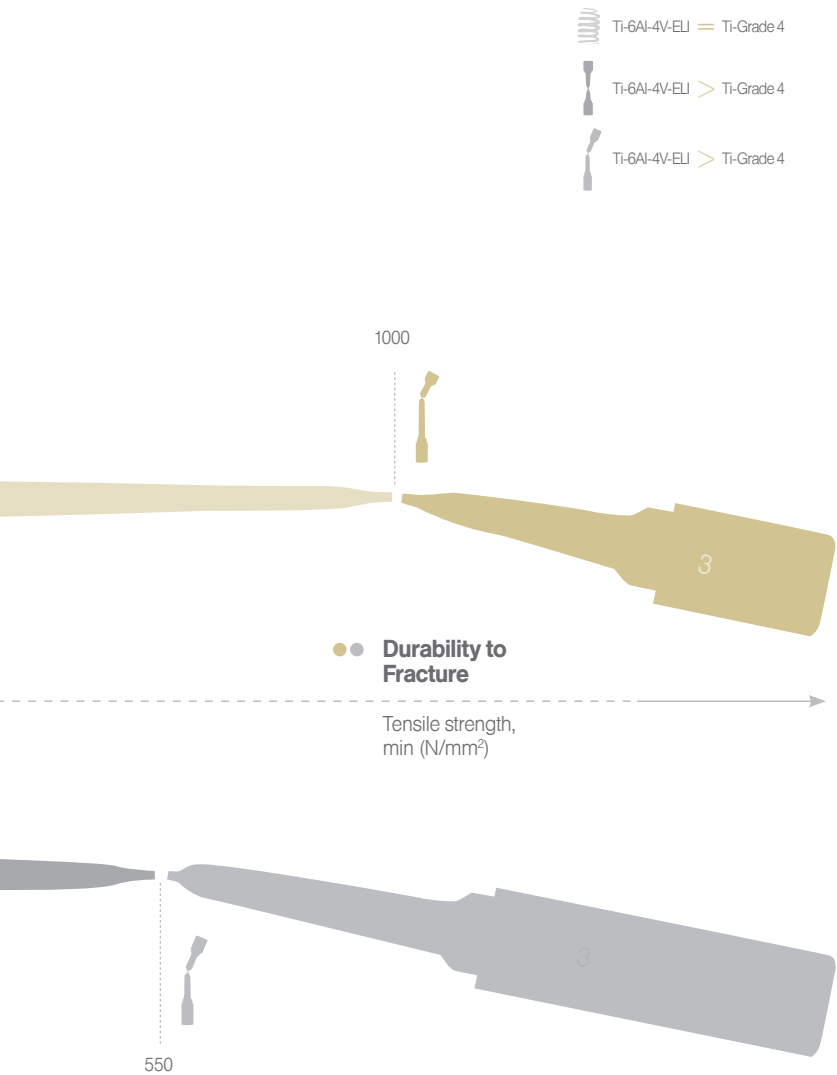

**Shock Absorbency**

Modulus of elasticity (1000X N/mm²)

**Durability to Deformation**

Yield strength, min (N/mm²)




Ti-6Al-4V-ELI = Ti-Grade 4
Ti-6Al-4V-ELI > Ti-Grade 4
Ti-6Al-4V-ELI > Ti-Grade 4
1000
3
Durability to Fracture
Tensile strength, min (N/mm²)
3
550

Overview

# Manufacturing Process

Structure (Raw Material)

MIS Surface Treatment

Sand-Blasting

Acid-Etching

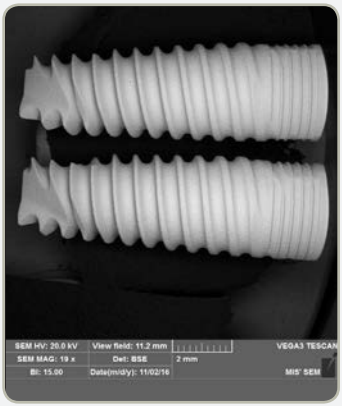
Roughness (Micro and Nano Structures)

The combination of sand-blasting and acid-etching induces micro 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.

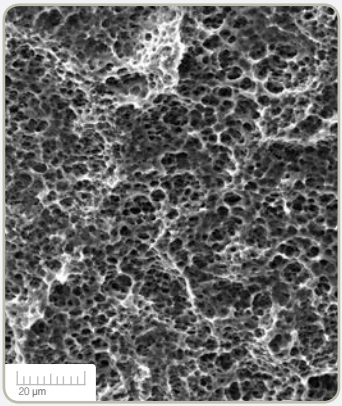
Overview

# 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 V3 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

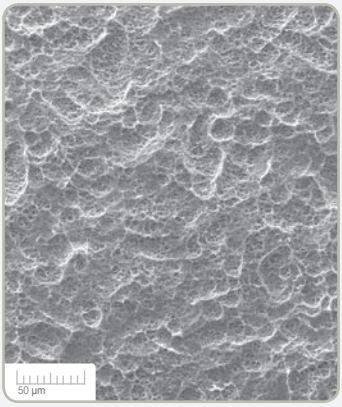
All MIS implants are sand-blasted and acid-etched. This surface treatment increases the implant surface area, creating both micro and nano-structures, while eliminating various surface contaminants.

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

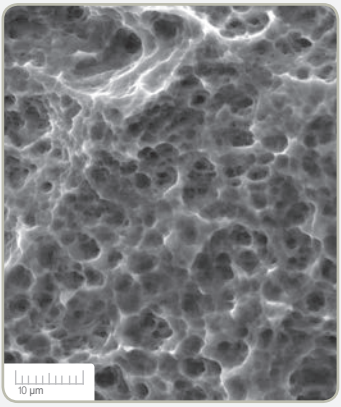
Sand-blasted and acid-etched surfaces have been substantially proven to maximize the BIC (Bone-to-Implant Contact), achieving rapid and long-lasting osseointegration.

## Surface composition

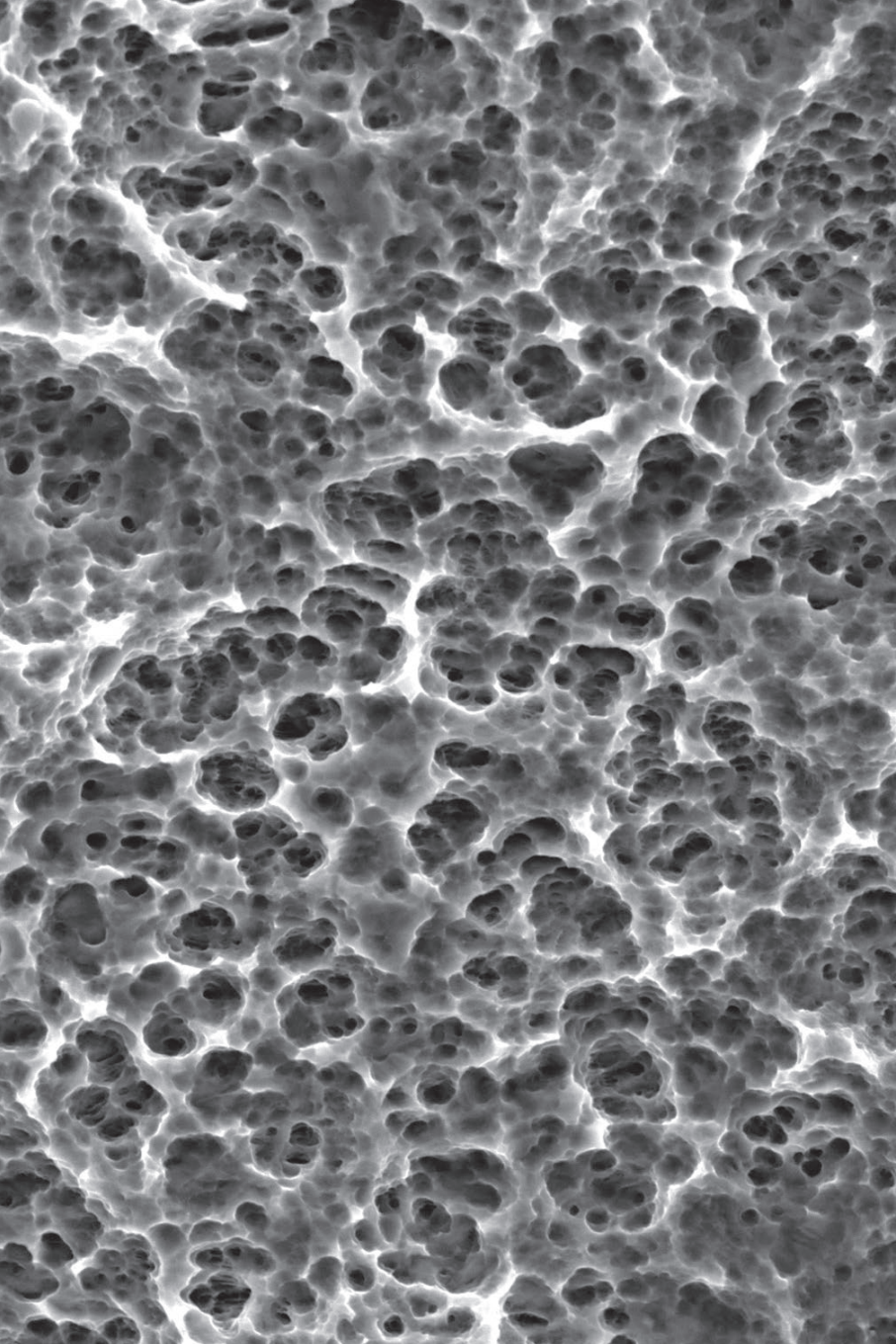
The outer surface of MIS implants, consist of a thin layer of pure titanium dioxide (TiO2). Acid-etching and packaging processes are performed in a controlled environment clean-room to ensure purity and quality. Implants are inspected by scanning electron microscope (SEM) and X-ray photoelectron spectroscopy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




SEM image of the implant surface showing the micro-structure



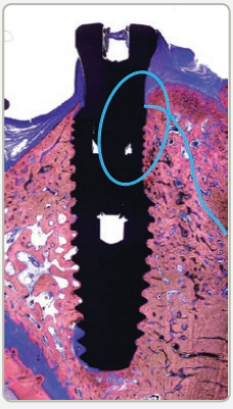

SEM image of the implant surface showing the nano-structure



Overview

# Histology

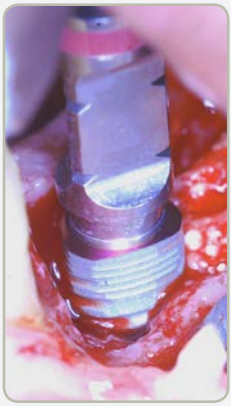
Histologic section of a V3 implant, 8 weeks after placement.
Courtesy of Prof. Rompen & Prof. Lambert, University of Liege, Belgium.

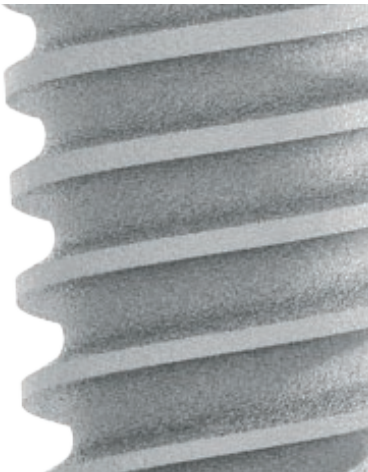


Overview

# 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. MIS surface treatment ensures surface purity and hydrophilic properties. The images below, demonstrate liquid "climbing" upwards on the implant surface.



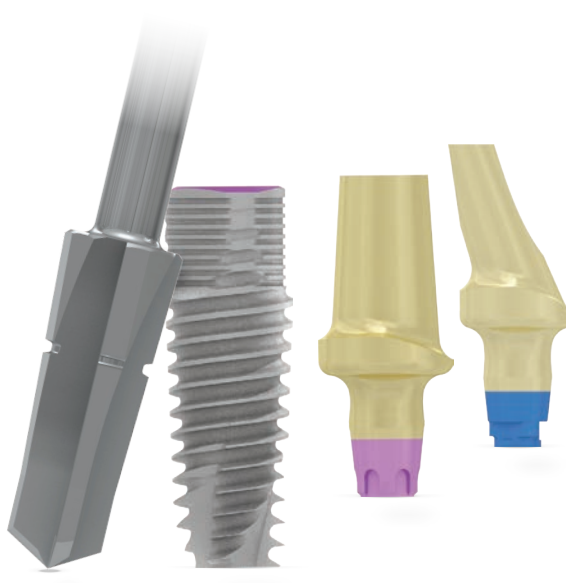


# Implants


18. Introduction: V3 Implant
19. Fixture - Technical Info.
20. External Design
21. Implant Range
22. Conical Connection
24. Procedure

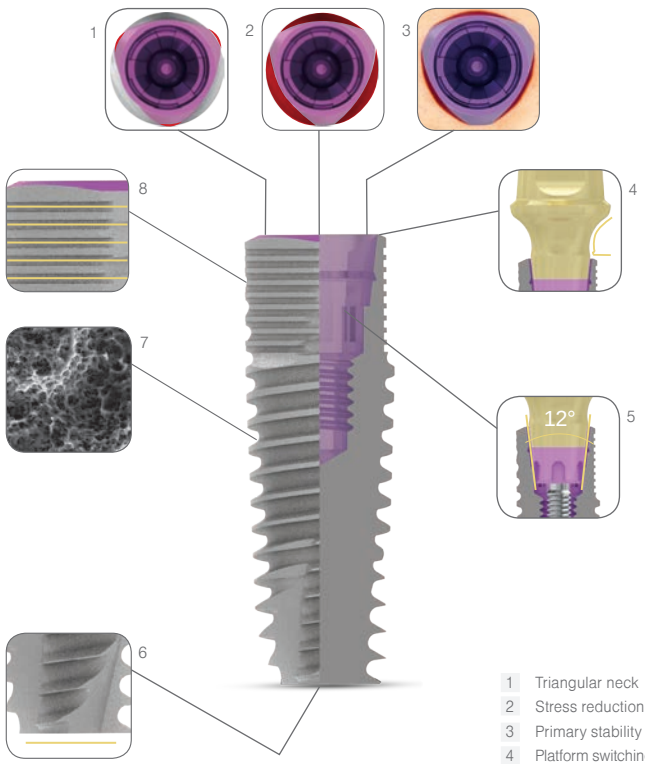
# V3
## Introduction

MIS is proud to introduce the V3, an addition to our implant selection, and part of the novel VCONCEPT. The V3 implant features a unique combination of attributes, which result in an innovative implant that provides high initial stability and a state of the art conical connection which incorporates platform switching technology. A large variety of superstructures and components are available, providing solutions for every possible clinical scenario. All superstructures, as are implants, are color coded, according to their restorative platform, with a golden anodized hue for best esthetic results.



# V3

## Fixture - Technical Info




1 Triangular neck
2 Stress reduction
3 Primary stability
4 Platform switching
5 Conical connection
6 Flat apex
7 Surface treatment
8 Micro-rings

# V3
External Design

## Platform switching

The V3 features platform switching, which keeps the implant-abutment connection away from the bone; minimizing bone resorption. Additionally, platform switching allows more vital growth of the soft tissue.

## Conical shape

- The conical root shape of the V3 implant and its unique thread design ensure superior primary stability, making it the implant of choice for a wide range of clinical cases and loading protocols.
- The root shape design makes the V3 an ideal implant when space is restricted due to adjacent teeth or implants.

## Three spiral channels and flat apex

- A flat cutting apex allows for final adjustments during placement procedures.
- Three cutting blades at the implant apex establish the self-tapping properties of the V3; supporting a simpler, safer and faster procedure.

## Dual thread

- The V3 features a dual thread design which increases the BIC (Bone to Implant Contact) over the entire body of the implant. The dual thread influences implant insertion rate (1.60mm), facilitating a more controlled and faster implant placement.
- The thread profile is especially designed for flawless, easy insertion and high primary stability.
- The V3 is self-tapping with mild bone compression, which enhances primary stability.

## Surface treatments

V3 implants are sand-blasted and acid-etched. These surface treatments increase the implant surface area by creating both micro and nano-structures and eliminating various surface contaminants. These treatments ensure surface purity and hydrophilic properties.

## Micro-rings

At the neck of the V3, “micro-rings” significantly increase the BIC (Bone to Implant Contact),avoiding bone resorption at the crestal zone.

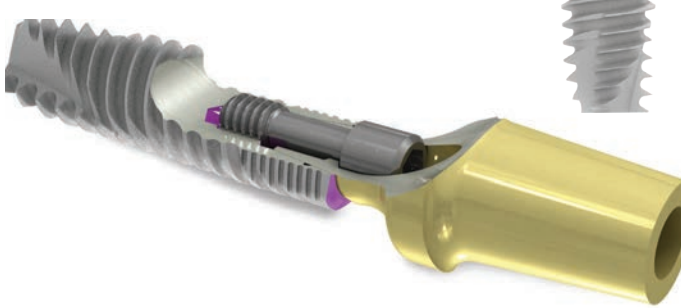
# V3
## Implant Range

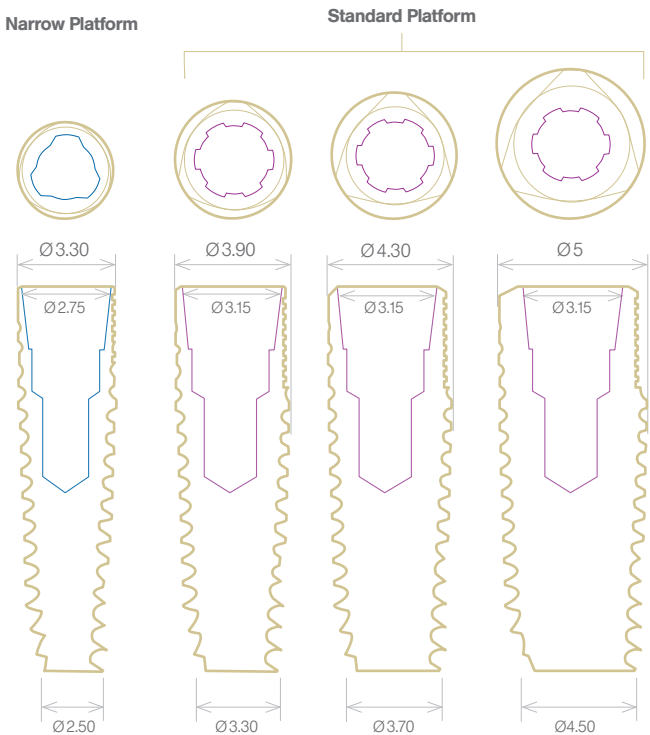
| Length | 8mm | 10mm | 11.50mm | 13mm | 16mm |
|---|---|---|---|---|---|
| Type<br>**Ø3.30mm**<br>Screw type implant<br>Narrow platform | | V3-10330  | V3-11330  | V3-13330  | V3-16330  |
| Type<br>**Ø3.90mm**<br>Screw type implant<br>Standard platform | V3-08390  | V3-10390  | V3-11390  | V3-13390  | V3-16390  |
| Type<br>**Ø4.30mm**<br>Screw type implant<br>Standard platform | V3-08430  | V3-10430  | V3-11430  | V3-13430  | V3-16430  |
| Type<br>**Ø5mm**<br>Screw type implant<br>Standard platform | V3-08500  | V3-10500  | V3-11500  | V3-13500  | V3-16500  |

* Implant package also includes: cover screw and final drill.

# V3
## Conical Connection

The V3 features a 12-degree conical connection to ensure a secure fit between the abutment and implant. By minimizing movement at this junction, bone loss is reduced at the crestal level. There is a three-position cone index within the conical connection to help orient the implant during insertion. The cone index also allows for proper abutment positioning. The narrow platform implants include a 3 slot index, while the standard platform implants include a 6 slot index.



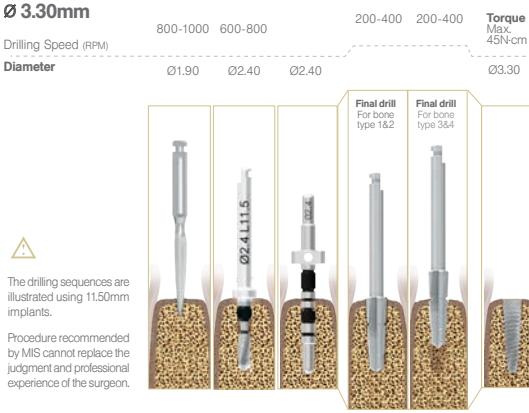

Narrow Platform
Standard Platform
Ø3.30
Ø3.90
Ø4.30
Ø5
Ø2.75
Ø3.15
Ø3.15
Ø3.15
Ø2.50
Ø3.30
Ø3.70
Ø4.50

# V3

## Ø3.30mm / Ø3.90mm Procedure

Recommended insertion torque: 35-60 Ncm.

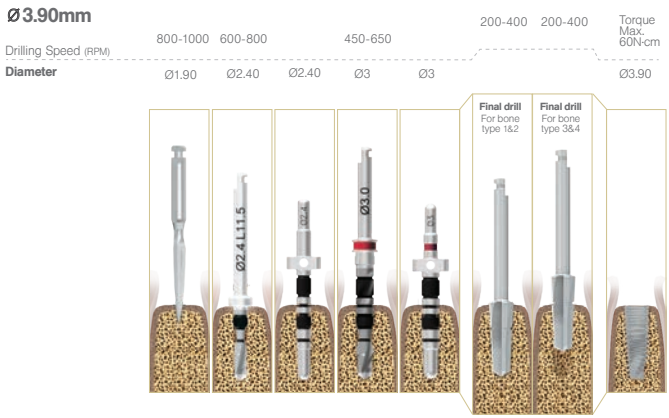
### Ø 3.30mm




The drilling sequences are illustrated using 11.50mm implants.

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

### Ø 3.90mm



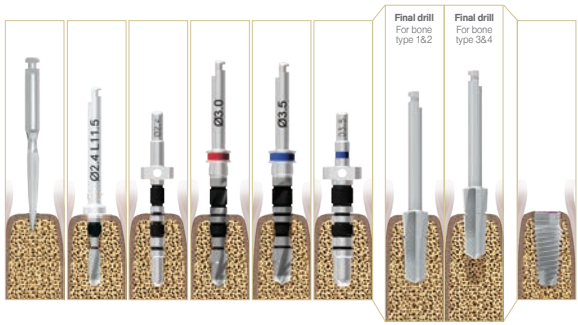
# V3

## Ø4.30mm / Ø5mm Procedure

Recommended insertion torque: 35-60 Ncm.

### Ø4.30mm

| Drilling Speed (RPM) | 800-1000 | 600-800 | | 450-650 | 350-550 | | 200-400 | 200-400 | Torque Max. 60N-cm |
|---|---|---|---|---|---|---|---|---|---|
| **Diameter** | Ø1.90 | Ø2.40 | Ø2.40 | Ø3 | Ø3.50 | Ø3.50 | | | Ø4.30 |




### Ø5mm

| Drilling Speed (RPM) | 800-1000 | 600-800 | | 450-650 | 350-550 | 300-500 | | 200-400 | 200-400 | Torque Max. 60N-cm |
|---|---|---|---|---|---|---|---|---|---|---|
| **Diameter** | Ø1.90 | Ø2.40 | Ø2.40 | Ø3 | Ø3.50 | Ø4 | Ø4 | | | Ø5 |

# Surgical Procedures

For MIS Implants

30. Indications & Contraindications
32. Step-by-Step Protocol

Surgical Procedures

# Indications & Contraindications



## Indications

MIS V3 conical connection implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. Using a one-stage surgical procedure, the implant allows immediate implantation and immediate function, when good primary stability is achieved and the occlusal load is appropriate.

Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore masticatory function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.



## Contraindications

The contraindications customary in oral surgery with other implant materials should be observed. These include patients taking corticosteroids or anticonvulsants and those receiving radiation or other immunosuppressive therapies. Patients with abnormal laboratory values for BUN, creatinine or serum calcium, patients with diabetes, cardiovascular disease, hypertension above 170/110mm Hg., osteoporotic crush fractures, respiratory disease, thyroid or parathyroid disease, should be excluded as well as patients with diagnosed malignancy during the past five years and those with nodular enlargements, tenderness or an unexplained lump in the head or neck. Implant procedures should not be performed on patients with active osteolythic, or an inflammatory or infectious process in the implant site.



## Other Contraindications

- Debilitating or uncontrolled disease
- Hemophilia, Granulocytopenia or other bleeding problems, Steroid use, Prophylactic antibiotics, Brittle diabetes
- Ehler-Danlos syndrome

- Osteoradionecrosis, Renal failure, organ transplantation, Anticoagulation therapy, Idiopathic hypersensitivity, Fibrous dysplasia

Regional enteritis:

- Lack of adequate training of practitioner
- Conditions, diseases, or treatment that severely compromise healing, e.g. including radiation therapy
- Poor patient motivation
- Psychiatric disorders that interfere with the patient's understanding and compliance with necessary procedures
- Unrealistic patient expectations
- Unattainable prosthodontic reconstruction
- Inability of patient to manage oral hygiene
- Patient hypersensitivity to specific components of the implants



## Risks

Risks associated with surgical procedures 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 health effects of implants..

The risks may include:

Inadvertent perforation of the nasal and maxillary sinus, local and systemic infections, perforation of soft tissue spaces and nerve injury. Temporary conditions that may result from implant placement may include pain and swelling, speech problems and gingivitis. Long-term problems may include nerve damage, local or systemic bacterial infections, and infectious endocarditis in susceptible individuals. Existing natural dentition may be compromised by improper implant placement.

The following list of organ systems with corresponding pathophysiological problems may influence risks:

a) **Cardiovascular:**
Coronary artery disease, arrhythmias
b) **Respiratory:**
Chronic obstructive pulmonary disease
c) **Gastrointestinal:**
Hepatitis, Malabsorption, Inflammatory bowel disease
d) **Genitourinary:**
Chronic renal failure
e) **Endocrine:**
Diabetes, Thyroid disease, Pituitary/Adrenal disorders
f) **Hematological:**
Anemia, Leukemia, Blood clotting disorders
g) **Musculoskeletal:**
Arthritis, Osteoporosis
h) **Neurologic:**
Stroke, Palsy, Mental retardation



## 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

This surgical manual is designed to provide an overview of the pre-surgical and surgical procedures applicable to the V3 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 relate (but not be limited) to the following conditions: Patients who are either taking or have taken 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 patient 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 radiopaque markers are recommended. These, coupled with computerized tomographic radiographs may later be altered to be used as computer based surgical guides.

**Step 4.**
Treatment Plan
(Patient cooperation)

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

Surgical Procedures

# Step-by-Step Protocol

**Step 5A.**
Implant Selection

V3 implants feature a range of diameters and lengths. V3 Standard platform implants are used in the premolar and molar areas, as well as 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.

Each MIS implant comes with labels including all relevant data related to the implant. It is critical that one label is kept as part of the patient's record for future reference.

**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. An emergency resuscitation apparatus should be available.

**Warnings:** V3 implants are supplied in a sealed and sterilized package. Implants should never be reused. 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. MIS recommended procedures are described on pages 24-25. However, it should be emphasized, that procedures recommended by MIS cannot replace the judgment and professional experience of the surgeon.

**Step 6.**
Osseointegration Phase

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

**Step 7.**
Restorative Phase

V3 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 overloading the implant. MIS superstructures and components must be used with all MIS implants.

12
24

**Step 8.**
Follow-up

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


BODY TRAIN
SHARED TOOLS

# Surgical Kits

38. Surgical Kit Description
40. Advanced Surgical Instrument Kit
42. Kit Contents

The Surgical Kit

# Surgical Kit Description

The innovative V3 surgical kit is designed for simple and safe implant placement procedures. The kit presents a novel ergonomic design that follows the surgical drilling sequence. In addition, the kit includes a set of length-based pilot drills and color-coded visual cues of both implant diameter and restorative platforms.

The kit, including a surgical ratchet is available for purchase- item number - MK-T051

**Warning!**
Avoid damage!

The sterilization kit-box and insert must be cleaned and sterilized before each use.

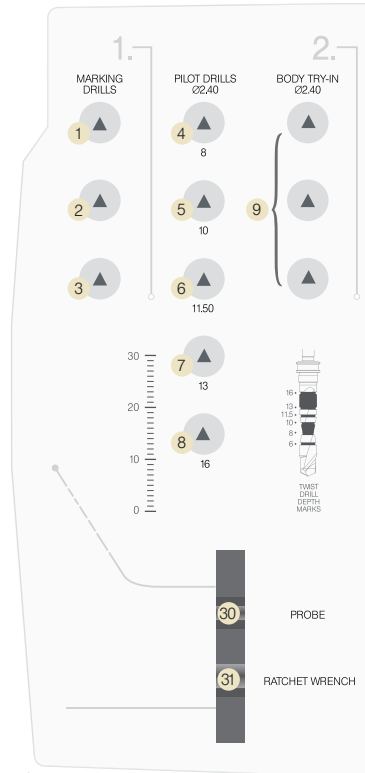
Please see sterilization instructions on page 60.


**MK-0051** V3 Surgical kit

The Surgical Kit

# Advanced Surgical Instrument Kit

**MK-0051** | With external irrigation drills




## MARKING DRILLS

1 MT-SMD10

2 MT-PDM24

3 MT-PD440

## PILOT DRILLS

4 CT-P2408

5 CT-P2410

6 CT-P2411

7 CT-P2413

8 CT-P2416

## BODY TRY-INS

9 CT-BTC24

10 CT-BTC30

11 CT-BTC35

12 CT-BTC40

## STEP DRILLS

13 CT-TDC30

14 CT-TDC35

15 CT-TDC40

## INSERTION TOOLS, NP

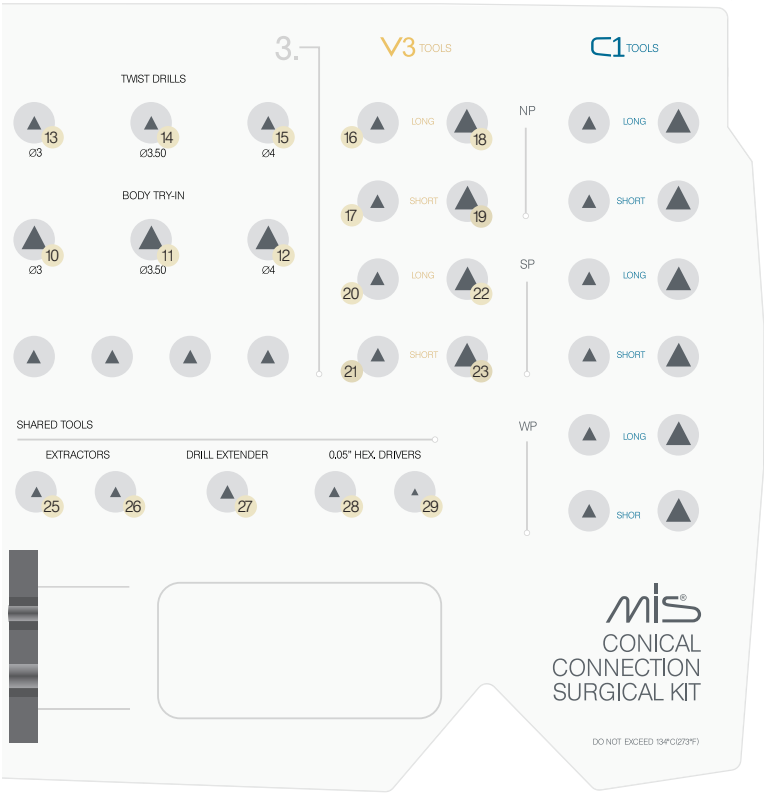
16 CT-NLM30

17 CT-NSM30

18 CT-NLR30

19 CT-NSR30

C1 conical connection insertion tools are supplied separately, MK-0054.




## INSERTION TOOLS, SP

20 CT-SLM30

21 CT-SSM30

22 CT-SLR30

23 CT-SSR30

## SURGICAL TOOLS

25 MT-RE160

26 MT-RE172

27 MT-DE001

28 MT-RDL30

29 MT-RDS30

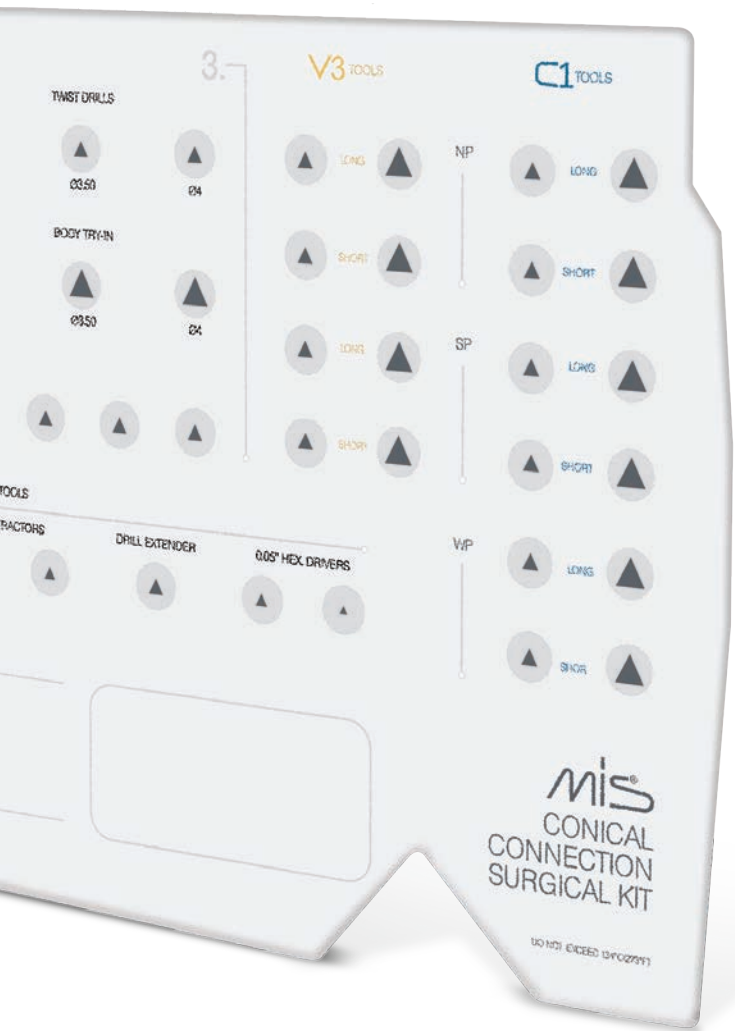
30 MT-BTI20

31 MT-RI030

The Surgical Kit

# Kit Contents

The V3 Surgical Kit includes tools that are designed especially for the step-by-step implant placement process. Correct preparation of the implant site ensures efficient and accurate installation and high primary stability.


3.
V3 TOOLS
C1 TOOLS
TWIST DRILLS
Ø3.50
Ø4
BODY TRY-IN
Ø3.50
Ø4
LONG
SHORT
LONG
SHORT
NP
SP
WP
LONG
SHORT
LONG
SHORT
LONG
SHORT
TOOLS
TRACTORS
DRILL EXTENDER
0.05" HEX DRIVERS
mis
CONICAL
CONNECTION
SURGICAL KIT

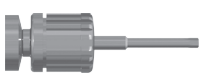
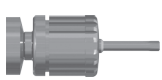
The Surgical Kit

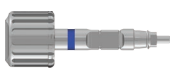
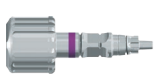
# Kit Contents

| | | | Dimensions | Material |
|---|---|---|---|---|
|  | **MT-SMD10** | Spade marking drill | Length 30mm | Stainless steel |
|  | **MT-PDM24** | Position drill mill Ø2.4mm | Ø2.40mm Length 32mm | Stainless steel |
|  | **MT-PD440** | Position drill Ø4mm | Ø4mm Length 32.7mm | Stainless steel |
|  | **CT-P2408** | Pilot drill with built in stopper Ø2.4/2.0 height 8mm | Ø2.40mm Length 28mm | Stainless steel |
|  | **CT-P2410** | Pilot drill with built in stopper Ø2.4/2.0 height 10mm | Ø2.40mm Length 28mm | Stainless steel |
|  | **CT-P2411** | Pilot drill with built in stopper Ø2.4/2.0 height 11.5mm | Ø2.40mm Length 33mm | Stainless steel |
|  | **CT-P2413** | Pilot drill with built in stopper Ø2.4/2.0 height 13mm | Ø2.40mm Length 33mm | Stainless steel |
|  | **CT-P2416** | Pilot drill Ø2.4/2.0 height 16mm | Ø2.40mm Length 37.5mm | Stainless steel |
|  | **CT-BTC24** | Body try in 2.40mm for tapered impl. procedure | Ø3.20mm Length 28.5mm | Titanium |
|  | **CT-TDC30** | Step drill Ø3/2.4mm, external irrigation (red) | Ø2.4-3mm Length 37.5mm | Stainless steel |
|  | **CT-BTC30** | Body try in 3mm for tapered impl. procedure | Ø3mm Length 28.5mm | Titanium |
|  | **CT-TDC35** | Step drill Ø3.5/3mm, external irrigation (blue) | Ø3.5-3mm Length 37.5mm | Stainless steel |
|  | **CT-BTC35** | Body try-in 3.50mm for V3 tapered impl. procedure | Ø3.5mm Length 28.5mm | Titanium |
|  | **CT-TDC40** | Step drill 4/3mm, external irrigation | Ø4-3mm Length 37.5mm | Stainless steel |
|  | **CT-BTC40** | Body try-in 4mm for V3 tapered impl. procedure | Ø4mm Length 28.5mm | Titanium |

The Surgical Kit

# Kit Contents

| | | Dimensions | Material |
|---|---|---|---|
|  | **MT-RE160** \| Int. connection abutment extractor, NP | Length 28.5mm | Titanium |
|  | **MT-RE172** \| Int. connection abutment extractor | Length 28.5mm | Titanium |
|  | **MT- DE001** \| Drill extender | Length 24mm | Stainless steel |
|  | **MT- RDL30** \| Long driver 0.05 inch | Length 23.5mm | Stainless steel |
|  | **MT- RDS30** \| Short driver 0.05 inch | Length 18.5mm | Stainless steel |
|  | **MT-BTI20** \| Implant site depth probe | Ø1.40mm Length 100mm | Stainless steel |
|  | **MT-RI030** \| Ratchet wrench | Length 84mm | Titanium |

| | | Dimensions | Material |
|---|---|---|---|
|  | **CT-NLM30** \| V3 coni. con. long insertion tool for motor, NP | Length 29mm | Stainless steel |
|  | **CT-NSM30** \| V3 coni. con. short insertion tool for motor, NP | Length 25mm | Stainless steel |
|  | **CT-NLR30** \| V3 coni. con. long insertion tool for ratchet, NP | Length 32.4mm | Stainless steel |
|  | **CT-NLR30** \| V3 coni. con. short insertion tool for ratchet, NP | Length 25mm | Stainless steel |
|  | **CT-SLM30** \| V3 coni. con. long insertion tool for motor, SP | Length 30.29mm | Stainless steel |
|  | **CT-SSM30** \| V3 coni. con. short insertion tool for motor, SP | Length 25mm | Stainless steel |
|  | **CT-SLR30** \| V3 coni. con. long insertion tool for ratchet, SP | Length 32.4mm | Stainless steel |
|  | **CT-SSR30** \| V3 coni. con. short insertion tool for ratchet, SP | Length 22.3mm | Stainless steel |

# Drills


50. Using MIS Drills
52. Color Code
54. Drilling Depth
56. Drill Indications
58. Final Drill
60. Drill Maintenance

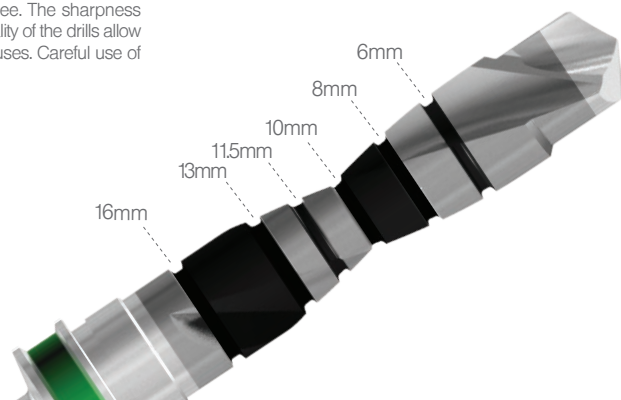
Drills

# 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 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 ledge 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 C1 Drill Stopper Kits (MK-CDS08, MK-CDS10, MK-CDS11, MK-CDS13) are a series of kits, each used for one specific implant length: 8, 10, 11.5 or 13mm.

For commonly used 3.75 or 4.2 implants, MIS offers a single assorted kit - the C1 Drill Stoppers Kit Standard Platform (MK-BC101), which includes all stoppers required for safe placement of Standard platform implants. All C1 Drill Stoppers Kits are compatible for use with the V3 implant.

C1 Drill Stoppers Kit

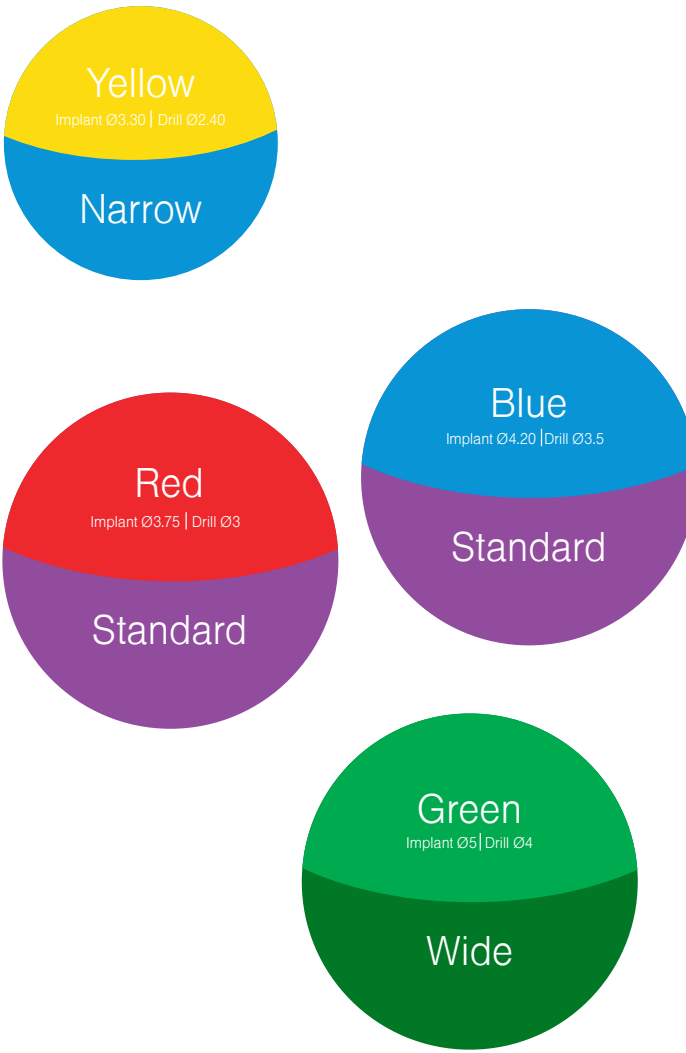

C1 Drill Stoppers Kit
Standard Platform (MK-BC101)


| | Diameter | Length |
|---|---|---|
|  | Ø3mm | 37.5mm |
|  | Ø3.50mm | 37.5mm |
|  | Ø4mm | 37.5mm |
|  | Ø4.50mm | 37.5mm |

Drills

# Color Code

Color-coding is used for easy identification of drill or implant diameters as follows:



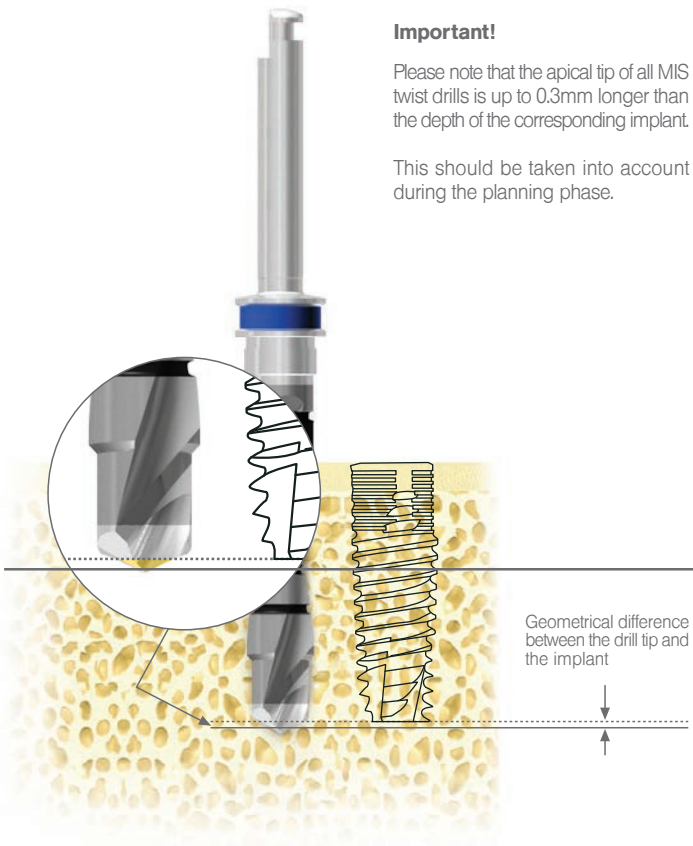
Drills

# Drilling Depth

**Important!**

Please note that the apical tip of all MIS twist drills is up to 0.3mm longer than the depth of the corresponding implant.

This should be taken into account during the planning phase.



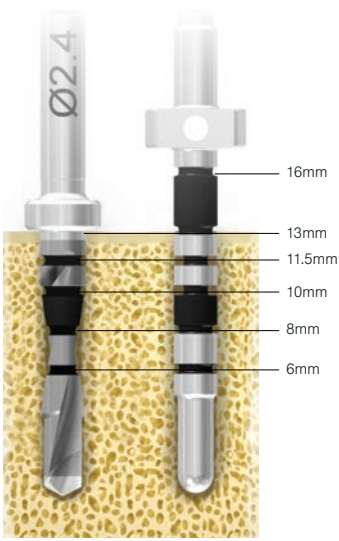
## Depth verification

Depth verification be done by using the Body Try-In tools (CT-BTCxx). (pic.1)

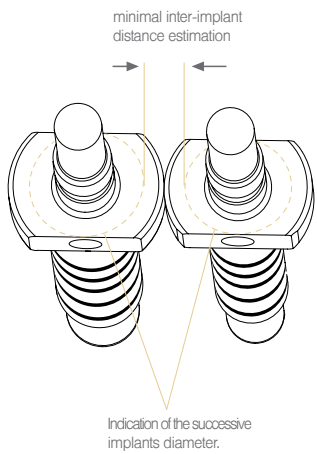
## A unique way to estimate the successive implant diameter and the required inter-implant space.

Prior to insertion of a dental implant– the evaluation of the successive implant diameter and the required biological space is a necessity. When coming to evaluate these two parameters, the CT-BTCxx system suggests a unique method – even when only pilot drills have been used and a required correction of the drill location may still be amended. The new suggested method may be used when inserting an implant is required next to a single tooth, between 2 teeth or next to another osteotomy, indicating 1.5mm on each side.

The compatible successive implant diameter is also indicated, as shown in the illustration below. (pic 2)



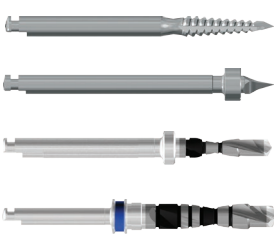

(pic.1)




(pic.2)

Drills

# Drill Indications

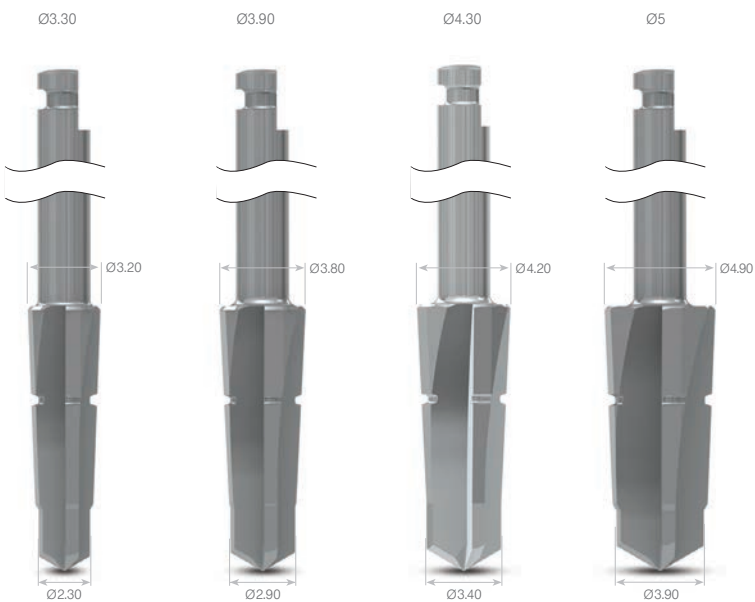


| | Recommended Speed |
|---|---|
| Position drill mill | 1200-1500 RPM |
| Position drill | 250-400 RPM |
| Pilot Drill | 500-1000 RPM |
| Step Drill | 400-600 RPM |

| Length & Diameter | Aim of Use |
| --- | --- |
| The position drill mill is features conical blade geometry of up to 2.4mm and a sharp tip. The drill is 32mm in length and its effective length is 9mm. The drill is made of stainless steel. | The position drill mill is used to mark a reference point for subsequent drills. It is especially useful in immediate placement procedures. |
| The position drill has a diameter of Ø4mm and a sharp tip. The position drill is 32.7mm in length and is made of stainless steel. | The position drill allows visualization of the actual position of the implant at the end of the drilling procedure. The short, sharp drilling head secures the drill on the bone while the 4mm ring seated above the drill head provides an indication as to the final position of the implant. |
| V3 Pilot Drills come in five different lengths: 8, 10, 11.5, 13 and 16mm. The first four 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. |
| Step Drills come in a variety of diameters and lengths. | Step Drills are used to widen the osteotomy. They are NOT length specific, and have laser markings for 6, 8, 10, 11.5, 13 and 16mm implants. The use of stoppers is highly recommended when using Step Drills. |

V3
# Final Drill

Final Drill for implant diameters



# V3

## Implant and Drill Measurements

Each V3 implant package contains a sterile, single-use Final Drill. The drills are recommended for use in bone types 1, 2 & 3. Each Final Drill has a predetermined length and diameter, matching the relevant implant shape and dimension ensuring maximum initial stability while preventing pressure on the implant neck. The length-specific final drills also promote a short and safe drilling procedure. The recommended drilling speed is 200-400 Rpm.

Implant and drill measurements

Drills

# Drill Maintenance

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





**Cleaning and Sterilization Instructions**

**Attention:** For your own safety, please wear personal protective equipment (gloves, glasses, mask).

**Pre-Cleaning:**

**1.** Soak the drills immediately after use in a detergent and disinfecting solution, preferably an enzymatic cleaning solution, with a pH level between 6-9, prepared with lukewarm water for 5 minutes.

**2**. Scrub the drills under running water with a soft nylon brush to remove any remaining blood or debris.

**3**. Rinse under tap water (at least 1 min).

**4**. Place the drills in a kit, support or rack to avoid any contact between instruments.

**Cleaning Procedure for Manual Cleaning:**

**5.** Prepare an ultrasonic bath with a cleaning solution at a concentration and temperature specified in the detergent manufacturer's instructions.

**6.** Immerse the drills completely and activate the bath for at least the recommended time in the detergent manufacturer's instructions.

**7.** Rinse under tap water (at least 1 min).

**Alternative - Automated Cleaning:**

**8.** Place the rack in a washer-disinfector and apply a cleaning procedure according to the manufacturer's recommendations.

**9.** Dry on a single-use, non-woven cloth or through a drying cycle of washer-disinfector or filtered compressed air.

**10.** Inspect the drills and discard those with defects. Repeat cleaning if necessary..

**11.** Place the drills in a kit and pack in a sterilization pouch.

**12**. Steam sterilize according to the chart below. Do not exceed the recommended temperature specified.

**13.** Keep the sterilization packaging in a dry and clean environment.

| Cycle type | Pre-vacuum | Gravity displacement |
|---|---|---|
| Temperature | 132º C / 270º F | 135ºC / 275ºF |
| Exposure | 4 min. | 10 min. |
| Drying time | 20 min. | 30 min. |



**Recommendations**

- Cutting tools should be used for a maximum of 30 uses.

- Distilled water should be used in order to prevent water spots.

- For all metal instruments, it is recommended to use anticorrosive disinfecting and cleaning agents. They should be Aldehyde free and Ethanolamine free.

- Use only autoclaves that meet the requirements of EN 13060 and EN 285.

- Use a validated sterilization procedure according to ISO 17665.

- For automated cleaning procedures, use a washer-disinfector approved according to EN ISO 15883.

# Surgical & Prosthetic Tools


64. Ratchet Range
66. Specialized Surgical Tools
68. Specialized Prosthetic Tools
72. Screw Tests
73. Maintenance

Ratchet

# MIS Ratchet Range

MIS offers a line of uniquely designed ratchets, to simplify both prosthetic screw tightening and implant insertion, allowing for an accurate and safe performance. 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.

Three ratchet types, to allow an accurate and safe procedure:

MT-RT070

**Torque Wrench**

Controlled torque for implant placement (35-75Ncm)

MT-RI030

**Mono-block Ratchet**

MT-RI040

**Torque Wrench**

Controlled tightening torque for prosthetic screws (10-30 Ncm).

## Warnings

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, and even to the bone-to-implant interface.

Beware that the recommended torque for implant placement is 35-60 Ncm.

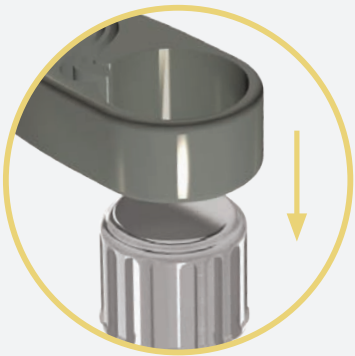
## Instrument Maintenance

- The device is delivered non-sterile.
- Cleaning and sterilization are required prior to use.

## Cleaning and Sterilization

For cleaning and sterilization instructions please refer to page 73.

**User Instructions:**



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

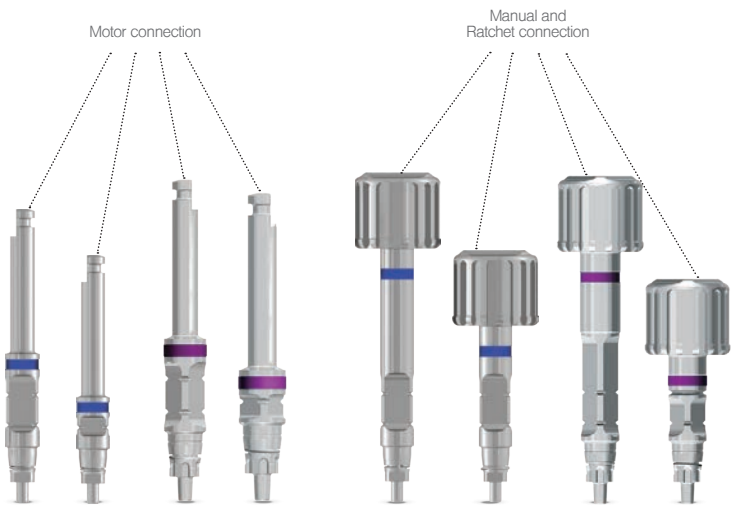
Clean thoroughly, immediately after use.

Surgical Tools

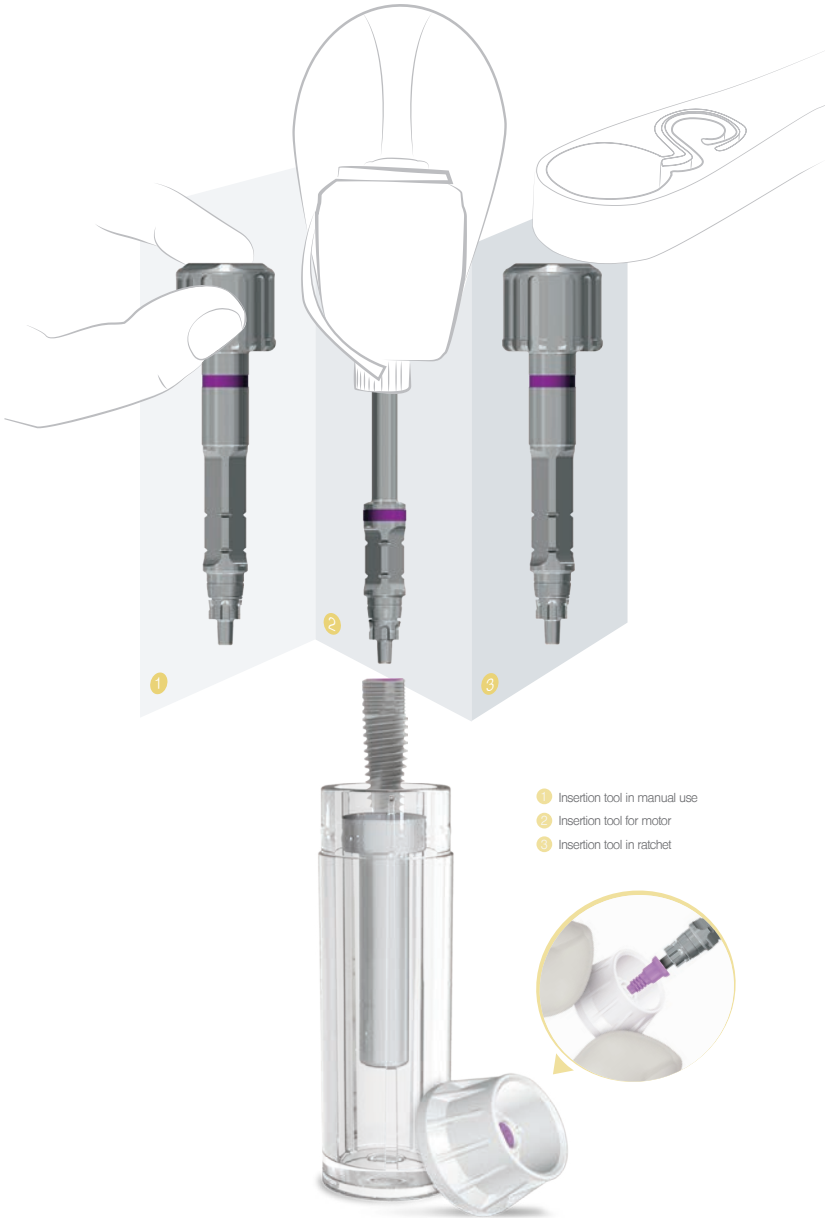
# Specialized Surgical Tools

## V3 Insertion Tools

V3 implants are divided into Narrow platform implants (3.30mm) and Standard platform implants (3.90, 4.30 and 5mm). Long and short insertion tools are available for each of the V3 platforms, for hand-piece connection and for use by ratchet/manually.




△ Narrow Platform
△ Standard Platform


1
2
3
1 Insertion tool in manual use
2 Insertion tool for motor
3 Insertion tool in ratchet

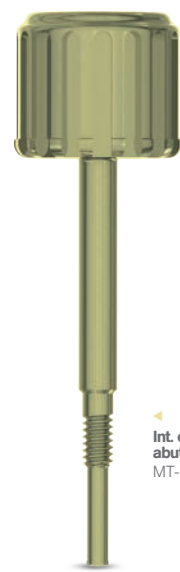
Prosthetic Tools

# Specialized Prosthetic Tools

**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; purple for Standard abutments and yellow for Narrow abutments.

**Int. connection abutment extractor**
MT-RE172

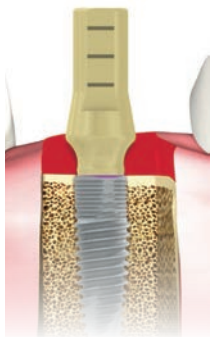


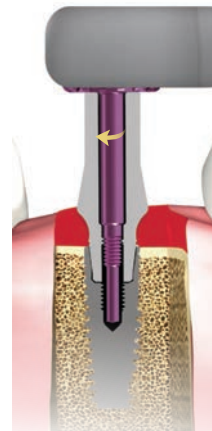
**Int. connection abutment extractor, NP**
MT-RE160

**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 Implants**





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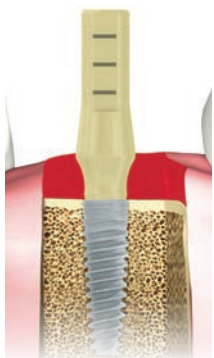
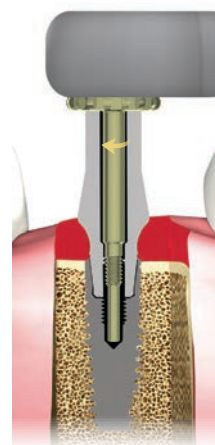
**For Narrow Implants**



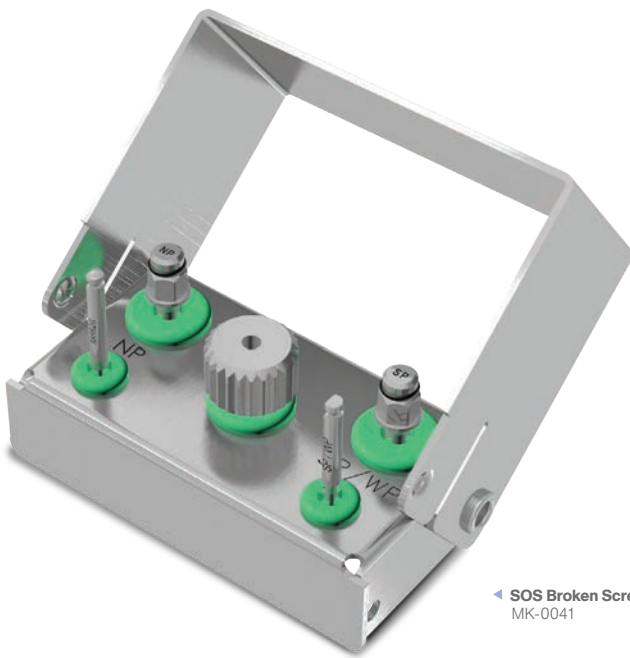


Prosthetic Tools

# SOS Broken Screw Kit

**SOS Broken Screw Kit**
MT-TF172 / MT-RT001/ MT-HW001/ MT-TF160/ MT-RT002

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-TF160

**Thread Former**
MT-TF172

**Hand Wrench**
MT-HW001

**Retriever**
MT-RT001

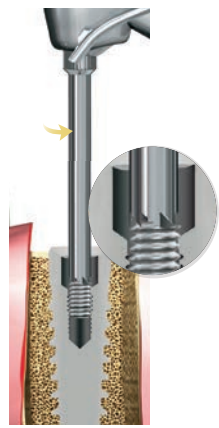
**Retriever**
MT-RT002

## 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:

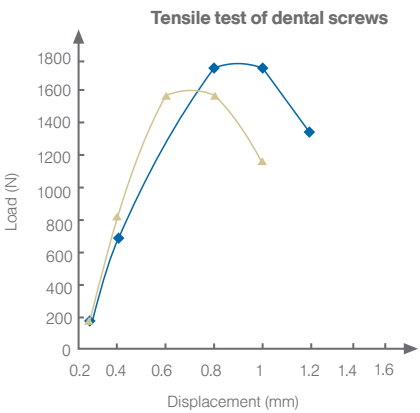
A. Use the thread former with care.

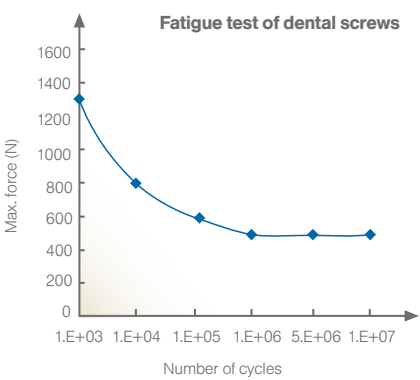
B. Be sure to align the thread former parallel to the long axis of the implant.

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.

Prosthetic Tools
# Screw Tests




**Test conditions:**

20 Ti-6Al-4V ELI, M2 type screws.
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.

# Instrument Maintenance

**Attention**:
For your own safety, please wear personal protective equipment (gloves, glasses, mask).

**Pre-Cleaning:**

- Disassemble the device if required.
- Soak all instruments immediately after use in a detergent and disinfecting solution, preferably an enzymatic cleaning solution, with a pH level between 6-9, prepared with lukewarm water for 5 minutes.
- Scrub the instruments under running water with a soft nylon brush to remove any remaining blood or debris.
- Rinse under tap water (at least 1 min).
- Place the instruments in a kit, support or rack to avoid any contact between them during the next cleaning procedure.

**Cleaning Procedure**
**Manual Cleaning:**

- Prepare an ultrasonic bath with a cleaning solution at a concentration and temperature specified in the detergent manufacturer's instructions.
- Immerse the instruments completely and activate the bath for at least the recommended time in the detergent manufacturer's instructions.
- Rinse under tap water (at least 1 min).

**Alternative: Automated Cleaning**

- Place the rack in a washer-disinfector and apply a cleaning procedure according to the manufacturer's instructions.

**Drying and Sterilization**

- Dry on a single-use non-woven cloth or through a drying cycle of a washer-disinfector or with filtered compressed air.
- Inspect the devices and discard those with defects.

Repeat cleaning if required.

- Assemble the device if required.
- Place the devices in a kit, and pack in sterilization pouch.
- Steam sterilize according to the table below. Do not exceed the recommended temperature specified.
- Keep inside the sterilization packaging in a dry and clean environment.

| Cycle type | Pre-vacuum | Gravity displacement |
|---|---|---|
| Temperature | 132° C / 270° F | 135°C / 275°F |
| Exposure | 4 min. | 10 min. |
| Drying time | 30 min. | 30 min. |



**Recommendations**

- Cutting tools should be used for a maximum of 30 uses.
- Distilled water should be used in order to prevent water stains.
- For all metal instruments, it is recommended to use anticorrosive disinfecting and cleaning agents. They should be Aldehyde, Ethanolamine, chlorine and acid free.
- Use only autoclaves that meet the requirements of EN 13060, EN 285.
- Use a validated sterilization procedure according to ISO 17665.
- For Automated cleaning procedures, use a washer-disinfector approved according to EN ISO 15883.


10
Standard
V3
V3

# Packaging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Packaging

# Implant Package

The innovative MIS packaging system is designed for simple and easy use. All of our implant boxes feature distinctive colors, large typeface, clear data labels and a pull tab for quick opening. Boxes are a uniform shape and height, specifically designed to fit in clinic cabinets for easy accessibility and compact space-saving storage.


**Implant identification markings**

Quick identification of implant size and length. Sticker on the box lid, specifies implant diameter, length and platform size

**Easy pull tab**

The convenient pull tab facilitates quick and easy opening during surgery.

**Logical storage**

Packages fit perfectly into clinic drawers for space-saving storage and easy identification.


## 4-Implant Package

A convenient 4-implant package is available. The drawer-like box is ideal for storage in drawers or cabinets for easy identification of implant type, diameter and length.

Implant removal from the sterile inner tube

## 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 may be brought into the sterile surgical field whenever needed. An anti-rotation mechanism inside the titanium sleeve insures a safe implant removal.

Cover screw

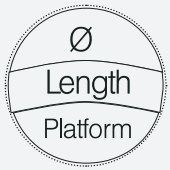
Implant

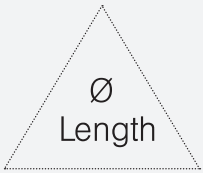
Packaging

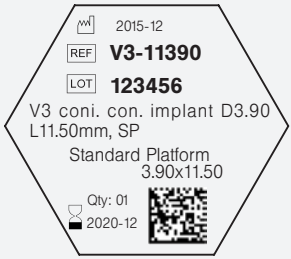
# Implant Identification Codes

Identification markings enable quick identification of implant diameter (top), implant length (center) and implant platform size (bottom).


**Identification labels:**



Packaging

# Implant Package Handling

The distinctive blue V3 implant boxes are a uniform shape and height, specifically designed to fit in clinic cabinets for easy accessibility and compact space-saving storage.


**Fig. 1**

The convenient pull tab facilitates easy and quick opening of the box during surgery.

**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.

Packaging

# Implant Package Handling

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

**Fig. 4**

Contra-angle hand piece

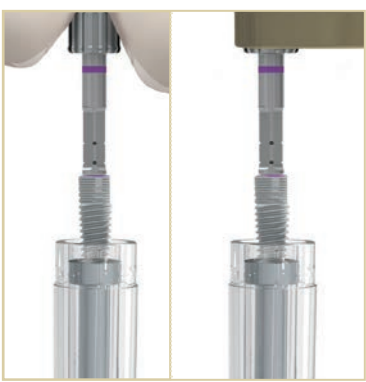


**Fig. 5**

Manual and Ratchet connection

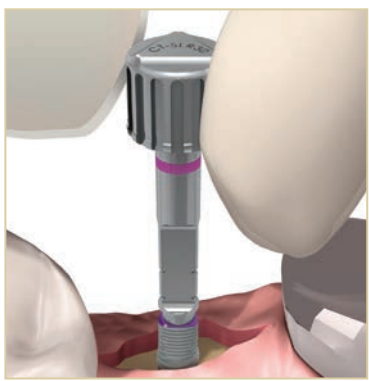


**Fig. 6**

Implant placement (illustrated manually).

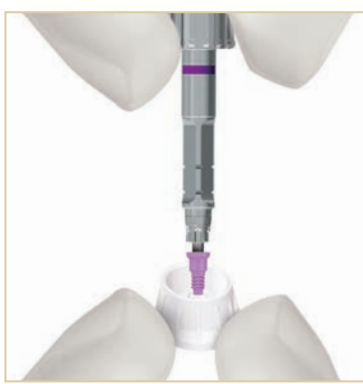


**Fig. 8**

Remove the cover screw using the CT-SLR30/ CT-SSR30 key

Packaging
# Implant Package Handling

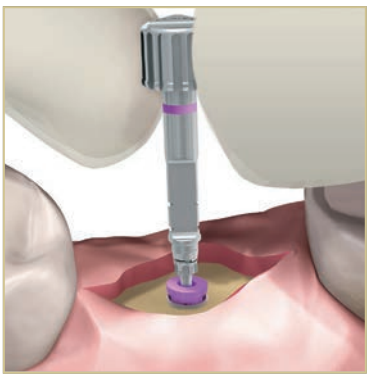


**Fig. 9**

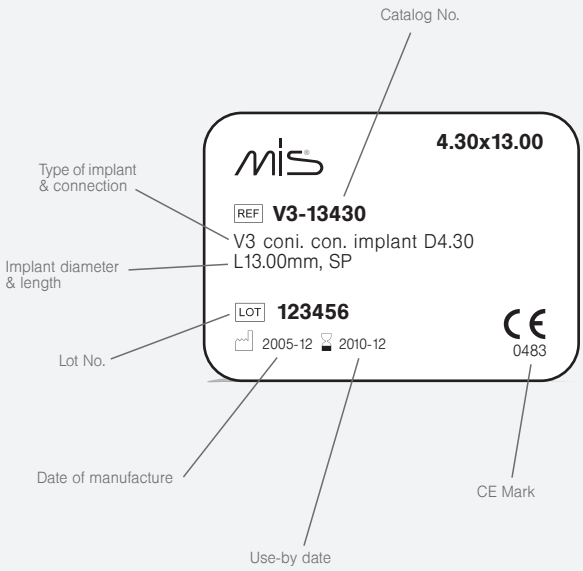
Attach the cover screw to the implant using the CT-S#R30 key. Tighten the cover screw using the MT-RDL/S30 KEY

**Fig. 10**

Attach the data label from the implant package onto the dental patient records.

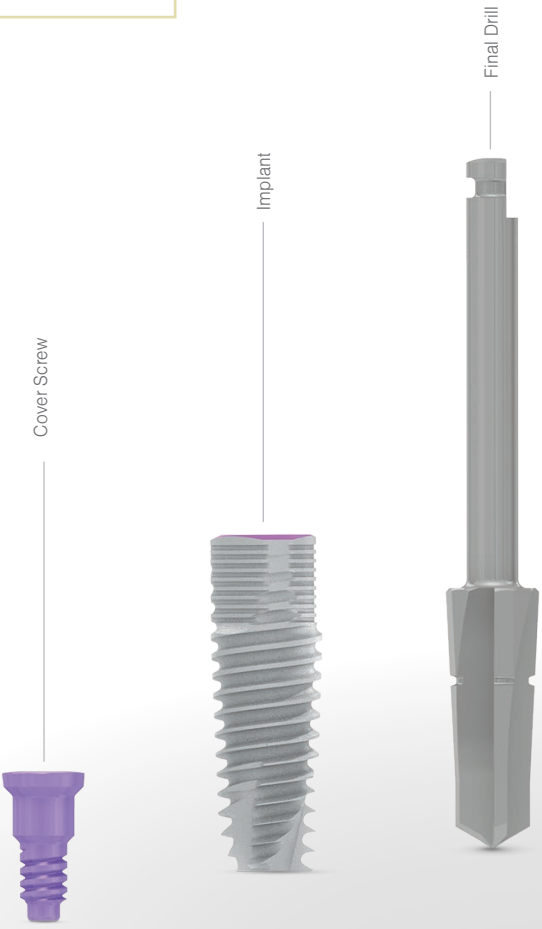
## Implant Data Label

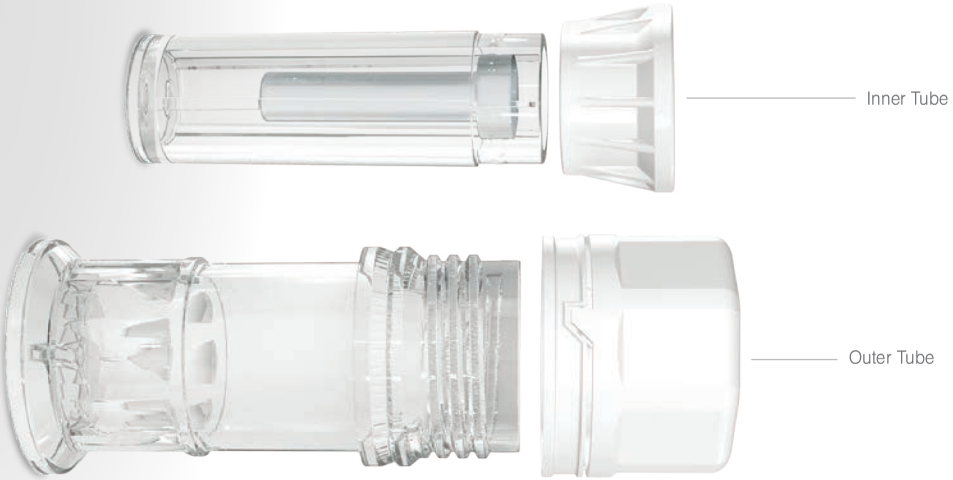
Each package contains three data labels, which include all required information pertaining to the implant. The following image illustrates the label:



Packaging

# Implant Package Handling



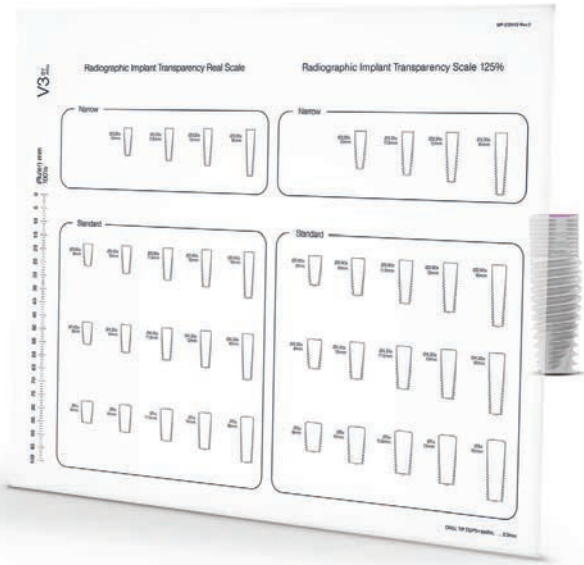

Inner Tube
Outer Tube

# Planning Transparency

MIS offers a planning transparency, illustrating the full V3 implant range. It includes two sets of images: one at actual 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 1:1 ruler.

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

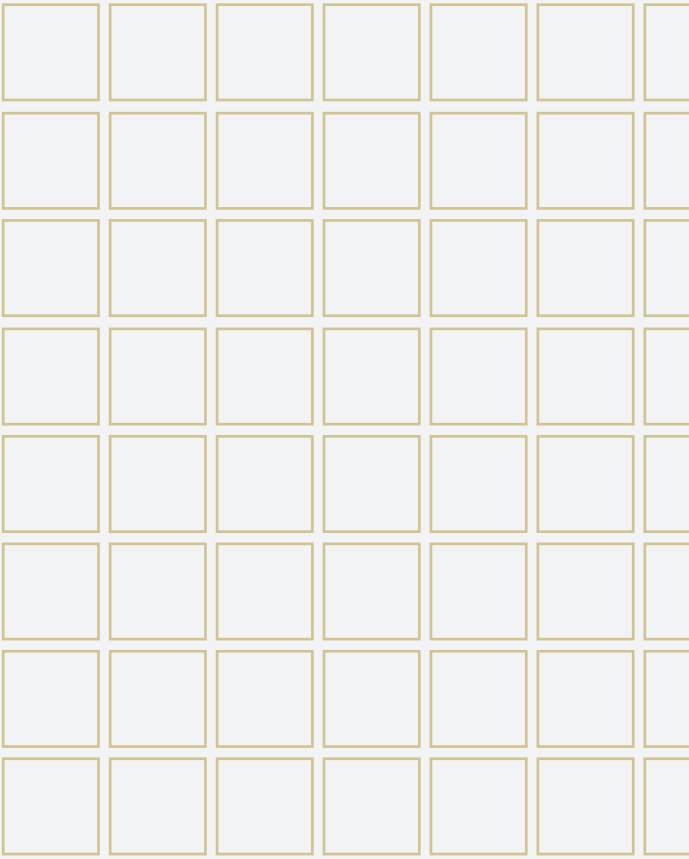
The transparency available for V3 implants is: Cat No. **MP-CONV3**

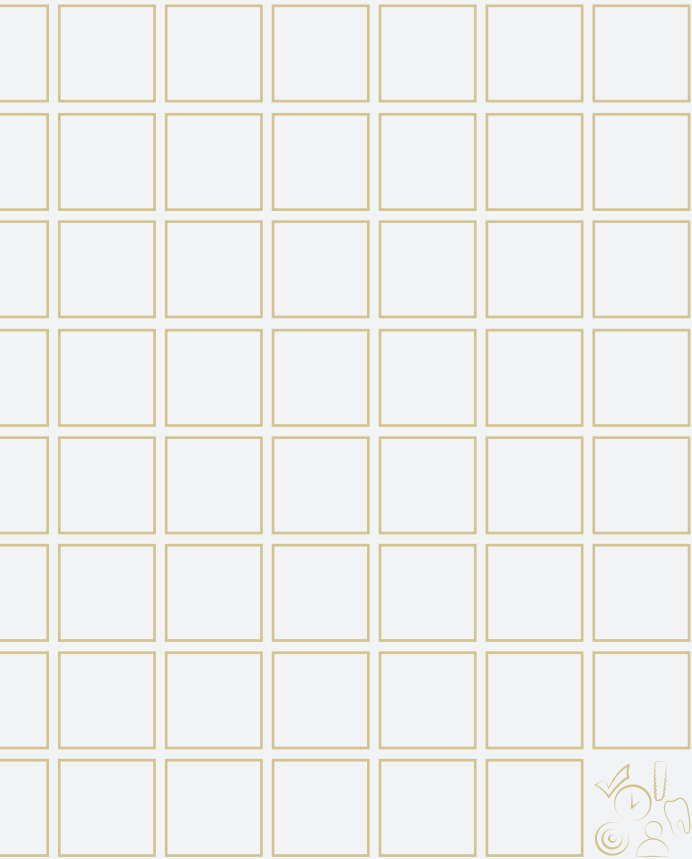


# Symbols

Key to symbols on labels and instruction leaflets:

| | |
|---|---|
| LOT Batch code | Manufacturer |
| REF Catalog number | Do not resterilize |
| Do not re-use | Do not use if package is damaged |
| Caution,consult accompanying documents | EC REP Authorised representative in the European community |
| Date of manufacture | Use-by date |
| STERILE R Sterilized using gamma irradiation | Keep away from sunlight |
| | Rx only Caution: U.S. federal law restricts this device to sale by or on the order of a dental professional |





MP-UI0V3 Rev2

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

MIS Quality System complies with international quality standards: ISO 13485:2003 – Quality Management System for Medical Devices, ISO 9001: 2015 – Quality Management System and Medical Device Directive 93/42/EEC. MIS products are CE marked.