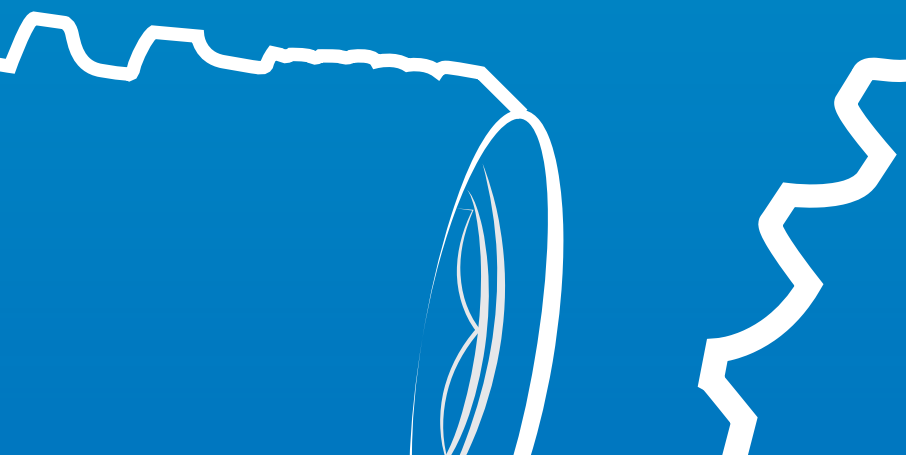
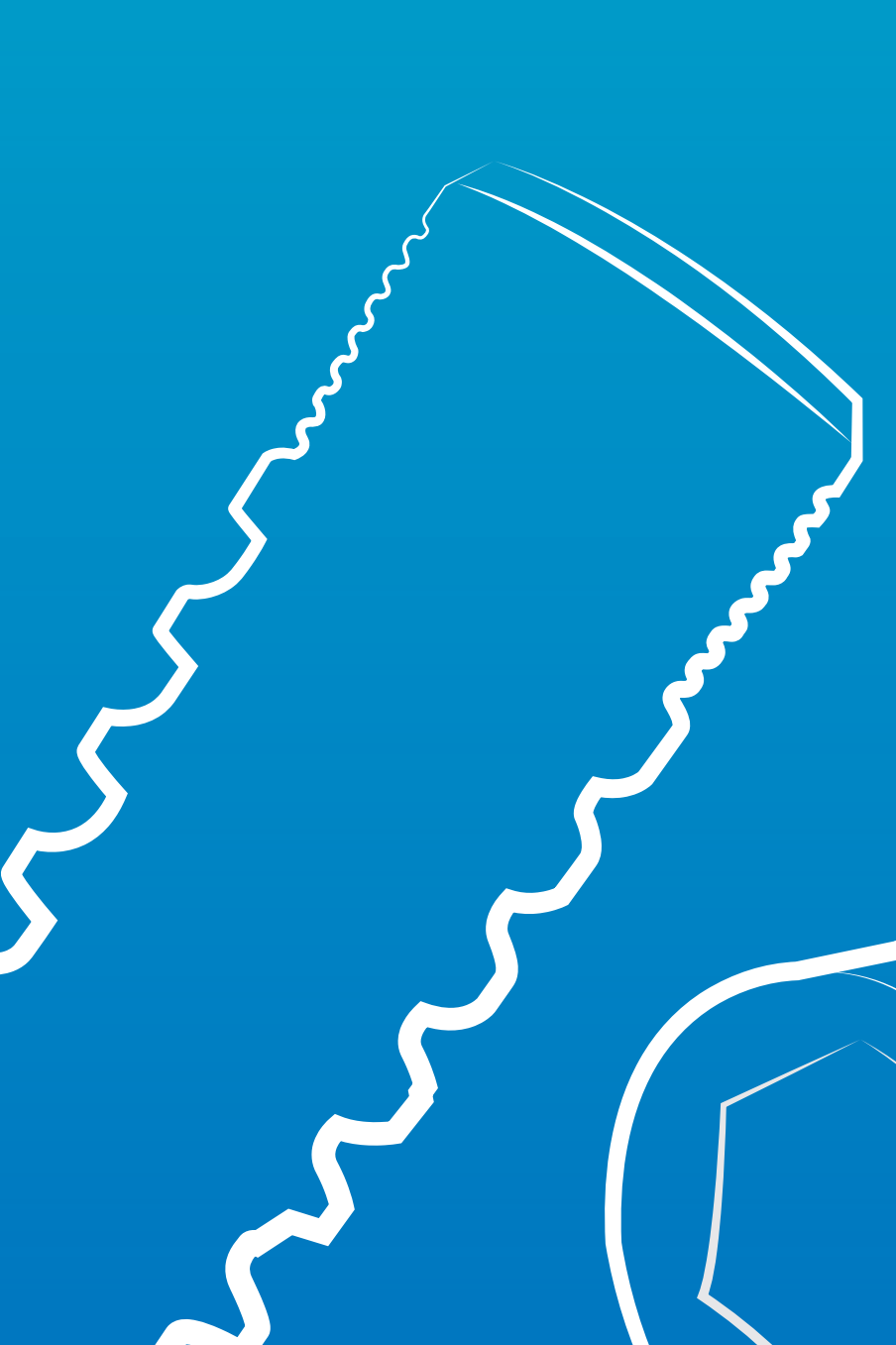
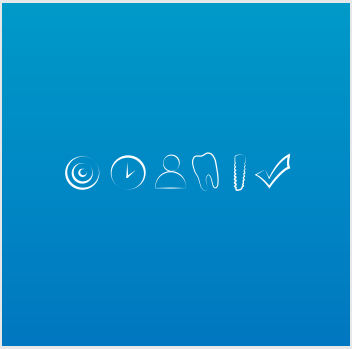
MIS C1 | **2017**

User Manual

The C1 implant system is an advanced implant design that offers a unique combination of surgical and restorative benefits, including a differential thread design to ensure superior initial stability in different clinical situations, platform switching and a conical connection with an anti-rotation index. Each C1 implant comes with a single-use final drill to ensure a safer and more accurate drilling procedure.





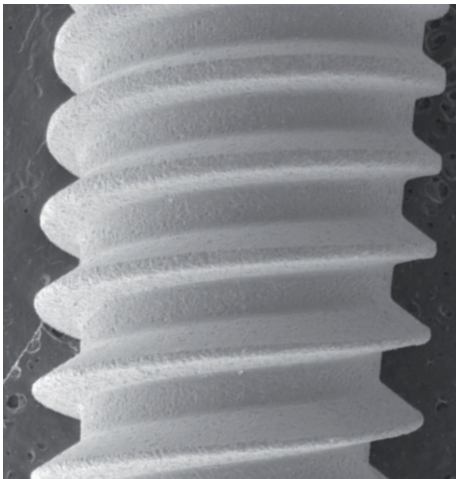


Questions, comments or requests will be addressed promptly by contacting MIS specialists directly through our e-mailing address: service@mis-implants.com. The MIS website may be accessed at www.mis-implants.com. This online site highlights current products and reflects all new discoveries and developments.

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 FDA cleared for marketing in the USA and CE marked.



Overview.

8. Introduction
9. Raw Material
12. Manufacturing Process
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 evaluations
- Cytotoxicity tests
- Sterility tests
- Removal torque values
- Histology
- Packaging integrity test

Overview

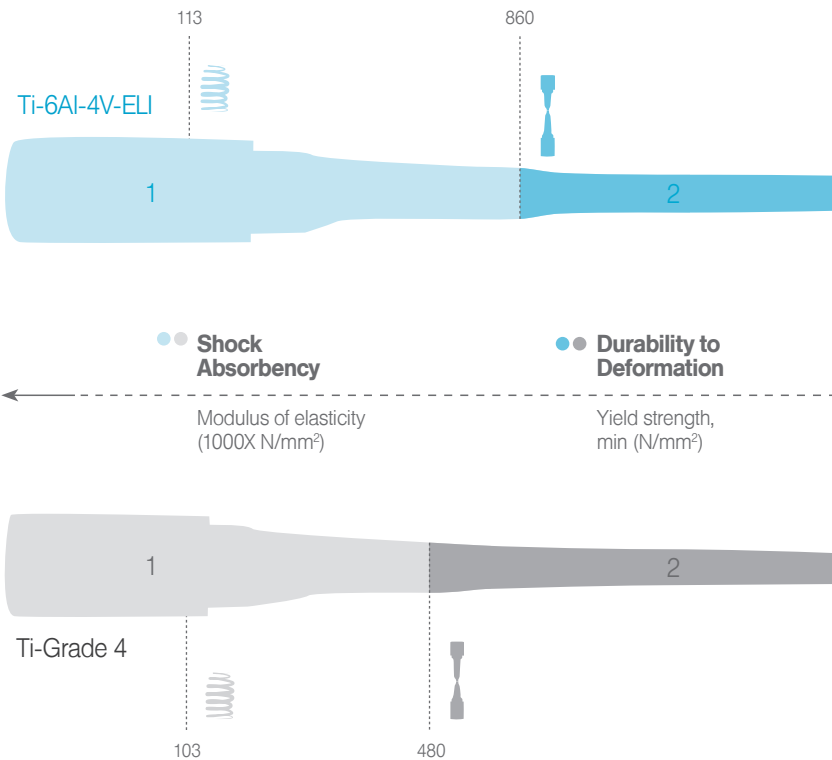
Raw Material

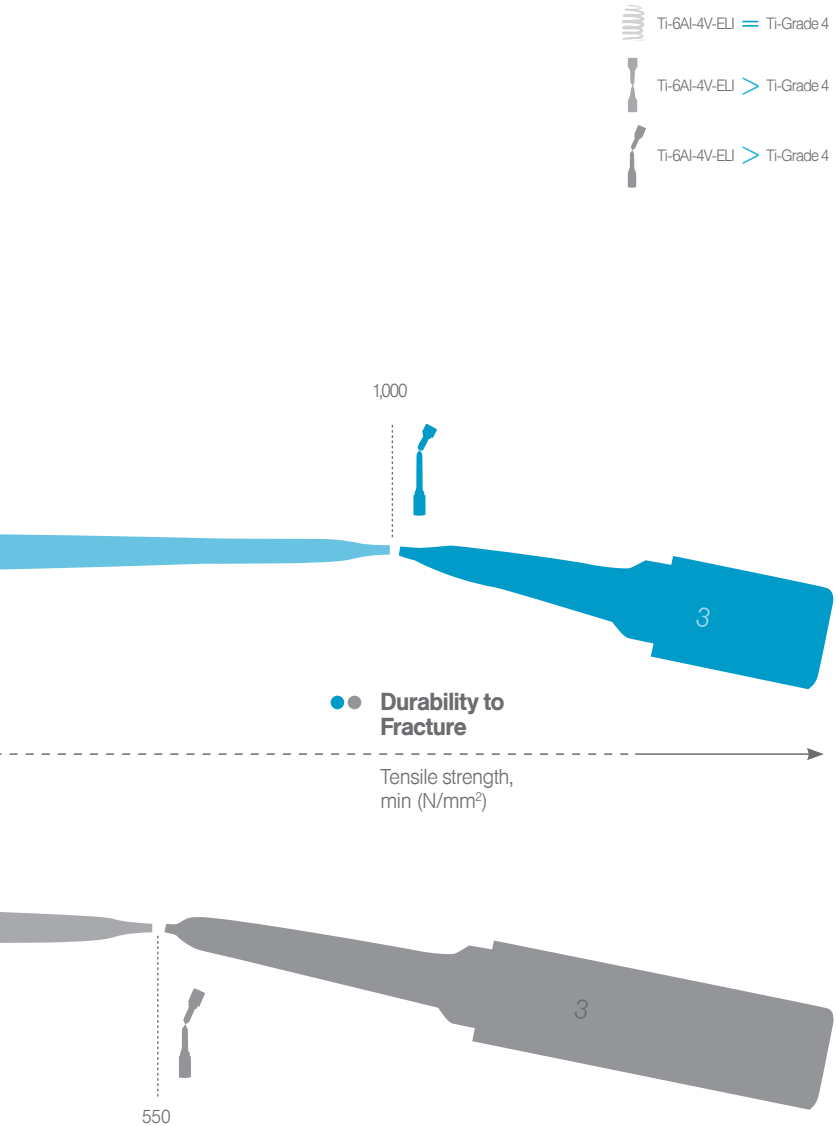
- Biocompatible
- Safe
- Long-term proven clinical success
- Superior mechanical properties

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




Ti-6Al-4V-ELI = Ti-Grade 4
Ti-6Al-4V-ELI > Ti-Grade 4
Ti-6Al-4V-ELI > Ti-Grade 4
1,000
3
Durability to Fracture
Tensile strength, min (N/mm²)
3
550

Overview

Manufacturing Process

Structure (Raw Material)

MIS Surface Treatment

Sand-Blasting

Acid-Etching

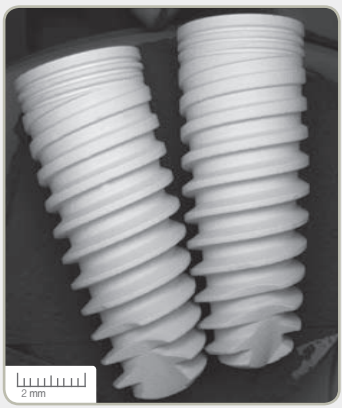
Roughness (Micro and Nano Structures)

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.

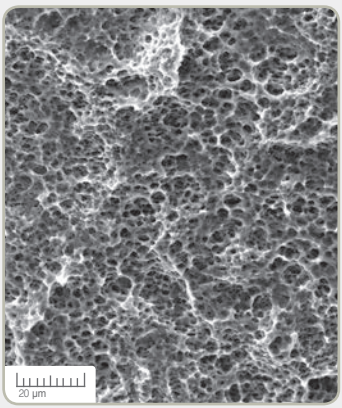
Overview

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 the raw material of the implant, morphology and surface chemical composition.



SEM image of two C1 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

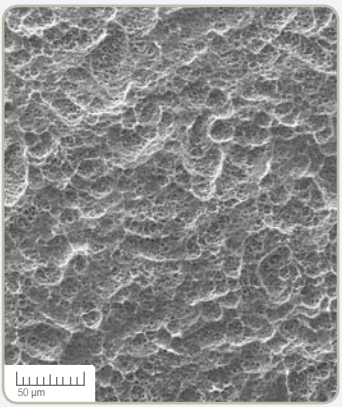
All MIS implants are sand-blasted and acid-etched. This surface treatment increases the implant surface area, creating both micro and nano-structures, while eliminating various surface contaminants.

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

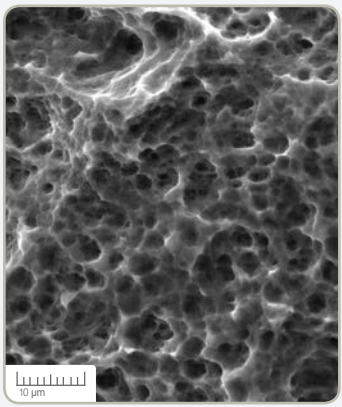
Sand-blasted and acid-etched surfaces have been substantially proven to maximize the BIC (Bone-to-Implant Contact), achieving immediate and long-lasting osseointegration.

Surface Composition

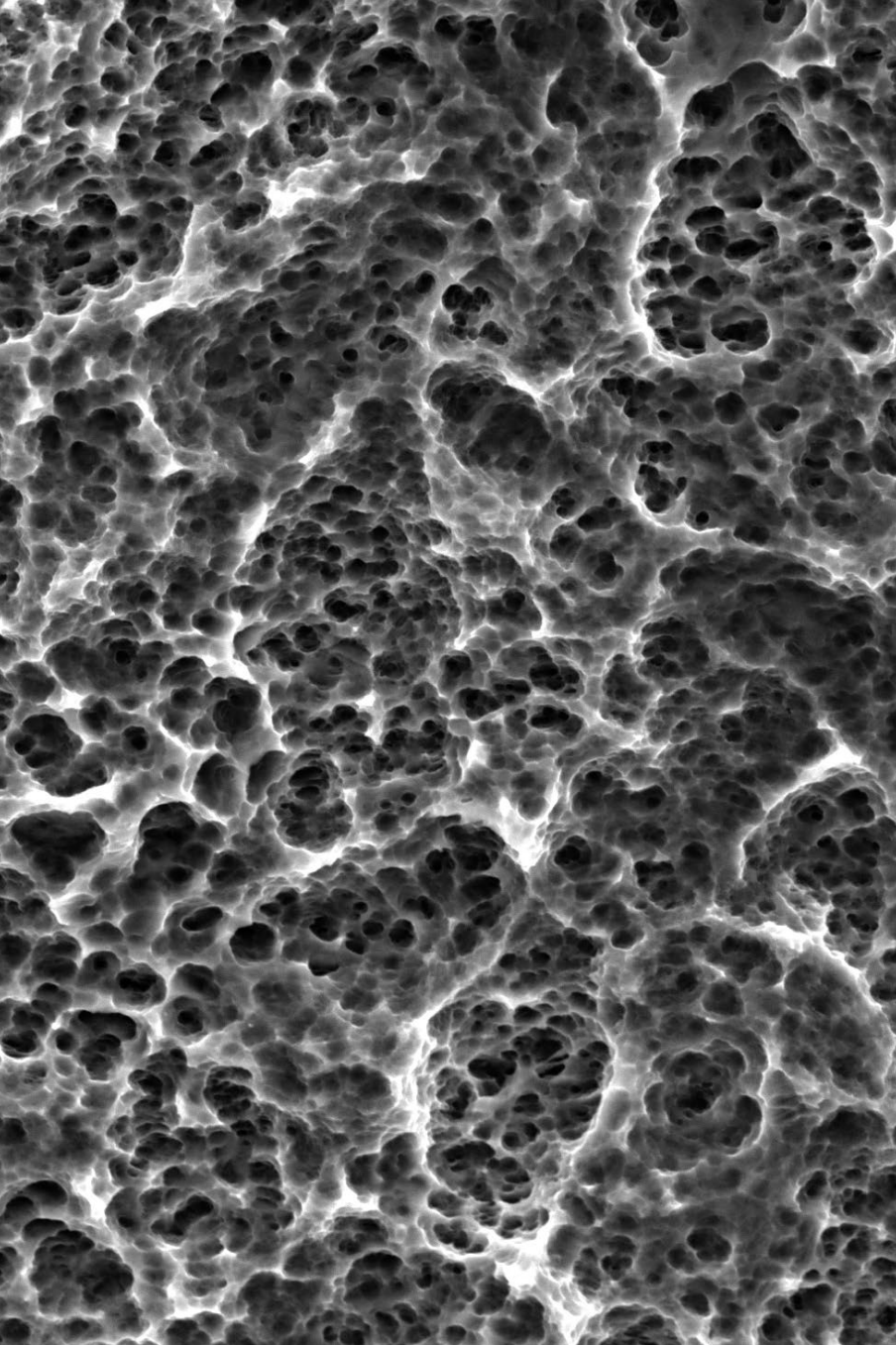
The outer surface of MIS implants, consist of a thin layer of pure titanium dioxide (TiO_2). Acid-etching and packaging processes are performed in a controlled environment clean-room to ensure purity and quality. Implants are inspected by electron microscope (SEM) scan and X-ray photoelectron spectroscopy (XPS), to ensure implants are free of contaminants.



SEM image of the implant surface showing the micro-structure

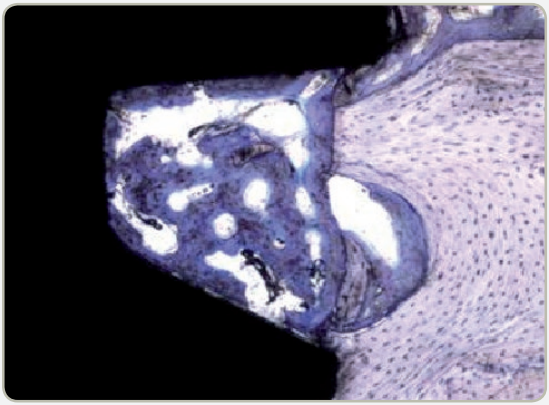


SEM image of the implant surface showing the nano-structure



Overview
Histology

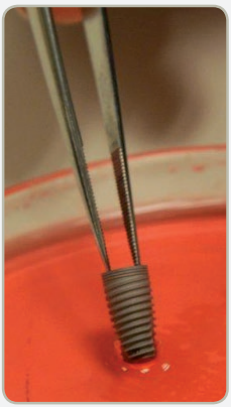
Histologic section of a C1 implant, 5 weeks after placement.
Courtesy of Paulo G. Coelho, DDS, PhD, NYU College of Dentistry.

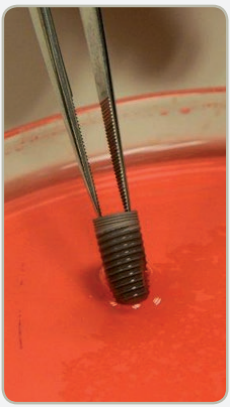


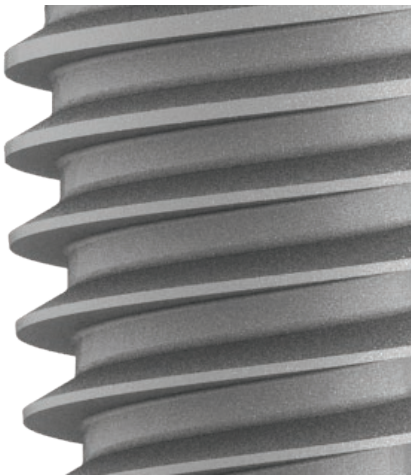
Histologic section of a C1 implant, 5 weeks after placement. Courtesy of Paulo G. Coelho, DDS, PhD, NYU College of Dentistry

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.







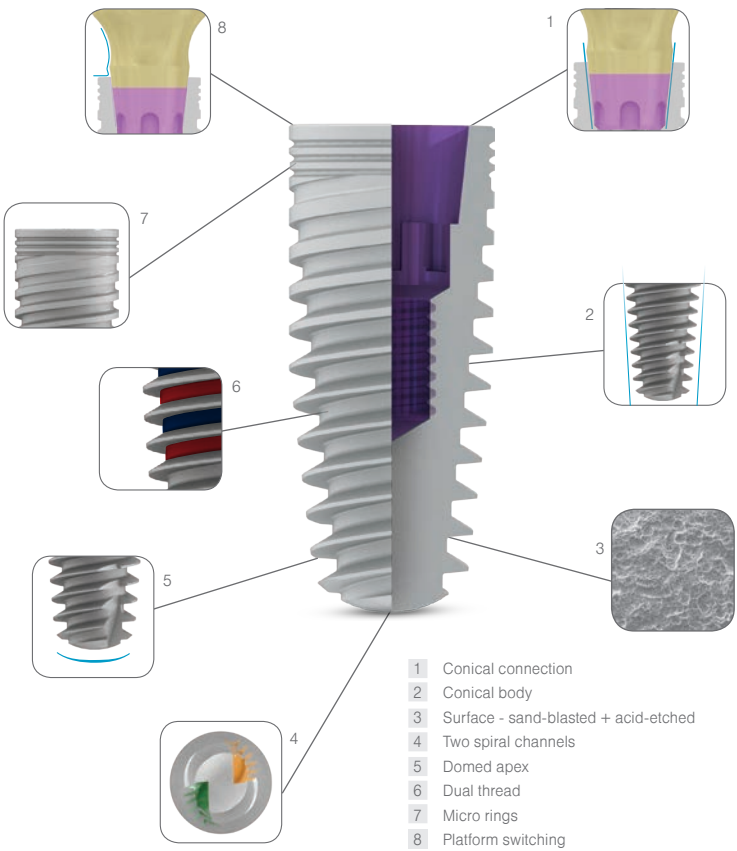
Implants.

20. Introduction: C1 Implant
21. Fixture - Technical Info
22. External Design
23. Implant Range
24. Conical Connection
26. Procedure

C1
Introduction

MIS is proud to introduce C1, an addition to our implant selection. C1 implants feature a unique combination of attributes that result in a new 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 implants and components are color-coded, according to their restorative platform, with a golden anodized hue for best esthetic results.

C1
Fixture - Technical Info



1. Conical connection
2. Conical body
3. Surface - sand-blasted + acid-etched
4. Two spiral channels
5. Domed apex
6. Dual thread
7. Micro rings
8. Platform switching

C1
External Design

Platform Switching

The C1 features platform switching, that keeps the implant-abutment connection away from the bone; minimizing bone resorption. Platform-switching additionally allows more vital growth of the soft tissue.

Conical Shape

- The conical root shape of the C1 implant and a unique thread design ensure superior primary stability, making the C1 the implant of choice for a wide range of clinical cases and loading protocols.
- The root shape design makes the C1 an ideal implant when space is restricted due to adjacent teeth or implants.

Two Spiral Channels and Domed Apex

The C1 features a domed apex, providing a high tolerance and safe procedure during insertion. Two cutting blades at the implant apex establish the self-tapping properties of the C1; supporting a simpler, safer and faster procedure.

Dual Thread

- The C1 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 (1.50mm), facilitating a simpler and controlled implant placement.
- The thread profile is especially designed for a flawless, easy insertion and high primary stability.
- The C1 is self tapping with mild bone compression that enhances primary stability.

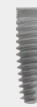
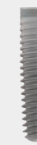
Surface Treatments

C1 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.

Micro-Rings

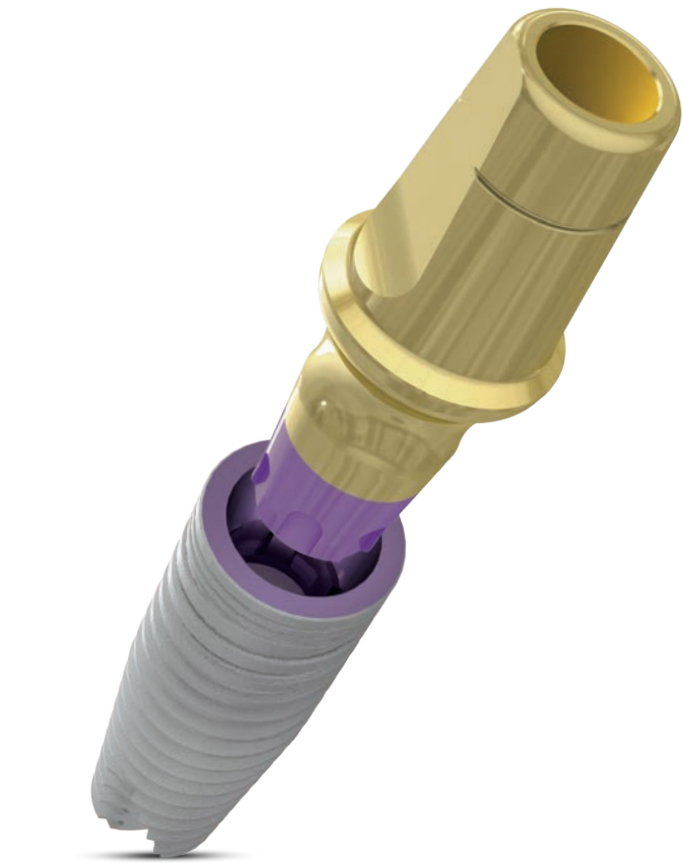
At the neck of the C1, micro-rings significantly increase the BIC (Bone to Implant Contact), avoiding bone resorption at the crestal zone.

C1
Implant Range

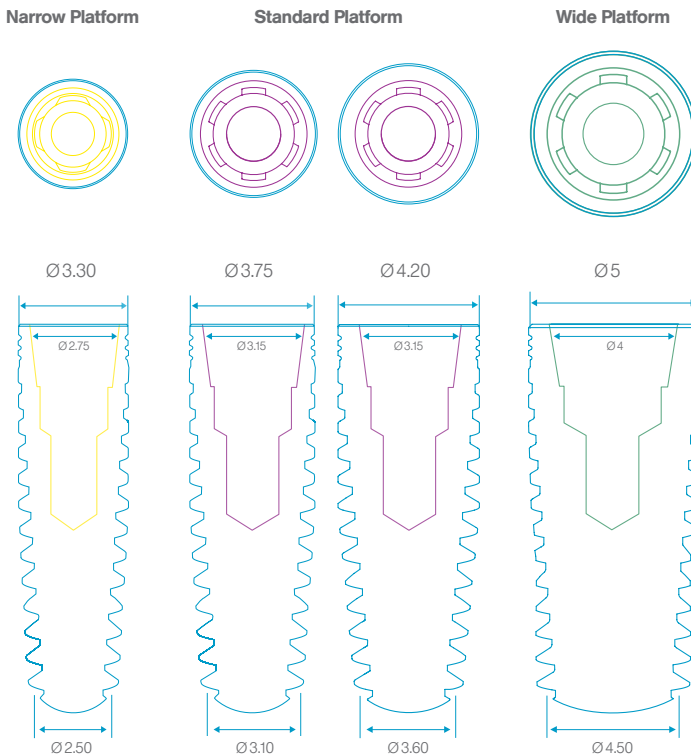
Length	8mm	10mm	11.50mm	13mm	16mm
Type **Ø3.30mm** Screw type implant Narrow platform		C1-10330 	C1-11330 	C1-13330 	C1-16330 
Type **Ø3.75mm** Screw type implant Standard platform	C1-08375 	C1-10375 	C1-11375 	C1-13375 	C1-16375 
Type **Ø4.20mm** Screw type implant Standard platform	C1-08420 	C1-10420 	C1-11420 	C1-13420 	C1-16420 
Type **Ø5mm** Screw type implant Wide platform	C1-08500 	C1-10500 	C1-11500 	C1-13500 	C1-16500 

* Implant package includes: a cover screw, a temporary cylinder and a final drill.

⊂1
Conical Connection



The C1 features a 12-degree conical connection to ensure a secure fit between the abutment and implant. By minimizing micro-movement at that junction, bone loss at the crestal level is reduced. There is a six-position cone index(four-position for Narrow platform) within the conical connection, to help orient the implant during insertion as well as for placing the abutment into the proper position.

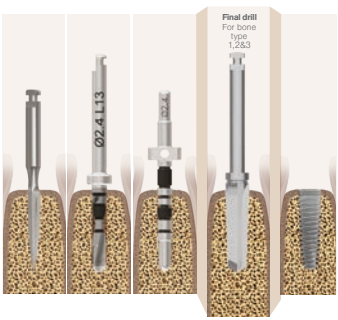


C1
Ø3.30mm / Ø3.75mm Procedure

Recommended insertion torque: 35-60 Ncm.

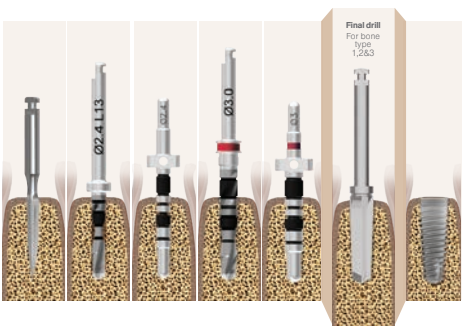
Ø3.30mm

Drill Speed (RPM)	1200-1500	900-1200		200-400	15-25
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø3 Ø3.60	Ø3.30



Ø3.75mm

Drill Speed (RPM)	1200-1500	900-1200		500-700		200-400	15-25
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø3	Ø3	Ø3 Ø3.60	Ø3.75



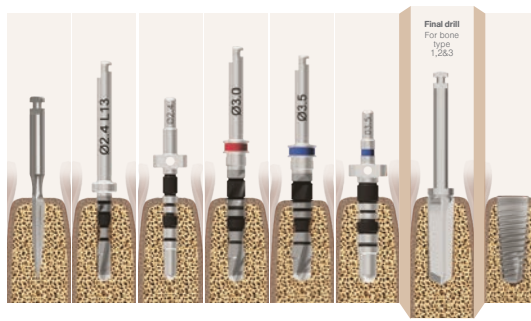
- Do not use the final drill for type 4 bone.
- The drilling sequence is demonstrated using a 13mm implant.
- Procedure recommended by MIS cannot replace the judgment and professional experience of the surgeon.

⊂1
Ø4.20mm / Ø5mm
Procedure

Recommended insertion torque: 35-60 Ncm.

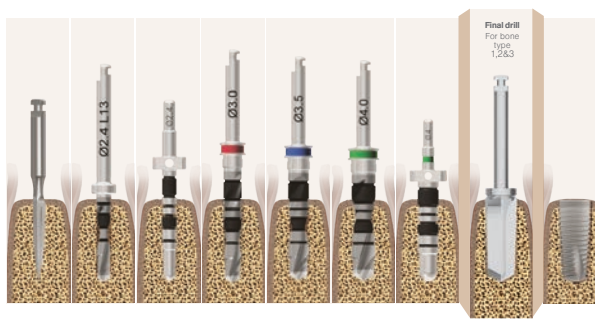
Ø4.20mm

Drill Speed (RPM)	1200-1500	900-1200		500-700	400-700		200-400	
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø3	Ø3.50	Ø3.50	Ø3.50 Ø4	Ø4.20



Ø5mm

Drill Speed (RPM)	1200-1500	900-1200		500-700	400-700	400-600		200-400	
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø3	Ø3.50	Ø4	Ø4	Ø4.10 Ø4.90	Ø5



Surgical Procedures.

For MIS Implants

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

Surgical Procedures
Indications & Contraindications

Indications

MIS C1 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 of 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, 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, including radiation therapy.

- Poor patient motivation

- Psychiatric disorders that interfere with patient 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 effects of implants on health.

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, Bleeding 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

The surgical manual is designed to provide an overview of the pre-surgical and the surgical procedures applicable to the C1 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 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 specif ic radiographs to be taken prior to, 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 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.

Step 5A.
Implant Selection

C1 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. An emergency resuscitation apparatus should be available. Each MIS implant comes with labels including all relevant data related to the implant. It is critical that one is kept as part of the patient's record for future reference.

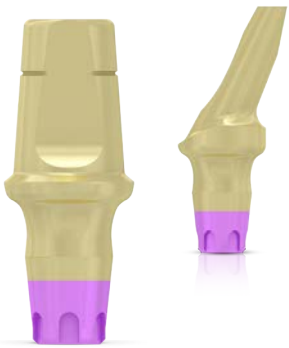
Warnings: C1 implants are supplied in a sealed and sterilized package. Implants should never be reused, and implants whose sterility is compromised should not be used. Implants should not be used later than the specific expiration date printed on the package. Implant placement should be performed in accordance with acceptable placement and loading protocols. 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.

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 restorative dentists are involved at the planning and surgical phases as active participants when making decisions affecting the choice of implant type and the 3-dimensional positioning of the implants.

12
24

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

C1 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.

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.


PROCEDURE
GUIDE
11.5
13

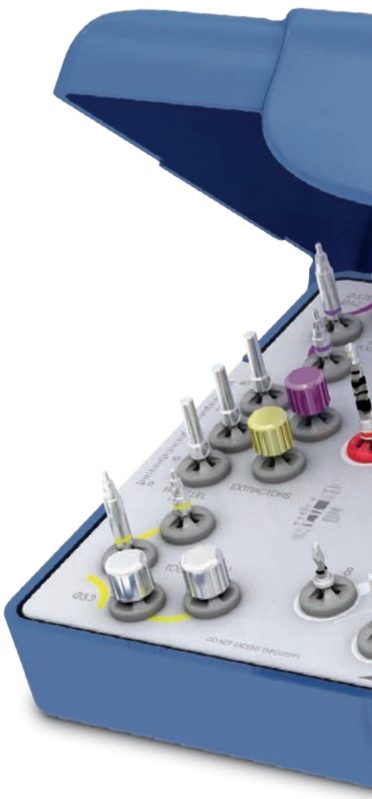
Surgical Kits.

38. Surgical Kit Description
40. Kit Contents

The Surgical Kit

Surgical Kit Description

The C1 innovative surgical kit is designed for simple and safe implant placement procedures. The kit introduces 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-T044

Warning!
Avoid damage!

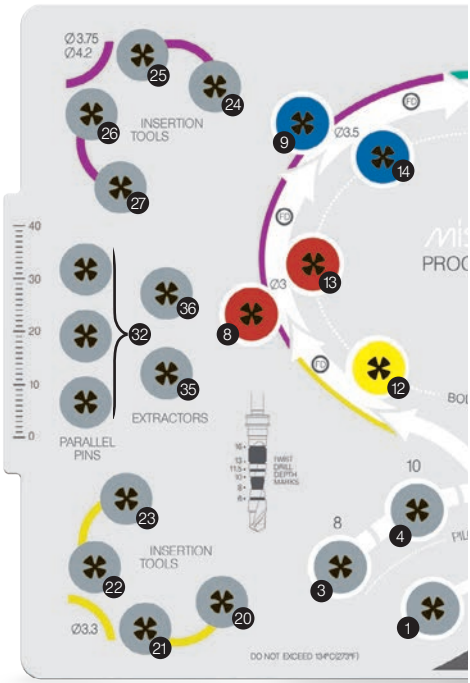
The sterilization kit-box and insert must be cleaned and sterilized before each use.

Please see sterilization instructions on page 62.

MK-0044 C1 Surgical kit

The Surgical Kit

Kit Contents



MARKING DRILLS

1 MT-SMD10

2 MT-TDN19

PILOT DRILLS

3 CT-P2408

4 CT-P2410

5 CT-P2411

6 CT-P2413

7 CT-P2416

STEP DRILLS

8 CT-TDC30

9 CT-TDC35

10 CT-TDC40

11 CT-TDC45

BODY TRY-INS

12 CT-BTC24

13 CT-BTC30

14 CT-BTC35

15 CT-BTC40

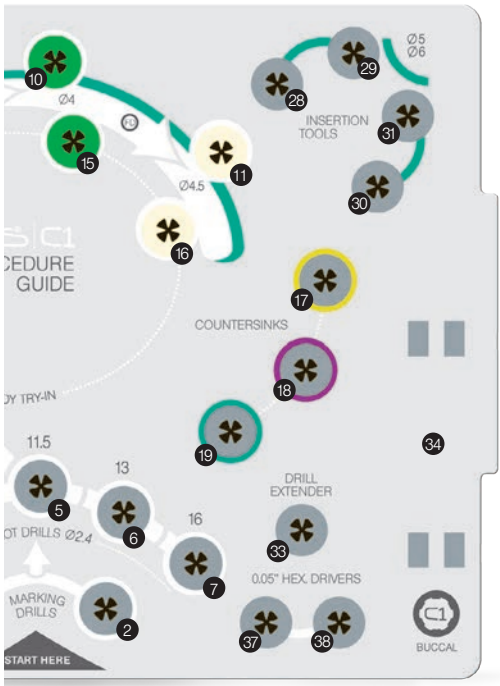
16 CT-BTC45

COUNTERSINKS

17 MT-CSN33

18 MT-GDN33

19 MT-GDN50



SURGICAL TOOLS

32 MT-PP240

33 MT-DE001

34 MT-RI030

35 MT-RE160

36 MT-RE172

38 MT-RDS30

37 MT-RDL30

INSERTION TOOLS

20 CT-NSR10

21 CT-NLR10

22 CT-NSI10

23 CT-NLI10

24 CT-SSR10

25 CT-SLR10

26 CT-SSI10

27 CT-SLI10

28 CT-WSR10

29 CT-WLR10

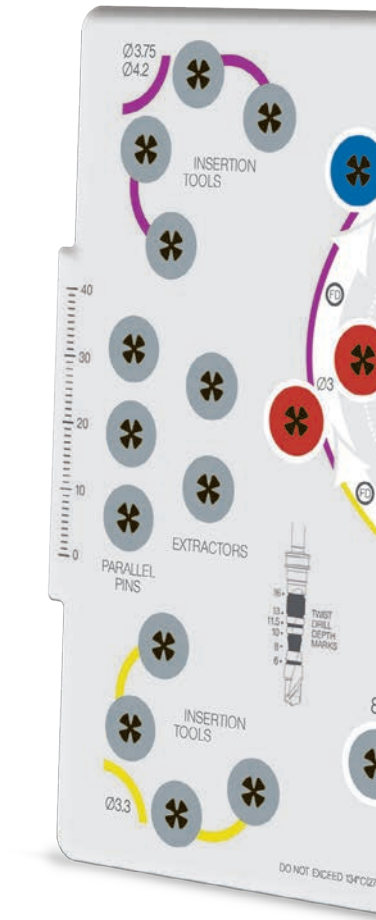
30 CT-WSI10

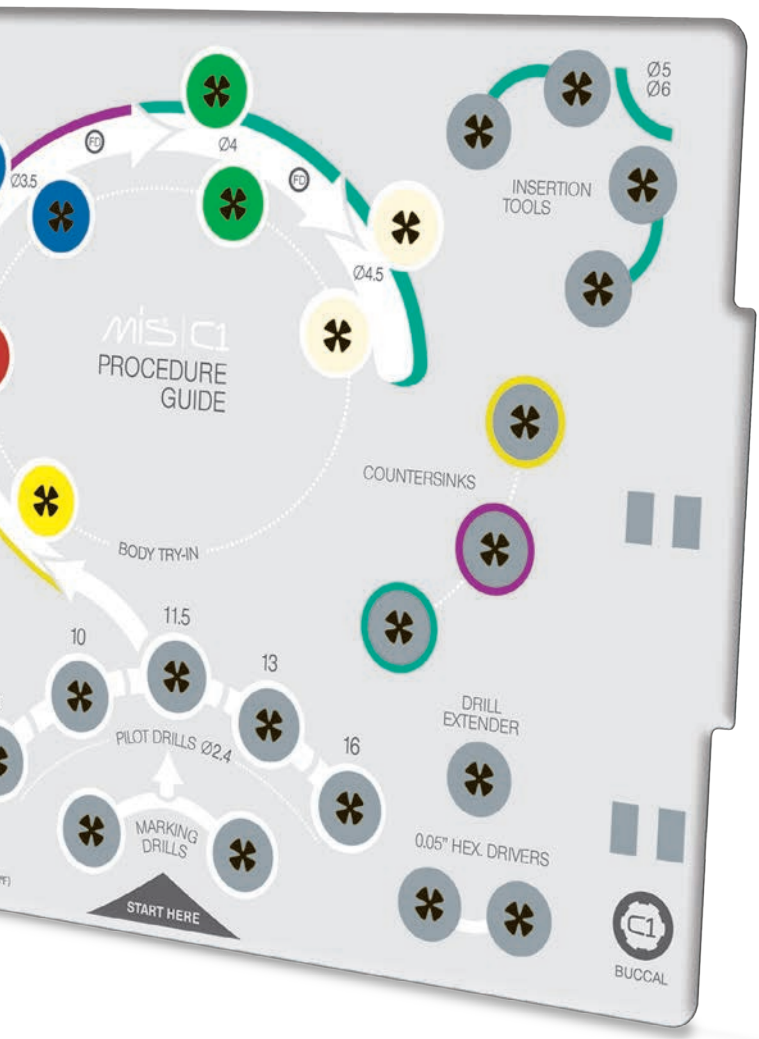
31 CT-WLI10

The Surgical Kit

Kit Contents

The C1 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.




Ø3.5
Ø4
Ø4.5
Ø5
Ø6
INSERTION TOOLS
MIS C1
PROCEDURE GUIDE
COUNTERSINKS
BODY TRY-IN
10
11.5
13
16
PILOT DRILLS Ø2.4
DRILL EXTENDER
MARKING DRILLS
0.05" HEX. DRIVERS
START HERE
C1
BUCCAL

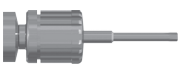
The Surgical Kit

Kit Contents

		Dimensions	Material
	**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 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 tapered impl. procedure	Ø4mm Length 28.5mm	Titanium
	**CT-TDC45** | Step drill Ø4.5/4mm, external irrigation	Ø4.5mm Length 28.5mm	Stainless steel
	**CT-BTC45** | Body try-in 4.5mm for tapered impl. procedure	Ø4.5mm Length 28.5mm	Titanium
	**MT-PP240** | Parallel pin Ø2.40mm for tapered impl. procedure	Ø2.40/Ø3mm	Titanium

The Surgical Kit

Kit Contents

		Dimensions	Material
	**MT-SMD10** | Spade marking drill	Length 27.5mm	Stainless steel
	**MT-TDN19** | Marking drill Ø1.9mm external irrigation	Ø1.90mm Length 34mm	Stainless steel
	**MT-RE160** | Int. conn. 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-CSN33** | Countersink for Narrow platform implant system	Ø3.30mm Length 26mm	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	Ø5mm/Ø6mm Length 26.8mm	Stainless steel

			Dimensions	Material
	**CT-NLI10**	Coni. con. long insertion tool, NP	Length 32mm	Stainless steel
	**CT-NSI10**	Coni. con. short insertion tool, NP	Length 24.5mm	Stainless steel
	**CT-NLR10**	Long ratchet insertion tool, coni. con., NP	Length 32mm	Stainless steel
	**CT-NSR10**	Short ratchet insertion tool, coni. con., NP	Length 24.5mm	Stainless steel
	**CT-SLI10**	Coni. con. long insertion tool, SP	Length 33mm	Stainless steel
	**CT-SSI10**	Coni. con. short insertion tool, SP	Length 25.5mm	Stainless steel
	**CT-SLR10**	Long ratchet insertion tool, coni. con., SP	Length 33mm	Stainless steel
	**CT-SSR10**	Short ratchet insertion tool, coni. con., SP	Length 23mm	Stainless steel
	**CT-WLI10**	Coni. con. long insertion tool, WP	Length 33mm	Stainless steel
	**CT-WSI10**	Coni. con. short insertion tool, WP	Length 25.5mm	Stainless steel
	**CT-WLR10**	Long ratchet insertion tool, coni. con., WP	Length 33mm	Stainless steel
	**CT-WSR10**	Short ratchet insertion tool, coni. con., WP	Length 23mm	Stainless steel
	**MT-RI030**	Ratchet wrench	Length 83mm	Titanium

Drills.

50. Using MIS Drills
52. Color Code
54. Drilling Depth
56. Drill Overview
58. Final Drill
60. Countersink Drills
61. Ceramic Drills
62. Drill Maintenance

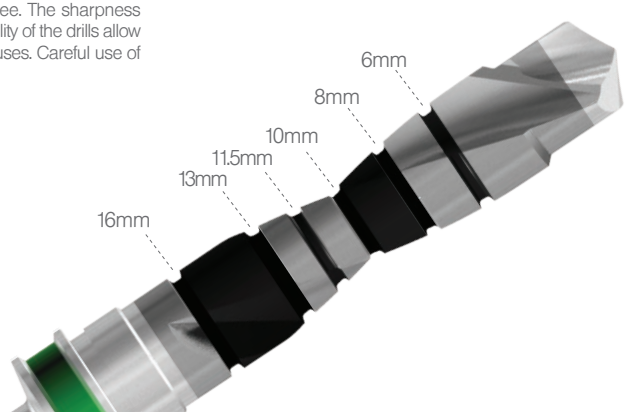
Drills

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. A short step (3mm) at the tip of the C1 drills, features the same diameter as the previous drill in the sequence, allowing preliminarily positioning inside the osteotomy for more accurate drilling.



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 the stoppers required for safe placement of Standard platform implants.

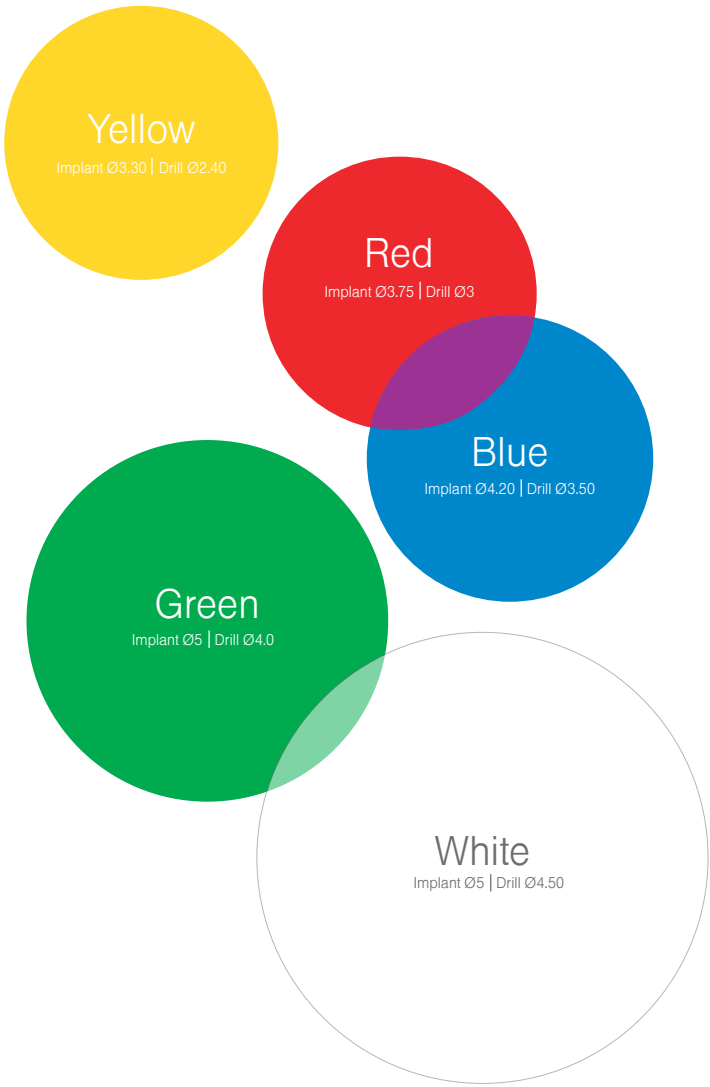
C1 Drill Stoppers Kit

C1 Drill Stoppers Kit
Standard Platform (MK-BC101)

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

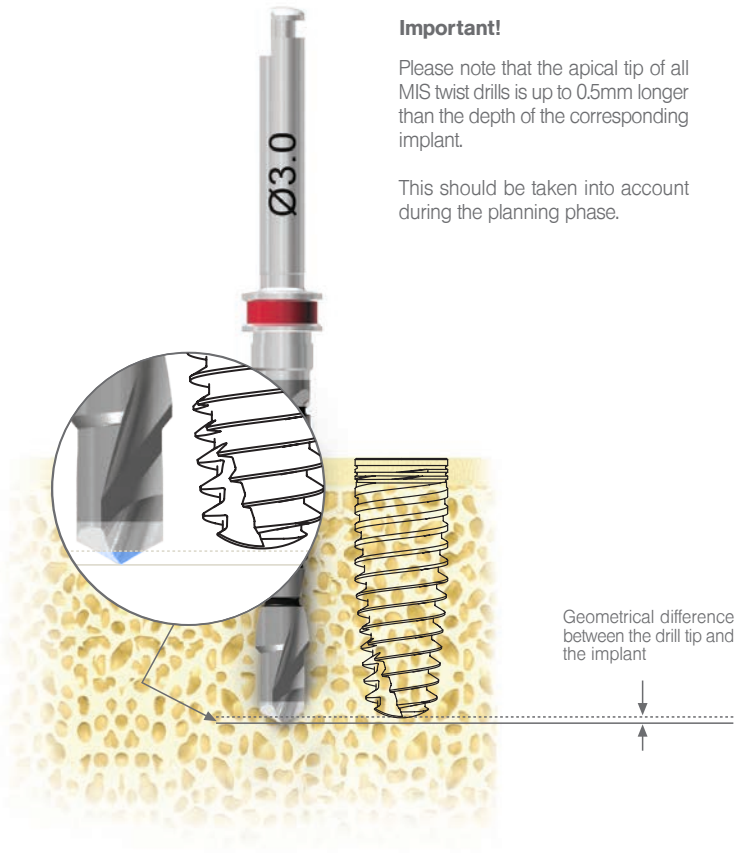
Drills
Color Code

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



Drills

Drilling Depth



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.

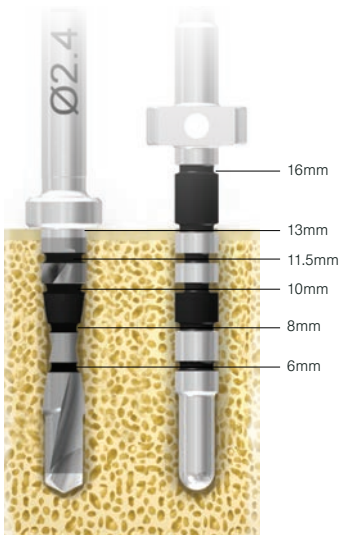
Depth Verification

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

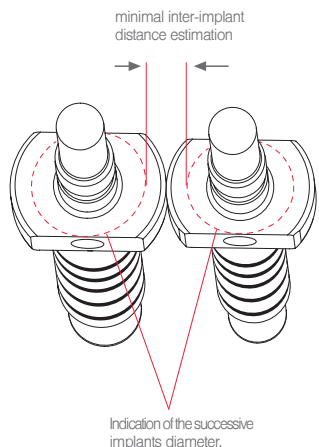
Evaluation of the Successive Implant Diameter

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)



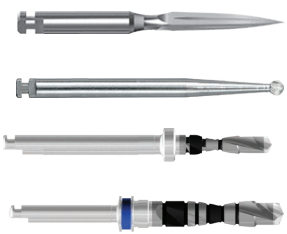
(pic.1)



(pic.2)

Drills

Drills Overview

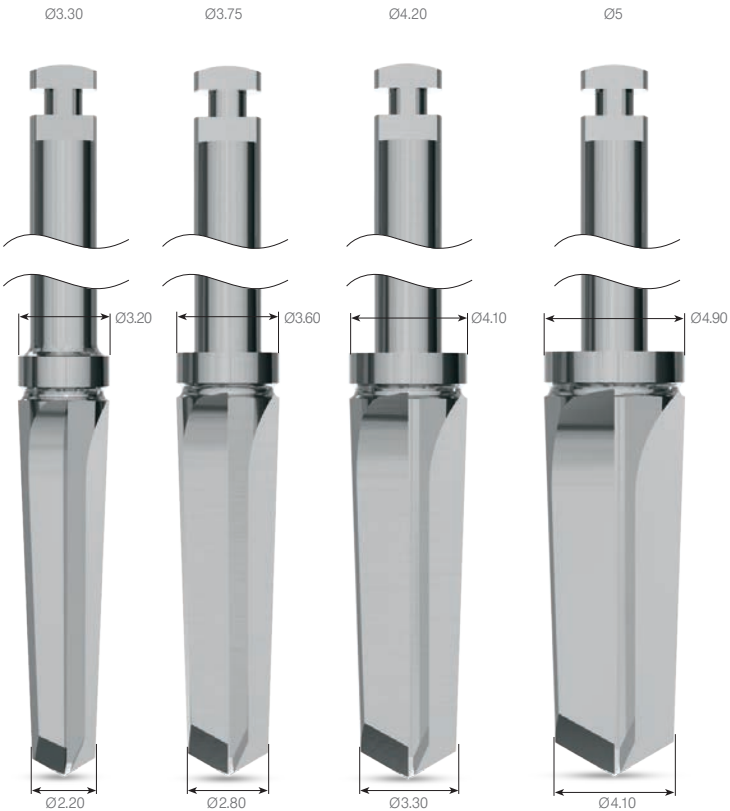


	Recommended Speed
Spade Drill	1200-1500 RPM
Marking Drill	1200-1500 RPM
Pilot Drill	500-1000 RPM
Step Drill	400-600 RPM

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 location for further drilling.
C1 Pilot Drills come in five different lengths: 8, 10, 11.5, 13 and 16mm and 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.

C1
Final Drill

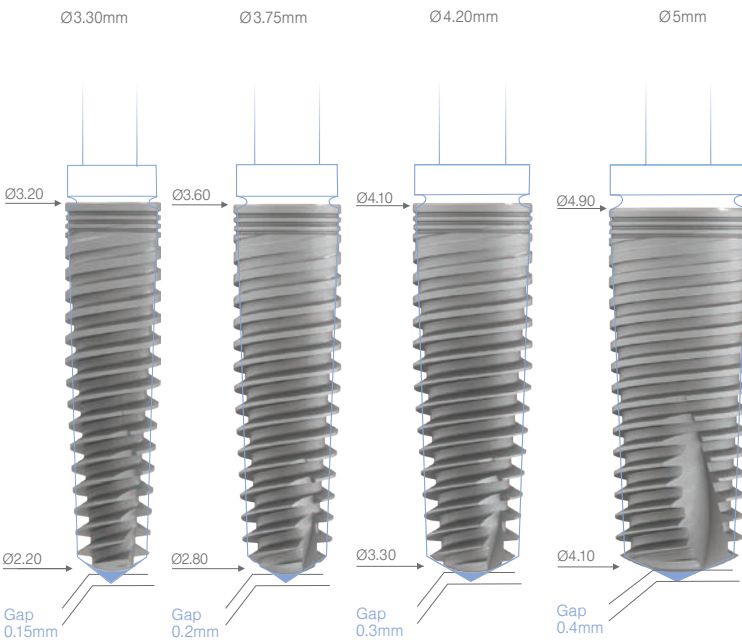
Final Drill for implant diameters



C1

Each C1 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



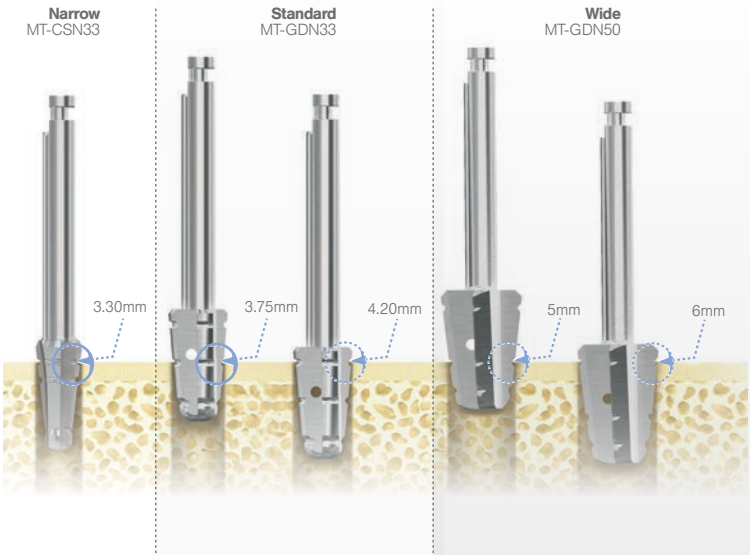
Drills

Countersink Drills

Countersink Drills (MT-CSN33, MT-GDN33, MT-GDN50)

Countersink Drills are used to enlarge the crestal area of the implant site, preventing excessive pressure on the implant neck. Depth marks of 3.30 appear on the Narrow platform Countersink Drill (MT-CSN33), 3.75 and 4.20mm marks appear on the Standard platform Countersink Drill (MT-GDN33), 5 and 6mm marks appear on the Wide platform Countersink Drill (MT-GDN50). The recommended drilling speed is 200-500 RPM.

When drilling into hard bone, extra care should be exercised to prevent overheating. Therefore, it is recommended to use lower drilling speeds with higher torque. In addition, to prevent excessive pressure on the bone or the need for extremely high insertion torque, it is strongly recommended to use the appropriate countersink drills upon completion of the drilling procedure.



Drills

Ceramic Drills

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

MIS Ceramic Drills are made from a high performance mixture of zirconium dioxide (zirconia) and aluminum oxide (alumina) ceramics. The mixture of these two materials provides 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

Drills Maintenance

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

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 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 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-weaved 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 required.

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

12. Steam sterilize according to the table 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, 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.

66. MIS Ratchet Range
68. Specialized Surgical Tools
71. Implant Site Depth Probe
72. Specialized Prosthetic Tools
74. SOS Broken Screw Kit
76. Screw Tests
77. Maintenance

Ratchet

MIS Ratchet Range

MIS offers a line of uniquely designed ratchets, to simplify both prosthetic screw tightening and implant insertion, allowing 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 (35-75 Ncm)

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.

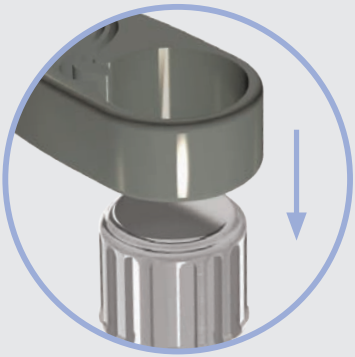
Instrument Maintenance

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

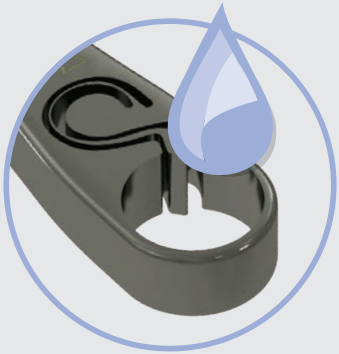
Cleaning and Sterilization

For cleaning and sterilization instructions please refer to page 75.

User Instructions



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



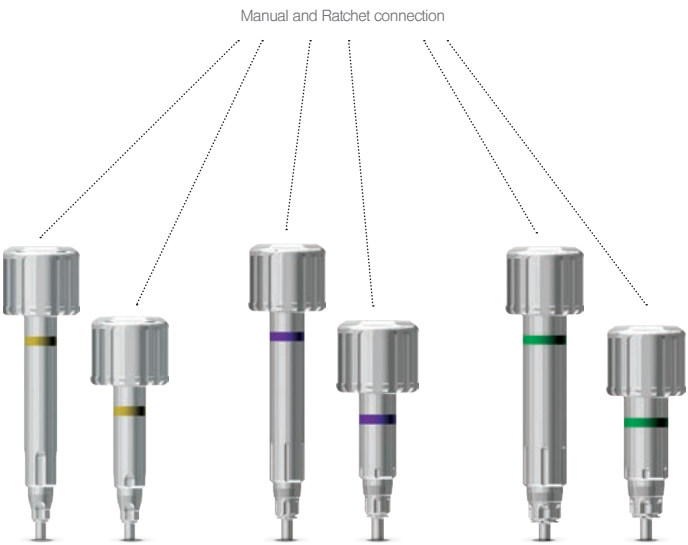
Clean thoroughly immediately after use.

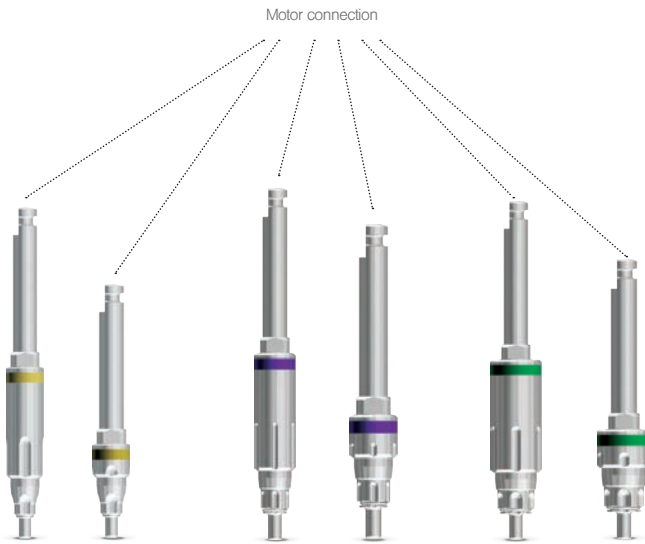
Surgical Tools

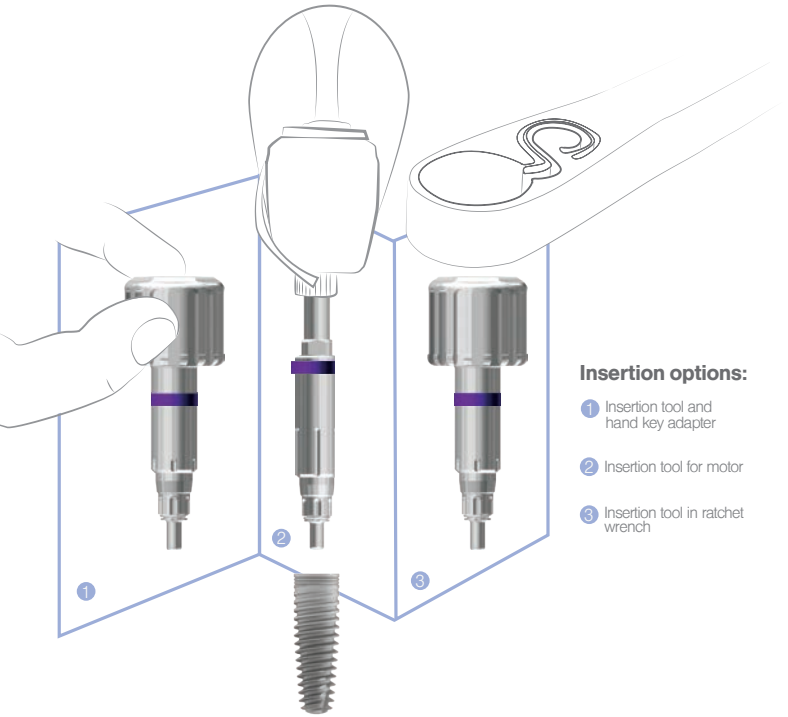
Specialized Surgical Tools

C1 Insertion Tools

C1 implants are divided into Narrow platform implants (3.30mm), Standard platform implants (3.75 and 4.20mm), and Wide platform implants (5mm). Long and short insertion tools are available for each of the C1 platforms.



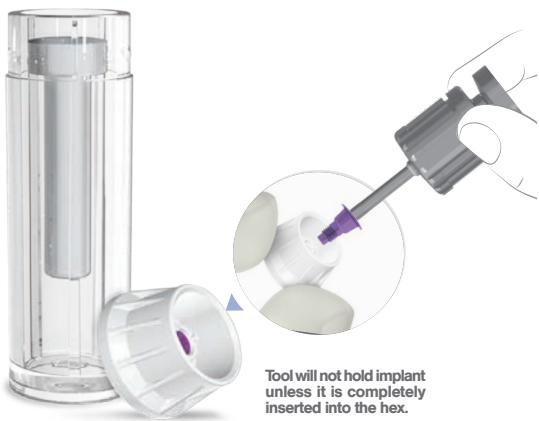

Motor connection



Insertion options:

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

Please note: In order to assure their efficient operation, tools should be fully inserted into the implants. A complete insertion of the tool optimizes the transfer of force during implant placement and enables simple release of the tool from the hex. whenever necessary.

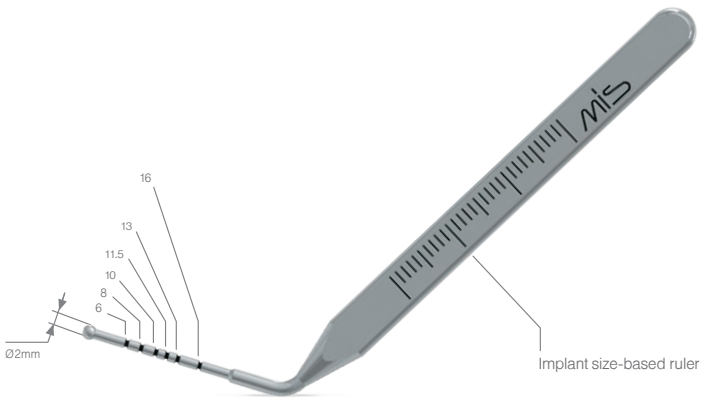


Tool will not hold implant unless it is completely inserted into the hex.

Surgical Tools

Implant Site Depth Probe

Implant Site Depth Probe
MT-BTI20



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: Ø2mm,
Total length: 87mm.

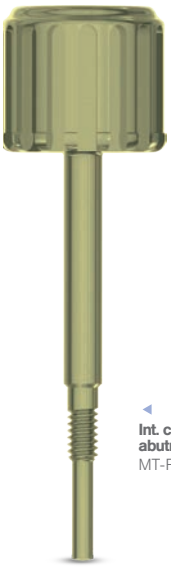
Prosthetic Tools

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 and Wide abutments and yellow for Narrow abutments.

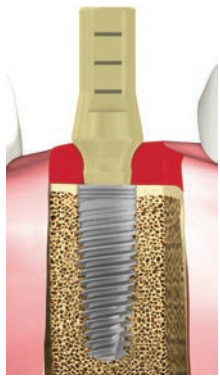
Int. connection abutment extractor
MT-RE172

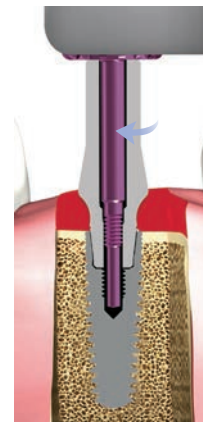


Int. connection abutment extractor, NP
MT-RE160

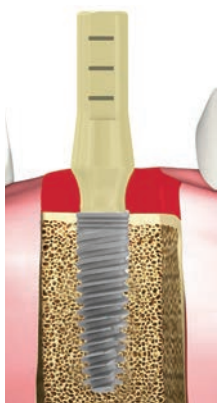
Extractor Key

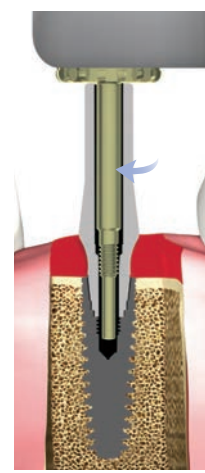
The Extractor Key applies vertical load parallel to the long axis of the implant. Thus, it can release a "locked" abutment from an implant.





For Narrow Implants



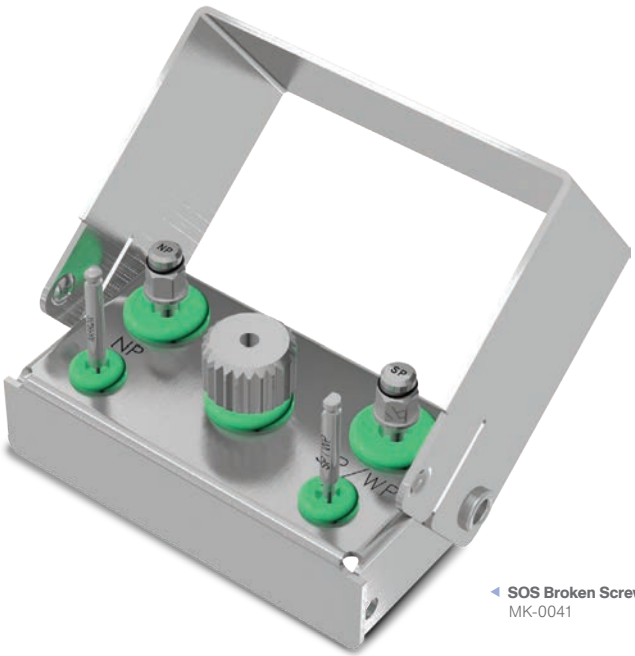


Prosthetic Tools

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

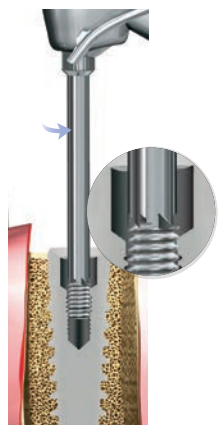
Retriever
MT-RT002

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.

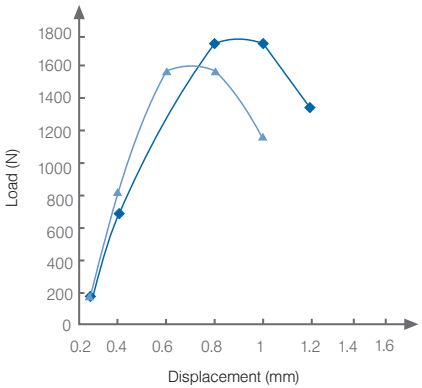
C. Always start by using a hand wrench. Apply gentle but firm force while turning the thread former in a clockwise direction. Release the pressure at the end of each complete turn by turning it 30˚ in a reverse direction, and repeat the action as needed.

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

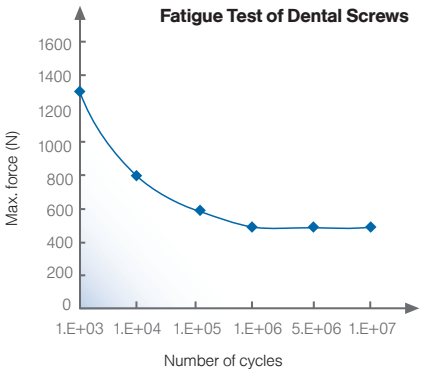
Prosthetic tools

Screw Tests

Tensile Test of Dental Screws



Fatigue Test of Dental Screws



Test conditions:

20 Ti-6Al-4V ELI, M2 type screws.
Loading frequency: 30Hz

i 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

These instructions for use covers surgical devices and accessories, tools & instruments made of stainless steel or titanium alloy (hereby under: "instruments")

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

Pre-Cleaning:

- Disassemble the instruments 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 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-weaved cloth or through a drying cycle of washer-disinfector or with filtered compressed air.
- Inspect the instruments and discard those with defects. Repeat cleaning if required.
- Assemble the instruments if required.
- Place the instruments 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	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 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.


mis®
Pu

Packaging.

80. Implant Package
82. Implant Identification Codes
83. Implant Data Label
84. Implant Package Handling

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 package

The Individual Implant Package

Each C1 package contains: Instruction For Use, an implant, a single-use final drill, a cover screw and a PEEK temporary cylinder. We recommend instructions be read carefully prior to use.

Removing the implant out of the sleeve

10 Implant Package

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

Cover screw

Implant

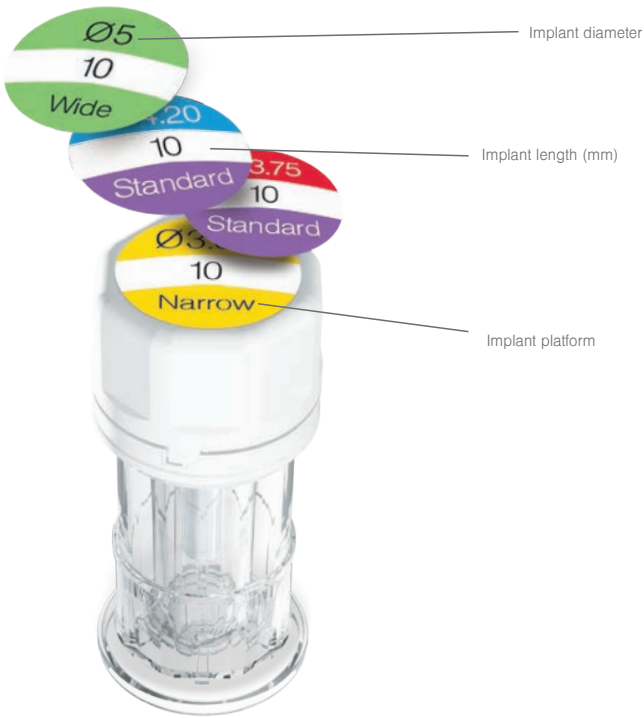
Double Container System

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

Packaging

Implant Identification Codes

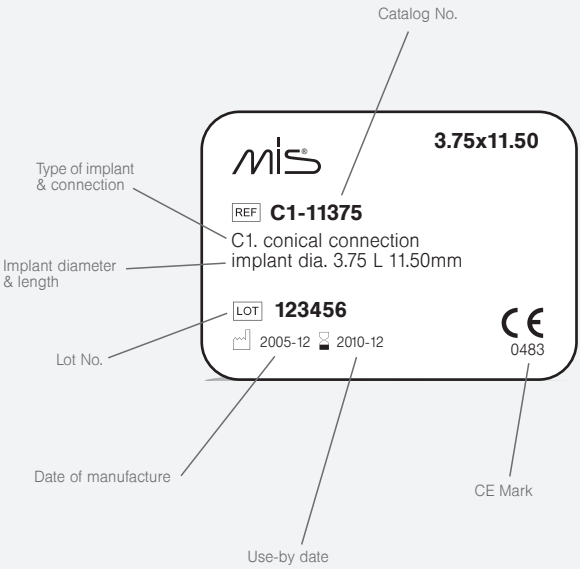
Identification markings on the outer tube cap enable quick identification of implant diameter (top), implant length (center) and implant platform size (bottom).



Packaging

Implant Data Label

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



Packaging

Implant Package Handling

The distinctive blue C1 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, quick opening of the box during surgery.

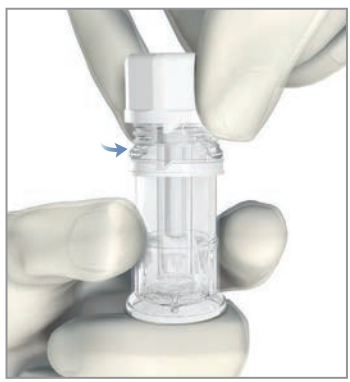


Fig. 2

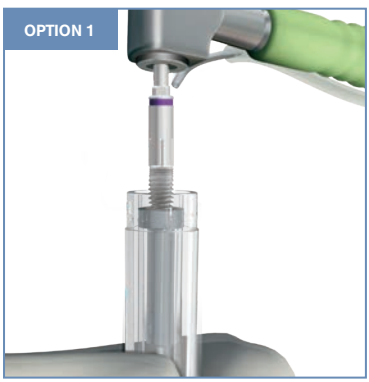
Open the outer tube by turning the cap counter-clockwise. Drop the sterile inner tube into the sterile field.

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. 4B
Hand wrench

Fig. 5

Ratchet

Fig. 6

Implant placement (illustrated using a manual wrench)

Packaging

Implant Package Handling

Fig. 7
Implantation procedure

Fig. 8
Open the bottom of the inner tube. Remove the cover screw using the CT-SLR10 key.

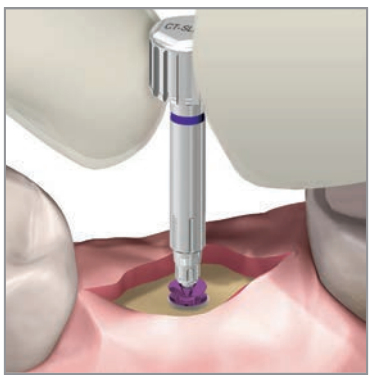


Fig. 9

Attach the cover screw to the implant using the CT-SLR10 key.

Fig. 10

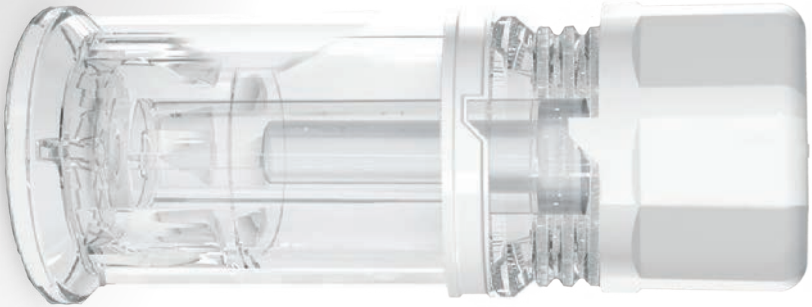
Attach the data label in the implant package on to the dental patient records.

Packaging

Implant Package Handling

Final Drill

Inner Tube



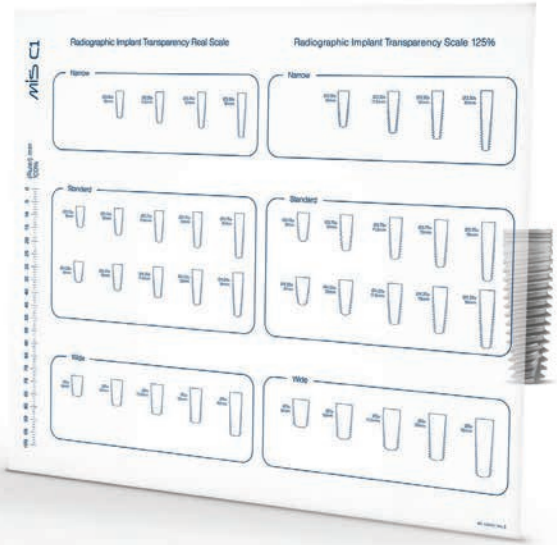
Outer Tube

Planning Transparency

MIS offers a planning transparency, illustrating the full C1 implant range. It includes two sets of images: one 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 can choose the best fitting implant diameter and length, as part of the planning process.

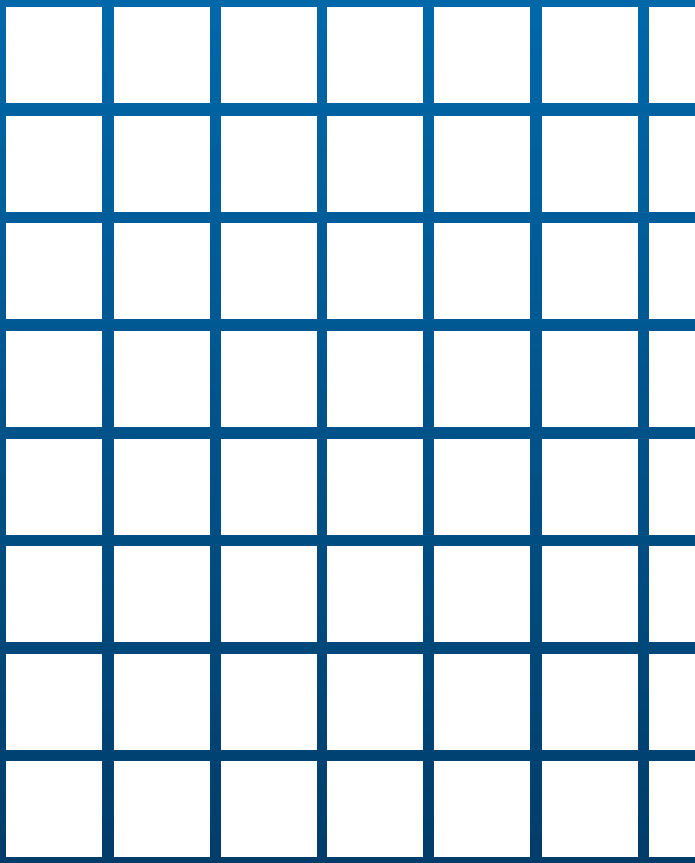
The transparency available for C1 implants is: Cat No. **MC-CONC1**

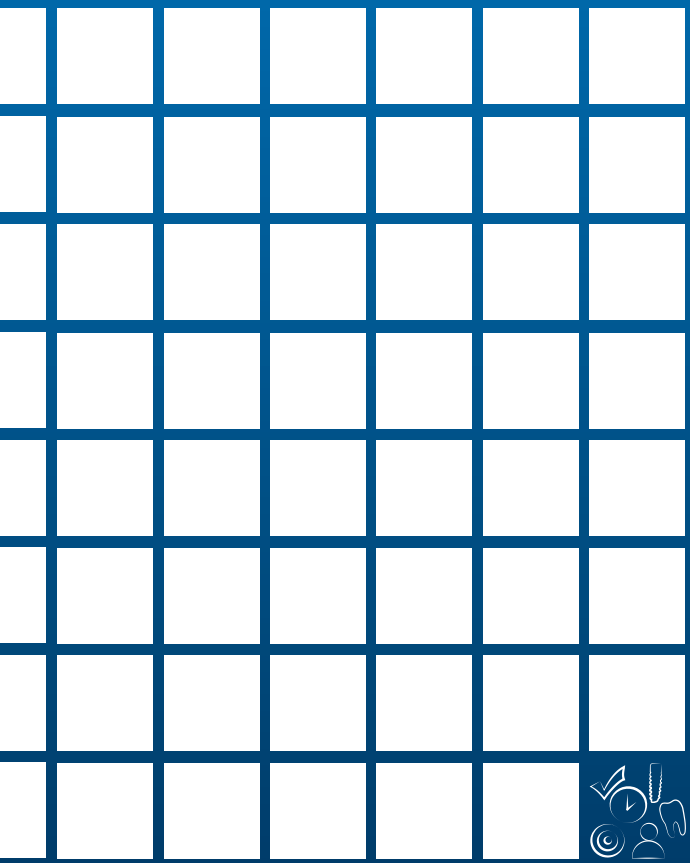


Symbols

Key to codes used:

2	Do not re-use		Date of manufacture
STERILE R	Sterilized using gamma irradiation		Do Not Use if Package is Damaged
2 STERILE	Do Not Resterilize	REF	Catalog number
	Caution, consult accompanying documents		Manufacturer
	Use-by date		Keep away from sunlight
LOT	Batch Code	Rx only	Caution: U.S. federal law restricts this device for sale by or on the order of a dental professional





MP-UMC1S Rev.2 03/2017

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 FDA cleared for marketing in the USA and CE marked.