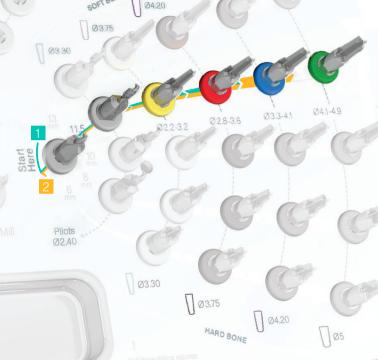


FOR MIS SEVEN IMPLANTS



STEP-BY-STEP GUIDED SURGICAL PROCEDURE



LOGICAL LAYOUT

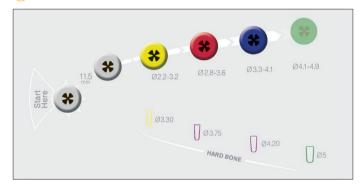
1 Example: Implant Ø4.20 / 11.5L; Soft Bone



Ø4.20 / 11.5L



2 Example: Implant Ø4.20 / 11.5L; Hard Bone



Ø4 20 / 11 5I



PRE-SURGICAL STEPS





VERIFICATION

The package includes:

- · A surgical template
- Documentation; including information specific to each planned implant.

KITS REQUIRED

The kit selection is marked on the MGUIDE box label.

 Prior to surgery: Ensure that surgical template, plan and documentation are all made according to the doctor's specifications, and for the relevant patient.



DISINFECTION

The MGUIDE template is shipped non-sterile. Therefore, the template must undergo disinfection prior to use.

DISINFECTION: Completely immerse in a 0.2% Chlorhexidine solution for 10 minutes at room temperature prior to surgery.

 WARNING! Do not autoclave. Steam sterilization will deform the template.



INITIAL TRY-IN

It is essential to try-in the template in the patient's mouth, prior to surgery. Correct seating and stability of the template must be confirmed, as well as sufficient space for surgical tools.

In order to avoid incorrect seating due to patient's anatomy change. MGUIDE Template should be used within 3 months from CBCT scan date. No changes shall be made to the oral cavity unless discussed with the MCENTER.

In rare cases, minor adjustments may be required.

PRECAUTIONS

GENERAL

- All MGUIDE drills and instruments are for use ONLY with the MGUIDE surgical template.
- Metal sleeves must be firmly attached to the template.
- Inspect all instruments prior to each surgery and replace if broken or dull.
- Ensure cooling of cutting instruments with sterile saline solution.
- Tissue punch is NOT equipped with built-in stoppers.
- The MGUIDE Kit to be used, is marked on the MGUIDE Box label.

HANDLING

- · Hold the template firmly while drilling.
- Drills and tools MUST engage the sleeve before contra-angle is activated.
- Avoid lateral pressure on the instruments, as it may result in a shift in template position, detachment of sleeves from the template or damage to instruments.
- Use an 'in-out' motion while drilling, slowly inserting the drill until the built-in stopper touches the sleeve.
- Do not over-tighten implant insertion tools and fixation pins. This may result in a shift in template position or damage to the template.





 $\label{eq:decomposition} \mbox{Drills and tools MUST engage the sleeve before contra-angle is activated.}$

(When applicable





MG-DFP20

MGUIDE drill for fixation pin, Ø2mm



MG-FP020

MGUIDE fixation pin, Ø2mm

FIXATION PINS

MGUIDE fixation pins are recommended for use in fully edentulous cases or if template stability cannot be guaranteed.

[•] Fixation pins may ONLY be used when included in the MGUIDE surgical plan and when pin location is guided by the template.

Template MUST be verified in position, and held firmly prior to drilling.

Use the MG-DFP20 drill ONLY! Drill until stopper touches the sleeve.

TISSUE PUNCH



TISSUE PUNCH

The tissue punch creates a round cut beneath the sleeve. This marks the implant position.





TISSUE REMOVAL

Remove the template, then manually remove punched gingiva.

Leave at least 2mm of attached gingiva around each implant site.
Tissue punch tools DO NOT have built-in stoppers.

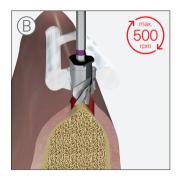
BONE MILL

(When applicable



BONE MILL

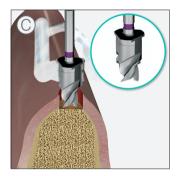
The bone mill is designed to flatten the alveolar ridge, when necessary, prior to drilling.



BONE MILL USE

A flat surface allows for a better approach for the starter drill, therefore increasing the accuracy for the rest of the drilling sequence.

[•] Use of a bone mill should be part of the planning stage.



BONE MILL STOPPER

A built-in stopper is used for depth control. Bone mill drills have a built-in stopper.

BONE ANCHOR OSTEOTOMY

(Å)

(When annlicable



STARTER DRILL

Anchor screws are used to vertically secure the template into an osteotomy created by the starter drill MG-D0624.



ANCHORING

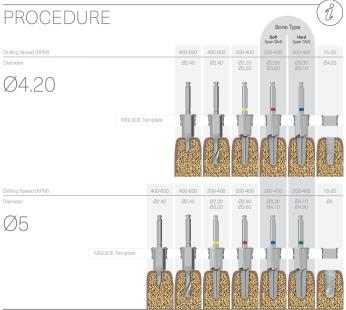
Anchor screws should be placed manually. If necessary, secure screws using a ratchet until stopper touches the sleeve.

Ø5.5mm sleeve	Ø4mm sleeve
MG-TAS55	MG-NTAS0

Do not over-tighten screws, as this may cause damage to the template.



- Do not use the last drill for bone types 3 or 4.
- The drilling sequence is demonstrated by a 11.5mm SEVEN implant.
- Procedure recommended by MIS cannot replace the judgment and professional experience of the surgeon.



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DIRECT RATCHET INSERTION TOOL

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(M/hen annlicable



IMPLANT INSERTION

The direct insertion tool should be attached to the implant manually prior to implant placement. It should remain connected to the implant plat the implant placement procedure has been completed, and then removed manually.



STABILIZE THE MGUIDE

The direct insertion tool may be used to stabilize the MGUIDE.

This option is valid only if the implant has significant primary stability.

Do not over-tighten the direct insertion tool, as this may cause damage to the template.

IMPLANT INSERTION OPTIONS



BY MOTOR

Recommended for initial implant placement.

Ø5.5mm sleeve	Ø4mm sleeve
MG-GMI10	MG-NMN10
	MG-NMS10
	IVIG-IVIVISTU



BY RATCHET

Orientation adjustment may be achieved only after template removal.

Ø5.5mm sleeve	Ø4mm sleeve
MG-GRI10	MG-NRN10
	MG-NRS10



BY RATCHET - DIRECT

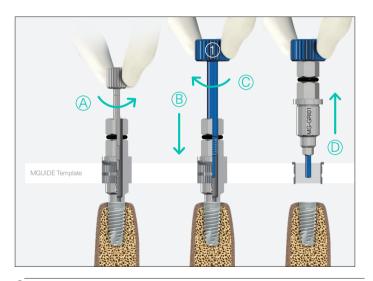
In cases where additional stability is required for the template.

Ø5.5mm sleeve	Ø4mm sleeve
MG-GRI01	MG-NRN01
MG-GRN01	MG-NRS01



The guided drill length gauge (MG-DLG55), verifies drill length and may be used before, during and after surgery.

Taking measurements: Place drill stopper in contact with the gauge. Measure to the drill tip.



After each use, the ratchet wrench's adapter should be removed and direct insertion tools should be disassembled prior to cleaning. Reassembly prior to sterilization is required.

EXTRACTION PROCEDURE

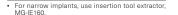
Unscrew pin



Insert extractor tool Turn clockwise to release



Pull up to remove





- · MGUIDE Template should be used within 3 months from CRCT scan date
- For cleaning and sterilization instructions, please refer to the 'Cleaning and Maintenance Instructions for Surgical Instruments' included.

Key to codes used:

Batch code



Manufacturer



Non-sterile



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MGUIDE SET FOR MIS SEVEN IMPLANTS PROCEDURE





MIS MGUIDE

The MIS Quality System complies with international quality standards: ISO 13485:2016 – Quality Management System for Medical Devices, ISO 9001: 2008 – Quality Management System and CE Medical Device Directive 93/42/EEC.