EN Instructions for Use

MIS MGUIDE Surgical Template and Prosthetic Template

DEVICE DESCRIPTION

The MGUIDE surgical template is intended for use in assisting placement of MIS dental implants.

The template is 3D printed and designed with an open-frame for maximum visibility, irrigation and accessibility. Guide sleeves are attached to the template in order to stop the drills at the precise position and depth planned.

The template can be tooth-supported, tissue-supported or a combination thereof.

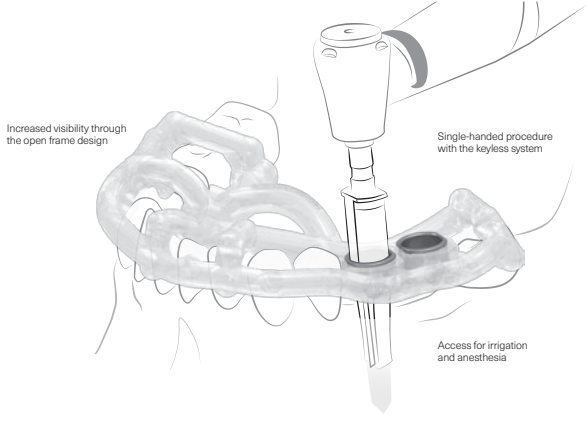
- Fixation pins are used in fully edentulous cases or if additional template stability is required.
- Tissue punch is used to create a round cut beneath the sleeve in order to mark the implant position.
- Bone mill is used to flatten the alveolar ridge, when necessary, prior to the drilling. A flat surface allows for a better approach for the starter drill, therefore increasing the accuracy for the rest of the drilling sequence. Bone mill drills have a built-in stopper for depth control.
- Anchor screws are used to vertically secure the template into the osteotomy created by the starter drill.
- All drills have a built-in stopper for depth control.
- Guided drill length gauge is used to verify drill length and may be used before, during and after surgery.
- Motor, Ratchet or Direct-ratchet insertion tools are used to place the implant through the guide template into the bone.

The MGUIDE prosthetic guide is intended for use in assisting the installation of an immediate screw-retained provisional bridge.

The MGUIDE prosthetic guide is a complementary product that can be ordered in cases where immediate loading is planned to be performed following the guided surgery. It is used as a positioning appliance that holds the provisional bridge in the patient's mouth while the clinician fixes the bridge to temporary abutments. The prosthetic guide is supported by the patient's oral anatomy (teeth, mucosa or a combination of both) and may be stabilized by fixation pins using the same reference points as in the surgical template.

INDICATIONS FOR USE

MIS dental implant systems 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. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.30mm & UNO) 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. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.



INTENDED USE

The MGUIDE surgical template is intended for use in assisting placement of MIS dental implants.

The MGUIDE prosthetic guide is intended for use in assisting the installation of an immediate screw-retained provisional bridge.

CONTRAINDICATIONS

- Patient hypersensitivity to specific components of the used materials.
- All contraindications for implant surgery are also applicable while placing implants by using the MGUIDE surgical guide. Refer to MP-UI101 (MIS Implants User Instructions) for more information.

WARNINGS

- The accuracy of the guided surgery depends on many different factors such as the quality of the CBCT scan, the quality of the impression and the complexity of the surgery.
- Prior to surgery: Ensure that the surgical template and the prosthetic template (if applicable), plan and documentation are all made according to the doctor's specifications, and for the relevant patient.
- It is essential to try-in the surgical 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 surgical and prosthetic templates should be used within 3 months from CBCT scan date. No changes shall be made to the oral cavity unless discussed with the MCENTER.
- MGUIDE surgical and prosthetic templates are designed for individual patient and for single-use only. Reuse could lead to the risk of infection and complications due to a loss of accuracy of fit and the precision of the components. This may lead to implant failure.
- MGUIDE surgical and prosthetic templates should not be modified as it can lead to incorrect seating of the guide.
- The surgical and prosthetic templates must undergo disinfection prior to use, otherwise they may lead to infection of tissues or infectious diseases.
- Do not autoclave. Steam sterilization might deform the template.
- MR safety information: MIS Dental implant systems have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of MIS Dental implant systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Inform us and your competent authority in the case of notice of life threatening incidents or a severe deterioration in health status related to one of our products.

CAUTIONS

- Inappropriate implant angulations and/or hard tissue or soft tissue deficits may cause a compromised esthetic result.
- To secure a successful long term treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene. Long term implant health is directly related to the maintenance of oral hygiene.
- Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of bone, soft tissue or osseointegration process (e.g. cigarettes smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the adjacent tooth)
- Due to the small size of the devices, care must be taken that they are not swallowed or inhaled by the patient.
- All cautions for implant surgery are also applicable while placing implants using the MGUIDE surgical guide. Refer to MP-UI101 (MIS Implants User Instructions) for more information.
- The MGUIDE surgical template is for use ONLY with MGUIDE drills and instruments.
- The MGUIDE prosthetic template is intended for use ONLY with MGUIDE fixation pins.
- 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.
- 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, fixation pins and anchoring screws. This may result in a shift in template position or damage to the template.
- Fixation pins may ONLY be used when included in the MGUIDE surgical plan and when pin location is guided by the surgical template. Template MUST be verified in position, and held firmly prior to drilling. Use the fixation pin drill ONLY and drill until stopper touches the sleeve.
- When using tissue punch tools, leave at least 2mm of attached gingiva around each implant site.
- Use of a bone mill should be part of the planning stage.
- Use the direct ratchet insertion tool only if the implant has significant primary stability.

MATERIALS

MGUIDE template	Acrylic resin
Guide sleeves	Titanium alloy (90% Ti, 6% Al, 4% V)

KEY TO CODES USED

MD — Medical device

For instructions for use and symbols glossary refer to: http://ifu.mis-implants.com

NON STERILE — Non-sterile

2 — Do not reuse

LOT — Batch code

REF — Catalog number

Manufacturer

Importer

Use by date

Keep away from sunlight

Keep dry

SN — Serial number

Patient number

Caution, consult accompanying documents

℞ only — Caution: U.S. federal law restricts this device for sale by or on the order of a dental professional.

MGUIDE is a custom-made device

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DISINFECTION INSTRUCTIONS

- The MGUIDE template is shipped non-sterile.
- Therefore, the template must undergo disinfection prior to use.
- Immerse the MGUIDE template completely, eliminating air pockets, in a high level disinfectant according to the instructions for use, such as CIDEX OPA (ASP) solution for a minimum of 12 minutes at 20°C or higher, to destroy all pathogenic microorganisms.
- Remove the MGUIDE template from the disinfectant solution.
- Rinse it thoroughly with highly purified sterile water as specified in the disinfectant's instructions for use - Rinsing Instructions. Finally, rinse using a 70% alcohol solution.
- Air-dry completely and immediately use or seal in a clean pouch to minimize recontamination.

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

MGUIDE Drills and Tools Cleaning and Sterilization

For cleaning and sterilization instructions, please refer to the 'Cleaning and Maintenance Instructions for Surgical Instruments' included.

STORAGE AND HANDLING

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

DISPOSAL

For disposal of the packaging and components comply with the currently applicable national waste disposal regulations in your country.

PROCEDURE STEPS

MGUIDE Surgical Template

For detailed instructions and images refer to MP-MG003 or MP-MG004, Step by step guided surgical procedure for seven implants/ for conical implants.

1. Verify that the package includes a surgical template and documentation, including information specific to each planned implant. Make sure that the surgical template, plan and documentation are made according to the doctor's specification and for the relevant patient.
2. Check for any special comments or remarks provided by the manufacturer. In case of any uncertainty - contact company representative for clarification.
3. Prepare the required kits for the surgical procedure. The kit selection is marked on the MGUIDE box label.
4. Disinfect the MGUIDE surgical template according to the disinfection section above.
5. Clean and sterilize all drills and tools according to the 'Cleaning and Maintenance Instructions for Surgical Instruments' supplied with them.
6. Try in the template in the patient's mouth and confirm the seating and the stability of the template. Check that the drills fit easily into the guide sleeves. Before use, ensure that all instruments are fully operational.
7. If fixation pins are included in the surgical plan, use the 'MGUIDE drill for fixation pin Ø2mm and drill through the fixation sleeves until the stopper touches the sleeve. Before and during the drilling, carefully verify the fit and stable position of the template and hold it firmly. Max recommended speed is 300 rpm. Mount the fixation pins and hand-tighten into the fixation pin sleeves.
8. When applicable, use the Tissue Punch to mark the implant position. Leave at least 2mm of attached gingiva around each implant site. Max recommended speed is 25 rpm. Remove the template and then manually remove punched gingiva.
9. When applicable, use the bone mill to flatten the alveolar ridge before starting the drilling procedure. Max recommended speed is 500 rpm. Stop the milling once the stopper touches the sleeve.
10. Create the osteotomy by using the starter drill. Max recommended speed is 600 rpm.
11. When applicable, place the Anchor screw to vertically secure the template into the osteotomy created by the starter drill. The anchor screws should be placed manually. If necessary, secure the screws using a ratchet until stopper touches the sleeve.
12. Execute the drilling sequence according to the recommended procedure as indicated in the relevant MGUIDE Surgical kit. For more information, refer to the procedure described in 'Step-By-Step Guided Surgical Procedure'.
13. Once the drilling sequence is completed, use the insertion tools to place the implant through the template until the stopper touches the sleeve. Motor insertion tool is recommended for initial implant placement. Orientation adjustment may be achieved by using the ratchet insertion tool after template removal.

Direct-ratchet insertion tool can be used in cases where additional stability is required for the surgical template. This option is valid only in case of significant primary stability. The direct insertion tool should be attached to the implant manually prior to implant placement. It should remain connected to the implant until the implant placement procedure has been completed, and then removed manually.

Insertion tool extractors are available in internal hex MGUIDE tools kit to assist in releasing the direct-ratchet insertion tool from the implant. Unscrew the pin and then insert the extractor. Turn it clockwise until the insertion tool is released and then pull it up.

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.

MGUIDE Prosthetic Template

When using an MGUIDE prosthetic template for immediate loading of a provisional bridge, please perform the following steps before the surgery:

1. Verify that the package includes a prosthetic template and documentation. Make sure that the prosthetic template, plan and documentation are made according to the doctor's specification and for the relevant patient.
2. Check for any special comments or remarks provided by the manufacturer. In case of any uncertainty - contact company representative for clarification.
3. Disinfect the MGUIDE prosthetic template according to the disinfection section above.
4. Attach the provisional bridge to the MGUIDE prosthetic template.

After the implantation procedure is completed and all implants are placed in the patient's mouth:

1. Remove the MGUIDE surgical guide from the patient's mouth.
2. Install the relevant Multi units or Connect abutments, as applicable.
3. Insert the MGUIDE prosthetic template along with the attached provisional bridge to the patient's mouth. If fixation pins are included in the surgical plan, mount the fixation pins and hand-tighten through the fixation pin sleeves. Confirm the seating and the stability of the prosthetic template.
4. Insert the temporary cylinders through the provisional bridge and hand-tighten them to the relevant implants or abutments.
5. Fill the voids between the temporary cylinders and the provisional bridge by applying a flowable composite in the upper third of the access holes.
6. Once the composite is fully set and all cylinders are attached, release the prosthetic screws from the cylinders and remove the prosthetic template with the provisional bridge from the patient's mouth.
7. Use an acrylic resin to fill the remaining voids between the temporary cylinders and the provisional bridge, extra-orally. After the resin is fully set, cut the cylinders to the desired heights below the occlusal plane.
8. Install the provisional bridge in the patient's mouth.