



User Manual
DENTAL IMPLANT SYSTEMS

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1. Medigma Biomedical Products

1.1 Medigma Dental Implant Systems Description:

Medigma Biomedical GmbH designs and manufactures technologically advanced dental implants solutions. Medigma's dental implant system includes Implants, abutments, associated restorative and dental laboratory components, instruments and accessories.

The dental implant systems include the lines listed below:

- ✓ Fix-a-Dent™
- ✓ Mars™
- ✓ FixTite™-S
- ✓ Fix-1™
- ✓ Fix Konisch™
- ✓ Grand Konisch™

1.2 Medigma Dental Implants Intended Use:

Medigma dental implants are intended for surgical placement in the maxillary and/or mandibular arch, to support crowns, bridges, or overdentures, in edentulous or partially edentulous patients. Restorations range from a single tooth restoration to a full mouth restoration. Medigma dental implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

Medigma offers two implants designs, with similar external design but different internal connection: Internal Hex implants: all diameters share one prosthetic platform.

Fix Konisch: with a unique conical hex connection for narrow diameter, standard diameter and wide diameter.

Grand Konisch: with a unified conical star connection for wide range of available implants sizes. Grand Konisch implants external shape design is based on Fix Konisch implants, hence offers all the benefits during and after the implantation procedure.

1.3 Medigma Dental Implants Contraindications:

- Dental implants should not be used in patients who are considered medically unfit for general oral surgical procedures.
- Patients who exhibit underlying factors that might affect the healing process of either the bone or the soft tissue (e.g., connective tissue disorder, steroid treatments, bone infections, cigarette smoking), should carefully evaluate the potential risks and benefits associated with the recommended treatment.
- The use of wrong implant sizes, insufficient amount of implants and/or improper implant positioning for prosthetic rehabilitation, may lead to mechanical failures, such as fatigue fractures in the implants, prosthetic and/or abutment screws.
- Inadequate volume and/or quality of remaining bone or soft tissue, infections and general diseases, may result in compromised esthetic results or unfavorable implant angulation, and cause osseointegration failure, both

immediately after surgery, or after osseointegration is initially achieved.

- Extra precaution should be taken when implanting a narrow platform internal hex implant in the posterior region.
- Implant placement and prosthetic design must accommodate each individual patient's conditions, such as bruxism or unfavorable jaw conditions, in order to reduce the risk of implant overload or fatigue failure.
- Routine treatment is not recommended for under-aged children until growth has stopped and epiphyseal closure has occurred.
- If the above contraindications exist, special accommodations should be considered.

Note: Please refer to appropriate clinical manuals and textbooks for information about treatment planning and medical evaluation.

1.4 Preoperative Considerations and Precautions:

- Prior to any surgical procedure, a comprehensive patient evaluation is necessary in order to determine factors that may put the patient at risk, due to the implantation procedure itself, or factors that may affect the healing process of either the bone and/or the soft tissue.
- Patients must be carefully examined and evaluated to determine proper radiographic, psychological and physical status.
- Patient's teeth and any associated bone or soft tissue deficits that can influence final results should also be evaluated.
- Constant communication and cooperation between the dental surgeon, the restorative dentist and dental laboratory technician is essential to achieve desired success.
- The use of improper techniques in either the implant placement or restoration process can result in implant failure and a substantial loss of surrounding bone.
- Do not reuse implants, cover screws, temporary abutments and abutments. Reusing these items may lead to increased risk for product failure and/or contamination, as functionality cannot be guaranteed.
- Sufficient residual bone volume is necessary in order to achieve high primary and secondary implant stability, for the implant to be able to handle prosthetic rehabilitation. In cases of inadequate bone volume, certain bone augmentation procedures should be considered.

1.5 Intraoperative Considerations and Precautions:

- All efforts must be made to minimize damage to the host tissue, paying special attention to thermal and surgical trauma, and to the elimination of contaminants and sources of infection.

- Implantation surgical procedures require a high degree of precision and care. The limits for acceptable tissue handling are much narrower in implantation than in general oral surgery. Any divergence from the surgical plan during implant placement increases the risk of osseointegration failure.

- It is imperative to pay close attention that tools and instruments are not swallowed or aspirated by the patient.

- After the implant is surgically placed, the surgeon will evaluate the bone quality and the implants initial stability, in order to determine when implant loading is possible.

1.6 Prosthetics Considerations and Precautions:

- Successful prosthetic restorations require proper stress distribution, passive adaptation and fitting of the bridge to the implant abutments, adjusting occlusion to the opposing jaw, and avoiding excessive transverse loading forces (particularly in immediate loading cases).

- Prosthetic metal substructures that are made out of gold-alloy should have a high gold content.

1.7 Implant Packaging:

- Each implant is packaged in a double vial. Product information is printed on a label on the outer package, and includes the lot number, product description, catalog reference number, manufacturing date and expiration date. Make sure to record implant size and lot number in patient's chart.

- Two 'peel-off' labels are included in the package, and can be directly fixed to the chart.

- The outer implant vial cap is color coded for easy identification of the implant platform size. An outer label is added to indicate implant diameter and length.

- Prior to using Medigma dental implants, inspect the package and labeling for integrity. The outer tube cap has a tear-off ring indicating proper closure. If the device is opened, damaged or contaminated in any way, it must not be used.

1.8 Product Sterility and Maintenance:

- All instruments used in surgery must be properly taken care of and maintained in good condition. Failure to do so may cause unwanted damage to the implant and/or other components.

- All implants are provided sterile (by gamma radiation), and are intended for single use only. To ensure sterility, dental implants must be used before the end of the expiration date indicated on the outer package label.

- Never reuse, reclean or resterilize a dental implant. These activities can adversely affect implant materials and alter the surface characteristics, which may result in poor function and implant failure.

- All abutments are supplied non sterile and must be sterilized before use. Steam sterilize the abutments in sterilization pouch, for 4 min at 132°C/270° F.

- Kits are supplied non-sterile. For sterilization use steam sterilization for 4 minutes at 132°C/ 270°F.

1.9 Product Training and Education:

- Proper preoperative planning and dental implant placement require special evaluation and consideration, compared to general dentistry. It is highly recommended that dental practitioners take specific courses with hands-on training in order to learn proper implantation techniques, including biomechanical requirements needed and proper radiographic evaluation.

- We strongly recommend that dental professionals, both beginners and experienced implantologists, always go through special training before undertaking a new treatment method, and consult with an experienced colleague. Medigma offers a wide global network of mentors available for this purpose.

- Surgical and restorative products used to achieve and maintain osseointegration, as described by Prof. Brånemark et al., should be utilized by personnel trained in these methods. Proper training is offered at several education centers. Please contact your local Medigma representative for more information regarding certified training centers.

- Medigma conducts a wide range of implantology courses at various levels. For additional information on courses offered by Medigma, please contact your local Medigma representative.

- This manual and the general Instructions for Use (IFUs) should be carefully read and precisely followed prior to starting treatment, in order to ensure the desired successful outcome.

1.10 General Warnings:

Note: Medigma dental implants have not been evaluated for safety, compatibility, heating or migration in the MR environment.

Note: The following caution text "Federal (USA) law restricts the sale of this device to, or on the order of, a licensed physician or dentist" refers to labels with "Rx Only".

2. Surgical Procedures

2.1 Examination and Treatment Planning:

- Examination and treatment planning should be carried out according to the clinic's routine.
- In many cases, Medigma implants can be placed and stabilized in minimal bone volume, and bone augmentation can be carried out at the same time.

2.2 Bone Quality:

- Ideally, dense compact bone provides good initial stabilization for the implant, while a more porous bone provides less retention, and therefore more bone-to-implant contact is necessary for a sufficient initial stability.

2.3 Vertical Bone Quantity:

- The amount of bone available for implant retention differs from site to site.
- The unique design of the FixTite™-S, Mars™, Fix-a-Dent™, Fix Konisch™, Fix-1™ and Grand Konisch™ implant lines allows excellent anchorage and stabilization in minimal bone volume anywhere along the jaw line.
- The FixTite™-S, Mars™, Fix-a-Dent™, Fix Konisch™, Fix-1™ and Grand Konisch™ implants lines is especially designed to enable angle changes during insertion. In order to change angle, the implant must be inserted parallel to the palatal bone walls allowing the expansion of the palatal aspect of the socket in the facial direction.

2.4 Horizontal Bone Quantity:

- To maintain vertical tissue dimension, make sure to allow at least 1.5mm of bone, lingual and buccal to the implant collar. The special narrowing of the implant collar diameter allows for favorable ridge adaptation, when crestal ridge width is limited.

2.5 Implant Insertion:

- It is possible to start implant insertion manually by using a Fixture Mount or Implant Driver and Surgical Wrench. The maximum tightening torque for implants is 50Ncm.
- Using the Surgical Torque Wrench, the Surgical Driver and a drilling unit can help avoid over-tightening of the implant.

- Implants are ideally installed at a stable and constant rate; however, using excessive insertion torque (greater than 50Ncm) in order to overcome bone resistance, may lead to damage of the implant, fracture or necrosis of the bone site (see appropriate clinical manuals).

Caution: Over-tightening may compromise the integrity of the internal hex connection, and over-compress the surrounding bone, which will compromise osseointegration.

• Implant Full Seating

The unique thread design of the FixTite™-S, Mars™, Fix-a-Dent™, Fix-1™, Fix Konisch™ and Grand Konisch™ implants allows the implant to be repositioned during insertion.

Note: Due to this desired feature, the implant might not necessarily stop at the bottom of the prepared site, and surgeons must pay close attention during implant insertion.

• Implant Insertion Speed

The thread pitch design of the FixTite™-S, Mars™, Fix-a-Dent™, Fix Konisch™, Fix-1™ and Grand Konisch™ implants allows the implant to be inserted up to four times faster compared to other implants. This means that less turns are required to fully position and situate the implant.

• Tilted Implants

Medigma's Implants may be tilted up to 45°. If the angulation is 30° or more, it is necessary to splint the tilted implants.

2.6 The Flapless Technique:

- A flapless technique should be used when sufficient quantity and quality of underlying alveolar bone and soft tissue are available.
- For correct site preparation, measure soft tissue thickness with a probe, and add the tissue thickness to the drilling depth.
- Following thorough preparation of the site, bone and/or connective tissue grafts should be placed.

Note: Caution! Prior to proceeding with a flapless procedure, you must confirm available bone and significant anatomical structures such as blood vessels, nerves, and concavities, with conventional diagnostic tools, such as radiographic imaging, probing and palpation.

3. Drilling Protocol

3.1 Drills Description and Properties

- Medigma's drills are produced from surgical stainless steel and are used with external irrigation.
- Drills are available in two length variations: Short 6-13mmL, and Long 8-18mmL.



3.2 Drills Intended Use:

- Medigma's drills are bone cutting instruments intended for use in reconstructive oral surgery to drill or cut into the upper or lower jaw to prepare the bone to insert an implant.

3.3 Depth Measurement System:

- Each Medigma implant line has unique measuring characteristics, allowing proper implant positioning at desired bone depth.
 - Dental practitioners should review and be thoroughly familiar with the measurement system in the clinical manual associated with the selected implant system, prior to making any drill preparations around vital bone structures, in order to achieve proper safety margins adjacent to any tooth and vital bone structures.
 - All drills and drill components are marked to enable adequate site preparation to the correct desired depth, and obtain a secure and predictable position.
- Note:** The marks on the twist drills indicate actual millimeter lengths, and correspond to the top of the implant collar.
- Final vertical positioning depends on several clinical parameters, such as: esthetics, tissue thickness, available vertical height, flapless procedure.
 - Failure to properly diagnose drill depth recommended by appropriate radiographic measurement tools can result in permanent injuries to nerves and other vital bone structures, by drilling beyond recommended depth. This can potentially lead to permanent numbness of the lower lip and chin, when conducting lower jaw surgery.

3.4 Depth of Drilled Site:

- When drilling in soft bone, the self-drilling feature of the implant allows the implant to be inserted into sites that have been prepared to a reduced depth. This feature becomes very useful in clinical cases that present close proximity to vital anatomical structures. It can also be utilized in softer bone when maximum condensation is desirable.
- When applying the self-drilling feature of the implant, drill to 1-2mm less than the total implant length, insert implant to drilled depth and continue to insert. The implant will drill its way into the final depth.

Note: Caution! If strong resistance (close to 50Ncm) is encountered at any point during insertion, rotate the implant counter-clockwise approximately 1/2 a turn to enable the self-tapping capacity of the implant, then continue to insert the implant. If strong resistance (close to 50Ncm) persists,

remove the implant, place implant back in sterile vial; at this point, sufficient depth of site can be verified with depth gauge or drill, and further widening of the site to either the cortical bone or to full depth can be considered.

- Implant self-drilling should not be attempted in dense bone.
- The drill preparation should be extended up to 1mm longer than the implant length.

Note: This drilling sequence is recommended to ensure optimal primary implant stability, when proceeding with Immediate Loading procedure.

3.5 Step-by-Step Clinical Procedure:

- When drilling, use an "in-and-out" motion, and drill in the bone for 1-2 seconds. Take the drill out without stopping the handpiece motor, allowing the irrigation to flush away debris. Proceed with this method to drill to the desired depth, in accordance with the bone quality and implant diameter. Stop drilling if there is no irrigation.
- All drilling procedures should be performed at low speed (800rpm -2000rpm). Pre-tapping (threading of the bone) and implant placement procedures should be accomplished at very low speed (~ 25-30rpm) or manually. All drilling and pre-tapping procedures require the use of dedicated, sharp instruments, under constant and profuse irrigation for cooling.
- Parallel Implant Positioning
 - * Parallel Pin is used during surgeries to indicate implant position and angulation, and to make implant placements as parallel as possible. A parallel pin should be used to check the drilling angle.
 - * When inserting multiple implants, proceed to the next implant site before continuing to the next drill sequence section. Place a parallel pin in each hole before proceeding to the next site. Align the next drill in the sequence parallel to the previous pin when available bone permits.
 - * If applicable, radiographic evaluation of the implant sites should be used, for precise surgical implant placement.

Note: Caution! The drill preparation should extend up to 1mm longer than the implant. It is important to allow for this additional length when drilling near vital anatomical structures.

- Twist Drill:

Drill to the appropriate desired depth using the Twist Drill (Drill Stops can be used).

- Pilot Drill:

* Max 2000 rpm, High Speed.

* A Tip Drill can be used before the Pilot Drill in order to facilitate initial site penetration and the creation of a crestal start point.

- Twist Drill 2.8mm:

* Max 2000 rpm, High Speed.

- Continue the site preparation procedure using Twist Drills according to the drilling protocol table below:

	SOFT BONE (TYPE D-IV)	BONE TYPE D-II-III	HARD BONE (TYPE D-I)
3.0mmD	1. 2.0	1. 2.0 2. (2.8)	1. 2.0 2. 2.8
3.3mmD	Fix-a-Dent™ implants: 1. 2.0 2. (2.8)	Fix-a-Dent™ implants: 1. 2.0 2. (2.8) 3. (3.2)	Fix-a-Dent™ implants: 1. Three Step*
	Fix-1™ implants: 2. 2.0	Fix-1™ implants: 1. 2.0 2. (2.8)	Fix-1™ implants: 1. 2.0 2. 2.8
3.5D/ 3.6mmD	1. Three-Step*	1. Three-Step* 2. (3.2)	1. Three-Step* 2. (3.2)
3.75mmD	1. Three-Step*	1. Three-Step* 2. (3.2)	1. Three-Step* 2. 3.2
4.2mmD/ 4.3mmD	FixTite™-S, Mars™, Fix Konisch™, Fix-1™ and Grand Konisch™ implants: 1. Three Step* 2. (3.6)	1. Three-Step* 2. (3.6)	1. Three-Step* 2. 3.6 3. (3.9)
	Fix-a-Dent™ implants: 1. Three Step* 2. 3.2		
5.0mmD	1. Three Step* 2. 3.6 3. 3.9 4. 4.2	1. Three Step* 2. 3.6 3. 3.9 4. 4.2 5. (4.6)	1. Three Step* 2. 3.6 3. 3.9 4. 4.2 5. 4.6
6.0mmD	FixTite™-S, Mars™, Grand Konisch™ implants: 1. Three Step* 2. 3.6 3. 3.9 4. 4.2 5. (5.2)	FixTite™-S, Mars™ and Grand Konisch™ implants: 1. Three Step* 2. 3.6 3. 3.9 4. 4.2 5. 5.2 6. (5.6)	FixTite™-S, Mars™ and Grand Konisch™ implants: 1. Three Step* 2. 3.6 3. 3.9 4. 4.2 5. 5.2 6. 5.6
	Fix-a-Dent™ implants: 1. Three Step* 2. 3.6 3. 4.2 4. 4.6 5. (5.2)	Fix-a-Dent™ implants: 1. Three Step* 2. 3.6 3. 4.2 4. 4.6 5. 5.2 6. (5.6)	Fix-a-Dent implants: 1. Three Step* 2. 3.6 3. 4.2 4. 4.6 5. 5.2 6. 5.6

Note: (x.x) drill to the depth of the cortex only. All measurements are in mm.

CAUTION: The drill preparation is up to 1mm longer than the implants.

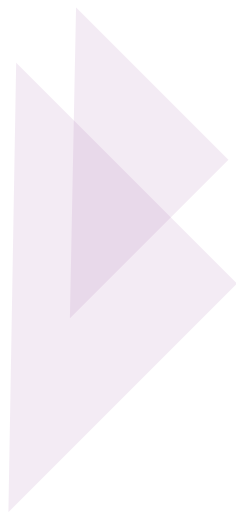
*** For initial drilling, you may use 2, 2.8 and 3.2 drills in sequence instead of the Three-Step drill.**

3.6 Drills Cautions and Warnings:

- Medigma dental drills should only be used by a licensed practicing dentist who has the specialization, skills and appropriate training in implantation and restoration of dental implants, in order to assure a successful treatment and outcome.
- Inspect drills for any kind of damage and/or any wear and tear that might have occurred, before each use. Discard defective drills.
- Ensure that the drill is completely in place and gripped within the handpiece collet before use.
- Maintain the handpiece in excellent working condition and properly lubricated.

- Do not exceed the maximum speeds indicated in this user manual.
- Avoid any excessive drilling speed and/or drilling duration, in order to avoid overheating and any complications associated with overheating.
- Make sure to continuously move the drill when in use in order to avoid localized heating.
- Clean and sterilize the drills with accordance to the sterility directions given in the instructions for use, prior to initial use and before each reuse.

Note: Before using Medigma drills, it is recommended to carefully review all indications, contraindications, recommendations, warnings and instructions, and fully comply with them.



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