Instruction for use Titanmagnetics®

K.00.01.EN14/06.23

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Definition of symbols

	Name Address YYYY-MM-DD	Manufacturer in combination with Manufacturing date			Consult instruction for use		Caution, Magnetic field		Caution!
	Do not reuse		Upper limit of temperature		Non-sterile		Do not use if package is damaged		Keep dry
REF	Order number	LOT	Batch code	UDI	Unique Device Identification	HIBC	Health Industry Bar Code	Qty.	Quantity
MD	Medical product	Rx only	Prescription	CE	CE mark	CE 0197	CE mark and identification of the notified body		Distributor
MR	MR Conditional	EC REP	European Representative						

1. Introduction

The instruction for use is part of the medical device. It contains important instructions for safety, use and disposal. Familiarise yourself with all operating and safety instructions before using the product. Only use the product as described and for the specified areas of application. Do not hand over the products to third parties.

1.1 Manufacturer/marketer within the EU

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1.2 Advantages of magnetic anchoring

+ easy and stressless insertion or extraction of prostheses (Gbara 1995), cost effective (Göhring 1997)
+ good implant and tissue supported retention and fit of dentures (Wirz 1994)
+ avoiding of unphysiological load on implants (Jäger/Wirz 1993, 1994, Vesper 1995)
+ easy mouth, implant and denture hygiene (Tiller 1993, 1995)
+ reduced effort for dentists and dental technicians (Stemmann 1995, 1997, Ziesche 1998)

A literature reference list can be ordered from the manufacturer.

1.3 Titanmagnetics®

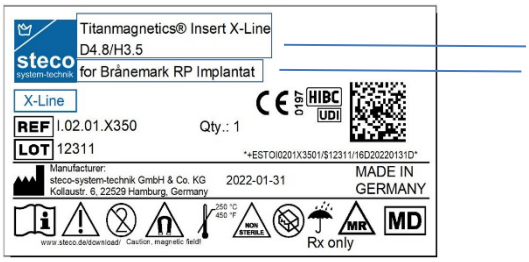
The Titanmagnetics® products are identified by the first letter of the article numbers (I/U/A/M/P/H). The product line is identified by the letter's X/Z/K/T of the article number. These instructions for use apply to the Titanmagnetics® system for oral and extraoral use. The following table shows product examples in the product lines.

	Identification	X-Line	K-Line	Z-Line	T-Line	Indication
Titamagnetics® Inserts						
Insert	I.01… I.02… etc.					Abutment for screwing into an compatible implant - Connection geometry depending on the implant system - Different abutment heights and product lines may be available - For all product lines, different prosthesis magnets with or without retention ring for silicone are offered - For X-Line and Z-Line, prosthesis magnets with collar for additional lateral stabilisation are offered
Titanmagnetics® secondary attachments						
Denture- / Prosthesis magnet	U.00.01… U.00.02…					Counter magnet of the insert, for incorporation into the denture or facial prosthesis (other forms available, e.g. with collar or retention ring).
Titanmagnetics® accessories						
Impression post	A.00.01...- A.00.02….		*			Magnetic impression of Titanmagnetics® inserts * Use the K-Line denture magnet for impression.
Laboratory replica	M.00.01… - M.00.05…					Model manufacturing without using the original implant abutment (Insert)
Positioning cuff	P.00.01… – P.00.03…				**	Protection of the perimplant area during polymerisation of the denture magnet and shaping of the denture base. **For the T-Line, a positioning cuff is not required.
Resilience ring	P.00.05.K1	-		-	-	To maintain the resilience distance to avoid the collision of the two magnets
Torque wrench adapter	H.00… H.08… etc.					Are used in torque wrenches and are intended for screwing in, tightening and/or loosening inserts - Available for various torque wrenches - There are separate torque wrench adapters for each product line - Z- and T-Line have the same magnet head diameter

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1.4 Label

The label of the insert shows the name of the insert and the compatible implant system.
The correct choice of insert for the compatible implant system via the catalog, the system groups or with a Steco employee should have been made before use.
Example:



Insert designation
Compatible implant system

1.5 Materials

Insert, secondary attachment, resilience ring, healing flange, impression post, laboratory replica, torque wrench adapter:
Housing: titanium ASTM F 67 (Grade 4) / Magnetic core: Sm_2Co_{17} (contains Fe and Cu), gastightly welded in titanium / Iron yoke: ST37 (only at T-Line)
Positioning cuff: dental silicone / Laboratory replica: steel 1.4122 (M.00.05.X900)

2. Use of Titanmagnetics®

2.1 Intended Purpose

The intended purpose of Titanmagnetics® is long-term, removable attachment of dental, facial and defect prostheses in and on the human body.

Indications

Geroprosthetics: Anchoring of hybrid and partial dentures on class III- (toothless jaw) and class II- (reduced number of teeth) prostheses (classification following “consensus paper” 12/2008). For class III treatment with removable denture, 6 implants are recommended in the upper jaw and 4 in the lower jaw. Depending on anatomic and prosthetic conditions, a various number of posts can be indicated. Due to the low lateral force on implant even short implants (6 mm) can be used (X-Line and Z-Line only).
Facial prosthetics: Anchoring of facial prostheses and resection prostheses. Please do not use the product for any other purpose.

Contraindications

- Dysfunctions such as bruxism.
- For the K-Line inserts, the implants should be at least 12 mm long.
- T-Line inserts and prostheses magnets with collar are not intended for oral use.
- Incompatibility or allergies to materials used.

2.2 User and environment

Titanmagnetics® should only be used by system-educated dentists, surgeons, dental technicians or anaplastologists and only in medical practices and laboratories. Product knowledge is acquired by studying the instructions for use or personal advice from personnel trained by Steco. The products may only be used in accordance with these instructions for use. The manufacturer accepts no liability for damage due to improper use.

3. Safety instructions

Special precautions have to be made when using magnets.

- Please note the information provided by the implant manufacturer!
- In individual cases, an immediate restoration is only possible with sufficient primary stability of the implant if the implant manufacturer offers the possibility of an immediate restoration and the distribution of the prosthetic retaining elements is suitable to avoid implant overload.
- Depending on the static distribution and type of prosthetic retaining elements, the restoration can only be mucosa-supported or also combined mucosa- and implant-supported (cover denture).
- Close cooperation between the surgeon, prosthodontist, anaplastologist, and dental laboratory is essential for successful implant treatment. It is strongly recommended to only use the Titanmagnetics® system with compatible Steco instruments and prosthetic components.
- The use of instruments and prosthetic components that are not intended for use in combination with the Titanmagnetics® system may lead to mechanical failure of components, tissue damage or unsatisfactory aesthetic results.
- If you are using a new component/treatment method for the first time, you can avoid possible complications by working with colleagues experienced in this field. Steco offers detailed consultation for this purpose.
- The strong magnetic field in MRI (Magnetic Resonance Imaging) diagnoses can destroy the insert and the denture magnet. It is recommended to remove the denture and the insert before MRI inspection. When in MRI environments, a magnetic field strength of (300 mT) must not be exceeded. There is no risk of injury, but there is a risk of weakening or reversing the polarity of the magnets, whereupon they must be exchanged. With aseptic storage, it is possible to rescrew the inserts again on the same patient without processing.
- Keep at least 1 cm distance to magnetic data storages and electronic devices! Cardiac pacemakers are not affected by Titanmagnetics® in regular use, because there is no direct contact (Völkel 1999).
- Loose inserts may lead to thread breakage and / or damage to the implant thread. Patients should immediately see their dentist, so that the inserts can be tightened again. Care has to be taken that the basal side of the prosthesis is funnel shaped around the magnetic head.
- When using the products intraorally, it is generally important to ensure that they cannot be swallowed or aspirated.
- If the titanium casing is damaged (perforation), the affected parts must be replaced immediately. The non-mouth-resistant magnetic alloy (Sm_2Co_{17}) can be released in case of damage and lead to a loss of magnetic force and further destruction of the titanium casing due to corrosion. The titanium shells, which are up to 0.2 mm thin, must never be ground.
- Magnetic cores are resistant to continuous temperatures up to 250 °C/ 450 °F and must not be soldered or lasered in. When soldering, the magnetic force is irreversibly lost due to the high heat. Laser welding can perforate the titanium shell.
- The individual parts are optimally adapted to the different implant systems. Therefore, only use Titanmagnetics® original parts and instruments. The inserts are part of an overall concept and may only be used with the associated Titanmagnetics® original parts and instruments in accordance with the Steco instructions and recommendations. Otherwise, any liability is excluded.
- Observe the torque of 20 Ncm! Too low or too high a torque can have a negative effect on the long-term stability of the connection.

3.1 Traceability

For risk control, damaged parts must be returned to the manufacturer or distributor, stating article and LOT numbers, insertion date, and implant location. Please note the REF and LOT numbers of the inserts and prosthetic magnets in the patient's file and passport! Some Titanmagnetics® products are marked with an UDI code (HIBC) on the label, which contains information about the manufacturer (Steco=ESTO) as well as the product and batch identification.

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3.2 Reporting of serious incidents
It is a legal requirement to report any serious incidents that occur in connection with the product to the manufacturer and/or the competent authority.

3.3 Adverse reactions
When required by the European Medical Devices Regulation (MDR, EU 2017/745), a Summary of Safety and Clinical Performance (SSCP) is available for the inserts. This SSCP is available at the following website: https://ec.europa.eu/tools/eudamed. The website will be available after the launch of the European Medical Devices Database (EUDAMED).

3.4 Special advice to patients
Please note important data such as batch number (LOT) and article number (REF) in the patient file and in the patient passport! Please inform your patients of the safety instructions!

4. Product information

4.1 Magnetic fields
Titanmagnetics® have a magnetic field which is static as the Earth's magnetic field. It is not comparable to the electromagnetic field of a mobile phone or high voltage power lines. The average magnetic field on the surface of Titanmagnetics® is up to 186 mT (X- and K-Line), 300 mT (Z-Line), or 143 mT (T-Line). It is lower than 40 mT (WHO exposure limit) in a distance of 5 mm from the surface. There is no evidence in the current literature that static magnetic fields occurring near the surface with a magnetic flux density of up to 300 mT can be locally damaging in humans. There are no clinical references for the small static magnetic fields of Titanmagnetics® being harmful to humans.

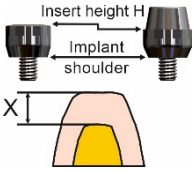
4.2 Technical data
For oral and extraoral use Titanmagnetics® are available in four product lines with different sizes, functional designs and retention forces.

Productline	**X-Line**		**Z-Line**		**K-Line**		**T-Line** (only extraoral)	
Surface	spherical		spherical		conical		telescopic	
Dimension	Height/Length	Diameter	Height/Length	Diameter	Height/Length	Diameter	Height/Length	Diameter
Inserts	div.	4.80 mm	div.	5.80 mm	div.	5.20 mm	div.	5.80 mm
Denture, prosthesis magnet	2.65 mm	4.80 mm	3.15 mm	5.80 mm	5.00 mm	5.20 mm	5.70 mm	5.80 mm
Withdrawal force*	**1.6 N / 163 g**		**3.0 N / 306 g**		**1.6 N / 163 g**		**1.4 N / 143 g**	
Positioning cuff	0.30 mm	15.0 mm	0.40 mm	15.0 mm	0.00 mm	15.0 mm	0.30 mm	15.0 mm
Resilience ring	-----	-----	-----	5.80 mm	6.00 mm	-----	-----	-----
Impression post	6.95 mm	4.80 mm	6.95 mm	5.80 mm	Use denture magnet!		7.50 mm	5.80 mm
Laboratory replica	9.00 mm	4.80 mm	10.00 mm	5.80 mm	7.50 mm	5.20 mm	10.50 mm	5.80 mm
Torque wrench adapter	div.	4.80 mm	div.	5.80 mm	div.	5.20 mm	div.	5.80 mm

*The withdrawal forces were determined according to ISO 13017.

5. Product selection

5.1 Selection of the suitable magnet
1. Perform a mucosal thickness measurement before screwing in
   - The inserts are offered with integrated spacer sleeves in different construction heights. The height specification from the designation of the insert refers to the distance between the implant shoulder and the functional surface (X-Line, Z-Line) or implant shoulder to the base of the cone of the K-Line or base of the telescope of the T-Line.
   - Inserts placed subgingivally should protrude at least 1 mm from the mucosa (H > X).
2. Check the product catalog or the system overviews, for the system group that matches the implant or plate system used (note the implant platform).
3. Decide whether you want to work directly on the implant, or on the plate for extraoral use, or with a base post (if available)
4. Select the appropriate product line according to the available space and the requirements for retention force and lateral guidance.
5. Choose the construction height according to the thickness of the skin over the implant or the plate so that the functional surface of the magnet construction protrudes by about 1 mm and note the construction height of the corresponding counter magnets.



5.2 Selection of the product line
The selection of the product line depends on space limitations, implant axis angle, retention force requirements and indication of implant fixture.

Product line	Application area	Special features
X-Line	oral / extraoral	Due to its flat surface, it is relatively independent of divergences or convergences of the implant axes, but also does not absorb lateral forces.
Z-Line	oral / extraoral	Due to its flat surface, it is relatively independent of divergences or convergences of the implant axes, but also does not absorb lateral forces.
K-Line	oral / extraoral	The 10° cone allows a maximum angle of 15° between two implants. The K-Line is a non-frictional taper that also absorbs lateral forces. For the K-Line, the implants should be at least 12 mm long.
T-Line	extraoral	The T-Line should always be combined with the X-Line or Z-Line. Several T-Line inserts can only be used exactly parallel to each other or if the prosthesis magnets are fixed in a soft prosthesis base.

6. Before use

6.1 Reusability / Durability
Titanmagnetics® Inserts, denture-, prosthesis-, magnets, positioning cuffs, resilience ring, impression posts and labortory replica are single use products only. Reuse is not allowed due to the risk of surface damages caused by mechanical extraction or processing treatment. Torque wrench adapters can be reused for up to 50 times if they are not damaged. Use of damaged or not clean instruments is on the user's own responsibility. Cleaning and sterilisation advices are available at www.steco.de/en. In compliance with the warnings, we guarantee at least 5 years against abrasion (perforation).

6.2 Instructions for sterilisation and disinfection/ processing instructions
This processing instruction applies to all Titanmagnetics® torque wrench adapters (H...) and to the one-time processing of Titanmagnetics® Inserts (I....) and positioning cuffs (P.00…).

General principles

All instruments must be cleaned, disinfected and sterilised prior to each use; this applies in particular to the first use following delivery because all instruments are delivered unsterile (Cleaning and disinfection following removal of the protective transport packaging; Sterilisation after packaging). Effective cleaning and disinfection are an essential prerequisite for effective sterilisation.

As part of your responsibility for the sterility of the instruments during use, please note that:
- in principle only adequate device and product-specific validated methods are used for the cleaning/disinfection and sterilisation,
- the used devices (washer-disinfector, steriliser) are regularly maintained and checked, and
- the validated parameters must be complied with during each cycle.

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Please also comply with the current legislation in your country as well as the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different specifications regarding effective inactivation of prions.
Attention: For the respective instruments, additional or deviating specifications must be observed (see chapter "Special instructions").

Cleaning and disinfection

Basic principles

If possible, an automated method (washer-disinfector) should be used for the cleaning and disinfection. A manual method - also when using an ultrasound bath - should only be used if an automated method is not available, due to the markedly reduced effectiveness and reproducibility of a manual method.
The pre-treatment should be carried out in both cases.

Pre-treatment

Procedure:

1. If applicable (see chapter "Special instructions"):
   Disassemble the instruments as far as is possible.
2. Rinse the disassembled instruments under running water for at least 1 min (temperature < 35°C/95°F).
   If applicable (see chapter "Special instructions"):
   Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments five times using a disposable syringe (minimum volume 1 ml).
3. Place the instruments in the pre-cleaning bath[1] for the specified exposure time in such a way that the implants are sufficiently covered. Make sure that the instruments are not touching. Aid the pre-cleaning by carefully brushing all internal (conical interdental brush) and external surfaces (at the start of the exposure time), at least 1 min each, for aids see chapter "Special instructions").
   If applicable (see chapter "Special instructions"):
   Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml) at the start and at the end of the exposure time.
4. Then remove the instruments from the pre-cleaning bath and rinse them thoroughly at least five times (for at least 1 min) with water.
   If applicable (see chapter "Special instructions"):
   Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least three times using a disposable syringe (minimum volume 1 ml) at the start and at the end of the exposure time.

When selecting the cleaning agent[1] to be used, it should be ensured that:

- it is generally suitable for the cleaning of metal and plastic instruments,
- the cleaning agent is compatible with the instruments (see section "Material durability").

The concentrations, temperatures, exposure times and rinsing guidelines specified by the manufacturer of the cleaning agent or the cleaning agent and disinfectant must be strictly observed. Only use freshly prepared solutions and water that is sterile or of low microbiological contamination (max. 10 microbes/ml) as well as low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/ highly purified water), and only use a soft, clean, lint free cloth and/or filtered air for drying.

[1] If for example, for health and safety reasons a combined cleaning agent and disinfectant is used, please consider that it should be aldehyde-free (as aldehyde fixes blood stains), and should be proven to be effective (e.g. VAH/DGHM or FDA/EPA approval/ clearance/ registration).

Please note that the disinfectant that may be used for pre-treatment serves only to protect the personnel and cannot replace the disinfection step to be carried out later, after cleaning.

Automated cleaning/disinfection (washer-disinfector)

When selecting the washer-disinfector, it should be ensured that:

- the washer-disinfector corresponds in principle to DIN EN ISO/ANSI AAMI ST15883 and that it has proven effectiveness (e.g. DGHM or FDA approval/ clearance/ registration or CE marking pursuant to DIN EN ISO/ANSI AAMI 15883),
- if possible, a verified programme for thermal disinfection (A_0 value ≥ 3000, alternatively for older devices at least 5 mins at 90 °C) is used (alternatively, if chemical disinfection is performed, the risk of disinfectant residue on the instruments should be taken into consideration),
- the used programme is suitable for the instruments and includes sufficient rinse cycles, (at least three depleting steps after cleaning (or neutralisation, if applied) (or neutralisation, if applied) or conductivity control recommended to effectively prevent detergent residues)
- only water that is sterile or of low microbiological contamination (max. 10 microbes/ml) as well as low in endotoxins (max. 0.25 endotoxin units/ml) is used for the rinsing (e.g. purified water/ highly purified water),
- the air used for drying is filtered and
- the washer-disinfector is regularly maintained and checked.

When selecting the cleaning agent system to be used, it should be ensured that:

- it is generally suitable for the cleaning of metal and plastic instruments,
- a suitable disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA approval/clearance/registration or CE marking) is additionally used (provided that there is no thermal disinfection) and that this is compatible with the used cleaning agent, that the programme used contains a sufficient number of rinsing cycles (at least two depleting steps after disinfection or conductivity control are recommended to effectively prevent residues of the disinfectant) and
- the chemicals used are compatible with the instruments (see section "Material durability").

The concentrations specified by the manufacturer of the cleaning agent, and if applicable the disinfectant, must be strictly observed.

Procedure:

1. If applicable (see chapter "Special instructions"): Disassemble the torque wrench adapters as much as possible
2. Place the instruments - using a close-meshed tray (small parts basket) - in the washer-disinfector. Ensure that the instruments are not touching and that a position is selected in which the spray jets of the washer-disinfector are not obscured.
3. Start the programme.
4. Remove the instruments from the washer-disinfector after the programme sequence.
5. Check and package the instruments as soon as possible after they are removed (see section "Checks", "Maintenance" and "Packaging", if applicable after additional drying in a clean location).

Verification of the general suitability of the instruments for effective automated cleaning and disinfection was provided by an independent, accredited testing laboratory using the G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the pre-cleaning agent and cleaning agent neodisher MediZym (Dr. Weigert GmbH & Co. KG, Hamburg). Worst case settings have been considered in relation to the procedure described above as well as to the concentration specified in the detergent instructions for use (considering the detergent manufacturer's specifications according to Note 1 in Chapter 6.6.2.2 of ISO 17664-1: 2021 as given above).

Manual cleaning and disinfection

When selecting the cleaning agent and disinfectant to be used, it should be ensured that:

- they are generally suitable for the cleaning and disinfection of instruments made out of metals and plastics,
- the cleaning agent - if applicable - is suitable for ultrasonic cleaning (no foam formation),
- a suitable disinfectant with proven effectiveness is used (e.g. VAH/DGHM or FDA approval/clearance/registration or CE marking) and that this is compatible with the used cleaning agent and
- the chemicals used are compatible with the instruments (see section "Material durability").

If possible, combined cleaning agents/disinfectants should not be used. Only in cases of very low levels of contamination (no visible soiling) can combined cleaning agents/disinfectants be used.
The concentrations, exposure times and rinsing guidelines specified by the manufacturer of the cleaning agent and disinfectant must be strictly observed. Only use freshly prepared solutions, water that is sterile or of low microbiological contamination (max. 10 microbes/ml) as well as low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/ highly purified water), and only use filtered air for drying.

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Manual cleaning

1. If applicable (see chapter "Special instructions"): Disassemble the instruments as much as possible
2. Place the instruments in the cleaning bath for the specified exposure time so that the instruments are completely covered by the liquid, careful brushing of the bores and the outer surface (at the beginning of the exposure time, at least 1 min each time, for aids see chapter "Special instructions").
3. Ensure that the instruments are not touching and that there are no air bubbles in the cavities.
4. If applicable (see chapter "Special instructions"):
   Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml) and a disposable cannula at the start and at the end of the exposure time.
5. Remove the instruments from the cleaning bath and rinse them thoroughly with water for 1 min at least three times.
6. If applicable (see chapter "Special instructions"):
   Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml).
7. Check the instruments (see section “Checks” and “Maintenance”).

Manual disinfection

1. Place the disassembled, cleaned and checked instruments into the disinfection bath for the specified exposure time in such a way that the instruments are completely covered by the liquid.
2. Ensure that the instruments are not touching and that there are no air bubbles in the cavities.
3. If applicable (see chapter "Special instructions"):
   Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml) at the start and at the end of the exposure time.
4. Remove the instruments from the disinfection bath and rinse them thoroughly with water for 1 min at least three times.
5. If applicable (see chapter "Special instructions"):
   Rinse of the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml) and a disposable cannula.
6. Dry the instruments by blowing off/ blowing out with filtered compressed air.
7. Package the torque wrench adapters as soon as possible after they are removed (see section “Packaging”, after additional drying in a clean location if necessary).

Verification of the general suitability of the instruments for effective manual cleaning and disinfection was provided by an independent, accredited testing laboratory using the pre-cleaning agent and cleaning agent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). Worst case settings were considered in relation to the procedure described above as well as to the instructions for use of the detergent and disinfectant.

Checks

Following the cleaning or cleaning/disinfection, check all of the instruments for corrosion, damaged surfaces, splintering and soiling (in particular on the wrench flats) and discard damaged instruments (for the limit on the number of reuses see section “Reusability”). Any instruments that are still dirty must be cleaned and disinfected again.
If applicable (see chapter "Special instructions"):
Pay particular attention to the O-rings on an intact surface. None of the components (e.g. a burr) that could find their way into the implant or the surgical site should be detached from the surface. Damaged O-rings must be replaced so as to guarantee a reliable hold of the torque wrench adapter in the torque wrench. In addition, pay attention to the intactness of the wrench flats.

Maintenance/assembly

Instrument oils and/or instrument lubricants must not be used.

Packaging

Please package the instruments in disposable sterilisation packaging (single-use packaging) that meets the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- suitable for steam sterilisation (temperature resistance up to at least 142°C (288°F) and sufficient vapour permeability)
- adequate protection for the torque wrench adapters and sterilisation packaging against mechanical damage

Sterilisation

Only the below listed sterilisation methods should be used for the sterilisation; other sterilisation methods are not permitted.
Steam sterilisation

- fractionated vacuum method or gravity displacement method[2] (with adequate product drying[3])
- steam steriliser in accordance with DIN EN 13060 or DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance evaluation (PQ))
- maximum sterilisation temperature 138°C (280°F; plus tolerance in accordance with DIN EN ISO 17665)
- sterilisation time (duration of exposure at the sterilisation temperature):

Country	Fractionated vacuum method	Gravity displacement method
Germany	at least 5 mins at 134°C	Not recommended
Germany	at least 20 mins at 121°C	Not recommended
USA	at least 4 mins at 132°C (270°F), drying time at least 20 mins	Not recommended
Other countries	at least 3 mins at 132°C (270°F) / 134°C (273°F) [4]	at least 40 mins at 121°C (250°F)
Other countries	at least 20 mins at 121°C (250°F)	Not recommended

[2] It is only permitted to use the less effective gravity displacement method if the fractionated vacuum method is not available

[3] The drying time predominantly depends on factors that are the sole responsibility of the user (e.g. type of steam steriliser actually used, how it is equipped (in particular passive or active drying) as well as its maintenance and calibration status, the actually used sterilisation cycle, the actually used packaging configuration, the actually used loading configuration and in particular the loading density etc.); instrument-specific aspects play a secondary role in this regard. The user is thus obligated to check whether the conditions actually used guarantee adequate drying.

[4] or 18 mins (inactivation of prions)

Moreover, do not use dry heat sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, or plasma sterilisation.
If applicable (see chapter "Special instructions"): It is not permitted to sterilise the torque wrench adapters when assembled (only H.06.01.X1/Z1/K1).
Verification of the general suitability of the torque wrench adapter for effective steam sterilisation was provided by an independent, accredited testing laboratory using the steam steriliser HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and using both the fractionated vacuum method and the gravity displacement method. For this purpose, typical conditions of a hospital or doctor’s practice were taken into consideration together with the above-described methods.

Storage

Following sterilisation, the torque wrench adapters must be kept dry and dust-free in the sterilisation packaging.

Material durability

When selecting the cleaning agents and disinfectants please ensure that they do not contain the following components:

- organic, mineral and oxidizing acids (minimum permitted pH value 5.5)
- strong alkaline solutions (maximum permitted pH value 8.5, neutral/enzymatic cleaners recommended)
- organic solvents (e.g. alcohols, ethers, ketones, petroleum ether)
- oxidizing agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons
- oils

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Never clean any of the instruments with metal brushes or steel wool.
All instruments may only be exposed to temperatures not exceeding 142°C (288°F).

Reusability

The instruments can - with appropriate care and provided if they are undamaged and uncontaminated (see also chapter "Checks") - be reused up to the number specified in chapter "Special instructions". Any further re-use beyond this limit or the use of damaged and/or soiled instruments is the responsibility of the user.
We assume no liability if these instructions are not followed.

Documentation

You can digitally monitor the number of times processing is carried out or document manually, referring to REF, LOT and date.

Special instructions

		Inserts	Positioning cuffs	Torque wrench adapters
Rinsing volume (disposable syringe with attached disposable needle)		-	-	1 ml
Brush		Soft standard brush (toothbrush)	Soft standard brush (toothbrush)	Blind cavities:conical interdental brush Outside: Soft standard brush (toothbrush)
Special procedure for	Dismantling	-	-	Only for variant with small screw: Unscrew screw For variants with O-ring: Do not dismantle O-ring
	Pre-treatment	Brushes	Not required	Blind cavities: rinse and brush Exterior: brush
	Manual cleaning/ disinfection	Brushes	Brushes	Blind cavities: rinse and brush Exterior: brush
	Mechanical cleaning/ Disinfection	In small parts basket	In small parts basket	In small parts basket
	Maintenance/ assembly	Standard Oiling or greasing prohibited	Standard Oiling or greasing prohibited	Pack variant with screw disassembled for variants with O-ring: Check, replace O-ring if necessary, oiling or greasing prohibited
Packaging		Standard	Standard	Standard
Sterilisation		Standard	Standard	Standard
Maximum permissible number of cycles		1 (!)	1 (!)	50

7. Storage

Store clean and dry! Can be stored in a non-sterile state until the best-before date has been reached (see sterilisation)! Use only with undamaged packaging! Conventional processing and repackaging are not permissable. If packaging is damaged upon delivery or accidentally damaged after unpacking the delivery, contact the manufacturer and do not use the product.



8. Maintenance / assembly

8.1 After implantation

- Patients should be called to the practice for 3-6 monthly recalls to check the titanium cases for wear and the inserts for loosening.
- Do not use metal instruments to avoid scratches on the Titanmagnetics® surface!

For oral use, also note:

- The denture and the inserts should be cleaned thoroughly twice a day. Cleaning should only be done with normal tooth or denture brush, no hard or sharp-edged objects and if possible no abrasive toothpaste.
- Increased plaque accretion on the high glossy polished surfaces of inserts was not determined (Tiller 1993, 1995). In case of accretion of plaque or calculus these should be removed immediately. Use only plastic instruments! Accretions on the functional surfaces can lead to increase distance between the two magnets and a resulting loss of retention force.
- The dentures have to fit correctly on the jaw. Reline denture base regularly, to avoid a purely implant-supported construction.

For extraoral use, also note:

- In order to avoid peri-implant inflammation, it is necessary for the patient to take care of the skin under and around the magnet. The recommended care in this regard consists of daily cleaning of the implants and the surrounding skin. Hygiene measures include regular and complete elimination of plaque on the implant surface. Careful hygiene (with soap and water) eliminates crusts more effectively than regular hygiene (Alsaeed, B.).
- To avoid further complications, possible pressure points caused by the facial prostheses must be reported to the anaplastologists in time and corrected if necessary.
- For skin recovery, the facial prostheses should be removed at night (Cernovsky).

9. Troubleshooting

Most frequent malfunctions	Possible cause	Action
Magnet does not hold the denture/ prosthesis	The distance between the insert and their countermagnet is too large. Plaque build-up, soiling or inserted incorrectly.	Remove plaque or soiling and work the denture or prosthesis in again.
Denture / prosthesis is rejected or no longer holds	Patient was in MRI (strong magnetic field).	Replace the magnets
Fracture of the insert	Incorrect loading by the denture and loosening of the insert.	Replace the magnets
Torque wrench adapter is stuck, snagged	Torque wrench adapter tilted or worn.	New torque wrench adapter is needed.

10. Disposal

The products can be disposed of like other potentially infectious products.
Safely dispose of contaminated or unusable medical devices as healthcare (clinical) waste in accordance with local healthcare, governmental and regulatory policies or guidelines.
When separating, recycling or disposing of packaging materials, local governmental and regulatory legislation on packaging and packaging waste must be complied with, where applicable.

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11. Installation

In the following, 3 constellations under which an application of Titanmagnetics® is possible are explained for your case situation:

11.1 Titanmagnetics® in an existing denture (Chairside)

a) Application of the insert



1. Remove the implant cover screw prior to application of the insert. Place the insert in the torque wrench adapter with its functional surface (convex or conical). An active magnet inside the torque wrench adapter causes an attraction of the magnetic insert.
   - The outer polygon key surfaces of the insert (X-Line: 8 faces; K-, Z-, T-Line: 10 faces) have to fit to the inside polygon key surfaces of the torque wrench adapter.
2. Now screw the insert into the implant carefully.
   - Please make sure not to tilt the thread. The last revolution is done under torque control (20 Ncm).
3. Tighten the firmly screwed insert after 10-14 days, checking the torque (20 Ncm).
   - To avoid loosening of the insert (fracture risk!), retighten the insert under torque control after 10 - 14 days! Never screw in the insert with pliers or manually!

b) Healing



The insert can be used as healing cap. Scar tissue surrounds the insert and will not be destroyed by abutment change (Prof. Donath). Allow a time lapse 10 - 14 days for tissue regeneration between insert application and functional impression.

c) Preparation of denture

The existing denture is carefully ground out at the positions above the magnets from the basal side.

- This cavity must be created in such a way that the insert and prostheses magnet lie under the prostheses base without any interference.

d) Using the positioning cuff



1. Pull the positioning cuff over the insert head, in mouth.
2. Place the denture magnet on top.
   - The positioning cuff protects the surrounding tissue and the functional surfaces from acrylic. Additionally, it provides a 0.3 mm resilience gap between the insert and the prostheses magnet. The positioning cuff is made of medical silicone at can be easily removed after the acrylic is cured.
   - If the magnetic head is more than 2 mm above the gingiva (e.g. with transgingival implants), the positioning cuff P.00...1 is used. The inverted funnel-shaped design of the positioning cuff leads to a corresponding shaping in the prostheses base. This guarantees a trouble-free fit.
   - For equigingivally placed inserts (1 - 2 mm above the gingiva) the positioning cuff P.00...2 is used.
   - For Titanmagnetics® K-Line, place an additional resilience ring on the insert surface. It provides the 0.3 mm resilience gap. The K-Line positioning cuff is perforated and will be pulled over the resilience ring.

e) Finishing



1. Polymerise denture magnets with auto curing polymer (e.g. Paladur, Kulzer) or composite adhesive (e.g. Quick up®; Voco GmbH) into the previously ground denture base.
2. The acrylic is filled from basal and the denture is placed in the mouth.
3. The patient must bite firmly until curing (time depending on material).
   - If the denture is disarticulated before complete polymerisation, the denture magnets may not be positioned correctly and this may lead to occlusion problems or premature wear of the Titanmagnetics®.
4. Carefully remove excess acrylic in the denture base without damaging the titanium housing.
5. Remove the positioning cuff and, if necessary, the resilience ring and finish the denture basally.

11.2 Titanmagnetics® in a new denture (Labside)

a) Application (see under 11.1)

b) Impression



Place the impression post on the insert. An active magnet inside the impression post will be attracted to the magnet inside the insert.

1. Check the seat with fingertips.
   - For impression of Titanmagnetics® K-Line, use the corresponding denture magnet (U.00.01.K500).
2. Take an impression using a closed individual tray which is blocked out on the implant positions for about 1 cm.
   - Apply impression material around the impression post for better stability.

c) Model manufacturing



Place the laboratory replica into the impression post. It will be attracted with the help of the integrated magnet.

- Pour the model in edge-stabile dental stone or model acrylic (in implant positions).

d) Bite measure / set up



The prosthesis magnets can be used to fix bite measurement templates or set up dentures.

- This makes bite impression and set up try-in more reliable. Separate prostheses magnets should be used.

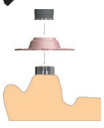
e) Metal framework / set up key



Block out part of the magnetic head of the insert in a funnel shape.

- Functionally and aesthetically optimal results are achieved when working with a previously fabricated prewall (set up).

f) Finishing

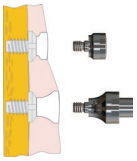


1. Pull the positioning cuff on the model over the head of the insert.
   - The positioning cuff serves to protect the functional surfaces when gluing in the denture magnets and to create a resilience of 0.3 mm.
2. Glue or polymerise the denture magnets with prostheses acrylic (e.g. Paladur, Kulzer) or composite adhesive (e.g. Quick up®; Voco GmbH) into the corresponding auxiliary part fits.
3. After fixing the denture magnet, remove the positioning cuff and, if necessary, the resilience ring and finish the denture basally.

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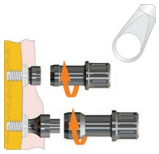
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11.3 Titanmagnetics® in a facial prosthesis



a) Selection of magnet

1. Select the suitable system group for the used extraoral implant or plate system (see catalog).
2. Decide on working with a base post, or directly on the implant or plate.
3. Choose the Titanmagnetics® product line according to the space limitations, force and lateral stability requirements.
4. Select the insert height according to the skin thickness above the implant or plate, so that the functional surface of the magnet head protrudes by 1 mm.
5. Consider the overall height of the insert and the prostheses magnets in your planning.



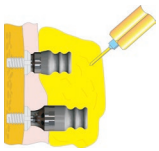
b) Application of the insert

Screw the insert into the implant using a torque wrench adapter and make sure that the spanner flats of the torque wrench adapter don't jam on the key surfaces of the magnet assembly. The recommended torque is 20 Ncm.

- Don't screw in with pliers or by hand, as the insert or implant may be damaged.
- Tighten the screwed insert after 10-14 days under torque control (20 Ncm).

c) Healing

The insert can already be used as a healing post. A Titanmagnetics® Healing Flange (E.00....) can also be used. The Healing Flange is placed on the insert to hold the dressing in place after the implant is exposed. This minimizes tissue proliferation. The Healing Flange has its own magnetic core and is made of tissue-friendly titanium. A scar cuff is formed around the final prosthetic abutment and is not destroyed again (Prof. Donath).



d) Impression

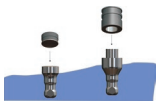
1. Place the impression post for the appropriate product line on the insert.
   - For the K-Line, the prostheses magnet can be used as an impression post.
   - For strongly inclined inserts, a variant of the impression post with a short collar is available for the X-Line.
2. The correct fit can be checked with a finger by gently jerking the impression post.
3. The area to be moulded with the impression posts is covered with impression material.



e) Model manufacturing

Place the laboratory replica into the impression post. It will be attracted with the help of the integrated magnet.

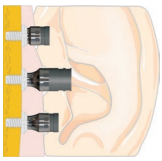
- Pour the model in an edge-stable dental stone or model acrylic (in implant positions).



f) Integration of prosthesis magnets

Before modelling the facial prostheses, make a plastic base, e.g. in wax, around the prostheses magnets to achieve correct positioning.

- Transfer the plastic base into silicone.



g) Finishing

1. Prostheses magnets are incorporated into the prosthesis by a polymerisation or vulcanisation process.
   - Make sure not to damage the titanium housing or to apply to much heat.
   - Care has to be taken that the retention ring is completely covered with prosthetic material.
2. The peri-implant area should be blocked out conically for completion to avoid interference by the prostheses base and to protect the surface of the insert.

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