Instruction for use Titanmagnetics®

K.00.01.EN12/07.21

Content

Definition of symbols in accordance with DIN EN ISO 15223-1

	Manufacturer		Keep dry		Do not reuse		Caution, Consult accompanying documents	REF LOT	Order number Batch code	CE 0197	Medical products acc. MDD 93/42/EWG
YYYY-MM-DD	Manufacturing date		Do not use if package is damaged		Caution, Magnetic field	250 °C 450 °F	Upper limit of temperature	UDI HIBC	Unique Device Identification Health Industry Bar Code	CE	Medical products of Class I according to MDR (EU) 2017/745
YYYY-MM-DD	Best-before date										

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)

1.3 Literature

A literature reference list can be ordered from the manufacturer.

1.4 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 letters 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 of the product lines.

	X-Line	Z-Line	K-Line	T-Line
Implant-specific implant abutments				
Insert (I)				
Prosthetic universal parts				
Denture- / counter magnet (U)				
Equipment				
Impression post (A)			K-Line denture magnet	
Laboratory replica (M)				
Positioning cuff (P)				
Resilience ring (P)				
Torque wrench adapter (H)				

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1.5 Materials

Insert, denture magnet, resilience ring, 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. Intended use

2.1 Purpose and indications for the use of Titanmagnetics®

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, various number of posts can be indicated. Due to the low lateral force on implant (only X-Line and Z-Line) even short implants (6 mm) can be used.
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 K-Line implants should be at least 12 mm long. T-Line must not be used in oral treatment. Incompatibility with materials used.

2.2 User and environment

Titanmagnetics® should only be used by educated dentists, surgeons, dental technicians or anaplastologists and only in medical practices and laboratories. 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.

- **NOTICE!** 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. With aseptic storage, it is possible to screw the inserts at the same patient on the original position without reprocessing.
- **NOTICE!** 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).
- **NOTICE!** 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.
- **NOTICE!** 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.
- **NOTICE!** 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 cutting can perforate the titanium shell.
- **NOTICE!** 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.

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 a UDI code (HIBC) on the label, which contains information about the manufacturer (Steco=ESTO) as well as the product and batch identification.

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 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 about 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) or 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 occurring near the surface magnetic fields with a magnetic flux density of up to 300 milli Tesla in humans can be locally damaging. There are no clinical references for the small static magnetic fields of Titanmagnetics® being harmful to humans.

4.2 Technical data

For oral and extra oral use Titanmagnetics® are available in four product lines with different size, functional design and retention force.

Product	**X-Line**		**Z-Line**		**K-Line**		**T-Line** (only extra oral)	
	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 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
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	Prothesenmagnet verwenden!		7.50 mm	5.80 mm
Modellimplantat	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
Withdrawal force*	1.6 N / 163 g		3.0 N / 306 g		1.6 N / 163 g		1.4 N / 143 g	

*The withdrawal forces were determined according to ISO 13017.

5. Product selection

5.1 Selection of the suitable magnet

Select the appropriate system group for the implant or plate system used from the range. Decide whether you want to work with a base post or directly on the implant or plate. Select the appropriate product line according to the space available and the requirements for retention force and lateral guidance. Select the abutment height according to the skin thickness over the implant or plate so that the functional surface of the magnet abutment protrudes about 1 mm. Observe the mounting height of the corresponding counter magnets.

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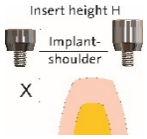
5.2 Magnet installation height



Inserts are offered in different heights with integrated distance sleeves. To choose the correct height, a measurement of tissue height is recommended. The height given in the product name and REF number is measured from implant shoulder to 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. Subgingivally inserted Titanmagnetics® should exceed tissue for 1 mm (H>X). For correct selection of insert, refer to product catalogue or system overviews.

5.3 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 / extra oral	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 / extra oral	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 / extra oral	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	extra oral	T-Line should always be combined with 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

Inserts, denture magnets and impression posts are single use products only. Reuse is not allowed due to the risk of surface damages caused by mechanical extraction or reprocessing 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 user's own responsibility. A cleaning and sterilization advices are available under www.steco.de. In compliance with the warnings, we guarantee at least 5 years against abrasion (Perforation).

6.2 Instructions for sterilisation and disinfection/ reprocessing instructions

This reprocessing instruction applies to all Titanmagnetics® torque wrench adapters (H...) and to the one-time reprocessing of Titanmagnetics® inserts (I....).

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 is 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.

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 (not applicable for the USA).

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 take into account 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.

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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 were taken into account in relation to the procedure described above as well as to the instructions for use of the detergent and disinfectant.

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 (not in the USA).

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.

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, brushing carefully (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 taken into account 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.

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TÜVRheinland ZERTIFIZIERT

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

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 this using the K.00.75…. form.

Special notes

		Inserts	Torque wrench adapter
Rinsing volume (disposable syringe with attached disposable needle)		-	1 ml
Brush		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	Blind cavities: rinse and brush Exterior: brush
	Manual cleaning/ disinfection	Brushes	Blind cavities: rinse and brush Exterior: brush
	Mechanical cleaning/ Disinfection	in small parts basket	in small parts basket
	Maintenance/ assembly	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
Sterilisation		Standard	Standard
Maximum permissible number of cycles		1 (!)	50

7. Storage and minimum shelf life

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 reprocessing and repackaging are not possible. If packaging is damaged on delivery or when the best-before date is reached, contact the manufacturer.

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8. Maintenance / assembly

8.1 Cleaning after implantation

Oral: 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! Do not use metal instruments to avoid scratches on the Titanmagnetics® surface! Accretions on the functional surfaces can lead to increasing distance between the two magnets and due to this to a loss of retention force. Patients are recommended to let the denture be checked every three months to review the function of the Titanmagnetics®. The dentures have to fit correctly on the jaw. Reline a denture base regularly.
Extra oral: 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 care we recommend 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	The distance between the denture magnet and the insert is too large. Plaque build-up or inserted incorrectly.	Remove plaque and work the denture magnet in again.
Denture 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.

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)

Application of the insert

Remove the implant cover screw prior to application of the insert. Place the insert in the torque wrench insert with its functional surface (convex or conical). 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. An active magnet inside the torque wrench adapter causes an attraction of the magnetic insert. 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). To avoid loosening of the insert (fracture risk!), retighten the insert under torque control after 14 days! Never screw in the insert with pliers or manually!

Healing cap

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 gap of 14 days for tissue regeneration between insert application and functional impression.

Preparation of denture

Remove the acrylic of the denture base to fit the inserts and the prostheses magnets.

Using the positioning cuff

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 prosthesis magnet. Positioning cuff No. 1 is used if the functional surface is 2 mm higher than the tissue (e. g. transgingival implants). Positioning cuff No. 2 is used if the functional surface is lower than 2 mm above the tissue level.
Pull the positioning cuff over the insert head. Place the denture magnet on top. Make sure that the denture magnet sits firmly on the positioning cuff. The conical shape of the positioning cuff (No. 1) leads to a recess around the prosthesis magnets which avoids interferences of the inserts with the prostheses base at divergent implants. The positioning cuff is made of medical silicone at can be easily removed after the acrylic is cured.
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.

Finishing

Fix the denture magnets in the denture with cold curing resin (e.g. Paladur, Kulzer) or composite adhesive (e.g. Quick up®; Voco GmbH). Apply the acrylic material from the basal side. Make sure to place some acrylic in the retention notch of the prosthesis magnet. Then, place the denture inside the mouth. The patient has to keep the bite position during curing time (refer to manual of acrylic manufacturer). If the acrylic is not fully cured this may lead to incorrect position of the prostheses magnets that causes failures in occlusion and early wear of the functional surfaces. Acrylic excesses have to be removed carefully without damaging the titanium surface.

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11.2 Titanmagnetics® in a new denture (Labside)

Application (see under 11.1)

Impression

Place the impression post on the insert. An active magnet inside the impression post will be attracted to the magnet inside the insert. Check the seat with fingertips. Take an impression using a closed individual tray which is spared out on the implant positions for 1 cm. Apply impression material around the impression post for better stability.

For impression of Titanmagnetics® K-Line, use the corresponding denture magnet.

Model fabrication

Place the model implant 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).

Bite registration / set up

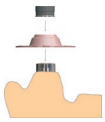
The prosthesis magnets can be used to fix bite registration templates or set up dentures. This makes bite impression and set up try-in more reliable. Separate prosthesis magnets should be used.

Metal framework / set up key

Integrate a metal framework for better stability. Before duplicating the master model with denture magnets, the implant surrounding area above the tissue should be blocked out conically. To achieve functionally and aesthetically optimized results, use a set up key for the wax-up of metal framework.

Finishing

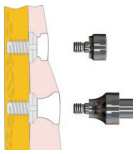
The positioning cuff protects the functional surfaces from acrylic and provides a 0.3 mm resilience gap. Pull the positioning cuff over the functional surface of the model implant. Use a composite glue or denture acrylic to retain the denture magnets. It is recommended to apply acrylic or (e.g. Paladur, Kulzer) composite adhesive (e.g. Quick up®; Voco GmbH). in the retention notch of the denture magnet. Remove the positioning cuff after gluing or polymerisation.



11.3 Titanmagnetics® in a facial prosthesis

Selection of magnets

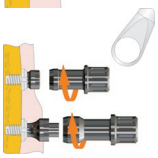
Select the suitable system group for the used extra oral implant or plate system. Decide for working with or without a base post. Choose the Titanmagnetics® product line according to the space limitations, force and lateral stability requirements. Choose the insert height according the soft tissue height in a way that the functional surface exceeds tissue for about 1 mm. Consider the overall height of the insert and the prosthesis magnets in your planning.



Application of the insert

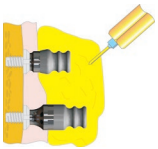
Titanmagnetics® are applied with the help of a torque wrench adapter and a torque wrench at 20 Ncm. The outer polygon key surfaces of the insert (X-Line: 8 faces; K-, Z-, T-Line: 10 faces) have to fit to the inner polygon key surfaces of the torque wrench adapter. An active magnet inside the torque wrench adapter causes an attraction of the magnetic insert. Now the insert can be screwed into the implant carefully. Please make sure not to tilt the thread. The last revolution is done under torque control (20 Ncm). To avoid loosening of the insert (fracture risk!), retighten the insert under torque control after 14 days! Never screw in the insert with pliers or manually!

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 gap of 14 days for tissue regeneration between insert application and functional impression.



Impression

For impression taking, use the impression posts that are offered for all product lines. For the K-Line, the prosthesis 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.The built-in magnet positions the impression posts force-fit on the inserts. The correct fit can be checked with a finger by gently jerking the impression post. The area to be moulded with the impression posts is covered with impression material.

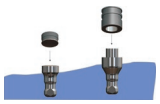


Model fabrication

Place the model replica into the impression post. It will be attracted with the help of the integrated magnet. Pour the model in an edge-stabile dental plaster stone or model acrylic (in implant positions).

Integration of prosthesis magnets

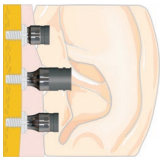
The facial prosthesis can be made in different work flows (e. g. stone mould). We recommend a stabile framework (acrylic or metal) for correct positioning of prosthesis magnets during the wax-up. This framework can be embedded in the silicone prosthesis afterwards. For all product lines different prosthesis magnets with or without retention ring for silicone are available. X-Line und Z-Line prosthesis magnets are also available with a collar for more lateral stability.



Finishing

Prosthesis magnets are incorporated into the prosthesis by 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.

The peri-implant area should be blocked out as conically as possible for completion to avoid interference by the prosthesis base and to protect the surface of the insert.



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