Instruction for use
Titanmagnetics® root cap magnets and obturator magnets

K.00.23.EN04/08.23

Content

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 only	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. Familiarize 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. Find out about updated instructions for use at www.steco.de/en/

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)
+ Magnet-retained hybrid prosthesis on root caps (Spielberg 2001)

A literature reference list can be ordered from the manufacturer.

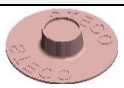
1.3 Titanmagnetics® secondary attachments

The following instructions apply to the Titanmagnetics® secondary attachments, what includes:

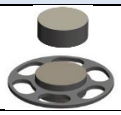
- Titanmagnetics® root cap attachment system, consisting of root cap magnet and the counterpart denture- or prosthesis magnet.
- Titanmagnetics® obturator attachment system, consisting of obturator magnet and the counterpart prosthesis- and obturator magnet.

The Titanmagnetics® products are identified by the first letter of the article number:
V = connecting parts / U = denture-, prosthesis magnet / P = positioning cuffs / M = model parts

Root cap magnets

Article	Identification	X-Line	Z-Line	Indication
Root cap magnet (V)	V.00.01….			Is glued into a cast root cap with an attachment adhesive.
Denture-, prosthesis magnet (U)	U.00.01….			counterpart for the root cap magnet, for incorporation into the denture.
Accessories				
Positioning cuff (P)	P.00.04.X1		-	Protects the gingival area during polymerization of the denture magnet.
Model sleeve (M)	M.00.03.X205			Forms the receptacle for the root cap magnet during modelling and is also burnt out.
Modelling aid (M)	M.00.04….			The root cap modelling aid is used to position the burn-out sleeve on the modelled root cap.

Obturator magnets

Article	Identification	X-Line	Z-Line	W-Line	Indication
Obturator magnet (V)	V.00….		 -		Magnets for obturators or septal prostheses available for acrylic and for silicone with retention ring. W-Line have plan surfaces and must be used also as counterpart.
Prosthesis magnet (U)	U.00….			-	Counterpart magnet for acrylic. Available with and without collar. Counterpart magnet for silicone. Available with retention ring and/or collar.

1.4 Materials

Titanmagnetics® secondary attachments:
Root cap magnet, obturator magnet, denture-, prosthesis magnet:
Housing and resilience ring: titanium ASTM F 67 (Grade 4) / Magnetic core: Sm_2Co_{17} (contains Fe and Cu), gastightly welded in titanium
Accessories:
Positioning cuff: dental silicone; Model sleeve: PMMA; Modelling aid: steel

2. Use of Titanmagnetics® secondary attachments

2.1 Intended purpose and indications for the use of root cap magnets and obturator magnets

Titanmagnetics® secondary attachments consists of root cap-, obturator-, denture-, prosthesis magnets have the intended purpose for long-term removable fixation of dental, facial and defect prostheses in and on the human body.

Indication

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). Depending on anatomic and prosthetic conditions a various number of posts can be indicated. The root cap magnets can be combined with implant-supported Titanmagnetics® or other retaining elements.
Facial prosthetics: Anchoring of facial prostheses and resection prostheses. Obturator magnets are used to couple segmented prostheses and/or obturators.

Contraindication

- dysfunctions such as bruxism
- incompatibility or allergis to materials used
- foreseeable regularly MRI examinations (see warnings)

2.2 User and environment

Titanmagnetics® products 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.

- 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 magnets. It is recommended to remove all Titanmagnetics® in and on human body 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.
- 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).
- 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-stable 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.

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 Titanmagnetics® components in the patient's file and passport! 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.

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! Dangers due to loosening, wear (perforation) as well as the MRI.

4. Product information

4.1 Magnetic field

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-Line) and 300 mT (Z-Line, W-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

Titanmagnetics® secondary attachments are available in three product lines with different sizes and retention forces.

Product line	**X-Line**		**Z-Line**		**W-Line** (not dental**)	
Surface	spherical		spherical		plan	
dimension	Height/Length	Diameter	Height/Length	Diameter	Height/Length	Diameter
Root cap magnet	2.50 mm	4.80 mm	3.00 mm	5.80 mm	-----	-----
Obturator magnet (with rentention ring)	2.50 mm	4.80 mm (11.50 mm)	3.00 mm	5.80 mm (11.50 mm)	2.65 mm	6.80 mm (14.00 mm)
Denture-, prostheses magnet (with retention ring)	2.65 mm	4.80 mm (11.50 mm)	3.15 mm	5.80 mm (11.50 mm)	-----	-----
Withdrawel forces*	1.6 N / 163 g		3.0 N / 306 g		3.3 N / 330 g	

* The withdrawal forces were determined according to ISO 13017. / **not in chewing function/ only obturators or similar

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Accessories for	X-Line		Z-Line		W-Line (not dental**)	
Positioning cuff	0.30 mm	15.00 mm	0.40 mm	15.00 mm	-----	-----
Model sleeve	2.05 mm	5.30 mm	-----	-----	-----	-----
Modelling aid	Shaft ISO 103 (2.35 mm) or ISO 123 (3.0 mm)		-----		-----	

5. Product selection

The selection of the product line depends on the space conditions and the requirements for retention force. For the use of obturator magnets in combination with silicone, magnets with additional retention rings can be used. For the selection of the correct root cap magnet, please refer to the overviews in the product catalogue or the system overviews.
The Titanmagnetics® are part of an overall concept and may only be used with the associated Titanmagnetics® original parts and instruments in accordance with the instructions and recommendations of steco-system-technik. Otherwise, any liability is excluded. If necessary, follow the general instructions for use the Titanmagnetics® system (www.steco.de/en/).

6. Before use

6.1 Reusability

Titanmagnetics® secondary attachments as well as positioning cuffs are to be used only once. Reuse is not permitted, as mechanical failure of the titanium shell or surface damage may result from reprocessing.

6.2 Instructions for processing (cleaning, disinfection and sterilisation) and reusability.

As a rule, Titanmagnetics® root cap- and obturator magnets are processed in the laboratory. Direct application of Titanmagnetics® secondary attachments on the patient is unusual and would require processing prior to use due to possible contact with injured oral mucosa. Please refer to the separate processing instructions for Titanmagnetics® on the website, which also apply to the processing of the root cap-/ obturator magnets (V.00…) and positioning cuffs (P.00…).: www.steco.de/en/download.

7. Storage

Store clean and dry! Use only with undamaged packaging! Conventional reprocessing and repackaging are not permissible. 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

After the installation

Increased plaque accretion on the high glossy polished surfaces of Titanmagnetics® 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 increase distance between the two magnets and a resulting loss of retention force. Patients are recommended to let the denture be checked every three months to review the function of the Titanmagnetics®. Patients should be called to the practice for a three-monthly recall to check the titanium cases for wear and the Titanmagnetics® for loosening. The dentures or obturators should be checked for correct fit. Attention should be paid to the possible need for relining.

9. Troubleshooting

Most frequent malfunctions	Possible cause	Action
Root cap magnet does not hold the denture	The distance between the root cap magnet and the denture magnet is too large. Plaque build-up or inserted incorrectly.	Remove plaque and work in the denture magnet again.
Denture/ facial prosthesis is rejected or no longer holds	Patient was in MRI (strong magnetic field).	Replace the magnets

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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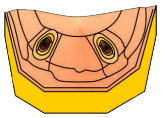
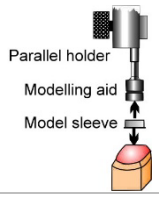
11. Installation Titanmagnetics® in a root cap

1. 

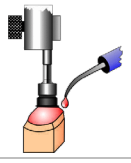
Model fabrication:
Fabricate the saw die model, then model a flat root cap as usual.

2. 

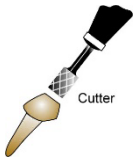
Modelling aid (only X-Line):
Insert modelling aid with attached model sleeve (for burning out) into the parallel holder.
Selection for 2.35 mm shank (ISO 103) or 3 mm shank (ISO 123) possible.
With Z-Line root cap magnets, the receptacles are modelled and parallelised in parallel.

3. 

Set up:
Set-up of the teeth according to aesthetic and functional aspects, fixation of the final set-up by pre-casting. Grind out the denture tooth for the magnet. Determine the position of the sleeve on the root cap with the modelling aid (place low above the stump, see total construction height).

4. 

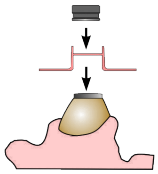
Modellation of root cap (only X-Line):
Waxing the model sleeve onto the root cap modellation. The sleeve is thinly waxed over in a circular pattern (conical shape). Embed the finished model, cast it and finish it as usual. There are no specifications regarding the alloy to be used.
For Z-line modelling, include directly against the root cap magnet blocked out with spacer (blasted area).

5. 

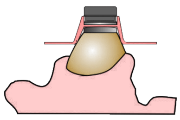
Finishing:
After casting and demolding clean the receptacle for the root cap magnet only slightly with a cylindrical cutter so that it fits and the glue line is not unnecessarily enlarged. Sandblast with aluminium oxide (110/125 µm, 2 bar). If necessary, polish the root cap.

6. 

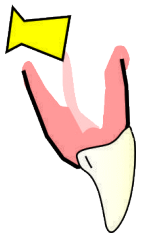
Gluing in the root cap magnet:
The convex root cap magnet is glued into the root cap with a mouth-resistant dental adhesive (e.g. PANAVIA™ 2.0). For this, both parts must be clean and free of grease! The magnet is glued in place with the highly polished, convex side (functional surface) facing upwards. The blasted underside of the root cap magnet is glued into the root cap. The (polished) edge of the magnet is not enclosed by the cast object.

7. 

Positioning cuff:
After the practitioner has cemented the root cap in the patient's mouth, the positioning cuff is pulled over the root cap (only if fitted into an existing denture).

8. 

Placing the denture magnet:
The denture magnet is placed on the positioning cuff with its highly polished concave functional surface. It centers itself. Check axial alignment on the positioning collar and correct if necessary.

9. 

Completion in the dental practice:
The denture is recessed in the area of the magnets from basal according to the size of the denture magnet. Cold polymer (e.g. Paladur, Kulzer) or composite adhesive (e.g. Quick up®; Voco GmbH) is placed in the recesses and on the retention groove of the denture magnet and the denture is inserted. Wait until the acrylic has set well (follow the manufacturer's instructions). Remove excess with a wooden or plastic spatula (non-magnetic). Ensure that the denture is funnel-shaped basally around the magnetic head.

Completion in the laboratory:
The denture magnet can be incorporated directly on the master cast into a new denture to be fabricated. The positioning cuff is pulled over the root cap on the model. The positioning cuff may have to be trimmed beforehand and individual areas blocked out with wax. The degreased denture magnet is placed on the positioning cuff and fixed if necessary.

After gluing the magnet in the root cap in the mouth, the denture can also be finished on the model of the moulded root cap. The procedure is largely the same as the one mentioned above. Due to the lack of magnetic force in the model, the positioning cuff and denture magnet must be carefully fixed. For a new fabrication, the finishing is done as usual in the casting process. The denture magnet can also be incorporated into an existing denture in the laboratory if the space has been ground free accordingly. A corresponding impression is required.

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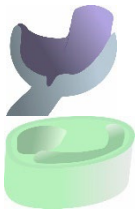
12. Installation Titanmagnetics® in an obturator



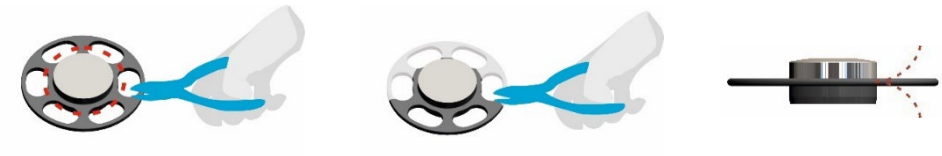
Fabrication of the model

The fabrication of the model depends on the extent of the defect and the planned rehabilitation. For regional defects, a conventional stone model might be adequate. For extended defects, multi-partial models might be required. Sometimes, it is necessary to fabricate models for interim stages.

Selection of the suitable magnet

Select the suitable size (product line) of the obturator Titanmagnetics® from the product line range. Combine components of the same product line only! For better retention in silicone, use corresponding obturator- or prosthesis magnet with retention ring. The retention ring can be cut and bend to adjust to space conditions. Please make sure not to damage the magnet capsule!

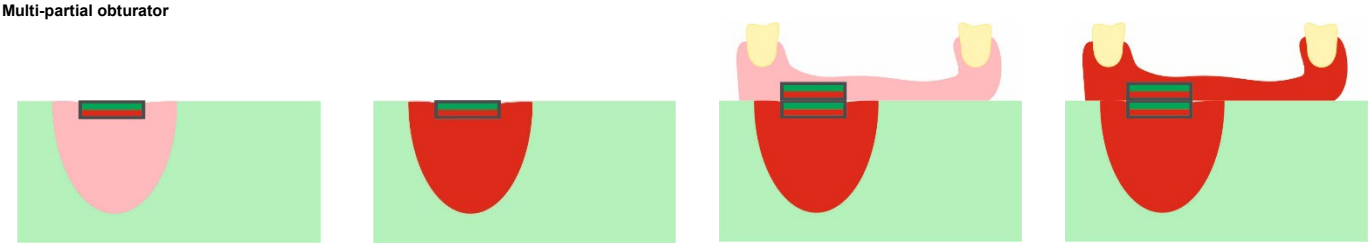
- Pay attention to the correct assignment of the concave/convex surfaces for the X- or Z-line and to the correct polarity of the W-line. The retention surfaces are sandblasted for a better bond to the denture material.



Modellation

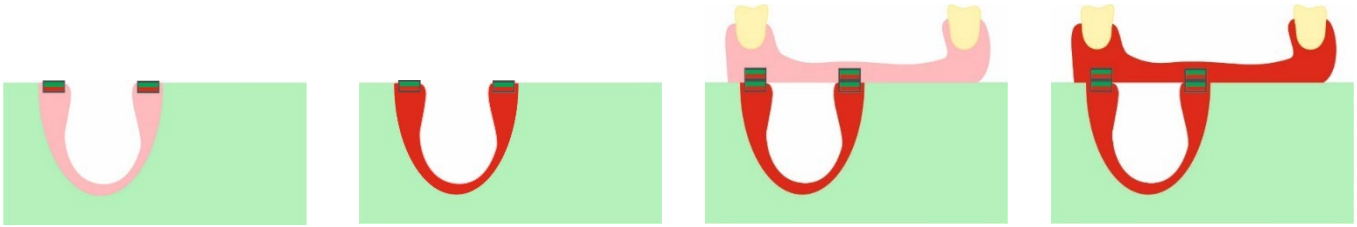
Depending on the construction of the multi-part obturators, different fabrication steps might be required. Usually, there are multiple steps to fabricate a segmented obturator.
Please make sure to combine parts only from the same product line (X-Line, Z-Line, W-Line)!
The selection of the product line is dependent on the size of the defect and the required retention force.
Following examples shortly illustrate the procedure of the fabrication of a multi-part obturator.

Multi-partial obturator



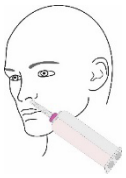
1. Modellation first part | 2. Finish first part | 3. Modellation second part | 4. Finish second part

Segmented hollow obturator



1. Modellation first part | 2. Finish first part | 3. Modellation second part | 4. Finish second part

13. Installation Titanmagnetics® in a septal prosthesis



Impression

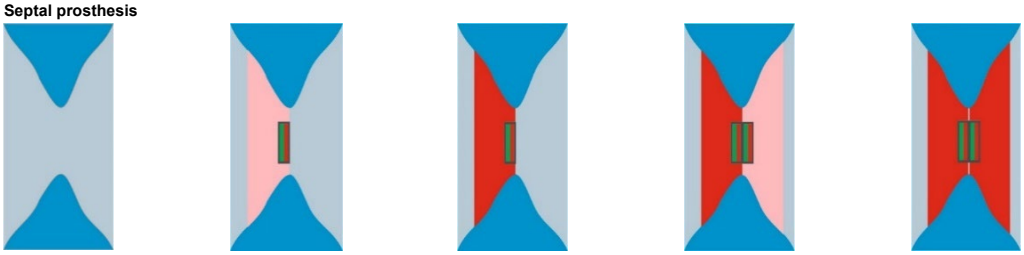
The impression taking of septal perforations is very difficult and is sometimes done with anesthesia. The fabrication of the model can be done based on conventional impression method or on 3D imaging technique in an additive procedure.

Selection of the suitable magnets

Select the suitable size (product line) of the obturator Titanmagnetics® from the product line range. Combine components of the same product line only! For better retention in silicone, use corresponding obturator- or prosthesis magnet with retention ring. The retention ring can be cut and bend to adjust to space conditions. Please make sure not to damage the magnet capsule!

- Pay attention to the correct assignment of the concave/convex surfaces for the X- or Z-line and to the correct polarity of the W-line. The retention surfaces are sandblasted for a better bond to the prosthesis material.

Septal prosthesis



1. Fabrication of the model | 2. Wax-up part 1 | 3. Finish part 1 | 4. Wax-up part 2 | 5. Finish part 2

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