

Titanmagnetics®

The following instructions apply to obturator Titanmagnetics® system, which consists of different obturator magnets, prosthetic universal parts and accessories. The Steco® products can be distinguished by the first letter in the product number (REF): V= Connecting parts U= denture/prosthesis magnet M= Modelling aid.

Manufacturer within EU/Distributor within EU

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Indications

Prosthetics: Retention of facial prostheses and obturators. Coupling of facial prostheses, septal prostheses and obturators.
Contraindications: Disfunctions e.g. bruxism

Technical data

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

Product	X-Line		Z-Line		W-Line	
	Height/Length	Diameter	Height/Length	Diameter	Height/Length	Diameter
Obturator magnet (with retention ring for silicone)	2,60 mm	4,80 (11,5) mm	3,00 mm	5,80 mm	2,65 mm	6,80 (14,0) mm
Denture magnet (with retention ring for silicone)	2,65 mm	4,80 (11,5) mm	3,15 mm	5,80 (11,5) mm		
Impression posts	6,95 mm	4,80 mm	6,95 mm	5,80 mm	-	-
Laboratory replica	9,00 mm	4,80 mm	10,00 mm	5,80 mm	-	-
Modelling aid ISO 103	32,55 mm	4,80 mm	-	-	-	-
Modelling aid ISO 123	32,55 mm	4,80 mm	-	-	-	-
Retention force*	1,6 N / 163 g		3,0 N / 306 g		3,3 N / 330 g	

* The withdrawal forces were determined according to ISO 13017.

Materials

Obturator magnet, denture magnet, impression post, model replica:

Housing: titanium ASTM F 67 (Grade 4) / Magnetic core: Sm₂Co₁₇ (contains Fe and Cu), gastightly welded in titanium
Laboratory replica: steel 1.4122 (M.00.05.X900)

Advantages of magnetic retention

- + 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)

Literature

A literature reference list can be ordered from the manufacturer.

Selection of magnet size

Obturator magnets are offered in different sizes and retention forces (product lines). Please see "magnets overview" in the catalog for correct selection of the size of the Titanmagnetics®. The selection of the product line depends on the space conditions, required retention force and lateral guidance. Titanmagnetics® are part of a general concept and must be used with original Steco® parts and instruments according to the recommendations of steco-system-technik only. Otherwise, liability is excluded.

Usage

Steco® products should be used by educated dentists, surgeons, dental technicians or anaplastologists only.

Cleaning advice

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 plastic instruments only! 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.

Storage advice

Store clean and dry! In the nonsterile condition storable until the use by (see sterilization advice)! Do not use if packaging is damaged! Conventional processing and repackaging are not possible. If packaging is damaged upon delivery, or when the best-before date has been reached, contact manufacturer.



Sterilization and disinfection advice

Please note the separate instructions on the next page!

Reusability / Durability

Obturator and denture magnets and also impression posts are single use products only. Reuse is not allowed due to the risk of surface damages caused by mechanical extraction or repressing treatment. In compliance with the warnings, we guarantee at least 5 years against abrasion (perforation).



Warning

Special precautions have to be taken when using magnets. Obturators or dentures have to be removed, as the strong magnetic field of MRI (Magnetic Resonance Imaging) diagnoses can destroy the magnet. Keep 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). Make sure to provide this information to the patient!



Loose Titanmagnetics® may lead to loss of magnet, wear and limited function.

Titanmagnetics® are heat proof up to 250°C/450°F. Therefore, they must not be soldered or welded! The heat would irreversibly damage the magnet. Laser can perforate the housing. In case of a damaged titanium housing the parts have to be exchanged as soon as possible. Damaged titanium housing leads to corrosion of the magnetics alloy (Sm₂Co₁₇) and with this to progressive damaging of the housing.



Never grind the 0,2 mm thin titanium housing!

For risk assessment, send damaged parts back to the manufacturer including the product REF, LOT, date of insertion and intraoral position. Please note relevant product data (REF, LOT) in the patients file and patient passport!



Some Titanmagnetics products are marked on their label with an UDI code (HIBC) which contains information to the manufacturer (Steco=ESTO) as well as device and production identification.



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-Line) or 300 mT (Z-Line) or 200 mT (D680). In a distance of 5mm, it is lower than 40 mT (WHO exposure limit).



There is no evidence in the current literature that static magnetic fields occurring near the surface with a magnetic flux density of up to 300mT (millitesla) can be locally damaging to humans.

Special advice to patients

Note relevant product data (REF, LOT, etc.) in the patient file and patient passport! Instruct the patient about risks of loosening, surface damages (perforation) or strong magnetics fields (MRI, substansions).

Sterilization and disinfection advice

General principles

Titanmagnetics® obturators are delivered already cleaned and ready for sterilization in special packaging suitable for moist heat (steam) sterilization. **However, they should always be sterilized before direct product use.**

As part of your responsibility for the sterility of the instruments during use, please note that:

- only adequate device- and product-specific validated methods must be used for sterilization,
- the sterilizer used must be regularly maintained and checked
- 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).



Cleaning and disinfection

No cleaning or disinfection is required, as Titanmagnetics® obturator magnets are packaged clean and ready for sterilization. If the packaging is damaged, with an associated potential contamination, the Titanmagnetics® must not be used.



Checks

Checks are not required, as Titanmagnetics® obturator magnets are packaged clean and ready for sterilization. Check that the packaging is intact and examine the Titanmagnetics® obturator magnets for any soiling, damaged surfaces, splintering or corrosion, and reject any damaged Titanmagnetics®. Soiled Titanmagnetics® must not be used.

Maintenance / assembly

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

Packaging

Titanmagnetics® can be sterilized in the original sterilization packaging, if it is undamaged.

Information on the original sterilization packaging (as a basis for your validation to be carried out in accordance with DIN EN ISO/ANSI AAMI ISO 11607):

- MELAFol transparent sterilization packaging suitable for steam sterilization (MELAG Medizintechnik oHG, Berlin), in accordance with EN ISO/ANSI AAMI 11607, sealing temperature (standard values) recommended by the manufacturer: 170-185°C (338-365°F). See the product data sheet for further data.
- Minimum strength of the sealed seam applied by steco-system-technik: 7.96 +/- 0.60 N/5 mm.

Sterilization

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

Steam sterilization

- fractionated vacuum method or gravity displacement method¹ (with adequate product drying²)
- steam sterilizer 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 sterilization temperature 138°C (280°F; plus tolerance in accordance with DIN EN ISO 17665)
- sterilization time (duration of exposure at the sterilization 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) ³	at least 40 mins at 121°C (250°F)
Other countries	at least 20 mins at 121°C (250°F)	Not recommended

¹ It is only permitted to use the less effective gravity displacement method if the fractionated vacuum method is not available.

² The drying time predominantly depends on factors that are the sole responsibility of the user (e.g. type of steam sterilizer actually used, how it is equipped (in particular passive or active drying) as well as its maintenance and calibration status, the actually used sterilization 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.

³ or 18 min. (inactivation of prions)

Moreover, do not use dry heat sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization. Verification of the general suitability of Titanmagnetics® for effective steam sterilization was provided by an independent, accredited testing laboratory using the steam sterilizer 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 sterilization, Titanmagnetics® must be kept dry and dust-free in the sterilization packaging. Please note that the storage time may be limited by the use by of the packaging.



Reuse

Titanmagnetics® are disposable products that must not be reused even after repeated processing.

We assume no liability if these instructions are not followed.



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



Manufacturer



Keep dry



Do not reuse



Caution, Consult accompanying documents



Order number
Batch code



Medical products acc. MDD 93/42/EWG



Manufacturing date



Do not use if package is damaged



Caution, Magnetic field



Upper limit of temperature



Unique Device Identification
Health Industry Bar Code

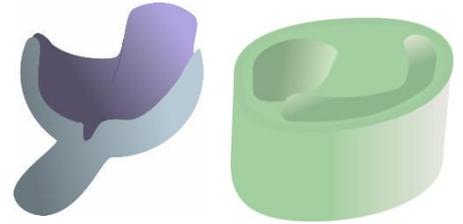


Use by

Titanmagnetics® in an obturator

Fabrication of the model

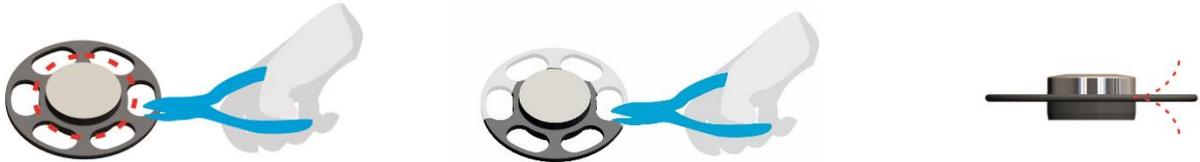
The fabrication of the model depends on the extent of the defect and the planned rehabilitation. For regional defects, a conventional stone model might be adequate. For extended defects, multi-partial models might be required. Sometimes, it is necessary to fabricate models for interim stages.



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 denture Titanmagnetics® 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!



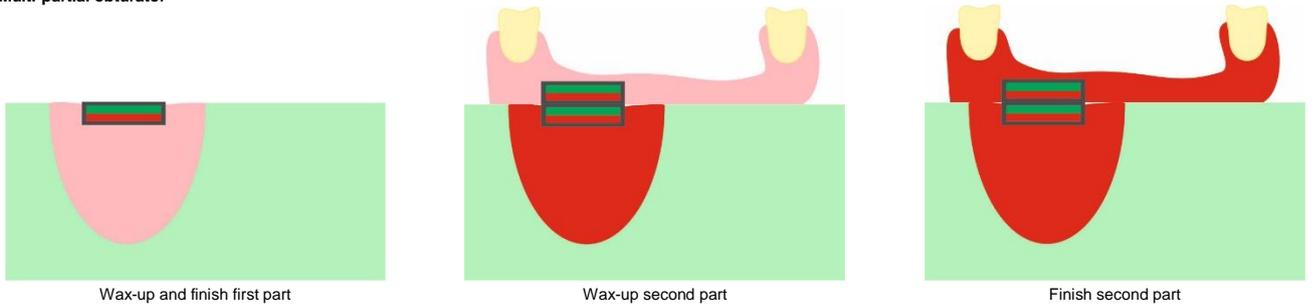
Fabrication of the obturator

Depending on the construction of the multi-partial 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)!

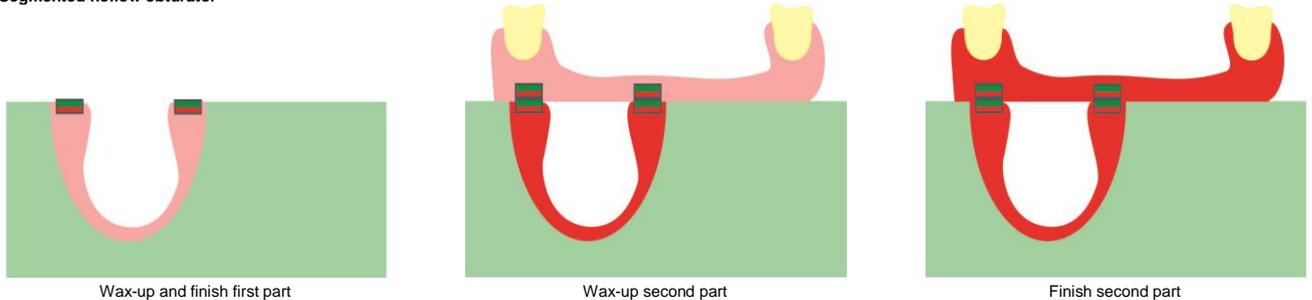
The selection of the product line is dependent on the size of the defect and the required retention force.

Following examples shortly illustrate the procedure of the fabrication of a multi-partial obturator.

Multi-partial obturator



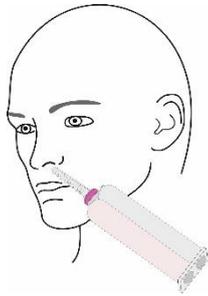
Segmented hollow obturator



Titanmagnetics® in a septal prosthesis

Impression

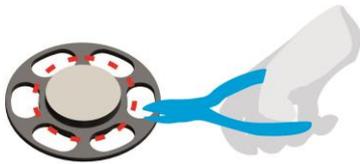
The impression taking of septal perforations is very difficult and is sometimes done with anesthesia. The fabrication of the model can be done based on conventional impression method or on 3D imaging technique in a additive procedure.



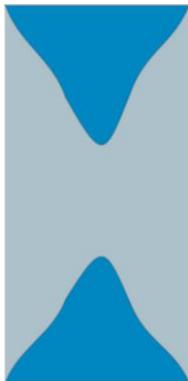
Selection of the suitable magnets

Select the suitable size (product line) of the obturator Titanmagnetics® from the product line range. Combine components of the same product line only!

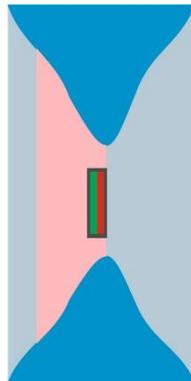
For better retention in silicone, use corresponding obturator and denture Titanmagnetics® with retention ring. The retention ring can be cut and bend to adjust to space conditions. Please make sure not to damage the magnet capsule!



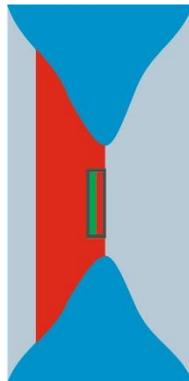
Septum prosthesis



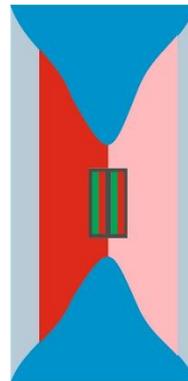
Fabrication of the model



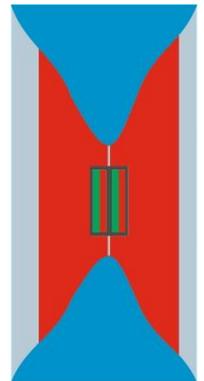
Wax-up part 1



Finish part 1



Wax-up part 1



Finish part 2