

StecoTitanmagnetics®

The following instructions apply to StecoTitanmagnetics® System. This system consists of implant-specific abutments (inserts), prosthetic universal parts and accessories. The Steco® products can be distinguished by the first letter in the product number (REF): I = Implant insert U = Denture magnet (Prosthesis-) P = Positioning cuff/resilience ring
 A = Impression post M = Laboratory replica H = Torque wrench insert O = Original parts of foreign manufacturers
 Manufacturer within EU
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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).
 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.
- Contraindications: Dysfunctions such as bruxism. For StecoTitanmagnetics® K-Line implants should be at least 12 mm long. StecoTitanmagnetics® T-Line must not be used in oral treatment.

Technical data

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

Product	X-Line		Z-Line		K-Line		T-Line (extra oral only)	
	Height/Length	Diameter	Height/Length	Diameter	Height/Length	Diameter	Height/Length	Diameter
Inserts for implants	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	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 insert	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.

Materials

Insert, denture magnet, resilience ring, impression post, laboratory replica, torque wrench insert:
 Housing: titanium ASTM F 67 (Grade 4) / Magnetic core: Sm₂Co₁₇ (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)

Advantages of magnetic anchoring

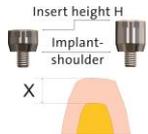
- + easy and stressless insertion or extraction of prostheses (Gbara 1995), cost effective (Göhring 1997)
- + good implant and tissue supported retention and fit of dentures (Wirz 1994)
- + avoiding of unphysiological load on implants (Jäger/Wirz 1993, 1994, Vesper 1995)
- + easy mouth, implant and denture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

Literature

A literature reference list can be ordered from the manufacturer.

Selection of inserts

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 StecoTitanmagnetics® should exceed tissue for 1 mm (H>X). For correct selection of insert, refer to product catalogue or system overviews.



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. Due to their flat surface, the X-Line and Z-Line are relatively independent of divergences or convergences of the implant axes, but also do not absorb any lateral forces. The 10° cone of the K-Line allows a maximum angle of 15° between two implants. The K-Line is a non-frictive cone that also absorbs lateral forces. 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. StecoTitanmagnetics® 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. Implant parts are adapted to the different implant systems.

Usage

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

Cleaning advice

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 StecoTitanmagnetics® 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 StecoTitanmagnetics®. 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 is 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

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 inserts 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).



Warning

Special precautions have to be made when using magnets. Keep distance to magnetic data storages and electronic devices! Cardiac pacemakers are not affected by StecoTitanmagnetics® in regular use, because there is no direct contact (Völkel 1999). Make sure to provide this information to the patient! 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, the insert and as far as possible the root post magnet before MRI inspection. Patients should avoid to stay next to electric substations. With aseptic storage, it is possible to screw the Titanmagnetics® inserts at the same patient on the original position without reprocessing.



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.

StecoTitanmagnetics® 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 process send damaged parts back to the manufacturer together with 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

StecoTitanmagnetics® 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 StecoTitanmagnetics® 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 StecoTitanmagnetics® being harmful 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, substations).

Sterilization and disinfection advice

General principles

Titanmagnetics® inserts are delivered already cleaned and ready for sterilization in special packaging suitable for moist heat (steam) sterilization. **However, they should always be sterilized before 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 the 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® inserts are packaged clean and ready for sterilization. If the packaging is damaged, with an associated potential contamination, the Titanmagnetics® inserts must not be used.



Checks

Checks are not required, as Titanmagnetics® inserts are packaged clean and ready for sterilization. Verify that the packaging is intact and the use by date is valid. Examine the Titanmagnetics® inserts for any soiling, damaged surfaces, splintering or corrosion, and reject any damaged inserts. Soiled inserts must not be used.

Maintenance / assembly

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

Packaging

Titanmagnetics® inserts 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® inserts 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, the inserts 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

The inserts are disposable products that must not be re-used even after repeated processing. With aseptic storage, it is possible to screw it in again after temporary removal of the Titanmagnetics inserts to perform an MRI.

We assume no liability if these instructions are not followed.



Medical products acc. MDD 93/42/EWG

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

StecoTitanmagnetics® 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 insert. An active magnet inside the torque wrench insert 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 and 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.



StecoTitanmagnetics® in a new denture (Labside)

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 inner polygon key surfaces of the torque wrench insert. An active magnet inside the torque wrench insert 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!

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-stable 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 esthetically 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 polymerization.



StecoTitanmagnetics® 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 StecoTitanmagnetics® 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

StecoTitanmagnetics® are applied with the help of a torque wrench insert 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 insert. An active magnet inside the torque wrench insert 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

Place the impression post on the insert. An active magnet inside the impression post causes an attraction. Check the seat with fingertips. Take an impression with 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 StecoTitanmagnetics® K-Line, use the corresponding denture magnet. Apply impression material on the impression post and the surrounding tissue according to the space requirements. Stabilize the impression material with an individual tray, wooden sticks or similar.

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 polymerization or vulcanization 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.

Use a positioning cuff to protect the functional surfaces from acrylic, and to provide a resilience space of 0.3 mm. Pull the positioning cuff over the functional surface of the model replica and place the positioning cuff on top. Make sure that the prosthesis 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 prosthesis base at divergent implants. The positioning cuff is made of medical silicone and can be easily removed after the acrylic is cured. If other material than acrylic is used, we recommend testing the positioning cuff with the prosthesis material to avoid bonding of the two materials.

