

StecoTitanmagnetics®

The following instructions apply to StecoTitanmagnetics® System. It contains implantat specific abutments (inserts) and prosthetic universal parts and accessories. The different 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
 stecco-system-technik GmbH & Co. KG • Kollastr. 6 • 22529 Hamburg • Germany
 Telephone +49 (0)40 55 77 81-0 • Telefax +49 (0)40 55 77 81-99
 email info@steco.de • www.steco.de



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 dentures 6 implants are recommended in the upper jaw and 4 in the lower jaw. Depending on anatomic and prosthetic conditions a various number of posts can be indicated. Due to the low lateral force on implant (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	Prothesenmagnet verwendet!		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 acc. DIN 17850 (Ti4) / ASTM F 67 (Grade 4)
 - Magnetic core: Sm2 Co17 (contains Fe and Cu), gastightly welded in titanium
 Positioning cuff: dental silicone
 Laboratory replica: steel 1.4122 (M.00.05.X900)

Advantages of magnetic anchoring

- + easy and stress less 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

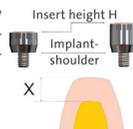
A literature reference list can be ordered from the manufacturer.

Selection of parts

Inserts are offered in different tissue heights with integrated distance sleeve. For choice of correct tissue height a measurement of tissue height is recommended. The height given in the product name and REF is measured from implant shoulder to functional surface. Subgingival inserted StecoTitanmagnetics® should exceed tissue for 1 mm (H>X).

For correct choice of insert refer to product catalogue or system overviews. The choice of product line depends on space limitations, implant axis angle and retention force requirements and indication of implant fixture.

StecoTitanmagnetics® are part of a general concept and must be used only with original Steco® parts and instruments according to the recommendations of stecco-system-technik. Implant parts are adapted to the different implants. Otherwise liability is excluded.



How to use

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

Cleaning advise

There could not be determined increased plaque accretion on the high glossy polished surfaces of inserts (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 magnet parts and due to this to a loss of retention force.

Patients are recommended to let the denture be checked in a time interval of three months to check out the function of the StecoTitanmagnetics®. The dentures have to fit correctly on the jaw. Reline a denture base regularly.

Storage advise

Store clean, dry and protected from sunlight! Do not use if packaging is damaged!



Sterilization and disinfection advise

The inserts are packed not sterile. They can be sterilized in their packaging, if it is not damaged. Sterilization can be performed with moist heat in an autoclave (gravity method or fractionized vacuum 132/134 °C, 3 bar, 5 min). Please refer to advise of sterilization equipment manufacturers instructions as well. Use validated processes only!



Reusability

StecoTitanmagnetics® (except torque wrench inserts) 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 only under responsibility of user. A cleaning and sterilisation advise is available under www.steco.de.

Warning

In use of magnetics special precautions have to be made. Keep distance to magnetic data storages and electronic devices! Cardiac pacemakers are not effected by StecoTitanmagnetics® in regular use, because there is no direct contact (Völkel 1999). The strong magnetic field in MRI diagnoses (Magnetic Resonance Imaging) can destroy the root post cap magnet 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. Make sure to provide this information to the patient!



Loose inserts may lead to thread breakage and / or damage to the implant thread. Patients should immediately go to the dental practice, so that the inserts can be tightened again. It is important to ensure that the prosthesis is formed basal funnel shape 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 a UDI code (HIBC) which contains information to the manufacturer (Steco=ESTO) as well as device and production identification.



Magnetics fields

There are no clinical references for the small static magnetic fields of StecoTitanmagnetics® to be harmful to humans. 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). 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.



Special advise to patients

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



Instruction for use StecoTitanmagnetics®

Explanation of symbols to DIN EN ISO 15223-1

- Keep dry
- Do not use if package is damaged
- Caution, Consult accompanying documents
- Upper limit of temperature
- Unsterile
- Sterilization in steam at 134 °C
- Order number
- Batch code
- Do not reuse
- Caution, Magnetic field
- Manufacturer
- Manufacturing date

CE 0197 Medical products acc. MDD 93/42/EWG

Further symbols

- UDI
- HIBC

Instruction for use

StecoTitanmagnetics® in an existing denture (chairside)

Application

The insert is applied after removing the implant cover screw. Prior to this the insert is placed in the torque wrench insert with its functional surface (convex or conical). The outside 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 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 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

The denture base is ground out in the place above the magnets to take in insert and denture magnet without interferences.

Using the positioning cuff

The positioning cuff protects the surrounding tissue and the functional surfaces from acrylic material. Additionally it provides a 0.3 mm resilience gap between the insert and the prostheses 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.

The positioning cuff is pulled over the insert head. The denture magnet is placed in the flat block-out. Make sure the denture magnet to sit firmly on the positioning cuff. The conical shape of the positioning cuff (No. 1) forms the denture base conically to avoid interferences of the inserts with the denture base at divergent implants. Due to the positioning cuff is made of dental silicone can easily be removed after the acrylic is cured.

For Titanmagnetics® K-Line an additional resilience ring is placed 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

The denture magnets are fixed in the denture with cold curing acrylic. The acrylic material is placed in the denture from the basal side. Make sure to place some acrylic in the retention notch of the prostheses magnet. After this the denture is placed in 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

The insert is applied after removing the implant cover screw. Prior to this the insert is placed in the torque wrench insert with its functional surface (convex or conical). The outside polygon key surfaces of the insert (X-Line: 8faces; 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 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 the insert with pliers or manually!

Impression

The impression post is placed on the insert. An active magnet inside the impression post causes an attraction. Check the seat with finger tips. The impression is taken with a closed individual tray which is spared out on the implant positions for 1 cm. Application of impression material around the impression post has proven to be advantageous. For impression of Titanmagnetics® K-Line the denture magnet can be used.

Manufacturing of model

The model implant is placed into the impression post. It will be attracted with the help of the integrated magnet. The model should be made of an edge stabil dental plaster stone or model acrylic (in implant positions).

Bite registration/ set up

The prostheses 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 prostheses magnets should be used.

Metal framework/ set up key

For better stability a metal framework should be integrated. Before doubling the master model with the prostheses magnets the implant surrounding area above the tissue should be blocked out conically. Functionally and ethetically optimized results are reached by using an set up key for modelling of metal framework.

Finishing

The position cuff protects the functional surfaces from acrylic and provides a 0.3 mm resilience gap. The position cuff is pulled over the functional surface of the model implant. The prostheses magnets will be fixed with composite glue or denture acrylic. It is recommended to apply acrylic or glue in the retention notch of prostheses magnet. The position cuff will be removed 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 the space limitations and force and lateral stability requirements. Choose the insert height according the soft tissue height in a way that the functional surface exceeds tissue for ca. 1 mm. Consider the overall height together with the prostheses magnets in your planning.

Application

StecoTitanmagnetics® are applied with the help of a torque wrench insert and a torque wrench at 20 Ncm. The outside 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 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 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

The impression post is placed on the insert. An active magnet inside the impression post causes an attraction. Check the seat with finger tips. The impression is taken with a closed individual tray which is spared out on the implant positions for 1 cm. Application of impression material around the impression post has proven to be advantageous. For impression of StecoTitanmagnetics® K-Line the denture magnet can be used. Apply impression material on the impression post and the surrounding tissue according the space requirements. Stabilize the impression material with an individual tray, wooden sticks or similar.

Manufacturing of the model

The laboratory replica is placed into the impression post. It will be attracted with the help of the integrated magnet. The model should be made of an edge stabil dental plaster stone or model acrylic (in implant positions).

Integration of prostheses magnets

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

Finishing

Prostheses magnets are fixed in the facial prostheses depending on the material in polymerisation or vulcanisation process. It is recommended to apply acrylic or glue in the retention notch of prostheses magnet. Make sure not to damage the magnets titanium housing or to apply to much heat.

The position cuff protects the functional surfaces from acrylic and provides a 0.3 mm resilience gap. The position cuff is pulled over the functional surface of the model implant. The prostheses magnet is placed in the flat block-out. Make sure the prostheses magnet to sit firmly on the positioning cuff. The conical shape of the positioning cuff (No. 1) forms the prostheses base conically to avoid interferences of the inserts with the prostheses base at divergent implants. Due to the positioning cuff is made of dental silicone can easily be removed after the acrylic is cured. If other material than acrylic is used, we recommend to test the position cuff with the prosthesis material to avoid bonding of the two materials.

