Instruction for use for root post caps

StecoTitanmagnetics®
The following instructions apply to root post cap magnetic system. It contains root post cap StecoTitanmagnetics, prosthetic universal parts and accessories.
The different Steco® products can be destinguished by the first letter in the product number (REF):
V = connection parts U = denture/ prostheses magnets P = positioning cuffs M = model parts

Manufacturer within EU
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Indication
1. Geroprosthetics: Anchoring of hybrid- and partial dentures on class III- (tootless 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. Root post cap Titanmagnetics can be combined with other retention elements.

2. facial prosthetics: anchoring of facial prostheses and ressection prostheses. Root post cap StecoTitanmagnetics® can be used for coupeling segmented prosthese and obturators.

Contraindications are dysfunctions such as bruxism as well as regulary MRI (magnetics resonance imaging) inspection.

Technical Data
For dental and extra oral use root post caps are availiable in two product lines with different size and retention force.

	X-Line		Z-Line	
Product	**Height/Length**	**Diameter**	**Height/Length**	**Diameter**
Root post cap magnet [V]	2.60 mm	4.80 mm	3.00 mm	5.80 mm
Prostheses magnet [U]	2.65 mm	4.80 mm	3.15 mm	5.80 mm
Positioning cuff [P]	0.30 mm	15.00 mm	0.40 mm	15.00 mm
Modelling sleeve [M]	2.05 mm	5.30 mm	----------	----------
Retention force*	1.6 N / 163 g		3.0 N / 306 g	
Modelling tool [M] only X-line, shank ISO 103 (2.35 mm) or ISO 123 (3.0 mm) D 4.8mm			----------	

*Retention forces have been determined acc. DIN 13992.

Materials
Root post cap StecoTitanmagnetics®, denture/ prostheses magnets:
- Housing: Titanium acc. DIN 17850 (Ti4) / ASTM F 67 (Grade 4)
- Magnetic core: Sm_2Co_{17}, gastightly welded in titanium

Positioning cuff: Dental silicone

Modelling sleeve: PMMA

Modelling tool: Steel

Advantages of magnetic anchoring
+ easy and stress less insertion or extraction of prostheses (Gbara 1995), cost-effectiveg (Göhring 1997)
+ good implantat 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 efford for dentists and dental technicians (Stemmann 1995, 1997, Ziesche 1998)

Literature
A literature reference list can be ordered from the manufacturer.

Selction of parts
The selection of the suitable product line depends on space limitations and retention force requirements. For integration of root post cap Titanmagnetics in silicone prostheses (e. g. obturators) magnets with additional retention rings are availiable. Please refer to product catalog and summary papers.

StecoTitanmagnetics® are part of a general concept and must be used only with original Steco parts and instruments according the recommendations of steco-system-technik. Othervise liability is excluded.

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

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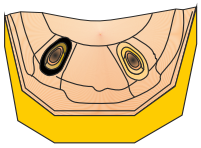
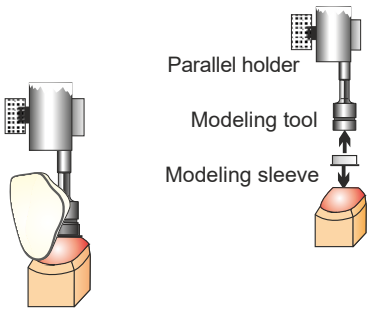
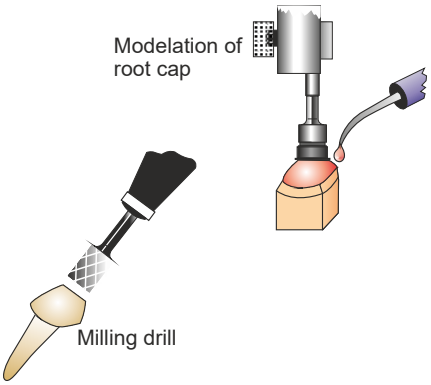
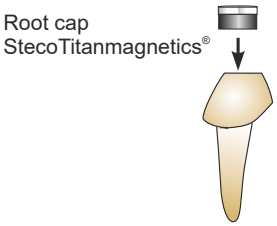
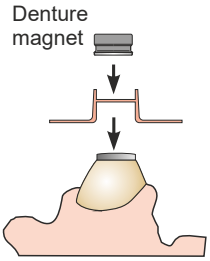
Instruction for installation of root post caps

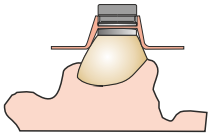


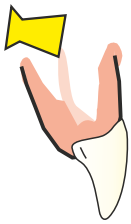












Manufacturing of model:
Make a normal single die stone model. Modelation of a flat root cap as usual.

Modeling tool:
Place the modeling tool in a parallel guide device.
Put the burn out plastic modeling sleeve on.
The modeling tool is available with 2.35 mm shank (ISO 103) or 3.00 mm shank (ISO 123).

Set up:
Set up teeth according esthetic and functional requirements. Fix the set up with a silicone or stone key. Adapt the teeth from the basal side to the root post cap. Plan enough space for root post cap magnet and denture magnet. Place the model sleeve close to the root cap with the help of the modeling tool.

Modelation of root cap:
Adjust the modeling sleeve to the root cap with wax or modeling acrylic. Make sure to put some wax arround the sleeve and to give the root cap a conical shape. Cast the root cap as normal. There are no limitations regarding the casting alloy.

Finishing:
Remove cast pearls inside the cavity with a cylindrical drill to make the magnet fit easily. Avoid unnecessary loss of material sand blast the retention surface with aluminium-oxide (110/125) and polish the root cap.

Gluing of root post cap:
The convex shaped root post cap is glued into the root cap with a mouth compatible dental adhesive. Make sure that all parts are clean, dry and free of grease. The magnet is attached with the polished side (functional surface) upwards. The sandblasted side of the magnet is glued into the root post cap. The polished edge of the magnet is not covered by the root post cap.

Positioning cuff:
After the root post cap has been cemented to the root, the positioning cuff is pulled over the root post cap magnet (only when denture magnet is placed into an existing denture).

Application of denture magnet:
The denture magnet is placed with it polished concave surface on the positioning cuff. It finds it place itselves. Make sure that it sits on the positioning cuff evenly.

Finishing in dental office:
The denture has to be spared out from the basal side to take in the root post cap and the denture magnet. Fast curing acrylic is applied to the retention notch on the outer surface of the denture magnet and to the space under the denture. Put the denture in place and wait for the acrylic to cure. Make sure that the patient holds the correct bite position. Remove recesses with a non-magnetics instrument (wood or plastic). Finish and smoothen the lower surface of the denture. The basal part of the denture surrounding the magnet should be funnel shaped to make sure that the denture can be placed without problems.

Finishing in dental laboratory:
The denture magnet can be integrated into a new denture directly on the master model. The position cuff is pulled over the root post cap. The edges of the position cuff have to be cut to fit perfectly. Fix the position cuff and block undercuts with wax. The clean, dry and degreased denture magnet is put on the position cuff. Make sure that it sits on the position cuff without clamping it.
The denture magnet can be integrated into a new denture if the root post cap is cemented in the mouth allready. Therefore an impression and a stone model of the oral situation with the root post cap is needed. The denture cast procedure is comparable to the above mentioned. Due to the missing magnetic force on the stone model the position cuff and the denture magnet have to be secured with sticky wax. The denture is casted as usual.
The denture magnet can be integrated in an existing denture if the basal side is ground out to provide enough space for the root cap and the denture magnet. A suitable impression of the cemented root cap is required.

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Cleaning advise
There could not be determined increased plaque accretion on the high glossy polished surfaces of StecoTitanmagnetics® (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 advice
Root post caps 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!

Reuseability
StecoTitanmagnetics® are single use products only. Reuse is not allowed due to the risk of surface damages caused by mechanical extraction or reprocessing treatment.

Warning
In use of magnets special precautions have to be made. Keep distance to magnetic data storages and electronic devices! Cardiac pacemacers 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 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!

Never grind the 0.2 mm thin titanium housing!

StecoTitanmagnetics® must not be soldered or welded! The heat would irreversibely 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.

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!

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-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).

Explanation of symbols


Keep dry

Sterilization in steam at 134 °C

Upper limit of temperature


Caution, Consult accompanying documents


Do not use if package is damaged


Do not reuse

Order number


Manufacturer

Unsterile


Caution, Magnetic field

Batch code

Medical products acc. MDD 93/42/EWG

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