

Titanmagnetics® Y-Line extrusion magnets

The following instructions apply to the Titanmagnetics® Y-Line extrusion magnet system, which consists of the extrusion magnets and different distance discs (positioning aid). The different Steco products are identified by the initial letters of the product number: V = connecting parts P = positioning cuffs

Manufacturer within EU

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Indication

1. Magnetic extrusion of teeth and roots. Raise a tooth/root before prosthetic supply (e.g. crowning).
2. For vertical build-up of the alveolar bone as pre implantation method or in the case of a damaged parodontium.

The attractive force between two magnets, which are attached to a fractured root and a thermoformed splint or a temporary prosthesis in a certain distance, is used to shift the fractured root. The positioning aids are used for positioning of the magnets in the requested distance (appropriate force). They are removed after fixing the magnets.

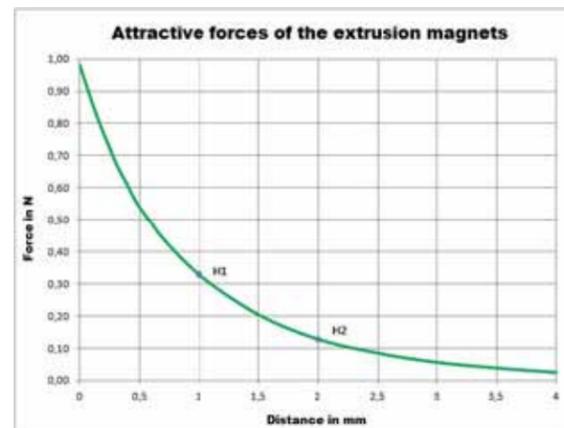
Technical Data

REF	Designation	Description	Diameter	Height
V.62.01.Y245.R	Titanmagnetics Y-Line for extrusion root	Magnet for fixation on the tooth/fractured root/etc.	3.80 mm	2.45 mm
V.62.01.Y245.C	Titanmagnetics Y-Line for extrusion crown	Magnet for fixation on the retaining element/thermoformed splint/temporary prosthesis/etc.	3.80 mm	2.45 mm
P.62.01.Y100	Positioning disc for Y-Line	Positioning disc Y-Line for parallel application of the magnets with a distance of 1 mm	4.50 mm	1.00 mm
P.62.01.Y200	Positioning disc for Y-Line	Positioning disc Y-Line for parallel application of the magnets with a distance of 2 mm	4.50 mm	2.00 mm

Average attractive forces of the extrusion magnets (DIN EN ISO 13017):

Distance in mm	Force in N
0 (maximum force)	0.98
1 (Y100)	0.33
2 (Y200)	0.13

The attractive force between two magnets increases with the reduction of the distance. Attractive forces for larger distances are shown in the following chart:



Material

Extrusion magnets:
- Housing: titanium acc. DIN 17850 (Ti4) / ASTM F 67 (Grade 4)
- Magnetic core: Sm2Co17, (contains Fe and Cu) gastightly welded in titanium
Distance discs (positioning aid): stainless steel 1.4122 X39CrMo17-1

Advantages of magnetic extrusion with Titanmagnetics Y-Line extrusion magnets/ literature

- + preservation of the natural tooth and the periodontium (Durham, Goddard, Morrison, 2003)
- + generation of a sufficient Implant ground through construction of bone (Bongard 2008, Hopmann/Neumeyer, Möhrig 2013)
- + the method is based only on biological principles (Hopmann, Neumeyer, Möhrig 2003)
- + little liability of the patient because of minor invasive procedure (König, Hermann 2007)
- + vitality of the pulpa is kept, differently to surgical extrusion (Krastrl, Weiger 2009)

Selection of the distance disc (positioning aid)

Choose the fitting distance disc (positioning aid) due to the required extrusion distance and force. The starting forces of the positioning aids H1 and H2, as well as the development of the forces, are shown in the table and the chart above.

If the forces may not exceed the value of 0,5 N, the distance between the magnets has to be at least 0,5 mm. In this case the magnet attached to the temporary prosthesis has to be removed before the distance falls below this value.

How to use

Steco® products should only be used by educated physicians, dentists, and surgeons.

Cleaning advice

The high glossy polished functional surfaces of the extrusion magnets are not susceptible for increased plaque accretion.

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. If necessary, the positioning aids should also be cleaned only with plastic instruments. Accretions on the functional surface can lead to increasing distance between the two magnets and due to this to a loss of extrusion force.

Storage advice

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

Sterilization and disinfection advice

The Titanmagnetics Y-Line extrusion magnets are packed unsterile. 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 advice of sterilization equipment manufacturers instructions as well. Use validated processes only!

The positioning discs are packed unsterile, too. They can be sterilized in their packaging (gravity method or fractionized vacuum 132/134 °C, 3 bar, 5 min).

Reusability

The extrusion magnets are single use products only. Reuse is not allowed due to the risk of contamination through deposits of the mounting synthetic. A sterile reconditioning cannot be guaranteed.

The positioning aids can be reused for up to 50 times if they are not damaged and there are no deposits of mounting material left on them. Reuse is not allowed if the positioning aids are damaged or grinded.

The operator bears the responsibility for reuse or the usage of damaged and/or soiled instruments. Reconditioning instructions can be found on www.steco.de. These instructions are significant for the positioning aids as well as for our torque wrench insert.

Warning

In use of magnets special precautions have to be made. 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). It is recommended to remove the extrusion magnets before MRI inspection, because the strong magnetic field can destroy the magnets. The magnets can lose their magnetic force when they are exposed to electromagnetic interference fields, too.

Make sure to provide this information to the patient!

The magnets are heat resistant until 250 °C/ 450 °F. They must not be soldered or welded. The heat would irreversibly damage the magnets. Laser welding can perforate the housing. In case of damaged titanium housing the parts have to be exchanged as soon as possible. Damaged titanium housing leads to corrosion of the magnetic alloy (Sm2Co17) and with this to progressive damaging of the housing.

Never grind the 0,2 mm thin titanium housing!

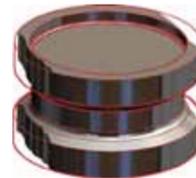
For risk assessment process send damaged parts back to the manufacturer together with product REF, LOT and date of insertion. Please note relevant product data (REF, LOT) in the patient passport! REF + LOT

The positioning aids can be grinded if there is not enough approximal space. It is recommended to grind the positioning aids only on two opposite sites. They should not be grinded further than to the inner boundary, which equates the diameter of the magnets.

There should be enough guidance left for the magnets, so they can be set in a central position to each other. Never use grinded positioning aids again! Safe reconditioning cannot be ensured.

When inserting the magnets, the positioning aid has to be secured against choking or inhalation by the patient. This happens by tethering a thread to the circumferential furrow in the positioning aid. The thread has to be tethered so tightly, that the wire cannot slide down from the positioning aid.

When inserting the magnets with the positioning aid, you have to be aware of not crushing the gingiva. This is particular important in the case of a subgingival tooth/root surface. It is advised to use the positioning aid for integration of the magnet on the root fragment, too. You have to be aware of not pasting over the contact surfaces of the magnets and the positioning aid when inserting them.



**Instruction for use
Extrusion magnets**

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Magnetic fields

There are no clinical references for the small static magnetic fields of Titanmagnetics® to be harmful to humans. 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® Y-Line is up to 170 mT. It is lower than 40 mT (WHO exposure limit) | a distance of 5 mm from the surface.

There is no evidence in the current literature that static occurring near the surface of magnetic fields with a magnetic flux density of up to 170 mT in humans can be locally damaging. Warnung vor magnetischem Feld

Special advice to patients

Note relevant product data (REF, LOT, etc.) in the patient file. Instruct the patient about risks of MRI diagnoses and habitation in areas of electromagnetic fields.

LOT

REF

Explanation of symbols



Not sterile



Sterilization in steam sterilizer at 134 °C



Do not reuse



Upper temperature limit



Charge/LOT number



Catalogue number



Warning magnetic field



Manufacturer



Medical product class IIb acc. MDD 93/42/EWG

Gebrauchsanweisung

To illustrate the workflow was shown on a model.

Magnet insertion

At first put together the two magnets (V.62.01.Y245.C und V.62.01.Y245.R) with the positioning aid (picture 1). Pay attention to the right orientation of the magnets! The polished surfaces have to be directed to the positioning aid.

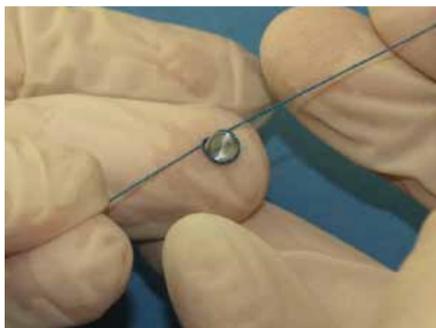


Pict. 1

The use of the positioning aid is necessary to guarantee parallel positioning of the magnets.

The magnets and the positioning aids have to be clean to ensure an axial orientation of the magnets.

Warning! The positioning aid has to be secured against choking/inhalation by using a thread! Therefore a thread has to be strapped in the circumferential furrow of the positioning aid. The wire has to be knotted tightly to ensure it does not loosen from the positioning cuff. (picture 2). The other end of the thread has to be fixed outside the patient. The positioning aid not only provides the right distance between the magnets, but also protects the polished contact surfaces from contamination with composite. For this reason it is advised not to remove the positioning cuff during the application of the composite. Even small residuals of composite on the polished surface of the magnets or between the magnets and the positioning aid can change the orientation of the magnets towards each other.



Pict. 2



Pict. 3

Before mounting the magnets on the tooth/root finally, the correct positioning with regard to the direction of the extrusion and space available to the mounting element, has to be checked. (picture 3).

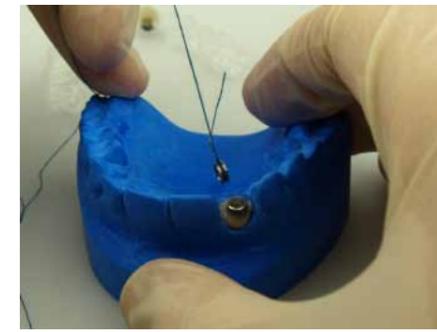
The extrusion magnet facing the root (V.62.01.Y245.R) is mounted with dual- or self hardening composite on the tooth/root (picture 4). Don't use solely optically curing composite, because it may not harden completely under the magnet.



Pict. 4

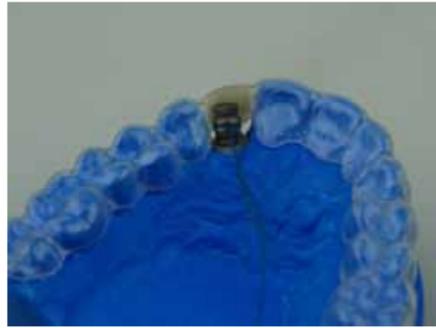


Pict. 5



Pict. 10

After the composite on the tooth/root is bonded (picture 5 and 6), the second magnet (V. 62.01.Y245.C) is fixed on the mounting element (template, splint or similar) (picture 7).



Pict. 6



Pict. 7



Pict. 11

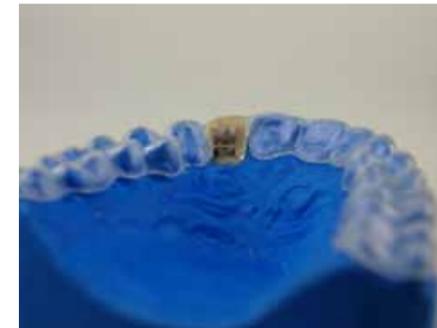
When fixing the magnet with composite, it has to be ensured that the magnet is covered with composite up to the polished contact surfaces (positioning aid marks boundary). Only in this case, a secure fixation and a hygienic surface can be assured. When the composite is bonded, the positioning cuff can be removed. Therefore the mounting element has to be extracted (picture 8-10).



Pict. 8



Pict. 9



Pict. 12

Afterwards the magnet can be surrounded with fixation composite. This prevents the appearance of unhygienic cavities between the mounting element and the magnet.

The surface of the composite should be as smooth as possible for hygienic reasons (picture 12). It is advised to polish the surface after hardening.

Repositioning of the secondary magnet (V.62.01.Y245.C)

For repositioning of the secondary magnet, it must be removed carefully from the mounting element (template, splint or similar). In the case of damaged titanium housing the magnet has to be exchanged!

Afterwards this magnet is positioned above the root side magnet (the one that is mounted on the tooth/root) with the help of the positioning aid. Finally the secondary magnet is fixed in the mounting element as described under Magnet insertion and the positioning aid has to be removed.

The operational procedure is shown on a model for demonstration.