

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

- Magnetic extrusion of teeth and roots. Raise a tooth/root before prosthetic treatment (e.g. crowning).
 - 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.

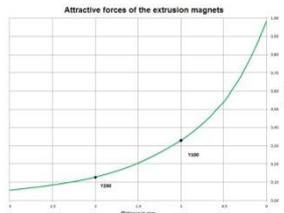
Technical Data

| 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):

| Abstand in mm | Kraft in N |
|--------------------|------------|
| 0 (maximale Kraft) | 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. ASTM F 67 (Grade 4)
- Magnetic core: $\text{Sm}_2\text{Co}_{17}$, (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 (Kraestl, 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

Please note the separate instructions on the next page.

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 ground. 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 adapter.



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 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 ($\text{Sm}_2\text{Co}_{17}$) 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



Instruction for use Extrusion magnets

The positioning aids can be grind if there is not enough approximal space. It is recommended to grind the positioning aids only on two opposite sites. They should not be reduced further than to the inner boundary, which equates to 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 reuse ground positioning aids again as safe reconditioning cannot be ensured.



When inserting the magnets, the positioning aid has to be secured against choking or inhalation by the patient. Therefore, a thread has to be strapped in the circumferential furrow of 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, take care not to dent 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. Also, do not paste over the contact surfaces of the magnets and the positioning aid when inserting them.

Magnetic fields

There are no clinical references of the small static magnetic fields of Titanmagnetics® being 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. In a distance of 5 mm, it is lower than 40 mT (WHO exposure limit). 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.



Special advice to patients

Note relevant product data (REF, LOT, etc.) in the patient file. Instruct the patient about risks of MRI scans on the magnets and habitation in areas of electromagnetic fields. The Titanmagnetics products are marked on their label with a UDI code (HIBC) which contains information of the manufacturer (Steco=ESTO) as well as device and production identification.



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 must 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 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 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. This does not apply to the USA, where it is always necessary to repack the inserts in new packaging.

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.

Repackaging is only necessary if the original sterilization packaging is damaged or if the inserts are removed from the original sterilization packaging, and for the USA. Please then pack the inserts in disposable sterilization packaging (single packaging) that meets the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA Clearance)
- suitable for steam sterilization (temperature resistance up to at least 142°C (288°F) and sufficient vapor permeability)
- adequate protection for the inserts and sterilization packaging against mechanical damage

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.

Reuse

The inserts are disposable products that must not be reused even after repeated processing.

We assume no liability if these instructions are not followed.



Explanation of symbols DIN EN ISO 15223-1



Manufacturer



Keep dry



Do not reuse



Caution, Consult accompanying documents



Order number



Batch code



Unique Device Identification



Health Industry Bar Code



Manufacturing date



Do not use if package is damaged



Caution, Magnetic field



Upper limit of temperature



Medical products
scc. MDD
93/42/EWG

A model was used to illustrate the workflow.

Magnet insertion

First, place the positioning aid between the magnets (V.62.01.Y245.C and V.62.01.Y245.R) (Fig. 1). Pay attention to the correct orientation of the magnets! The polished surfaces have to be directed to the positioning aid.

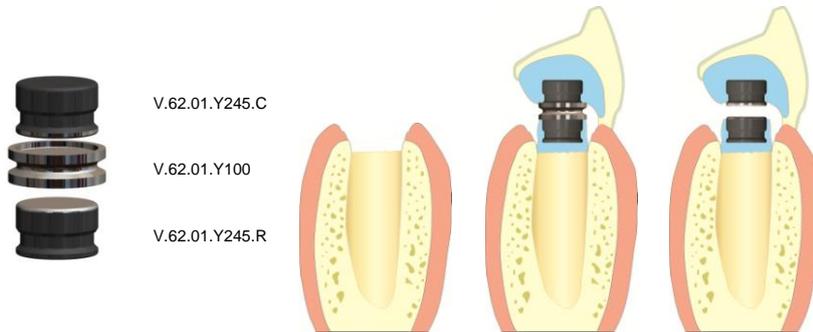


Fig. 1

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.

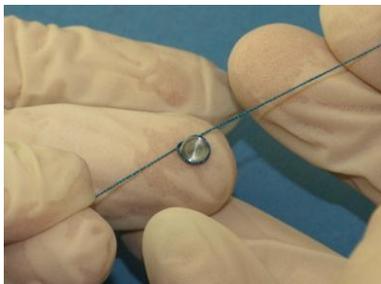


Fig. 2



Fig. 3



Fig. 4

Warning! The positioning aid has to be secured against choking/inhalation by using a thread! This 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. (Fig. 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.**

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

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



Fig. 5



Fig. 6



Fig. 7

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



Fig. 8

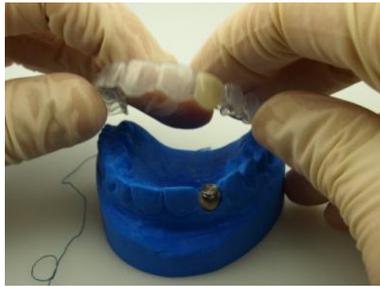


Fig. 9

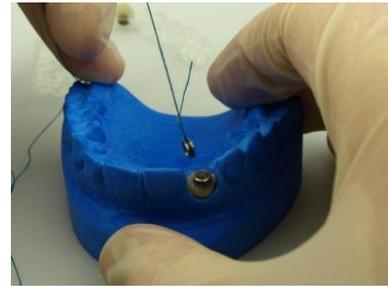


Fig. 10

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 (Fig. 8-10).

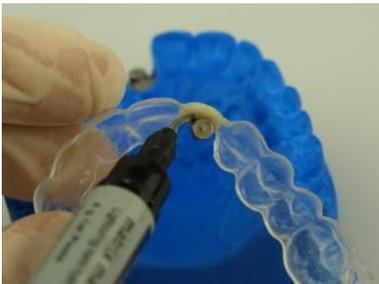


Fig.11



Fig. 12

Afterwards, the magnet can be surrounded with fixation composite. This prevents the appearance of unhygienic cavities between the mounting element and the magnet (Fig. 11).

The surface of the composite should be as smooth as possible for hygienic reasons (Fig. 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.

If the titanium case is damaged, the damaged magnet must be replaced due to the risk of corrosion!