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 distance discs (positioning aids) are identified by the initial letters of the product number: V = connecting parts P = positioning cufs.

Technical Data

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

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

<table>
<thead>
<tr>
<th>Distance in mm</th>
<th>Force in N</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (maximum force)</td>
<td>0.98</td>
</tr>
<tr>
<td>1 (Y100)</td>
<td>0.33</td>
</tr>
<tr>
<td>2 (Y200)</td>
<td>0.33</td>
</tr>
</tbody>
</table>

The positioning aids are used for positioning of the magnets in the requested distance (appropriated splint or a temporary prosthesis in a certain distance is used to shift the fractured root). The magnetic 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 (appropriated 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 (appropriated splint or a temporary prosthesis in a certain distance is used to shift the fractured root).

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 reduced before the forces 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 magnets and due to this 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).

Application of the magnets with a distance of 1 mm

The magnets are heat resistant until 250 °C / 450 °F. They must not be soldered or welded. Safe reconditioning cannot be ensured.

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 (Völker 1999). It is recommended to label 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 sterilized if there is not enough approximal space. 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 magnets and due to this a loss of extrusion force.

There is no evidence in the current literature that static magnetic fields of Titanmagnetics® is up to 170 mT. It is lower than 40 mT (WHO exposure limit) I a distance of 1 m from the surface. There is no evidence in the current literature that static magnetic fields with a magnetic flux density of up to 170 mT in humans can be locally damaging. Warning 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.

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) I a distance of 1 m from the surface.
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.

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.

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.

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).

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

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).

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.