Instruction for use Extrusion magnets

K.62.01.EN04/12.21

Content

Definition of symbols

	name adress YYYY-MM-DD	Manufacturer, Manufacturing date			Consult instruction for use		Caution, Magnetic field		Caution!
	Do not reuse		Upper limit of temperature		non-sterile		Do not use if package is damaged		Keep dry
REF	Order number	LOT	Batch code	UDI	Unique Device Identification	HIBC	Health Industry Bar Code	Qty.	Quantity
MD	Medical product	Rx only	Prescription	CE	CE mark	CE 0197	CE mark and identification of the notified body		

1. Introduction

The instruction for use is part of the medical device. It contains important instructions for safety, use and disposal. Familiarise yourself with all operating and safety instructions before using the product. Only use the product as described and for the specified areas of application. Do not hand over the products to third parties.

1.1 Manufacturer/ marketer within the EU

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1.2 Advantages of magnetic extrusion with Titanmagnetics® Y-Line extrusion magnets

+ 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 (Krastl, Weiger 2009)

1.3 Literature

A literature reference list can be ordered from the manufacturer.

1.4 Titanmagnetics®

The following instructions apply to the Titanmagnetics® Y-Line extrusion magnet system, which consists of the extrusion magnets and different positioning aids. The different Steco products are identified by the initial letters of the product number: V = Connecting parts; P = Positioning aids; S = Set
All products are shown in the following table.

REF	Product description	Figure
V.62.01.Y245.C	Extrusion magnet for crown	
V.62.01.Y245.R	Extrusion magnet for root	
P.62.01.Y100	Positioning aid H 1.00 mm	
P.62.01.Y200	Positioning aid H 2.00 mm	

1.5 Material

Extrusion magnets:
- Housing: titanium acc. ASTM F 67 (Grade 4)
- Magnetic core: Sm_2Co_{17}, (contains Fe and Cu) gastightly welded in titanium

Positioning aids: stainless steel 1.4122 X39CrMo17-1

2. Intended use

2.1 Indications

Magnetic extrusion of teeth and roots.
1. To elevate a tooth/tooth root prior to a prosthetic restoration (e.g. crowning) if they are too deep for a prosthetic restoration but potentially suitable for a prosthetic restoration after successful extrusion (crown-root ratio more than 1:1, space conditions, periodontal condition).
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.

2.2 Contraindication

1. Intolerance to the materials used.
2. Inaccessibility of the tooth or tooth root to attach the magnet.
3. Ankylosis or hypercementosis (the additional load would cause the penetration of the anchor teeth).
4. Vertical root fracture
5. Longitudinal fracture of the tooth

The criteria are not absolute and do not apply if the purpose of extrusion is to increase the amounts of bone in a jaw chamber prior to placement of a dental implant (Bach, N., et. al. 2004).

2.3 User and environment

Steco-products should only be used by doctors, dentists, surgeons and dental technicians familiar with the system and only in medical practices and laboratories. The products may only be used in accordance with these instructions for use. The manufacturer accepts no liability for damage due to improper use.

3. Safety instructions

When handling with magnets, special precautions apply.

- **NOTICE!** When carrying out MRI (Magnetic Resonance Imaging) diagnoses, the extrusion magnets must be removed beforehand to avoid damaging the magnets. The magnetic force can also be lost when working with electromagnetic interference fields, for example in transformer stations.

- **NOTICE!** Keep at least 1 cm distance from magnetic data storage devices and electronic equipment. Cardiac pacemakers are not affected by Titanmagnetics® when used as intended, as there is no direct contact (Völkel 1999).

- **NOTICE!** If the titanium casing is damaged (perforation), the affected parts must be replaced immediately. The non-mouth-resistant magnetic alloy (Sm_2Co_{17}) can be released in case of damage and lead to a loss of magnetic force and further destruction of the titanium casing due to corrosion. The titanium shells, which are up to 0.2 mm thin, must never be ground, otherwise the corrosion protection will be lost.

- **NOTICE!** Magnetic cores are heat resistant until 250 °C/ 450 °F and must not be soldered or lasered. The high level of heat applied during soldering will cause an irreversible loss of magnetic force. Laser cutting can perforate the titanium sheath.

- **NOTICE!** 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.

- **NOTICE!** 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.
- **NOTICE!** Also, do not paste over the contact surfaces of the magnets and the positioning aid when inserting them.
- **NOTICE!** When attaching the magnets, make sure that the distances are maintained with the help of the positioning aids in order to avoid rapid extrusion. Rapid extrusion poses the risk of tearing the periodontal ligament and causing dental ankylosis (Bach N., et. al.2004). Rapid extrusion is achieved with forces above 50 g. Forces of 15 g for the root of a lower incisor and 60 g for a molar are sufficient for slow extrusion. Some authors recommend that the maximum force for a slow movement should not exceed 30 g, while fast extrusions are performed with forces above 50 g (Bach N., et. al.2004). It should be noted that the force increases with decreasing distance and thus possibly enters the range of rapid extrusion. Depending on the therapeutic approach, the treatment should be interrupted and the magnet repositioned.
- **NOTICE!** It is not recommended to combine other magnets with Titanmagnetics extrusion magnets or to stack several extrusion magnets, as otherwise unpredictable forces may occur, which in the worst case may lead to tooth loss or ankylosis.

3.1 Traceability

For risk control purposes, damaged parts must be returned to the manufacturer or distributor, stating REF and LOT numbers and insertion date. The extrusion magnets are marked on the label with a UDI code (HIBC) containing information on the manufacturer (Steco=ESTO) as well as product and batch identification.

3.2 Reporting of serious incidents

It is a legal requirement to report any serious incidents that occur in connection with the product to the manufacturer and/or the competent authority.

3.3 Special advice to patients

Please note important data such as batch number (LOT) and article number (REF) in the patient file! Please inform your patients about the safety instructions!

4. Product information

4.1 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.

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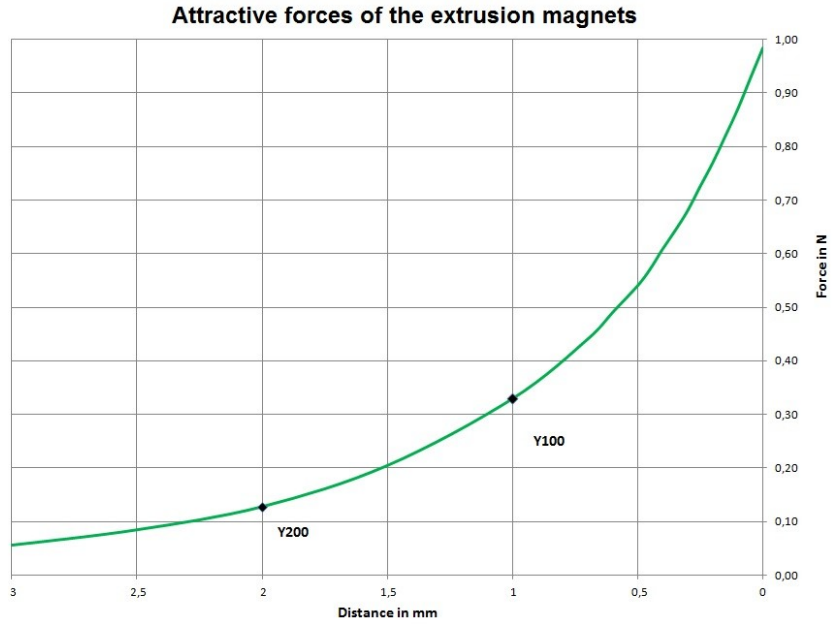
4.2 Technical Data

REF	Designation	Description	Diameter	Height
V.62.01.Y245.C	Titanmagnetics Y-Line extrusion magnet (crown) for fixation on splint	Magnet for fixation on the retaining element/thermoformed splint/temporary prosthesis/etc.	3.80 mm	2.45 mm
V.62.01.Y245.R	Titanmagnetics Y-Line extrusion magnet (root) for fixation on root	Magnet for fixation on the tooth/fractured root/etc.	3.80 mm	2.45 mm
P.62.01.Y100	Positioning aid for Y-Line H1	Positioning aid 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 aid for Y-Line H2	Positioning aid 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	Weight in g
0 (maximum force)	0,98	100
1 (Y100)	0,33	33
2 (Y200)	0,13	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:

5. Product selection

5.1 Selection of the positioning aid

Choose the fitting positioning aid (distance 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.

6. Before use

6.1 Reusability/ Durability

Due to the possible contact with the oral mucosa, reprocessing of the extrusion magnets and the positioning aid is necessary. Extrusion magnets are to be used only once. Reuse is not permitted as surface damage may occur. The positioning aids can be reused up to 50 times with appropriate care and provided they are undamaged and not dirty. Any reuse beyond this or the use of damaged and/or soiled instruments is the responsibility of the user. Provided that the warnings are observed, we guarantee at least five years of durability against chafing (perforation).

6.2 Instructions for sterilisation and disinfection/ reprocessing instructions

These reprocessing instructions apply to the positioning aids and to the one-time reprocessing of the extrusion magnets.

General principles

All instruments must be cleaned, disinfected and sterilised prior to each use; this applies in particular to the first use following delivery because all instruments are delivered unsterile (Cleaning and disinfection following removal of the protective transport packaging; Sterilisation after packaging). Effective cleaning and disinfection is an essential prerequisite for effective sterilisation.

As part of your responsibility for the sterility of the instruments during use, please note that:

- in principle only adequate device and product-specific validated methods are used for the cleaning/disinfection and sterilisation,
- the used devices (washer-disinfector, steriliser) are regularly maintained and checked, and
- 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).

Attention: For the respective instruments, additional or deviating specifications must be observed (see chapter "Special instructions").

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Cleaning and disinfection

Basic principles

If possible, an automated method (washer-disinfector) should be used for the cleaning and disinfection. A manual method - also when using an ultrasound bath - should only be used if an automated method is not available, due to the markedly reduced effectiveness and reproducibility of a manual method.

The pre-treatment should be carried out in both cases.

Pre-treatment

Procedure:

1. Rinse the disassembled instruments under running water for at least 1 min (temperature < 35°C/95°F).
2. Place the instruments in the pre-cleaning bath[1] for the specified exposure time so that the instruments are sufficiently covered. Make sure that the instruments are not touching. Support the pre-cleaning by carefully brushing all surfaces (at the beginning of the exposure time, at least 1 min each time, for aids see chapter "Special instructions").
3. Then remove the instruments from the pre-cleaning bath and rinse them thoroughly at least five times (for at least 1 min) with water.

When selecting the cleaning agent[1] to be used, it should be ensured that:

- it is generally suitable for the cleaning of metal and plastic instruments,
- the cleaning agent is compatible with the instruments (see section “Material durability”).

The concentrations, temperatures, exposure times and rinsing guidelines specified by the manufacturer of the cleaning agent or the cleaning agent and disinfectant must be strictly observed. Only use freshly prepared solutions and water that is sterile or of low microbiological contamination (max. 10 microbes/ml) as well as low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/ highly purified water), and only use a soft, clean, lint free cloth and/or filtered air for drying.

[1] If for example, for health and safety reasons a combined cleaning agent and disinfectant is used, please take into account that it should be aldehyde-free (as aldehyde fixes blood stains), and should be proven to be effective (e.g. VAH/DGHM or FDA/EPA approval/ clearance/ registration).

Please note that the disinfectant that may be used for pre-treatment serves only to protect the personnel and cannot replace the disinfection step to be carried out later, after cleaning.

Automated cleaning/disinfection (washer-disinfector)

When selecting the washer-disinfector, it should be ensured that:

- the washer-disinfector corresponds in principle to DIN EN ISO/ANSI AAMI ST15883 and that it has proven effectiveness (e.g. DGHM or FDA approval/ clearance/ registration or CE marking pursuant to DIN EN ISO/ANSI AAMI 15883),
- if possible, a verified programme for thermal disinfection (A_0 value ≥ 3000, alternatively for older devices at least 5 mins at 90 °C) is used (alternatively, if chemical disinfection is performed, the risk of disinfectant residue on the instruments should be taken into consideration),
- the used programme is suitable for the instruments and includes sufficient rinse cycles, (at least three depleting steps after cleaning (or neutralisation, if applied) (or neutralisation, if applied) or conductivity control recommended to effectively prevent detergent residues)
- only water that is sterile or of low microbiological contamination (max. 10 microbes/ml) as well as low in endotoxins (max. 0.25 endotoxin units/ml) is used for the rinsing (e.g. purified water/ highly purified water),
- the air used for drying is filtered and
- the washer-disinfector is regularly maintained and checked.

When selecting the cleaning agent system to be used, it should be ensured that:

- it is generally suitable for the cleaning of metal and plastic instruments,
- a suitable disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA approval/clearance/registration or CE marking) is additionally used (provided that there is no thermal disinfection) and that this is compatible with the used cleaning agent, that the programme used contains a sufficient number of rinsing cycles (at least two depleting steps after disinfection or conductivity control are recommended to effectively prevent residues of the disinfectant) and
- the chemicals used are compatible with the instruments (see section “Material durability”).

The concentrations specified by the manufacturer of the cleaning agent, and if applicable the disinfectant, must be strictly observed.

Procedure:

1. If applicable (see chapter "Special instructions"): Disassemble the torque wrench adapters as much as possible
2. Place the instruments - using a close-meshed tray (small parts basket) - in the washer-disinfector. Ensure that the instruments are not touching and that a position is selected in which the spray jets of the washer-disinfector are not obscured.
3. Start the programme.
4. Remove the instruments from the washer-disinfector after the programme sequence.
5. Check and package the instruments as soon as possible after they are removed (see section “Checks”, “Maintenance” and “Packaging”, if applicable after additional drying in a clean location).

Verification of the general suitability of the instruments for effective automated cleaning and disinfection was provided by an independent, accredited testing laboratory using the G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the pre-cleaning agent and cleaning agent neodisher MediZym (Dr. Weigert GmbH & Co. KG, Hamburg). Worst case settings have been considered in relation to the procedure described above as well as to the concentration specified in the detergent instructions for use (taking into account the detergent manufacturer's specifications according to Note 1 in Chapter 6.6.2.2 of ISO 17664-1: 2021 as given above).

Manual cleaning and disinfection

When selecting the cleaning agent and disinfectant to be used, it should be ensured that:

- they are generally suitable for the cleaning and disinfection of instruments made out of metals and plastics,
- the cleaning agent - if applicable - is suitable for ultrasonic cleaning (no foam formation),
- a suitable disinfectant with proven effectiveness is used (e.g. VAH/DGHM or FDA approval/clearance/registration or CE marking) and that this is compatible with the used cleaning agent and
- the chemicals used are compatible with the instruments (see section “Material durability”).

If possible, combined cleaning agents/disinfectants should not be used. Only in cases of very low levels of contamination (no visible soiling) can combined cleaning agents/disinfectants be used (not in the USA).

The concentrations, exposure times and rinsing guidelines specified by the manufacturer of the cleaning agent and disinfectant must be strictly observed. Only use freshly prepared solutions, water that is sterile or of low microbiological contamination (max. 10 microbes/ml) as well as low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/ highly purified water), and only use filtered air for drying.

Manual cleaning

1. Place the instruments in the cleaning bath for the specified exposure time so that the instruments are completely covered by the liquid, careful brushing of the bores and the outer surface (at the beginning of the exposure time, at least 1 min each time, for aids see chapter "Special instructions").
2. Ensure that the instruments are not touching and that there are no air bubbles in the cavities.
3. Remove the instruments from the cleaning bath and rinse them thoroughly with water for 1 min at least three times.
4. Check the instruments (see section “Checks” and “Maintenance”).

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Manual disinfection

1. Place the disassembled, cleaned and checked instruments into the disinfection bath for the specified exposure time in such a way that the instruments are completely covered by the liquid.
2. Ensure that the instruments are not touching and that there are no air bubbles in the cavities.
3. Remove the instruments from the disinfection bath and rinse them thoroughly with water for 1 min at least three times.
4. Dry the instruments by blowing off/ blowing out with filtered compressed air.
5. Package the torque wrench adapters as soon as possible after they are removed (see section “Packaging”, after additional drying in a clean location if necessary).

Verification of the general suitability of the instruments for effective manual cleaning and disinfection was provided by an independent, accredited testing laboratory using the pre-cleaning agent and cleaning agent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). Worst case settings were considered in relation to the procedure described above as well as to the instructions for use of the detergent and disinfectant.

Checks

Following the cleaning or cleaning/disinfection, check all of the instruments for corrosion, damaged surfaces, splintering and soiling (in particular on the wrench flats) and aidard damaged instruments (for the limit on the number of reuses see section “Reusability”). Any instruments that are still dirty must be cleaned and disinfected again.
If applicable (see chapter "Special instructions"):
Pay particular attention to the O-rings on an intact surface. None of the components (e.g. a burr) that could find their way into the implant or the surgical site should be detached from the surface. Damaged O-rings must be replaced so as to guarantee a reliable hold of the torque wrench adapter in the torque wrench. In addition, pay attention to the intactness of the wrench flats.

Maintenance/assembly

Instrument oils and/or instrument lubricants must not be used.

Packaging

Please package the instruments in disposable sterilisation packaging (single-use packaging) that meets the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- suitable for steam sterilisation (temperature resistance up to at least 142°C (288°F) and sufficient vapour permeability)
- adequate protection for the torque wrench adapters and sterilisation packaging against mechanical damage

Sterilisation

Only the below listed sterilisation methods should be used for the sterilisation; other sterilisation methods are not permitted.
Steam sterilisation

- fractionated vacuum method or gravity displacement method[2] (with adequate product drying[3])
- steam steriliser 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 sterilisation temperature 138°C (280°F; plus tolerance in accordance with DIN EN ISO 17665)
- sterilisation time (duration of exposure at the sterilisation 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)[4]	at least 40 mins at 121°C (250°F)
Other countries	at least 20 mins at 121°C (250°F)	Not recommended

[2] It is only permitted to use the less effective gravity displacement method if the fractionated vacuum method is not available

[3] The drying time predominantly depends on factors that are the sole responsibility of the user (e.g. type of steam steriliser actually used, how it is equipped (in particular passive or active drying) as well as its maintenance and calibration status, the actually used sterilisation 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.

[4] or 18 mins (inactivation of prions)

Moreover, do not use dry heat sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, or plasma sterilisation.
If applicable (see chapter "Special instructions"):
Verification of the general suitability of the torque wrench adapter for effective steam sterilisation was provided by an independent, accredited testing laboratory using the steam steriliser 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 sterilisation, the torque wrench adapters must be kept dry and dust-free in the sterilisation packaging.

Material durability

When selecting the cleaning agents and disinfectants please ensure that they do not contain the following components:

- organic, mineral and oxidizing acids (minimum permitted pH value 5.5)
- strong alkaline solutions (maximum permitted pH value 8.5, neutral/enzymatic cleaners recommended)
- organic solvents (e.g. alcohols, ethers, ketones, petroleum ether)
- oxidizing agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

Never clean any of the instruments with metal brushes or steel wool.
All instruments may only be exposed to temperatures not exceeding 142°C (288°F).

Reusability

The extrusion magnets are not suitable for reuse. The positioning aids can be reused up to the number specified in the chapter "Special instructions", provided they are undamaged and free of dirt (see also chapter "Inspection"). Any further use or use of damaged and/or soiled instruments is the responsibility of the user.
We assume no liability if these instructions are not followed.

Documentation

You can digitally monitor the number of times processing is carried out or document this using the K.00.75.… form.

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Special notes

		Extrusion magnets	Positioning aids
Brush		Soft standard brush (toothbrush)	Soft standard brush (toothbrush)
Special procedure for	Dismantling	-	If composite residues are still present or ground: Dispose (no reuse)
	Pre-treatment	Brushes	Brushes
	Manual cleaning/ disinfection	Brushes	Brushes
	Mechanical cleaning/ Disinfection	in small parts basket	in small parts basket
	Maintenance/ assembly	Standard Oiling or greasing prohibited	Standard Oiling or greasing prohibited
Packaging		Standard	Standard
Sterilisation		Standard	Standard
Maximum permissible number of cycles		1 (!)	50 (only if no composite residues are present or positioning aids are not ground)

7. Storage and minimum shelf life

Store clean and dry! Can be stored in a non-sterile state until the best-before date has been reached (see sterilisation)! Use only with undamaged packaging! Conventional reprocessing and repackaging are not possible. If packaging is damaged on delivery contact the manufacturer.

8. Maintenance / assembly

8.1 Cleaning

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 magnet 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.

9. Troubleshooting

Possible malfunction	Possible cause	Action
Root not extruded by at least 0.5 mm after at least two weeks	Forces too low, ligaments not cut.	Reposition magnets, cut ligaments if indicated.
Root is not extruded vertically	No positioning aid used to ensure parallel alignment of the magnets.	Reposition the magnets. If the magnet is damaged during repositioning, please replace it.

10. Disposal

The products can be disposed of like other potentially infectious products, according to country-specific legal regulations.

11. Installation

The workflow was shown on a model for illustration.

11.1 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.

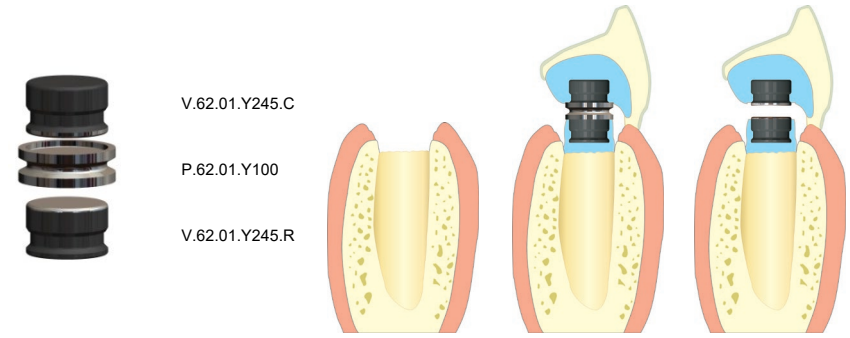

Fig. 1

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.

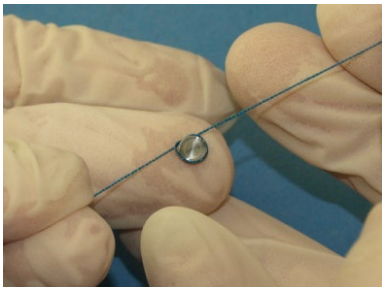

Fig. 2

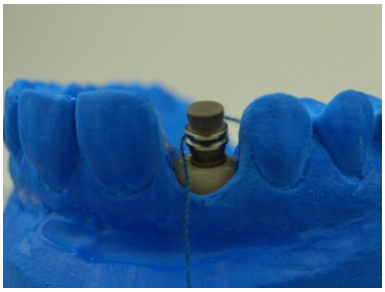

Fig. 3

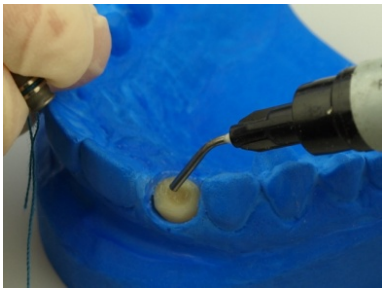

Fig. 4

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.

Note the alignment of the magnet poles to each other. The polished surface of the extrusion magnet for the root must face the polished surface of the extrusion magnet for the splint, otherwise they will repel each other.

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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.

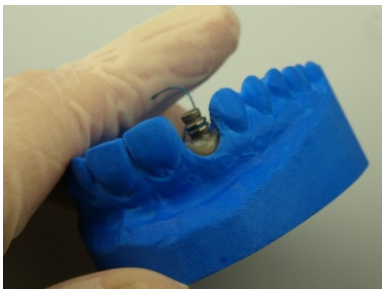

Fig. 5

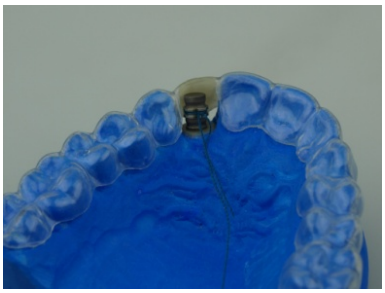

Fig. 6

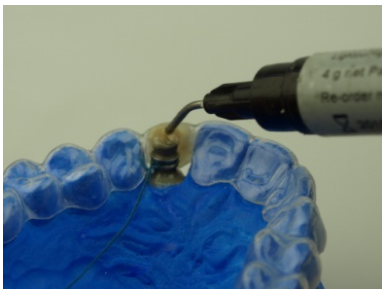

Fig. 7

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).

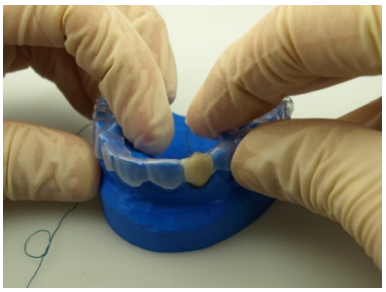

Fig. 8

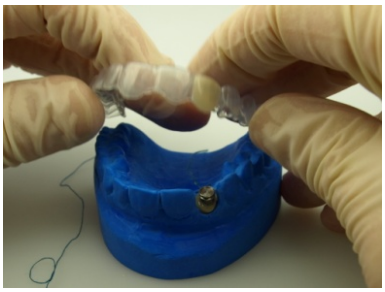

Fig. 9

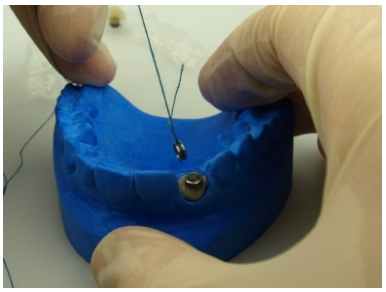

Fig. 10

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).

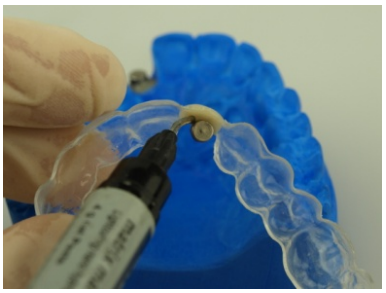

Fig.11

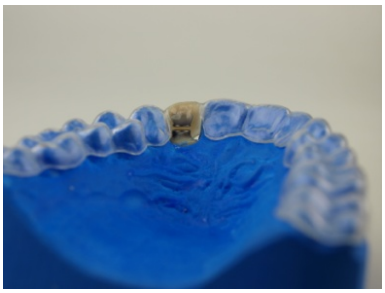

Fig. 12

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.

11.2 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!

11.3 Duration of the treatment

The duration of the treatment depends on the size, the condition of the tooth to be extruded and the distance (force) of the two magnets as well as the severance of the ligaments and cannot be clearly predicted. Results can be observed after only a few days but also after several months. For anterior teeth, the literature usually describes a period of one week for 1 mm, with severed ligaments.

11.4 Completion of the treatment

After reaching the desired retention height, the extrusion magnets are carefully detached from the tooth by removing the luting composite. In difficult-to-reach situations, the magnet can also be removed destructively with rotating instruments under suction. Care must be taken not to damage the tooth and surrounding tissue.

To stabilise the tooth position for prosthetic use, it is recommended to retain the tooth.

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