














## Content:

1. Introduction
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4. Product information
5. Product selection
6. Before use
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10. Disposal
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## Key to symbols

	Name Address YYYY-MM-DD	Manufacturer in combination with Manufacturing date			Consult Instructions for use		Medical product
	Do not reuse	Rx only	Prescription		Non-sterile	Qty.	Quantity
	Order number		Batch code		Unique Device Identification		Health Industry Bar Code
	CE mark		European Representative		Caution!		Distributor

## 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.

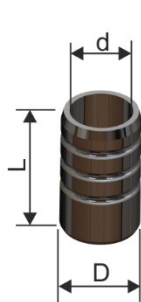
### 1.1 Manufacturer

steco-system-technik GmbH & Co. KG • Kollastr. 6 • 22529 Hamburg • Germany  
Telephone +49 (0)40 557781-0 • Fax +49 (0)40 557781-99 • Email [info@steco.de](mailto:info@steco.de) • [www.steco.de](http://www.steco.de)

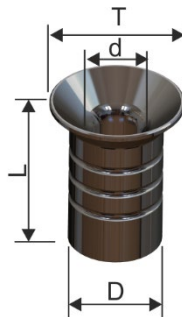
### 1.2 Description of the StecoGuide system components

The StecoGuide system consists of single, double and guide sleeves made of titanium with various diameters and lengths, and titanium reference balls of various diameters. Accessories: template drills and pressing tools for the titanium sleeves.

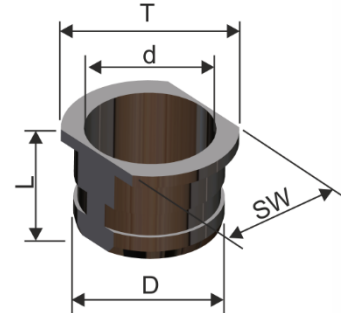
The following letters stand for: D = outer diameter, d = inner diameter, L = length, T = funnel/collar diameter, SW = width across flats



Titanium single sleeves,  
Titanium outer sleeves open for lateral access



Titanium double sleeves



Titanium guide sleeves, Thommen sleeves,  
anchor pin sleeves, Titanium collar sleeves

### 1.3 Materials

The sleeves and reference balls defined in these Instructions for use are made of: pure titanium ASTM F67 (Grade 4)

Template drills: carbide

Insertion tools: 1.4305 steel

## 2. Using StecoGuide

### 2.1 Intended purpose

StecoGuide sleeves and equipment for implant planning and template-guided surgery are intended for determining optimal prosthetic and anatomical/surgical implant positions and for insertion into planning and drilling templates.


#### Indication:

The inner diameter of the titanium sleeves is specified by the number after the D in the product number (e.g. inner sleeve M.27.03.D235 = diam. 2.35 mm).

- Titanium reference balls are used for simple X-ray diagnostic imaging and as reference elements for computer-aided implant planning systems.
- Titanium single sleeves are indicated for pre-implantation planning and simple surgical implementation of planned implant positions.
- Titanium double sleeve systems are indicated for use in planning and drilling templates and during the first drilling steps (e.g. pilot drilling). The titanium outer sleeve is the master sleeve of the titanium double sleeve system and it accommodates the titanium inner sleeves. The titanium inner sleeve reduces the diameter to the nominal size of the drill. The outer diameter of the titanium inner sleeve must be suitable for the inner diameter of the titanium outer sleeve. An open outer sleeve enables drilling in tight spaces by means of lateral insertion. A titanium inner sleeve with an inner diameter of 1 mm is available for template-guided endodontics.
- Titanium guide sleeves are indicated for insertion into surgical drilling templates for use with drills that have corresponding cylindrical guide elements or are guided in separate inserts (drill keys).



Specific indications are listed in the following table.

 The double sleeve systems StecoGuide (Universal), StecoGuide for Thommen Medical and StecoGuide CeHa, shown in the table below, are not compatible with each other.

System	Device image	REF	Dimensions in mm	Indication
Titanium reference ball		M.27.09.D...	$\varnothing$ 2.5 and $\varnothing$ 5.0	Simple X-ray diagnostics and as reference elements for computer-aided implant planning systems e.g. $\varnothing$ 5.0 mm for mucosal thickness measurement or $\varnothing$ 2.5 mm position marker
Titanium single sleeve		M.27.01.D...	D = $\varnothing$ 3.0 d = $\varnothing$ 2.0 / L 5.0 and d = $\varnothing$ 2.35 L 5.0 and 10.0	Pre-implantation planning and simple surgical implementation of planned implant positions - particularly suited to use in planning templates - easy to measure in X-ray images - for standard drill shank - simple surgical guidance
Titanium collar sleeve		M.27.31.D...	D = $\varnothing$ 3.0 d = $\varnothing$ 2.0 L = 5.0	Pre-implantation planning and simple surgical implementation of planned implant positions - collar diameter 4.0 mm
Titanium double sleeves (universal) 		M.27.03.D...	D = $\varnothing$ 3.5 d = $\varnothing$ 1.5 to $\varnothing$ 2.8 L = 6.0 or 10.0 T = $\varnothing$ 5.0	<b>Titanium inner sleeve with funnel:</b> - easy insertion - can be replaced - can be inserted directly into a template as a "single sleeve" - funnel diameter 5.0 mm - collar height see 11.3
		M.27.24.D...	D = $\varnothing$ 3.5 d = $\varnothing$ 1.16 to $\varnothing$ 2.35 L = 5.0 T = $\varnothing$ 5.0	<b>Titanium inner sleeve with depth stop:</b> - for drills with a small depth stop - collar height see 11.3
		M.27.28.D...	D = $\varnothing$ 3.5 d = $\varnothing$ 1.0 L = 5.0 T = $\varnothing$ 5.0	<b>Titanium inner sleeve for endodontics:</b> Insertion into surgical drilling templates for use with 1.0 mm Endoseal drills (ATEC Dental) - collar height see 11.3
		M.27.02.D...	D = $\varnothing$ 4 d = $\varnothing$ 3.5 L = 5.0 and 6.0 T = $\varnothing$ 5.0	<b>Titanium outer sleeve:</b> - sits securely in the template - collar height see 11.3
		M.27.18.D...	D = $\varnothing$ 5.0 d = $\varnothing$ 3.5 L = 6.0	<b>Titanium outer sleeve open for lateral access:</b> - for limited space - drills can enter over complete sleeve length - inner sleeve can enter in upper area, but is guided in lower area to prevent tilting
Titanium double sleeves for Thommen Medical 		M.27.25.D...	D = $\varnothing$ 3.55 d = $\varnothing$ 2.02 and $\varnothing$ 2.88 L = 6.0 T = $\varnothing$ 5.0	<b>Titanium inner sleeve with funnel:</b> - for VECTODrill pilot drills $\varnothing$ 2.0 mm and step drills $\varnothing$ 2.8 mm - collar diameter of the depth stop $\varnothing$ 5.0 mm - collar height 0.5 mm
			D = $\varnothing$ 4.4 d = $\varnothing$ 3.55 L = 6.0	<b>Titanium outer sleeve:</b> - sits securely in the template - for VECTODrill pilot drills $\varnothing$ 3.5 mm – collar diameter 5 mm - collar height 0.5 mm
CeHa double sleeves 		M.27.06.D...	D = $\varnothing$ 4.5 d = $\varnothing$ 1.6 to $\varnothing$ 3.8 L = 5.0 T = $\varnothing$ 6.0	<b>Titanium inner sleeve with funnel:</b> - suitable for CeHa outer sleeves d 4.5 mm - funnel diameter $\varnothing$ 6.0 mm
		M.27.05.D...	D = $\varnothing$ 5.0 d = $\varnothing$ 4.5 L = 5.0 T = $\varnothing$ 6.0	<b>Titanium outer sleeve:</b> - sits securely in the template - collar height see 11.3
Titanium guide sleeve		M.27.15.D...	System-related	- for "full-guided" surgical kits - alternative sleeves for open planning systems - diameters and lengths adapted to the guide sleeves of established surgical kits Indicated for insertion into surgical drilling templates for use with drills that have corresponding cylindrical guide elements or are guided in separate inserts (drill keys). <b>For the dimensions, see the sleeve overview/order form</b>
Anchor pin sleeve		M.27.20.D...	D = $\varnothing$ 3.5 d = $\varnothing$ 1.5 L = 10.0	Insertion into surgical drilling templates for use with (e.g. 1.5 mm) drills and anchor pins for intraoperative fixation of drilling templates

#### Contraindications:

- The titanium sleeves must only be used with intact cylindrical instruments.
- The use of conical drills does not guarantee that the drill will be safely guided in the sleeve, and can lead to the drill tilting. - Damaged or deformed titanium sleeves do not guarantee adequate drill guidance, and must not be used.
- If the patient has allergies, or suspected allergies, to the materials used in the device, the device must not be used.

















## 2.2 User and environment

StecoGuide drill sleeves must only be used by doctors, dentists, surgeons and dental technicians who are familiar with the system and only in medical practices/clinics and laboratories. Knowledge of the device is acquired by studying the Instructions for use or an in-person consultation with staff trained by Steco. The devices must only be used in accordance with these instructions for use. The manufacturer does not accept any liability for damage caused by improper use.

## 3. Safety instructions

When handling drill sleeves, special precautions apply:

-  Make sure that the devices are not exposed to any forces which could cause them to be deformed. Even a small distortion can result in the drill no longer passing through the sleeve.
-  Familiarise yourself with the different sleeve systems (titanium double sleeves, titanium guide sleeves etc.) to avoid selecting the wrong sleeve.
-  If you are using a new component/treatment method for the first time, you can prevent possible complications by collaborating with colleagues experienced in this field. Steco offers detailed advice for this purpose.
-  Close collaboration between surgeons, prosthodontists and dental technicians is vital for a successful implant treatment.
-  Only use cylindrical instruments, as otherwise reliable guidance cannot be guaranteed.
-  Make sure that you have drills that match the titanium sleeves. Check that the drills, drill sleeves or drill keys fit easily into the drilling template. The use of conical drills does not guarantee that the drill will be safely guided in the sleeve, and this can lead to the drill tilting.
-  The drill should be inserted into the titanium sleeve of the drilling template before the rotation starts. If the drill is already rotating when it is inserted into the titanium sleeve of the drilling template, it may tilt.
-  Make sure that the titanium inner sleeve fits correctly in the titanium outer sleeve or drilling template, and use an instrument to push it into position if required.
-  If a titanium sleeve is accidentally dropped into the patient's mouth, it may be swallowed or aspirated, causing possible suffocation or injury. Therefore, small components must be used with the utmost caution.
-  Consult the Instructions for Use of the surgical instruments used to avoid excessive heat build-up during drilling. Moreover, badly worn instruments should be discarded because they can contribute to overheating.
-  Only start the drill rotating when it is safely guided in the template sleeve. Take the necessary precautions to cool the drill while drilling. Do not apply excessive force to the drilling template during the surgery.
-  Make sure of adequate cooling during drilling.
-  Always consult the Instructions for Use of your guided surgical system.
-  The safety of the StecoGuide devices in an MRI environment has not been tested because template-guided implant surgery is not usually performed in an MRI environment. No investigations have been carried out into heating up, migration or image artefacts during an MRI scan. Therefore, performing an MRI scan on a patient in the presence of these devices may cause injury to the patient.

## 3.1 Traceability





For risk control, please return any damaged parts to the manufacturer or distributor and state the catalogue number and LOT number, date of use and implant site. Please note the REF and LOT numbers of the StecoGuide components in the patient documentation. StecoGuide drill sleeves are identified on the label with a UDI code (HIBC), which contains information about the manufacturer (Steco=ESTO) and the device and batch identification.

## 3.2 Reporting of serious incidents

As required by law, any serious incidents that occur in connection with the device must be reported to the manufacturer and/or the competent authorities.





## 4. Product information

### Instructions for use

-  The titanium sleeves are suitable for purely reference templates, laboratory-made planning and drilling templates and for full-guided planning and surgery templates (guide sleeves). The titanium balls are suitable for simple planning and reference templates.
-  Titanium planning and drill sleeves and X-ray reference balls can be used in various types of templates. The templates can be fabricated using a thermoforming, powder, milling or 3D printing technique, or other suitable method. Suitable holes can be made in the template using the template drill from the StecoGuide system (max. rotational speed 1,500 rpm, drill shank 2.35 mm). The shape of the drill is specifically adapted to the outer geometry of the single and titanium double sleeves, so the titanium sleeves only have to be pressed into the template. Polymerisation is also possible due to the retention grooves on the outer surface of the sleeves. To do this, acrylic is used to insert the titanium sleeve or ball into a suitable recess in the template. Since the sleeves and balls are made of titanium, they cause fewer artefacts and are easy to measure on CT, OPG and other radiography images.
-  The geometry of the StecoGuide sleeves is saved in many planning programs and can be included directly in the implant planning for fabricating the drilling template. Take note of the sleeve length and the length of both implant and drill when planning a depth stop to suit the drill and implant length.
-  Check the fit of the titanium sleeves with the corresponding drill for manageability before the surgery. The surgical instrument must neither jam in the titanium sleeve nor have too much play to ensure optimal guidance. The titanium sleeves should be securely fixed in the template so that they cannot be swallowed or aspirated. The titanium inner sleeves can also be inserted into the titanium outer sleeve while on the drill.

## 5. Product selection

### Selection instructions:

-  The inner diameter of the titanium sleeves is specified by the number after the D in the product number (e.g. M.27.03.D235 = diam. 2.35 mm).
-  The product designations specify the outer diameter (D), inner diameter (d) and total length (L). The collar diameter of the titanium double sleeves is 5.0 mm, and 6.0 mm for the CeHa double sleeves. The titanium double sleeves, CeHa double sleeves and titanium double sleeves for Thommen Medical are not compatible with each other.
-  The titanium drill sleeves are manufactured with a slight oversize to the nominal diameter to guarantee reliable drill guidance. A drill with a diameter of 2.35 mm is reliably guided in a 2.35 mm (D235) drill sleeve. Do not use drills that have too much play in the drill sleeves because this may result in considerable deviations from the planned drilling position.
-  Selecting the correct drill sleeve depends on the type of drilling template that is envisaged. For planning templates, the cylindrical titanium single sleeves are recommended because they also enable an axis measurement and they are also suited to simple drill guidance. If only a pilot drill is to be guided, a titanium single sleeve or a titanium inner sleeve from one of our titanium double sleeve systems can be used, depending on the drill diameter. If different drill diameters are to be guided in a drilling template and the depth stop is not crucial, the combination of a titanium outer sleeve with different titanium inner sleeves can be used. For full-guided drilling templates, it is recommended to use the titanium guide sleeves, considering the surgery protocols for the respective system.



## 6. Prior to use

### 6.1 Reusability/durability

The titanium sleeves and balls are intended for single use on one patient only. The device must not be re-used. Re-use is prohibited because it may cause patient contamination if there is inadequate reprocessing. Furthermore, there is a risk of damage to the drill sleeves when they are removed from the template plastic.



### 6.2 Sterilisation and disinfection instructions

These processing instructions apply to the one-time processing of all StecoGuide drill sleeves and reference balls. The instructions only apply to the drill sleeves and NOT the drilling template.



#### General principles

All instruments must be cleaned, disinfected and sterilised before being used for the first time. This applies in particular to the first use following delivery because all the devices are delivered non-sterile (Cleaning and disinfection following removal of the protective transport packaging; Sterilisation after packaging). Effective cleaning and disinfection are essential prerequisites for effective sterilisation.

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

- adequate device- and product-specific validated methods must always be used for cleaning/disinfection and sterilisation,
- the equipment used (washer-disinfector, steriliser) must be 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).

#### Cleaning and disinfection

##### Basic principles

If possible, an automated method (washer-disinfector) should be used for 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 efficacy and reproducibility of a manual method. Pre-treatment should be carried out in both cases.

##### Pre-treatment

1. Rinse the instruments under running water for at least 1 minute (temperature < 35°C/95°F).  
Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments five times using a disposable syringe (minimum volume 1 ml).
2. Place the instruments in the pre-cleaning bath<sup>1</sup> for the specified contact time in such a way that the instruments are sufficiently covered. Make sure that the instruments are not touching. Aid the pre-cleaning by carefully brushing all the inner and outer surfaces (at the start of the contact time, each for at least 1 minute.) For cavities, use suitable interdental brushes. For the exterior, use soft standard brushes.  
Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml) at the start and end of the contact time.
3. Then remove the instruments from the pre-cleaning bath and rinse them thoroughly at least five times (for at least 1 minute) with water. Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least three times using a disposable syringe (minimum volume 1 ml) at the start and at the end of the contact time.

When selecting the detergent<sup>1</sup> to be used, ensure that:

- it is suitable for cleaning metal and plastic instruments,
- it is compatible with the instruments (see section "Material durability").

The concentrations, temperatures, contact times and rinsing guidelines specified by the manufacturer of the detergent or the combined detergent 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) and 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 detergent and disinfectant is used, please take into account that it should be aldehyde-free (as aldehyde fixes blood residues) and have proven efficacy (e.g. VAH/DGHM or FDA/EPA approval/ clearance/ registration).

Please note that the disinfectant that may be used during pre-treatment is for personal protection only and cannot replace the disinfection step to be carried out later, after cleaning.

#### Automated cleaning/disinfection (washer-disinfector)

When selecting the washer-disinfector, ensure that:

- the washer-disinfector conforms to DIN EN ISO/ANSI AAMI ST15883 and has proven efficacy (e.g. DGHM or FDA approval/ clearance/ registration or CE marking pursuant to DIN EN ISO/ANSI AAMI 15883),
- if possible, a verified program for thermal disinfection ( $A_0$  value  $\geq 3000$  or, for older washer-disinfectors at least 5 minutes at 90°C) is used (if chemical disinfection is performed, there is a risk of disinfectant residue on the instruments),
- the program used for the instruments is appropriate and contains enough rinse cycles (at least three diminishing steps after the cleaning (or neutralisation, if applied) or conductivity monitoring recommended to effectively prevent detergent residue),
- only water that is sterile or of low microbiological contamination (max. 10 microbes/ml) and 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 detergent system to be used, ensure that:

- it is suitable for cleaning metal and plastic instruments,
- if thermal disinfection is not used, an additional suitable disinfectant with proven efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) will be used and that this is compatible with the detergent used, the program used includes a sufficient number of rinse cycles (at least two diminishing steps after disinfection or conductivity monitoring recommended to prevent detergent residue effectively) and
- the chemicals used are compatible with the instruments (see section "Material durability").

The concentrations, temperatures, contact times and rinsing guidelines specified by the manufacturer of the detergent and disinfectant must be strictly observed.

##### Procedure:

1. Place the instruments into the washer-disinfector using a close-meshed tray (small parts basket). 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.
2. Start the program.
3. Remove the instruments from the washer-disinfector when the program has finished.
4. Check and package the instruments as soon as 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 detergent Neodisher MediZym (Dr. Weigert GmbH & Co. KG, Hamburg). The Worst Case settings were considered with regard to the above-described method and the concentration specified in the Instructions for Use of the detergent (in compliance with the information from the detergent manufacturer pursuant to note 1 in section 6.6.2.2 of ISO 17664 as specified above).

#### Manual cleaning and disinfection

When selecting the detergent and disinfectant to be used, ensure that:

- they are suitable for cleaning and disinfection of metal and plastic instruments,
- the detergent - if applicable - is suitable for ultrasonic cleaning (no foam formation),
- suitable disinfectant with proven efficacy is used (e.g. VAH/DGHM or FDA approval/clearance/registration or CE marking) and that this is compatible with the detergent used and
- the chemicals used are compatible with the instruments (see section "Material durability").

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



The concentrations, contact times and rinsing guidelines specified by the manufacturer of the detergent and disinfectant must be strictly observed. Only use freshly prepared solutions, water that is sterile or of low microbiological contamination (max. 10 microbes/ml) and 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 into the cleaning bath for the specified contact time in such a way that the instruments are completely covered by the liquid and carefully brush them (at the start of the contact time, for at least 1 minute per tool: For cavities, use suitable interdental brushes. For the exterior, use soft standard brushes)
2. Ensure that the instruments are not touching and that there are no air bubbles in the cavities. Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml) and a disposable cannula at the start and at the end of the contact time.
3. Remove the instruments from the cleaning bath and rinse them thoroughly with water for 1 minute at least three times. Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml).
4. Check the instruments (see section "Checks" and "Maintenance").

## Manual disinfection

1. Place the cleaned and checked instruments into the disinfection bath for the specified contact 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. Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml) at the start and at the end of the contact time.
3. Remove the instruments from the disinfection bath and rinse them thoroughly with water for 1 minute at least three times. Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml) and a disposable cannula.
4. Dry the instruments by blowing off/blowing out with filtered compressed air.
5. Package the instruments as soon as they are removed (see section "Packaging", after additional drying, necessary, in a clean location).

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 detergent Cidezyme/Enzol and the disinfectant Cidex OPA (ASP, Johnson & Johnson MEDICAL GmbH, Norderstedt). In this case, the Worst Case settings were considered with regard to the above-described method and the Instructions for Use of the detergent and disinfectant. In this case, the Worst Case settings were considered with regard to the above-described method and the concentration specified in the Instructions for Use of the detergent and disinfectant (in compliance with the information from the detergent manufacturer pursuant to the note in section 6.6.3 and note 1 in section 6.7.3 of ISO 17664, as specified above).

## Checks

Following the cleaning or cleaning/disinfection, check all of the instruments for corrosion, damaged surfaces, flaking and soiling and discard 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.

## Maintenance/assembly

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

## Packaging

Please package the instruments in disposable sterilisation packaging (single-use packaging), which 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 instruments and sterilisation packaging against mechanical damage

## Sterilisation

Only the methods listed below should be used for sterilisation. No other sterilisation methods are permitted.

### Steam sterilisation

- fractionated vacuum method or gravity displacement method<sup>2</sup> (with adequate drying<sup>3</sup>)
- steam steriliser conforming to 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/ANSI AAMI ISO 17665)
- sterilisation time (contact time 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 4 mins at 132°C (270°F) / 134°C (273°F) <sup>3</sup>	at least 40 mins at 121°C (250°F)
Other countries	at least 20 mins at 121°C (250°F)	Not recommended

<sup>2</sup> It is only permitted to use the less effective gravity displacement method if the fractionated vacuum method is not available

<sup>3</sup> The drying time mainly 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.

<sup>4</sup> or 18 mins (inactivation of prions)

Moreover, do not use dry heat sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, or plasma sterilisation.

Verification of the general suitability of the instruments 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 instruments must be kept dry and dust-free in the sterilisation packaging.

## Material durability

When selecting the detergents and disinfectants, please ensure that they do not contain any of 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
- oils

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 titanium sleeves and balls are intended for single use on one patient only. The device must not be re-used. Any re-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

The StecoGuide drill sleeves and reference balls are only processed once. Therefore, it is not necessary to document the number of times they have been processed.



## 7. Storage and shelf life

Store in a clean and dry place. The devices do not have a minimum shelf life because they are made from surgical titanium. Once installed in the template, the sleeves have the same expiry date as the drilling template.

## 8. Maintenance/assembly

No maintenance or assembly is specified for the devices because they are one-part, single-use devices. The devices are pressed into a drilling template or glued in.

## 9. Troubleshooting

Most common malfunctions	Possible cause	Action
Drill stuck in sleeve	Sleeve too narrow in relation to the drill. Sleeves or drills used multiple times (abrasion at the periphery)	Procure a new drill or another sleeve
Drill does not fit through the sleeve	Sleeve too narrow	Procure a suitable drill or another sleeve

## 10. Disposal

The devices can be disposed of in the same way as other potentially infectious devices in accordance with country-specific legal regulations.

## 11. Installation

### 11.1 Methods of template fabrication

#### a. Conventional

The planning or drilling template is fabricated individually for the patient's jaw on a dental model using a conventional method. Thermoforming methods, powder or casting techniques and equivalent methods are used.

For the conventional template production method, some template drills are adapted to the sleeve geometry.



1. Planning model study model



2. Wax up implant position



3. Thermoformed template or similar



4. Radiopaque filled



5. Drill sleeve position



6. Press or glue in sleeves

#### b. 3D procedure using planning software and a CAD/CAM technique

The planning or drilling template is fabricated using a 3D production process.

The sleeve geometry can be integrated into 3D planning software. For this, 3D data (STL file) of the geometry is provided to the software manufacturer, enabling the user to select possible titanium sleeves from a library. The position of the titanium sleeve is placed on the same axis as the planned implant position. In some systems, the distance between the titanium sleeve and the implant is preset to a standard value. In other systems, it can be adjusted according to the user's requirements (e.g. drill length).

Examples of programs containing StecoGuide drill sleeves are: SICAT, coDiagnostiX (Dental Wings), 3Shape Implant Studio, exoplan (exocad), Smop, Romexis (Planmeca), Implastation (ProDigiDent), Blenderfordental, Med 3D Implantology, Mesantis, Organical (R+K), CTV.



### 11.2 StecoGuide in a planning template

#### Titanium reference balls

The reference balls are glued in the desired position on the planning template or enclosed with a thermoformed template. The reference balls can be used in X-ray diagnostics as a reference for estimating tissue dimensions or as reference markers when overlaying 3D data sets from different sources.

#### Titanium single sleeves

Thanks to their cylindrical shape, titanium single sleeves are ideal for assessing possible implant axes and positions in 3D X-rays. The template drill that is specifically suited to the titanium single sleeves is used to drill a hole in the drilling template at the desired position and in the desired axis. The template drill has the shape of the outer surface of the titanium sleeves. The use of these template drills creates a hole with a press fit for the titanium sleeve, which enables the titanium sleeves to be pressed into the template. The titanium sleeves have grooves on their outer surface for gluing or polymerisation fixation. The titanium sleeve is pressed into the template drill using the special insertion tool (for diam. 2.35 mm), but it can also be glued in place.



### 11.3 StecoGuide in a drilling template

The titanium sleeves are placed in the position corresponding to the extended axis of the planned implant position or the axis in which the surgical instrument is to be guided. The position can be planned by the dental technician or dentist on the basis of experience or 3D imaging systems using suitable planning software.

#### Pilot drilling with titanium single sleeves

Titanium single sleeves give the user the option of using the template drill to create a hole adapted to the sleeve geometry in order to press the titanium sleeve into the template. If the template is fabricated using digital processes, the desired fit and drill sleeve geometry are taken into account in the software. Once the titanium sleeve has been inserted into the template, the pilot hole can be drilled using an appropriate, cylindrical drill.

#### Pilot and other drills with the titanium double sleeve system

With the titanium double sleeves, different titanium inner sleeves can be inserted into the same titanium outer sleeve (tube-in-tube principle). Thus different drill diameters can be guided with just a single outer sleeve. The fit between the two titanium sleeves is important in order to guarantee precise drilling. However, titanium inner sleeves without titanium outer sleeves can also be secured in the template as pilot drill sleeves.

Depending on the drill sleeve used (outer or inner sleeve), a hole is drilled using the respective template drill at the desired position and in the desired axis, and the titanium sleeves are pressed into this hole. An insertion tool can simplify the handling. If the template is fabricated using digital processes, the desired fit and drill sleeve geometry are taken into account in the software. Gluing or polymerisation fixation of the titanium sleeve can be performed in addition.

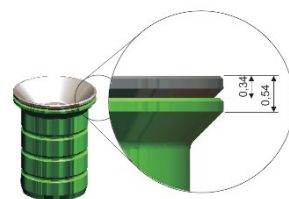
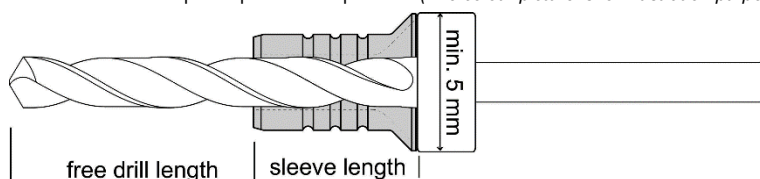
#### StecoGuide titanium outer sleeve open lateral for access

The laterally open titanium outer sleeve (not compatible with CeHa double sleeves or Thommen Medical double sleeves) is open along its entire length so that the surgical drill can be inserted from the side. The upper part of the open titanium outer sleeve is open down to the full equator. The lower part is only open to the width of the drill diameter that passes through the largest titanium inner sleeve. The drill can therefore be inserted from the side, over the entire length of the titanium sleeve. The titanium inner sleeves (M.27.03.D... or M.27.24.D... or M.27.28.D...) can be inserted from the side, into the upper part of the open titanium outer sleeve. In the lower part, the resulting arms hold the titanium inner sleeve in position and prevent tilting.



## Depth stop

To position the titanium sleeves with depth stop function, the upper edge of the titanium sleeve must be placed at the correct distance from the implant. This distance is defined as the length of the drill from the tip to the depth stop. With titanium double sleeves, the titanium inner sleeve sits 0.34 mm above the titanium outer sleeve, and this should be taken into account when planning a depth stop. For titanium inner sleeves with a funnel, the depth stop of the drill should be at least 5 mm in diameter so that it does not extend into the funnel, as that would mean that a depth stop cannot be planned. *(The colour picture is for illustration purposes only)*



## Pilot and other drills with the CeHa double sleeve system

With StecoGuide CeHa double sleeves, different inner sleeves can be inserted into the same outer sleeve (tube-in-tube principle). CeHa outer sleeves have an inner diameter of 4.5 mm, while CeHa inner sleeves have an outer diameter of 4.5 mm and different inner diameters. Thus different drill diameters can be guided with just a single outer sleeve. The fit between the two sleeves is important in order to guarantee precise drilling. However, inner sleeves without outer sleeves can also be secured in the template as pilot drill sleeves.

Depending on the drill sleeve used, a hole is drilled using the respective template drill at the desired position and in the desired axis to create a press fit. If the template is fabricated using digital processes, the desired fit and drill sleeve geometry are taken into account in the software. With CeHa double sleeves, the inner sleeve sits 0.34 mm above the outer sleeve, and this should be taken into account when planning a depth stop.

Gluing or polymerisation fixation of the sleeve can be performed in addition.

CeHa inner sleeves have a funnel. The depth stop of the drill should be at least 6 mm in diameter so that it does not extend into the funnel. With smaller depth stops, reliable planning is not possible.

## Pilot and other drills with the titanium double sleeve system for Thommen Medical

The titanium double sleeves can be inserted into each other (tube-in-tube principle). With the titanium double sleeves for Thommen Medical, the titanium inner sleeve sits 0.5 mm above the titanium outer sleeve, and this should be taken into account when planning a depth stop. Thus, the initial drilling steps can be carried out with one titanium outer sleeve and two titanium inner sleeves using the unguided 2.0, 2.8 and 3.5 mm VECTOdrill™ drills. The fit between the two titanium sleeves is important in order to guarantee precise drilling. The depth stop is inspected visually by checking the markings on the VECTOdrill™ drills.

If the template is fabricated using digital processes, the desired fit and drill sleeve geometry are taken into account in the software. For conventional drilling template fabrication, a 4.4 mm hole should be planned for the titanium outer sleeve. If only the titanium inner sleeves are to be used as pilot sleeves, a 3.55 mm hole in the template should be planned.

Gluing or polymerisation fixation of the titanium sleeve can be performed in addition.

## Fully guided

Titanium guide sleeves are supplied for various fully guided instruments from different manufacturers. Ideally, titanium guide sleeves are selected in digital implant planning programs according to the desired implant system, and included in the planning of the drilling template. The vertical alignment of the drill sleeve depends on the selected implant length and the length of the possible drills. When planning the vertical sleeve position, additional drill keys and guide elements on the drill must be taken into account. For titanium guide sleeves, the upper edge of the sleeve forms the depth stop for the drill and the guide key.

Titanium guide sleeves can be glued or pressed into milled or printed drilling templates. As part of digital drilling template planning, the clearance between the drill sleeve and the drilling template can usually be specified in order to determine the desired fit (adhesive or press fit). The resulting fit is also affected by the fabrication process and must be tailored to the individual requirements of the user.

## 11.4 StecoGuide for securing a drilling template

In order to stabilise drilling templates on an edentulous or partially edentulous jaw, several anchor pins are inserted through the sleeves in the template and anchored in the cortical bone. Depending on the availability of StecoGuide anchor pin sleeves in the planning software, the sleeves can be included in the digital template planning.

## 11.5 StecoGuide Guided endo for endodontics

With StecoGuide drill sleeves and 3D planning software (e.g. coDiagnostiX™ or other systems) and specially adapted drills for guided endodontics, the drilling channel can be defined for access to obliterated teeth. The drill sleeve is positioned virtually in the planning software, in the planned drill axis and at the correct height for the desired drill. The drill sleeve is inserted into the milled or printed drilling template. Depending on the adjusted fit, the drill sleeve can be pressed in or also glued. Then the 1.0 mm ATEC spiral drill is precisely guided through the StecoGuide endo sleeve.



To avoid the drill being deflected on the enamel surface and breaking, prior perforation of the enamel is recommended.

