EndoPilot²

Processing instructions (cleaning, disinfection (if applied) and sterilization)

Attachment to the user manual (scope USA)

Contents

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Schlumbohm

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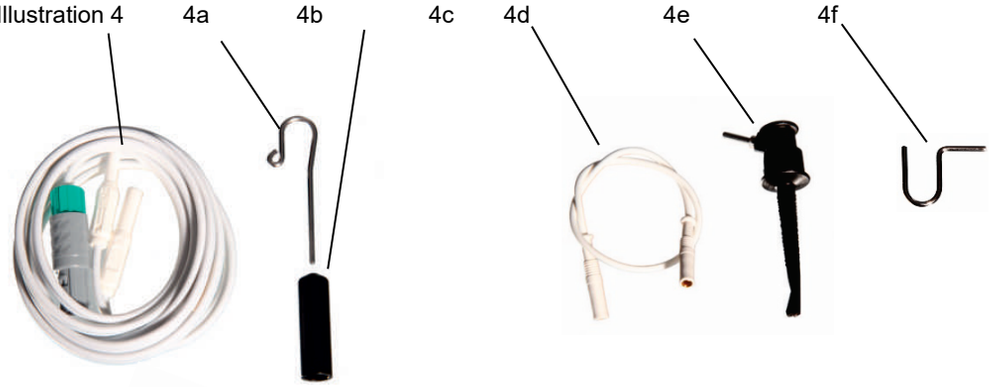
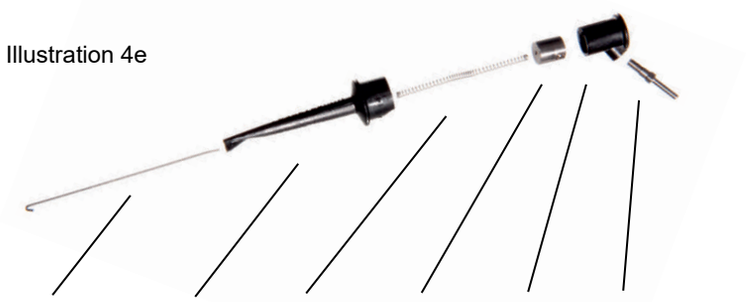


Illustration 4e



Contact wire, housing, spring, threaded bush, knob, contact

You can dismantle the patented file clamp (4e) for processing.
A universal wrench for ultrasonic-instruments can be used as a tool for assembly (with a wrench size of 3.2 mm).

Illustration 5

Illustration 6

Illustration 7

Description of the single parts and assignment of the relevant processes

ill.	*Designation*	*Description*	*Ref.*	*Chapter*
1	Control unit	Only the control unit with a touch screen	Ref. no.: 110 2010	Ch. 2
2	Power supply	Power supply with primary plug Input: 100 – 240 V AC Output: 12 V DC 1.25 A Input: 100 – 240 V AC Output: 12 V DC 1.50 A	 Ref. no.: 109 2322 Ref. no.: 110 2203	Ch. 2
3	Wireless foot switch	Bluetooth wireless foot switch, single pedal	Ref. no.: 109 2361	Ch. 2
4	Apex cable set Ref. no.: 109 2311 from version v06 on	4a – Measuring cable with plug 4b – Lip clip 4c – Cap for the plug socket 4d – Cable for file clamp 4e – File clamp (can be dismantled) The file clamp can be dismantled (see illustration 4e) To dismantle, the contact is unscrewed and removed from the knob. You can clean all parts individually. At the end of assembly, firmly tighten the contact again. Caution. Check if the device is functioning properly. Loose parts may fall out and enter the patient's mouth.	Ref. no.: 109 2312 Ref. no.: 109 2314 Ref. no.: 109 2318 Ref. no.: 109 2315 Ref. no.: 109 2316	Ch. 2 Ch. 1 Ch. 1 Ch. 1 Ch. 1
	Retainer for apex cable	4f (mounted on the device)	Ref. no.: 110 2303	Ch. 1
5	Contra-angle handpiece	For the apex measurement / fully insulated 1:1 gear, with ISO-E coupling	Ref. no.: 109 0126	A3*
6	Motor	Motor with apex measuring contact, LED power indicator and ISO-E connection	Ref. no.: 109 0112	Ch. 2
7	D-Pack	DownPack handpiece with a LED display 7a – Screw cap 7b – blue O-ring	Ref. no.: 109 0151 Ref. no.: 540 5173 Ref. no.: 364 2901	Ch. 2 Ch. 1 Ch. 1

A3* Note the user manual and processing instructions for the contra-angle: See document 609 2210

1. Processing instructions for thermostable products

1.1. General Information

Read the processing instructions carefully and completely. Follow the instructions section by section.

All products/product components must be cleaned, disinfected (if applied) and sterilized before each application; this applies in particular to the first use after delivery, since all products/product components are delivered non-sterile (cleaning and disinfection (if applied) take place after removal of the protective transport packaging; sterilization after repackaging).

Effective cleaning is an indispensable prerequisite for effective sterilization. Supplementing the requirements in the USA, we recommend disinfection as additional step between cleaning and disinfection for this as well.

As part of your responsibility for the sterility of the products/product components during application, please note that
- only sufficiently device-specific and product-specific validated methods are used for cleaning, disinfection (if applied) and sterilization,
- the equipment used (washer or – if applied - WD `washer-disinfector´ and sterilizer) is regularly maintained and correctly checked and
- the validated parameters are adhered to during each cycle.

Material resistance:
When selecting cleaning agents and disinfectants, please make sure that the following components are not included:
- organic, mineral and oxidizing acids (minimum permissible pH value 5.5)
- strong alkalis (maximum permissible pH value 12, slightly alkaline cleaner recommended)
- organic solvents (e.g. alcohols, ethers, ketones, benzines)
- Oxidizing agents (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

Always refrain from cleaning products/product components with metal brushes or steel wool.
All products/product components may only be exposed to temperatures not exceeding 138°C (280°F)!

If possible, an automated method (washer or – if applied - WD) should be used for cleaning and disinfection (if applied). Due to its significantly lower effectiveness and reproducibility, a manual method, even when using an ultrasonic bath, should only be used if an automated method is not available.
Pre-treatment must be carried out in both cases.

Please also observe the legal regulations valid in your country and the hygiene regulations of your medical practice or hospital. This applies in particular to the different specifications regarding effective prion inactivation.
Additional or deviating specifications apply to some products/product components (see chapter `Special instructions´ in the attachment).

1.2. Pre-treatment

Immediately after the application (within a maximum of 2 h) all visible residuals must be removed from the products/product components:

Care must be taken when selecting the cleaning and – if applied – disinfection agent to ensure
- that these are suitable for the cleaning and – if applied - disinfection of instruments made of metals and plastics in principle,
- that these are suitable for ultrasonic cleaning (no foam development),
- that these are legally marketed in the USA,
- that the disinfectant (if applied) has a tested effectiveness (FDA approval) and
- that these are compatible with the products/product components (see chapter `Material resistance´, section 1.1.).

The concentrations, temperatures, soaking times and rinsing specifications specified by the manufacturer of the cleaning and (if applied) disinfection agent must be adhered to in any case. Use only freshly prepared solutions, only DI water (The bacterial load must correspond at least to that of drinking water with a maximum of 100 CFU/ml. The endotoxin load should be not higher than 0.25 endotoxin units/ml.). Only use a soft, clean and lint-free cloth and/or filtered air for drying.

Procedure:
1. Remove externally visible dirt with a disposable cloth dipped in the cleaning and – if applied - disinfection bath.
2. Dismantle the products/product components as far as possible (see also the chapter `Special instructions´.
3. Place the products/product components in the cleaning and (if applied) disinfection solution in the ultrasonic bath (temperature <35°C/95°F) and activate the ultrasound for the specified soaking time (but not less than 5 min).
4. After switching off the ultrasound, manually remove all visible dirt in a separate cleaning bath. Use a clean soft brush (at least 1 minute brushing) that you only use for this purpose; never use metal brushes or steel wool. (For recommendations on the brush type, see `Special instructions´ in the attachment)
5. Rinse or flush thoroughly with DI water for at least 1 minute (The bacterial load must correspond at least to that of drinking water with a maximum of 100 CFU/ml. The endotoxin load should be not higher than 0.25 endotoxin units/ml.).

Now continue to section 1.3. If an automated method is not available continue to 1.4

1.3. Automated cleaning with washer or – if applied – cleaning / disinfection with washer–disinfector (WD)

Care must be taken when selecting the washer or (if applied) washer-disinfector to ensure
- that the washer or – if applied – washer-disinfector is legally marketed in the USA,
- that the washer disinfector has a tested effectiveness (ANSI AAMI ISO 15883, FDA approval) in principle,
- that a tested program for thermal disinfection (A_0 value ≥ 3000 or – for older devices – at least 5 min at 90°C/194°F) is used wherever possible (risk of disinfectant residues on the products/product components in the event of chemical disinfection),
- that the program used is suitable for the products/product components and contains sufficient rinsing cycles (at least three degrading steps after cleaning (respectively neutralization, if applied) or conductance based rinsing control recommended in order to prevent effectively remnants of the detergents),
- that only DI water is used for rinsing (The bacterial load must correspond at least to that of drinking water with a maximum of 100 CFU/ml. The endotoxin load should be not higher than 0.25 endotoxin units/ml.) (The DI supply of the device must be checked regularly, as bacteria can accumulate in cartridge systems. Periodically changed filter systems to reduce the bacterial load are recommended.),
- that the air used for drying is filtered (oil-free, low bacterial count and low particle count) and
- that the washer or – if applied - washer disinfector is regularly maintained and correctly checked.

Care must be taken when selecting the cleaning agent system used to ensure
- that these are suitable for the cleaning of instruments made of metals and plastics in principle,
- that these are legally marketed in the USA,
- that – if a washer and disinfector as well as no thermal disinfection is used – a suitable disinfectant with tested effectiveness (FDA approval) is additionally used and that this is compatible with the cleaning agent used and
- that the chemicals used are compatible with the products/product components (see chapter `Material resistance´ in section 1.1.).

The concentrations, temperatures, soaking times and rinsing specifications specified by the manufacturer of the cleaning agent and – if applied - disinfectant, must be adhered to in any case.

Procedure:
1. Place the dismantled products/product components (see chapter `Pre-treatment´) in the washer or – if applied - washer-disinfector. Make sure that the products/product components do not touch each other in the process. Use a “small parts basket” for smaller components (see `Special instructions´).
2. Start the program.
3. Remove the products/product components from the washer or – if applied – washer-disinfector at the end of the program.
4. Inspect and pack the products/product components as soon as possible after removal (see the chapters `Inspection´, `Maintenance´ and `Packaging´, if necessary after additional drying in a clean place).

An independent accredited and recognized (§ 15 (5) MPG) *test laboratory (Medical Device Services – DR. ROSSBERGER GmbH, Gilching, Germany) has provided proof of the general suitability of the products/product components for effective automated cleaning and disinfection by using of an ultrasonic bath of the SONOREX series with 35 kHz (BANDELIN electronic, Berlin, Germany) for pre-cleaning and the WD G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) as well as the pre-cleaning and cleaning agent Neodisher MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg, Germany). The selected parameters corresponded to the Vario-TD program of Miele.*
An independent accredited and recognized (§ 15 (5) MPG) *test laboratory (Medical Device Services – DR. ROSSBERGER GmbH, Gilching, Germany) has provided proof of the general suitability of the products/product components for effective automated disinfection (full relevance only outside the USA) by using of the WD G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany). The selected parameters corresponded to the Vario-TD program from Miele.*

1.4. Manual cleaning and – if applied - disinfection

Care must be taken when selecting the combined cleaning- and disinfection agent to ensure
- that these are suitable for the cleaning and disinfection of instruments made of metals and plastics in principle,
- that these are legally marketed in the USA,
- that these are suitable for ultrasonic cleaning (no foam development),
- that disinfectant (if applied) has a tested effectiveness (FDA approval) and
- that these are compatible with the products/product components (see chapter `Material resistance´ in section 1.1).

The concentrations, temperatures, soaking times and rinsing specifications specified by the manufacturer of the cleaning/ disinfection-agent must be adhered to in any case. Use only freshly prepared solutions, only DI water (The bacterial load must correspond at least to that of drinking water with a maximum of 100 CFU/ml. The endotoxin load should be not higher than 0.25 endotoxin units/ml.). Only use a soft, clean and lint-free cloth and/or filtered air for drying.

Procedure
Cleaning:
1. Place the dismantled products/product components (see chapter `Pre-treatment´) in the ultrasonic bath filled with the cleaning agent for the specified soaking time so that the products/product components are sufficiently covered. Make sure that the products/product components do not touch each other in the process and activate the ultrasound (do not use any heating function) for the specified soaking time (but not less than 5 min).
2. After switching off the ultrasound, support cleaning in a separate cleaning bath by completely brushing off all internal and external surfaces with a soft brush (for at least 1 minute). (For recommendations on the brush type, see `Special instructions´ in the attachment)
3. Then remove the products/product components from the cleaning bath and rinse or flush these thoroughly with DI water at least three times (for at least 1 minute each) (The bacterial load must correspond at least to that of drinking water with a maximum of 100 CFU/ml. The endotoxin load should be not higher than 0.25 endotoxin units/ml.).
4. Inspect the products/product components (see the chapters `Inspection´ and `Maintenance´).

Disinfection (if applied)
5. Place the dismantled, cleaned and inspected products/product components in the ultrasonic bath in a fresh disinfectant solution for the specified soaking time so that the products/product components are sufficiently covered. Make sure that the products/product components do not touch each other in the process.

6. Then remove the products/product components from the disinfection bath and rinse or flush these thoroughly with DI water at least five times (for at least 1 minute each) (The bacterial load must correspond at least to that of drinking water with a maximum of 100 CFU/ml. The endotoxin load should be not higher than 0.25 endotoxin units/ml.).

Drying

7. Dry the products/product components by blowing off/blowing out with sterile filtered compressed air.
8. Pack the products/product components as soon as possible after drying (see the chapter `Packaging´, if necessary after additional drying in a clean place).

An independent accredited and recognized (§ 15 (5) MPG) *test laboratory (Medical Device Services – DR. ROSSBERGER GmbH, Gilching) has provided proof of the general suitability of the products/product components for effective manual cleaning by using of an ultrasonic bath of the SONOREX series with 35 kHz (BANDELIN electronic, Berlin) for pre-cleaning and cleaning as well as the cleaning agent Enzol/Cidezyme (ASP Deutschland GmbH, Aldingen, Germany) for both pre-cleaning and cleaning steps.*
For outside the USA, an independent accredited and recognized (§ 15 (5) MPG) *test laboratory (Medical Device Services – DR. ROSSBERGER GmbH, Gilching) has provided proof of the general suitability of the products/product components for effective manual disinfection, which can be transferred to application of e.g. Cidex OPA (ASP Deutschland GmbH, Aldingen, Germany).*

1.5. Inspection

After cleaning or cleaning/disinfection, check all products/product components for corrosion, damaged surfaces, chipping, dirt and discoloration, and remove damaged products/product components (for the numerical restriction on reuse see the chapter `Reusability´). Products/product components that are still dirty must be cleaned and disinfected again.

1.6. Maintenance / Using service oil

Reassemble the dismantled product if required.
(see the chapter `Special instructions´).
Instrument oils must not be used with these products. (see the chapter `Special instructions´).

1.7. Packaging

Please pack the products/product components in disposable sterilization packaging (one-way packaging) which corresponds to the following requirements (material/process):

- ANSI AAMI ISO 11607
- Suitable for steam sterilization (temperature resistance up to min. 138°C (280°F) sufficient vapor permeability)
- Products/product components or sterilization packaging are sufficiently protected against mechanical damages

1.8. Sterilization

Only the sterilization methods listed below are to be used for sterilizing the products/product components; other sterilization methods are not permitted.

1.9. Steam sterilization

- Fractionated vacuum method[1] (with sufficient product drying[2])
- Steam sterilizer according to ANSI AAMI ST79 (or DIN EN 13060/DIN EN 285)
- Validated according to ANSI AAMI ISO 17665 (valid sterilizer-specific IQ/OQ and product-specific performance qualification (PQ))
- Maximum sterilization temperature 132°C (270°F; plus tolerance according to DIN EN ISO 17665:2017)
- Sterilization time (exposure time at sterilization temperature):

Country	Fractionated vacuum method	Gravitation method
USA	Minimum of 4 min at 132°C (270°F) minimum drying time of 20 min[2]	not recommended

[1] At least three vacuum steps
[2] The actual drying time required directly depends on parameters that are the sole responsibility of the user (load configuration and density, sterilizer condition,...) and must therefore be determined by the user. Nevertheless, drying times should not be less than 20 minutes.

Flash sterilization is generally not permitted.
Do not use hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

An independent accredited and recognized (§ 15 (5) MPG) test laboratory (Medical Device Services – DR. ROSSBERGER GmbH, Gilching) has provided proof of the general suitability of the products/product components for effective steam sterilization by using the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum method. Typical conditions in clinics and doctor's practices as well as the method described above were considered here.

1.10. Storage

After sterilization, the products/product components must be stored in the sterilization packaging in a dry and dust-free manner.

1.11. Reusability

The products/product components can – with due care and provided that they are undamaged and free of dirt – be reused at least up to the number indicated in the chapter `Special instructions´. The user is responsible for any further use beyond this. The use of damaged and/or dirty products/product components is not permitted. All liability is excluded in the event of non-observance.

Special instructions (here you will find further information on individual parts that require a special procedure)

Item no.	Item name	Brush	Special/additional procedure for				Packaging	Sterilization	The maximum permissible number of cycles	The corresponding recommendation for classification recommendation (if used as intended) FDA guidance for reprocessing:2015 chapter VI
			Pre-treatment	Manual cleaning/ disinfection	Automated cleaning/ disinfection	Maintenance/ Assembly				
109 2316	File clamp EndoPilot	Standard and conical interdental brush of type IDB-GK, green, 3-6.5 mm, item no. 266668 ORBIS Dental, Münster for thin diameters in the housing and the threaded bush: cylindrical interdental brush of type IDB-W, white, 2.8 mm, item no. 266666 ORBIS Dental, Münster	Remove the cable, unscrew the contact (by using a universal wrench for ultrasonic-instruments, size 3.2 mm). Remove the knob and separate the parts, also push the threaded bush out of the knob (if necessary, use a dental probe) then: immerse, brush inside and outside (small inside holes with interdental brushes, thin diameter in housing and threaded bush with the fine, cylindrical type IDB-W 2.8 mm), Ultrasound	completely dismantled: immerse, brush outside and inside (small inside holes with interdental brushes, thin diameter in housing and threaded bush with the fine, cylindrical type IDB-W 2.8 mm), Ultrasound	completely dismantled: small parts in the “small parts basket”	Assembly: 1. Insert the threaded bush into the knob, loosely screw in the contact 2. Insert the contact wire into the housing and press the housing onto the table in a vertical position 3. Place the spring and knob onto the contact wire standing in a vertical position 4. Align the knob, press it down and tighten the contact firmly (by using a universal wrench for ultrasonic-instruments, size 3.2 mm). Also see illustration 4e and table: `Description of the single parts´ (row 4) Do not oil	Pre-assembled, Transparent sterilization packaging (simple)	Pre-assembled, standard procedure	300	semi-critical-device
109 2315	File cable (for file clamp)	Standard, and conical interdental brush of type: IDB-GK, green, 3-6.5 mm, item no. 266668 ORBIS Dental, Münster	Immerse into the cleaning solution, brush, (inner surfaces of the socket with conical interdental brush) Ultrasound	brush (inside holes with conical interdental brush), ultrasound	in the “small parts basket”, openings facing downwards	Do not oil	Transparent sterilization packaging (simple)	Standard procedure	300	semi-critical-device
109 0151	Down-Pack hand-piece parts: Screw cap 540 5173 and O-ring 364 2901	Standard, and conical interdental brush of type: IDB-GK, green, 3-6.5 mm see above	Dismantled, immerse into the cleaning solution, brush, (inner surfaces of the cap with conical interdental brush) Ultrasound	immerse dismantled, brush inside and outside (small inside holes with conical interdental brush), ultrasound	Dismantled, small parts in the “small parts basket”,	Do not oil *Change the O-rings after 50 cycles*	not pre-assembled Transparent sterilization packaging (simple)	not pre-assembled Standard procedure	300 (O-rings 50 cycles)	semi-critical-device

2. Processing instructions for thermolabile products

2.1. General principles

All products/product components must be cleaned and disinfected before each application; this also applies in particular to the first use after delivery, as all products/product components are delivered non-sterile (cleaning and disinfection after removal of the protective transport packaging). Effective cleaning and disinfection are indispensable prerequisites for safe use.

As part of your responsibility for the safety of the products/product components during application, please note that only sufficient product-specific validated methods for cleaning and disinfection are used and that the validated parameters are adhered to for each cycle.

Material resistance:
When selecting disinfectants, please make sure that the following components are not included:
- Acids or alkalis (disinfectants for residue-free surface disinfection on an alcoholic basis are recommended)
- other organic solvents (e.g. aldehydes, acetone, ethers, benzines)
- Oxidizing agents (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons
- Oils (including instrument oils)

Always refrain from cleaning products/product components with metal brushes or steel wool.

All products/product components may only be exposed to temperatures not exceeding 60°C (140°F)!

Please also observe the legal regulations valid in your country and the hygiene regulations of your medical practice or hospital.
Additional or deviating specifications apply to some products/product components (see the chapter `Special instructions´).

2.2. Pre-treatment

Immediately after the application (within a maximum of 2 h) all visible residuals must be removed from the products/product components and the products/product components must be disinfected:

Procedure:
Pre-treatment
1. Separate components that require separate cleaning, disinfection and sterilization according to the specific processing instructions (see `Special instructions´ in the attachment).

2.3. Manual cleaning and disinfection

Selecting the disinfectant
Care must be taken when selecting the disinfectant to ensure
- that these are suitable for the residue-free disinfection of medical surfaces made of metals and plastics in principle (alcoholic basis, without fragrances and perfumes),
- that these have a tested effectiveness (e.g. VAH/DGHM listing / CE marking or for the US: FDA-cleared high-level disinfectants)
- that the chemicals used are compatible with the products/product components (see the chapter `Material resistance´ in section 2.1.).

The concentrations, temperatures and soaking times specified by the manufacturer of the disinfectant must be adhered in any case. Only use a fresh solution and a soft, clean and lint-free disposable cloth for drying.

Procedure:
Cleaning
1. Remove the remaining products/product components from all accessible places in the relevant areas (see the chapter `Special instructions´ in the attachment) with a disposable wipe soaked in at least 50 ml of disinfectant.
2. Repeat step 1 until the surface appears free of visible residues.
3. Inspect the products/product components (see the chapters `Inspection´ and `Maintenance´).

Disinfection
4. Wet the products/product components on all accessible places in the relevant areas (see the chapter `Special instructions´ in the attachment) with a disposable wipe soaked in at least 50 ml of disinfectant and allow the disinfectant to have an effect according to the soaking time specified by the manufacturer of the disinfectant (but not less than 5 minutes, moisten again if it dries too quickly).
5. Repeat step 4.
6. Allow the surface to completely dry.

An independent officially accredited and recognized (§ 15 (5) MPG) test laboratory (Medical Device Services – DR. ROSSBERGER GmbH, Gilching) has provided proof of the general suitability of the products/product components for effective pre-treatment/manual cleaning and disinfection by using the disinfectant Bacillol AF (Paul Hartmann AG, Heidenheim). The method described above was considered here.

2.4. Inspection

After cleaning or cleaning/disinfection, check all products/product components for cracks, damaged surfaces, dirt and discoloration and remove damaged products/product components (for the numerical restriction on reuse see the chapter `Reusability´). Products/product components that are still dirty must be cleaned and disinfected again.

2.5. Maintenance

Instrument oils must not be used.

2.6. Packaging and storage

Packaging is not required.
Repeat the cleaning/disinfection (see the chapter `Cleaning/Disinfection´) at the beginning of each day of treatment.

2.7. Sterilization

Sterilization is generally not permitted.

2.8. Reusability

The products/product components can – with due care and provided they are undamaged and free of dirt – be reused at least up to the number indicated in the chapter `Special instructions´. The user is responsible for any further use or the use of damaged and/or dirty products/product components. All liability is excluded in the event of non-observance.

Special instructions (here you will find further information on individual parts that require a special procedure)

Item no.	Item name	Relevance/frequency (according to the risk-based approach)	Special/additional procedure for		Sterilization	The maximum permissible number of cycles	The corresponding recommendation for classification (if used as intended) FDA guidance for reprocessing:2015 Chapter VI
			Pre-treatment, manual cleaning and disinfection	Maintenance/ Assembly			
109 2312	EndoPilot apex connection cable (from the EndoPilot apex cable set, item no. 109 2311)	Mandatory after each use: - All surfaces	Standard	Do not oil	Sterilization not permitted	1000	Non-critical-device
		Not permitted: - Plug/socket (interior)	Standard	Do not oil	Sterilization not permitted	1000	(No patient contact)
109 2315	EndoPilot file cable (from the EndoPilot apex cable set, item no. 109 2311)	***This component is thermostable and must be steam sterilized (see specific processing instructions for steam sterilization, see section 1)*** *Separate cleaning, disinfection and sterilization (no wipe disinfection is intended)*					
109 2316	EndoPilot apex file clamp (from the EndoPilot apex cable set, item no. 109 2311)	***This component is thermostable and must be steam sterilized (see specific processing instructions for steam sterilization, see section 1)*** *Disassemble the file clip and then perform separate cleaning, disinfection and sterilization (no wipe disinfection is intended)*					
109 2314	EndoPilot apex lip clip (from the EndoPilot apex cable set, item no. 109 2311)	***This component is thermostable and must be steam sterilized (see specific processing instructions for steam sterilization, see section 1)*** *Separate cleaning, disinfection and sterilization (no wipe disinfection is intended)*					
109 2318	EndoPilot cap for the plug socket (from the EndoPilot apex cable set, item no. 109 2311)	***This component is thermostable and must be steam sterilized (see specific processing instructions for steam sterilization, see section 1)*** *Separate cleaning, disinfection and sterilization (no wipe disinfection is intended)*					
110 2010 or 110 2011 110 2301 110 2302	EndoPilot² control box (and extension modules, when mounted) Holder for hand-pieces right side Holder for hand-pieces left side	Mandatory after each use: Touch screen	Standard	Do not oil	Sterilization not permitted	1000	Non-critical-device (No patient contact)
		For additional safety (recommended at least once per working day): - All other surfaces	Standard				
		Not permitted: - Plug/socket (interior)	Not permitted				

The user should follow the CDC “Recommendations from the Guidelines for Infection Control in Dental Health-Care Settings” (2003).
Barrier protection (like barrier- sleeves) can be used and will not have influence on the function of the device. The prescribed thorough cleaning and disinfection must not be omitted. Keep barrier protection away from hot surfaces like the D-Pack-needle and the Back-Fill handpiece

Special instructions

Item no.	Item name	Relevance/frequency (according to the risk-based approach)	Special/additional procedure for		Sterilization	The maximum permissible number of cycles	The corresponding recommendation for classification (if used as intended) FDA guidance for reprocessing:2015 Chapter VI
			Pre-treatment, manual cleaning and disinfection	Maintenance/ Assembly			
109 0112	Endo-Pilot Endo motor	Mandatory after each use: - before dismantling the contra-angle handpiece to be processed separately: Contra-angle handpiece and front part (until the separating line) of the motor - after dismantling the contra-angle handpiece to be processed separately: Front part (until the separating line) of the motor	Standard	Do not oil, Connect the contra-angle directly before the usage	Sterilization not permitted	1000	semi-critical- device
		For additional safety (recommended at least once per working day): Front (after dismantling the contra-angle handpiece to be processed separately) - All other surfaces	Standard				No patient contact
		Not permitted: - Plug/socket (interior)	Not permitted				No patient contact
109 0151	D-Pack handpiece	Mandatory after each use: - before dismantling the heating needle to be processed separately and the front nut: Heating needle/front nut and front part (until the separating line) of the handpiece - after dismantling the heating needle to be processed separately and the front nut with O-ring: Front part (until the separating line) of the handpiece	Standard	Do not oil, connect the heating tip directly before the usage	Sterilization not permitted	1000	semi-critical- device
		For additional safety (recommended at least once per working day): Front (after dismantling the heating needle to be processed separately) - All other surfaces	Standard				No patient contact
		Not permitted: - Plug/socket (interior)	Not permitted				No patient contact
	D-Pack front nut 540 5173 With O-ring 364 2901	***These components are thermostable and must be steam sterilized (see specific processing instructions for steam sterilization, see section 1)*** *Separate cleaning, disinfection and sterilization (no wipe disinfection is intended)*					

The user should follow the CDC “Recommendations from the Guidelines for Infection Control in Dental Health-Care Settings” (2003).
Barrier protection (like barrier- sleeves) can be used and will not have influence on the function of the device. The prescribed thorough cleaning and disinfection must not be omitted. Keep barrier protection away from hot surfaces like the D-Pack-needle and the Back-Fill handpiece

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