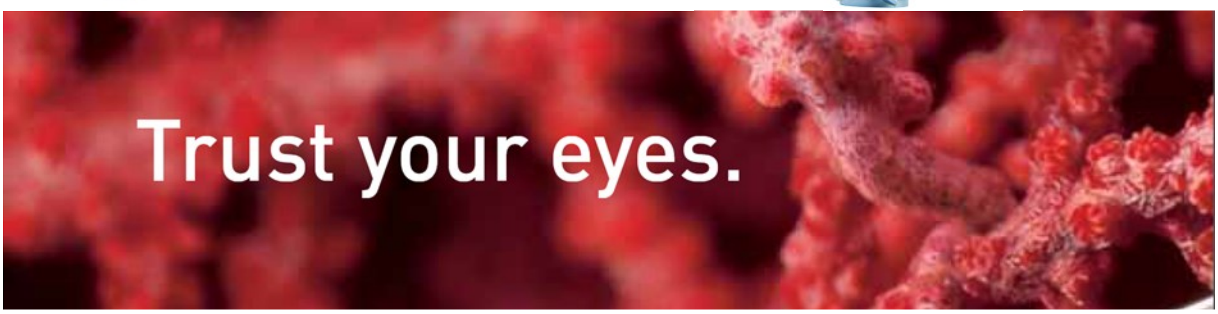
Reprocessing Instructions for re-sterilisable SCHWIND Products

Original Instruction for Use

Reprocessing of SCHWIND re-sterilisable medical products referring to the standards of Council Directive EN ISO 17664 & 93/42/EEC



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IMPORTANT NOTE

Dear Customer

Until February 2017, the SCHWIND AMARIS, CARRIAZO-PENDULAR (and likewise all other products mentioned herein) has been placed on the market under the company name "SCHWIND eye-tech-solutions GmbH & Co.KG" (with identical address).

Contents Page

1 GENERAL INFORMATION

1.1 Symbols for Warnings, Precautionary Measures and Notes

The following conventions are used in this manual:

WARNING!

This symbol advises the user of serious danger for the patient and the user.

CAUTION!

The symbol informs the user that particular care is required for safe and efficient operation of the system.

IMPORTANT NOTE

This symbol provides the user with useful or additional information.

1.2 Notes on the Reprocessing Instruction

This **Reprocessing manual** contains information which is necessary and essential for safe and efficient reconditioning of SCHWIND medical products for sterile application.

The **Reprocessing manual** supplements the information given in the user manuals for the respective medical products and is only valid with the manual of these medical products. Please read them thoroughly and follow the instructions.

The **Reprocessing manual** does not contain **any** information for cleaning and disinfection of surfaces of SCHWIND medical products.

IMPORTANT NOTE

Cleaning and disinfection of surfaces of SCHWIND medical products and their parts / components is described in the respective User Manuals.

In case of new findings SCHWIND may make changes to this manual.

IMPORTANT NOTE

The present manual contains the ORIGINAL INSTRUCTIONS, which are legally binding.

Translations of these must bear the words **"Translation of the English Original Instructions".**

2 SAFETY

2.1 Safety Instructions and Restrictions for Use

IMPORTANT NOTE

The user / operator is responsible for cleaning, disinfection and sterilisation of components and instruments and must ensure that only suitable devices, cleaning and disinfection solutions as well as product-specific reconditioning instructions and parameters as recommended by SCHWIND are used.

The reconditioning process may only be performed by trained and specialised staff.

In addition, pay attention to the manufacturers' instructions regarding purifying agents and disinfectants, disinfectors and sterilisers.

Efficient pre-cleaning, disinfection and cleaning are essential for an effective sterilisation.

Keep in mind to comply with additional regulations and guidelines possibly existing in your country and/or clinic, also with regard to a deactivation of prions.

If the user does not comply with this instruction, he will do it on his own risk. In this case, SCHWIND will not assume any liability for resulting damages.

Omission of effective reconditioning will have impact on the treatment results and endanger the health of operating personnel and of the patient.

The cleaning and disinfection must be done in an appropriate room for it (no operating room).

Always wear the prescribed protective clothing during reconditioning.

CAUTION! Instrument damage!

All parts and elements are very sensitive instruments and should be treated with utmost care.

Aggressive purifying agents may damage the surface of parts or even the medical device itself.

Do not use any abrasive detergents, scrapers or knives for cleaning! This could result in unforeseen damages to components.

SCHWIND recommends using only the purifying agents and disinfectants listed in the table in chapter 4.1.2, which were tested for their efficiency by means of a validation.

All parts and instruments must be cooled down to room temperature and dried before use.

Also see the additional instructions regarding the „Requirements for purifying Agents and Disinfectants“ in chapter 4.1.1.

WARNING!

Device damage! Danger of short-circuits!

Only undertake cleaning, disinfection and sterilisation works with the device disconnected.

Cleaning, disinfection and sterilisation works without disconnecting the device could cause damages to the device itself and personal injury due to short circuits.

WARNING!

Risk of health endangering!

Contacts with patient secretions and/or reconditioning solutions may put your health at risk.

3 COMPONENTS OF SCHWIND PRODUCTS FOR STERILE USE

3.1 General Information

This reconditioning manual is to be used **exclusively** for the products of SCHWIND eye-tech-solutions listed in the following (see chapters 3.2 and 3.3).

These products are not sterile when delivered and must therefore be reconditioned according to this manual prior to their first use (also see chapter 5 Description of Reconditioning Process).

IMPORTANT NOTE

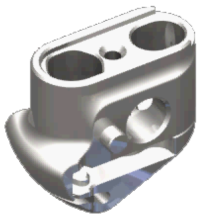
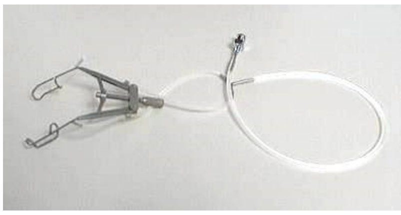
Start with **PRE-CLEANING** of the parts listed in this manual immediately **after each surgical treatment** **(within 30 minutes after use)**.

The entire reconditioning process must be completed quickly.

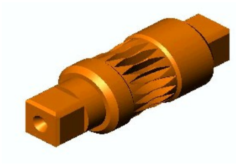
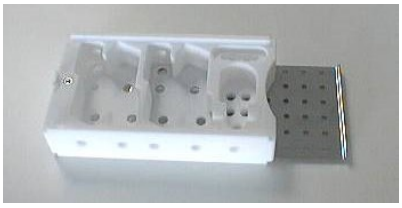
IMPORTANT NOTE

In order to prevent material changes, consider the reconditioning cycles for the medical products and its components as listed in the right table column of the chapters 3.2 and 3.3.

3.2 CARRIAZO-PENDULAR Microkeratome

Product name / Weight (gram) Material	Figure	Type of Cleaning No. of Reconditioning Cycles
• **Cutting head** / 33 g Stainless steel		**Manual or Automatic** No restriction
• **Suction rings** / 15 g Stainless steel		**Manual or Automatic** No restriction
• **Eyelid speculum** / 14 g Stainless steel and silicone		**Manual** **Steel:** No restriction **Tubings:** To change upon visible signs of material aging!
• **Shaft / screw** / 10 g Stainless steel • **Motor sleeve** / 10 g Aluminum		**Manual or Automatic** No restriction

Components of SCHWIND Products for Sterile Use

Product name / Weight (gram)	**Figure**	**Type of Cleaning**
Material		**No. of Reconditioning Cycles**
• **Tonometer** / 26 g Glass, stainless steel and silicone		**Manual** No restriction
• **Automatic pendulum axis (drive gear)** 4 g, Brass		**Manual** No restriction
• **Sterilisation tray** / 700 g Stainless steel and PTFE synthetics Polytetrafluorethylen)		**Manual or Automatic** Manual: Pay attention to the ball pressure locks and grooves on both sides! To change upon visible signs of material aging!
• **Plastic holder for Pendular drive** / 131 g, Article no. 1365101 [1] PTFE synthetics (Polytetrafluorethylen)		**Manual or Automatic** To change upon visible signs of material aging!

CAUTION **Damage of the device!**

Disassemble the **Pendular system** prior to cleaning by separating the turret from the motor, removing the spiral wheel from the turret and pulling off the sleeve (see chapter 5.1).

[1] Only holders with article number 1365101 (delivery or TSC after October 2012) can be reprocessed! **Do not sterilise previous version of holders with article no. 1365100!** They can be damaged during the sterilisation process.

CAUTION

Damage of the device!

The following parts of the Carriazo-Pendular may NOT be reconditioned / sterilised as described in this manual:

- **Drive/motor**
- **Control board**
- **Foot switch**
- **Drive/motor cable**

Cleaning/disinfection procedure of these parts is described in the user manual of the Carriazo-Pendular microkeratome.

IMPORTANT NOTE

Carriazo-Pendular disposable blades and **disposable tubings** are delivered in a sterile package and are **ready for use** upon delivery. As disposable products, they may **not** be used a second time and, thus, require no reconditioning.

3.3 AMARIS Excimer Laser

Product name / Weight (gram) Material	Figure	Type of Cleaning No. of Reconditioning Cycles
• **AMARIS steri- pen** / 37 g Stainless steel and PEEK synthetics (polyether-etherketone)		**Manual or Automatic** To change upon visible signs of material aging of the synthetic peak.
• **AMARIS caps for microscope and joystick** / 44 g Silicone		**Manual or Automatic** To change upon visible signs of material aging!

CAUTION

The **caps** are to be inserted during machine cleaning procedure with the opening downward into a rinsing basket and secured from above with a filter cover or something similar to prevent rotation!

4 PURIFYING AGENTS AND CONDITIONS

4.1 Purifying Agents and Disinfectants Recommended by the Manufacturer

All above mentioned processes, disinfectants and cleaning agents and/or compounds were tested for their efficiency according to DIN EN ISO 17664 in the respective stated procedure by an independent laboratory accredited to Council Directive EN/IEC ISO 17025.

4.1.1 Requirements for purifying Agents and Disinfectants

- Only use disinfectants licensed for the cleaning of medical instruments such as, for example, CE labelling, FDA authorisation or list of disinfectants approved by the DGHM, and which are compatible with the materials of the medical products.
- Cleaning agents and disinfectants must be compatible.
- Pay attention to freedom of aldehydes in order to avoid protein buildup.
- Use non-foaming cleaning agents for manual ultrasonic cleaning.
- In case of automatic cleaning/disinfection, the cleaning agent must be compatible for use together with the disinfector.
- Observe the manufacturers' instructions with regard to the production of solutions, the concentration and temperature as well as the reaction time.
- The reaction time indicated by the manufacturer should not be considerably exceeded.
- Pay attention to the expiration date of purifying agents and disinfectants.
- After opening, use solutions within the period recommended by the manufacturer.
- Do not use any solutions with visible contamination.
- Observe the time of exposure for baths recommended by the manufacturer.

4.1.2 Recommended puryfying Agents and Disinfectants

Automatic Cleaning / Desinfection	Manual Cleaning	Manual disinfection
Neodisher mediclean Dr. Weigert GmbH & Co.KG	**Bodedex forte** Bode Chemie GmbH & Co.	**Korsolex plus** Bode Chemie GmbH & Co.

4.2 Water Quality

Only use sterile or germ-free (max. 10 germs per ml) and endotoxin-free water (max. 0.25 endotoxin units per ml) such as, for example, Aqua purificata/ Aqua purificata valde (purified water /highly purified water) as stated in the European Medical Book or in the US Pharmacopeia.

This is valid for the application of disinfectors.

IMPORTANT NOTE

Normal de-ionised water from ion exchangers contains on average 200 germs per ml and is, thus, not suitable for reconditioning.

4.3 Compressed Air

Use filtered, oil-free compressed air for desiccation, also when applying a disinfector.

4.4 Number of Reconditioning Cycles

- **Metal components (stainless steel):**

  Applying this reconditioning manual basically **does not interfere** with the life span of the instruments. The actual life cycle of a product is only determined by normal wear and damage during use.

- **Components made of silicone and/or synthetics (PEEK / PTFE[1])**

  Using this reconditioning manual, the parts should be changed as recommended in chapters 3.2 and 3.3, in order to prevent material changes.

[1] (PEEK) Polyetheretherketon, PTFE syntetics (Polytetrafluorethylen)

4.5 Risk Assessment and Categorisation of Medical Products According to the RKI[1] Guideline

According the RKI guideline the operator is obliged to categorise the products by taking into consideration the following criteria (see tables below).

A. With regard to type of subsequent treatment:

Non-critical	▪ Medical products only coming into contact with intact skin.
Semi critical	▪ Medical products only coming into contact with mucosae and pathologically changed skin.
Critical	▪ Medical products designed for a use with blood, blood products or sterile pharmaceutical products. ▪ Permeation of skin or mucosae (coming into contact with blood, internal tissue or organs).

B. Based upon constructive and details concerning material and engineering:

Group A (without particular requirements)	▪ Smooth surfaces. ▪ Without lumina/cavities.
Group B (with increased requirements)	▪ Long, narrow, and particularly terminal lumina. ▪ Cavities with only one opening. ▪ Complex, hardly accessible surfaces. ▪ Limited amount of applications/reconditioning cycles.
Group C (particularly high requirements)	▪ Thermolabile, i. e. not steam-sterilisable (in case of critical products). ▪ After application with oily/viscose substances. ▪ After application in rigid tissues.

[1] RKI – Robert Koch Institute in Germany

Purifying Agents and Conditions

Regarding the recommended application range and product design SCHWIND eye-tech-solutions issues the following non-binding recommendation:

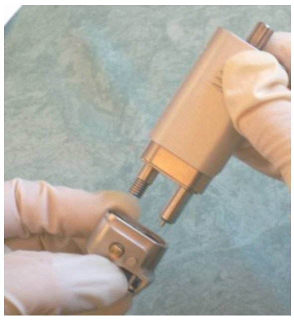
Criteria	Group A	Group B	Group C
Non-critical	▪ AMARIS steri-pen ▪ AMARIS caps for microscope and joystick ▪ Pendular motor sleeve ▪ Pendular motor drive with screw ▪ Pendular pendulum axis (drive gear) ▪ Pendular sterilisation tray ▪ Plastic holder for Pendular drive		
Semi critical	▪ Pendular tonometer ▪ Pendular lid speculum	▪ Pendular suction rings	
Critical	▪ Pendular cutting head		

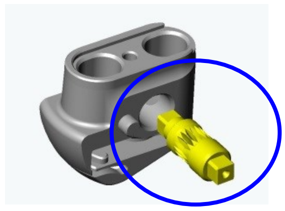
The operator / conditioner must do a final binding categorisation in written form.

5 DESCRIPTION OF RECONDITIONING PROCESS

The reconditioning process will only be complete if it consists of the **cleaning** / **disinfection** and the subsequent **sterilisation.** The order of the cleaning processes described in the following must absolutely be followed.

5.1 Disassembly of the Carriazo-Pendular and AMARIS Parts before the Reprocessing

Product Name	Components / Accessories	Disassembly
Carriazo-Pendular 	**Disassembly the system before cleaning (heads, motor)!** No tools necessary for disassembly!	
	Motor drive with screw	Take off the motor cover from the motor, by loosening the screw. 
	Cutting head	Separate/unscrew the **cutting head** from the motor drive. . 

Product Name	Components / Accessories	Disassembly
	Motor sleeve	Remove the **motor sleeve** 
	Pendulum axis (drive gear)	Take out the **pendulum axis (drive gear)** of the cutting head  No further disassembly of the cutting head necessary.
	Suction rings	No disassembly necessary.
	Lid speculum	No disassembly necessary (Do not take off the tubings!)
	Tonometer	No disassembly necessary.
	Sterilisation tray	No disassembly necessary.
		CAUTION **Equipment damage!** **All other Carriazo-Pendular parts, ea. drive/motor, console, foot switches and the drive/motor cable MAY NOT BE reconditioned / sterilized according to this guidance.**

IMPORTANT NOTE

The **assembly procedure** of the **Carriazo-Pendular microkeratome** will be performed in reversed order. Refer also to the User Information No. 01-07 “Assembly Instructions for new Disposable Blade”.

Product Name	Parts	Disassembly
AMARIS	**Steri-pen**	No disassembly necessary.
	Caps for microscope and joystick	Remove the caps from the microscope or joystick. No further disassembly necessary.

5.2 Preparation of Location for Reconditioning (Soaking)

- **Immediately after uses, but latest after 30 minutes, place** the disassembled components into a synthetic container filled with **purified water** to avoid contamination drying and to facilitate the subsequent cleaning process.
- Thereby, make sure that the parts are completely covered and entirely disassembled without tools. Also avoid touching the parts in order to prevent them from damages.
- For reasons of personal protection it is recommended to add a **disinfectant** to the water (conforming to the manufacturers' indication).
- Pay attention to material compatibility and aldehyde freedom in order to avoid buildup of possibly existing protein contamination.

5.3 Preparations before Cleaning (Pre-Cleaning)

- Pre-cleaning in the bath must be performed **immediately after use, but latest after 2 hours** with aldehyde-free and non-fixing purifying agent for instruments compatible with the applied material.
- Clean all freely accessible surfaces carefully from adherent contamination with a soft synthetic brush (e.g. a tooth brush) according to their grade of contamination. Pay particular attention to rough surfaces like threads, fluting of handles etc. Do not use any metallic brushes, steel wool or similar abrasive substances.
- For personal protection it is mandatory to use suitable hand/mouth and eye protection.
- It might be necessary to add another disinfection phase or to use a **purifying agent** with disinfecting impact for reasons of personal protection.
- The manufacturer's information regarding concentration, temperature and time of exposure must be complied with.
- Rinse parts with cavities, hoses or tube systems, e. g. Pendular suction rings or eyelid retractors twice with a syringe, each time **20 ml of cleaning agent.**
- All movable parts must be cleaned completely through turning in order to reach hidden surfaces.

5.4 Cleaning, Disinfection and Drying

Effective cleaning / disinfection is absolutely required so that the subsequent sterilisation can achieve the desired absence of germs.

You should give the automatic cleaning / disinfection preference to the manual cleaning / disinfection due to a higher efficiency and better reproducibility.

One of the procedures described in chapters 5.4.1 or 5.4.2 is to be applied.

5.4.1 Automatic Cleaning / Disinfection

- Use disinfectors meeting the requirements of DIN EN ISO 15883 as well as possible country-specific regulations (CE-labelling). In particular, rinsing adapters are required for addition to lumina instruments. Only supply water of the previously mentioned quality (see chapter 4.2) and compressed air as defined above (see chapter 4.3), if provided by the disinfector.

  The applied disinfection program should have an efficiency of $A_0 = 3000$.
- Use cleaning agents and disinfectants compatible with each other, with the products and the disinfector (apart from thermal disinfection processes) and suitable for this purpose.
- Pay attention to the manufacturer’s instructions with regard to labour protection, concentration, reaction time, refinishing, time of exposure as well as potential naturalisation.
- **Automatic cleaning not recommended** for the Pendular **pendulum axis** in order to exclude material damage and loss of function.
- **Automatic cleaning not recommended** for the Pendular **eyelid speculum** since only with a manual cleaning can it be guaranteed that the tubings remain on the eyelid speculum.
- **Automatic cleaning not recommended** for the Pendular **tonometer** since the best cleaning efficiency can be obtained only by manual movement of the motor cover during the washing process.

Cleaning / disinfection process

- Put the products in suitable baskets or sieves with a silicone inlay or something similar. Make sure that they do not get into contact with each other or with metal parts and that possible fixation elements like silicone pins or similar product parts are not shielded from cleaning.
- In order to especially preserve eye-contact surfaces of the cutting head, please place it in the basket with the flat motor side upper surface facing down.
- Arrange the baskets inside the disinfector according to the manufacturer’s instructions.
- Connect instruments like lumen instruments to the rinsing supplies of the disinfector without obstructing permeability.
- **Run a complete cleaning and disinfection cycle.**

Drying after automatic cleaning / disinfection

- Remove the products after cooling off, dry them, if necessary, with compressed air as described above and examine them for possibly remaining contamination or damage. Then pack them immediately.

5.4.2 Manual Cleaning / Disinfection

- **Use non-foaming purifying agents and disinfectants** compatible with each other and with the products and whose efficiency is proven for the present purpose.
- Pay attention to the manufacturer's instructions with regard to labour protection, concentration, reaction time, refinishing, time of exposure as well as possible neutralisation.

Cleaning process

- Put the products into an **ultrasonic bath with cleaning agent** (see chapter 4.1) and make sure they are fully covered and avoid scratches by:
  - Placing the instruments separately on a sieve during cleaning and disinfection so that they neither get into contact with others nor lay one on top of the other.
  - Only using synthetic sieves or additional rubber mats for the instrument tray.
- **Rinse** lumen instruments **twice** with a minimum of **20 ml purifying agent** by using a syringe respectively at the beginning and at the end of the cleaning phase.

Intermediate rinsing

- After the reaction time indicated by the manufacturer rinse the instruments with fresh water. Rinse lumen instruments at least **twice** with each time **20 ml of fresh water** by means of a syringe.
- Repeat the cleaning process if there is still any contamination or clouding of water.

Disinfection process

- Place the products in a container with **disinfectant** and make sure they are fully covered and avoid scratches by:
  - placing the instruments separately on a sieve during cleaning and disinfection so that they neither get into contact with others nor lay one on top of the other.
  - only using synthetic sieves or additional rubber mats for the instrument tray.
- **Rinse** the lumen instruments twice by using a syringe with a minimum of **20 ml purifying agent** respectively at the beginning and at the end of the cleaning phase.

Rinsing

- After the reaction time indicated by the manufacturer, **rinse** the instruments with fresh water. Lumen instruments must be rinsed at least **two times** with a syringe with at least **20 ml of fresh water.**

Dissection after manual cleaning/ disinfection

- Dry the parts with compressed air, check them for possible contamination or damage and pack them immediately.

5.5 Control / Maintenance / Test

Control – see description chapter 5.4.

The products mentioned here do not require any maintenance.

5.6 Packaging

- The delivered sterilisation tray is intended for admission of the following Pendular accessories during the sterilisation procedure:
  - Max. 4 suction rings,
  - One pendulum axis and
  - One cutting head (together 91 gram).
- All other components are to be sterilised either doubly packed in paper/foil, or simply packed in paper/foil in a sterilisation container.
- The sterilisation containers must meet the requirements of DIN EN ISO 11607 and/or DIN EN 868-8 and be suitable for steam sterilisation (steadily to 141°C, steam-permeable).

Pay attention to avoid scratches or other damage.

5.7 Sterilisation

Only products which were **treated, cleaned and disinfected** according to the above mentioned procedures may be sterilised.

A fractionated vacuum process must be applied; the steam steriliser must be designed according to **DIN EN 13060 and/or DIN EN 285** and validated according to **DIN EN ISO 14937**as well as **DIN EN ISO 17665-1**.

IMPORTANT NOTE

Observe times of exposure for sterilisation of 5 minutes with at least 134°C and 2 bars.

The maximum sterilisation temperature must not exceed 138°C.

If a deactivation of prions according to RKI is required, the time of exposure must be at least 18 minutes with the above mentioned process data.

WARNING!

Danger of burns!

Allow the parts to cool down after sterilisation.

The above stated parameters may be exceeded upwards (except for the synthetic caps); however, this will cause a higher wear of the material.

If the parameters are undershot and/or a different sterilisation process is used such as dry heat, ethylenoxide, formaldehyde, low-temperature plasma or radiation, the manufacturer will not assume any liability. In this case, the operator must prove the suitability of the procedure by means of a validation.

5.8 Assembly of the Parts after Sterilisation

The assembly of all parts shall be performed after the sterilisation procedure directly before application.

All parts are to be assembled again in reverse order as shown in chapter 5.1 "Disassembly of the Carriazo-Pendular and AMARIS Parts before the Reprocessing".

5.9 Storage, Packaging

The environment of the storage location must be dry. The packaging must not affect the sterility of the products determining the admissible duration of storage.

5.10 Cleaning and Sterilisation Chart

Product / Components	Soaking / Pre-cleaning	Manual cleaning and disinfection	Automatic cleaning or disinfection	Steam sterilization
	Refer to chapters 5.2 and 5.3	Refer to chapter 5.4.2	Refer to chapter 5.4.1	Refer to chapters 5.6 und 5.7
		For **cleaning agents** and **disinfectants**–refer to chapter Fehler! Verweisquelle konnte nicht gefunden werden.		**Max. temp. 138°C**
CARRIAZO-PENDULAR				
Cutting head	Yes	Yes	Yes	Yes
Suction rings	Yes	Yes	Yes	Yes
Eyelid speculum	Yes	Yes	**No**	Yes
Automatic pendulum axis	Yes	Yes	**No**	Yes
Sterilization tray	Yes	Yes	Yes	Yes
Plastic holder for Pendular drive	Yes	Yes	Yes	Yes
Pendular applanation tonometer	Yes	Yes	**No**	Yes
Sterilisable motor cover (sleeve) and screw	Yes	Yes	Yes	Yes
▪ **Electrical Motor** ▪ **Motor cord** ▪ **Foot switch** ▪ **Console**	**No**	**No**	**No**	**No**
	The cleaning / disinfection procedure (surface wiping disinfection) is described in the Carriazo-Pendular User Manual			
SCHWIND AMARIS				
Steri-pen	Yes	Yes	Yes	Yes
Caps for microscope and joystick	Yes	Yes	Yes	Yes

6 VALIDATION OF RECONDITIONING PROCESS

The formerly listed instructions were validated by SCHWIND eye-tech-solutions as SUITABLE for reconditioning of the above mentioned components / instruments for medical products. The validation was performed by „Medical Device Services – Dr. Rossberger GmbH“ in Gilching, which is accredited according to EN ISO/IEC 17025 and the Council Directive 93/42/EWG.

Test reports of the mds – Medical Device Services Laboratory

- Test 095405-10-A 10-03-24 vg
- Test 095405-10-B 10-03-24 vg
- Test 095405-10-C 10-03-24 vg
- Test 095405-10-D 10-03-25 vg
- Test 095406-10 10-02-25 vg

6.1 Automatic Cleaning / Disinfection

The disinfector **Desinfektor G 7836 CD, Miele, Gütersloh** and the purifying agent **Neodisher mediclean** with a concentration of **2%** were used for the validation process.

6.2 Manual Cleaning / Disinfection

The purifying agent **Bodedex forte** with a concentration of **0,5%** was used.

The disinfectant **Korsolex plus** with a concentration of **3%** was used.

6.3 Sterilisation

For the validation a fractionated vacuum process was applied in the steriliser **Systec V-150, Systec Labor-Syststemtechnik, Wettenberg.**

Appendix: Safety data sheets, product information of Bodedex forte, Korsolex plus and Neodisher mediclean.

7 MANUFACTURER / TECHNICAL ASSISTANCE / APPLICATION SUPPORT

SCHWIND eye-tech-solutions offers a comprehensive warranty and service support.

Highly qualified representatives from our SERVICE and CUSTOMER SUPPORT departments are available to support you and to solve any operational questions.

Should you have any questions, please do not hesitate to contact our Service or Customer Support Hotline. The Service Hotline is free of additional charges (only regular telephone charges are incurred).

Our customers outside of Germany should use the service hotline provided by our local distributor or authorized Service Representative first.

If you have any questions, do not hesitate to contact us.

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