



Instrument Care & Cleaning Guide

Version 4.11

Complete Instrument Maintenance and
Care Instructions Inside, Including:

TASS
Management

Sterilization
Guidelines

Automated
Cleaning

Manual
Cleaning

Today's Precision...Tomorrow's Vision™



**"ASICO Offers the Most Comprehensive report on
TASS management to date"**

Nick Mamalis MD
University of Utah- Salt Lake City, Utah



ASICO Instrument Care Guide

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Summary of the ASICO Instrument Care Guide

This information guide is a cleaning guide for all ASICO products. Some instruments require specialized reprocessing and cleaning instructions that are explained in the Directions For Use (DFU) document individually prepared for those instruments. A copy of the DFU for the specialized product is supplied with each purchase of such instruments. To request a DFU for a particular product, contact ASICO to see if one is available.

All the instructions and procedures in this document must be followed without deviation. In case of deviations, ASICO shall not be responsible for damage to the products.

ASICO has tested these instructions with the help of a certified testing lab and will retain the right to make modifications to this document based on new findings for reprocessing instructions from time to time.

ASICO is committed to producing the highest quality and most innovative ophthalmic surgical instruments. All ASICO instruments pass through Quality Control methods according to ISO 13485 standards and are certified for the same. Before the first cleaning/disinfection and sterilization process, carefully inspect the instrument to ensure the quality, finish, and overall conditions have been met.

Introductory Information

ASICO products are provided to customers in a non-sterile state, unless they are disposable and single-use product, which are provided 100% sterilized and labels as such. These instruments **must be** cleaned and sterilized before every use. Proper cleaning steps need to be followed to ensure that the sterilization steps are effective. Adhering to these steps in every cycle is required.

Robert Koch Institute¹ (RKI) establishes guidelines for all surgical instruments. All ASICO surgical instruments can be classified as per the guidelines established by the RKI. Instruments that do not come in contact with blood, tissue and skins are classified as Non-Critical or Critical A instruments. Instruments that are used in surgical procedures involving blood, tissue, or other body membranes, and that have high requirement for decontamination requirements are categorized as Critical Instruments, and more specifically, Critical B or Critical C instruments. This Classification helps in separating instruments during the cleaning process, based on the nature of cleaning – least critical to most critical – that is Critical A to Critical C.

The steps given below are the result of an independent third party lab test. Results based on specifications from the standards are mentioned in 'References – Lab Testing Data' on Page 11 of this document.

Reprocessing procedure

As per ASICO's independent lab testing data, using mechanical processes such as pre-cleaning and ultrasonic cleaning greatly increases the effectiveness of the cleaning process.

¹ RKI Guidelines – Robert Koch Institute in Germany – <http://www.rki.de>
Valid date: 10/31/2011

For effective reprocessing, the pre-treatment should begin as soon as the surgery/operation has been completed but no more than 30 minutes after the surgery. The complete Cleaning process must take place within the next two (2) hours of completing the pre-cleaning.

TASS Management

Cleaning and sterilization procedures described in this document are primarily aimed at preventing a post-operative disease called Toxic Anterior Segment Syndrome (TASS). According to the Center for Disease Control, ‘Toxic anterior segment syndrome (TASS), an acute, noninfectious inflammation of the anterior segment of the eye, is a complication of anterior segment eye surgery. According to a recent report published by the American Society of Cataract and Refractive Society (ASCRS)², TASS may be caused by ‘irritants on the surfaces of intraocular surgical instruments...accumulated as a consequence of inadequate or inappropriate instrument cleaning...heat stable endotoxin from overgrowth of gram-negative bacilli in water baths of ultrasonic cleaner...’³ Based on the publication, ASICO recommends that adhering to the cleaning booklet guidelines will more thoroughly address the concerns for TASS.

The following instruments in **Figure 1 and 2** have been tested by an independent third party lab specifically for developing cleaning methods to address concerns on TASS.

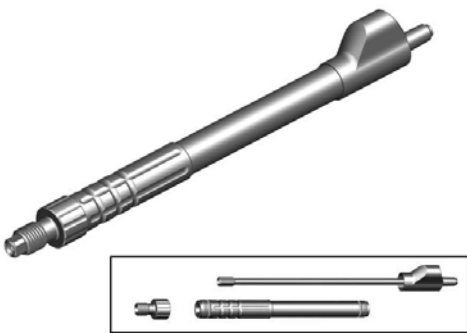


Figure 1: ASICO Cleaning I/A Handle (AE7-0029)

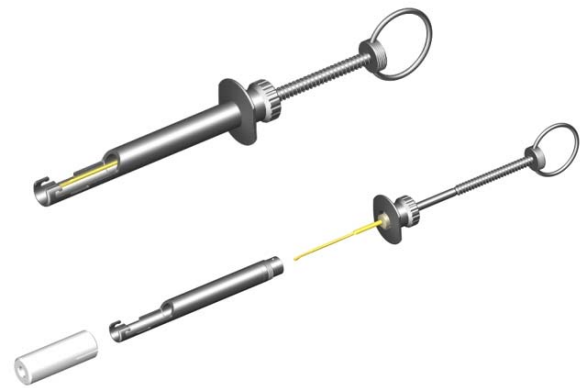


Figure 2: ASICO Cleaning Injector (AE-9063CSP)

Pre-Cleaning Steps

1. All instruments that have been used must be submerged into cold, de-ionized water (<40°C) immediately after use for removing gross (large) soiling.
2. All surfaces must be cleaned with a soft bristle toothbrush to remove macroscopic contaminants. Special attention is required for uneven surfaces (such as knurled handles) to remove all macroscopic contaminants.
3. Scrub the inside and outside of the instruments with a soft bristled nylon brush until all visible soil is removed.

² Mamalis N, Edelhauser HF, Dawson DG, Chew J, LeBoyer RM, Werner L. Toxic anterior segment syndrome. J Cataract Refract Surg 2006;32:324--33.

³ ASCRS/ASORN – Special Report – Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments
http://www.ascrs.org/TASS/upload/TASS_guidelines-CBC.pdf
 Valid date: 10/31/2011

4. **DO NOT** use a fixating detergent or hot water (>40°C) – this may cause fixation of the residue on the instrument causing the reprocessing steps to fail.

A fixating detergent contains aldehyde solution that may cause fixation of the blood contaminants on the instrument.



Figure 3: No Fixation Detergent and Hot Water should be used for cleaning.

5. Soak the instruments in an enzymatic detergent with a pH level between 6-9 for 10 minutes at 40°C (source: lab test data.)
6. If a disinfection solution is used, ensure that it is aldehyde-free. After using an aldehyde-free solution, the instrument must be rinsed with distilled or deionized water at least 3 times.
7. For all lumina (example: Irrigating and aspirating devices), use a disposable syringe (50ml or more) and rinse in normal direction of flow at least 3 times with distilled or deionised water.
8. If some instruments appear worn, damaged, porous or corroded, these must be separated after the pre-cleaning steps.
9. For Micro-instruments, special cleaning steps and tools must be used. Careful handling of the micro-instruments is required in the pre-cleaning and sterilization procedure.
10. For Micro-instruments, a special syringe with a silicone cover must be used to flush the micro-instrument thoroughly before subjecting it to other cleaning steps.

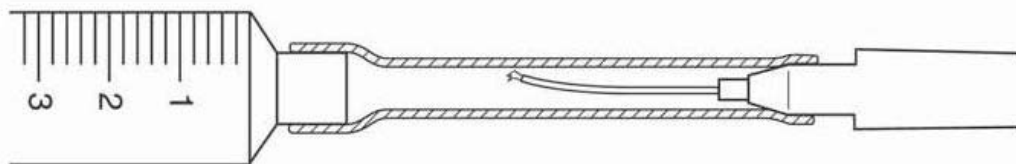


Figure 4: Micro instruments need special cleaning tools

Ultrasonic cleaning

Some instruments may be heavily soiled during a surgery/operation. These instruments will require additional pre-cleaning via an ultrasonic bath. When ultrasonic cleaning is done, care must be taken that the exposure time and concentrations recommended by the manufacturers of the cleaning solution are observed, and cleaning and disinfection agents are compatible with instruments (especially stainless steel and titanium.)

1. The instruments must be placed on a silicone mat in the ultrasonic cleaner.

2. To reduce or avoid endotoxin contamination, it is recommended to change the cleaning solution from the ultrasound cleaner after each and every use.
3. If more than one instrument is being placed in the ultrasonic cleaner, ensure that **none of the instruments** have any large areas of corrosion (rusted, flaky, or deep stained before placing in the cleaner.
 - a. If you find instruments that have macroscopic corrosion, they must be separated and removed from the ultrasonic cleaning process and should be pre-cleaned and inspected as per ‘Inspection Requirements’.
 - b. If the instruments that are separated do not have corrosion after careful observation, they can be ultrasonically cleaned in a separate batch.
4. **DO NOT** place instruments in contact with any metal surface on the ultrasonic cleaner.



Figure 5: Always use silicone mat for ultrasound cleaning



Figure 6: DO NOT put instruments in contact with the metal

5. When using deionized water, instruments must be completely submerged in the water. When using a cleaning solution, the same care must be taken to submerge the instrument completely in the cleaning solution.
6. Instruments with hinges and joints must be treated in an open state.
7. Soak the instruments in an enzymatic detergent and turn **on** the ultrasonic bath (38 KHz) for 10 minutes.
8. After the ultrasonic treatment, scrub the inside and outside of the instruments with a suitable soft bristled nylon brush until all visible soil is removed
9. Flush the internal channels and the outside with demineralised water to remove the cleaning detergent. A free drain of water through the instruments is required
10. Ensure that the ultrasonic bath is not contaminated before use. Contamination can increase the risk of corrosion and impairs the effective cleaning process.
11. Criteria for contamination – visibly observe the water in the bath for contaminations, dirt, debris, or other coloration of the water. If contamination is observed, the water bath must be replaced with new distilled water.
12. The use of ultrasound baths and strong cleaning fluids (alkalis pH > 9 or acids pH < 5) can reduce the life span of products. The manufacturer accepts no liability what so ever in such cases



Figure 7: Sterilization water needs to be replaced after each sterilization cycle to reduce the risk of endotoxic contamination

Automated Cleaning Procedure

In some cases, if there is access to an Automated Cleaning device such as a washer or disinfectant, a general purpose cleaning program (eg. Vario TD) may be used.

Ensure that the disinfectant possesses the basic, tested effectiveness – either DGHM or FDA approval or CE marking. One example is Miele disinfectant G7735 CD.

The following steps can be used for Automated Cleaning:

1. The instruments must be placed in a tray and put in the washer/disinfectant.
2. The cycle to be followed is given below:
 - I. 3 minute pre-cleaning with deionized cold water.
 - II. 5 minute cleaning at 55°C with 0.5% solution of cleaner. Drain the solution after the 5 minutes.
 - III. 2 minutes neutralization with deionized cold water.
 - IV. Drain the water after neutralization and rinse with cold water for 2 minutes.
3. For rinsing, the cold water to be used must be either sterile, or have a low-microbe-count (less than 10 microbes/ml). The water must be deionised water with a sufficiently low endotoxin and particle concentration.
4. Follow the special instructions given by the manufacturer of the washer/disinfectant for the machine.
5. After the cycle is finished, the instruments need to be inspected as per ‘Inspection Requirements’ as outlined on Page 6 of this document.

Manual Cleaning

For a manual cleaning process, follow the Pre-cleaning steps above, and then proceed with the below steps:

1. The steps for ultrasonic cleaning must be followed.
2. Manual disinfection can be done by submerging the instruments in a disinfection agent. Manufacturer’s instructions on the disinfection agent must be followed.
3. **DO NOT combine** two or more disinfection agents or cleaning agents unless it is known that the agents are compatible.
4. The concentration and exposure times of the agents must be followed without fail.

5. After the agent is used, remove the instruments and rinse with freshly distilled or deionized water at least 5 times with a disposable syringe of 10ml. Repeat this cleaning process if the last rinse solution is not clear or if impurities are still visible on the product.
6. The products can be dried using filtered, compressed air.
7. After the cycle is finished, the instruments need to be inspected as per 'Inspection Requirements'.

Sterilization Guidelines

After either the Automated Cleaning or Manual Cleaning process, **ONLY** clean instruments with no surface debris as per Inspection Requirements can be sterilized.

The times and temperature specifications given below are minimum requirements for sterilization. In some cases, if the sterilization time and temperatures are exceeded, they may cause stress in the material.

Only the sterilization criteria listed below are to be used. If other forms of sterilization are used, they must be validated beforehand by the user.

If other sterilization procedures such as ethylene oxide, formaldehyde, or low-temperature plasma sterilization are used, please observe respective valid standards (ANSO AAMO OSP 14937, EN ISO 14937) and verify the suitability and effectiveness in principle of the procedure, taking into account the specific product geometry as part of the validation. ASICO assumes no responsibility if any other sterilization procedure other than the one given in this document is used.

Please consult with your autoclave manufacturer or hospital guidelines for specific times.

Depending on the sterilization autoclave, the following sterilization processes need to be used:

Parameters for the pre-vacuum cycle:

1. 3 pre-vacuum phases with at least 60 millibar
2. Heat up to a minimum sterilization temperature of 132°C;
maximum temperature 137°C
3. Minimum Holding time: 3 min
4. Drying time: **minimum 10 min!**

Parameters of the gravity cycle:

1. Heat up to a minimum sterilization temperature of 132°C;
maximum temperature 137°C
2. Minimum Holding time: 34 min
3. Drying time: **minimum 10 min!**

Parameters of Flash Cycle:

1. Unwrapped instruments
2. Heat up to a minimum sterilization temperature of 132°C;
maximum temperature 137°C
3. Minimum Holding time: 10 min
4. Drying time: **minimum 10 min!**

Sterilization Guidelines (excludes diamond knives)

Method of Sterilization	Sterilizer Type	Sample Configuration	Temp.	Exposure Time
Steam	Gravity Displacement	Wrapped	132°C (270°F)	34.0 min.
Flash	Gravity Displacement	Unwrapped	132°C (270°F)	10.0 min.
Steam	Prevacuum	Wrapped	132°C (270°F)	3.0 min.
Flash	Prevacuum	Unwrapped	132°C (270°F)	3.0 min.

Inspection Requirements

After the cleaning cycle is complete (either the Automated Cleaning or Manual Cleaning), the following steps must be taken to ensure that the reprocessed instrument is inspected as per requirements:

1. Instrument must be macroscopically clean – free from visible protein residues, impurities, debris, soil, etc.
2. Instruments which are fresh out of the sterilizer need to be cooled prior to a functional test.
3. Instrument with fine operating tips, ends or long visible parts, may be inspected under a microscope or magnifying glass for non-visible debris.
4. Instruments with hinges and locks can be oiled with paraffin oil-based agent prior to a functional test.
5. If instrument appears to be worn, damaged or porous, it must be separated from all other instruments. The same must be done for corroded instruments. This group of instruments may no longer fulfill their function and must either be repaired or replaced.
6. After inspecting the instruments, if the instruments are found to be clean and functional, they need to be packed and stored according to the ‘Storage Requirements’ on page 9.
7. These acceptability criteria are based on the relevant specifications given in the following documents: AAMI TIR 30, EN ISO 15883-1:2006 and the guidelines of DGKH, DGSV and AKI

Storage Requirements

After the inspection of the instruments is complete, the following steps must be taken to ensure proper storage of reprocessed instruments:

1. Instruments must be properly stored in a dry, ambient temperature.
2. The storage period depends on the type of packaging that is used.
3. If instruments are stored in a sterilization tray, they must be stored in a safe, dry place.
4. Instruments may be stored in the original package they were received in, but it should be ensure that box is completely dry on the inside and out.
5. Instruments with protective caps must be stored with the cap on the instrument.

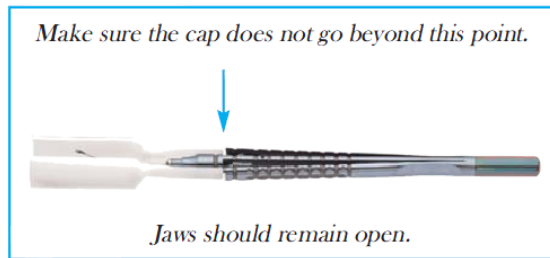


Figure 8: Putting the Protective caps on the Micro-instruments



Figure 9: Micro-instruments stored in Sterilization tray

Note About Metals

Stainless steel is an alloy of various metals. It is a hard material that is resistant to but not free from corrosion. It is the material of choice for fine instruments that need to retain their shape and sharpness.

Titanium is a very durable yet lightweight metal, almost half as light as stainless steel. It is also resistant to but not free from corrosion. It is very pliable in comparison to stainless steel. Therefore it is the material choice for bulkier or more complex instruments that do not need to retain their sharpness.



Figure 10: Stainless steel instruments (eg: AE-4390)



Figure 11: Titanium instruments (eg: AE-9063CSP)






Note from the Manufacturer

- Surgical instruments made from high-grade stainless steel and titanium can be reused many times, provided they are reprocessed as specified. Chemical and thermal treatment will cause stress in the material, causing them to age.
- If the type of material limits the number of reprocessing cycles, this is indicated on the user instructions enclosed with the product.
- High-grade steels must not be permanently exposed to environments conducive to corrosion (e.g., chloride or iodine ions and their vapors) over long periods of time.
- Long delays before reprocessing must be avoided.
- When reprocessing manually, care must be taken that no damage is caused by the use of metal brushes, scouring agents or by the exertion of too much force.
- Products must be stored appropriately during sterilization (not on top of each other and fixed in place with sterilization strips or sterilization plates).
- Products should be sterilized in a "relaxed" state:

- hinges and joints open
- locks unlocked
- cannulas removed from headpieces
- **DO NOT** allow residues to dry on lumen instruments (e.g., cannula). Before they are to be laid aside, flush them out with sterile or low-bacteria (max. 10 bacteria/ml) distilled or deionized water.
- Only agents suitable for sterilization are to be used on the hinges and joints of instruments.
- The use of distilled or deionized water for all reprocessing cycles (including pre-cleaning) is recommended because tap water can cause the concentrations of ions on the surface of the steels to increase.
- Cleaning adapters accompany instruments insofar as these are needed for manual reprocessing or to connect lumen instruments to washing or disinfecting machines. Their use is explained in the cleaning instructions which accompany the product.
- It must be noted that when using alkaline cleaning solutions, certain materials such as aluminum may become corroded. In such cases, the manufacturer of the cleaning solution must be consulted.
- When using hydrogen peroxide H₂O₂ (for example in Miele's OXIVARIO® method), titanium instruments may become discolored. These discolorations can be attributed to changes in the thickness of the oxide layer and do not affect the quality of the instruments. This method is not suitable for products made from aluminum.

Stains on instruments

If you observe stains on the instrument post cleaning and sterilization, please note the following important indicators.

Color of Stain	Cause	Solution
Brown-Orange 	Phosphate deposits from detergent used	Try removing with pencil eraser. If stain does not come off, use a neutral detergent. Rinse instruments thoroughly with distilled water.
	Rust in water used in autoclave	
Dark brown 	Dried blood	Clean instruments thoroughly before sterilization.
Purple-black 	Detergent used contains ammonia	Rinse instruments thoroughly before sterilization.
Blue-black 	Dissimilar metals being autoclaved together	Separate instruments by metal type before sterilization.
Black 	Acid reaction	Remove with pencil eraser. Use a neutral detergent in the future.

References – Lab testing Data

ASICO has performed independent testing of devices for the pre-cleaning, manual cleaning, and automated cleaning processes. The study information is given below.

Reprocessing validation study information	<p>The following testing test devices, materials & machines have been used in this validation study;</p> <p>Detergent: Mediclean forte (Dr. Weigert, Hamburg, Germany)</p> <p>Lubrication: Neodisher IP konz</p> <p>Washer / Disinfector: Miele 7735 CD</p> <p>Instrument Rack: Miele E 327-06</p>
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Acceptance Criteria

The acceptance criteria are based on the relevant specifications given in the following documents: AAMI TIR 30, EN ISO 15883-1:2006 and the guidelines of DGKH, DGSV and AKI:

- At the end of the cleaning process the items shall not show any visual contamination (visual inspection).
- The total amount of residual proteins on and in the items as determined with the modified OPA method (described in EN ISO 15883-1:2006, C2) shall be less than 200 µg per item (corresponding to an extinction value of 0.02) or 6.4µg/cm² what-ever is lower.
- The average cleaning result via the radionuclide method shall be less than or equal to 5 counts per second; the result of a single evaluation shall not exceed 10 counts per second.

The cleaning process is judged as successful if the instruments meet the requirements of ISO15883-1:2006 and AAMI TIR30.

References and Standard Titles

Identification	Title
DGKH, DGSV, AKI	Publication date: May 2007: International Journal of Sterile Supply: Guideline compiled by the DGKH, DGSV and AKI for Validation and Routine Monitoring of Automated Cleaning and Disinfection Processes for Heat-Resistant Medical Devices as Well as Advice on Selecting Washer-Disinfectors:
AAMI TIR 12:2004	Designing, testing, and labeling reusable medical devices for reprocessing in healthcare facilities: A Guide for Device Manufacturers
AAMI TIR 30:2003	TIR 30 "A compendium of processes, materials, test methods, acceptance criteria for cleaning reusable medical devices
AAMI ST-81:2004	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
ISO 17664:2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
EN ISO 15883-1:2006	Washer/-disinfectors - Part 1: General requirements, terms and definitions and tests; German version EN ISO 15883-1:2006
EN ISO 15883-2:2006	Washer/-disinfectors - Part 2: Requirements and tests for washer/disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes receivers, utensils, glassware, etc. (ISO 15883-2:2006); German version EN ISO 15883-2:2006
Robert Koch Institute (RKI) Guidelines	<ol style="list-style-type: none"> 1. The Robert Koch Institute Guidelines for reprocessing of medical devices was utilized in the independent lab testing. 2. More information about RKI can be found on http://www.rki.de/

AT A GLANCE:

ADVICE:	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. In case of damage the device should be reprocessed before sending back to the manufacturer for repair.	
Reprocessing Instructions	Automated Cleaning Process	Manual Cleaning Process
Preparation at the Point of Use:	Remove gross soiling by submerge the instrument into cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.	
Transportation:	Do not replace used instruments into the tray before cleaning. Safe storage and transportation in a closed container to the reprocessing area to avoid any damage and contamination to the environment.	
Preparation for Decontamination:	All instruments, which have been used or contaminated have to be removed out of the tray for cleaning	
Pre-Cleaning:	Soaking the instruments in an enzymatic detergent with a pH level between 6-9 for 10 min at 40°C Scrub the inside and outside of the instruments with a suitable soft bristled nylon brush until all visible soil is removed	
Cleaning:	Automated Cleaning: Put the instruments on a tray and put the tray in the washer disinfectant and start the cycle: 3 min. pre-cleaning with cold water 5 min cleaning at 55°C with 0,5 % Mediclean forte 2 min neutralisation with tap water If applicable 2 min lubrication with Neodisher IP konz 10 min draining Special instructions of the manufacturer of the automated washing machine have to be followed.	Ultrasonic cleaning: <ul style="list-style-type: none"> • Soaking the instruments in an enzymatic detergent and turn the ultrasonic bath (38 KHz) on for 10 min • Scrub the inside and outside of the instruments with a suitable soft bristled nylon brush until all visible soil is removed • Flush the internal channels and the outside with demineralised water to remove the cleaning detergent. A free drain of water through the instruments is required
Disinfection:	Automated Disinfection: Automated Thermal Disinfection in washer/disinfectant under consideration of national requirements in regards to A ₀ -Value (see EN 15883)	Manual Disinfection: Submerge the instruments in an disinfection agent. Follow the instructions of the manufacturer of the detergent according to time, temperature and concentration. Flush the internal channels and the outside with demineralised water to remove the disinfection detergent. A free drain of water through the instruments is required
Drying:	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfectant. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.	Manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air
Functional Testing, Maintenance:	Visual inspection for cleanliness, assembling and functional testing according to instructions of use. If necessary perform reprocessing process again until the instruments are visibly clean.	
Packaging:	Appropriate packaging for sterilization according ISO 11607 and EN 868	
Sterilization:	Parameters for the pre-vacuum cycle: 3 prevacuum phases with at least 60 milli bar Heat up to a minimum sterilization temperature of 132°C; maximum temperature 137°C	

	<p>Minimum Holding time: 3 min Drying time: minimum 10 min!</p> <p>Parameters of the gravity cycle: Heat up to a minimum sterilization temperature of 132°C; maximum temperature 137°C Minimum Holding time: 34 min Drying time: minimum 10 min!</p> <p>Parameters of Flash Cycle: Unwrapped instruments Heat up to a minimum sterilization temperature of 132°C; maximum temperature 137°C Minimum Holding time: 3 min Drying time: minimum 10 min!</p> <p>** Sterilization of instruments by applying a fractionated pre-vacuum process (according . ISO 13060 / ISO17665) under consideration of the respective country requirements</p>
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.
Reprocessing validation study information	<p>The following testing test devices, materials & machines have been used in this validation study;</p> <p>Detergent: Mediclean forte (Dr. Weigert, Hamburg, Germany) Lubrication: Neodisher IP konz</p> <p>Washer / Disinfector: Miele 7735 CD Instrument Rack: Miele E 327-06</p> <p>Details: Cleaning: See report 07708020805-1 SMP GmbH Sterilization: See report 09908021007 SMP GmbH</p>
Additional Instructions:	If the described chemistry and machines are not available, it is the duty of the user to validate his process. Please contact the manufacturer of the cleaning agent and the machines for their recommendations.
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	