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Handling Guidelines for Optimal Performance

Guide to the Proper Care and Handling of Ophthalmic Surgical Instruments

In accordance with EN ISO 17664-1

OPHTHALMOLOGY

Operating as one. Focused on you.

Corza Medical is a medical device and biosurgery company with decades of experience delivering innovative products to the global surgical community. We are committed to providing an exceptional customer experience, high quality products and outstanding value.

Our mission is to aid and champion the surgical community with outstanding products and remarkable service that save time, money and effort. We provide medical devices as well as biosurgery products and technologies that serve surgeons and their teams, distributors and OEM partners around the world.

With an expanding platform of industry-leading brands, our goal is to deliver an exceptional customer experience and outstanding value to the entire surgical community.

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Introduction — Read me first

This general reprocessing guide is applicable to Katena Products, Inc.'s (Katena) reusable ophthalmic surgical instruments. Specific, validated, reprocessing instructions are enclosed with each individual instrument or device; they include specific warnings, accessories, and special limiting/additional instructions. All references to Katena reusable ophthalmic surgical instruments are applicable to the following instrument brands:

Katena
ASICO
Rhein Medical

Deviations from this reprocessing guide are the sole responsibility of the user/facility. This Guide is written in accordance with EN ISO 17664-1.

These instructions are intended for use by trained professionals only.

Do not soak instruments in solutions containing chlorine or chloride to prevent corrosion or damage to surgical instructments.

Instruments shall not be reused after they have been used on patients with, or suspected of having, Creutzfeldt-Jakob Disease (CJD), Bovine Spongiform Encephalopathy (BSE), or Transmissible Spongiform Encephalopathy (TSE). Instruments used in connection with patients with these diseases shall be destroyed properly to eliminate the risk of cross-contamination.

Do not process these delicate microsurgical instruments in an automated washer unless it has delicate cycles, chemistries, and water quality compatible with the instruments. Follow the manufacturer's instructions for the automated washer; user/facility should independently validate the automated washer being used.

The validated mechanical cleaning process (manual brushing, lumen purging, pre-soaking, and ultrasound) uses a 1% Liquinox or similar solution. Other near pH neutral cleaning agents may be used; however, Katena recommends that the user/facility validates their own process and materials.

Katena does not recommend using toxic disinfectants or enzymatic detergents for ophthalmic surgical instruments because they add chemical burden to the cleaning process and increase the potential of causing Toxic Anterior Segment Syndrome (TASS).*

*See Appendix D, TASS resources

Inspecting New Instruments

Although Katena makes every effort to provide users/facilities with an instrument of the highest quality and consistency, all users/facilities are encouraged to inspect each new instrument before first use.

1. Carefully remove the instrument from its packaging. Preserve the original packaging while the instrument is inspected.
2. Examine the instrument under magnification, preferably using a microscope, to ensure the instrument meets Katena's high standards.
3. Notify Katena immediately if any problems are noted. Returned products must be sent back to Katena in the original packaging.

The useful life of instruments is determined by wear and damage during use as well as inspections before use and after reprocessing. Reprocessing according to these instructions should not affect the usability of surgical instruments.

Preparing an Instrument for First Use

When inspection of a new instrument confirms it is in acceptable condition, user/facility can proceed to clean and sterilize it as described in this document.

All new instruments must be cleaned and sterilized by the user/facility prior to being used for the first time.

Preparing an Instrument for Next Use

After an instrument has been used in surgery, the reprocessing (preparation for an instrument's next use) should begin as soon as possible. This is critical to prevent debris and undesirable fluids from drying on or inside the instrument. It is much more difficult to remove debris or fluid coatings that have dried on an instrument.

To avoid this difficulty, instruments should be:

- Wiped, rinsed, and/or flushed during and/or immediately after use to minimize accumulated debris and fluids
- Instruments should be kept moist until they can be cleaned

Proper cleaning and decontamination are essential for effective sterilization. A sterilization process will not be effective if debris is dried on the instrument or trapped in its crevices/lumens.

The reprocessing of surgical instruments consists of the following steps:

- Manual cleaning
- Ultrasonic cleaning
- Inspection and lubrication
- Packaging
- Sterilization
- Storage until next use

Manual Cleaning

Cleaning is the prerequisite for sterilization of surgical instruments.

Cleaning (definition): The removal of visible and invisible soil (blood, proteins, and other contaminants) from all surfaces, crevices, lumens, and joints of surgical instruments. This process starts in the operating room.

Katena Instrument Wipe
K20-5040

Immediately after, or during, surgery:

1. Remove excess soil from instruments with a moistened, sterile instrument wipe (K20-5040) or other non-shedding sponge wipe designed specifically for cleaning delicate instruments.
2. Rinse all instruments in the surgical tray with sterile water or distilled or demineralized water if available. This includes all instruments in the tray, not just the instruments that were used in surgery.
3. Keep used instruments either moist (covered by a wet towel) or submerged in a basin filled with sterile water or distilled or demineralized water until further cleaning is possible. Use an appropriately sized basin; enough space should be provided such that the instruments do not touch each other nor do they come into contact with the sides of the basin. The tray depth should be sized to prevent the overspill of fluid. Use a silicone finger mat to secure the instruments when possible.

The recommended maximum duration for instrument submersion prior to cleaning is less than 60 minutes.

Soft brush for
manual cleaning

As soon as possible after surgery:

1. Disassemble an item, when possible, for cleaning. Keep all parts together and protected from being misplaced or intermixed with parts from other similar devices.
2. Clean all instruments. Gently scrub stubborn stains with a soft-bristled brush, paying attention to less accessible areas — hollow tubes, slots, stops, ends, joints, box locks, and serrations. Debris that collects in these areas could cause corrosion to develop.

Reusable brushes and other cleaning implements that are designed and used to clean microsurgical instruments should also be cleaned and decontaminated after each use. It is best, and recommended, to use single use brushes.

3. Prior to pre-soak and cleaning steps: Flush a minimum of two (2) times all inside channels/lumens using a 10-cc syringe with 1% Liquinox or similar solution. Alternately, use a small diameter bottle/tube brush to clean inside channels/lumens, utilizing a 1% Liquinox or similar cleansing solution. Disperse the fluid in a different bowl to avoid contaminating the soaking solution in the ultrasonic tank.* Thoroughly rinse all instruments with distilled or demineralized water.

Flush with
demineralized water

* Supporting information may be found in Appendix F

4. Ultrasonic cleaning is the commended cleaning method; however, user facility has the option to use a validated manual cleaning method: Pre-soak all instruments in 1% Liquox at 35 °C for 20 minutes; Brush all accessible exterior and interior surfaces; Rinse with distilled water.

What to avoid

- Do not allow medicines, viscoelastic, irrigating solutions (saline), or protein residue to dry on instruments.
- Do not use corrosive cleaning agents such as bleach. Cleaning solutions and rinses at or near pH7 (neutral) are best. Aggressive cleaning agents with a pH ≤ 3 or ≥ 11 may damage an instrument's metal surface.
- Do not use metal brushes, steel wool, or abrasive powders. These items and materials will damage the surface finish of the instruments, making them significantly more susceptible to corrosion.

Ultrasonic Cleaning

Some surgical instruments may not be ultrasonically cleaned. Special Reprocessing Instructions are included in the packaging of each of these instruments.

The ultrasonic cleaner is the best method to thoroughly clean delicate micro-instruments. This device uses high frequency (42 kHz, 360W) sound waves to separate particulate matter from instrument surfaces. Ultrasonic cleaning is superb for dislodging debris that has settled into inaccessible areas (i.e. box locks, joints, and serrations) as well as obstructions in cannulas and needles. Prior to ultrasonic cleaning, all visible debris should be removed from the instrument(s).

Ultrasonic cleaners vary; follow the instructions supplied by the cleaner's manufacturer. The following guidelines may prove helpful:

- Recommend the use of two (2) ultrasonic cleaners (one for static soaking and ultrasonic cleaning; the other for distilled or demineralized water rinsing) dedicated only for use on eye surgery instruments to reduces potential of cross contamination.
- Place instruments on a silicone finger mat in an ultrasonic tank's wire or perforated basket. Prior to using ultrasonic agitation/vibration, pre-soak the instruments for 5 minutes with 1% Liquinox or similar solution at 60°C.
- Heat the distilled or demineralized water or 1% Liquinox or similar solution prior to ultrasonic use to maximize the cleaning effect. Heat the solution to an approximate temperature of 60°C (140°F).
- Separate the ultrasonic cleaner used for cleaning the instruments with 1% Liquinox or similar solution from the ultrasonic cleaner used for rinsing the instruments with distilled or demineralized water. This will minimize the potential for cross-contamination.
- Ensure that the ultrasonic tank is not contaminated before use. Visually inspect for debris, dirt, or discoloration both the tank using the 1% Liquinox or similar cleaning solution and the tank for the distilled/demineralized water. If contamination is present in the tank, immediately replace the respective solution.

*Supporting information may be found in Appendix D

- Check each instrument to be cleaned for corroded areas. Manually clean any instrument exhibiting corrosion prior to ultrasonic cleaning.
- To prevent impact damage, instruments should not touch each other in the tray. Sort instruments by similar metal, preventing contact between dissimilar metals. Contact of this type is a cause of galvanic corrosion. This will provide the best cleaning results and avoid damage to delicate instrument tips.
- Repeated contact between instruments of dissimilar metals may result in creating the friction mechanism necessary to magnetize instruments. Use an instrument demagnetizer should instruments become magnetized.
- Place the instruments on a silicone finger mat in a wire or perforated basket and suspend it in the cleaning solution. Ensure that all instruments are completely submerged during ultrasonic cleaning. All instruments that have hinges and/or joints should be in their open state.
- If a basket is not used, do not place the instruments directly on the surface of the ultrasonic cleaner's metal tank basin — use a silicone mat.
- A cleaning cycle of 10 minutes should be adequate if an ultrasonic cleaning process is used regularly. Stubborn stains, however, may require additional cleaning time.
- After cleaning, thoroughly rinse the instruments under warm running water. This will avoid thermal shock of instruments as well as redeposition of contaminants onto instrument surfaces. Give the instruments a final rinse using distilled or demineralized water in a clean ultrasonic tank. Thoroughly rinse and flush instruments with lumens, using distilled or demineralized water.[1]
- Dry instruments with a hot air blower, compressed air, or a lint free cloth.
- Empty, clean, rinse, and dry the ultrasonic cleaner after use. Following use, perform preventive maintenance and validate the proper functioning of the ultrasonic cleaner according to the manufacturer's recommendations.
- Change the distilled or demineralized water in the ultrasonic cleaner after each use; change the 1% Liquinox or similar cleaning solution when it becomes visibly soiled or a least once daily as directed by the manufacturer's recommendations.

Washer-Disinfector Use

Note: Katena does not recommend the use of washer-disinfectors as part of its instrument best practices cleaning and handling guidelines.

Do not process these delicate microsurgical instruments in an automated washer-disinfector unless it is equipped with compatible delicate cycles, chemistries, and water quality. Follow the manufacturer's instructions for the automated washer; otherwise, user/facility should independently validate the device.

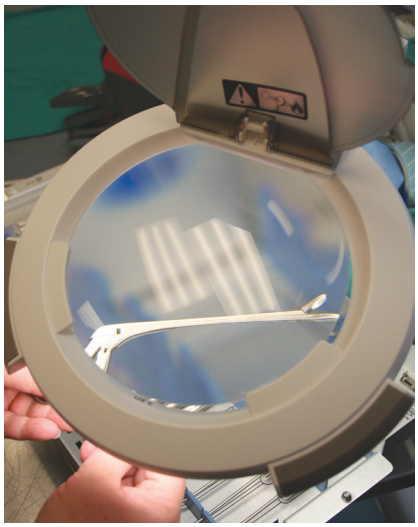
Inspection and Lubrication

User/Facility should verify that the instruments are clean with no visible soil and are functioning properly prior to sterilization. Katena recommends using a surgical grade lubricant on instruments that require it.

Inspection

- Visibly inspect each instrument for debris and damage, preferably under magnification (Photo on next page)

[1]See Appendix F



Examine instruments under magnification

Remove damaged instruments (i.e. bent tips, misaligned jaws) from the set; they must be repaired or replaced. User/Facility should never attempt to repair an instrument. Only qualified technicians should attempt an ophthalmic instrument repair.[2]

Lubrication

- For instruments requiring lubrication
  - Only apply a lubricant approved for use with surgical instruments
  - Apply to all moving parts, box locks, joints, and catches
- As the next step in reprocessing the instruments is sterilization, only a surgical grade lubricant that can withstand the high temperatures of steam sterilization should be used

Never use ordinary lubricant oils as they can become gummy when exposed to steam sterilization's high temperatures.

Delicate microsurgical instruments should not require a lubricating bath. If a lubricating bath or dip is used, the instruments must be completely free of stains and corrosion. Lubricating film that covers corroded joints or box locks provides an aggressive environment that promotes severe instrument corrosion during steam sterilization. Ultimately, this degradation will result in frozen or cracked joints and box locks.

Storage

The best way to store, protect, and sterilize delicate surgical instruments is in a specifically designed sterilizing case. Katena offers a variety of cases made of stainless steel, aluminum, or plastic. Cases are available in a range of sizes that can accommodate single instruments up to a complete set.

- Stainless steel and aluminum cases are more expensive than plastic but will last for several years of active use while providing the instruments with maximum protection.
- Plastic cases are best suited for single or small sets of instruments. These are inexpensive but have a limited lifespan.

[2] See Repairs, page 10

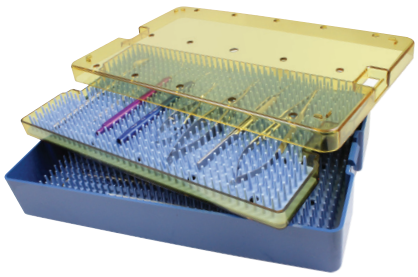
All cases offered by Katena include autoclavable silicone mats with a series of flexible "fingers" designed to hold each instrument firmly in place. This prevents instruments from touching each other and possibly being damaged. For best protection, the mats and fingers can be cut with scissors to accommodate instruments of unusual shape or size.

All cases and finger mats are perforated to facilitate circulation of steam and drainage. Some larger stainless steel and aluminum cases also feature racks to protect and securely hold delicate instruments like IOL manipulators, phaco spatulas, and cannulas.

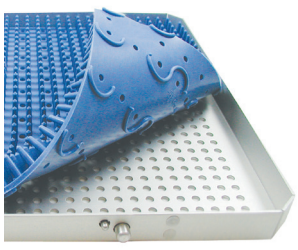
Sterilizing Trays

Use the chart below to determine the tray that best suits user/facility needs.

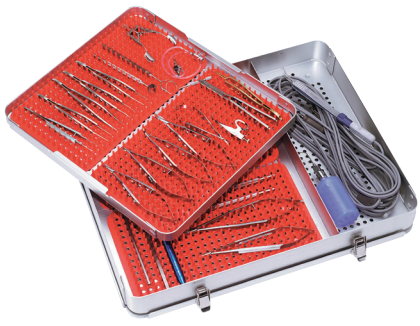
Material	Catalog #	# of instruments	S-Channel Mat	Cannula Rack Included	Comments
Plastic	K9-2018	1-2	NO	NO	
	K9-2020	2-3	NO	NO	
	K9-2025	4-6	NO	NO	[1] Double level
	K9-2030	10-15	NO	NO	
	K9-2040[1]	20-25	NO	NO	
	AST21	2	NO	NO	
	AST21S	3	NO	NO	
	AST22	2	NO	NO	
	AST28	10-15	NO	NO	
	AST34[1]	20-30	NO	NO	
	AST54	25-30	NO	NO	
	AST57[1]	50-60	NO	NO	
Aluminum	K9-2320	6-8	YES	NO	[2] Double level with large side compartment
	K9-2330	10-17	YES	NO	
	K9-2340	16-20	YES	NO	
	K9-2350[2]	35-50	NO	NO	
Stainless steel	K9-2100	8-12	NO	NO	[3] Features separate compartments for cannulas and hooks
	K9-2200[3]	20-25	NO	YES	
	K9-2300[3]	30-40	NO	YES	



K9-2040
Double-Level
plastic tray



S-Channel mat for
improved air flow



K9-2350
Double-Level
aluminum tray with
side compartment for
accessories

Handling

All microsurgical instruments must always be handled with the greatest care while being transported, cleaned, treated, sterilized, and stored. This is especially true for blades, fine tips, and other delicate points. Below are guidelines for handling and storing microsurgical instruments:

- Katena recommends storing instruments in the same container used during sterilization. This will reduce unnecessary handling of the instruments. A sterilizing case must be sized to accommodate and adequately protect a particular set of instruments.
- Arrange instruments in the tray such that they are not touching each other.
- Firmly seat each instrument in the tray to prevent movement and possible damage during handling. Sterilizing trays that feature soft silicone finger mats are ideally suited to accommodate instruments of various sizes and shapes.
- Always store and sterilize diamond knives in a separate container. Katena has tray options for holding 1, 2, or 3 knives.
- Store instruments in a dry area at ambient temperature.

Trays should be stored and transported flat. Storing or carrying trays on their sides or at an angle may cause instruments to shift within the tray, risking damage to the delicate tips of microsurgical instruments.

Always keep delicate tips protected with a tip guard when an instrument is not in use. Katena provides a line of color-coded protective tip guards in various sizes. The tip guards are vented for sterilization purposes.

- Katena recommends that the user/facility follow facility procedures with respect to instrument tip guards. If the facility process is to utilize instrument tip guards:
  - Great care should be taken when placing or removing a tip guard. Delicate instruments can easily be damaged during this critical step.
  - Frequently replace the protective tip guards. Immediately replace any tip guard that is discolored or cracked.

K9-1265 K9-1255 K9-1245 K9-1235 K9-1225 K9-1215

Packaged 100 per catalog number

Sterilizing

Katena recommends that the user/facility sterilize surgical instruments using the steam sterilization procedure that is regularly used in hospitals and surgery centers. The following table provides the suggested cycles based on AAMI and AORN recommended practices. These sterilization cycles are validated using Katena instruments and sterilizing cases through an independent US FDA registered third-party laboratory.

Do not use steam sterilization temperatures exceeding 137°C (280°F)

Steam Sterilization cycle	Preparation	Temperature	Exposure Time (Minimum time)	Drying Time (Minimum time)
Gravity Displacement	Wrapped	132°C / 270°F	15 minutes	30 minutes
Dynamic Air Removal**	Wrapped	132°C / 270°F	4 minutes	20 minutes
Dynamic Air Removal	Wrapped	134°C / 273°F	3 minutes	20 minutes
Immediate-Use (Flash) (Gravity or Dynamic Air Removal)	Unwrapped	132°C / 270°F	3 minutes	N/A

** Pre-Vacuum or Steam Flush Pressure Pulse (SFPP) is classified as Dynamic Air Removal Steam Cycle by AAMI.

The above parameters/cycles have been validated. If other methods, times, and temperatures are used, the user should validate these methods.

Additional Guidelines for Sterilization:

- Only sterilize instruments that have been cleaned, are free of soil, and have been inspected per the previous sections of this guide.

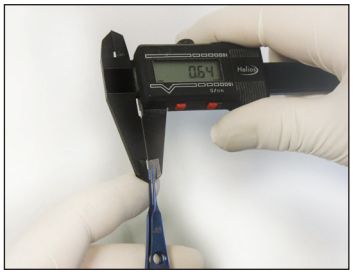
Do not use "flash" or immediate-use steam sterilization (IUSS) as a time saving process or as a substitute for standard instrument reprocessing. Immediate use sterilization cycling is designed to manage unanticipated urgent needs and is not meant to be an alternative to maintaining an adequate inventory of instruments.

- Verify that the sterilizer is functioning properly on a scheduled inspection cycle: weekly is minimum; more often is preferable.
- Ensure that preventive maintenance, cleaning, and inspection of the sterilizer is performed on a scheduled basis according to the manufacturer's instructions.

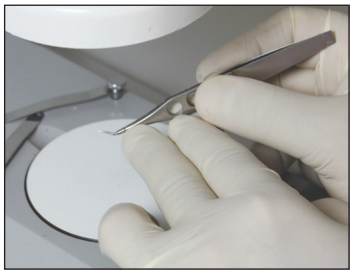
Repairs

User/facility must never attempt to make repairs of microsurgical instruments. Service and repairs are to be referred only to trained, qualified persons. It is important to properly investigate the credentials and experience of your repair service. Not all companies and individuals claiming repair capability are competent to repair the delicate, precise designs of microsurgical instruments used in ophthalmic surgery.

Katena's surgical instruments are handmade by highly trained and skilled master craftspeople. These artisans prepare for this exacting technical trade by completing an apprenticeship program that involves rigorous training and evaluation. Placing these precisely crafted instruments in the hands of lesser trained people risks further damage to the instruments, often beyond repair.



Instruments are carefully brought back to original specifications



All repairs are performed under high magnification

Katena advises caution when selecting an individual or company to repair surgical instruments. For your convenience, Katena has a surgical instrument repair program. Utilizing this service assures user/facility of quality instrument repair and care.

Disposal

Follow country-specific laws and regulations for the proper disposal and disposal procedures of sharps and/or biohazardous material.

Regulatory Information

Any serious incident related to our products should be reported to Katena and to the healthcare authority of the country where the incident occurred.

Appendix A — Understanding Stainless Steel

Most surgical instruments are made of stainless steel. Stainless steel is an alloy consisting of various components that make it more resistant to staining and corrosion. "Stainless steel" does not mean absence of stains; a better definition would be "stains less". Stainless steel is resistant to stains and corrosion; it is not impervious. Stainless steel is not "stain free" or "stain proof".*

Of the many kinds of stainless steel, there are two types that surgical instruments are made from customarily:

- 300 Series Steel (Austenitic): Contains a small percentage of carbon and is considered the most stain-resistant of all steels. It is commonly used in hospitals for sinks, basins, and sterilizing containers. In ophthalmology, 300 series stainless steel is typically used for making speculums and handles for instruments including hooks, retractors, and knives.
- 400 Series Steel (Martensitic): Contains a higher percentage of carbon and can therefore be heat-treated to attain the desired degree of hardness. The percentage of carbon content determines its hardness — the more carbon, the higher the attainable hardness.

For surgical instruments:

- Steels with a lower percentage of carbon typically are used for making forceps, needle holders, and hemostats.
- Steels with a higher percentage of carbon are used for scissors and cutting instruments. This is the reason why forceps and needle holders tend to be more resistant to staining than scissors.

During the manufacturing process, the steel is:

Milled, filed, ground, polished

And then:

Brushed, matted or otherwise finished

All these processes disrupt the steel surface and produce instruments with a non-glare finish. After final finishing, Katena instruments are exposed to an electropolishing, or passivation, process to seal the instrument surface. This process significantly enhances the instrument's resistance to corrosion.

*Some stainless steel may contain higher than 0.1% w/w Cobalt and is considered as carcinogenic, mutagenic or toxic to reproduction ('CMR') substances according to Regulation (eu) 2017/745.

Appendix B — Understanding Stains on Stainless Steel

Rust on instruments will create permanent damage; stains can be removed. Most stains are not indicators of rust but may be indicative of other issues with instrument processing and handling. Here are a few guidelines:

- Brown/orange stains: These stains could indicate rust; however other causes are possible. Here is a simple test to determine the cause
  - Rub a pencil eraser vigorously on the stain
  - Is a pit mark revealed?
    - If so, it is rust
  - If the metal underneath is smooth, the stain may be caused by
    - Baked-on blood
    - Saline solution
    - Cold sterilization solution
    - Inappropriate detergents insufficiently rinsed from the instrument(s)' surface
- Dark brown/black stains: Possibly caused by exposure to
  - Dried blood
  - Inappropriate detergents
  - Acids
- Black stains: May be caused by exposure to acids, ammonia, or bleach
- Blue-black stains: Could be caused by different types of metal processed together in an ultrasonic cleaner or steam sterilizer
- Light and dark spots: Possible cause - Mineral deposits from water spots if instruments are air dried and distilled or demineralized water is not used

Spots caused by mineral deposits

Appendix C — Understanding Titanium

Titanium is a lustrous, silver colored metal that has high tensile strength and good corrosion resistance. These qualities make titanium a preferred choice in many industrial, manufacturing, and medical applications. Titanium is always bonded to another element in nature; considerable time and effort is required to extract the metal and prepare it properly. For that reason, titanium is usually more costly than other materials such as stainless steel.

Titanium is increasingly popular for surgical instruments; some manufacturers now use it extensively or exclusively. For certain types of instruments, titanium does offer a functional advantage over stainless steel. For example, suturing with a needle holder that has become magnetically charged is frustrating to a surgeon; the needle becomes difficult to release. Titanium cannot be magnetically charged; use of the material eliminates this problem. Where the advantages of titanium can be realized, Katena provides options for stainless steel or titanium construction. These options are available in many of Katena's needle holders, forceps, tying forceps, and choppers.

Although titanium has high tensile strength, it cannot be hardened. This is a disadvantage when compared to stainless steel in certain instrument categories. Hardness is particularly important for instruments that need to hold a cutting edge. Scissors are one example where stainless steel holds an advantage over titanium. Scissors made from titanium will require frequent sharpening; it will dull quickly. Hardened stainless-steel scissors will require less frequent sharpening. Where surgical instrument hardness matters, stainless steel is a better option than titanium.

Cost is another differentiator between stainless steel and titanium instruments. Good quality titanium will add 15-20% more to the cost of an instrument as a result of materials extraction costs and difficulties in machining. There are many grades of titanium available; while titanium is often touted as superior to stainless steel based on the material, poor quality titanium, or titanium-based cutting instruments may be inferior to the quality and performance of stainless steel.

Appendix D — TASS Resources

The risk of contamination and infection during surgery is a significant concern for all healthcare facilities. This concern is what drives how much time and effort is expended on cleaning and sterilizing surgical instruments. Specific to cataract surgery is toxic anterior segment syndrome (TASS). TASS is an acute inflammation of the anterior chamber (or segment) of the eye following cataract surgery, resulting in toxic damage to intraocular tissue.

There is a large body of published information on this rare, serious condition. The section below lists a few resources for understanding TASS:

Case Studies — TASS Outbreaks

TASS can have many possible causes, making prevention difficult. In places where outbreaks have occurred, a multi-faceted approach to preventing a subsequent outbreak is implemented; this makes pinpointing a specific cause difficult. This is described here:

Toxic Anterior Segment Syndrome After Cataract Surgery --- Maine, 2006

Reported by: M Kelley, Maine Dept Health and Human Svcs. A Srinivasan, MD, Div of Healthcare Quality Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases; A Pelletier, MD, Div of State and Local Readiness, Coordinating Office for Terrorism Preparedness and Emergency Response, CDC.

Some studies suggest a cause for a TASS outbreak. The following study concluded that improper maintenance of a steam autoclave was the cause in this case:

Outbreak of toxic anterior segment syndrome following cataract surgery associated with impurities in autoclave steam moisture

Division of Infectious Diseases, Mayo Clinic, Jacksonville, FL 32224, USA. hellinger.walter@mayo.edu Infect Control Hosp Epidemiol. 2006 Mar;27(3):294-8. Epub 2006 Feb 22.

Description of TASS

Many publications provide useful information about the symptoms, diagnosis, treatment, and prevention of TASS.

Toxic anterior segment syndrome

Mamalis, Nick MD. Journal of Cataract & Refractive Surgery: February 2006 - Volume 32 - Issue 2 - p 181-182 doi: 10.1016/j.jcrs.2006.01.036

Toxic Anterior Segment Syndrome (TASS)

Updated: May 03, 2017. Author: Jean Deschênes, MD, FRCSC; Chief Editor: Hampton Roy, Sr, MD

Prevention of TASS

> *"Finding a causative action in TASS can be a challenge. Often the cause is unknown, even after thorough investigation. Clinical literature reveals case studies in which a multiplicity of potential causes of TASS have been identified. Many factors before, during, and after cataract surgery such as bacterial endotoxin residues, viscoelastic residues, and exotoxins can be a potential source of TASS.*
>
> *Many risk reduction strategies can be associated with the multiplicity of potential causes of this condition. The most obvious are awareness of the problem, communication, and using good surgical techniques."*

Toxic anterior segment syndrome—More than sterility meets the eye

Janet Johnston RN. AORN Journal, Volume 84, Issue 6, December 2006, Pages 967-984. First published: 05 December 2006.

The aforementioned sources offer a sampling of available information about TASS; they are not intended to be a comprehensive reference. There are many potential causes of TASS, and not all of them are tied directly to the cleaning and sterilizing of surgical instruments. Following the guidelines in this booklet for cleaning, sterilizing, storing, and handling Katena's ophthalmic surgical instruments should assist your organization's strategic approach for preventing TASS.

In December 2015, "Recommendation Regarding Use of Enzyme Detergent for Cleaning Intraocular Surgical Instruments" was jointly released by the American Society of Cataract & Refractive Surgery (ASCRS), American Academy of Ophthalmology (AAO), and the Outpatient Ophthalmic Surgery Society (OOSS). The following link allows a download of this clinical guideline: ASCRS, AAO, and OOSS Release Specialty-Specific Guidelines for Ophthalmic Instrument Cleaning and Sterilization. (https://asoa.org/news/guidelines-for%C2%A0ophthalmic-instrument-cleaning)

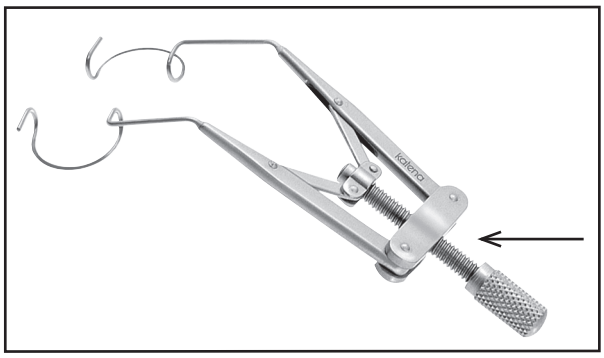
Katena does not recommend using toxic disinfectants or enzymatic detergents for ophthalmic surgical instruments; they add chemical burden to the cleaning process and increase the potential of causing toxic anterior segment syndrome (TASS).

Should a user/facility choose to use an enzymatic cleaner at any point in the cleaning process, Katena recommends that the directions for use supplied by the enzymatic cleaner's manufacturer be followed and that particular care be taken prior to sterilization to rinse copiously and remove completely any residue or remaining enzymatic cleaner from the surface of the instrument.

Appendix E — Instruments Requiring Special Attention

Adjustable Speculums

All areas with threads need to be completely cleaned and dried. Pay attention to areas which might be inside the base assembly. Rotate the knurled thumb mechanism several turns to expose hidden threads to complete cleaning and drying.



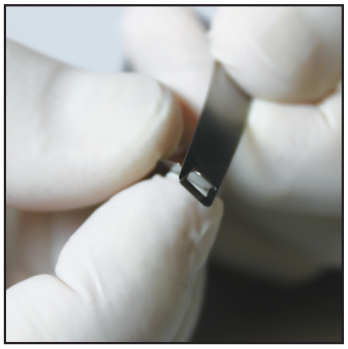
Diamond Knives

Never allow the diamond blade to touch anything harder than tissue nor completely submerge a diamond knife in an ultrasonic cleaner.

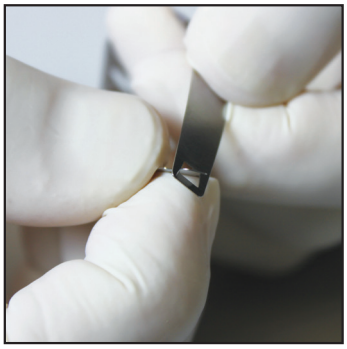
- Cleaning: Immediately after using a diamond knife, the blade must be rinsed with distilled or demineralized water. Alternately, the knife may be cleaned using the Rhein Medical Blade Cleaning System (09-7017 and 09-7018). This will prevent cell particles or viscoelastic materials from sticking to the blade.
- If possible, ultrasonically clean the diamond knife. Holding the handle, suspend only the blade into the fluid. Be certain that the blade does not touch any other instruments or the sides of the cleaner.
- Never completely submerge a diamond knife in an ultrasonic cleaner.
- Keep the diamond blade retracted during sterilization cycles.

Spring Handle Scissors, Forceps, and Needle Holders

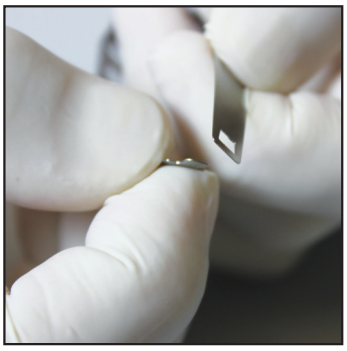
Spring handle instruments are specially designed for cleaning. A simple disassembly of the box lock gives easier access to difficult-to-clean areas. For more detail, see the illustrations below.



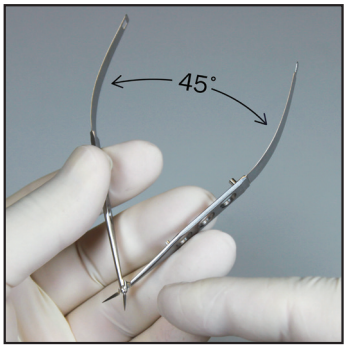
Grasp instrument by springs



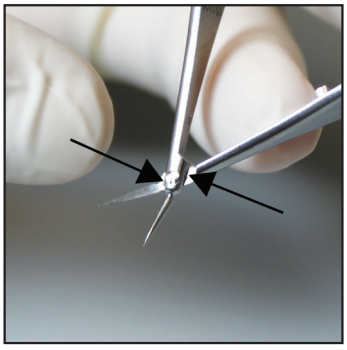
Turn spring with tab 45°, aligning with corners of box



Gently pull tab end through box



Carefully spread handle open up to 45°



Remove all debris around pin or screw area

Micro Forceps and Micro Scissors

Cleaning instructions:

- Clean instrument immediately after each use by rinsing in distilled or demineralized water; this will aid in the removal of surgical residue (i.e. blood, saline, tissue). If it is not possible to clean the instrument immediately, keep it moist to prevent residue from drying on the instrument.

- Under a microscope, carefully remove all residue from the instrument tips with a soft moistened wipe or soft bristled brush. Wipe instrument tips in one direction only from the instrument handle toward the tips. Do not scrub or apply force.

- Attach a syringe filled with distilled or demineralized water to the cleaning tube luer lock connector. The connector is supplied with the instrument. Do not use tap water or saline.

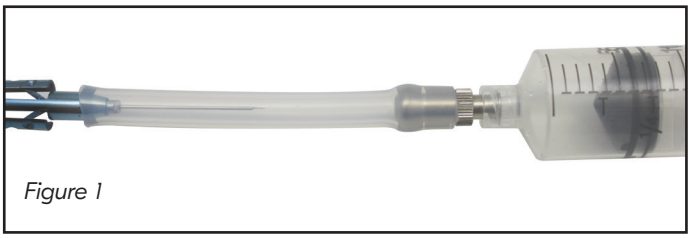


Figure 1

- Carefully place the silicone cleaning tube over the end of the instrument and attach it to the front of the handle (Figure 1). Gently depress the syringe plunger to flush the instrument with the distilled or demineralized water. Repeat this step several times.

- Carefully remove the syringe from the cleaning tube connector and attach another syringe containing isopropyl alcohol. Gently depress the syringe plunger to flush the instrument with isopropyl alcohol and remove any remaining water.

- Carefully remove the syringe from the cleaning tube connector and attach another syringe. Gently depress the syringe plunger to flush the instrument with air. This will dry and/or remove any residual isopropyl alcohol. Repeat until the instrument is thoroughly dried.

- Securely place the cleaned and dried instrument in a tray suitable for sterilization.

Aspirating Cannulas, Aspirating Speculums, and Bi-manual Instruments

Always clean in the direction from smallest to largest openings.

Properly removing any debris remaining inside an aspirating instrument is the best way to clean and sterilize it. Accomplish this by submerging the instrument's small port(s) in distilled or demineralized water and aspirate into a syringe. Flushing in this direction prevents debris from occluding the small ports. Any instrument that becomes clogged should be repaired by Katena.

Appendix F — Cannula Flushing and Drying Guidelines

[1]Minimum flush volume is the minimum amount of distilled or demineralized water required to forcefully flush through the lumen during cleaning. If the cannula was used with heavy fluids like a viscoelastic, continue flushing with distilled or demineralized water until the water flows freely through the lumen.

[2]Minimum drying volume is the minimum amount of air to be forced through the lumen with a dry syringe following the flushing step. Compressed air may be substituted for a syringe.

Cannula Gauge	Minimum Flush Volume[1]	Minimum Drying Volume[2]
25-30	5ml	10ml
19-24	10ml	10ml

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Should you wish to place an order, have any questions, or require further clarification of any of the information contained in this booklet, please contact Customer Service who will direct your call to the appropriate person. Email inquiries may be sent to inquiries.corzaeye@corza.com.

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