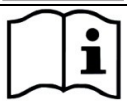
Fimco

EN

Owner's guide, cleaning and maintenance of FIMCO
Ophthalmic surgical instruments

	"Caution, see instructions for use for important safety information"
	"Consult the instructions for use"
	Batch number : it allows the traceability of the product
	Product reference : it allows to identify it
	Manufacturer of the product, with name and address
	Product manufacturing date
	"Do not use if packaging is damaged"
	"Keep away from moisture"
	"Keep away from sunlight"
	"Device delivered in a non-sterile state"
	Unique device identifier
	Medical device
	CE marking, xxxx is the number of the notified body

FIMCO
410 Rue Louis Mouillard
66000 PERPIGNAN
France
: +33 (0)4 68 83 32 35
: +33 (0)4 68 87 66 03
: fimco.france@orange.fr

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www.fimco-france.com

1) INTENDED USE

FIMCO instruments are ophthalmic medical device aiming at performing surgical acts such as cutting, incising, piercing, spreading, keep spread out, increasing the tissues rigidity, applying a localized pressure, guiding and bending an implant, calibrating a loop, protecting the eye during surgery, letting a fluid circulate, scrubbing, maneuvering, manipulating, scraping, gripping and removing foreign bodies, indicating a dimension, an orientation or a distance, hooking, hooking and testing the elongation of the muscle, leaving a mark thanks to a pressure, containing a liquid, gnawing, gripping a tissue, probing and dilating.

FIMCO instruments are intended for surgical ophthalmic operation. The instruments should be used in ophthalmic microsurgery by a qualified healthcare professional. The instruments are used on all types of patients (adults - children - babies) who requires surgery and do not have any contraindication.

2) DESCRIPTION AND MATERIALS

The FIMCO instruments are reusable surgical devices used for ophthalmic surgery.
All instruments are delivered non-sterile and must be cleaned and sterilized by the health care facility prior to use.

The surgical instruments are mainly made of medical grade stainless steel and may include titanium, titanium alloy (TA6V), chrome-plated brass, silver, aluminum, polytetrafluoroethylene (PTFE), polyether ether keton (PEEK), silicone, epoxide resin, polyoxymethylene (POM-C), polyphenylsulfone (PPSU), tungsten carbide, glass (Pyrex), or quartz.

3) INDICATIONS

FIMCO instruments are used in refractive surgery, cataract surgery, eye dryness, glaucoma surgery, retina surgery, age related macular degeneration (AMD) surgery, dacryocystorhinostomy surgery, presbyopia surgery, corneal graft (keratoplasty) surgery, keratoconus, chalazion, stye, conjunctivitis, myodesopsia, diabetic retinopathy, keratitis, optic neuritis, pinguecula, pterygion, uveitis, strabismus surgery, ocular enucleation and evisceration.

4) COMBINATION OF MEDICAL DEVICES

FIMCO cannulas handles, short cannulas handles, Luer connectors, silicone tubes and connectors, and syringes must be assembled only with FIMCO cannulas (and reciprocally). It is forbidden to make assemblies between FIMCO devices and competitors devices: as there is no evidence of compatibility. FIMCO declines all responsibility in case of accidents resulting from assembly between its devices and those of the competition.

If necessary, the silicone tubes of the double way cannulas can be replaced. The F528C double way cannula must be used with the Ø1.5mm silicone tube. All other double way cannulas must be used with the Ø1.1mm silicone tube.

5) PERFORMANCE CHARACTERISTICS OF THE DEVICE AND EXPECTED CLINICAL BENEFITS

The performance of instruments is the correct realization of their intended use according to the surgical technique and the correct achievement of performance of associated devices. Based on the clinical evaluation, all residual risks are deemed acceptable when weighed against the benefits to the patient base on current knowledge/the state of the art.

6) CONTRA-INDICATIONS

- Allergy or sensitivity to instrument materials
- Any condition that would preclude the correct of progress of the surgery
- Any case not described in the indications

7) POTENTIAL ADVERSE EFFECTS, COMPLICATIONS AND RESIDUAL RISKS

The residual risks, adverse effects and complications that may occur with the use of FIMCO instruments that are listed below may lead to a new operation or to the extension of the operation time:

- Injury to the patient or operator
- Instrument breakage / risk of debris remaining in the patient. Damaged or broken instruments can be dangerous for the user, the patient or a third party.
- Tissue or vascular injury
- Post-operative infection
- Biological / allergic reaction
- Disassembly of components
- Premature wear / deterioration of instruments due to misuse

8) INSTRUMENTS HANDLING

The health care facility is responsible for pre-cleaning, cleaning and sterilization of instruments prior to use, in accordance with validated methods. The following recommendations do not substitute for the sanitary rules in force: standards, guides, government notices, ministerial texts, etc. A cleaning process done without respecting qualification ranges can lead to sterility or toxicity risks.

From a functional perspective, an inspection must be carried out prior to use to check for any burrs or debris that could damage tissue or personal protective equipment. The inspection must also look for any sign of corrosion or contamination that could cause infection, inflammatory reaction or instrument breakages. Furthermore, the integrity of tools must be verified (abnormal size or handling; damaged or worn surface; chips of materials; marking and measure readability and play; scissors and knives blades conditions). Finally the functionality (opening, closing, stopping) of the devices must be checked several times before operation: they should not present too much resistance. Any device deemed to be dull or non-functional in any manner should be returned to FIMCO for maintenance or exchange. The instructions hereafter must be followed in order to maintain optimal efficiency and safety of instruments:

- Chemicals or cleaning substance based on chlorine, aldehyde, alcohol, acid or abrasives which are likely to damage the instruments must not be used.
- Phosphoric acid must not be used for the neutralization of alkaline residues after the cycle of automated machine cleaning on instrumentation packaging trays and on instruments made up of polymer pieces (example: handles).
- The pre-disinfection temperature should be < 45°C to avoid the risk of fixing residues.

It is imperative that the instructions for use, temperature, concentration, action time, etc., are strictly respected. Otherwise, problems may occur with the instruments, such as visual changes in the material (color change).

If rust forms on one instrument, it can contaminate others; so rusty instruments should not be mixed with intact instruments to avoid contacts that could be hazardous to sterilization.
All personnel in contact with soiled instruments should observe good hygiene and use appropriate protective equipment (gloves, mask, apron, etc.).
Sharp or pointed devices must be handled with the utmost care.

a) Greasing and lubrication

After use and cleaning, it is sometimes necessary to lubricate articulated parts or any moving parts of instruments. Use only sterilizable maintenance oil and permeable to water vapor. A white oil without additives, with certified biocompatibility and approved for sterilization (moist heat) is required. Apply the appropriate amount of oil for the size of the instrument directly to the joint area. Distribute the oil evenly by opening and closing the instrument several times. Remove excess oil with a clean lint-free cloth.

b) Control, maintenance and verification

After each use and cleaning:

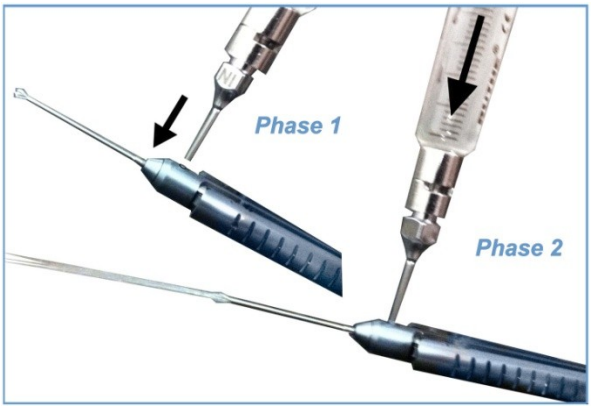
- Let the instrument cool down to ambient temperature after cleaning.
- check the instrument for cleanliness, functionality and damage, and isolate instruments that are twisted, deformed, worn, bent, broken, cracked, or instruments with dismantled parts.
- Check compatibility with associated instruments.
- Immediately remove a damaged instrument.

c) Packaging

- Protect instruments with thin tips.
- Place the instrument in its storage compartment or in the appropriate tray. Make sure cutting blades are protected.
- Package the trays according to the sterilization process (make sure that the packaging prevents any further contamination of the instrument between the final phase of its treatment and its next use).
- Package the instruments in suitable sterilization packages allowing the maintenance of the sterile state until the next use.
- For longer periods of time, the microforceps (F250A, F250A5, F251A, F251A5, F251A9, F251B, F251B5, F253A, F253A5, F253A9, F253B, F254A, F255A, F143MI, and F144MI) must be lubricated at the end of the pre-cleaning process (see Part 9).

9) PRE-CLEANING TREATMENT

The microforceps (F250A, F250A5, F251A, F251A5, F251A9, F251B, F251B5, F253A, F253A5, F253A9, F253B, F254A, F255A, F143MI and F144MI) must be cleaned prior to automatic cleaning, using the cannula provided with the instrument and the health care facility's cleaning agent:



Phase 1: Insert the cannula into the hole
Phase 2: Inject the cleaning product
Phase 3: Repeat phase 1 and 2 with controlled water

Dried surgical residues may complicate the cleaning process making it inefficient or accelerate corrosion of stainless steel. Pre-disinfection processing aims to make subsequent cleaning easier. It is also intended to protect staff while handling instruments and avoid contamination of the environment. All reusable devices must undergo immediate pre-disinfection processing or be immediately treated in a washer-disinfector after use. If immediate pre-disinfection is impossible, instruments may be preserved in demineralized water until pre-disinfection.

- Pre-disinfection processing is achieved by dipping instruments, for a minimum of 15 minutes, in a neutral or alkaline solution that does not contain aldehyde nor ethanol. Preferably use a solution that does not fix proteins. Strictly follow the manufacturer’s instructions for use and ensure that the products used are compatible with the instruments.
- Use suitable cleaning and disinfection products. If there is a delay between pre-disinfection and washing, rinse the instrument thoroughly with running water before cleaning and disinfection with washer-disinfector.
- If necessary, clean the instrument with ultrasound, see Cleaning section.
- Remove all visible organic residues (blood, bone, etc.), special attention will be paid to grooved or hollow devices.
- The use of metallic brushes, abrasive sponges and other articles likely to damage the instruments must be avoided. The use of soft-bristled brushes and swabs with dimensions adapted to the devices to be treated is preferred to clean the parts from all biological residues (blood, bone, …) that can potentially alter the action of detergents and decontaminants. Pay special attention to cannulated devices.
- The use of a mechanical action through manual or ultra-sonic means is recommended (§a)).
- Devices that can be disassembled should be disassembled prior to pre-disinfection processing (except for double way cannulas which shall assembled the whole time). Additionally, devices with movable components that do not facilitate disassembly should be

manually articulated during the pre-disinfection processing step in order to evacuate additional residues.

- Preferably immerse instruments in a solution of combined enzymatic-type cleaner and disinfectant which does not bind proteins. Avoid the use of disinfectants containing aldehydes which have a binding effect. Follow the conditions of use recommended by the manufacturer and ensure the compatibility of the product with the instruments.
- The instruments should then be carefully rinsed in a controlled water to avoid interference between the cleaning solutions. It is important to refer to the instructions supplied by the manufacturer of these products.
- Long waiting times for treatment should be avoided - e.g. overnight or at weekends - because of the risk of corrosion and the effectiveness of the cleaning. Immersion in demineralized water prevents residues from drying out and facilitates subsequent washing.
- In case of long waiting periods between pre-disinfection and cleaning, wash the instruments with controlled water before cleaning and disinfection with a washer-disinfector.

CAUTION: Packaging trays and baskets must not be in contact with decontaminating solutions for a long time. Chrome-plated brass cannulas and aluminum boxes must never be in contact with sodium hydroxide, otherwise they will be corroded. Clean dirty areas and rinse immediately.

10) CLEANING

The instruments must be thoroughly cleaned after disassembly if assembly/disassembly is possible. We recommend the exclusive use of mechanized pre-disinfection and cleaning methods with a washer disinfector compliant with the requirements of ISO 15883 series. Refer to the manufacturers' instructions on how to use the washer-disinfector. The detergent shall be compatible with medical applications, instruments materials and present no known residual toxicity for the patient. In case the process cannot be done automatically, a manual process shall be used by reproducing the conditions described in the cleaning recommendations. The cleaning cycle must include a final rinse with a controlled water. Time, water flow and rinsing volumes shall be sufficient to reduce as much as possible the level of cleaning agent residues left on the product surface. Instruments should be carefully dried to avoid recontamination.

a) Ultrasonic cleaning

This cleaning method is particularly suitable for threading tools or instruments with deep grooves. The equipment must be validated by the user and used with products adapted to the materials of the instruments. Perform ultrasonic cleaning for 10 to 20 minutes to preclean instruments with dried residues or as an effective mechanical support before cleaning and disinfection in washer disinfector.

b) Automated washing

Ensure that the washer disinfector is conform (CE marking), maintained and qualified according to the applicable standards. Use only products compatible with the instruments, aldehydes-free, and complying with the Standard Prion Protocol (SPP) if necessary. Follow the instructions for concentration, temperature and duration of action.
Use neutral or alkaline pH detergents.

Follow the washing procedures to ensure proper protection of the instruments. After cleaning and disinfection in washer disinfector, check that all residues have been removed. If necessary, repeat the cleaning process with brushing until all visible residues are removed.

Table 1 - Recommended automated washing protocol

Phase	Time	Recommended temperature	Type of water / Detergent
Pre-Cleaning	4 min	Cold (<30°C)	Water
Cleaning	10 min	Heated, 55°C	Neodisher Septoclean* 10mL/L (1%)
Intermediate rinse	3 min	>30°C and <60°C	Softened or demineralised hot water
Thermal disinfection	5 min	Heated, 90°C	Demineralised hot water
Drying	20 min	Air at 99°C	Not applicable (Air)

*or strictly equivalent product

As appropriate, dry residual moisture by means of a complementary drying cycle in the machine or lint-free wiping squares and compressed air without water particle due to condensation.

Note: *In the case of patients with suspected or confirmed transmissible spongiform encephalopathie (TSE), the cleaning procedure for the washer-disinfector shall be done after a decontamination process conform to the instruction DGS/RI3/2011/449. Three inactivation processes, none of which is an absolute guarantee, are possible:*

- *Steam sterilization at 134°C for 18 minutes,*
- *Immersion in 1N sodium hydroxide for 1 hour at room temperature,*
- *Immersion in sodium hypochlorite 20,000 ppm, for 1 hour at room temperature.*

The use of sodium hypochlorite or sodium hydroxide is not recommended as they cause corrosion of the instruments. None of the three methods is an absolute guarantee. In accordance with the World Health Organization's guidance, the safest and most unambiguous method of avoiding residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration.

11) STERILIZATION

Instruments must be sterilized before use. They must be compatible with water steam sterilization at a temperature not exceeding 140°C. In accordance with the government instructions on the non-transmission of unconventional transmissible agents and the standards in force (specially ISO 17665-1), we recommend to use a water steam sterilization (in compliance with the requirements of the ISO 17665 series) with a **validated cycle** including a period of **18 minutes at 134°C/2 bars** and followed by a vacuum drying cycle of 30 minutes minimum. The packaging used must be CE marked for a use as sterile barrier for autoclave sterilization. Use absorbent paper for the package before using the products. The cycle of sterilization and drying must be validated by the end user according to the sterilizer manufacturer's recommendations.
The instruments must be packaged in suitable packaging allowing the maintenance of the sterile state. Indicate on the sachet the date of sterilization and the expiry date in accordance with the data of the sachet manufacturer.

Any other methods of sterilization (ethylene oxide or oxygen peroxide at low temperature) are not recommended and are the sole responsibility of the user.

Instruments must be prepared in such a way that all surfaces are in direct contact with water vapor: hinged instruments and sliding instruments must be slightly open. **Instruments with protections marked "STERILISABLE" must be sterilized with them**. Complex instruments manually dismantlable must be dismantled, and all parts must be wedged in the sterilization box. Health care facilities shall validate and qualify, using appropriate techniques, their equipment and methods used for autoclave sterilization, in accordance with the current standards for sterilization of medical devices using moist

heat. The health care facility assumes final responsibility for the validity of the sterilization of the products and their maintenance in this state.

Sterilization recommendations are given for information purposes only. The user/processor must comply with the laws and regulations of the country in which it is established. Under no circumstances can the manufacturer be held responsible for the sterility of sterilized devices within the health care facility.

12) REUSE OF DEVICES

The instruments are intended to be reused. The number of reuses depends on the integrity of each instrument. There is no theoretical limit to its reuse as long as it fulfills the claimed performance and providing that it does not show sign of wear, distortion, damage or loss of performance.
Prior to reuse, the devices must be pre-disinfected, cleaned and sterilized (as described in previous sections).

13) STORAGE, HANDLING AND TRANSPORT

Surgical instrumentation must be handled with care and should be stored carefully in a clean room under normal humidity conditions. Instruments must be protected from UV rays and all corrosive environments. When transporting sterilized instruments to the site of use (operating room), the sterile state must be maintained. Use sterile packaging to maintain the sterile state of the instruments. Be aware of the risk of falls and/or injuries.
Used instruments should be transported to the supply department in closed or covered packaging to avoid unnecessary contamination.
Dropping may result in breakage or damage to the instrument and/or injury to the operator. Use rigid trays or containers.

14) ELIMINATION AND NON-FUNCTIONAL INSTRUMENTS

The end of life for each device is determined when the device's characteristics or performance indicate that the health or safety of the patient or user may be compromised. The device's lifetime depends on many factors, including but not limited to, method and duration of use and level of reprocessing. Hence FIMCO does not define the maximum number of uses. Careful inspection and functional testing should be completed (see part 8 for more information about inspection and functional testing). Examine the cutting edges, flutes, tips, shafts, handles, mechanisms, and features of the working end, as applicable, for dulling, chipping, warping, cracking, or other indications of material degradation or compromised structural integrity. The laser marking should remain readable. If the device displays any of these signs of wear or other indications of malfunction, it is recommended to discontinue use and replace the device. Per the surgical technique, actuate moving parts and assemble devices to test for sticking or obstruction. If moving or assembled parts have limited functionality, replace the device(s).
FIMCO provides repair (refurbishment) services for its instruments, and can evaluate the condition of an instrument. Any non-functional device or device in need of repair must be returned to FIMCO in sterile condition and with proof of sterilization, as FIMCO ensures the safe disposal of its devices. If a non-functional device is shipped without proof of sterilization, the device will be returned to the healthcare facility.

15) WARNINGS AND PRECAUTIONS

The manufacturer recommends that all personnel responsible for handling and using the devices read and understand this information before use. The use of surgical instrumentation requires knowledge of anatomy, biomechanics, and ophthalmic surgery. Surgical instrumentation must be used only by a qualified surgeon operating in accordance with current information on the state of scientific progress and state the art of ophtalmologic surgery.

- Care and maintenance are essential to preserve the life and efficiency of the instruments.

- Do not bend or apply severe stresses on instruments, as this may cause breakage or failure, resulting in injury to the patient or operator.
- Do not attempt to modify the instrument.
- The user should ensure that the equipment is in good condition and working properly before use and in particular that there is no trace of corrosion.
- Visually inspect each instrument before use to detect and isolate worn, deformed, twisted, damaged, contaminated or defective instrument. Such instruments must be replaced immediately with new instruments (except for contaminated instruments that must be cleaned, disinfected and sterilized prior to be used).
- All instruments, if used frequently, are subject to natural wear and tear. Replace the most frequently used and fragile instruments regularly, especially if they tend to twist or deform and wear out (especially probes and manipulators).
- If an instrument is broken during surgery, all broken fragments and debris should be removed from the patient.
- Ensure that no moisture remains on the laser marking area. If a brownish stain forms, strongly wipe the stain away with a soft rag.
- During the surgery, devices may experience a variety of forces which cannot be fully anticipated. Even with proper reprocessing, maintenance, and inspection, devices may reach the end of their lifetime during surgery. A replacement or alternative should be available to the surgeon.
- FIMCO instruments must be used only for the functions for which they are intended.
- In the case of reference number F807C (Roth-Rapp myometer) it is mandatory to realize all traction in the instrument's axis (longitudinal axis). Otherwise the assessment of the muscle elongation will be wrong.
- Galezowski probes (F600A, F601A, F602A, F603A, F604A, F605A, F606A, F607A, F608A, F609A, F610A, F610B), Bowman double probes (F610C, F611A, F612A, F613A, F614A et F614B), must be as aligned as possible with the axis of the lachrymal canal, from insertion to withdrawal. Otherwise the devices might break and hurt the patient.

Note: *The instructions provided in this manual have been validated by FIMCO to prepare FIMCO reusable surgical instruments for reuse. It is the responsibility of the user/treatment manager to ensure that the treatment, as actually performed using treatment equipment, materials and personnel, achieves the desired result. This requires routine verification and/or validation and monitoring of the process.*

It is the surgeon's responsibility to provide the patient with all necessary information prior to the operation, including adverse events related to the operation, implants and instruments.

FIMCO declines all responsibility in incidents linked to an intervention on the instrument by an unauthorized person. The warranty does not apply if the case of disassembly, modification or intervention is carried out on the instrument, only FIMCO should intervene on these instruments.

FIMCO shall not be liable to any direct or indirect injury suffered by the customer in the event of the inappropriate use, care, cleaning or sterilization of the medical device.

16) SERIOUS INCIDENT

"Serious incident" means any incident that directly or indirectly led, might have led or might lead to any of the following: the death of a patient, user or other person; the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; a serious public health threat.

Any serious incident that has occurred in relation to FIMCO instruments should be reported to FIMCO and the competent authority of the Member State in which the user and/or patient is established.