USE AND MAINTENANCE
of reusable surgical instruments

PRESENTATION

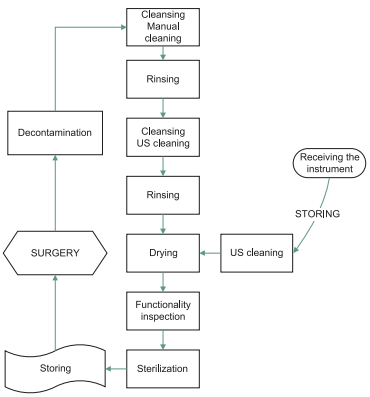
Thank you for your choice. The instrument you have purchased has been manufactured with the highest quality materials. Each instrument must be looked upon as unique, it has been manufactured with extreme attention and carefully tested by highly trained staff. We recommend you to follow the indication of this sheet in order to grant a long life and everlasting functionality to your instrument.
Each instrument has been manufactured for its specific intended use; usage with a different purpose will inevitably cause deterioration.

WARRANTY

The reconditioning of the devices, carried out in accordance with the manufacturer's instructions, will not alter its chemical and physical properties. All Janach® ophthalmic surgical instruments are unconditionally guaranteed for life against manufacturing defects when used for their intended surgical purpose. In the event any Janach® instrument should fail as a result of a manufacturing defect, it will be replaced or repaired at no charge. End of life is normally determined by wear and damage due to use. Any specific limitations on the number of reprocessing cycles shall be made available with the device. We cannot accept any liability for failure of products which have been modified in any way from their originals or for any failure due to misuse or application which is not in accordance with the manufacturer's intentions.
It is not possible to determine the exact number of maintenance and sterilisation cycles which the instrument may undergo. If not otherwise stated, the user himself must determine the life of the instrument by properly checking the functionality of the device after each usage.

FIRST USE

Upon reception, remove the instrument from packaging, store in a dry place free from corrosive agents.
Instruments are supplied unsterile and it is therefore necessary to accurately clean and sterilise them before use. Ultrasound cleaning is recommended, the cycle must not be longer than 5 minutes, washing should be made with demineralized water and detergent (follow detergent manufacturer's instructions for use). Use only proper detergents suitable for surgical instruments cleaning. We do recommend to protect the delicate tips of the instruments with sterilisable silicone protective tubes or other specific protections making sure that this will not interfere in any way with the washing and sterilisation procedures.



POST SURGICAL CLEANING AND MAINTENANCE

In order to extend the life of the device you must effect the following reconditioning procedures as soon as reasonably possible after use:

1. Decontamination
2. Cleansing and manual cleaning
3. Rinsing
4. Cleansing and ultrasound cleaning
5. Rinsing
6. Drying
7. Maintenance and inspection
8. Sterilisation

Decontamination

Soak the devices in a disinfectant solution (follow manufacturer's instructions) immediately after use and make sure to attain to the following advices:

a) Wear proper protective devices as indicated by your procedures

b) Inspect all cannulas and tubings making sure that liquids pass through by injecting, where possible, 10 ml of demineralised water for 10 times.

c) If indicated in the device's instructions for use, disassemble the instrument in order to make sure that all the parts of the instruments are in touch with the disinfectant solution.

d) Make sure that all the parts of the instruments are in touch with the disinfectant solution and, if indicated in the device's instructions for use, disassemble the instrument.

Decontamination must be carried out in appropriate rooms according to user's approved procedures.

Cleansing and ultrasound cleaning

The agent of the cleansing must be non-corrosive and preferably of enzymatic origin. Strictly attain to manufacturer's instructions for details. We recommend to frequently change the solution in order to avoid loss of detergent power and to avoid corrosion of the device caused by dirt and residuals piled up in the solution.
It is recommended to effect manual cleansing followed by appropriate ultrasound washing for better results

Manual cleaning

1. Soak the devices in an appropriate disinfectant solution (follow manufacturer's instructions) immediately after use.
2. Remove organic residuals and impurities using appropriate delicate non-abrasive brushes. Use the most appropriate mechanical device. taking into consideration the type of instrument and the fragility of the components of the instrument itself
3. Inspect all cannulas and tubings making sure that liquids pass through by injecting, where possible, 10 ml of demineralised water for 10 times.

Ultrasound cleaning

Washing of ophthalmic surgical and microsurgical devices requires extreme attention and care due to the reduced dimensions of the devices
To assure proper cleansing we advice to use ultrasonic washers.

1. Place the instrument inside the washer, for a maximum of 5 minutes, with the detergent solution prepared according to manufacturer's instructions.
2. Make sure that the instruments are completely in touch with the solution and that all the joints are well opened.
3. You may protect the most delicate parts with silicone caps. Make sure that such protections do not interfere with proper cleaning.
4. Avoid contacts among instruments while performing ultrasonic washing

Delicate instruments such as coaxial retinal microforceps and microscissors, as well as forceps with teeth smaller than 0,2 mm, may be subject to negative effects from ultrasounds. Ultrasounds might stress and damage the most delicate parts. We recommend to handle these devices with extreme care, making sure to position them safely avoiding reciprocal contact.
We recommend not to use ultrasonic washing for diamond knives.

Rinsing:

After each cleaning and washing process, rinse thoroughly with demineralized water. Make sure to remove all the detergent solution from the surface of the instruments.

Drying

Dry the instruments with compressed air. Make sure that the air is filtered in accordance to user's approved procedures.

Maintenance and inspection

After the cleaning procedures, the instruments must be free from organic residuals and other impurities. Should this not be achieved, repeat the procedure. Inspect the instruments with magnifying devices before sterilization and verify functionality and integrity. Damaged instrument or instruments showing evidence of corrosion must be rejected in order to avoid extending corrosion to other instruments in proper conditions.
Joints and pins may be lubricated with paraffin oils. Do not use silicone oils, these may cause rust and promote concentration of dirt and organic residuals. Do not lubricate the interior of the shaft of the coaxial microforceps and microscissors. Use lubricants suitable for autoclave sterilization and always refer to manufacturer's instructions.

AUTOCLAVE STERILIZATION

Sterilization does not replace cleaning. Always follow manufacturer's instructions when using sterilization devices.
Correct sterilization may be granted only by following the present instructions, any modification must be validated. The validation must be carried out by the user. Always use a validated procedure in agreement with the official pharmacopeia.
The instruments are ready for sterilization only after they have undergone the following procedures: decontamination, washing, cleaning, rinsing and drying. The devices must be placed in the autoclave only if free from organic residuals, perfectly dried and in good state.
Use only validated autoclaves in accordance to ISO standards. It is user's liability to apply the correct provision of law and to train personnel accordingly.

We recommend using the following sterilization parameters:

MATERIAL	min	°C	BAR
Surgical instruments, surgical drapes, tempered glass	5-7	134	2,2
Rubber and plastic	15-20	121	2,1

Steam residuals on the stainless steel of the devices may give start to corrosion processes that will eventually damage the instruments. Use extreme care with the final drying cycle and make sure that the instruments are perfectly dried. The good functionality of the autoclave must be verified and assured in order to grant proper maintenance of the surgical instrument under treatment. For proper maintenance of the sterilization system, always refer to manufacturer's instructions.

WARNING

Our surgical instruments must be used only by ophthalmic surgeons. Ophthalmic surgeons are the only users with appropriate knowledge of the destination of use and of the correct features of the instruments. Any different use, rather than those indicated by E. Janach srl is under user's liability; such different use may compromise the health and safety of both patient and user. The personnel of the operating rooms must be properly trained and have the level of k nowledge required to handle and to effect proper maintenance of the surgical instruments. The choice of the proper surgical procedure is made by the surgeon based on its personal experience. Instruments must be carefully inspected following each surgical procedure in order to assure full functionality. Do not use devices that show signs of damage or deterioration. If this happens, send the instruments to E Janach's repair service and do not, in any case, rely on other repair services.
It is the user's responsibility to acquire the correct techniques and the provisions of law for the correct maintenance of our reusable surgical instruments. It is the user's responsibility to ensure that all the maintenance procedures are carried out by properly trained staff by means of appropriate equipment and validated processes as defined by international laws and guidelines reference.
The user willing to adopt sterilisation procedure that differ from those approved by E. Janach srl must have such procedure validated in accordance to regulatory framework and will take the responsibility for damages and malfunctions to the devices. Always use sterilising devices in perfect working condition.
For a correct maintenance of our surgical instruments we strongly recommended to follow manufacturer's instructions when using cleaning and disinfectant solutions in order to avoid damaging the devices. Always make sure to use the proper solutions for the instruments under maintenance.
All E. Janach srl devices include delicate parts and precise components and therefore have to be accurately treated and protected following each use.
Put extreme care while treating hinges, pivots, cannula, small tubings or any other parts with a complex geometry, where there might be a concentration of organic residuals and other impurities.
Do not treat the instruments at temperatures above 135°C.

NOTES

1. E. Janach srl surgical instruments are crafted with biocompatible materials in accordance with applicable regulations:
   a. martensitic and austenitic stainless steel
   b. titanium alloy Ti6Al4V ELI (Grade 5)
   c. medical silicon
   d. polymers such as PEEK and PTFE
   These devices include delicate parts and precise components and must be handled with care in order to extend their life. If manufacturer's instructions for maintenance are correctly followed, the instruments might be re-sterilised many times, theoretically an infinite number of times. It must be though taken into account that each heat and/or chemical treatment stresses the material and causes deterioration. It is not therefore possible to give a precise number of cleaning-sterilisation processes that the instruments must undergo. The product lifetime, unless otherwise stated, is thus determined by the user, who must check the device and verify its working condition after each use.
2. The most relevant procedure for the maintenance is undoubtedly the removal of organic residuals from the surface of the surgical instruments. Such residuals might interfere with a correct sterilisation and may additionally give start to pitting corrosion. The organic residuals are rich in chlorides, these are ions that, by reacting with the metallic ions of the instruments, might considerably effect the corrosive process by modifying its kinetics. Chemical solutions used for cleaning must not be aggressive against stainless steel, because they might provoke corrosion of the surgical instruments.
3. Do not use saline solutions to rinse the instruments after cleaning. Use only demineralized water.
4. The quality of the steam used for the autoclave sterilisation affects the process of corrosion. In particular, the percentage of dry steam must be close to 100%, in order to avoid small parts of water getting the instruments surfaces wet thus giving start to corrosive processes. The composition of the water used in the autoclave is important in order to minimise corrosion. Use of water free of salts and incondensable material is required in order to allow the production of saturate steam with the highest concentration of dry steam. Alkalinity indeed promotes water moving into the steam.
5. Proper full drying must be carried out in order to extend the live of the devices.
6. The instruments must be properly placed in their containers at a correct distance from one another in order to allow steam to easily reach all the surfaces to be treated. Instruments placed improperly, in contact with one another, reduce the surface of heat exchange between the instruments and the steam. At the same time they promote condensation formation and consequently corrosion.
7. Always use the correct protections needed for delicate instruments (silicon caps and other supplied devices) in order not to hamper a correct sterilisation process.

ISO 9001
ISO 13485

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