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 usage, 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 the 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 original specifications (includes any changes of the engraving) 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 instruments 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 demineralised 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 sterisilable 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 STERILISATION
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. Cleaning and manual cleaning
3. Rinsing
4. Cleaning and ultrasound cleaning
5. Drying
6. Maintenance and inspection
7. Sterilisation

Sterilisation does not replace cleaning. Always follow manufacturer’s instructions when using sterilisation 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 residues, perfectly dried and in good state. The validation must be 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 sterilisation parameters:

<table>
<thead>
<tr>
<th>MATERIAL</th>
<th>min</th>
<th>°C</th>
<th>BAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical instruments, surgical drapes, tempered glass</td>
<td>5-7</td>
<td>134</td>
<td>2.1</td>
</tr>
<tr>
<td>Rubber and plastic</td>
<td>15-20</td>
<td>121</td>
<td>2.1</td>
</tr>
</tbody>
</table>

Steam residues 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 dry and in good condition. The quality of the autoclave is the responsibility of the user and must be verified and assured in order to grant proper maintenance of the surgical instrument under treatment. For proper maintenance of the sterilisation 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 the responsibility of the correct use of and 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 personnel of the operating rooms must be properly trained and have the level of knowledge 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 his 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. This happens especially to the instruments to E. Janach’s repair service and do, 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 use properly approved sterilisation procedures, make sure to use the proper solutions for the instruments under maintenance.

All E. Janach srl devices include delicate parts and precise mechanics, it is important 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 residues 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. martenitic 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 thoroughly taken into account that each heat and/or chemical treatment stresses the material and causes deterioration. It is 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 undeniably the removal of organic residues from the surface of the surgical instruments. Such residues might interfere with a correct sterilisation and may additionally give start to pitting corrosion. The organic residues 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 life 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.