

## General Requirements

This guide is applicable to all Leone instruments, pliers, rotary instruments (drills) and accessories, hereinafter referred to as instruments. The instruments must be cleaned, disinfected and eventually sterilized. Leone instruments are supplied non-sterile, thereby it is necessary cleaning and disinfection, once removed from the original packaging, and before their reuse. It is suggested to keep separate the contaminated instruments from the cleaned one, avoiding the placement on the same tray.

*We accept no liability for any damage or injuries caused by the reuse of claimed single-use products.*

## 1st PHASE

---

### Instruments collection

The instruments must be collected and visually inspected. Dispose of the damaged or not perfect instruments.

*It is suggested the use of personal protective equipment (PPE), during the phase of instruments collection.*

### Decontamination

The instruments, after their use (and before their first use) must be immediately soaked, as they are, in a bath containing a disinfectant product aldehyde-free, suitable and compatible for the disinfection of instruments. Do not use disinfectants or cleanser with high percentage of chlorides and oxalic acid. In case of Titanium instruments, avoid hydrogen peroxide. The efficacy of disinfectants must be substantiated according to local regulatory dispositions. It is necessary to follow carefully the activation time, soak times, and the concentrations specified on the product's label.

*It is suggested to perform the decontamination phase in adequate locals where circulation of air is ensured . It is suggested the use of personal protective equipment (PPE).*

### Ultrasonic bath (optional)

The ultrasonic bath can be a support to the manual cleaning or to the automatic cleaning, but can not replace them. The instruments must be fully soaked in the bath. In order to minimize the obscured surface areas, articulated instruments must be opened. The bath temperature must not exceed 50°C, it is necessary to follow carefully the concentrations specified on the product's label. The efficacy of the ultrasonic bath is limited to flexible materials. Do not treat together instruments made up of different materials, since the ultrasonic treatment can generate an ion transfer that may cause engraving, holes and cracks on the instrument's surface.



After ultrasonic treatment, the instruments must be either thoroughly manually rinsed to remove all detergent and disinfectant residues.



### Manual cleaning: Cleansing– Brushing – Rinsing – Drying

The instruments must be soaked in a cleanser bath (or disinfecting-cleanser). It is necessary to follow carefully the activation time, soak times and the concentrations specified on the product's label. In order to minimize the obscured surface areas, articulated instruments must be opened.

### Manual brushing

Thereafter, the instruments must be carefully brushed in the cleanser bath (eventually disinfectant) to remove organic residue not been eliminated by the detergents. Use dedicated brush with soft bristles and swabs with special attention to the instrument's critical areas as joints, knurls and hollow.

### Rinsing

Rinse the instruments thoroughly with water to remove detergent's residue. Rinsing is necessary after ultrasonic bath and manual brushing.

### Drying

After rinsing the material must be thoroughly dried. Paper cloth or lint-free cloth can be used. The use of compressed air to dry instruments with narrow lumens is preferable to eliminate water residue.

*It is suggested the use of personal protective equipment (PPE).*

### Disinfection: chemical or thermal disinfection

With chemical disinfection, the instruments must be soaked in disinfecting solution. It is necessary to follow carefully the activation time, soak times and the concentrations specified on the product's label. Rinse the instruments with copious quantity of water to remove chemical product residues.

With thermal disinfection, a thermostatic bath is used. Thermal disinfection is preferable than chemical disinfection as it is easier to perform and there are no chemical residues.

*It is suggested the use of personal protective equipment (PPE).*



## 2nd PHASE ALTERNATIVE

---

### Automatic cleaning with washers

Automatic cleaning is performed through washers that clean, disinfect, rinse and dry the instruments using standard programs.

The equipment must be certified according to local regulatory dispositions. Thermal disinfection is suggested with purified water and air.

Before performing chemical disinfection verify that the chemical products are suitable for the instruments. It is necessary to carefully follow the activation time, soak times and the concentrations specified on the product's label.

The articulated instruments must be opened and the instrument, avoid mutual contact among the instruments. At the end of the treatment ensure that the instruments are perfectly dry.

## 3rd PHASE

---

### Control and maintenance of instruments



The instruments must undergo to visual and functional control in order to verify cleaning, integrity and the absence of corrosion with special attention to the instrument's critical areas as joints, knurls and hollow.

In this phase perform the maintenance and lubricate the instruments with the use of white oil basis for medical purposes, for example, resistant to temperatures reached during steam sterilization.

Instruments must not be treated with care agents containing silicone oil. This can adversely affect the instrument's functionality and also the steam sterilization results.

## 4th PHASE

---

*Use ONLY the procedures below for sterilization.*

### Packaging(SBS) for autoclavable instruments

Packaging is preliminary to the sterilization process: instruments must be wrapped in package representing a sterile barrier system (SBS). SBS (the packaging) has to allow the sterilization, provide physical protection, maintain sterility until they are used. It is suggested to use a SBS appropriate for the instruments and in line with the standards for packaging regulation for medical devices sterilized in autoclave. Apply an external indicator to verify the process. Please remind that the Leone Surgical kit and organizers can be wrapped and sterilized with the instruments.

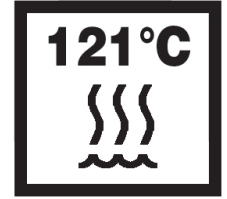


## Steam sterilization for instruments

Sterilize using a steam autoclave only the instruments that show on the label “steam sterilization” and/or the following symbol.

Verify that the autoclave is class B, conforming to the standard EN 13060 and EN 285, that ensures the sterilization of hollow and porous instruments.

To ensure the effectiveness of the process it is necessary to follow the manufacturer instructions about the load of the material inside the autoclave and avoid the contact between the SBS and the internal part of the autoclave.



Sterilization must be performed according to a validate procedure, tracked constantly and according to ISO 17665-1 “Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices”. It is recommended to sterilize instruments and surgical accessories by autoclaving, following this parameters: temperature 121°C (250°F), pressure of 1 atm, minimum time of exposition 20 minutes. The autoclave must be regularly inspected and maintained according to the indications of the procedure.

At the end of the sterilization process, verify that the instruments are perfectly dry, without humidity residuals on it, they can be placed on a clean and dry cloth for at least 10 minutes, avoid ventilate environment .

## Sterilization for not autoclavable plastic instruments

Sterilize plastic or gum instruments with Glutaraldehyde 2% based solution. It is necessary to follow carefully the activation time, soak times and the concentrations specified on the product’s label. After the sterilization process, it is necessary to rinse the instruments thoroughly with sterile solution to remove detergent’s residues. After rinsing, the material must be thoroughly dried and wrapped in SBS package.

*The tools, once processed, must be kept in the sterilized packaging to avoid actions that can damage the SBS as bumps, drops of packs and rubbing.*