CLEANING AND MAINTENANCE OF FCI SURGICAL INSTRUMENTS

Generalities

- This document is intended to provide instructions for handling, decontaminating, cleaning and sterilizing FCI reusable surgical instruments, unless different instructions are provided with the instrument.
- The equipment, personnel, cleaning/decontaminating agents and procedures all participate in the efficiency of the process. It remains however the user's responsibility to make sure the process has produced the expected results. This requires a validation and routine surveillance of the procedures. All the cleaning and sterilization processes need to be validated. However, we can only provide general advice for adequate cleaning and sterilization of reusable instruments.

Warning

- Unless otherwise indicated, instruments are delivered non-sterile by FCI and should not be used without being cleaned, disinfected and sterilized.
- New instruments **must** be cleaned and sterilized before initial use.
- Instruments should not be soaked in sodium hypochlorite or any kind of solution containing chlorine or chloride, as they promote corrosion.
- Only use cleaning and decontaminating solutions adequate for use on surgical instruments. Comply with the soaking time, temperature, water quality and concentration recommended in the manufacturers' instruction for use
- Never use metallic brushes or scouring pads
- Instruments made of different metal or metallic alloys should be processed separately to prevent corrosion by contact.

Limits in the number of treatments

FCI does not define an appropriate maximum number of uses for its reusable instruments.
Instruments' lifespan depends on several factors including the method and duration of each use and the treatments performed between each use.
An inspection followed by a functional test before use is the best method to determine when an instrument should be discarded.

Instructions

- **Point of use**
  - Instruments should be cleaned immediately after use, to prevent blood or any other organic substance from drying on surface or in cavities.
  - After each use, you should:
    1- Remove all contaminants (antiseptic products, biological material …) by wiping the instruments with a lint-free cloth,
    2- Rinse the reusable instruments carefully with demineralized or distilled water,
    3- Flush all lumen instruments (such as cannulas, suction pipes, hand pieces ...) several times with demineralized or distilled water to remove any particles that could prevent the liquid from entering the instruments.

- **Confinement and transport**
  - During transport, soiled instruments should be kept separate from non-contaminated instruments.
  - When handling soiled instruments, comply with the existing caution instructions
  - Instruments should be processed as quickly as possible after use.
  - Instruments should remain damp to prevent soiling from drying.

- **Preparing the cleaning (decontamination)**

1- When needed, pull apart cannulated instruments and instruments with removable nozzle (mainly microsurgical instruments).
2- Wipe the largest soiling with an unwoven pad soaked in a decontamination solution.
3- Flush lumen instruments (cannulas, suction pipes, hand pieces, removable nozzles …) several times with a decontamination solution.
4- In the decontamination bath, instruments should be soaked in open position for the length of time recommended by the supplier.
5- Rinse the instruments and flush the hollow ones (cannulas, suction pipes, hand pieces, removable nozzles …) with demineralized or distilled water until full removal of the decontamination solution.

- **Procedure for manual cleaning**

1- When needed, pull apart cannulated instruments and instruments with removable nozzle (mainly microsurgical instruments).
2- Prepare the cleaning solution as recommended by the supplier. It is possible to use a combined solution of decontamination and cleaning product. Comply with the instructions for use.
3- In the decontamination bath, instruments should be soaked in open position for the length of time recommended by the supplier.
4- Flush lumen instruments (cannulas, suction pipes, hand pieces, removable nozzle …) several times with the cleaning solution.
5- Brush the instruments with a soft brush while maintaining them within the cleaning solution. Pay special attention to rough surfaces, lumens, joints, blind holes and moving parts.
6- Use a swab of the correct diameter and length for cleaning hollow instruments (such as cannulas, suction pipes, hand pieces, instruments with a blind hole ...).
7- Rinse instruments with demineralized or distilled water until full removal of the cleaning solution.
8- Lumen instruments (such as cannulas, suction pipes, hand pieces, instruments with a blind hole ...) and instruments with moving pieces should be flushed / rinsed with demineralized or distilled water until full removal of the cleaning solution. Then, flush /rinse the instruments with 100% alcohol to remove any trace of water and flush/dry them with air.
9- Cleaning cycle in ultrasonic tank (if possible): manual cleaning cycle can then be completed by an ultrasonic cleaning cycle of 5 to 10 minutes with a fresh cleaning solution. At the end of the cycle, rinsing steps « 7 »and « 8 » must be repeated.
Refer to section « Ultrasonic Cleaning Procedure» for ultrasonic cleaning tank instructions for use.
10- Cleaning and rinsing operations should be repeated until full removal of any visible soiling.
11- Carefully dry the instruments with a medical fabric, hot air or compressed micro-filtered air.

- **Procedure for ultrasonic cleaning**

When the cleaning process includes the use of an ultrasonic tank, follow the recommendations below:

1- Do not process different metals within the same ultrasonic cleaning cycle.
2- Instruments should not come into contact with one another during the cycle. Place instruments on a silicone mat, to prevent them from coming into contact with the sides of the tank.
3- For manually adjusted machines, each time the water is renewed, you must allow for a degassing period as ultrasounds degas water before cleaning
4- An ultrasound frequency between 25 and 50 KHz for 5 to 10 minutes is recommended.
5- The cleaning solution should be replaced before showing visible traces of soiling.
6- Empty and clean the ultrasonic tank every day of use, or more frequently in case of visible soiling. Follow the manufacturer's instructions for cleaning and emptying the ultrasonic tank.
7- Ultrasonic cleaning should not be the only cleaning method used.

- **Automatic cleaning and thermal disinfection with washer-disinfector**

Because chemical residues remaining on the instruments can cause unwanted reactions, FCI doesn't recommend the use of chemical liquid sterilizers or disinfectants for cleaning instruments.
Below are instructions on thermal disinfection of instruments with an automatic washer-disinfector.
Recommendations:

- Do not process microsurgical instruments in a washer-disinfector, except when it has a delicate cycle.
- Only use washer-disinfectors meeting the requirements of the 15883 ISO Standard (AAMI ST15883) with a proven efficiency (CE marking or FDA approved), properly installed, qualified and maintained.
- For thermal disinfection use a valid disinfection program and a sufficient number of rinsing cycles (A0 > 3000, for at least 10 minutes at 93°C/199°F for used instruments).
- Only use cleaning agents compatible with a washer-disinfector.
- Do not go above the concentration and temperature recommended by the detergent manufacturer.

Procedure:
1- In case of visible soiling, pre-clean the instruments by hand with a pH neutral solution.
2- Place the instruments on adapted supports to prevent excessive movement or contact with other instruments.
3- Place the sterilization racks in the washer-disinfector as recommended in the manufacturer's loading instructions.
4- Lumen instruments (cannulas, hand pieces …) should be connected to the adequate washer rinsing ports, after carefully checking they are not blocked.
Make sure all the hinged/joint instruments are open and lumen instruments (cannulas, hand pieces …) are placed not horizontally but diagonally, to make runoff easier.
5- Start the cleaning cycle.
6- After the end of the cycle, carefully inspect each instrument to check if it is clean, intact and ready for use. In case of any visible soiling on the instrument after the cleaning process, the instrument should be reprocessed or cleaned manually.
7- After processing, check that there is no cleaning agent left in the lumens. Lumen instruments (cannulas, hand pieces …) should be dried using compressed micro-filtered air or medical fabric.

- **Inspection and functional test**

Before preparing sterilization, all reusable instruments should be inspected, tested and maintained:

1- Check for traces of organic residue or corrosion,
2- Check for possible damages and/or wear,
3- Check the proper functioning of all joints and moving pieces and the functionality of assemblies and connections,
4- Sort and remove from the cycle any soiled or deteriorated instrument,
5- When needed, lubricate the joints, hinges and other moving pieces (refer to « Maintenance » section).

- **Maintenance**

- The instruments joints, hinges and moving pieces should be regularly lubricated (in particular after an ultrasonic bath) with a lubricant meant for medical grade surgical instruments, to reduce friction and wear.
- Complying with the lubricant supplier's instructions is highly recommended. The lubricant used must be compatible with the chosen sterilization method.

- **Packing**

- If instruments are sterilized individually, the use of specialized bags is recommended. The bags should be big enough for the instruments to be placed in an open position. Instruments should NEVER be sterilized in a closed position.
- If the instruments are sterilized together or by batch, the use of the appropriate size of sterilization racks with silicone pads is recommended. Instruments should not come into contact with one another. The use of protection nozzles made of soft silicone tubing, of an appropriate size and thickness is recommended. Do not use protection nozzles made of rubber or plastic, as they could melt during autoclaving and damage the instruments.

- **Sterilization Cycles**

FCI instruments may be sterilized using the following methods:

- **Ethylene Oxide:**

Gas concentration: 850±50mg/l	Temperature: 37°C – 47°C
Exposure time: 3- 4 hours	Relative humidity: 70% HR minimum

- **Stan Autoclaving:**

Type of autoclave	Gravity displacement	Prevacuum
Configuration	Wrapped	Wrapped
Temperature	121°C to 123°C 250°F to 253°F	132°C to 135°C 270°F to 275°F
Exposure Time	15 to 30 minutes	3 to 4 minutes

- **"Flash" Autoclaving:**

Type of autoclave	Gravity displacement	Prevacuum
Configuration	Unwrapped	Unwrapped
Temperature	132°C / 270°F	132°C / 270°F
Exposure Time	3 minutes	3 minutes

- Notes:

- Sterilization cycles described above correspond to standard procedures and should produce a sterile device. Because of differences between sterilization equipments and in the microbial charge of devices when used clinically, FCI cannot recommend specific cycle parameters. It is each user's responsibility to control and validate that the sterilization cycle will provide the right level of guarantee of an appropriate sterilization of the instruments.
- FCI does not recommend "flash" autoclaving for reusable instruments. "Flash" autoclaving should only be reserved for emergency reprocessing, i.e. in case of a problem of asepsis.

- **Storage before use**

After sterilization, reusable instruments should be stored in their sterilization covering in a dry and dustless place. Instruments' life span depends on the used sterile barrier and on the storage, environmental and processing conditions.

A maximum life span for sterilized reusable instruments should be defined before use by each healthcare facility.

- **Inactivation of unconventional transmissible agents**

The World Health Organization recommends three inactivation methods while indicating that none of them is faultless. They are:

- Autoclaving in certain conditions (porous load autoclave between 134°C/273°F and 138°C/280°F for 18 minutes),
- Soda (1N for 1 hour at 20°C/68°F),
- Sodium hypochlorite (with 2 % of free chlorine for 1 hour at 20°C/68°F).

1. Chemical inactivation of unconventional transmissible agents

Chemical inactivity is obtained either with 1 N soda for 60 minutes at 20°C/68°F, or with sodium hypochlorite at 6 chlorometric degrees (bleach (?) water freshly diluted by half) for 60 minutes at 20°C/68°F.

The use of sodium hypochlorite is not recommended as it promotes corrosion of the instruments.

Soaking for 60 minutes at 20°C/68°F in a 1N soda solution prepared with demineralized or distilled water is recommended. Inactivation must be followed by very careful rinsing, until neutralization of the bath pH. The presence of soda residues on the instruments during sterilization is responsible for significant corrosion. The presence of chloride ions in the city waters makes the soda solution corrosive. This is why demineralized or distilled water is required.

Chemical inactivation must be followed by very careful rinsing with demineralized water.

2. Physical inactivation of unconventional transmissible agents

Physical inactivation requires the use of damp heat. The process is performed in an autoclave at a temperature not be lower than 134°C/273°F for a length of time no shorter than 18 minutes.