SOP-INST-13-01 **INFORMATION FOR CLEANING, DISINFECTION AND STERILIZATION OF REUSABLE MEDICAL DEVICES**

GENERAL PROCEDURE

This document is intended for health-care providers to ensure that the critical elements and methods of decontamination, disinfection and sterilization are incorporated into health care procedures.

This document complies to the international standard ISO 17664 :2004 (CAN/CSA-ISO 17664 :2004), to the Canadian standards Z314.0-13 and Z314.8-14 and to Health Canada requirements: « Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices. »

Also, the following documents are referenced for Medical Device Reprocessing /Sterile Processing Department employees. These employees should be familiar with most of these work instructions.

a) **« Unité de retraitement des dispositifs médicaux (unité de stérilisation) », Le directeur des communications du Ministère de la Santé et des Services sociaux, Québec (2011).**

b) **« Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings. » 3rd edition, May 2013, from Public Health, Ontario.**

c) **« Best Practices Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-Critical Medical Devices. » in B.C. Authorities, December 2011.**

Introduction

IMPORTANT NOTICE: **We strongly recommend that you read carefully the different instructions contained in this document before using any medical devices intended to be reprocessed. In case of damage during the operation, the surgical device must be exchanged immediately. Each further use can cause complications and/or risk to people during the operation.**

The different requirements described in this SOP* apply in all or in parts for the following activities:

1- General instructions for the reprocessing of surgical devices;
2- Limitations and restrictions for the reprocessing treatment;
3- Preparation of surgical devices at the point of use, before the retreat;
4- Preparation of surgical devices before the cleaning process;
5- Cleaning and disinfection of surgical devices;
6- Drying and lubrication of surgical devices;
7- Sterilization and validation of the sterilization process;
8- Inspection, maintenance and testing of surgical devices;
9- Packaging of the surgical devices;
10- Repairs of surgical devices;
11- Handling and storage of reprocessed surgical devices;
12- Warranties.

1- General instructions for reprocessing surgical devices

All devices must be removed from the transport packaging before use. All other packaging, caps and/or protective elements must also be removed and disposed.

All surgical devices were manufactured with care and precision and sometimes represent a high investment. This is why their maintenance, according to established standards, is elementary and essential for obtaining a good shelf life for the devices. Everyone must apply recommended measures in correlation with the information given by the manufacturer, basic rules for hygiene and regulatory requirements concerning device protection in the working areas (please refer to the section « References » at the beginning of this document for applicable standards).

To maintain as low as possible the risk for patient and devices users, Instrumentarium provided this SOP* describing different processes for suitable preparation, usage, handling, cleaning, disinfection, sterilization, packaging and storage for reusable surgical devices. Every staff member responsible for the usage, reprocessing or sterilization of our devices must be qualified and properly trained for handling and usage of the surgical devices and their accessories.

All new products must be submitted (after their delivery and before every usage) to a thorough visual inspection and to a good working conditions inspection. Each product must be verified for irregularities. Inspections must include crack and traces of corrosion. Devices joints must be lubricated using a medical grade lubricant that can tolerate high temperatures. Never use an industrial lubricant because the devices will become sticky when exposed to high temperatures. Check the ease of operation of articulated devices. Do an adequate functioning control in reference to point of use of the device.

All defective devices must not be used and have to go through a complete reprocessing cycle before being returned.

All single-use devices and components must be discarded following their usage. Never reuse these devices or sterilize them for a second time. Each surgical device must be disinfected and cleaned after each usage. The surgical device users must cooperate in preserving of these devices by maintaining adequate handling and this on a permanent basis.

*** SOP: Standard Operating Procedure**

Precautions to be taken before using a new or a repaired surgical device

In most cases, new surgical devices have not been sterilized and must be treated before the first usage. Each device must be cleaned, disinfected and sterilized before being used. The cleaning process must never be neglected because residues on the devices, such as processing, packaging or maintenance material can produce stains or patches during sterilization.

Even if surgical devices were meticulously manufactured and according to high quality standards, the users of the devices must conform to existing and approved SOP* so that they remain functional and maintain their appearance. An inadequate handling as well as an inadequate usage can result in a premature failure of the surgical device. Also, all new devices can be sensitive to different cleaning procedures.

Surgical devices returning from repairs must be removed from their packaging before being stored. All protective products and film layers must also be removed. Devices must be stored in a cabinet or in a dry room, free from dust, at room temperature. Devices must never be stored near chemical products that can release corrosive vapours. Microsurgery devices must be placed in special supports or on fixing devices before their first treatment to avoid risk of damaging the products.

New surgical devices coated with a weak passivation layer can react more noticeably to critical treatment conditions than older devices.

Cleaning, disinfection and sterilization of reusable surgical devices must be done only by skilled and well-trained employees for the handling and the use of devices, accessories and related material.

Products that will be used later are made for an operating usage and in different surgical disciplines and fields. It is important to go through each device and to inspect them for breaks, cracks or defectiveness before being used.

It is essential to inspect with thoroughness parts like blades, tips, latches, as well as all moving parts of the device. The inspection for of good functioning of articulated surgical devices is also essential .

2- Limitations and Restrictions for Treatment

Note: Cleaning and disinfection processes must conform to the International Standard ISO 15883-1, « Washer/disinfector, Part 1 : General Requirements, Terms and Definitions and Tests.

Stainless Steel devices must never be submerged in a saline solution because this solution may have a corrosive effect on some devices. Chlorine is considered to be the most dangerous type of salt. Chlorides salts react easily with the passivation layer and, according to its concentration, may cause well-known damages to the devices. Choride is the main reason for devices being damaged by corrosion (crack or fissures). Many possible sources of chloride exist.

For the same reason, it is preferable to avoid long interval between time where the device is used and it's re-treament, independantly of the cleaning or decontamination processes being used (as an example, during a night or a weekend). **It is critical to avoid staining or contaminating surgical devices to dry before being cleaned.**

Staff members must use only distilled or demineralized water for the cleaning, disinfection, sterilization or rinsing processes. The quality of the water used for the treatment of devices plays a major role in their conservation. Never use tap water. The cleaning or disinfecting solutions must be free of the following ingredients:

- Acids with a pH below 5 or oxidizing acids;
- Alkaline with a pH below 10;
- Organic solvents, alcohol-based disinfectants, phenols, ammonia, benzene, halogens, or halogenated hydrocarbons;
- Highly concentrated salt solutions (NaCl) and oxidizing agents.

***SOP: Standard Operating procedure**

Surgical devices must never be stored near chemical products that can release corrosive vapours.

It is critical to never use surgical devices that are damaged, incomplete or showing loose parts. If devices should deteriorate while being used in surgery, they should immediately be set aside and replaced. Otherwise, following every subsequent use of the device, a risk of complications can occur that could affect patient's health. Always return damaged devices (with or without their components) to Instrumentarium for repair or replacement.

Never try to repair yourself the damaged surgical devices:

- Inspect all devices to verify if they are damaged or have sharp edges, loose screw or other missing pieces or rough surfaces;
- Inspect all joint on the device;
- Device must open and close in a flexible manner;
- Inspect edges to make sure that they are working properly.

To avoid any damage to the devices or to avoid possible contamination risk to the immediate environment, always carry used devices to the re-treatement department in adequate containers.

The surgical devices used in microsurgery are delicate surgical devices and requires a « gentle » re-treatement process.

Warning: Dropping surgical devices can easily damage them (broken scissors tips, bent pliers. etc.).

If users of surgical devices sold by Instrumentarium should deviate from the established SOP*, a new method should be used and would have to be validated by the same users. **If the surgical devices are used on patients suffering from Creutzfeldt-Jakob disease or a possibility of infection from this disease, or by a VIH infection, the surgical devices must not be reused. They must be thrown away. Instrumentarium decline all responsibility for reutilization of these devices.**

3- Preparation of Surgical Devices at the Point of Use, Before Retreatment

All staff members working in a Health Care or in a re-treatment process for surgical devices must be aware of the applicable procedures and processes and have experience with the applicable standards. These standards describe the precautions to be taken while handling the devices to avoid injuries from sharp edges of the surgical devices. Appropriate clothing and protective equipment must be wear at all-time while handling contaminated or potentially contaminated devices (please make reference to applicable internal procedures or to SOP* described at the beginning of this document).

During surgery, in the operating rooms, surgical devices are contaminated by blood, by organic tissues, bone particles, bone marrow, hemostatic drug residues, and by the skin disinfectant, by lubricating products, etc. Devices could also have been contaminated by corporal fluids containing viruses or pathogens.

It is critical to avoid stained or contaminated surgical devices to dry before being cleaned. Every subsequent step of cleaning and sterilization will be facilitated by avoiding blood, corporal fluids, bone particles, tissue fragments and saline solutions or disinfectant to dry on the devices and complicate the cleaning and disinfection processes.

Due to a risk of surgical device corrosion, it is preferable to avoid the long intervals between usage and re-treatment.

Soaking after usage in surgery

If dry cleaning and decontamination of the surgical device is impossible immediately after surgery, store them in an enzymatic solution. A poor cleaning or the omission of cleaning the surgical devices can leave glued particles or dried secretion that will remain on the devices after cleaning process and will complicate or resist to further sterilization processes.
All surgical devices must be cleaned and disinfected after every use. The staff responsible for the re-treatment of the devices must make sure to place the stained devices in distilled or demineralized water and this, immediately after their usage. This working method will greatly ease the cleaning of the devices.

***SOP: Standard Operating Procedure**

The staff members must only use distilled or demineralized water for all cleaning, disinfection, sterilization or rinsing processes for surgical devices. The quality of the water used for the treatment of the devices plays an important role for their preservation.

Immediately after use, the devices must be cleaned from large residues with a cloth or with a disposable paper. It is critical to clean the surgical devices before contamination dries on them. Do not use water with a temperature below 40°C.

4- Preparation of surgical devices before the cleaning process

Never use metal brushes or metal sponges for cleaning. Do not oil plastic components.

To prevent any risk of cross contamination, all surgical devices must be carried out to the treatment room, in a closed or covered container. Contaminated surgical devices transport is carried out in a closed system from the operation rooms and stations to the sterilization area. The dry decontamination system must be preferred and used as often as possible.

When wet decontamination is used, the devices must be immerged preferably in a combined solution of cleaning and disinfectant products that does not fix the proteins. **Avoid using disinfectant solutions containing aldehydes and that have the fixation effect.** The manufacturer's instructions concerning concentration and action period, and should this happen, the addition of special cleaning additive must be respected.

Unused surgical devices following a surgery must be treated the same way as the used devices.

Before devices cleaning or sterilization, staff members must make sure that all the protective packaging has been removed (including device tip protectors).

Devices must be placed in the loading baskets and arranged in such a way that it will allow for adequate cleaning. A rough handling of the surgical devices could result in damaging them, because scissors hard metal tip can break or small pillars could get distorted. To avoid this situation, it is recommended, after use, to properly and delicately put down the devices. The devices loading baskets must not be overfilled. Waste, residual skin disinfection products, saline water solutions must never penetrate in the containers.

Dismantling (Standard Devices and Devices That Can Be Dismantled)

Staff members must make sure that for articulated devices (like scissors, needles stand, pliers, etc.) they are being treated in open position to allow adequate cleaning. The containers should remain closed to avoid any further drying of the surgical devices. The best cleaning results are obtained in presence of dismantled or open surgical devices to allow the disinfectant solution to get in contact with all surfaces.

If the device can be dismantled, clean it dismantled, piece by piece. (Note: Keep all parts together and protect them so that they don't get lost or get mixed with similar devices or from a different manufacturer).

A great number of small surgical devices, such as those with an articulated diameter inferior to 3 mm and intended for mini-invasive surgery with sensible components sensibly filigreed, cannot be dismantled nor set up by the user.

Decontamination

This generally implies cleaning, disinfecting, rinsing and drying processes. Decontamination can be done either by a mechanical or manual treatment.

Widespread use of ultrasounds for devices cleaning must not be considered as being the only cleaning method, but always a preliminary step to manual or mechanical cleaning. The ultrasound cleaning is highly recommended eliminating stains in joints, cracks, cannulas and other hard to reach areas. If the ultrasound process is used, all treated devices have to be inspected and all devices damaged by vibrations have to be put away.

5- Cleaning and Desinfection of Surgical Devices

In presence of heat-stable surgical devices, it is recommended to use a machine thermal treatment disinfection process and steam sterilization.

Note: An unfavourable water chemical composition will have a negative effect on the treatment process as well as on the external appearance and the nature of the devices components. Different quality of tap water can leave traces on the devices, forming hard layers of materials, very difficult to eliminate (depending on the water hardness and its temperature).
For microsurgery surgical devices, a special cleaning process is required: Special baskets and appropriate storage support have to be used. Should this situation arise, loading chariots equipped with a special washing technique should be used.

When using cleaning or disinfecting products, instruction related to concentration, temperature and immersion time must always be met. Also, information related to material compatibility for all devices which are not made with stainless steel must be known and observed.

Devices containing coagulation residues that cannot be eliminated by an intensive cleaning process (3% oxygenated water, using a brush, with ultrasound), must be placed aside since their functionality and their sterility cannot be guaranteed.

C**leaning of the surgical devices is one of the most important steps in the decontamination process.**

All surgical devices have to be cleaned and disinfected after each use. Staff members of the designated areas must make sure to put the dirty devices in distilled water, and this, immediately after their use. This way to process will ease the cleaning process of the device.

An efficient cleaning of the surgical device is critical for the sterilization process. The surgical devices intended to be sterilized must be clean and without any visual residues. This is done by a visual inspection of the devices. Critical areas (handles, joints, etc.) require particular inspection.

Articulated surgical devices have to be immersed in the solution, in an open position, and by minimizing their stacking surfaces. The treatment of hollow surgical devices (pipes, cannulas, etc.) and devices with cavities is always very difficult. This is why staff members have to make sure that these devices are permeable and that the interior cavities are completely in contact with the solution.

All cleaning and disinfecting solutions used must be prepared on a daily basis. If some solutions are used for a too long period, the following problems could occur:

- A risk of corrosion generated by a high concentration level of the cleaning/disinfection solutions (this situation is due to evaporation);
- An insufficient disinfection caused by accumulation of contaminants. It is critical to inspect all devices carefully between each step of the cleaning process and to make sure that there are no visible stains (or dirt) on the devices. Special care should be taken for cracks, bolts, tips, hollow tubes and other hard-to-reach areas. Separately inspect cables and connectors for cracks, friction, etc. Never use damaged devices. Dismantable or cutting-edge devices must be handled with care.

Pre-Cleaning Process

Place the devices to be cleaned in cold water for about 5 minutes. If possible, dismantle the device and clean it in cold water using a soft brush until there are no visible traces of residues. Stained surgical devices must be submerged in a soft enzymatic detergent or sprinkled with a foam or gel pre-cleaning solution. Rinse cavities, drills and threads with a compression spray for a minimum period of 10 seconds (pulsation method).

Using ultrasounds, clean the surgical devices for a period of 15 minutes using an ultrasonic bath containing 40°C demineralized water and 0.5% alkaline solution. The ultrasonic frequency must be of at least 3.5 kHz. Then, remove the surgical devices and rinse them with cold water.

Cleaning/Disinfection

Preparation

Place the dismantled and/or open devices on a device tray. Place the tray on a device support inside the cleaning/disinfectant unit and start the cleaning cycle. Refer to the following pages for a description of the required steps for the cleaning process.

a) Cleaning and Disinfection by Machine

Machine cleaning allows to reach cleaning and disinfection standard level. This information is also valid for particular cases where the surgical devices are particularly dirty. Machine cleaning is preferably applicable to devices having been submitted to a dry decontamination process. In case where humid disinfection process was used, a disinfectant containing less foaming cleaning agents must be used and has to be rinsed thoroughly, since the foam may risk reducing the irrigating pressure necessary in the machine cleaning process and to alter the result. That information is also valid for particular situations where very stained surgical devices were submitted to a manual prewash or by ultrasound equipment.

Mechanical treatment requires to observe the following items:

- The preliminary condition for an efficient mechanical treatment is the adequate loading of sieves, baskets and supports, etc. The articulated devices must be stored in an open position;
- The baskets must not be overloaded in order for the devices to be well splashed;
- Large surface devices must be placed in the machine in such a way that they don't act as a screen for other devices, interfering then with the washing process;
- Devices having cavities (turbines, trocar cover, respiratory systems, etc.) must also be cleaned inside. To that effect, it is advisable to use particular supports, adapted to the devices and equipped with rinsing machines;
- To avoid any possibility of damage, the surgical devices must be placed or stored according to their mechanical fragility.

Prewash rinsing and the rinsing stages, use demineralized or distilled water together with an alkaline cleaning agent (0.5%) and a neutralizing agent (1 ml/l).

Not recommended: Tap water, since an unfavourable chemical composition water would have a negative influence on the treatment process.

Prewash

To eliminate coarse stains and foaming substances, use cold water without any additives.

Cleaning

According to the device to be cleaned, using demineralized water at a temperature between 40°C and 60°C, clean the surgical device for a minimum period of 5 minutes. Use a product with a neutral pH or with an alkaline product. The choice of the cleaning product is carried out according to the composition of the device, its proprieties and by the cleaning power required.

For chemical products used, the manufacturer's information has to be followed:

- Concentration of the product;
- Temperature;
- Time required.

The automatic measurement of the volume of the liquid chemical products must be controllable.

b) Thermo-chemical Disinfection

Use demineralized water without any additives. The thermos-chemical disinfection must be done by using demineralized water at temperatures of 80°C and 95°C, for a period according to ISO 15885 international standard.

For the cleaning products, we recommend products that have of pH between 9 and 10. You must use a disinfectant conceived for machine disinfection process having a determined efficiency.

Intermediate Rinsing

Use hot or cold demineralized water without additives. Plan many intermediate rinses to make sure that all the disinfectant solution has reached an acceptable toxicity safety level.

Final rinse

Use demineralized water at a maximum temperature of 60°C.

Drying

The machine used must provide a perfect drying. The drying temperature is set accordingly to the thermal stability of the product. To avoid an aging processing of the materials, the drying temperature should not be more than 95°C.

Cleaning cycle

Instructions

1-	Pre-rinse #1:	One (1) minute (demineralized water, without any additives);
2-	Empty the water;	
3-	Pre-rinse #2:	Three (3) minutes (demineralized cold water, without additives);
4-	Empty the water;	
5-	Hot water cleaning (55°C):	Wash/clean for ten (10) minutes. Add the cleaning agent at 45°C (alkaline cleaning agent, with a concentration of 0.5%);
6-	Empty the water solution;	
7-	Neutralization:	Three (3) minutes using hot water (below 40°C) and the neutralizing agent (concentration of 1 ml per litre);
8-	Empty the water solution;	
9-	Final rinse:	Two (2) minutes using hot water (below 40°C), without any additive;
10-	Empty the water solution;	

The rinsed surgical devices must be immediately removed after the end of the machine program, because otherwise corrosion could appear due to the residuary dampness in the machine, if it remains closed. Following cleaning, a disinfectant product conceived for the machine disinfection process must be used. It is appropriate to limit the temperature in all the steps of the rinsing cycle as well as for the final drying (Reference: ISO 15883-4 standard). The process cleans at specific temperatures (above 65°C) adding for disinfection, a suitable product for machines cleaning, according to an adequate concentration and time cycle.

Automated process for disinfection of surgical devices has been validated using the following processes:

- Utilization of the cleaning/disinfection unit Miele G 7736 CD;
- Temperature of 55°C +/- 5°C for a time period of 5 minutes;
- Drying cycle: 60°C, +/- 5°C, for a time period of 30 minutes.

c) Thermal Disinfection

A process doing a separate cleaning cycle before the disinfection process must always be preferred. A machine treatment can be done either by thermal or by thermos-chemical process. It is recommended to generally choose the thermal disinfection process. By using water without any salt, the recommended thermal disinfection is done by using a temperature above 80°C for a period conforming to the requirements A_0 of ISO 15883-1 standard, annex A, "Disinfection Washers, General Requirements, Terms and Definitions and Trials."

For a disinfection process to be used for bacterias (including mycobacterium, fungi and thermo-sensitive viruses), an A_0 value of 600, corresponding to a maintained period of 10 minutes at a temperature of 80°C. This A_0 value can also be reached by using a temperature of 90°C for a tenth of the holding period, being one (1) minute. If the process efficiency becomes essential criteria for the destruction of the thermo-resistant viruses (like Hepatitis B), a value A_0 of 3000 must be used, corresponding to a temperature of 90°C for a period of five (5) minutes. "It is recommended to generally choose the value A_0 of 3000 for the programs used for the disinfection of the reusable medical devices." (Reference: Dr. Rosenberg.)

Staff members operating the machines are responsible for implementing the A_0 value. Program structure depends on the requirements for the cleaning stages, disinfection, quality of the final rinse and of the nature of the product to be treated. The general requirements to the cleaning and disinfection machines described in ISO 1588 standard, first part, are applicable to the washer/disinfector and washing tunnels.

Prewash

In cold water without additives to eliminate the rough stains and the foaming substances.

Cleaning

In demineralized or distilled hot water, the cleaning is done at temperatures between 40°C and 60°C, for a minimum period of 5 minutes.

First rinse

Use hot or cold water. Rinsing of the alkaline detergent residues will be facilitated by the addition of an acid-base neutralizer.

Second Rinse

Use hot or cold water, without any additive. Depending on the products to be rinsed and to the quality and the safety of the required ulterior rinse, there will be many intermediate rinses without any additives (ex: ophthalmic surgical devices).

Final Rinse

Using demineralized or distilled water, the thermal disinfection is done at temperatures between 80°C and 95°C, for an adequate period of time according to A_0 according to the ISO 15883 standard. Stains, incrustation and corrosion on the devices will be avoided by using demineralized water.

d) **Manual Cleaning and Disinfection**

We recommend using a manual cleaning process for optimal results for residues on all surgical devices having a push/pull handle, handle with a pipe and devices that have stacking surfaces.

Manual cleaning is done using cleaning products and by not fixing the proteins, with or without antimicrobial and/or help of enzymes. We recommend using soft clothes that don't pill, synthetic brushes and/or cleaning pistols. Never use metal brushes or scouring pads to clean the devices. Make sure that the devices with joints are cleaned in the open or closed position.

The cleaning and disinfection agents used must be adequate for cleaning/disinfection of the surgical devices and have to be compatible. The disinfectant must be of a proven efficiency. Use distilled or demineralized water. The cleaning product must not have fixing proprieties. If possible, apply the cleaning product under pressure in the cavities, then brush with caution. The devices must be totally cleaned, rinsed and be free of any foreign matters.

Use hot water (minimum of 40°C) and a pre-soaking product or cleaning agent. The enzymatic cleaners should be used to take off any protein sediment. For enzymatic cleaning and rinsing, the manufacturer instructions must always be followed. Clean and rinse using a neutral Ph product or the most neutral possible. **Change the cleaning solution on a daily basis.**

Do not use abrasive cleaning products. Use the "Stains Remover" product (Instrumentarium catalogue number 3.740).

Rinsing Phase

The use of demineralized water for the final rinse is recommended avoiding corrosion by chloride in the final rinse water, but also to avoid stains in general and to stabilize the surfaces in anodic aluminum. Demineralized water for the final rinse don't leave crystalline residues which could interfere with a low temperature sterilization process (reference: EN 285 standard, Annex B).

Thoroughly rinse all internal channels with demineralized water, using a soft brush with a smaller diameter than the tube.

Ultrasound cleaning process can also be used. Inspect and remove all accessories that can be damaged by the vibrations.

Instructions

1. Place the surgical devices in cold water for a period of five (5) minutes;
2. Brush under cold water the device using a soft plastic brush for as long as all visible particles are removed;
3. The interior hollows, the threading and all other hollows are rinsed using a water cleaning pistol for a period of ten (10) seconds. Brush again;
4. Do a thorough rinse using water.

Afterwards, completely submerge the surgical devices in the disinfection solution and use the appropriate cleaning auxiliaries (Ex. soft brush, etc.). Finish the cleaning process with a new rinse with demineralized water. After cleaning and rinsing, completely dry the devices with care, using sterile compressed air, giving a special attention to the internal channels and to out-of-reach areas.

e) Cleaning and Disinfection Using Ultrasounds

The use of ultrasounds is particularly appropriated for the cleaning of stainless steel devices and hard plastic material. The cleaning and disinfection of very delicate devices (microsurgery devices) can be done thoroughly and without any damage in the ultrasounds tub. High-performance ultrasound units can dissolve the dry stains, even at hard-to-reach reachable places.

Treatment using ultrasounds intervene in the following situations:

- As an effective mechanical support in the case of manual cleaning process;
- To eliminate dry stains before or after a machine treatment;
- To improve the cleaning process as an integral part of the manual cleaning process;
- For reduced time of disinfection and simultaneous intensive cleaning.

To get the high-performance effects from an ultrasound cleaning process, it is required to follow the following instructions:

- Fill the tub according to the manufacturer's instructions;
- Add to water an appropriate detergent or a combined cleaning and disinfecting product;
- When adding detergents and disinfectants, the dosage, the temperature, the time of action of the ultrasounds must agree with the manufacturer's instructions;
- It is recommended to fill the tub with hot water (covering all the devices);
- The temperatures above 50°C may cause blood encrustation by proteins denaturing;
- The freshly prepared disinfecting or cleaning solution must be degased before the first usage.

On top of the previous instructions, other important operations should be followed:

- Totally immerse the surgical devices in the cleaning solution;
- Be sure to open the devices with joints and the scissors before placing them in the ultrasonic tub; this is to avoid as much as possible surfaces overlapping;
- Place the devices only in baskets that won't affect the efficiency of the ultrasounds system;
- Make sure that large devices don't create a shadow zone unaccessible to ultrasounds; place the surgical devices in a vertical position or place them horizontally, avoiding the devices to be in contact with another;
- Never overload the baskets.

When using efficient equipment, the action time of the ultrasounds will approximately be 5 minutes using a frequency of around 35 and 40 kHz.

Following the ultrasound treatment, it is best suited to proceed to an abundant manual rinse. The manual rinse can be done using tap water and the remaining cleaning and disinfecting products have to be eliminated. To avoid any water stains, it is preferable to use for the final rinse demineralized or distilled water.

The surgical devices used in microsurgery have to be fixed using a special locking system to avoid any damages to the devices.

The following controls are also done at this stage:

- Visual control of the cleanliness, perfect condition of the surgical devices (cracks, bolts, tips, hollow pipes and all hard-to-reach areas). Check separately cables and connectors for cracks, friction, etc.;

- Device functional control.

If a device can be dismantled, clean it and dismantle it piece by piece. Keep all the device parts together in order not to lose them. Prepare the devices for sterilization. After cleaning and before sterilization, it is highly recommended that the mobile parts, like joints, bolts be lubricated with a safe physiologic product.

Staff members have to make sure that the disinfectant solution is changed on a daily basis. The disinfectant solution expiration dates must always be respected.

6- Drying and Lubrication of Surgical Devices

A good cleaning process and a proper maintenance program will provide good functioning and long life to your devices. Following the cleaning and disinfection, the surgical devices must be removed from the « Cleaning and Disinfection » area and immediately be dried. If necessary, because of effectiveness and its speed, compressed air can be used for the drying process. However, compressed air used must be sterile.

If the drying length has to be shortened due to the addition of a rinsing product, you must make sure of the device compatibility with the rinsing product. The complete drying of the load must be provided by the cleaning machine. The surgical devices must be removed from the cleaning machine as soon as the cleaning program is completed. If necessary, due to its rapid action, filtered compressed air (without any impurities) could be used for the drying process.

Following cleaning and before sterilization of the surgical device, it is strongly recommended that the mobile parts of the device, such as joint, bolts, etc., are lubricated with a physiological safe product. Before lubricating the devices, it is essential that they be exempt from stains and corrosion spots. Use only recommended and validated lubricant. Lubrication of corroded devices is detrimental, especially at the hinges. Industrial oils or lubricants must never be used to lubricate surgical devices.

The next step following the cleaning process is the preparation of the surgical devices to sterilization, in the « Clean » area (Sterilization department). In this process, devices must be inspected, sorted out and looked after according to the existing maintenance program.

Preparation of the surgical devices for the sterilization process

Following the cleaning and rinsing cycles, immediately and carefully dry the devices using a sterile compressed air gun, bringing special care to the inner duct and to unreachable areas.

7- Sterilization and Sterilization Process Validation

It is important to always remember that cleaning is not sterilizing and sterilizing is not cleaning. Plasma or Hot-Air sterilization is not allowed for products with plastic parts, as the synthetic materials will be damaged.

Introduction

Our surgical devices are reusable and conform to applicable ANSI/AAMI/ISO sterilization standard requirements. Wrapping or packaging of devices to be sterilized must comply to ISO 11607 international standard. Packaging must be suitable to the devices and form an adequate protection barrier against microbiological contamination.

It is important to follow the sterilizer manufacturer instructions for loading and operating the steam sterilizer. **The sterilization load density may affect the sterilizer parameters and performance. When loading the sterilizer, one must always meet the maximum recommended load.**

Steam sterilization is recommended. Steam sterilization is carried out with the help of saturated vapour, generally at temperature ranging from 132 °C to 135 °C. Too many chemical indicators in a sterilization load may cause stains, especially when in direct contact with the devices.

Before sterilization, devices must have been cleaned and they must be clean, free from pieces, tissue or foreign matter.

It is critical to apply only sterilization/sterilizer processes that allows an approved sterilization validated process. Staff must always respect directives for use of the different sterilizer used.

All surfaces of the devices to be sterilized, including internal surfaces and tube ducts, must be exposed. The devices must be aerated before use.

Following sterilization, make sure that the sterilized device wrapping is not damaged. Sterilization indicators must also be inspected.

Sterilization Process.

All surgical devices must be sterilized before every surgery. For device sterilization, we recommend a validates steam sterilization process (as an example: Sterilizer that conforms to EN 285 standard and validated according to ISO 17665-1 standard).

Important parameters for surgical devices sterilization are pressure, temperature and the level of gas not condensed in the vapour. It is not necessary to control charges for chemical indicators or bio-indicators if the three parameters are permantely met.

Vapours used in the sterilization process must be free from impurities and must not influence in any way the sterilization mode or cause damage to the sterilizer or the device.

Devices must not be stacked. To optimize the sterilization process, do not overload the sterilization trays. Make sure that the filters and the sterilizer are always clean.

STERILIZATION PARAMETERS

Sterilization Method	Type of Sterilizer	Exemple of Configuration	Temperature	Time
Vapour	Standard Gravity	« Wrapped »	132°C to 135°C (270°F to 275°F)	10 - 25 minutes
Vapour	Standard Gravity	« Wrapped »	121°C to 123°C (250°F to 254°F)	15 - 30 minutes
Vapour	Standard Gravity	« Unwrapped »	132°C to 135°C (270°F to 275°F)	10 - 25 minutes
Vapour	Standard Gravity	« Unwrapped »	121°C to 123°C (250°F to 254°F)	15 - 30 minutes
Vapour	Prevacuum	« Wrapped »	132°C to 135°C (270°F to 275°F)	3-4 minutes
Vapour	Prevacuum	« Unwrapped »	132°C to 135°C (270°F to 275°F)	3 - 4 minutes

Sterilization cycles validations were done by using a « Tuttnaur Steam-Autoclave » sterilizer. Parameters used were the following:

- **A dry vacuum;**
- **Temperature ranging fromv132°C to 137 °C;**
- **Cycle time: 3 to 4 minutes.**

Suggested cycles are based on ANSI, AAMI and ISO recommended practices. Other methods, time and temperature can also be used; however, the users should validate these methods.

NOTE: Please consult the sterilizer manufacturer to confirm the adequate time and temperature parameters.

Density of sterilization loads will affect the sterilization process. Also, sterilizers have different characteristics and performances. So, cycle parameters should always be verified with the sterilizer manufacturer's instructions and directives to make sure that the sterilizer specific configuration and load levels are met. Due to variations found in using different types of sterilizers and the variation in the bioburden levels on devices according to different clinical situations for each institution, hospitals have the responsibility of implementing the different processes according to existing standards and to make sure that each process is followed closely (cleaning, decontamination, functioning and visual controls, packing, sterilization, etc.), and define specific validation protocols for individual tray assembly so that SAL (Sterility Assurance Level) is always met. Make sure to reference to the common ANSI/AAMI standards or to your hospital SOP* (or specifications).

ETO (Ethylene Oxide) is also recommended due to its low sterilization temperature process required as well as its moisture level observed. The only restriction in this sterilization process is that using this gas sterilization, the cycle and the aeration period is much longer. It is also important to make sure that ETO residual level meets established standards.

Instrumentarium is recommending sterilizing its devices using a steam sterilizer, method usually used in hospitals and surgical centres. Also, manufacturer cycle parameters should be followed.

Other sterilization methods, time and temperatures can also be used. However, the user (s) would have to validate these methods. Please contact the sterilizer manufacturer to find out the proper temperature and the cycle period for adequate sterilization.

Devices intended to be sterilized must be packed as soon as possible. Follow your sterilizer manufacturer's instructions for proper processing and loading operations. All surfaces of the devices to be sterilized, including internal surfaces and tube canals, must be exposed to beams or vapour.

Plasma and hot air sterilization are not authorized for surgical devices with plastic components because devices would be damaged.

8- Inspection, Maintenance and Testing of Surgical devices

Inspection and Testing

It is critical to inspect frequently the surgical devices: before and after each utilization. These inspections must be done to detect before use the presence of cracks, fissures, or defects. It is essential to inspect thoroughly devices critical parts like blades, tips, latches, handle structures, joints or grooves on jaws, as well as all mobile parts. Results from the cleaning process must be controlled by a visual inspection.

After cooling to room temperature, the surgical devices must be submitted to a visual inspection, allowing detection of albumen residuals and other stains. Devices which are not free of residuals must be submitted to an all new complete preparation process. Isolate stained, blunted, distorted, non-operational or damaged surgical devices. The different surgical devices are all adapted to a specific use. Inspections must be conceived to make sure that all devices not conforming to this specific use are discarded from usage. In case of doubt, proper testing methods must be developed.

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Before functional control, articulated and threaded devices have to be lubricated (spray or droppers). Controls are done only when the devices are reassembled.

The following items have to be controlled while the inspections before the sterilization cycle: weariness of parts, defective parts, waterproof joints and rings must be intact. If defective parts are founded, they must immediately be removed and discarded. Damaged, blinted or distorted canulas must also be removed.

Maintenance

Maintenance operations are done before functional controls. To maintain surgical devices in a good condition, maintenance products must be applied on joints, tips, assemblies or threads, and sliding surfaces (pliers, scissors, punch, etc.) following the cleaning and disinfection processes. This allows avoiding metal on metal friction as a step to prevent corrosion caused by friction.

To carry out maintenance on the surgical devices, they must be cooled down to room temperature. Maintenance products must be applied manually in the joints, threads and sliding surfaces. This is also valid for articulated devices that were treated with a special cleaning process using oxygenated water. The maintenance products have to be spread out evenly on the devices by manipulating joints/sliding surfaces. The remaining of the products must be removed using a lint-free cloth.

Immersion bath has to be rejected due to a contamination risk.

Plastic surfaces can't be treated with devices maintenance products.

9- Packaging of Reprocessed Surgical Devices

The main reason for packaging surgical devices is to protect them so that they don't get re-contaminated. Sterile surgical devices packaging must act as a sterile barrier so that they avoid introduction of microorganisms in the package and allows aseptic handling of the package. Packaging must be developed or conceived in a way to allow easy opening of the package in aseptic conditions.

The sterile barrier presents a microbial barrier that prevents, in defined conditions, contamination of the surgical devices. Among these conditions, we can include:

- Temperature;
- Pressure;
- Moisture;
- Sun light;
- Cleanliness;
- Bioburden.

Protective packaging is a supplementary packaging conceived for damage protection to the sterile barrier system, from assembly up to its usage.

Packaging is playing a decisive role on the sterilization process and as such, all the packaging systems (sterile barrier system and protective packaging) must be compatible with the sterilization method. The packaging must not absorb more than usual, the sterilization environment and also bring modification to the sterilization process. The ability of the packaging regarding the sterilization results must be controlled in accordance to the sterilization process validation, previous processes (packaging, sealing, and assembly) must also have been validated. If new packaging that was not yet controlled (as part of a validation process), and that is used in a normal functional situation, a new evaluation of performance will have to be planned (validation).

Effective drying also plays an important role in maintaining the value of the surgical devices. Residual moisture can result in damage to the devices due to corrosion. When using nonwoven fabrics, always make sure that these products do not interfere with good drying of the devices.

Marking has to be possible and include the following information:

- Sterilization date;
- The employee who did the packaging;
- Expiration date (if it is appropriate)
- The content.

10- Repairs of Surgical Devices

Our specified guarantee would be cancelled if the surgical devices were repaired by companies or individuals that were not approved by Instrumentarium.

For hygiene and safety reasons, all surgical devices returned for repairs must have been retreated.

Never use damaged devices. Do not attempt to repair yourself devices. Only refer to qualified and competent individuals for services and repairs. Refer to Instrumentarium for any questions related to surgical devices repairs.

11- Handling and Storage of Retreated Surgical

a) Handling

Staff members must avoid any contact of surgical devices with aggressive cleaning products as well as acids. Surgical devices get corroded and their function weakened if they come in contact with aggressive products. Devices must not come in contact or exposed to acids or aggressive cleaning products.

All surgical devices have to be manipulated with care while being transported, cleaned, treated, sterilized and stored. This applies particularly for blades, fine tips and for all delicate devices or parts.

b) Storage

Non-sterile surgical devices

Devices can corrode due to unfavourable storage conditions. To avoid corrosion, surgical devices must be stored in a dry and dust protected areas. To avoid any humidity (condensation) formation on surgical devices, high temperature fluctuations must be avoided.

Always make sure that fragile device tips are covered and protected when being unused. Storage area must be organized in such a way that will exclude any possibility of device to damage each other. An appropriate system must be developed so that it will promote adequate disposition and transparency and reduce the risk of injury to the users.

Closed storage systems should be promoted to guarantee a supplementary protection against contamination. Surgical devices must be stored in a dry, clean and open space area. The room temperature should ideally be maintained between 5^{o}C and 40^{o}C.

New and/or returned devices (from repairs) have to be stored in a dry and in ambient temperature cabinet or storage room. Surgical devices must not be stored in any way near chemical products that can release corrosive vapours. This is the reason why surgical devices cannot be stored in the same area of chemical products.

Sterile Surgical Devices

To keep the device sterility until their use, sterile packaging is an elementary condition to preserve devices sterility, an environment with a low level of dust, dry and free from high temperature fluctuations. Keep sterile devices away from sunlight and artificial light. Sterilized surgical devices must be adequately stored in a way to protect their integrity. Ideally, a separate room should be available for sterilized surgical devices. This location should be accessible to authorized employees only (wearing clean and adequate clothing).

12- Guarantee and warranty

All our surgical devices are unconditionally guaranteed against manufacturing defects. Any device having a manufacturing defect will be repaired or replaced with no charges. Our surgical devices are designed and manufactured to meet the highest quality levels. We decline all responsibilities due to a failure of modified surgical devices from the original or for failures caused by misused or by a wrong application of the devices. This is a situation which is considered as nonconforming by the manufacturer and the guarantee and warranty will become void if products are repaired by companies or persons who have not been approved by Instrumentarium.

In case of surgical devices being used on patients with Creutzfeldt-Jakob Disease (CJD) or even if CJD is only suspected or suffering from a VIH infection, devices cannot be reused and must be destroyed. Instrumentarium declines all responsibilities for reusing these devices.

All devices and components planned for a single use must be discarded after their use. Never reuse or re-sterilize disposable medical devices.

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APPENDIX « A »

ENDOSCOPY DEVICES AND COAGULATION CABLES AND DEVICES, MONO-POLAR AND BIPOLAR

The mono-polar and bipolar HF devices are used for invasive surgery and are applied in combination with a HF surgery device. The electric connectors of the HF instruments must be fully inserted into the cable connectors. Only push/pull the flat connector to connect and disconnect the connexion cable.

All devices are supplied in a non-sterile state and must therefore be disinfected and sterilized before each usage. These surgical devices must only be used by qualified and trained personnel.

Inspect carefully all devices to look for potential visual defects. Do not use cables with a fragile or defective insulation.

HF cables connect handles, electrodes and mono-polar and bipolar coagulation devices to HF (High Frequency) instruments.

HF instrument power : Whatever mode is used, be sure to use to lowest power possible of the HF instrument (maximum peak voltage : 250Vp).

Be sure to inspect on a regular basis, before and after each usage, the instrument insulation. Inspect devices for cracks, cuts or notches that can cause an insulation efficiency decrease causing a risk of burn injuries or electrical discharge when in contact with charged electrodes. Instruments with damaged insulation must be immediately replaced otherwise it could imply health risks for patients, users or third parties. Always verify if metal parts are visible under the protective insulation layer.

A damaged endoscope must be immediately removed and sent to the device manufacturer, indicating the nature of the defectiveness.

Endoscopic devices that can be dismounted must be dismounted before machine treatment. Only wash by machine elements that were validated by Instrumentarium. The machine and the loading baskets must guarantee the cleaning effectiveness of internal hollow through adequate adaptors.

Devices containing coagulation residues that cannot be removed with an intensive cleaning (a 3% oxygenated water solution, using an adequate brush, ultrasound) must be put aside since either their functioning or their required hygienic condition is not guaranteed anymore.

Dried residue raises a problem, especially for endoscopic surgical devices since residues are very difficult to eliminate from narrow hollow and can cause a malfunctioning of the joints. This is why these devices have to be reprocessed immediately after their use.

Residues on endoscope and optical fibre cables glass surfaces can be removed with alcohol soaked swabs. Only use wood or plastic stem swabs that will withstand to alcohol to avoid any damage. Metallic components are not appropriate because they can easily scratch glass surfaces. Alcohol is not appropriate to remove blood leftovers. Inspect the endoscope lenses to see if they show traces of scratches or cracks; this could result in an optical leakage and even result in a complete breakdown of the device.

If cleaning is not adequate or difficult by using available methods and processes, it is recommended eliminating coagulated residues on HF instruments with the help of a preliminary treatment with a 3% oxygenated water solution. For high frequency surgical devices (handle and cables), they can be treated the same way as for regular surgical devices.

Check optical fibre cables to detect breaks of luminous fibres by approaching one end (optical – distal side) to a light source and by submitting the other end (optical – light connector side) to a visual inspection. Presence of black stains indicates that some fibres are broken. If 30% of luminous fibres are broken, the light source is not powerful enough and the luminous cable or the whole endoscope has to be repaired.

It is necessary, when immersing an endoscopic instrument in a disinfecting and cleaning solution, to bend, to shake or to move the different parts so that air pockets and bubbles are removed from the channels and cavities and then allow the product to get in contact with the internal surfaces of the instrument.

Refrain from applying maintenance products, either by machine or manually, on optics, joints, current electrical conductors since this could result in major breakdown or malfunctioning of the instrument.

Recommended cleaning and sterilization procedures for endoscopes and for re-treatment of reusable endoscopic mono-polar and bipolar forceps. They all can be treated by the same method used for regular surgical devices.

1- During surgery, devices that are not used must be placed under a damp sterile field or submerged in a sterile water tub to avoid hardening of the different crumb.

2- Immediately after use, gross contamination should be removed from the device with a disposable cloth or paper. Following surgery, submerge all devices that can be dismantled or not and that has a cleaning chanel, in an enzymatic solution for at least a 15 minutes period. This process will ease a rapid and effective reduction of blood, saline and tissues crump (Note: When possible, dismantle the device and open the jaws).

All devices that cannot be dismantled and that possesses a cleaning channel has to be thoroughly rinsed using a cleaning disinfecting solution. Make sure that there is enough penetration of the solution in the device.

Warning: **Never use caustic products, bleaching or saline solution with this type of device.**

3- Meticulously clean devices using a nylon soft brush together with a mild soap solution to remove dried blood stains, traces of fluids and other crumbs. Clean the interior of the tubes using a small brush or a pipe cleaner. Cleaning of the device using ultrasound is not recommended since a premature degradation of the protective coating. Only use appropriate detergents or disinfectants for endoscope machine treatment. Never go beyond 60°C during a program phase.

For endoscopic devices « Inserts », as well as for isolated tubes, always hold them down, in an enzymatic solution (by following carefully the enzyme solution manufacturers recommandations), infuse them with the solution until clear water shows.

The endoscopes must be firmly secured when using machine wash. Make sure that the process allows a perfect and effective cleaning of external surfaces as well as the hollow parts. Rinse water must be treated in an appropriate way to prevent re-contamination of the disinfected endoscope.

4- Surgical device jaws and hinges must be cleaned using a small nylon brush. **Never use metal brushes**. Clean the remaining devices with a damp sponge. Re-infuse, submerge and rinse the surgical devices meticulously using distilled or demineralized water.

5- Between each cleaning stage, inspect for visible stains on the device. Visually inspect the devices to see that they are not broken, cracked or rusted. The stained devices must be put aside for decontamination.

6- Lubricate all moving parts to make sure of proper functioning of the device before sterilization process (hinges, rotation knobs, etc.). Always use a medical grade lubricant that can stand up to high temperature. Never use industrial lubricating oils because they will become sticky when exposed to high temperatures.

7- We can assure good functioning of surgical mini-invasive devices and for rigid endoscopes only by doing a functional control. All dismantled devices must be reassembled. All functions of the device must be submitted to a new control before every endoscopic surgery.

8- If possible, after the controls, the devices should again be dismantled for the sterilization process. Glass surface cleanliness must be controlled (lenses, eyepiece and entrance/exit light sources). Before sterilization, check the device functioning (lever action), button rotation, stop notch system, faucets, pistons, etc.

Note: Always clean the surgical devices as soon as possible following their use. Make sure that the devices were not damaged during surgery. If damage is visible (or obvious), call Instrumentarium or call one of our Sales Representatives for repair servicing.

Ultrasonic Bath

Regarding mini-invasive surgical devices, endoscopic accessories and HF devices, only pieces designated by the manufacturer can be treated using ultrasounds. Optical and optical fibre cables must never be cleaned using an ultrasound bath.

Sterilization Process:

Sterilization process can be carried out using either ethylene oxide or vapour (autoclave). Never use steam sterilization process for devices that are not wrapped. In order to have an extended device shelf life, avoid any contact of the devices among themselves during the sterilization cycle. Never exceed temperatures of 270-275° F (132-135° C). Allow roughly a period of 30 minutes to the sterilized devices so that they dry and cool down.

Storage:

Store the devices away from the sunlight. It is strongly recommended stocking the surgical devices in their original packaging until their use. Responsible staff members must make sure that the device tips are protected so that they cannot be damaged either by other devices nor by the storage method. To avoid any potential deterioration of the device insulating layer, do not clean them by placing these devices in a loose manner with hard or non-isolated products.

Information to respect before using a surgical device

Before surgical device use, check for:

- Potential or possible deterioration of the insulating layer;
- Good grip of the device.

Never use any device when:

- Insulating layer is damaged;
- Tearing points are visible;
- You notice an unusual behaviour of the device. In this situation, replace the device by one coming from Instrumentarium.

Couple bipolar or mono-polar electrodes to the generator only when the generator is turned off. Otherwise, the user or the patient risk to be burned or to receive electric discharge.

Repairs

Refer to Instrumentarium for questions related to surgical devices repairs.

Surgical Devices Guarantees

The guarantee given by Instrumentarium would be automatically cancelled if the devices should be repaired via a third party (person or companies) not approved by Instrumentarium.

Instrumentarium categorically forbid to proceed to modifications to the devices (ex: tips distortion, etc.). Any modification or any derogation to the supplied instructions (this SOP*) would lead to the cancellation of the guarantee given by Instrumentarium.

All our surgical devices are guaranteed unconditionally against manufacturing defects. Any device showing an industrial defect will be repaired or replaced, without any charges. Our surgical devices are designed and manufactured to satisfy the highest quality levels. We decline all responsibilities due to a failure of modified surgical devices from the original or for failures caused by misused or by a wrong application of the devices

*** SOP: Standard Operating Procedure**

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