

Instruments and Maintenance

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Rationale

The role of endoscopic techniques in the diagnosis and treatment of respiratory diseases has been well established for some time. These techniques involve the use of sophisticated instruments, some disposable and sterile, others costly, complex and reusable such as fiberoptic bronchoscopes and most of the accessory instruments.

The aims are to:

- Impede, in patients who undergo endoscopic procedures, the onslaught of infections caused by the transmission of micro-organisms from patient to patient, or due to environmental contamination of instruments.
- Impede the false positivity of the samples caused by the external contamination of the specimens (pseudo-infections).

The specific procedures which permit the reprocessing of the instruments must also guarantee:

- Protection for technicians responsible for the cleaning of the instruments, both because of the risk derived from professional exposure and because of infected material and toxic substances.
- Maximum maintenance of the instruments.

As a rule it must be assumed that all patients undergoing an endoscopic examination should be considered potentially afflicted by infections transmittable by blood and by secretions. It therefore follows that reprocessing adopted procedures must always be the same both for instruments used on patients with infectious diseases and those used on patients considered to be free of infectious diseases [1-5].

Definitions

Classifications of medical instruments

The classification suggested by E.H. Spaulding in 1968 is still considered valid.

The risk of infection is classified on the basis of the level of invasiveness of the techniques in which the instruments are used.

Critical Instruments: are those which come in to contact with normally sterile tissues or with skin or mucosa which are not intact. These instruments must necessarily undergo a sterilisation before being used.

Semi-critical Instruments: are those which come into direct or indirect contact with integral mucous. These must “at least” undergo a high level disinfection.

Non critical instruments: are those which come into contact with intact skin. For this category an “intermediate-low level of disinfection is sufficient [6].

Treatment of material and of medical-surgical devices

Sterilisation: procedure which deactivates all micro-organisms, including bacterial spores; is the final result of physical and/or chemical procedures which through repeatable methodology, both standard and documented, aims to destroy any living micro-organisms whether pathological or non pathological, in vegetative or spore form. Practically a group of objects is considered sterile when there is a reduction equal to 10^6 of the initially present burden (in other words a one in 10^6 chance of contamination following the sterilisation process).

High level disinfection: a procedure which seeks to deactivate all vegetative forms of bacteria and *mycobacteria*, fungi and viruses, but is not always successful in making all bacterial spores inactive.

Intermediate level disinfection: procedure which deactivates *mycobacteria*, vegetative forms of bacteria, some viruses and some fungi.

Low-level disinfection: procedure which deactivates most bacteria, some viruses and some fungi.

In interventional pneumonology, all instruments, except fiberbronchoscopes, and videobronchoscopes, are considered to be critical instruments and must therefore undergo a process of sterilisation [1, 3, 7, 8]. It is however sufficient for endoscopic and flexible instruments to undergo a high level disinfection process; if on the other hand they are to be used in a sterile field they must be sterilized [8].

It is good practice, however, to submit all instruments to the process which offers the highest guarantee of safety i.e. sterilisation [7].

Fiberoptic bronchoscopes and endoscopic accessories are especially difficult instruments to deal with, because of their particular construction and structure. This difficulty creates an easy contamination of flexible instruments by organic material and the subsequent removal can be difficult [1, 7-9].

The most common factors associated with the transmission of micro-organisms are caused by inadequate manual cleaning, the omission of leak-test, the use of inadequate disinfectant, inadequate rinsing and finally of the contamination of the apparatus used.

Techniques for washing, disinfecting and sterilising

To obtain maximum efficacy from the process of sterilisation/disinfection it is necessary to act on a pre-established, constant, standardised and reproducible protocol [7, 8, 10] which is different for each instrument (Table 1).

Table 1. - Different protocols of sterilisation and disinfection for different equipments

Fiberoptic bronchoscopes	Rigid Bronchoscopes	Accessories (forceps)	Rigid Optic - Prisms
Pre-wash			Pre-wash
	Decontamination	Decontamination	Decontamination
Cleaning & Use detergent	Cleaning & Use detergent	Cleaning & Use detergent	Cleaning & Use detergent
Leak-test & inspection			
	Ultra-sound Washing		
Drying	Drying	Drying	Drying
High-level Disinfection			
Or			
Sterilisation	Sterilisation	Sterilisation	Sterilisation
Storage	Storage	Storage	Storage

Cleaning, disinfecting and sterilising stages of flexible endoscopes

Each operative unit must use precise protocols, procedures and operative instructions for reprocessing instruments. Such regulation must be written down and easily available to all operators, and must be approved by the epidemiological services. Each procedure must be performed with maximum care and follow a defined sequence.

Pre-Wash

This must be performed immediately after an endoscopic procedure to remove organic residue that may remain on the distal extremity of the instruments, the internal operative channel or in the valves. It must be performed in the endoscopic suite and consists of the aspiration of abundant cleaning solution through the operative channel of

the fiberoptic bronchoscope, while the distal extremity is cleaned with gauze soaked in cleaning solution. The next step consists in transferring the instrument and accessories to the cleaning room which must be separated from the endoscopic suite.

Cleaning & Deterision

Each operator must wear protective individual clothing according to legislative regulations.

Cleaning

Must be accurate and performed manually by the operator, immediately, on termination of the examination so as to stop any organic residue remaining on the instrument after pre-washing from becoming dry. The efficiency and safety of the subsequent process of disinfection and sterilisation depends on this procedure because it permits a significant destruction of the bacterial burden by removing all organic residue [11, 12].

For each single instrument a different set of brushes must be used [13]. It is advisable to use disposable brushes.

Deterision is performed using a neutral, enzymatic, non-frothy detergent and this solution must be changed after each use.

Visual inspection & leak-test

Leak-test, which includes an accurate visual inspection, has the aim of verifying that the fibroscope has not been damaged during the examination and that it has lost none of

the characteristics of integrity and impermeability.

The procedure must be performed by applying a tester on the valve (ETO-Valve) before immersing the instrument in the detergent liquid for cleaning. The diminution of pressure in the tester and/or the formation of bubbles in the liquid in which it is immersed, permits the identification of loss of permeability of the instrument. The tip of the bronchoscope must be angled pushing on the nearby lever to locate eventual small lesions. Some washing endoscopes machines automatically execute this test: if problems are noted the disinfection procedure is stopped by the machine. A damaged working channel can be a font of contamination and represent a vehicle of infection [13].

Sending a damaged fiberoptic bronchoscope, which has not been disinfected (and is therefore potentially infected) for repair must be effected according to specific procedures indicated by the manufacturer e.g. in appropriate containers or af-

ter sterilisation with Ethylene Oxide Gas which does not damage the injured fiberoptic bronchoscope.

Drying

All material must be well-dried after cleaning and before proceeding to disinfection to avoid diluting the disinfectant. The same applies if it necessary to perform a high-level automatic disinfection or sterilisation with gas plasma of peroxide and hydrogen at low temperatures. The instrument must be taken from the container in such a way as to allow the liquid to drain away, rinsed with the water externally and in the channels to eliminate all enzymatic detergent present and dried with a small towel. The channels and the valves are dried by blowing compressed air at low pressure into them.

Disinfection

HIGH-LEVEL DISINFECTION [1, 4, 8, 9, 12, 15-17]

High-level disinfection is the minimal requirement for semi-critical instruments and so is indicated only in the case of the fiberoptic bronchoscope. It is preferable to use disinfectant and automatic washing endoscopes machines or this can be done manually by immersing the instrument in a container filled with a disinfectant solution which is suitable for the necessary immersion period. The best disinfectants are usually solutions with a glutaraldehyde base or peracetic acid or orthophthalaldehyde.

For manual disinfection these minimum immersion times are recommended:

- GLUTARALDEHYDE 2%
 - 30 Mins. At room Temperature (20°C)
- PERACETIC ACID
 - 30 Mins. At room Temperature (20°C)
- ORTHOPHTHALALDEHYDE
 - 30 Mins. At room Temperature (20°C)

These times are considered sufficient to eliminate all vegetative bacterial forms, *mycobacteria* [18] and all viruses including HIV. Peracetic acid and orthophthalaldehyde are less irritating and have a faster action than glutaraldehyde.

Sterilization

ETHYLENE OXIDE GAS

Ethylene oxide (ETO) gas is used with autoclaves, the use in Italy is regulated by resolution 56/83 of the Ministry of Health and is limited to operators in possession of a license issued by the Regional committee (RD n. 147/27 Art. 31). The efficacy of ETO gas is influenced by the temperature, humidity and exposition time. It is possible to sterilise material which is sensitive to heat or hu-

midity. The most important limits of this method are co-related to the toxicity of the products used in the process (the instruments require a long period, (a minimum of 8 hours to a week, of degasification) due to the possibility of toxic residue remaining on the instruments and the duration of sterilisation (from 2 to 5 hours).

HYDROGEN PEROXIDE GAS PLASMA

This is a recently introduced method of sterilisation of instruments sensitive to the heat which functions through the atomisation of Hydrogen Peroxide activated by radio frequency (Microwaves). It is a process which takes place inside the autoclave (ASP® Sterrad® Johnson & Johnson Company, USA) in the same way as an autoclave for steam sterilisation [15, 19].

The material to be sterilised must be put into particular cellulose free packages. At the end of the cycle, usually 75 minutes, non toxic water and oxygen are formed. Application can be made on all thermolabile objects which must be clean, decontaminated and totally dry.

STERILISATION SYSTEM WITH PERACETIC ACID STERIS SYSTEMI®

This is a system which uses a mix buffered with peracetic acid at temperatures comprised between 50°C to 55°C. The sterilisation is controlled by a processor and certified by a print-out chemical and biological indicators. The concentrated disinfectant solution (buffered peracetic acid at 35%) together with an anticorrosive composition are contained in a mono-dose capsule which is inserted in the sterilisation machine and perforated by the operator before each cycle of sterilisation. Peracetic acid is automatically diluted at 0.2% with water filtered by the machine. The system, using appropriate irrigators, allows the solution to flow into the internal channels of the instrument. The standard cycle, which includes rinsing with sterile water, lasts about 30 minutes. At the end of the sterilisation cycle it is necessary to remove the processed instruments and accessories using an aseptic technique. It is not possible to treat more than one endoscopic instrument at one time with this system, and sterilisation is only guaranteed at that moment, so the instruments must be used immediately [19, 20].

Storage

Fiberoptic bronchoscopes and videobronchoscopes must be kept in a dry place, in appropriate cupboards and with the flexible part in vertical position with ETO-cap (ventilation-key) inserted and with valves removed, away from high temperatures and direct sunlight. Some authors [1, 7, 8, 11] advise the instillation of isopropyl alcohol inside the operative channels of flexible instruments.

Cleaning, disinfection and sterilization of rigid instruments and accessories

Sterilisation

HOT STEAM AUTOCLAVE SATURATED UNDER PRESSURE

This method is preferable for all those instruments which are not altered by heat and humidity. It works through the action of hot steam saturated under pressure at a temperature of 121°C or 134°C.

Sterilisation with an autoclave is quick, effective, easily usable and toxic free and is the first choice in all situations in which it can possibly be used [5].

STERILISATION WITH PERACETIC ACID

It is possible to sterilise instruments for rigid bronchoscopy with peracetic acid through the Steris Sistem1® [19]. A tray with handles and a cover is used and the instruments are placed inside and they can be transported to a sterile field. As with flexible instruments sterility is only guaranteed at the moment and so does not last.

Storage

Rigid instruments and accessories sterilised in an autoclave or with ethylene gas or with hydrogen peroxide gas plasma are conserved in appropriate containers or sealed in envelopes with expiry date and occurred process indicator clearly visible. Envelopes and containers must be disposed in such a way as to maintain integrity for all the period of validity. Some products, such as silicon tracheo-bronchial stents, have a limited and defined number of cycles of sterilisation.

Recommendations

- **Before the instruments is re-used, each of them must be adequately re-processed in accordance with the indications of the manufacturers and compatible with materials and method chosen (Grade A).**
- **Cleaning, disinfection and sterilisation of instruments must be effected after each examination by expert personnel trained in the appropriate institution (Grade C).**
- **In the sub-divisions of the areas there must be a well-defined separation of “clean areas” and “infected areas” so as to keep used instruments separate from reprocessed ones in order to avoid risk of contamination (Grade C).**
- **Fiberoptic bronchoscope are considered semicritical instruments and as such must be submitted to at least one**

high-level disinfection; in particular situation of use in contact with sterile tissues or sterile cavities they must necessarily be sterilized (Grade A).

- **Reusable accessories which penetrate the mucosa (i.e. biopsy forceps) must be submitted to sterilisation preferably in an autoclave (Grade A).**
 - **The use of disposable non-sterile critical accessories must be preceded by a sterilisation process (Grade A).**
 - **All instruments for rigid bronchoscopy or thoracoscopy must be considered critical and must be sterilised as such (Grade A).**
 - **To obtain the best results from a sterilisation/disinfection process it is necessary to follow an established, reproducible and standardised protocol (Grade C).**
 - **The various stages must be followed correctly according to a precise and specific sequence for each type of instruments (Grade C).**
 - **During cleaning of instruments personnel must wear protective clothing, gloves, masks and overalls, so called individual protective devices (Grade A).**
 - **Flexible instruments must be inspected after use and submitted to leak-test (Grade C).**
 - **All instruments must be cleaned immediately after use, an appropriate detergent, to remove all contaminated organic matter. An accurate manual cleaning with detergent is the most important stage for the success of the entire process. Before proceeding to disinfection or sterilisation all materials must be well-cleaned and deterged (Grade A).**
 - **For manual disinfection the following minimum times of immersion are recommended (Grade A).**
 - **GLUTARALDEHYDE 2% 30 Mins. At room Temperature (20°C);**
 - **PERACETIC ACID 30 Mins. At room Temperature (20°C);**
 - **ORTHOPHTHALALDEHYDE 30 Mins. At room Temperature (20°C).**
- Minimum immersion time as established by the manufacturer must always be controlled and respected.**
- **The use of automatic washing endoscopes machines is advisable to avoid risk of inhalation of vaporized disinfectant by personnel (Grade B).**

- **Removable parts and accessories of bronchoscopes must be replaced in such a way as to maintain their sterility for all period of validity (Grade A).**
- **Some materials such as silicon tracheobronchial stents have a limited and defined number of cycles for sterilisation (Grade A).**

Appendix 1

Elements of good practice

- All precautions of infection control must be applied to all patients who must be considered potential carriers of infectious diseases (Italian Dlgs 28.09.90).
- All instruments must correspond to rules of safety established by CEE directive 93/42.
- When possible it is a good practice point to proceed to the sterilization of flexible instruments.
- Many of the accessories used in interventional pneumonology are disposable and already sterile; for these it is necessary to follow the manufacturers recommendations, to control the sterilization and expiry date (these must be reported on the package) and to adopt an adequate procedure to maintain their sterility both in storage and during their use.
- Disposable materials must not be reused and must be disposed of in the appropriate manner.
- All personnel involved in endoscopic procedures must be informed and educated about rules of prevention and control of hospital infections.

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