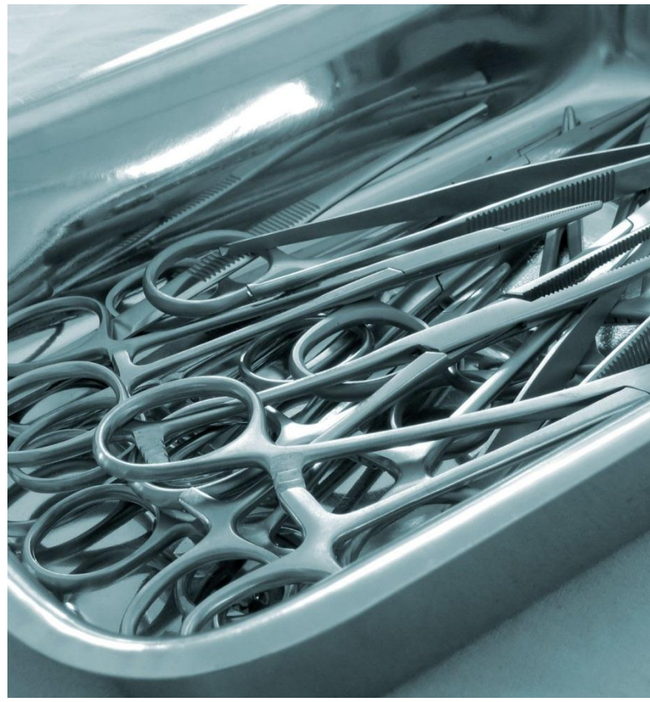
Instrument Cleaning and Re-processing in the Veterinary Sector



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REPROZYME MANUAL

REPRODIS HLD4I

TRUSTED INFECTION CONTROL

TRUSTED INFECTION CONTROL

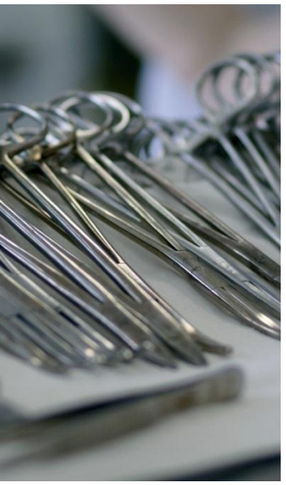
Instrument Cleaning and Re-processing

1. Decontamination

The reprocessing of a medical or veterinary instrument for re-use implies that the instrument should be thoroughly decontaminated. Decontamination is the process by which microorganisms are removed or destroyed in order to render the instrument safe for re-use. Decontamination includes the sub-processes of pre-cleaning, disinfection and/or sterilisation.

2. Cleaning

Detailed cleaning is the first stage of decontamination. Cleaning of an instrument usually involves exposure to detergents or an enzymatic solution. Instruments should be completely immersed when brushed manually to avoid splashes (and aerosol movement) of contaminated material. Closed machine cleaning will avoid contaminant dispersion into the environment. Note, however, that machine cleaning will seldom remove stubborn, dried on material, fully and manual pre-cleaning with a suitable brush is important before introduction of the instrument into the re-processing machine.



Instruments

Instruments that have been re-processed and are safe and ready for re-use.

Following the manual pre-cleaning process, the instruments should either be manually soaked for the specified time in REPRO**ZYME MANUAL** Enzymatic Instrument and Equipment Cleaner or submitted to machine cleaning using REPRO**DIS HLD4I** Instrument Disinfectant.

No matter what style of subsequent disinfection or sterilisation is adopted for an instrument, cleaning is still the first and most vital part of the decontamination process. Inadequate cleaning may render useless the subsequent stage of disinfection or sterilisation.

3. Instrument Disinfection and Sterilisation Processes

Disinfection is a chemical or physical process that destroys pathogens such that an instrument or other item is safe for re-use. Many instruments are suitable for steam or other heat (autoclave) disinfection/sterilisation. Heat sensitive instruments, typically endoscopes, are not suitable. Flexible endoscopes in particular must be chemically disinfected to at least High Level (see below). Manual soaking of endoscopes is suitable but increasingly automatic machine disinfection or sterilisation with suitable chemicals (which include an enzymatic process) is becoming available.

Chemical disinfectants: A chemical disinfectant should be capable of destroying most pathogens but may not be able to cope with bacterial spores. There is a broad spectrum of chemical disinfectants that have different antimicrobial activities. Most of them do not necessarily kill all microorganisms or spores that are present on an inanimate object but instead reduce the number of microorganisms to a level that is not harmful to health. Disinfectants are used on inanimate objects only and not on living tissue.

Official Certification: All instrument disinfectants sold in EU must be certified independently under code 93/42/EEC of the Medical Devices Directive and bear the certification reference assigned to the inspecting agent.

4. Categories of Disinfectant

The broad category of chemical disinfection may be subdivided into high-level, intermediate- level and low-level disinfection according to the anti-microbial activity of the disinfectant. Categories are established by the performance qualities of disinfectants when measured against internationally established microbiological protocols such as EN tests. These protocols will specify the exact criteria, including levels of soilage and exposure time for the disinfectant tests.

Low level disinfectant (LLD):
LLD is an agent that destroys low levels of vegetative bacteria (except tubercle bacilli) and lipid viruses and some fungi, but not bacterial spores. LLD would be expected to destroy at least 99.9% of a microorganism colony. The reduction rates in colonies of these microorganisms would be unlikely to afford adequate protection in high-risk environments such as kennels, catteries and veterinary surgeries where the transit of animals is frequent. LLD are generally regarded as simple “household disinfectants”.

Intermediate-level disinfectant (ILD):
ILD is an agent that destroys all vegetative bacteria, including certain levels of tubercle bacilli, lipid enveloped and some non lipid enveloped viruses, and fungus spores, but not bacterial spores. Subject to the exposure time and concentration of the ILD there would be an expectation that 99.99% of colonies of qualifying microorganisms would be destroyed.

High-level disinfectant (HLD):
A high-level disinfectant is a chemical or physical agent or process that is capable of killing bacterial spores and all tubercle bacilli when used in sufficient concentration, temperature, and under strictly specified conditions (The relevant instrument specific EN approved microbiological test should provide evidence of HLD effectiveness against named microorganisms and notably, bacterial spores). Any HLD is also expected to be effective against lower orders of microorganisms such as vegetative bacteria, fungi and viruses.

Some of the chemicals used as HLDs can also be used as chemical sterilants, which can kill bacterial spores in high numbers. REPRO**CHEM HLD4I** High Level Disinfectant is also classed as a sterilant because of its performance.

Sterilant:
An agent that destroys all viable forms of microbial life to achieve sterilisation. Sterilisation methods remove or destroy all forms of microbial life including bacterial spores by either physical or chemical processes. It is recommended that any instrument or equipment classified as critical that comes in contact with the blood stream or with sub dermal tissues be cleaned and sterilised in between each use. Sterilisation is accomplished principally by steam under pressure, by dry heat, and by chemical sterilants. The choice of the method for sterilisation depends on a number of factors including the type of material that the object to be sterilised is made of, the number and type of microorganisms involved, the classification of the item, and availability of methods.

5. Categories of Microorganisms

Gram Positive Bacteria/Gram Negative Bacteria:
Gram-positive and Gram- negative refers to how a bacterium reacts to a Gram stain. If it takes the initial stain, it will be purple and be considered Gram-positive. If it doesn’t take the initial stain, it will be pink and Gram-negative. The difference is the outer casing of the bacterium. A Gram-positive bacterium will have a thick layer of peptidoglycan (a sugar-protein shell) that the stain can penetrate. A Gram-negative bacterium has an outer membrane covering a thin layer of peptidoglycan on the outside.The outer membrane prevents the initial stain from penetrating. (Examples of Gram-negative bacteria
– *Escherichia coli, Salmonella typhii* (typhoid), and *Bordetella bronchiseptica* (kennel cough). Examples of Gram-positive bacteria – *Staphylococcus aureus, Streptococcus pneumonia, Clostridium tetanii.*

Mycobacteria:
Any of various slender, rod-shaped, aerobic bacteria of the genus *Mycobacterium*, which includes the bacteria that cause tuberculosis and leprosy. (Greek prefix myco denotes a relationship to fungi).

Fungi and Yeasts:
Any of numerous eukaryotic (cells of the higher organisms containing a true nuclei bounded by a nuclear membrane) organisms, which lack chlorophyll and vascular tissue and range in form from a single cell to a body mass of branched filamentous hyphae that often produce specialized fruiting bodies. Examples of fungi and yeasts – *Candida albicans* (thrush), *Trichophyton mentagrophytes* (ringworm), *Aspergillus* (Pulmonary infection).

Lipid virus (also referred to as enveloped viruses):
A virus whose core is surrounded by a coat of lipoprotein (a fatty membrane) whose disruption renders the virus non-infectious. Viruses included in this structural category are generally easily inactivated by many types of disinfectants including low level disinfectants. Examples are HIV, herpes, HCV, HBV and myxoviruses (influenza).

STERILANT:

An agent that destroys all viable forms of microbial life to achieve sterilisation. Sterilisation methods remove or destroy all forms of microbial life including bacterial spores by either physical or chemical processes.

Decreasing order of resistance of microorganisms to disinfection and sterilisation and the level of disinfection or sterilisation

TYPES OF ORGANISM LEVEL:	
Organism	**Recommended Disinfection Level**
Prions: (e.g., Creutzfeldt-Jakob Disease)	(134-137C Sodium Hydroxide soap for one hour- 18 min pre-vacuum steam sterilization)
Bacterial spores: (*Bacillus anthracis*)	**STERILISATION**
Other spore forming bacteria: (*Clostridium tetani, Clostridium difficile, Bacillus subtilis / cereus*)	**HLD**
Mycobacterium tuberculosis:	**HLD**
Non-lipid or small viruses: (e.g. *polio, coxsackie, Parvo*)	**HLD**
Fungi: (e.g. *Aspergillus, Trichophyton, Candida*)	**HLD**
Bacteria: *(S. aureus, P. aeruginosa)*	**ILD**
Lipid viruses: (HIV, HBV, HCV, herpes, myxoviruses)	**ILD**

Flexible Endoscope

These items are called critical items because of the high risk of infection if such an item is contaminated with any microorganism before penetrating the tissue.

Non lipid virus:
A virus whose nucleic acid core is not surrounded by a lipid envelope. These viruses are generally more resistant to inactivation by disinfectants. These are also referred to as hydrophilic viruses (coxsackie, enteroviruses, etc.)

Protozoa:
Any of a subkingdom (Protozoa) of microscopic animals made up of a single cell or a group of more or less identical cells and living in water or as parasites, including ciliates, flagellates, rhizopods, and sporozoans. *Cryptosporidium* and *Giardia* are protozoan organisms, which cause the parasitic infection. *Cryptosporidium* exists in either the free-swimming (trophozoite) form or the oocyst (dormant) form. *Cryptosporidium parvum* is now recognized as a human pathogen which can cause severe diarrhoeal illness.

6. Categories of Medical/ Veterinary/Dental Instruments

Risks of infection from equipment
The risks of infection from equipment may be classified into three categories. Placing instruments and equipment into one of the following categories can be helpful in choosing the proper level of disinfection or sterilisation needed in order to protect the patients and the health care personnel.

Low risk (non-critical items)
Non-critical items are items that come into contact with normal and intact skin such as stethoscopes or with the inanimate environment (e.g. walls, floors, ceilings, furniture, sinks, etc). Cleaning with a detergent and drying is usually adequate. Stethoscopes are usually cleaned and in rare cases they should be disinfected if used on infectious or highly susceptible patients.

Intermediate risk (semi-critical items)
Semi-critical items are items that do not penetrate the skin or enter sterile areas of the body but are in close contact with mucous membranes or with non-intact skin. Cleaning followed by HLD is usually adequate. Examples include respiratory equipment, flexible endoscopes, laryngoscopes, specula, endotracheal tubes, thermometers, and other similar instruments.

Hierarchy of decontamination procedures for instruments and devices

DISPOSABLE	NON-CRITICAL	SEMI-CRITICAL	CRITICAL
Dispose of item	*Clean*	*Clean*	*Clean*
	Dry and Store	*High Level Disinfect or Sterilise*	*Sterilise*
		Dry and Store	*Dry and Store*

High risk (critical items)
High risk items are items that penetrate sterile tissues such as body cavities and the vascular system. These items are called critical items because of the high risk of infection if such an item is contaminated with any microorganism before penetrating the tissue. Cleaning followed by sterilisation is required. High-level disinfection may sometimes be appropriate if sterilisation is not possible (e.g. flexible endoscopes). Examples of high-risk items include surgical instruments, intra-uterine devices, vascular catheters and implants, etc.

Single use items
These items may be used in critical, semi-critical, or noncritical areas; however, they are single use items that are prepackaged with the appropriate level of disinfection or sterilisation and are disposed of after a single use.

7. Cleaning of Instruments – Generally

- Wear heavy-duty rubber gloves, a plastic apron, eye protection, and mask during cleaning.
- Soak the instruments in normal tap water containing a detergent.
- Scrub instruments and other items vigorously to completely remove all foreign material using a soft brush, detergent, and water. Hold items under the surface of the water while scrubbing and cleaning to avoid splashing. Disassemble instruments and other items with multiple parts, and be sure to brush in the grooves, teeth and joints of items where organic material can collect and stick.
- Rinse items thoroughly with clean water to remove all detergent. Any detergent left on the items can reduce the effectiveness of further processing.
- Inspect items to confirm that they are clean.
- Allow items to air dry or dry them with a clean towel if chemical disinfection is going to be used. This is to avoid diluting the chemical solutions used after cleaning. Items that will be high-level disinfected by boiling or steaming do not need to be dried.

Immersible flexible endoscopes - suggested cleaning and disinfection procedure

Following the use of the endoscope it is important that the following is performed immediately based on use with a medical aspirator/suction unit or channel irrigators:

- Withdraw endoscope from the patient and remove gross contamination with damp tissue.
- Press blue (air and water) button for approximately 10 seconds ensuring there is a good water flow. If it is to be some time before the endoscope will be cleaned, empty the water channel using the procedure shown herein.
- Flush the biopsy system by pressing the red button whilst the suction system is running. Repeat with air to empty the channel. Alternatively a large syringe and tubing can be used with the suction connector situated on the light guide plug.
- Turn off light source and remove plug from mains. Endoscope and bottle can be disconnected if required.

WARNING:
LIGHT-GUIDE PROBE MAY BE VERY HOT AND COULD CAUSE BURNS

Ensure good water flow

Checking of endoscope

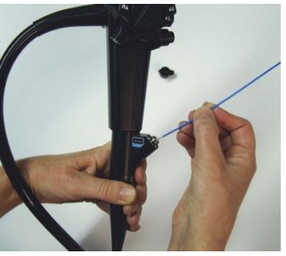
Cleaning and disinfection

This procedure is based on REPRO**ZYME MANUAL** Enzymatic Instrument and Equipment Cleaner and REPRO**DIS HLD4I** High Level Instrument Disinfectant. Read instructions and safety information before use. For a list of suppliers contact Medimark Scientific.

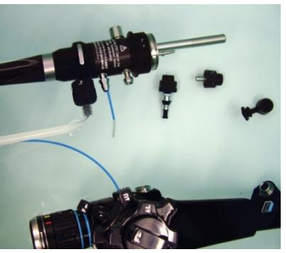
Inspecting

LEAK-TEST ENDOSCOPE ACCORDING TO INSTRUCTIONS SUPPLIED WITH YOUR ENDOSCOPE.
CONTACT MANUFACTURER / SUPPLIER IF INSTRUMENT FAILS TEST.

Examine the insertion tube and particularly the bending section rubber for signs of damage and areas where water may leak into the endoscope. Check the seals either end of the rubber and ensure the cover glasses are not cracked or missing. If in doubt do not proceed with cleaning and contact VES for assistance.



Insertion of cleaning brush through biopsy port



Brushing of suction channel

Cleaning

WARNING: Wear Gloves when handling Chemical concentrates and any other chemical disinfectant. Protect eyes. Wash contact areas thoroughly in water. If ingested give copious water. Seek medical advice.

Fill a large bowl with cold water plus REPRO**ZYME MANUAL** Enzymatic Instrument and Equipment Cleaner. Dilute at 1 in 50 (e.g. 20ml REPRO**ZYME** in each 980ml of clean water). Always discard after use.

Place the endoscope insertion tube into the bowl. The whole instrument can be immersed if required. Wash using kitchen roll/hand towel. Ensure there is no material left around the air/ water nozzle.

Pull off the rubber biopsy port cap and wash. Clean biopsy port entrance thoroughly with cotton bud. Wash any instruments at this time.

Brushing

Ensure that the flexible tip of the endoscope is straight. Insert the cleaning brush (if two are supplied, use narrow one marked “working channel”) through the biopsy port on the hand piece and pass down the biopsy channel. Gently pass the brush down an inch at a time without kinking. If you feel an obstruction, stop pushing and contact manufacturer / supplier for assistance. When the end of the brush emerges from the tip of the endoscope wash in the bowl and pull brush back through channel. Repeat the brushing procedure until you are sure the channel is clean.

Pull off the red suction button. Holding the hand-piece upright, two holes will be visible - one going forward, the other going to the right towards the light-guide cable. Pass the cleaning brush through the hole going forwards.

Remove the suction unit tubing from the light-guide plug. Pass the cleaning brush (if two are supplied use the wide one marked “suction channel”) through the hole going to the right. The brush should emerge from the suction connector on the light-guide plug this time. You may encounter slight resistance as the brush comes out of the plug.

Flushing

Re-connect the biopsy port cap and red button. Connect the suction system to the suction port and turn on. Alternatively a large syringe and tubing can be used. Press the red (suction) button and aspirate enzyme solution from the bowl through the biopsy channel until solution starts to fill the aspirator bottle (or syringe).

Rinsing detergent

Fill a second bowl with clean tap water. Place the insertion tube in the bowl and rinse using paper hand towel.

Press the red button as before to aspirate clean water through the biopsy channel.

Disinfecting

Fill a third bowl with cold water and REPRO**DIS HLD4I** High Level Instrument Disinfectant diluted 1 in 20 (e.g. 50ml REPRODIS in 950ml of clean water).

Place the insertion tube in the bowl, ensuring it is completely submerged. Place any instruments and brushes in bowl.

Press the red button to aspirate the REPRO**DIS HLD4I** solution through the biopsy channel and into the aspirator bottle. Do not allow air to enter the tip of the channel. Turn off aspirator and when suction level is zero, release the red button. The biopsy port cap can be removed and placed in the bowl and open biopsy port can be filled with solution.

Leave to soak for the required contact time but no longer:

- 10 minutes – Bacterial, Fungicidal, Virucidal, Sporicidal,Tuberculocidal and Immunocompromised protection

Rinsing

Fill a fourth bowl with demineralised water. Place endoscope in bowl and rinse well.

Replace biopsy cap if necessary. Press the red button to aspirate demineralised water through the biopsy channel.

Drying

Remove the insertion tube from the bowl and dry using fresh paper hand towel.

Press the red button to aspirate air through the biopsy channel until you are sure it is dry.

Emptying air/water channel

Plug in the light source again and turn on. Re-connect endoscope and bottle if required. Press the blue button to ensure there is still a good jet from the air/water channel.

Pull out the water bottle tube from the light-guide plug. Hook up water bottle tubing on its holder to stop water syphoning out.

Press finger or thumb firmly over the end of the water bottle port on the endoscope light-guide plug.

Press the blue button until the jet of water from the nozzle stops. Hold up the endoscope so that the insertion tube hangs down without touching the floor. Depress the blue piston for a further 10 seconds until no more water is coming from the nozzle. Cover the blue piston and pass air through the channel to aid drying.

Storing

Using a soft tissue, dry the end of the insertion tube.

Check the image is still sharp. Contact manufacturer / supplier if you are unsure in case some damage has occurred.

The endoscope is now ready for storage. Always store hanging vertically. Turn off the light source, empty the water bottle and reprocess the water bottle and the aspirator.

This protocol does not guarantee sterility of the endoscope. Higher levels of disinfection can be achieved with the following procedures:

- Use of an all channel irrigator to disinfect the internal channel system
- Final rinse in 70% ethyl alcohol to aid drying

Details of these procedures can be found in the original manual for your instrument. .

Aspirate REPROCHEM HLD4I through the biopsy channel

Aspirate air through the biopsy channel

Scope in storage hanging vertically