



Instruction Manual

GB - STERILISATION INSTRUCTIONS HAND INSTRUMENTS MANUFACTURER: GDC

1 WARNINGS Instruments are not sterile upon receipt and must be sterilised before use in accordance with the following instructions. Instruments can be damaged by alkaline and acidic detergents. Always use a pH(7) neutral detergent or solution. Do not exceed 134°C. Remove all packaging prior to cleaning and sterilisation.

Contaminated instruments should be handled with gloves and eye protection should be used.

2 Limitations Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use. NEVER clean colour-etched probes or black composite instruments in ultrasonic baths.

INSTRUCTIONS

3 Point of use: Remove all excess soil with disposable cloth paper wipe.

4 Containment and Transportation: Protect delicate or fine instruments from damage. Instruments should be reprocessed as soon as is reasonably practical following use. Instruments left standing wet may stain or corrode.

5 Preparation for cleaning: No specific requirements. Disassembly not required

I. Rinsing- Immediately after surgery, rinse instruments under warm (not hot) water. It may be helpful to use a nylon toothbrush to rinse the lock boxes and joints of the instrument. Be sure to remove all blood, body fluids, and tissue.

II. Cleaning- If you do not clean your instruments immediately after rinsing, instruments should be submerged in a solution of water and neutral pH (7) detergent. They should never be placed in saline solution, as it may cause corrosion and eventually irreversible damage to the instrument.

6. Ultrasonic Cleaning For micro and delicate instruments, use manual cleaning (step C). Instruments should be processed in a cleaner for the full recommended cycle time – usually 5 to 10 minutes.

Place instruments in open position into the ultrasonic cleaner. Make sure that "Sharp" (scissors, knives osteotomes, etc.) blades do not touch other instruments.

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All Instruments have to be fully submerged. Do not place dissimilar metals (stainless, copper, chrome plated, etc.) in the same cleaning cycle. Change solution freq

7. Automatic Washer Sterilizers - Follow manufacturers recommendations but make sure instruments are lubricated after last rinse cycle and before sterilization cycle.

8. Manual Cleaning - Most instrument manufacturers recommend ultrasonic cleaning as the best and most effective way to clean surgical instruments, particularly those with hinges, locks and other moving parts. If ultrasonic cleaning is not available observe the following steps.

- I. Use stiff plastic cleaning brushes (nylon, etc.) Do not use steel wool or wire brushes except specially recommended stainless steel wire brushes for instruments such as bone files, or on stained areas in knurled handles.
- II. Use only neutral PH(7) detergents because if not rinsed off properly, low PH detergents will cause breakdown of stainless protective surface and black staining. High PH detergent will cause surface deposit of brown stain, which will also interfere with smooth operation of the instrument.
- III. Brush delicate instruments carefully and, if possible, handle them totally separate from general instruments.
- IV. Make sure all instrument surfaces are visibly clean and free from stains and tissue. This is a good time to inspect each instrument for proper function and condition.

Check and make sure that : Scissors blades glide smoothly all the way (they must not be loose when in closed position). Test scissors by cutting into thin gauze. Three quarters of the length of blade should cut all the way to the scissor tips, and not hang up. Forceps (pickups) have properly aligned tips. Hemostats and Needle Holders do not show light between the jaws, lock and unlock easily, joints are not too loose. Check Needle Holders for wear on jaw surfaces. Suction tubes are clean inside. Retractors function properly. Cutting instruments and knives have sharp, undamaged blades.

- V. After scrubbing, rinse instruments thoroughly under running water. While rinsing, open and close Scissors, Hemostats, Needle Holders and other hinged instruments to make sure the hinge areas

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are rinsed out, as well as the outside of the instruments.

7. AFTER CLEANING - If instruments are to be stored, let them air dry and store them in a clean and dry environment.

8. AUTOCLAVING - If instruments are to be reused or autoclaved:

Maintenance:

- A. Lubricate all instruments which have any "metal to metal" action such as scissors, hemostats, needle holders, self-retaining retractors, etc. Recommend surgical lubricants such as instrument milk are best. Do not use WD- 40, oil or other industrial lubricants.
- B. Put instruments up for autoclaving either individually or in sets.

9 Inspection and Function Testing: Inspection and Function Testing: Visually inspect to ensure all contamination has been removed. Check for distortion, damage and wear. Cutting edges should be free of defects. Discard damaged, worn or corroded instruments. Ensure that detachable tips are secure

10 Drying: Dry using paper towelling or dry heat not exceeding 134°C.

11 Packaging for Sterilisation: Instruments may be loaded into dedicated instrument trays or general purpose sterilisation trays. Ensure that cutting edges are protected.

A. Individual Instruments

Disposable paper or plastic pouches are ideal. Make sure you use a wide enough pouch (4" or wider) for instruments with ratchet locks such as needle holders and hemostats so the instrument can be sterilized in an open (unlocked) position.

B. Instrument Sets

Unlock all instruments and sterilize them in an open position. Place heavy instruments on bottom of set (when two layers are required). Never lock an instrument during autoclaving. It will not be sterile as steam cannot reach the metal to metal surfaces. The instrument will develop cracks in hinge areas because of heat expansion during the autoclave cycle. Do not overload the autoclave chamber as pockets may form that do not permit steam penetration. Place towel on bottom of pan to absorb excess moisture during autoclaving. This will reduce the chances of getting "Wet packs". Make sure the towels used in sterilization of instruments have no detergent

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residue and are neutral – PH(7) if immersed in water. This can be a real problem as laundries frequently use inexpensive but high PH(9-13) detergents and do not properly rinse out or neutralize those detergents in the final wash/rinse cycle. Also, sometimes bleaches such as Clorox are added and are not neutralized.

12 Sterilization Parameters such as time, pressure and temperature vary according to the type of sterilizer, materials being sterilized and individual models within sterilizer brands. The first step in determining the settings for the sterilizer is to refer to the manufacturer's instructions. Sterilizers are medical devices, requiring clearance by the Food and Drug Administration before manufacturers may offer them for sale. The FDA requires rigorous testing to ensure an adequate margin of safety in each cycle type described in the instructions. Failing to follow the instructions of the manufacturer is ill advised, since it may result in inadequate sterilization of the instruments or devices in the sterilizer. It is never appropriate to use a household device, such as a toaster oven, for sterilization of dental instruments, devices, or equipment.

A. Steam autoclave

Steam autoclaves are the most commonly used type of heat sterilizer in dental practices. Two types of processes employ steam under pressure. The difference between the two is the manner in which the machine evacuates the air from the sterilization chamber and then introduces the steam.

Gravity displacement sterilizers rely on the forces of gravity to force air out of the chamber through air escape vents. The steam entering the chamber from the water reservoir displaces the air as it leaves the chamber. The combination of pressurization of the chamber, steam and a high temperature for a prolonged period has the ability to kill virtually all microorganisms. This is the most common type of autoclave found in dental offices. A typical cycle for wrapped instruments includes heat-up and pressurization time, followed by a 15-to-30-minute cycle during which sterilization is taking place (121°C at 15 psi). The sterilization cycle time decreases as the temperature is increased. It is important to use cycle times and temperatures described in the owner's manual, and never to interrupt the sterilization cycle to remove or add items, or for any other reason. Interruption of the cycle will result in instruments that are not sterile and therefore not safe for use on patients. After the sterilization cycle, the sterilizer

must depressurize and the packs remain in the sterilizer for drying. The drying phase may take anywhere from 20-45 minutes. The unit must only be opened after completion of the drying cycle. Upon removal from the sterilizer, sterile packs must be stored in a clean, dry area. Packs that become wet, torn, contaminated, or otherwise compromised require resterilization.

B. Prevacuum autoclaves (also called Class B or Type B sterilizers)

Use a variety of technologies to remove air from the chamber before the steam enters, thus creating a vacuum. Most use a pulse vacuum to ensure elimination of air from the chamber. This is generally a more efficient means of pressurizing the chamber; therefore, the operator may notice some minor time saving in the start-up of the prevacuum sterilizers. Most prevacuum sterilizers use a temperature of 132°C-135°C for 3-10 minutes to achieve sterilization. This higher temperature may be unacceptable for some items, such as Teflon-coated instruments. Total time for pressurization, sterilization, venting and drying is generally considerably shorter than that for gravity sterilizers - about 45 minutes.

C. Dry-heat sterilization (convection and static air)

Dry-heat sterilization employs high temperatures for extended periods to achieve sterilization of instruments. The method of heat circulation in dry-heat sterilizers is usually convection, which helps to ensure that the heat circulates throughout the sterilization chamber during the process. Mechanical convection is more effective; the sterilizer contains a fan or blower that continually circulates the heated air to maintain a uniform temperature throughout the chamber. Most commercially available dry-heat sterilizers on the market today are of this type.

The higher temperature of a dry-heat sterilizer means that paper will scorch and plastic will melt. Specialized packaging material is available for dry-heat sterilizers. The manufacturer's instructions should be checked for compatibility of instruments, devices, and materials with the unit.

D. Unsaturated chemical vapor sterilization

Unsaturated chemical vapor sterilization relies upon the use of a proprietary chemical that contains formaldehyde, alcohol and other inert ingredients, instead of water, to produce a vapor to promote the sterilization. Use of this proprietary chemical also results in the vapor having less

humidity and therefore being less corrosive to sensitive instruments than if water were used

13. CAUTION – At the end of the autoclave cycle – before the drying cycle – unlock autoclave door and open it more than a crack (about 3/4"). Then run dry cycle for the period recommended by the autoclave manufacturer. If the autoclave door is opened fully before the drying cycle, cold room air will rush into the chamber, causing condensation on the instruments. This will result in water stains on instruments and also cause wet packs. If you have any unusual staining on your instruments during sterilization, contact your local instrument representative

14. COLD STERILIZATION - Most cold sterilization solutions render instruments sterile only after a 10 hour immersion. This prolonged chemical action can be more detrimental to the surgical instruments than the usual 20 minute autoclave cycle. If the instruments need to be "disinfected" only, cold sterilization is okay as disinfection will place in only 10 minutes. But keep in mind the difference between:

STERILE – an absolute term (no living organism survives) and

DISINFECTED – basically clean.

Always use the proper sterilization/cleaning technique to render the instrument in required condition for use. For instruments with Tungsten Carbide inserts (Needle Holders, Scissors, Tissue Forceps), we do not recommend use of solutions containing Benzyl Ammonium Chloride which will destroy the Tungsten Carbide Inserts

15 Manufacturer contact: See brochure for telephone and address of local representative or telephone GDC Tel: +91 1882244566

These instructions have been validated by the manufacturer as being capable of preparing a device for re-use. It remains the responsibility of the reprocessor to ensure that the reprocessing has actually achieved the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be properly evaluated for effectiveness and potential adverse effects.