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Instruments Reprocessing

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Foreword: The UNI EN 1639 norm defines the hand-operated dental instrument as “Dental instrument designed to function in response to the operator’s manual movement without any power source”. In this short writing we will indicate in principle the general procedures to be followed for a correct handling of the stainless steel, reusable dental hand instruments with relation to the use of the autoclave.

The instruments treatment has not only the scope to obtain a correct sterilization of the instruments and to maintain his sterile condition up to the moment of its use, but also to grant the mechanical characteristics in accordance to his use.

The sterilization process is actually a number of by processes, and each of them if not properly performed, may prejudice the achievement and maintenance of the sterile condition of the instruments.

Some of the processes indicated below are common to almost all sterilization systems; in any case they mainly refer to the most commonly used and widely known: sterilization in autoclave via saturated steam.

1. PREPARATION OF STERILIZATION AREA: Before beginning treatment of the instrument, it is necessary to designate a sterilization area, that is a space dedicated to all those operations necessary for sterilization, separated from other areas of practice, where it is possible to freely and safely keep whatever necessary to perform the pre-sterilization process.

It is not necessary to have a separate room but it is recommendable to identify and use a specific area purposely dedicated to that scope. The area dedicated to decontamination operations before disinfection and cleaning (disinfection immediately after use – washing, etc.) must be separate from the area dedicated to the subsequent processes.

The working area must have continuous flat and easily washable surfaces.

After reprocessing, the surfaces must be washed and disinfected, as it should be any surface of the dental practice which may become in contact with the infection agents.

When moving from the working point, specially when it is far from the sterilization place, the same operations indicated at “Preparation for disinfection and cleaning” must be followed with procedures and equipment for personal protection suitable to grant the operator safety.

As an example the instruments must be fixed using perforated instrument trays with fixing frames to avoid possible damaging of instruments.

Container for transportation must be anti shock material and have safety locking to avoid accidentals opening and/or loss of liquids. The container must clearly show the sign “biological risk” of contamination, indicating the content and departure and arrival addresses and must be handled exclusively by purposely trained personal. Even the container opening and instruments handling as well as following treatment operations must be exclusively done by trained operators.

After use, the container must be washed and disinfected with the same procedure and care of the instrumentation.

2. DECONTAMINATION: In order to carry out proper sterilization, it is of the utmost importance to know the initial microbial charge of the instrument to be sterilized.

Generally speaking a microbial charge equal or less then 10^2 CFU/100 cm² (CFU = units forming colonies) is compatible with the most used sterilization process like saturated steam chemical, vapour ethylene oxide, etc.

Unfortunately the full knowledge of the procedure for evaluation of the micro-organisms on the product (ref. UNI EN 1174-1, -2 and -3), the necessary experience and the structure required to detect the bio-burden, very seldomly are compatible with the activity of the dental practice. For this reason it becomes of the utmost importance considering that the sterilization process virtually begins at the moment of decontamination.

In fact, only the strict respect of the operations preceding the sterilization can grant a low initial microbial charge and therefore the possibility of killing all micro-organisms present. It remains however necessary to validate and therefore verify, the sterilization process.

On the other hand even a “bio-burden declaration” supplied by the manufacturer would be useless. In fact, even if the packaging are designed to keep an acceptable cleaning level, the re-usable instruments are introduced to the market with a not sealed packaging and are afterward repeatedly handled during various movements between manufacturer, dealers and final user and therefore subject to various variations of the ambient conditions.

The decontamination is actually an operation including four different processes: preparation for disinfection and cleaning, cleaning, disinfection and drying.

Preparation for disinfection and cleaning: Immediately after use on the patient, reusable instruments must be disinfected by placing them in solutions known to be effective also against HIV to eliminate the risk of infection for the dental operator, the “drying” of work residues on the instruments must be avoided in order not to compromise the effectiveness of the disinfection and sterilization and to avoid corrosion.

Many dental products used on patients have corrosive effects and it is better to remove them from the instrument as quickly as possible.

Instruments that can be disassembled, or that are articulated, must be opened so that all their parts are in contact with the disinfectant.

To avoid the fixing of proteins, the pre-disinfection products must be a combination of disinfectant and detergent; the instruments must never be placed in a physiological solution of sodium chloride because the contact, especially for long period, may cause corrosion and rust.

In any case avoid long periods of disinfection (a night, a weekend...). Disinfectant/detergents solutions must be renewed daily because the prolonged use of these solutions can lead to the risk of corrosion due to the presence of dirty or an increase concentration caused by the evaporation of water.

Furthermore disinfection capacity could decrease significantly, to the point of being ineffective.

For the sake of the dental operator’s protection against infections,



it must be remembered that immersion of the instruments immediately after use on the patient has only a limited effect so that, as already stated, the operator should wear appropriate protective devices as a precautionary measure.

Cleaning: After removing the instruments from the disinfectant/detergents solutions, they must be rinsed abundantly in running water, removing any remaining residue. Metal brushes or sponges which would damage the instruments shall NOT be used. Preferably nylon brushes shall be utilized. For the cleaning of satin finished instruments (including trays, etc.) it is necessary to clean with movements following the sense of the finishing. In any case avoid abrasive detergents and excessive manual pressure. At the same time take care not to hit or drop the instruments; the use of enzymatic, non corrosive, detergents is recommended. To avoid water stains, demineralized water should be used for final rinse, and the instrument dried immediately afterwards. Ultrasonic cleaning is particularly effective on difficult to remove residue; particular care must be taken, however, to avoid instruments touching each other, to overload the trays and most of all to avoid placing particularly delicate instruments, such as mouth mirrors, which would surely be damaged.

The cleaning process can also be conducted via "washing machine", in this case foam-free disinfectant/detergents must be used; there is also a product (called lubricating milk) that acts as both lubricant and antioxidant.

Thermal disinfectors can be of the thermal or thermo-chemical type; the first being the more preferable choice. Washing cycles must include: pre-wash, without detergents or disinfectants; cleaning (temperatures between 40 and 60°C); first wash, with solutions; second wash with water only; thermal disinfection (temperatures between 80 and 90°C) with final rinse, preferably with demineralized water and then drying.

To avoid rendering the treatment ineffective the machine must be loaded correctly, that is not overloaded with instruments and without using supports other than those supplied with the machine. The shape of the instruments must be taken into consideration during loading and they must not be forced, the articulated ones must be opened, while delicate instruments (ex. Probes, curettes, etc.) must be fastened in appropriate supports to avoid dents.

Statistically speaking, the most used process today is manual washing. However, automatic treatment of the instrument represents an indispensable premise for the quality of the results in terms of safety.

Even regulations establish that washing and disinfection of instruments be conducted according to procedures that are validated and documented: only automatic treatment, in specific machines, can guarantee that all the requirements are met. The same recommendations are made by influential institutes such as the Robert Kock Institute of Berlin; the use of the mechanical rather than manual treatment of the instruments is required.

The dedicated machineries are washing, disinfecting and drying the instruments in a closed circuit and this is the only way to satisfy the fundamental requirements that the treatment of the instruments must reflect from a dental point of view, that is safety, convenience and documentation.

Disinfection and drying: After drying, the instruments must be immersed in a disinfecting solution (obviously different from the one used for immersion immediately after use on the patient) that needs to be refreshed constantly, and then, after waiting for the appropriate time to obtain disinfection, they must be washed in demineralized, decontaminated water, and dried immediately.

Drying must be performed accurately using where possible heat or uncontaminated drying materials.

Compressed air can be used when filtered, air for drying if it is filtered. Drying accuracy is of the utmost importance in order not to compromise the correct and indispensable contact of the instrument with the sterilizing solution.

As regards to disinfecting solutions in this case the recommendations indicated under "Decontamination" also apply.

3. INSPECTION, MAINTENANCE, AND TESTS: All the instruments must be accurately inspected and use immediately taken out of views even if there is only the doubt that their original characteristics have been altered and that they must be altered. They must result as being perfectly clean from a macroscopic point of view.

The joints of articulated instruments (needle holders, extraction tweezers, haemostatic tweezers, scissors, etc., etc.) must be lubricated with sterilizable products (e.g., paraffin oil prescribed by "European Pharmacopeia" and lubricating milk); the use of these products prevents the corrosion caused by friction in the joints.

The lubricants must be biologically compatible and appropriate for steaming; it is preferable not to use substances containing silicone because they could compromise the smooth operation of the instruments and the sterilizing action of the steam.

Tests must then be conducted to verify correct operation, and these can be more or less simple such as testing the proper opening and closing of the needle holder.

4. PACKAGING: The purpose of packaging is to keep the instrument sterile until it is used, that is until the package is opened.

The material must allow the correct removal of air and the contact of the instrument with the sterilizing agent. There are different types of packaging material and undoubtedly the most common is the paper with laminated polyester/polypropylene film variety, with inseparable layers, in the form of envelopes, self-sealing envelopes and rolls.

Other types can be "medical grade" paper sheets, Tyvek-polyester combinations (envelopes and rolls only for ETO and Gas Plasma), TNT or even containers (in steel, aluminium, and plastic materials in particular) equipped with gasket and filters (in paper and cloth) but the most important of all is that the packaging is bacteria- and humidity- tight, resistant to the various packaging, sterilization and storing operations and thus being safe, practical and economical.

With the exception of "passing" autoclaves, that is autoclaves used in operating rooms where there is a direct connection from the sub-sterilization to the operating room, whereby flash sterilization occurs (134°C for 4 minutes), the instruments must be sealed, packaged or in any case placed inside appropriate containers to remain sterile.

Flash sterilization must be limited to emergency situations and in any case, if it is deemed convenient, for sterilizing instruments to be used exclusively on one patient during the same operation. As already stated the most used packaging material is envelopes and rolls made of paper + plastic material and for this reason it is important that they are not packed with too many instruments, in order to leave sufficient space between them to allow for the correct passage of the sterilizing agent.

It is surely useful that a double seal be placed on envelopes and rolls for major security.

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However it must be highlighted that double packaging (two envelopes) does not, as assumed in the past, prolong sterilization and therefore storing times.

5. STERILIZATION: As already indicated, the most used form of sterilization today is the saturated steam autoclave and therefore the procedures that follow will focus on this.

This sterilization system is based on the relation between temperature, pressure and volume.

The aim of the temperature is to sterilize, the saturated steam distributes the heat onto the instrument evenly (due to thermal exchange) and the pressure increases the latent heat of water evaporation.

When the steam comes into contact with the instrument, which is at lower temperature, it transmits its heat to and forms condensation on it, simultaneously increasing its temperature.

The condensation with its transmission of temperature, is lethal for microorganisms.

Thermal exchange continues progressively until the temperatures of the instrument and of the steam are balanced, and at that point condensation stops.

Other factors, for example the extraction of air from the chamber, are not technically a part of the steam sterilization process, but they do help to reduce the risk of shadows during sterilization caused by air pockets, and favour the sterilization of hollow instruments.

Sterilization cycles generally recommended for autoclaves (example related to a saturated steam autoclave with fractioned vacuum) have a temperature of 134°C, with working time of 7 minutes and a pressure of 2.1 bars and 121°C, with working time of 15 minutes and a pressure of 1.1 bars (Medical Device Agency – 1997); exposure times refer to standard operating conditions, i.e. with standard working temperature and pressure.

The particular importance of the drying cycle of the packaged instruments must be underlined; if this is not carried out correctly it could compromise both the integrity of the instrument by causing corrosion, and conservation of sterilization because water, or small parts of it, could lead to the formation of bacteria, which would cause the risk for the doctor to eventually transmit an infection to the patient.

Sterilization process controls: It is necessary to conduct these in order to verify that the sterilization process is correct.

The correct functioning of the sterilization process can be verified by checking physical, chemical and biological parameters.

Physical parameters can be checked on the autoclave itself, with the indicators of pressure, temperature, time, etc.; it is preferable that the autoclave undergo periodical calibration in a qualified laboratory.

Chemical parameters can be checked via “process indicators” (e.g., the ink indicators placed on envelopes and rolls) that simply react to the exposure to temperature without providing any indication on whether the sterilization is more or less completed or the success of the sterilization cycle and practically only serve to distinguish between sterilized and non-sterilized envelopes; then there are the “process integrators”, normally used for the sterilization of implant parts, that indicate for example even if the steam has passed inside the package; finally there are the “multi-parameter indicators”, also used rather infrequently, like the preceding integrators, which are made to react with different parameters critical to the process.

The control of the biological values is the most used to evaluate the process efficiency.

These tests include in addition to the time/temperature factors, other factors influencing the biological deactivation; in this case standardized samples of microorganisms in the form of spores are used (in accordance with UNI EN 866 - series regulations from part -1 to part -8).

The UNI EN 556-1:2002 regulations indicate that the proof that a medical device is sterile is provided by initial validation of the sterilization process and following revalidation showing the acceptability of the process and the data obtained during checks and systematic monitoring that show that the confirmed process has actually been conducted.

Regulation also indicates that successful sterilization can be predicted by the level of microbiological charge on the products, by the resistance of the microorganisms containing this microbiological charge and by the extent of the treatment imposed during sterilization.

6. STORING: So as not to compromise the antimicrobial barrier represented by the packaging, it must be stored in areas free of dust, humidity or contaminated air and in any case before storing the devices it is necessary to check for accidental openings (holes, tears, etc.) in the package, to be done before using the instrument on the patient.

The instrument must therefore be stored in a designated area, a closed and clean environment (for example a cupboard that can be cleaned easily and that is reserved for storing instruments) with a temperature between 18 and 22° and with relative humidity between 35 and 50°.

The improper conservation of the instruments not only compromises its sterile condition, but the instrument itself, because the condensation caused by thermal changes, external agents and other factors could lead to the corrosion of the instrument.

The conservation time of the sterile condition is certainly influenced by the handling and storing system of the packaging, but the most influencing factor is the material used for packaging.

As a general example we can notice that:

- Paper-polyester/polypropylene may keep instruments sterile for up to 60 days in a closed cupboard;
- Tyvek/polyester combination, up to 2 years, as stated by manufacturer;
- Medical Grade paper and TNT, 25/30 days;
- Container with gasket and filters, 25/30 days.

As a precaution it is preferable not to stock the instruments for more than 30 days; however it is better to reduce this time as much as possible for economic reasons.

If an instrument is used only every 30 or even 60 days, this would mean that not only a higher number instruments in stock but also a lower utilization with consequence longer recovery time of the investment.

It has finally to be noted that at the moment of sterilizing the instruments the dentist become in a certain way a “manufacturer of medical devices supplied in sterile condition” and must therefore issue procedures and perform validation tests also with relation to the storing system of the instruments, and he must therefore proof that his conservation system (procedures, materials, equipment and ambient) can actually maintain the instrument sterile up to his use.

7. PLASTIC INSTRUMENTS NOTES: The instruments partially or completely fabricated with plastic material are sensible to temperature and therefore need to be cold sterilized or using low temperature system (ethylene oxide gas plasma ozone etc.).



Plastic material have particular characteristics from chemical and mechanical point of view; we are now examining two of this "limit" material.

PTFE: PTFE (poly tetra fluorine ethylene) is better known with commercial names like Teflon, Fluon, Algoflon, Hostafon, etc. were some stabilizers and fluidifiers are added to obtain better characteristics like the coating with non-sticking material on the kitchen pans; PTFE can resists temperature over 200° and it is in addition very resistant to chemical agents.

Instruments, or part of them, manufactured with this material can therefore be used with the most powerful thermal disinfectors having disinfection cycles up to 95°C and drying cycle which can reach 115°C as well as the heaviest autoclave cycles which should however not exceed 136°C.

Polycarbonate: Polycarbonates is often used in dental equipment like some type of impression trays or even as a button for a colour coding system of the stainless steel impression trays. This type of material shall be carefully handled because it is resisting up to a maximum 140°C. It is therefore important to have a very precise control of the autoclave temperature and most of all avoid using solvents or other chemical aggressive solution for cleaning and disinfection.

In any case which ever is the product used it is necessary to carefully rinse any part of the surface and coupling with other materials.

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