RECONDITIONING
REUSE OF MEDICAL DEVICES

THEL OF REBUILDING PROCESS OF MEDICAL DEVICES FOR REUSE

CLASSIFICATION OF PRESIDI REUSABLE
The classification proposed by Spaulding (1977), still considered valid internationally, divided all medical devices, and any tool used for servicing, for diagnostic or therapeutic purposes, into three categories depending on the extent of the risk of infection that their use entails. Specifically, the devices are classified as:

- **critics**
- **semicritical**
- **noncritical**

CRITICAL DEVICE

Surgically invasive device which penetrates the skin or mucosa, or in contact with blood and blood products or sterile drugs
a) A critical device: Critical device that has no cavities or so points accessible.
b) disPositive critical B: Critical device that has cavities or awkward spots.

Kingquired requested STERILITY

Dourdevice semi-critical

device in contact with the mucosa integrates or with non-intact skin
a) A critical device: Critical device that has no cavities or so accessibili.b points)
Critical Device B: critical device that has cavities or so points accessible.

Kingquired requested STERILITY DESIRABLE -Disinfection HIGH LEVEL

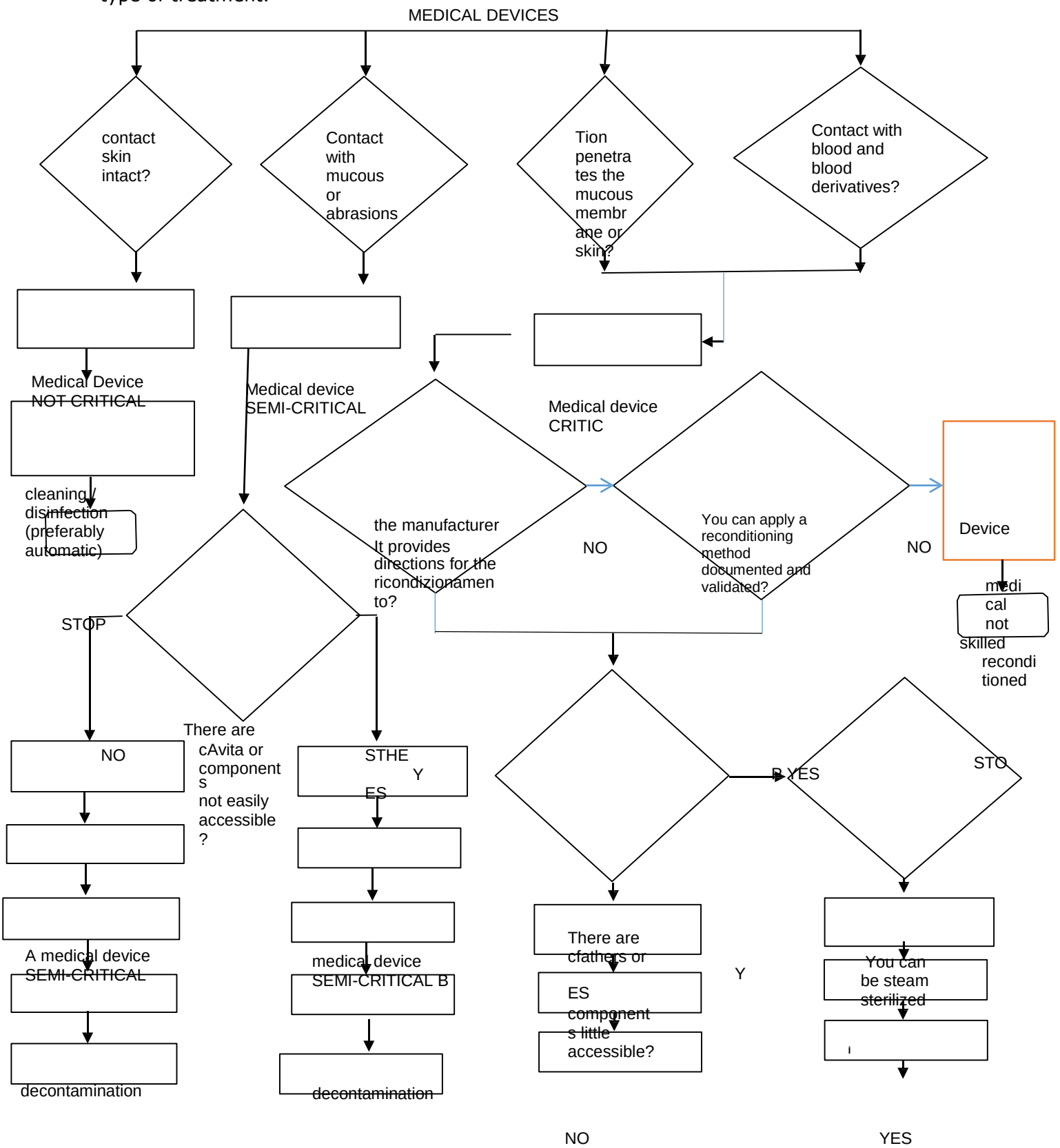
OFNOT CRITICAL device
device in contact with the skin intact
Requirement CLEANING

ANALYOU RISK CLINICAL

THEthe DM should be classified through appropriate analysis of clinical risk with the goal of identifying the class (articles critical, semi-critical or non-critical).
It is therefore possible that the same medical device can belong to multiple classes risk for the fact that it can be used in different applications.

DIAGRAMMA FLOW

THEthe flow chart is a guide for the classification of DM BTLock and the identification of the type of treatment.



theashi
ng

washing

A medical device
SEMI-CRITICAL

medical device
SEMI-CRITICAL B

disinfection

disinfection

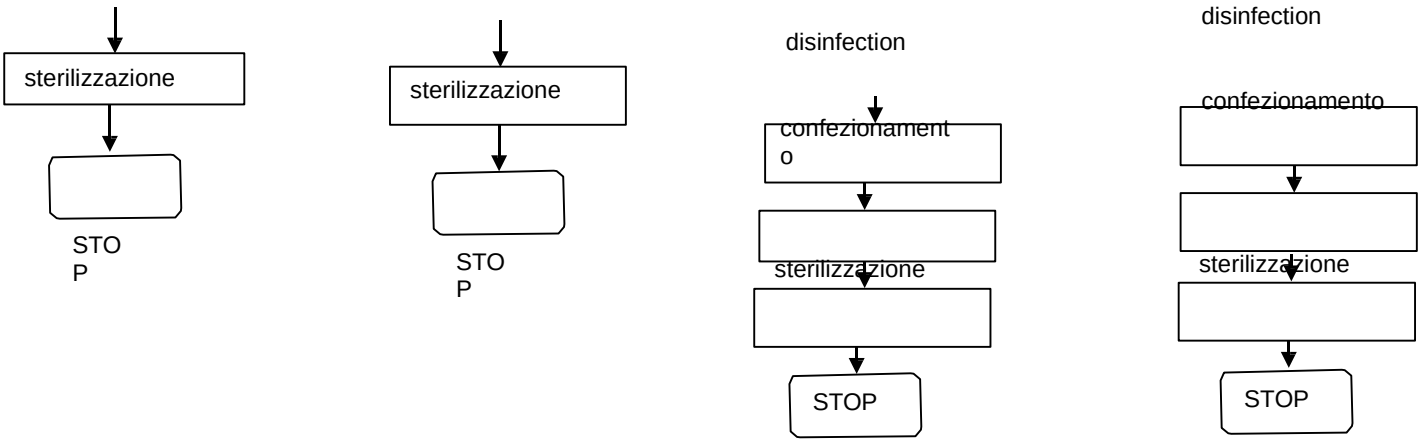
decontamination

decontamination

washing

confezionament
o

confezionament
o



THEL OF REBUILDING PROCESS DMR

The reconditioning process of reusable medical devices are expected to be complied with all the treatment steps to ensure medical devices having microbial load conventionally set to N = 1012 cfu with a SAL not exceeding $10^{-}6$).

The reconditioning of the DMR process involves several stages:

1. preparation of the material,
2. collection,
3. decontaminazione,
4. washing,
5. dISINFECTING,
6. drying,
7. control and maintenance,
8. packaging,
9. sterilizzazione

1. PREPARATION OF MATERIAL

TheobOBJECTIVE of this phase is to obtain a low microbial load garrison garantendo safety conditions for the operator; This is done by:

- us ing DPI for the operator who is in contact with the material to be treated,
- reduction of microbial load on the DM (decontamination, cleaning),
- total removal of dirt on the surfaces of the DM (cleaning and rinsing).

BARRIER DEVICES

TYPE	FUNCTION	WHEN TO USE IT	TREATMENT AFTER USE
COPRICAPO TNT	Its function is to contain the cApelli dall'aerosol protecting the environment. It prevents contamination of the environment containing the possible fall	At every stage of the process	Mosingle-use
GLOVES NITRILE DISPOSABLE	Protection	In all activities involving theNo biological or chemical risk	Mosingle-use
GLOVES NITRIL EN388 EN374 E374	Reduce the incidence of contaminazione of hands, but do not prevent injuries from needles or sharp.	anythe manual washing of DMR	Dpersonalize. Detergerand externally after orach use and store dry. Remove when they present signs deterioration, or squamature thesions.
SURGICAL MASK to be used together with occProtective Hiali.	mucosal protection nose, mouth splashing or aerosolization of liquid contaminants	In all activities where there is the possibility of contamination with thereliquids or aerosols. (eg washing, rinsing, drying with compressed air ...)	Mosingle-use
SHIELD / VISOR cloptical axis 1 to be used in combination with surgical mask	Eye protection, mucous membranes of the nose and mouth splashing or aerosolization of liquid contaminants.	In all activities where there is the possibility of contamination with thereliquids or aerosols. (eg washing, rinsing, drying with compressed air ...)	Forcustomization of the device. Reusable. Detergerand after the use as technical details
CFRIENDS IN DISPOSABLE TNT	Skin Protection	At all stages of	Mosingle-use.

	and divided	ricondizionamento that we consider "dirty" or during which it may cause splashes, aerosilizzazione and in all activities involving biological risk	
APRONS PLASTIC	Skin protection and uniform worn over the disposable shirts TNT	anythe manual washing of DMR	Mosingle-use.

2. RAccolta

Nell'ambulatorio dentistry collecting material starts from the studio where the operator for assistance to the chair, dopor wearing the expected DPI, it collects all the equipment used for the surgery on the patient.

THEoperating NDICATIONS

Theophealth eratore who performed the surgery on the patient:

- eliminates needles and sharp using the special container placed as possible to the work station,
- He removes the burs from the paddles and operates as indicated by the procedure "cleansing and sterilization of dental burs and files"
- It performs a 20-second flussing to each handpiece and then detaches it from the cord and puts it on the conveyor tray,
- It collects and puts all of the tools used on the tray and transfers them in the reconditioning.

3. DECONTAMINATION

Phase of the reconditioning process necessary to guarantee a more secure by manipulation of DM recondition din the part of operators.
It is performed by immersing the instruments in a disinfectant solution for effective action against the HIV virus.
THEchoice of decontamination to be used should take into account the compatibility of the active substance with the materials of medical devices to be reconditioned and must be documented and performed by competent personnel.

Note 1: MD September 28, 1990 provides that "Reusable principals must, after use, be immediately immersed in a chemical disinfectant to acknowledge the effect on HIV before dismantling or cleaning, to be carried out as a preparation for sterilization."
THEto decontamination it can be carried out with different methods than immersion in a chemical disinfectant provided to demonstrate and ensure the same results.

Note 2: Follow the instructions provided by the medical device manufacturer to be treated

THEOperating NDICATIONS:

- wear PPE,
- use dedicated containers, provided with an internal grid, lid and having suitable dimensions to the load, for BTLock tools can be used the related box.
- set up the decontamination solution respecting the contact time indicated by the disinfectant manufacturer:

decontamination:

identification of known or foreseeable hazards and actions taken to prevent the causes of the danger (risk scale is dUNI / TR 11408: 2011).

Pericolo	Cause	dejection	Rational
DANNEGGIAMENTO OF DM	**solutions scavengers not adequate**	Use scavengers compatible thethe DM Use the decontaminant in the manner specified by the manufacturer of the same	Under Decree of 28.09.1990 "Regulations for protection from infection Professional HIV in health and care facilities public and private, "the decontaminant must possess recognized efficacy on HIV. The decontaminant must be free of protein-fixing effect (eg. Aldehyde-based products have fixing effect). The effectiveness of action of the scavenger is only ensured under conditions of use recommended by the manufacturer regarding concentration, temperature and exposure time. Avoid long time between decontamination and subsequent treatment intervals since the prolonged use of the same solution may result in corrosion problems due to dirt and / or for increasing the concentration result of evaporation of the decontamination solution
	incorrect mode of use of the decontaminant	Use the decontaminant according to manner specified by the manufacturer of the same with particular attention to concentration and contact time	
N DM	**Decontaminante**	Follow the manufacturer's instructions of	THE'Prolonged use of the same solution can

	exhausted	decontaminante Replacing the decontaminant Ogni volta is present visibly dirty and cleaning of the tank	comportare reduction action disinfectant for the inactivation of the active ingredient or for the presence of contaminants (dirt)
	Lack of contact on all surfaces	Follow the instructions of the manufacturer of the DM (eg dismantling)	Check outwhich are all external and internal surfaces of the instruments to treat,and including the lights and cavities are accessible to the decontaminant. If possible dealer to remove it according to the manufacturer, (seals, opening the taps etc ..) Arrange the instruments in an
	incorrect mode of use of the decontaminant	Use the decontaminant according to procedures indicated by the manufacturer with particular attention to concentrations, temperatures and	
	Contaminazione of the solution decontaminant	Replace when decontaminating necessary.	THE'Prolonged use of the decontamination can determine the'Inactivation of the active ingredient and the consequent proliferation

operator controls

Vheck:
- data of the decontaminant deadline: every time you prepare the solution,
- data and time the sol preparation. decontaminant: every time you dip the DM,
- pRESENCE of organic residues in the sol. decontaminant: every time you dip the DM,
- functionality of the containers used for the decontamination: by visual examination.

4. WASHINGOR

The washing of a DM is an essential prerequisite for an effective action of the successive phases of disinfection and / or sterilization. The presence of organic material on DM prevents contact disinfectant or sterilizing agent, be it chemical or physical, on the surfaces, and it therefore reduces the activity and effectiveness. Only clean DM ensure
proper disinfection and / or sterilization.
THE'of DM on washing effectiveness it is hampered by the presence of organic residues fixed on the surfaces, therefore, the washing can be preceded by a pre-treatment (eg immersion in decontamination solution, pre-automatic washing, ultrasonic bath etc ..) aimed at avoiding this drawback.
It 'important to note that in the pre-wash, temperatures higher than 45 ° C may cause coagulation of the proteins and their fixing on the surfaces and thus impair the effectiveness of the washing. The washing must be concluded with a rinsing step which has the purpose of reducing chemical residues on the DM Treaty.
The washing process preceding the disinfection and can be manual or automatic.

manual washing

THE'effectiveness of hand washing is influenced by several uncontrollable variables that depend on the operator and / or dto accessories for washing, therefore, it is to be preferred, where possible, the automatic washing.
One does not clean the instrument, even when subjected to sterilization, it does not guarantee the attainment of sterility. All new DM, before being subjected to sterilization, should be washed to remove any residue from the processing of oily substances specified.
Questa washing mode is to be applied at the time when the information from the DM data sheet exclude the automatic washing, in the event that this is not a washing machine and automatic disinfection or in case of failure of the same.

Manual cleaning:

identification and reduction of known or foreseeable hazards (scale of the risks taken from UNI / TR 11408: 2011)

Pericolo	Cause	dejection	Rational
DM NOT CLEAN	**washing accessories inadequate**	Check outare the integrity and adequacy of the accessories used	glThe accessories must allow full treatment of the instrument. assuring also the access to the interior of lumens and / or cavities.
	Complessità strutturale the DM	Follow the manufacturer's instructions of the DM about disassembly mode and positioning. Pay special attention to any cavity, threads, etc. Valutare determine the most effective cleaning (eg ultrasonic + mechanical removal with washer-disinfectors fitted with appropriate accessories)	THE manufacturer must provide adequate instrucOperating ni to indicate the most appropriate procedures to be implemented during the reconditioning process of DM (UNI EN ISO 17664)
	Detergenti Ofdisinfectants not adjusted	Use the cleaner in the manner thendicate from the same manufacturer	The detergent / disinfectant must be without effect fisting one protein (eg. Aldehyde-based products have effettor staring). Products based on proteolytic enzymes break down the protein substance facilitates cleaning, in

			particularly of the tools with complex structures and difficult to reach areas (eg. cannulated or tubular structures, etc.). The detergents and disinfectants are effective when used according to the instructions of the
	inadequate washing procedure	Gnsure disassembly of all the components of an assembled DM. Attuare properly to the manufacturer's instructions the detergent-sanitizer concerning concentration, temperature and exposure time.	The inner and outer surfaces of DM assembled, cannulated, concave, should be achieved by effective mechanical action to remove any dirt. Failure to respect the instructions of the detergent / disinfectant manufacturer may compromise the final outcome of the wash.
DANNEGIAMENTO OF DM	**water quality Drying tdared and insufficient**	Use demineralized drinking water at the stage of final rinse and proceed instant-dry by appropriate means (eg forced air, cloths that do not release fibers, etc.	The stagnation of water on the DM can determine the fixing of calcareous residuals or dthe rust and possible microbial growth
	Accessories lavagio thenadeguati	Use accessories such as abrasiveness not to damage the DM area	Evitare metal brushes and brushes abrasive to avoid the creation of lesions on the DM area

operator controls

Vheck:
- data detergent deadline: every time you prepare the solution,
- data and time of preparation of the cleaning solution: each washing of DM,
- pRESENCE of organic residues in the cleaning solution to wash the DM,
- practical accessories for washing: by visual examination.

WASH BASIN IN ULTRASOUND

THEin cleansing in ultrasonic bath:
- It occurs after the formation of small gas bubbles generated by the sonic waves which, in turn, produce of areas of vacuum able to remove dirt from the surfaces that is deposited on the bottom of the tank,
- Non is an alternative to automatic washing but is preparatory to it, in that it allows the separation of the organic residues dto the surfaces of the DM (internal and external) are difficult to reach.

The DM subjected to washing in the ultrasonic bath must subsequently be washed to remove the residue detached previously. According to what established by the procedure "cleansing and sterilization of burs and files in dentistry" treatment in an ultrasonic cleaner, it must be followed by a washing in automatic washer disinfector.

THEOperating NDICATIONS:

- wear PPE,
- set up the solution with Colloidal Range 3%,
- perform the cycle Degas for 15 min., to be repeated at each set-up of the solution, to dissolve the course gases contained in the liquid,
- bitrre DMs in the tank basket, taking care to open hinged instruments placing them so that they are completely immersed in the solution and that there are no gray areas,
- cover the device with its lid,
- start the 15 minute wash cycle,
- finished the washing cycle ultrasonic extract the basket from the tank and place it under a running cold water jet,
- transfer the material to a washing drum and activate a washing in Washer Disinfectors,
- at the end of the work shift to clean the inside of the ultrasonic bath, dry thoroughly and put the lid.

WASH BASIN IN ULTRASOUND:

identification and reduction of known or foreseeable hazards (scale of the risks taken from UNI / TR 11408: 2011).

Pericolo	Cause	dejection	Rational
DM NOT CLEAN	**Ultrasonic energy thensufficiente**	Check outperiodic function equipment (temperature / time / power) Check the choice of parameters	Attuare preventive maintenance on equipment to ultrasound
	exhausted bath	Replacing the detergent / disinfectant when necessary and cleaning of the tank	Follow the manufacturer's instructions. The effectiveness of the
	recontamination post trattcatkin	Check outare hygiene stations and surfaces jobor adopt appropriate behaviors	Sanitization of environments and surfaces
	Flushing thenadeguata	Evitare gray areas between the DM immersed in solution and open articulated instruments	NoNo overload the bathtub adultrasuoni THE'ultrasound treatment must be guaranteed on all

			DM surfaces (disassembly, opening ....)
DANNEGIAMENT O OF DM	**Late drying and thensufficiente**	Use appropriate means (eg forced air, pannthe that do not release fibers, etc.	Improper drying can be determined on the DM presence of corrosion, rust, and the increase of the charge Microbial on its surfaces
	the DM incompatibilities a cleanser - disinfectant or the washing method	Check outare compatibility of the DMPresenza instrucOperating ni manufacturer	Use the cleaning agent in concentrations and with manner specified by the manufacturer of the same

operator controls

Vheck:
- data of the disinfectant / cleaning agent deadline: every time you prepare the solution,
- data and time of preparation of the solution for each wash of DM,
- pRESENCE of organic residues in the solution: each washing of DM. withcontrol of the product entering the DMR in ultrasound

WASHING MACHINE WITH WASHING AND DISINFECTION (Washer Disinfector)

The automatic washing using equipment with standardized programs, repeatable and therefore convalidabili.
The washing used must have a control system automatic equipment of all the stages of the process, with alarms and system blocks in the event of non-conformity or failure.
Should preferably have a system for recording the characteristic parameters of the individual phases of the process to demonstrate compliance to the validated cycle, ie, dosing of chemicals used, time and temperature.
THEa series of standards EN ISO 15883 establishes the performance requirements and safety of washing and disinfection equipment.
One type of wash program may consist of the following stages:
- prelavaggio with cold water (max 40 ° c),
- washing with detergent and hot water,
- neuneutralization (if necessary),
- rinsing,
- dISINFECTING,
- Drying (if any): the drying reduces the moisture content of the DM.

THEignition of specific LED on the front panel of the WD signal the need to top up the finished product that can be: salt, rinse, neutralizing. The operator in charge of this activity must be able to interpret the signal reading and must be able to make the necessary top-ups. Of course you have to have surgery in a stock
dthe products and track the expiration time.
THEto the WD function it should be periodically validated by accredited technicians and a document issued should be kept in the clinic.
The products used for the WD function must be compatible with your machine and with DM processed by it.

THEoperating NDICATIONS

- wear PPE,
- disporre the DM of the relevant grids so that each part is available to the action of washing and disinfection (disassembled, open, non-overlapping, not fitted into each other ...),
- disporre DM cables at an angle,
- check that the WD arms are free in their path,
- load the pan detergent powder,
- close the door and start the cycle,
- at cycle end open the door of WD for a few minutes in such a way as to facilitate the drying of the load.

WASHING MACHINE WITH WASHING AND DISINFECTION (Washer Disinfector)

Pericolo	Cause	dejection	Rational

DM NOT CLEAN / DISINFECTED	**Caricamento inadequate**	Check outare positioning the DM to avoid gray areas Check outare the free movement of the impellers Dry use of trolleys and accessories suitable Arrange the concavity downwards and open articulated instruments	THE'mechanical action of washing should ensure contact and the action of the detergent throughout t the inner and outer surface of the DM
	Complessità structural the DM	Follow the manufacturer's instructions of DM circin the disassembly mode.	glassembled / articulated instruments if not properly open, they can have protein at the end of washing residues
	Deposits and residues organic	Use appropriate procedures for decontamination Use ultrasonic tank if necessary Ensure that the cycle includes a phase of	Dry dirt with high temperatures I favorno coagulation of residues protein
	ISFFICACY action mechanics (water pressure and speeda contact	Perform periodic maintenance of the equipment. Check the free movement of the impellers Check outare the correct positioning of the basket.	THE'device mechanical action must issser guaranteed so that the water pressure can reach every part of inserted DM.
	Cwashing onditions and / Thermal odisinfezione unreached	Check outperiodic function equipment (temperature / time) Verify that the counting of washing time or disinfection beginning is reached youmperature set. Check outare the choice of parameters	Attuare preventive maintenance on washing and disinfection equipment.
RICONTAMI N AIZonE DEL DM	**Carico / unloading from stit lator**	Use line equipment Adopt suitable behavior	A load washed and disinfected must istory treatise on clean surfaces and in sanitized environment.

operator controls

Vheck:
- data detergent deadline: every time you change the container,
- Cleaning efficiency (UNI EN ISO 15883-1, section 6.10.3): daily,
- parameters of the cycle: at the end of each cycle before the release of the DM,
- gwashing iranti: at each washing cycle check the free movement of the washing impellers,
- umResidual Idita (UNI EN ISO 15883-1, item 6.12): Quarterly if the equipment is provided with a drying cycle.

5. OFdisinfecting

THEin disinfection is the later step in the reconditioning process to the washing stage and is carried out for further reduce the microbial load present on the surface of the DM. It can be done in two ways:
- chemical (manual cleaning and ultrasonic),
- Thermal (washing and disinfection equipment).

chemical disinfection

THEto chemical disinfection takes place at low temperature, for a defined time, and the disinfectant action is exerted through the use of suitable chemicals; It is influenced by several variables that depend primarily by the operator.

Thermal disinfection

THEThermal disinfection takes place through the thermo disinfection (washing and disinfecting apparatus) whose action disinfettante is exerted simultaneously by the action of water and / or steam at a temperature and for a time defined depending on the level of reduction of the bacterial load that you want to achieve. (Eg. 80 ° for 10 minutes - 90 ° C per 5 minutes - 93 ° for 3 minutes: UNI EN ISO 15883-1)
The damping level of the microbial load depends on the temperature and contact time.

THEdisinfectors:

- it is preferable to chemical disinfection by eliminating the toxicological hazards that could arise from chemical residues left on dm treated for staff and patients,
- Non requires the disposal of chemical disinfectants through dedicated assignment paths,
- It is an easily controllable process. fashionslli different washer disinfector

6. TOSCIUGATURA

After the disinfection phase all DM must be dried to avoid compromising the characteristics of SBS bitrosi and the drying effectiveness of the sterilization cycle and to limit damage to the DM.

Nota: The steam sterilizers are able to dry the condensation generated during the sterilization phase but hardly able to dry the one present at the start of the sterilization cycle.

TOn order to avoid damage to the DM, after rinsing, it is necessary to carry out the drying with suitable accessories (eg medical compressed air, cloths that do not release fibers, etc.)

Late or insufficient drying may determine the natural growth of micro-organisms and the eventual formation of calcareous residuals and / or rust on the DM

TOSCIUGATURA: identification and reduction of known or foreseeable hazards (scale of the risks taken from UNI / TR 11408: 2011).

Pericolo	Cause	dejection
DANNEGGIAMENTO OF DM	Drying accessories inadequate	Use accessories such as not to damage the surface of DM (eg compressed air, towels that do not release fibers, etc.).
	late and insufficient drying	Dry immediately after the previous stage Use appropriate means (eg compressed air, cloths that do not rilascino fibers, etc.).
INCREASE CARICA MICROBIAL	Natural growth of microorganisms	Dry immediately after washing
	Contaminated air compressed	Use filtered air (at least HEPA H12)
	Prolonged use of towels	Replace the cloth when wet

operator controls

realFicare:

- no residual water on DM: DM on each treaty,
- characteristics of the drying towel: at every use.

7. CONTROL AND MAINTENANCE

Assembly And Control Of DM

Phases of the reconditioning process to be carried out after the washing and drying process and before dand packaging.

The DM should undergo visual inspection to verify cleanliness, integrity, rust and corrosion on surgical instruments.

And 'necessary to check the functionality of the DM and containers (as medical devices) following the frequency and methods that must be provided by the manufacturer

sccording to the UNI EN ISO 17664)

Nota:

- in the absence of the manufacturer's directions checks and their frequency must be performed in accordance with procedures

defined internal,

- repairs of DM are only permitted if carried out by the manufacturer or by personnel specially trained and authorized by the manufacturer.

working Advice

Theophealth eratore that deals with this activity must:

Use the magnifying glass with light source, verify the absence of rust or residual material, replace the damaged DM,

8. PACKAGING

Later step in the reconditioning process to the drying stages and recomposition of the kit and the preliminary

sterilizzazione.
The packaging is the inclusion of activities of DM in a sterile barrier system (SBS). The SBS has the objective of allowing the sterilization, to provide physical protection, maintain sterility up to the site of use and allow aseptic presentation. The choice of SBS must take into account the characteristics of the DM, the procedures of use and the type of sterilization. To distinguish the DM processed from non-processed, they can be used chemical indicators of class 1 (UNI EN ISO 11140-1).
TOome conditions of handling, transportation and storage subsequent sterilization require a protective packaging for the SBS in order to ensure the maintenance of the barrier characteristics up to ensure aseptic presentation of the DM; it is necessary that every dental practice projects of protective packaging systems and
definisca the control parameters according to their own risk analysis.

Winding Sheet

The sheets for DM winding can be of paper, TNT or entirely of polymeric material (Kimberly).
They are used for the packaging of drapes and surgical instruments in baskets / baskets.
The package is sealed with the use of special ribbons that can be fitted with process (Class 1, UNI EN ISO 11140-1 indicator).
The packaging is done by following the bending mode locking systems that create labyrinth so
impEdire the entry of microorganisms. bending mode

packing

Envelopes preformed or rolls of paper and plastic laminate heat sealable

THEand preformed envelopes or rolls are used for the dimensions of the kit packaging and / or limited weight.
The packaging is made by introducing the material into the envelope being careful not to cause tension or tears.
In the roll obtained by packaging must be ensured that the weld is at least 3 cm from the edge opening side to allow easy opening; the side of the correct opening is indicated with a symbol on the paper side.
THEto welding of the packaging must take place with temperature, pressure and time indicated by the envelope manufacturer.

Tyvek envelopes

disposable material, is constituted by the coupling of two layers of synthetic material (paper side and transparent side It composed of a laminate of polyester / polyethylene, permeable to the sterilizing agent. Presents high values of water repellency, resistance to lacerations, tears and perforations, is extremely flexible and not
sthe breaks or will not tear as easily as the paper for medical use. Can only be subjected to sterilization gas plasma or ethylene oxide; It is not indicated for the steam sterilization.

THEoperating NDICATIONS

- introducing the material into the envelope being careful not to provoke tensions and lacerations,
- gnsure a heat seal that is at least 3 cm from the edge to the opening side
  gnsure a smooth opening (the right opening side is indicated with a symbol on the paper side),
- used for the heat-sealing pressure and temperature as indicated by the manufacturer of the
- envelope, insert the envelope in the instruments, if they are formed by more parts, decomposed,
- insert into the envelope slightly open scissors and properly protected,
- insert the envelope all sharp instruments protected by a suitable protective sterilized, close all the
- tools articulated to the first notch,
- orrientare DM leads with the opening facing the paper side,
- roll up the pipes so as to avoid bottlenecks,
- adhere to the interior space of the envelope in such a way as not to create tension between
- DM and envelope, perform a continuous heat-sealing has no wrinkles.

9. STERILIZATION

Phase of the reconditioning process in which inactivate all the microorganisms (including spores) remained after the washing and disinfection. A DM is considered sterile when it is free of viable microorganisms. European standards for medical devices require, where it is necessary to provide a sterile DM, that the risk of microbiological contamination is minimized using all available practical means. Despite undergoing cleaning and disinfection, the DM can, before sterilization, be carriers of microorganisms. The purpose of the sterilization process is to inactivate microbiological contaminants and, therefore, to transform the DM in tailings that do not

I am.
The inactivation of a pure culture of microorganisms by the saturated steam can be approximated to a process with exponential trend; inevitably this means that there is always a finite probability that a microorganism may survive regardless of the duration of the process applied. It follows that the sterility of each item
I knowttoposto sterilization can not be guaranteed and the sterility of the treated DM must be defined in terms of probability of existence of a surviving microorganism on that article.
Vhyenas therefore defined a sterile DM which has undergone a sterilization process that ensures the theoretical probability of the presence of a viable microorganism in a million DM (level of sterility assurance, SAL 10^{-6})
A DM can only be considered sterile when it can be shown (through traceability) that has been subjected to a validated process that ensures the above-mentioned effectiveness.

Sterilization Methods

CHEMICAL: Plasma gas (for heat-sensitive materials):
THEin gas plasma sterilization is a low-temperature sterilization of the DM method.
The plasma gas is the result of a strong energy field on the gaseous matter that then, disintegrated at the molecular level produces a series of highly reactive unstable particles.
These particles, by their nature, tend to stabilize again if the energy field ceases to act on the starting gas. It allows processing of almost all of the thermolabile DM in short times (about 50 minutes).

PHYSICAL: saturated vapor (For heat-resistant materials) All DM BTLock International:
Steam is the sterilizing agent safer, cheaper, faster and harmless and that is why it is used in all health areas. Steam sterilization is ensured by the sterilizers which are devices provided with a room perfect sealing and resistant to high pressures. The presence of air within the chamber of the sterilizer determines the drop in temperature from the set during a cycle and, for this reason, affect the outcome of sterilization.
THEin steam sterilization is achieved by the combined action of four factors:

- **pressure**: It is necessary to raise the boiling point of water, therefore the sterilization temperature increases in proportion of the Rising of pressure,
- **temperature**: Has to reach values sufficient to ensure the destruction of the microorganisms,
- **time**: The temperature is only effective if kept constant for specific times. (The higher the temperature, the shorter the time),
- **humidity**: To obtain an effective sterilization process, the steam must be saturated (100% relative humidity). The temperature of the steam under pressure progressively increases in proportion to the pressure of the steam.

THEa relationship between the parameters (time, temperature, pressure) are indicated by the European regulations, UNI EN 285 and UNI EN ISO 17665

TIME (min)	TEMPERATURE (° C)	Pressure (bar)
5 - 7	134° C.	2.1
15-20	121° C.	1.1

Today, steam sterilizers, the new generation are computerized, with several already set cycles that are chosen by the operator in relation to the material to be treated and ensure the strict respect of the parameters for the achievement of the sterilization process.

of saturated steam sterilization phases

1. air removal,
2. steam introduction,
3. achievement of the temperature and the penetration of steam into the load,
4. sterilizzazione,
5. drying / drying,
6. bilanciamento baric / equalization.

CLASSIFICATION OF STEAM STERILIZER

A. SMALL STEAM STERILIZER (UNI EN 13060)

THEin the sterilization chamber is below a sterilization unit (30X30X60 cm.) and is mostly used in surgeries and dental surgeries
Depending on the type of material that can be sterilized, the small sterilizers are divided into 3 categories

Class / type of cycle
Intended use

(Briefly expressed) UNI EN 13060

B
Big small sterilizer
(gmainsails small sterilizer)
all types of loads as described in standard test loads, ie solid products, cables and bulk or packaged porous
N
Naked solid
(I knowbulk shores)
I knowthe bulk material
S
Specified by the manufacturer
(specificati by the manufacturer)
I knowthe types of products specified by the sterilizer manufacturer must include in addition to the pbulk roducts at least one of "porous load", "small porous load", "load of cable type A", "Load type B cable", "load individually wrapped" and "load in double pack"

B. STERILIZERS A LARGE STEAM (UNI EN 285-UNI EN ISO 17665)

THEin the sterilization chamber is equal to or greater than a unit of sterilization (30x30x60 cm.) and is used maggiormente in hospitals and dental surgeries.

CONTROLS ON STEAM STERILIZER

Prhyme to initiate a sterilization cycle, it is necessary that the sterilizer is subjected to the controls which periodicità is the one recommended by the technical standards; However, individual programs of periodic tests may be defined on the basis of risk analysis.

LOAD OF MATERIAL IN STERILIZER

THEoperating NDICATIONS

- set up the load within the sterilizer placing the envelopes and bundles of paper into metal baskets (no more than bordi)
- NoNo put the packs in contact with the inner surfaces of the sterilization chamber, not
- overlap parcels and envelopes
- onvideo thumbnail filter container must not be supported other packages, do not
- stack the concave devices even if individually wrapped.

DISCHARGE OF MATERIAL FROM STERILIZER

THEa discharge phase of the sterilizer is a very important phase in which you accept the DM as sterilized so it is fondamental to be entrusted to properly trained personnel.
It 'a delicate stage because you can easily re-contaminate the DM because the permeable parts of SBS can be wet and very stressed. Considering also the temperature gap in which the load is subjected (passes from about 80 ° C the sterilization chamber at about 20 ° C environment in which they download) all the air contained in the SBS reduces its volume and, particularly in the transport container, it draws air from the outside. Therefore handling procedures, the hygiene of the people involved and the hygiene of the environment are crucial to prevent possible recontamination of the sterilized DM.

operator controls:
Check:
- the successful completion of the run cycle,
- integrity of each SBS: at each cycle,
- pRESENCE SBS visibly wet; condensation affect the maintenance of sterility only if interested porous surfaces, the package in such a case must be regarded as being,
- viraggio chemical indicators of class 1 (process indicators).

Note: The operator in this activity wearing heat-protective gloves which must be subjected to periodic washing defined by the head of the dental practice.

- withedell'integrità control the color change of the SBS
- withcontrol of the presence of condensation

- withcontrol seal heat sealing

MOVIMENTAZIONE AND STORAGE OF STERILE DM

The DM, once treated, must be handled and stored in such a way as to ensure the maintenance of microbiological characteristics obtained from the reconditioning process.
condenvironmental inherently free and inadequate handling practices may affect these characteristics; if no contamination controlled environments is essential to use disposable protective packaging or appropriately sanitized (containers, trucks, closed cabinets, ...).
The DM, once treated, must be handled and stored in such a way as to ensure maintaining the microbiological characteristics obtained from the reconditioning process.

Moof SBS storage mode
- devono be handled as little as possible,
- NoNo need to come into contact with sources of moisture or dirty surfaces,
- Non must be assembled by elastic,
- the reserve of sterile equipment must be checked periodically to evaluate the wear and the deadline and the possible surplus of DM that are not used (reorganization of surgical instruments Park)
- devono be kept in chronological order of the deadlines.

Momode of use of SBS
Theoperatore must:
- verify the hygienic state of the table on which you will put down the SBS,
- perform hand hygiene with an alcohol solution,
- verify the indicator uniform color change process placed on SBS,
- vAlso check that the SBS is intact, dry, dust-free,
- verify the deadline.
- gnsure the aseptic opening of SBS with correct maneuvers.

MOVIMENTAZIONE AND STORAGE OF STERILE DM

Tempthe conservation of the SBS
THEUNI EN 11607-1 introduces the concept of "stability test" to be carried out to demonstrate that the SBS maintains its integrity over time. The test consists in the real-time evaluation of the aging SBS associated with accelerated aging (laboratory tests).
Based on the laboratory results and certification to what tested, it is possible to establish a specific period of time in which an SBS remains sterile.
Note: the retention period of infertility depends on the events and not only by time.

TRACCIABILITÀ

It defines traceability system a registration system to uniquely identify the dourdevice medical means of labeling and all the elements that are considered critical that characterize the process it has undergone and the patient on which it was used.
They must be tracked at least:
- the physical and / or chemical parameters of the washing process, disinfection and sterilization,
- glthe results of the controls, periodic inspections, maintenance carried out on the equipment,
- the results of monitoring and / or indicators used to monitor the sterilization process
- the unique identification of the operators involved in the process and responsible for the checks required operators (eg People loading, the recomposition, the packaging of the kits, ...),
- the actual composition of the individual kit and their traceability,

FILING OF DOCUMENTS

THEto documentation must be cataloged, archived, remain legible and available in the places of use or easily available from staff, accrual, you may have need for consultation.

Documentation that must be provided by the manufacturer
- manuwings of use of the equipment,
- instructions for preparation procedures,
- instructions for maintenance and control of equipment and DM.

concerning the process are available on:
- the results of checks and periodic checks,
- Records of chemical parameters / physical equipment,
- maintenance of the equipment,
- traceability of DM.