Practice Hygiene

1. Principles Pertinent to the Evaluation Criteria

This chapter deals with the basics, objectives, concepts, and measures of practice hygiene.

Formerly, hepatitis B was regarded as an occupational disease of dentists. Occasionally, a transmission of hepatitis B from a dentist to a patient has indeed been demonstrated. Since the occurrence of the AIDS epidemic, a high hygiene standard is claimed by the medical professional associations and the patients. This standard should provide an efficient protection against infections, particularly those by pathogens transmitted by blood and saliva. Today it is known that HIV is not exactly transmitted easily. However, even HIV can be transmitted by occupational contact. The hepatitis B virus (HBV) often attains a high titer in the blood of healthy carriers, who are not necessarily aware of their condition. This similarily also pertains to hepatitis C viral infections. Therefore, the hygiene standard is determined by the hepatitis B and C viruses. Thereby, a general protection against infections transmitted by blood is ensured but there is no absolute infection protection. In conjunction with the occurrence of the variants Creutzfeldt-Jakob disease (CJD) in humans, which are caused by prions and have been related to the epidemic of the bovine spongiform encephalopathy (BSE) especially in Great Britain, it became necessary to inactivate this new category of pathogens. The WHO recommended autoclaving at 134 °C during 18 minutes (prion program), and this approach was also adopted for Switzerland (CJD regulation).

The Swiss law on medicaments (Heilmittelgesetz; HMG, SR 812.21) intends to ensure that only high-quality, safe, and effective medicaments (medicinal products and medical devices) are put on the market. The regulation on medical devices (Medizinprodukteverordnung; MepV, SR 812.213) brought into effect on April 1, 2010, should ensure a safe handling of medical devices. It regulates the measures for the quality assurance related to reprocessing of medical devices.

Objective of Practice Hygiene

is the prevention of the transmission of infections from one patient to another, to members of the practice team and dental laboratory, and vice versa.

Basic Elements of Practice Hygiene

For all patients, the same hygiene standard is required. Hence, there is no specific risk patient. Measures are equally designed for the protection of patients as well as that of the practice team. The following items require particular attention related to the prevention of infection transmission:

- Hands of the dentist, DH, PA, and DA
- Contaminated cutting and pointed instruments
- Chips of dental materials and aerosols
- Surfaces

Practice hygiene constitutes a comprehensive package of measures which regulates the procedures in the practice from the perspective of infection transmission, and which has to be completely satisfied by all members of the practice team. Practice hygiene is not a peripheral part of the dentist's service but an obligation.

Responsibility of the Dentist

The dentist carries full responsibility for the hygiene in their practice. They determine the hygiene concept, arrange the instruction of all members of the practice team, and check the compliance with the concept. Even in daily routine and pressed for time they attempt to be an example. Patients have a right to an optimal care in hygienic terms just as much as to an optimal treatment.

Application of the Evaluation Criteria

The evaluation criteria of the quality guidelines allow a self-assessment and a practice evaluation by the practice team. They also enable a comparison of the own ideas with the quality expectations of the authors of the manual.

The responsible practice owner should be able to reveal weak spots or problem areas and to improve these as quickly as possible using appropriate measures. In doing so, they go by the insight that practice hygiene comprises a chain of well-matched measures, whose efficacy is determined by the weakest link.

2. Evaluation Criteria

HYGIENE CONCEPT	▪ There is an elaborate, periodically checked hygiene concept for all procedures in the practice. ▪ The current hygiene plan is hung up and clearly visible. ▪ The hygiene concept and plan are known to all members and are basically satisfied by everybody. In the context of the implementation, slight variations in everyday practice can happen occasionally. ▪ The members of the practice team are trained concerning issues of practice hygiene immediately upon entrance and then at regular intervals. Regular checks are carried out. ▪ The dental treatment unit is organized in such a way that later handing-over is unnecessary or exclusively involves instruments designated for that.
PERSONNEL HYGIENE	▪ All members of the practice team possess a sufficient protection against HBV. The HBV vaccination is checked and, if necessary, arranged by the practice owner. ▪ The procedure in the case of accidental injuries with blood is discussed case by case and recorded based on a template. ▪ Protective clothing is worn only in the practice or clinic zone. It is changed daily or in the case of visible contamination. ▪ Gloves are worn during all work with patients contact with blood or saliva is possible; at work with aerosols, face masks and goggles/protective screens should be worn as well.
HAND HYGIENE	▪ At the start and after conclusion of the treatment period (morning, noon, evening): wash hands with soap and cold water. ▪ Hygienic hand disinfection using a registered alcoholic preparation before and after every treatment as well as upon interruptions of work and each changing of gloves ▪ Surgical hand disinfection and sterile gloves prior to surgical interventions ▪ New gloves for every patient; minimum requirements in the event of serial examinations (of children): disinfect gloves between individual examinations (after a maximum of six examinations gloves are to be changed in any case). ▪ The practice team does not wear rings, watches, and bracelets; fingernails are short and unpainted.
INSTRUMENTS	▪ Processing of instruments is delimited to three areas for a) disinfection of contaminated instruments, b) cleaning, control, maintenance, and wrapping, c) sterilization and storage. Areas b) and c) are spatially divided from the treatment unit; area a) is clearly marked (near the treatment unit). ▪ Disinfection under controlled conditions in a disinfection bath or better still in a thermodisinfector ▪ Sterilization of the instruments in a validated steam autoclave ▪ Documentation of the sterilization cycles, regular technical maintenance (according to the manufacturer's recommendation), and regular validation of the autoclave using appropriate indicators ▪ All instruments intended for invasive interventions are sterilized in disposable wrappings or filter trays using the prion program (134 °C, 18 min.). ▪ Storage of sterilized instruments assorted in disposable wrappings or filter trays labeled with the date, stowed in tightly closing cupboards or drawers only for the appropriate period of storage ▪ Handpieces and contra-angle handpieces intended for surgical interventions are precleaned by machine and wrapped for sterilization, for all other interventions they are precleaned by machine and disinfected. Drills intended for all interventions are sterilized. ▪ Instruments intended for non-invasive treatments are, if possible, sterilized and stored unpacked in aerosol-tight drawers which are not opened during treatments. Drawers are emptied and disinfected at least once a month, the contents are sterilized, disinfected, or disposed of.

SURFACES/AUXILIARY EQUIPMENT	▪ After use, all materials and appliances which have come into contact with blood/saliva or aerosols are disposed of or disinfected and stored in a way that a re-contamination is excluded. ▪ Systematic disinfection of surfaces on every change of patient according to the hygiene plan using pre-wetted disposable wipes. The disinfection radius is determined by the extent of the contamination. ▪ The dental unit should preferably be equipped with a water disinfection system; if this is not the case, water is let run from all taps for at least three minutes in the morning and after longer interruptions of work. ▪ In the case of invasive interventions, solely sterile rinsing solution is used.
IMPRESSION TRAYS/WORKPIECES/ DENTURES/RADIOGRAPHS	▪ Impression trays/workpieces/dentures from a patient's mouth are effectively disinfected and labeled before they leave the practice. ▪ Whatever comes from the laboratory and is inserted in a patient's mouth is also disinfected. ▪ The procedure is basically agreed upon with the dental technicians. ▪ The X-ray cycle is organized in a way that the developing device is not contaminated.
PRACTICE WASTE	▪ All waste is disposed of according to a written concept. ▪ Cutting and pointed waste materials are disposed of in stab-resistant, liquid-tight, sealable, and labeled containers. ▪ Hazardous waste is properly disposed of. ▪ During processing of not yet disinfected instruments, the personnel wears thick household rubber gloves.

3. Explanatory Notes Concerning the Evaluation Criteria

Hygiene Concept

The goal of practice hygiene is the prevention of an infection transmission to or from the patient. An important prerequisite is the separation of the practice into a clinic zone (treatment rooms, processing of instruments) and other rooms. All work processes should be organized in a way that at each step the infection risk is minimal.

Important processes:
- Concept related to equipment and instrumentation with regard to treatment processes
- Flow of instruments
- Change of patient
- Hand disinfection
- X-ray cycle
- Material traffic with the dental laboratory

By means of protective measures, the contact with blood and body fluids is to be avoided as far as possible.

Periodical training of the personnel and hygiene controls are to ensure a consequent implementation of the hygiene concept.

A written hygiene plan regulates the type and extent of as well as the responsibility for the specific hygiene measures (see appendix 1 taken from Wiehl & Guggenheim 1993)

Protective Measures

Vaccinations

Via blood, oral and respiratory secretions, members of the practice team can be exposed to a variety of infectious agents, e.g. hepatitis B and C viruses, herpes simplex virus, cytomegalovirus, HIV, influenza viruses, *Mycobacterium tuberculosis,* staphylococci, and streptococci. It is therefore indicated to immunize as far as possible.

All members of the practice team who are not immune to the hepatitis B virus should be vaccinated (the costs are borne by the health insurance). Those who refuse the vaccination are informed about potential consequences and confirm the refusal in writing. In this connection, it should be pointed out that the HBV vaccination does not protect against other hepatitis virus infections. Additional vaccinations, e.g. against influenza, poliomyelitis, mumps, measles and rubella, tetanus, pertussis, and diphtheria, can make sense. In the case of a pregnancy or diseases, the fiduciary or family doctor should be consulted.

Occupational Safety

Gloves (latex, nitrile or vinyl) are always worn for the protection of the patient and the personnel, at work in the mouth or if contacts with blood, saliva, and/or mucous membranes occur. Attention: take latex allergies (also in patients) into account! Non-sterile gloves are sufficient for simple examinations/treatments; sterile gloves are worn for oral surgical interventions. At the end of treatment and before leaving the treatment zone, the gloves are taken off and disposed of on site.

Thick household gloves are worn when disinfecting and cleaning the instruments, when dealing with concentrated disinfection solutions and other skin-irritating chemicals as well as when handling contaminated waste.

The *face mask* of multi-layered fleece protects the lower half of the face against infectious chips flying around and prevents the inhalation of aerosols. It should fit tightly and remain dry. If it has been exposed to aerosols or has become wet, in any event at the end of treatment, it is replaced.

During *serial examinations of children* the face mask and gloves do not have to be changed for every patient. Gloves can be disinfected up to six times but must be changed if they come in contact with blood, if the gloves are perforated or soiled, or if there is evidence of illness in the child.

Safety goggles with sideways protective shields protect the eyes against injuries and infection. After every patient it is disinfected. Also patients are protected by goggles against aerosols and chips.

Work clothing is worn only in the practice to avoid spreading of germs from the practice. Best suited are an apron or coat which is tightly closed in the front, or a shirt without breast pockets, pants, and work shoes closed in the front. Work clothing is changed daily or when contaminated with blood. If possible, it is stored separate from the everyday clothes. Work clothing (cotton) can be washed using a normal wash cycle.

Long hair is tied together in the back.

Injuries

The risk of an occupational HIV infection is very low, but the consequences are disastrous. Potentially serious consequences associated with a low risk of infection also hold true for hepatitis C. Therefore, it is important to avoid HIV and HCV exposures. In the case of an exposure, the medical evaluation has to take place immediately. For this purpose, the name, address, and phone number of the respective physician have to be known to all members of the practice team.

Needles, scalpel blades, and other sharp instruments are to be regarded as potentially infectious and therefore have to be handled as carefully as possible so that no injuries can ensue.

Essential precautions:
- Needles should be disposed of in a suitable collecting container as soon as possible after usage. Two-handed recapping has to be avoided by all means.
- Hand contact with contaminated rotating instruments has to be avoided.
- Thick household gloves should be worn when cleaning instruments; instruments should be cleaned separately.

The procedure in case of an accidental exposure to blood/saliva is to be regulated in writing so that appropriate measures can be taken immediately:

- Disinfection of the wound
- Confidential information of the involved parties (patient, supervisors, practice leader)
- Recording of the circumstances, e.g. by means of the accident report for occupational injuries (see Appendix 2 from Wiehl & Guggenheim 1993) in three copies (for the physician, the accident insurance, and the practice). It serves as the basis for the assessment of the infection risk.
- Making contact with the physician

A written manual on the procedure in case of stab injuries and contamination of open wounds should be posted in a place of the practice, where it is clearly seen by the personnel.

Disinfection and Hand Care

The hands constitute an important vehicle for the transmission of an infection. Therefore, great importance should be attached to their protection, disinfection, and care. The recommended procedure is depicted in the diagram "Hand protection in dental therapy" (see p. 7).

Hands are washed with cold water and liquid soap and then carefully dried. They should be treated regularly with a moisturizing hand creme. Fingernails are to be cut short and unpainted.

In the case of prolonged work in patients, a change of glove can help to keep the skin as dry as possible. When gloves are perforated, a change is indicated as soon as it is allowed by the treatment of the patient.

Thick household gloves are worn at work with pointed/sharp objects or skin-irritating chemicals and disinfectants.

Disinfection and Sterilization of Instruments

Basics

The objective of disinfection is a reduction of germs (except spores) by at least five log levels. The result is not a permanent condition but restricted to the moment. By means of a sterilization (e.g. 121 °C, 15 min.) not only viruses, vegetative bacterial cells, and fungi, but also bacterial spores are inactivated by at least six log levels. By means of the prion program in the autoclave (134 °C, 18 min.), prions are inactivated as well (CJD regulation 2002).

Sterilization includes disinfection and cleaning prior to the sterilization, the sterilization process proper, and the storage following sterilization. In the field of sterilization several European norms have been ratified, whose implementation in the dental practice has been discussed by the SSO committee of practice hygiene and environment (Guggenheim et al. 1999). In 2010, Swissmedic has published the guideline "Good practice for processing medical devices in medical and dental practices and by other users of small steam sterilisers", which takes into account the revised Swiss medical devices regulation (2010).

Therein, instruments to be reprocessed are divided into three classes depending on their infection risk:

I) Uncritical instruments have upon use only superficial contact with the skin.
II) Semicritical instruments come during utilization into contact with the mucosa or with defective skin.
III) Critical instruments penetrate during utilization the skin or mucosa and come into contact with blood. These products have to be sterile for use.

Procedure

Since reasonably the number of disposable articles in the dental practice has to remain limited, most instruments are reused. They are reprocessed according to the risk class before being used again. Processing of the instruments takes place in three phases: a) disinfection of used instruments; b) cleaning, control, maintenance, and wrapping of the instruments; and c) sterilization and storage until the next usage. These operations should be undertaken in three areas which optimally are spatially separated from the treatment unit. If the area intended for disinfection (a) is close to the treatment unit (e.g. in clinic rooms), it should be clearly demarcated.

The rearrangement of contaminated instruments is carried out using thick household gloves. The disinfection of the instruments is made either by means of thermodisinfection (automatic setting: 95 °C, 3–10 min.) with cleaning and rinsing agent or by means of immersion disinfection. For this purpose, the instruments are completely immersed. The minimum time of exposure required for the particular concentration of the disinfectant has to be observed under controlled conditions (e.g. stopwatch). Disinfectants are replaced regularly according to the manufacturer's specifications.

Following the disinfection, the instruments are cleaned, checked, and maintained, before they are wrapped (transparent sterilization bag or tray) and labeled with the date and batch number. In this area, it can be worked without gloves.

Subsequently, the instruments are sterilized in a validated autoclave. The sterilization process must be reliably and easily controllable (example day's protocol sterilization from appendix B KIGAP).

Example day's protocol sterilization

Sterilizer: _____ Responsible person: _____ Date: _____

Vacuum test

Batch number: _____ ☐ ok ☐ not ok Signature: _____

Bowie&Dick test/hollow load challenge test

Test used: _____ Lot number: _____

Test ☐ passed ☐ failed

Batch number: _____ Signature: _____

In case of "failed", measures taken: _____

_____

Renewed test ☐ passed ☐ failed

Batch number: _____ Signature: _____

Batch control

Batch number: _____

Program: _____ Load

Program run ☐ compliant ☐ non-compliant

Chemical indicators ☐ compliant ☐ non-compliant

Integrity of the wrapping ☐ compliant ☐ non-compliant

Release: ☐ yes ☐ no Signature: _____

Batch number: _____

Program: _____ Load

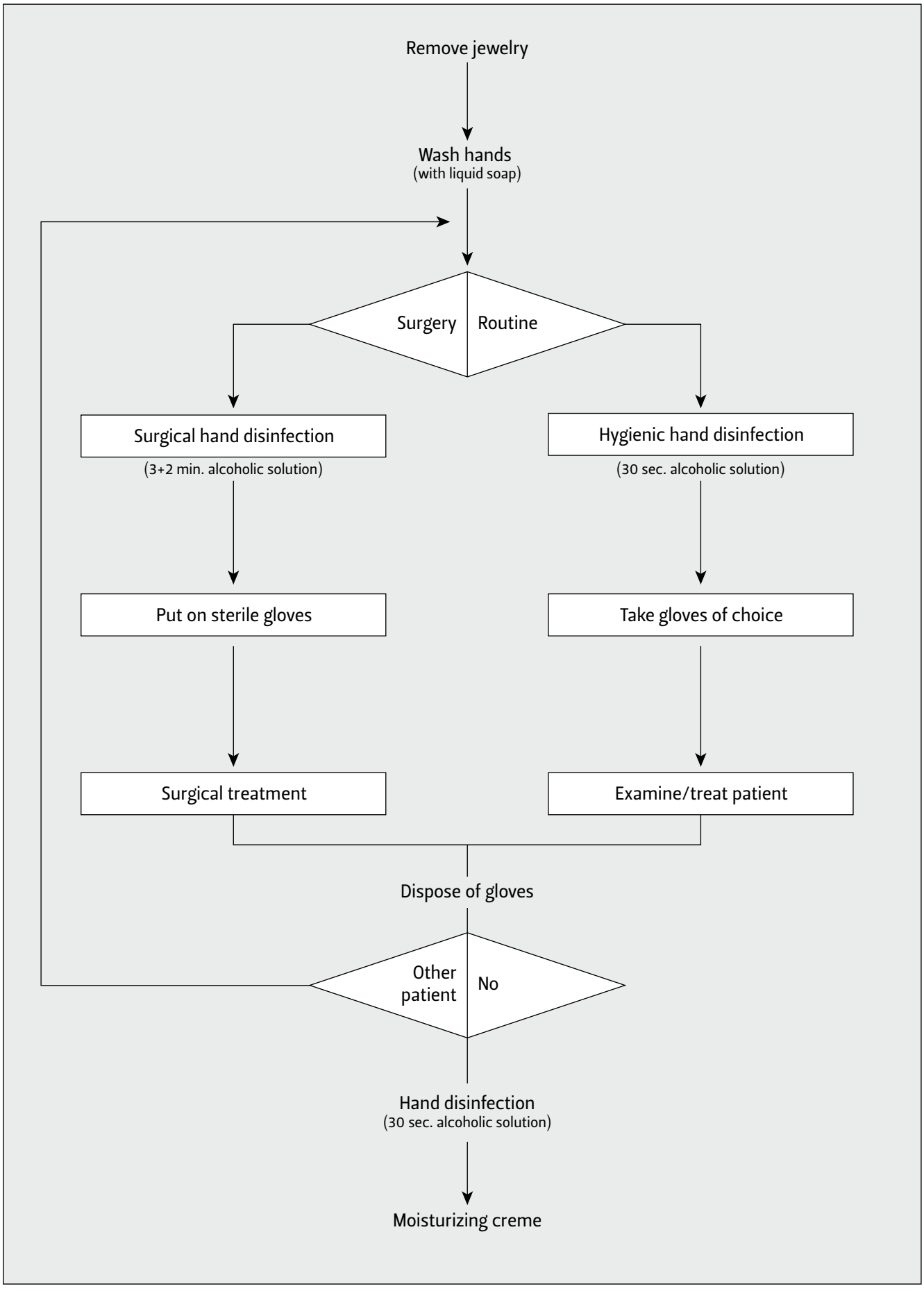
Program run ☐ compliant ☐ non-compliant

Chemical indicators ☐ compliant ☐ non-compliant

Integrity of the wrapping ☐ compliant ☐ non-compliant

Release: ☐ yes ☐ no Signature: _____

Protection of hands during dental therapy



Sterilization Controls

A complete sterilization control essentially involves the following items: device check, treatment control, batch monitoring, and control of sterile goods (see recommendations from appendix A KIGAP).

Concerning the preservation of sterility following the sterilization (storage), maximum periods of storage apply which depend on the type of wrapping, the type of storage, and the location of storage (Guggenheim et al. 1999). All instruments intended for invasive interventions are sterilized in a disposable wrapping or in filter trays using the prion program. Instruments intended for non-invasive interventions – if at all possible – are sterilized and then stored unwrapped in aerosol-tight drawers. During treatments, these are not opened; once a month they are cleared out and disinfected, while the contents are sterilized, disinfected, or disposed of.

Handpieces and contra-angle handpieces are precleaned by machine and disinfected, for surgical interventions they are wrapped and sterilized.

Validation

By means of the validation, it should be demonstrated that the device is correctly installed and ready for operation and that

Recommendations on necessary controls related to the processing of sterile medical devices

TYPE	WHAT?	HOW?	WHEN?	DOCUMENTS	REMARKS
DEVICE CHECK	Operational readiness	Visual inspection (cleanliness, door system, display unit etc.)	Daily at the start of work	No entry necessary (work instruction)	
	Leakage test (vacuum test) (if cycle exists)	Empty chamber, according to manufacturer	Weekly[a]	Sterilization protocol	Entry of result and initials
	Hollow load challenge test (if cycle exists)[b]	B&D test package, program according to manufacturer or Helix test, program according to manufacturer	Daily, if porous goods are sterilized regularly At least once a week	Sterilization protocol	Entry of result and initials
TREATMENT CONTROL	Process indicators	Attach to every packaging if not already imprinted	Every batch, every packaging	No entry necessary (work instruction)	
	Labeling	Write down sterilization date and batch number (if already known) as well as package content (if not apparent) on packaging	Every batch, every packaging	No entry necessary (work instruction)	
	Check of wrapping	Check seal seams for continuous sealing, check containers and trays for clean fasteners	Every batch, every packaging	No entry necessary (work instruction)	
BATCH MONITORING	Batch release	Add a class-5 or -6 chemical indicator to the batch, in the case of hollow parts, it is advantageous to use a process challenge device (PCD)[b]	Every batch	Sterilization protocol	Entry of result and initials
	Process printout	Check process printout for correctness of process values, sign off	Immediately after the end of the program	File signed printout in folder, sterilization protocol	Entry of results and initials
	Wrapping	Check wrapping for integrity, check treatment indicators on envelope	Immediately after the end of the program	Sterilization protocol	Entry of results and initials
CHECK OF STERILE GOODS	Release for use	Check wrapping for integrity, mind expiration date	Always before use	Addendum to sterilization protocol if necessary	Entry of results and initials if addendum is necessary

[a] at least three times a month (CEN ISO TS 176652:2009, Tab. A3)
[b] combination by means of Batch Monitoring System (BMS) possible

the processes can be applied effectively. It comprises three tests: a check of the installation, a functional check, and a check of the processes.

Most easily the initial validation takes place upon delivery; thereafter, a process challenge device (helix test) with a class-5 or -6 chemical indicator is added to every batch. This test proves, on the one hand, an adequate steam penetration and, on the other hand, demonstrates a correct sterilization process.

Surface Disinfection

It must be taken into account that by means of aerosols and direct contact during treatments of patients, saliva mixed with blood spreads over the treatment area. Working surfaces and furniture contaminated in such a way are decontaminated with an appropriate disinfectant that is approved in Switzerland when the patient is changed. Using a soaked disposable wipe, the surfaces are thoroughly mechanically processed.

Disinfection of Impression Trays, Dentures, and Work-pieces

Suited for the disinfection of impression trays, dentures, and workpieces are, on the one hand, the spray disinfection in a closed system and, on the other hand, the immersion disinfection. Manufacturer's specifications concerning the concentration and time of exposure of the disinfectant as well as the material compatibility have to be considered.

Preferably, the disinfected object is wrapped in a transparent bag as a sign for the performed hygiene measure. The procedure and labeling related to disinfected workpieces must be agreed upon with the dental technician.

The Water System in the Dental Unit

The water system in the dental unit can be contaminated by oral bacteria or water germs (e.g. *pseudomonas aeruginosa, legionella pneumophila*) if the dental unit is not equipped with a functioning disinfection device. The germ load can be reduced by letting run water during at least three minutes from all taps in the morning and after longer interruptions of work.

For invasive interventions solely sterile rinsing solution rather than the water from the dental unit is used.

Disposal of Waste

Waste lacking a risk of infection or injury such as napkins, wrapping material etc. is put in the garbage and disposed of with the domestic waste collection.

Solid waste exhibiting a risk of infection such as swabs soaked with blood or saliva etc. are disposed of using a double-bag system, i.e. they are collected in plastic bags at the place of origin and then put into normal garbage bags. Saliva and blood are disposed of without disinfection via the sewer system.

Pointed and sharp waste exhibiting a risk of injury such as needles, scalpels etc. are collected and disposed of in stab-resistant, liquid-tight, sealable, and labeled containers. Amalgam residues after removal from the mouth are put in a jar containing a disinfectant. Prior to disposal, it has to be decanted.

Process scheme (validation)

EVALUATION UPON ACCEPTANCE	PROPER INSTALLATION AND INFORMATION ON A SAFE OPERATION	▪ Are all necessary documents available? ▪ Is the device safely installed? ▪ Is the water quality appropriate? ▪ Are the necessary sterilization programs available?
FUNCTIONAL EVALUATION	PROPER FUNCTION	▪ Are pressure/temperature sensors properly installed? ▪ Is the system tight? ▪ Are safety/error detection systems properly functioning? ▪ Are vacuum/hollow load challenge tests ok?
EVALUATION OF PERFORMANCE	APPROPRIATE STERILIZATION PARAMETERS	▪ Are time, pressure, and temperature figures in the course of three reference loads ok? ▪ Are the products dry after sterilization? ▪ Is the wrapping of the products damaged?

Report:
- Determination of necessary corrective actions
- Definition of the measures for routine monitoring

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Appendix 1

Hygiene plan

What? Application area		With what? Disinfectant	How? Application	How long? Duration	Why? Time of application	Steriliza-tion	Storage
Hands	hygienic surgical						
Protective clothing							
Instruments							
Trays, tablets							
Drills, diamond burrs, Arkansas whetstones, silicone polishers							
Silicon carbide grinding instruments, rubber polishers, polishing brushes							
Endodontic instruments	handles plastic/ metal color coded						
Handpieces and contra-angle handpieces							
Turbines							
Waste	general pointed/sharp						
Surfaces	tray, instru-ment table, cupboards, handle, switching strips headrest pad, armrests, spittoon						
Floor							
Dentures							
Impression trays							
Casts							
Suction unit							

Appendix 2

Accident report in case of occupational injuries

1. Particulars of employee

Name: First name:

Gender: Date of birth:

Profession/function:

EE since: Professional experience after graduation: ..... years

Hepatitis B vaccination ☐ yes ☐ no
Last vaccination: Titer:

2. Type of injury

Date of accident: Time: Location:
Detailed description of accident:

In your view could the accident have been avoided?
☐ yes ☐ no
If yes, in what way:

Circumstances	Injury level	Contamination by
Injury		
☐ Superficial (scratch)	☐ Injection needle	☐ Blood
☐ Deep (bleeding)	☐ Sewing needle	☐ Biological fluid with blood (visible)
Mucosal exposition		
☐ Mouth		
☐ Eye	☐ Scalpel	☐ Biological fluid (no blood visible) If biological fluid, which one?
Exposition of the skin		
☐ Skin intact with prolonged contact time .... min.		☐ Others, which one?
☐ Damaged skin (specific description):		

In case of an injury, was blood visible on the injuring object? ☐ yes ☐ no

3. Particulars of patient

Name: First name:

Patient number: Gender: Date of birth:

Risk factors	HIV serology	Hepatitis B serology	
a) None	☐ positive	☐ HBsAg	☐ HBeAG
b) Drug addiction	☐ negative	☐ positive	☐ positive
c) Homosexuality	☐ unknown	☐ negative	☐ negative
d) HIV-positive partner	If positive:	☐ unknown	☐ unknown
e) Polytransfusion	Receives ZDV (zidovudine)		
f) Country with high HIV prevalence	☐ yes ☐ no		
g) Other	HIV infection stage I, III, IV according to CDC classification BAG-bulletin Nr. 36, 586, 1992		