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Processing Instructions for reusable orthodontic and dental Instruments

in compliance with EN ISO 17664

1. General Basics

Before each Use the Instrument must be cleaned, disinfected and sterilised; as well this applies particularly for the first time Use after Delivery, because the Instruments are delivered unsterile (Cleaning and Disinfection after Removal of Transport Protective Packaging; Sterilisation in steriliseable Package). Effective Cleaning and Disinfection is an indispensable Condition for effective Sterilisation.

Within the scope on your Responsibility for the Sterility of the Instrument in Use, please make sure that
- solely sufficient device-specific and product-specific validated procedures for Cleaning/Disinfection and Sterilisation will be implemented,
- used Devices (Disinfector, Sterilisiser) will be periodically maintained and tested and
- the validated Parameters will be followed within each Cycle.

In Addition please note the statutory Provisions of your Country and the Hygiene Regulations of the Medical Practice or Hospital.

Several Instruments require additional Treatment.
For this note Chapter 10: *Product-specific Instructions*!

When using or processing the instrument always wear appropriate personal protective equipment, e.g. eye wear, face mask, chemical-resistant gloves and appropriate clothing. Blood, tissue and infective materials pose an infection control risk.

2. Cleaning and Disinfection

2.1 Basics
As far as possible for Cleaning and Disinfection of the Instruments a machine Procedure (Disinfector) should be preferred.
A manual Procedure – even using an Ultrasonic Bath – should be applied only if a machine Procedure is unavailable, due to notedly lower Effectiveness.
Several Instruments require additional Treatment.
For this note Chapter 10: Product-specific Instructions.
Pre-treatment must be effected in both Cases.

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This device complies with the requirements of Directive 93/42/ECC concerning medical devices. Classification: I CE

2.2 Pre-treatment
Immediately after Use (within maximal 2 hours) visible Contamination – if present - must be removed from the Instruments.

Disassemble the Instruments as far as possible (see 10 *Product-specific Instructions*).
For that Purpose use running Water or a Disinfectant Solution.
Rinse all existing Lumina/Blind Holes of the Instrument 5 Times using a disposable Syringe (minimum Volume 5ml, if necessary with fitted Cannula).

The Disinfectant must be free of Aldehyde (otherwise Fixation of Blood Contamination), must possess a proved Effectiveness (e.g. DGHM-Approval, FDA Approval or CE-Marking), must be qualified for the Disinfection of the Instruments and must be compatible with the Instruments (see 8. *Resistance of Materials*).

For manual Removal of Contamination only use a soft Brush or a soft clean Cloth solely dedicated for that Purpose, but never Metal Brushes or Steel Wool.

Please note, that the Disinfectant used within the Pre-treatment only serves as Operator Protection and cannot substitute the subsequently – after passed Cleaning – effected Disinfection Step.

2.3.1 Machine Cleaning/Disinfection
(Desinfektor (Washer-Disinfector))

Please make sure within the Choice of the Disinfector,
- that the Disinfector strictly possesses a proved Effectiveness (e.g. DGHM-Approval, FDA Approval or CE-Marking according to DIN EN ISO 15883),
- that as far as possible a proved Program for thermal Disinfection (A_0-Value > 3000 or – using older Machines – not less than 5 minutes at 90 °C) is available (In case of chemical Disinfection Risk of Disinfectant Residues on the Instrument),
- that the used Program is qualified for the Instruments and includes a sufficient Number of Rinse Cycles,
- that for closing Rinsing only sterile or low-germ (max. 10 Germs/ml) and low-endotoxin (max. 0,25 Endotoxin Units/ml) Water (e. g. purified water/highly purified water) will be used,
- that the Air used for Drying will be filtered and
- that the Disinfector will be periodically maintained and tested.

Please make sure within the Choice of the Detergent System,
- that it is strictly qualified for the Cleaning of Instruments made of Metals,
- that – in Case no thermal Disinfection is effected – additional a qualified Disinfectant with proved Effectiveness (e.g. DGHM-Approval, FDA Approval or CE-Marking) has to be used and that the Disinfectant must be compatible with the used Detergent and
- that all used Chemicals must be compatible with the Instruments (*see 8. Resistance of Materials*).

The Concentrations specified by the Manufacturer of the Detergent and, if necessary, Disinfectant must be strictly observed.

Workflow:
1. Disassemble the Instruments as far as possible (see 10 *Product-specific Instructions*).
2. Place the disassembled Instruments into the Disinfector. Make sure that the Instruments do not touch each other.
3. Start the Program.
4. Remove the Instruments from the Disinfector after the Program terminated.

5. Prove the Instruments and package them immediately after removing from the Disinfector (*see 3. Inspection, 4. Maintenance and 5. Packaging*), if necessary after additional Drying at a clean Place.

The Evidence of Qualification of the Instruments for effective machine Cleaning and Disinfection was provided by an independent accredited Test Laboratory using the Disinfector 7836 GD(thermal Disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the Detergent Neodisher mediclean (Dr. Weigert GmbH & Co. KG, Hamburg). At this the procedure described above was followed.

2.3.2 Manual Cleaning and Disinfection

Please make sure within the Choice of the Cleaning and Disinfectant Agents,
- that they are strictly qualified for the Cleaning respectively the Disinfection of Instruments made of Metals,
- that the Detergent – if applicable – is suitable for Ultrasonic Cleaning (no Foam Development),
- that a qualified Disinfectant with proved Effectiveness (e.g. DGHM-Approval, FDA Approval or CE-Marking) has to be used and that the Disinfectant must be compatible with the used Detergent and
- that all used Chemicals must be compatible with the Instruments (*see 8. Resistance of Materials*).

Combined Cleaning and Disinfecting Agents should not be preferred. Only in Cases of very low Contamination (no visible Contamination) Combined Cleaning and Disinfecting Agents can be used.

The Concentrations and Reaction Times specified by the Manufacturers of the Cleaning and Disinfectant Agents must be strictly observed.
Please use only sterile or low-germ (max. 10 Germs/ml) and low-endotoxin (max. 0.25 Endotoxin Units/ml) Water (e. g. purified water/highly purified water) respectively for Drying only filtered Air.

Workflow: Cleaning
1. Disassemble the Instruments as far as possible (see 10 *Product-specific Instructions*).
2. Place the disassembled Instruments into the Cleaning Solution for the scheduled Application Time, making sure they are completely covered (if necessary under Ultrasonic Support or careful manual Brushing with a soft Brush). Make sure that the Instruments do not touch each other. Rinse all existing Lumina/Blind Holes of the Instrument 5 Times at the Beginning respectively at the End of the Reaction Time using a disposable Syringe (minimum Volume 5ml, if necessary with fitted Cannula).
3. Remove the Instruments from the Cleaning Solution and rinse them at least 3 times with Water. Rinse all existing Lumina/Blind Holes of the Instrument 5 Times using a disposable Syringe (minimum Volume 5ml, if necessary with fitted Cannula).
4. Prove the Instruments (*see 3. Inspection and 4. Maintenance)*.

Disinfection
5. Place the cleaned and proved Instruments into the Disinfectant Solution for the scheduled Application Time, making sure they are completely covered. Make sure that the Instruments do not touch each other. If necessary /(see 10 *Product-specific Instructions*): Rinse all existing Lumina/Blind Holes of the Instrument 5 Times at the Beginning respectively at the End of the Reaction Time using a disposable Syringe (minimum Volume 5ml, if necessary with fitted Cannula).

6. Remove the Instruments from the Disinfectant Solution and rinse them at least 3 times with Water.
   If necessary /(see 10 *Product-specific Instructions*):
   Rinse all existing Lumina/Blind Holes of the Instrument 5 Times using a disposable Syringe (minimum Volume 5ml, if necessary with fitted Cannula).
7. Dry the Instruments with filtered compressed Air.
8. Package the Instruments immediately after removing from the Disinfectant and Drying (*see 5. Packaging*), if necessary after additional Drying at a clean Place.

The Evidence of Qualification of the Instruments for effective manual Cleaning and Disinfection was provided by an independent accredited Test Laboratory using the Detergent Cidezyme/Enzol and the Desinfectant Cidex opa (Johnson & Johnson GmbH, Norderstedt). At this the procedure described above was followed.

3. Inspection

Inspect all Instruments after Cleaning respectively Cleaning/Disinfection on Corrosion, damaged Surfaces, loose Scews, Springs and Tool Tips, Spalling as well as visible Contamination.
Separate damaged Instruments (*numerical Limitation of Reuse see 9. Reusability*).
Still contaminated Instruments must be cleaned and disinfected again.

4. Maintenance

Due to the utilised Materials – proper Handling and Reprocessing assumed – a Treatment with any Rust Protection Spray is neither required nor allowed.
If possible, Instrument Lubricants should not be used. Nevertheless, if required, e. g. for movable Instruments, make sure that only Instrument Lubricants (White Oil) will be used, that in Consideration of the maximum applied Sterilisation Temperature are strictly qualified for Steam Sterilisation and have a proved Biocompatibility.
In that case apply the Lubricant sparingly to the movable Parts (NOT the total Instrument).
We recommend neodisher®IP Spray (Dr. Weigert GmbH & Co. KG, Hamburg).

5. Packaging

If allowed, reassemble the Instruments (see 10 *Product-specific Instructions*).
Sort the cleaned disinfected Instruments into Sterilisation Trays.
The Use of Sterilisation Trays with close-fitting Retainers with Regard to the Contact Area (Instrument – Retainer) can affect the Sterilisation Efficiency (Evidence of Qualification under Responsibility of the User).

Package the Instruments (respectively the Sterilisation Trays) into Disposable Sterilisation Packaging (single or double Packaging) and/or Sterilisation Containers according to the following Requirements:
- DIN EN ISO 11607/ANSI AAMI ISO 11607
- qualified for Steam Sterilisation (Temperature Resistance at least 141 °C, sufficient Steam Permeability)
- sufficient Protection of the Instruments and Sterilisation Packaging against mechanical Damage
- periodically maintained according to the Manufacturers Instructions (Sterilisation Containers)

6. Sterilisation

Attention: Several Instruments cannot be sterilised in assembled Condition (see 10 *Product-specific Instructions*)!

For Sterilisation only the following Sterilisation Procedures are applicable; other Sterilisation Procedures are not valid.

Steam Sterilisation
- Fractionated Vacuum Method or Gravitation Method (with sufficient Drying Procedure)
  The Use of the less effective Gravitation Method should be applied only if the Fractionated Vacuum Method is unavailable.
- Steam Steriliser according to DIN EN 13060 / DIN EN 285
- validated according to DIN EN ISO 17665 (former: DIN EN 554 / ANSI AAMI ISO 11134) (valid IQ/OQ (Commissioning and product-specific Performance Assessment))
- maximum Sterilisation Temperature 138 °C (280 °F, plus Tolerance according to DIN EN ISO 17665 (former: DIN EN 554 / ANSI AAMI ISO 11134))
- Sterilisation Time (Exposure Time while Sterilisation Temperature) at least 20 min at 121 °C (250 °F) or 3 min at 132 °C (270 °F)/134 °C, *respectively 18 min at 132 °C (270 °F)/134 °C (Deactivation of Prions)*

The Evidence of Qualification of the Instruments for effective Steam Sterilisation was provided by an independent accredited Test Laboratory using the Steam Steriliser Systec V-150 (Systec GmbH Labor-Systemtechnik, Wettenberg) using both the Fractionated Vacuum Method and the Gravitation Method. At this usual Conditions in Medical Practices and Hospitals as well as the procedure described above were followed.

The Flash Sterilisation Procedure is strictly NOT allowed.

Furthermore do NOT use Hot Air Sterilisation, Irridation Sterilisation, Formaldehyde Sterilisation, Ethylene Oxide Sterilisation or Plasma Sterilisation.

7. Storing

Store the Instruments between Uses in the Sterile Package in a dry and dust-free Place.

8. Resistance of Materials

Please make sure within the Choice of the Detergents and Disinfectants, that the following Chemicals are NOT included:
- organic, mineral und oxidating Acids (minimum allowable pH-value 5.5)
- strong Bases (maximum allowable pH-value 10, neutral/enzymatic or alkalescent Detergent recommended)
- organic Solvents (e. g. Ethers, Ketones, Benzines)
- Oxidants (e. g. Peroxides)
- Halogens (Chlorine, Jodine, Bromine)
- aromatic and halogenated Hydrocarbons

NEVER use Metal Brushes and Steel Wool for Cleaning the Instruments and Sterilisation Trays.

NEVER expose the Instruments to Temperatures above 141 °C (286 °F)!

9. Reusability

The Instruments can – adequate Carefulness assumed and unless they are undamaged and not contaminated – be reused, as long as a sufficient Function and Assembly is possible.

Product Life Time is heavily varying dependent upon the Handling, a Specification of a Number of Reprocessing Cycles is not practicable.
Each furthermore Reuse or Use of damaged or contaminated Instruments runs under the Responsibility of the User.

Disregarding this the Manufacturer excludes any Reliability.

10. Product-specific Instructions

10.1 Forceps, Scissors:
Pre-treatment, Manual Cleaning and Disinfection: Open and close the Instrument during Rinse Processes several Times.
Frequently open and close the Instrument several Times when it is placed in Cleaning Solution.
Machine Cleaning/Disinfection: ONLY in half opened Position, if necessary fixed on the Disinfector Basket.

10.1.1 Band and Bracket Remover Pliers with removable Plastic-Tip (HSL 2221-14, HSL 22111-14, HSL 2211-14, HSL 22211-14, HSL 222-14, HSL 221-12):
(In Addition to 10.1) For Cleaning and Disinfection remove the Plastic-Tip. Reassemble it before Packaging und Sterilisation.
Damaged or aged Plastic-Tips (Fissures, Flaws, rough Surface, Discolouration, ...) must be replaced.

10.2 Handles for Mouth Mirrors, Cheek Retractors and Curettes:
Caution: For Cleaning, Disinfection and Sterilisation disassemble the Instruments.
An effective Processing in assembled Condition is not possible.
For Machine Cleaning/Disinfection place the Instruments into the Disinfector with the Opening down.

10.3 Clamping Tweezers:
Pre-treatment, Manual Cleaning and Disinfection: Open and close the Instrument during Rinse Processes several Times.
Frequently open and close the Instrument several Times when it is placed in Cleaning Solution.
Machine Cleaning/Disinfection: ONLY in half opened Position, if necessary fixed on the Disinfector Basket.

11. Risks that are combined with the use of the instrument

This instrument is permanently subjected to a risk control process. In this context all known risks were minimised by means of product design and furthermore by explicit instructions and warnings.

Nevertheless are existing residual risks by use of the instrument, particularly:
- Infection and tissue reactions caused by contamination
- Biological incompatibility
- (Cross-) infection
- Infection of personnel with used instruments
- Swallowing or Aspiration of loosened Parts

The control of these residual risks rests with the user. An indefensible increase in the risks will be caused particularly by:
- Use by not sufficiently qualified and skilled personnel.
- Default or shortening of the Processing Instructions respectively processing in a not validated process.
- Handling, processing and disposal by not sufficiently qualified personnel.
- Non-compliance with the instructions for the inspection for damage and wear before packaging into the sterilisation packaging.
- Use/Reuse of contaminated, corroded, damaged or worn instruments.
- Non-compliance or incomplete compliance with the Processing Instructions.