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EFFECTUM MEDICAL
YOUR START-UP TO MARKET

Processing (Cleaning, Disinfection and Sterilization) Instructions

Femoral Trial Component

A. PURPOSE

This document contains recommendations for the safe handling, effective care, cleaning, disinfection and sterilization of Effectum Medical reusable surgical instruments, instrument trays and cases. The information provided does not apply to Effectum Medical implants.

B. INTRODUCTION

All instruments are to be cleaned, disinfected and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

You are responsible for the sterility of the instruments. Therefore, please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD (Washer-Disinfector), Sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Please pay attention to avoid a higher contamination of the complete sterilization tray during application by separate collection of contaminated instruments (without laying back into the sterilization tray). Pre-clean the contaminated instruments, clean, disinfect, then sort them back into the sterilization tray and sterilize the completely equipped sterilization tray.

Instruments shall to be cleaned separate from instruments trays and cases, also lids shall be removed from cases prior to cleaning.

Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions.

ATTENTION: In case additional or deviating procedures are required for specific instruments, see chapter SPECIFIC ASPECTS.

C. CLEANING AND DISINFECTION

C.1. BASICS

If possible, an automated procedure (WD) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered[1].

The pre-treatment step is to be performed in both cases.

C.2. PRE-TREATMENT

Body fluids and tissue should not be allowed to dry on instruments, please remove any impurities after application but within a maximum of 2 hours. To avoid contamination, soiled devices should be separated from non-contaminated devices.

Pay attention to the following points during selection of the cleaning detergent [2]:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the cleaning detergent with the instruments (see chapter C9 MATERIAL RESISTANCE)

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

PROCEDURE

a. Disassemble the instruments as far as possible (see chapter E DISSASSEMBLY INSTRUCTION).
b. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F). Actuate movable parts at least three times during pre-rinsing if applicable (see chapter D SPECIFIC ASPECTS).
c. Rinse all lumen of the instruments at least three times at the beginning of the soaking time.
d. Soak the disassembled instruments for the given soaking time (but not less than 5 min) in the pre-cleaning solution[2] (ultrasonic bath, ultrasound not activated) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush (at beginning of soaking, aids see chapter D SPECIFIC ASPECTS). Actuate movable parts at least three times during pre-cleaning if applicable (see chapter D SPECIFIC ASPECTS).
e. Rinse all lumen of the instruments at least three times at the end of the soaking time.
f. Activate ultrasound for an additional soaking time (but not less than 5 min).
g. Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Actuate movable parts at least three times

during post-rinsing, if applicable (see chapter D SPECIFIC ASPECTS). Rinse all lumen of the instruments at least three times during post-rinsing.

C.3. AUTOMATED CLEANING / DISINFECTION

Pay attention to the following points during selection of the washer-disinfector (WD):

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- possibility for an approved program for thermal disinfection (A0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection – danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Pay attention to the following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter C.9. Material Resistance)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

PROCEDURE:

a. Disassemble the instruments as far as possible (see chapter E DISSASSEMBLY INSTRUCTION)
b. Transfer the disassembled instruments in the WD (pay attention that the instruments have no contact).
c. Connect the instruments to the rinsing port of the WD if applicable (see chapter D SPECIFIC ASPECTS)
d. Start the program.
e. Disconnect from rinsing port if applicable and remove the instruments of the WD after end of the program.
f. Check and pack the instruments immediately after the removal ((see chapter C.4 VISUAL INSPECTION / FUNCTION TESTING, chapter E. DISSASSEMBLY INSTRUCTION, chapter C.6. PACKAGING and chapter F. PLACEMENT SPECIFICATION FOR STERILIZATION), if necessary after additional post-drying at a clean place).

C.4. VISUAL INSPECTION / FUNCTION TESTING

Reusable instruments shall be visually inspected carefully prior to sterilization for the following characteristics:

Cleanliness:	Ensure that all visible blood or other impurities have been removed.
Damage or wear:	Visually inspect for damage, including but not limited to, corrosion, damaged surfaces cracks or wear.
Functionality:	Including but not limited to sharpness of cutting devices, movement of joints and couplings (see chapter D. SPECIFIC ASPECTS)

Do not further use damaged instruments (for limitation of the numbers of re-use cycles see chapter C.10. REUSABILITY).

Still dirty instruments are to be cleaned and disinfected again.

C.5. MAINTENANCE

Assemble disassembled instruments again (see chapter E. DISSASSEMBLY INSTRUCTION).

Lubricate hinges, threads and other moving parts according to chapter E. DISSASSEMBLY INSTRUCTION. Use only instrument oils (white oil) admitted to steam sterilization, considering the maximum possible sterilization temperature and with approved biocompatibility. DOnly apply a small amount to the relevant location (no sprayingof the complete instrument!).

For several instruments, the use of instrument oils must not be performed (see chapter D. SPECIFIC ASPECTS).

C.6. PACKAGING

Insert the cleaned and disinfected instruments in standard sterilization trays (see chapter F. PLACEMENT SPECIFICATION FOR STERILIZATION) and pack them in sterilization containers, which fulfill the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)

A maximum weight of 7.2kg per content of the sterilization container must not be exceeded.

C.7. STERILIZATION

Please use for sterilization of Effectum Medical devices only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure[3, 4], (with sufficient product drying[5])

- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 138 °C (280 °F; plus, tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature)

The following parameters are to be used for the sterilization of Effectum Medical devices with fractionated vacuum and dynamic air removal:

Area	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Drying Time (minutes)
USA	4	132°C (270°F)	20[5]
Germany	5[6]	134°C (273°F)	
Other countries	4	132°C (270°F) / 134°C (273°F)	

The sterilizer manufacturer's operating instructions shall be followed. When sterilizing multiple instruments in one steam sterilization cycle, ensure that the maximum sterilization load is not exceeded. Drying times will vary according to load size and should be increased for larger loads.

The sterilizer must be properly installed, calibrated, validated and maintained.

ATTENTION: Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, flash/immediate use sterilization as well as plasma sterilization!

C.8. STORAGE

Packaged products should be stored in a dry, dust-free environment, protected from direct sunlight, pests and extremes of temperature and humidity.

C.9. MATERIAL RESISTANCE

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:

- organic, mineral or oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum admitted pH-value 10.1, neutral/enzymatic or weak alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons
- oil (only silicone parts)

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.

Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments and sterilization trays by use of metal brushes or steel wool.

Please do not expose any instruments and sterilization trays to temperatures higher than 142 °C (288 °F)!

C.10. REUSABILITY

The instruments can be reused – in case of adequate care and if they are undamaged and clean – for 100 reprocessing cycles or a maximum of 5 years after the date of manufacture (the earliest occurrence of the two is applicable), unless otherwise indicated in chapter D. SPECIFIC ASPECTS. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

D. SPECIFIC ASPECTS

n/a

E. DISSASSEMBLY INSTRUCTION

n/a

F. PLACEMENT SPECIFICATION FOR STERILIZATION

n/a

G. SPARE PARTS

n/a

H. ADDITIONAL INFORMATION

The instructions provided above have been validated as being capable of preparing reusable surgical instruments.

An independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory demonstrated the fundamental suitability of the instruments for an

- EFFECTIVE AUTOMATED CLEANING AND DISINFECTION by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the pre-

cleaning and cleaning detergent Neodisher Mediclean (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

- EFFECTIVE STEAM STERILIZATION by application of the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum/dynamic air removal procedure.

For this, typical conditions in clinic as well as the specified procedure were considered.

It is the responsibility of the processor to ensure that reprocessing is performed using the appropriate equipment and materials and that personnel in the reprocessing facility has been adequately trained in order to achieve the desired results. This normally requires validation and routine monitoring of the process. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Please ensure latest revision of Care & Maintenance Instruction available at Effectum Medical.

I. CUSTOMER SERVICE INFORMATION

For further information, please contact:

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1 In case of application of a manual cleaning and disinfection procedure a product and procedure specific validation under sole responsibility of the user is required.
2 In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel's safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (see chapter C.9. Material Resistance). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel's safety, but cannot replace the disinfection step later to be performed after cleaning.
3 At least three vacuum steps
4 The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure and requires a sterilizer, program, parameter, and product specific validation under sole responsibility of the user.
5 The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...)
and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.
6 respectively 18 min (inactivation of prions, not relevant for USA)