

Processing (cleaning, disinfection, and sterilization) of surgical needles

1 Fundamental points

All surgical needles 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 surgical needles (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 surgical needles.

You are responsible for the sterility of the surgical needles. 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, sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the doctor's practice or of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions (not relevant for USA).

Please pay attention to the additional and deviating requirements as specified in chapter "Specific aspects".

2 Cleaning and disinfection

2.1 Basics

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the surgical needles. 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.

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

2.2 Pre-treatment

Please remove coarse impurities of the surgical needles directly after application (within a maximum of 2 h).

1. Rinse the surgical needles at least 1 min under running water¹ (temperature < 35 °C/95 °F).
2. Remove manually all visible impurities by use of a clean and soft brush (or a clean, soft, and lint-free cloth) only to be for this, in no case metal brushes or steel wool.
3. Rinse again at least 1 min under running water

¹ 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 surgical needles (see chapter „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.

2.3 Automated cleaning/disinfection (WD (Washer-Disinfector))

Pay attention to following points during selection of the 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 surgical needles)
- fundamental suitability of the program for the surgical needles 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 following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- only use of detergents, which do not require neutralisation by acid.
- 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 surgical needles (see chapter „material resistance,.)

Rinsing agent must not be used (Use of recommended water quality improves drying and avoids spots).

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

1. Transfer the surgical needles in a small parts basket into the WD (pay attention that the surgical needles have no contact).
2. Start the program.
3. Remove the surgical needles of the WD after end of the program.
4. Check and pack the surgical needles immediately after the removal (see chapters „check,, „maintenance,, and „packaging,, if necessary after additional post-drying at a clean place).

The fundamental suitability of the surgical needles for an effective automated cleaning and disinfection was demonstrated by an independent accredited test laboratory by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal

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

2.4 Manual cleaning and disinfection

Pay attention to following points during selection of the cleaning and disinfection detergents:

- fundamental suitability for the cleaning and disinfection of instruments made of metallic or plastic material
- in case of application of an ultrasonic bath: suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- application of a disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible with the used cleaning detergent
- compatibility of the used detergents with the surgical needles (see chapter „material resistance,“)

Combined cleaning/disinfection detergents should not be used.

Only in case of extremely low contamination (no visible impurities) combined cleaning/disinfection could be used.

Pay attention to the instructions of the detergent manufacturers 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.

Cleaning

1. Soak the surgical needles for the given soaking time in the cleaning solution so that the surgical needles are sufficiently covered. Pay attention that there is no contact between the surgical needles. Assist cleaning by careful brushing with a soft brush or with ultrasonic treatment.
2. Then, remove the surgical needles of the cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water.
3. Check the surgical needles (see chapters „check,“ and „maintenance,“).

Disinfection

4. Soak the surgical needles for the given soaking time in the disinfectant solution so that the surgical needles are sufficiently covered. Pay attention that there is no contact between the surgical needles.
5. Then, remove the surgical needles of the disinfectant solution and post-rinse them at least five times intensively (at least 1 min) with water.
6. Dry and pack the surgical needles immediately after the removal (see chapter „packaging,“, if necessary after additional post-drying at a clean place).

The fundamental suitability of the surgical needles for an effective cleaning and disinfection was demonstrated by an independent accredited test laboratory by application of the cleaning detergent Cidezime/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt) considering the specified procedure.

3 Check

Check all surgical needles after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities. Do not further use damaged surgical needles (for limitation of the numbers of re-use cycles see chapter „reusability,“). Still dirty surgical needles are to be cleaned and disinfected again.

4 Maintenance

Instrument oils must not be used.

5 Packaging

Please insert the cleaned and disinfected surgical needles in the corresponding sterilization trays (e.g. REF 8900-250x200x45, Ernst Kratz GmbH, Dreieich). Packaging without sterilization box is not recommended (danger of damage of the sterilization packaging or of injury).

Please pack the sterilization trays in single-use sterilization packagings (single or double packaging) and/or 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 surgical needles as well as of the sterilization packagings to mechanical damage

Beschränkung der Wiederverwendung siehe Kapitel „Wiederverwendbarkeit,“. Noch verschmutzte Wundnadeln müssen erneut

6 Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure^{2,3} (with sufficient product drying⁴)
- 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) at least 5 min⁵ at 132 °C (270 °F)/134 °C (273 °F)
- 2 at least three vacuum steps
- 3 The less effective gravity displacement procedure must not be used.
- 4 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.
- 5 respectively 18 min (inactivation of prions, not relevant for USA)

The fundamental suitability of the surgical needles for an effective steam sterilization was demonstrated by an independent accredited test laboratory 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 and doctor's practice as well as the specified procedure were considered.

The flash sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

7 Storage

Please store the surgical needles after sterilization in the sterilization packagings at a dry and dust-free place.

8 Material resistance

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

- organic, mineral, and oxidizing acids (minimum admitted pH-value 6.5)
- stronger lyes (maximum admitted pH-value 10.2, 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

Please do not clean any surgical needles, sterilization trays, and sterilization containers by use of metal brushes or steel wool.

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

9 Reusability

The surgical needles can be reused – in case of adequate care and if they are undamaged and clean – 10time. The user is responsible for each further use as well as for the use of damaged and dirty surgical needles (no liability in case of disregard).

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Specific aspects

Art. no	rinsing volume	Cleaning aids	specific/additional procedure in case of				packaging / sterilization	maximum admitted cycle number	recommended classification according to RKI/BfArM/ KRINKO guideline (only Germany, with respect to intended use)
			pretreatment	manual cleaning/ disinfection	automated cleaning/ disinfection	Maintenance			
surgical needles	-	tooth brush	brush outside		in closed small parts basket	lubrication not admitted	standard procedure	30	critical B
all sterilization trays	-	-	Dismantle sterilization tray into bowl, lid, and mat, Brush lid and bowl outside and inside, brush all sides of the mat intensively	not recommended as less effective: Dismantle sterilization tray into bowl, lid, and mat, Brush lid and bowl outside and inside, brush all sides of the mat intensively	dismantle sterilization tray into bowl, lid, and mat opening downwards each	lubrication not admitted	standard procedure maximum admitted total weights (REF 8900-250X200X45: 1470 g, REF 8900-500X200X45: 2760 g)	-	-