Update Hygiene and maintenance according to EN ISO 17664:2017

PEOPLE HAVE PRIORITY

Contents

W&H Symbols

WARNING!
(risk of injury)

ATTENTION!
(to prevent
damage occurring)

General explanations,
without risk to
persons or objects

Thermo washer
disinfectable

Sterilizable up to the
stated temperature

Hygiene and maintenance prior to initial use

> The medical device is sealed in PE film and not sterilized when delivered.
> The PE film and the packaging are non-sterilizable.

> Clean, disinfect and lubricate the medical device.
> Sterilize the medical device.

Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.

This hygiene update in accordance with EN ISO 17664: 2017 supplements the chapter Hygiene and maintenance of the attached instructions for use.

> Wear protective clothing, safety glasses, face mask and gloves.

> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.

Cleaning agents and disinfectants

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
> Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
> It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
> Use disinfectants which have been tested and found effective by the Verbund für Angewandte Hygiene e.V (VAH = Association for Applied Hygiene), the Österreichischen Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA).

The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.

The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

> Send worn or damaged medical devices and/or medical devices with material changes to an authorized W&H service partner.

Processing cycles

> We recommend a regular service for the W&H medical device in accordance with the attached instructions for use .

Clean the medical device immediately after every treatment, to flush out any liquid (e.g., blood, saliva etc.) and to prevent settling on the internal parts.

> Operate the medical device for at least 10 seconds at idle speed.*
> Ensure that all outlets are rinsed out.*

> Wipe the entire surface of the instrument with disinfectant.
> Remove the root canal instrument.*
> Remove the medical device.*

Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfectant step after cleaning.

*if applicable

Do not place the medical device in liquid disinfectant or in an ultrasonic bath!*

> Clean the medical device under running tap water (<35°C / 95°F).
> Rinse and brush off all internal and external surfaces.
> Move moving parts back and forth several times.*
> Remove any liquid residues using compressed air.

*if applicable

W&H recommends automated cleaning and lubrication with W&H Assistina 3x3.

> Follow the instructions in the Assistina Instructions for use.

*if applicable

> W&H recommends wiping down with disinfectant.

Evidence of the medical device's basic suitability for effective manual disinfection was provided by an independent test laboratory using the »mikrozid® AF wipes« disinfectant (Schülke & Mayr GmbH, Norderstedt).

W&H recommends automated cleaning and disinfection using a washer-disinfector (WD).
> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of washer-disinfectors, cleaning agents and/or disinfectants.

Evidence of the medical device's basic suitability for effective automated disinfection was provided by an independent test laboratory using the »Miele PG 8582 CD« washer-disinfector (Miele & Cie. KG, Gütersloh) and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg).
> Cleaning at 55 °C (131 °F) – 5 minutes
> Disinfection at 93 °C (200 °F) – 5 minutes

*if applicable

> Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
> Remove any liquid residues using compressed air.

Inspection

> Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
> Reprocess any medical devices that are still soiled.
> Sterilize the reassembled medical device following cleaning, disinfection and lubrication*.

*if applicable

See enclosed Instruction for use!

Pack the medical device and the accessories in sterilization packages that meet the following requirements:

> The sterilization package must meet the applicable standards in respect of quality and use and must be suitable for the sterilization method.
> The sterilization package must be large enough for the sterilization goods.
> The filled sterilization package must not be under tension.

W&H recommends sterilization according to EN 13060, EN 285 oder ANSI/AAMI ST79.

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of steam sterilizers.
> The program selected must be suitable for the medical device.

Recommended sterilization procedures

> Fractionated pre-vacuum process (type B)
> Gravity displacement process (type N)
> Sterilization time at least 30 minutes at 121°C (250°F) or at least 3 minutes at 134°C (273°F)
> Maximum sterilization temperature 135°C (275°F)

> Evidence of the medical device's basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L steam sterilizer (Firma W&H Sterilization S.r.l., Brusaporto (BG)) and the CertoClav MultiControl MC2-S09S273 gravitation sterilizer (CertoClav GmbH, Traun).
> Fractionated pre-vacuum process (type B): temperature 134°C (273°F) – 3 minutes*
> Gravity displacement process (type N): temperature121°C (250°F) – 30 minutes**

* according to EN 13060, EN 285, ISO 17665 / ** according to ANSI/AAMI ST55 , ANSI/AAMI ST79

> Store sterile goods dust-free and dry.
> The shelf life of the sterile goods depends on the storage conditions and type of packaging.

Manufacturer

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Form-Nr. 51013 AEN
Rev. 000 / 21.11.2018
Subject to alterations