OSSTELL
A W&H COMPANY

SmartPeg reusable

Cleaning and maintenance

Prior to the first clinical use, and after each use the reusable products must be cleaned, disinfected and sterilized according to the instructions below:

POINT OF USE-INITIAL TREATMENT

After use products should as far as possible be kept moist or immersed in sterile water during the clinical procedure to avoid drying.

After the clinical procedure the product should be disinfected by either immersion in a bath or wiping with a disinfectant wipe.

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

CLEANING/DISINFECTION

Manual cleaning/disinfection

> Clean the products under running tap water (< 35°C / < 95°F).
> Rinse and brush off all surfaces (1 minute minimum) until no visible contaminants / soil remain.
> Manual Disinfection after manual cleaning in immersion bath with suitable disinfectant solutions. It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.

Manual cleaning was validated with running tap water for 1 minute.

Manual disinfection was validated using disinfectant CaviCide (Kerr Dental), exposure time: 3 minutes

CLEANING/DISINFECTION

Automated cleaning/disinfection

Suitable washer disinfectors as well as cleaning and neutralization agents are to be used for automated cleaning. The instructions from the manufacturer of the washer disinfector must be followed. Cleaning and neutralization agents are to be dosed and used in accordance with the manufacturer's instructions.

A cleaning program with thermal disinfection (A0 ≥ 3000) is recommended.

Either demineralized water or water which satisfies this level of purity is recommended for the disinfection.

> Step 1 Pre-cleaning cold tap water (< 40 °C) for 1 minute.
> Step 2 Cleaning 0.5% cleaner 55°C for 5 minutes
> Step 3 Rinsing with tap water for 1 minute
> Step 4 Thermal disinfection with demineralised water >90°C for 5 minutes

Automated cleaning/disinfection was validated in a washer-disinfector type Miele Professional PG8581 using the cleaning agent neodisher® MediClean forte (0.5%, from Dr. Weigert) in the Vario TD program.

INSPECTION AFTER CLEANING

Before sterilization, all products must be inspected with the naked eye for visible soil, impairments and/or corrosion.

Particular attention should be paid to design features such as, threads and mating surfaces. If remaining soil/contamination is detected, re-perform the cleaning process. Check all markings on products for visibility and readability by inspection with the naked eye. Defective products must be discarded.

STERILIZATION

Sterilization is to be performed corresponding to the following instruction:

Preparation for sterilization:

Place components in an approved sterilization pouch (for the US market: FDA-cleared) for use with the recommended sterilization parameters. Packaging must comply with the requirements according to EN ISO 11607, ANSI/AAMI ST79 and AAMI TIR12.

Every sterilization package must have a sterilization indicator and sterilization date.

Parameters

(acc. to ISO 17665, EN 13060, EN 285 and AAMI TIR12)

Method	Cycle	Temperature	Exposure time	Dry time
Steam	Dynamic air removal (prevacuum)	134° C	3 min	20 min
Steam	Dynamic air removal (prevacuum)	132° C (270°F) 135° C (275°F)	4 min 3 min	20 min
Steam	Gravity	134° C (273° F)	10 min	30 min

Validation was performed with the products wrapped in Steriking® See-Through Heat Sealable Rolls sterilisation packing acc. to EN ISO 11607 using a steriliser type Tuttnauer 3870 HSG for the dynamic air removal steam sterilisation process with 3 pre-vacuum pulses.

STORAGE

Store the sterilized components in dry and dust-free environment at room temperature.

Lifetime

The reusable SmartPeg can be expected to function after being reprocessed **up to 20 times as long as the integrity and performance of the product are maintained.**

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