KeyGuide® Surgical Guide Steam Sterilization Validated Instructions

KeyGuide is a disposable medical device, customized (3d printed) for a single-patient; indicated for intra-oral use in guided dental implant surgery by a dental professional. The 3D printed medical device requires steam sterilization prior to use in surgery via the validated process entailed below.

A validated sterilization process is used to render the medical device free from viable microorganisms. Note that in a sterilization process, the nature of the microbial death is expressed in terms of probability and although reduced to a very low number, it can never be reduced to zero.

PRE-STERILIZATION

1. CLEANING

Thoroughly remove any visible soil remaining on the surface. Alcohol can be used to wipe the surface of the surgical guide to ensure a clean part is resulted from this process. No contamination shall be found by the naked eye or felt by running fingers on the surface of the part. Special attention should be given to edges, hollows and other geometries.

2. DRYING

Dry the part, especially in the hollows and geometries. Compressed air can be used for air drying the medical device.

3. INSPECTION

Once dried, inspect the medical device for damage or cracks. Replace the part if needed.

4. PACKAGING

Only use sterilization pouches in compliance with the requirements according to DIN EN ISO 11607/ ANSI/AAMI ST79/AAMI TIR12:2010, e.g. disposable sterilization packages (single or double packages) temperature-resistant up to at least 137 °C (279 °F) and sufficient steam permeability.

Follow the instructions for use provided by the packaging manufacturer when packaging the medical device prior to sterilization. Any labeling should be placed or written on the non-porous side of the pouches. When sealing, pouch seals should be smooth and free from bubbles, wrinkles, and folds. Paper–plastic pouches containing the medical device should not be placed within wrapped sets or containment devices.

Consult the instructions for use provided by the sterilizer manufacturer regarding the use of any sterilizer accessories. Sterilizing equipment should have demonstrated efficacy (e.g. FDA clearance, EN 13060 or EN 285 compliance).

STERILIZATION

Note: Packaged medical devices must be placed on edge to prevent the collection of condensate that could impede device and package drying and to ensure appropriate exposure of the medical device to the sterilant. Place the packaged medical devices in the chamber in a manner that allows for adequate air removal, penetration of steam into each package, and steam evacuation. Follow the steam autoclave processing directions for your region per the below parameters. See table below.

PROCESSING PARAMETERS FOR THE UNITED STATES AND COUNTRIES FOLLOWING THE US STEAM STERILIZATION GUIDELINES:

Sterilizer Type:	Prevacuum
Preconditioning Pulses:	4
Temperature:	132°C
Full Cycle Time:	4 minutes
Dry Time:	30 minutes
Test Article Configuration:	Individually double pouched in 5.5" x 10" and 7.5" x 13" pouches (Cardinal Health self-sealed pouch CAT #92713-510(k) K153540); Packaged test articles placed on edge in the chamber

PROCESSING PARAMETERS FOR THE EUROPEAN UNION(EU) AND OTHER COUNTRIES FOLLOWING THE EU STEAM STERILIZATION GUIDELINES:

Sterilizer Type:	Prevacuum
Preconditioning Pulses:	4
Temperature:	134°C
Full Cycle Time:	3 minutes
Dry Time:	30 minutes
Test Article Configuration:	Individually double pouched in 5.5" x 10" and 7.5" x 13" pouches (Cardinal Health self-sealed pouch CAT #92713-510(k) K153540); Packaged test articles placed on edge in the chamber

POST STERILIZATION

After exposure of the medical device to the full sterilization set points, allow the device to cool with the sterilizer load. The packaged devices should not be handled prior to cooling. A minimum drying time of 30 minutes is recommended; longer drying times may be required depending on the equipment, loading configuration, and ambient conditions present in the sterilization area.

STORAGE

The products should be stored, in their package, in a dry place, at normal temperature (18–25°C/64–77°F). Use the sterilized components within the stated time period from the sterile bag manufacturer.

Do not reuse
When "Do not reuse" devices are supplied non-sterile and require sterilization prior to usage, the appropriate sections in these guidelines may be applied.

Do not resterilize
Devices are not designed to perform as intended after the first usage or an additional sterilization process. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use, cleaning and/or resterilization may compromise the integrity of the design and/or material, leading to diminished safety, performance and/or compliance with relevant specifications.

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Rev 01/2021