



To whom it may concern

Sterilization of Laryngoscope System

Hygiene is an issue where requirements as well as risks are always increasing. The goal is to constantly improve the protection of patients and users from contamination which could be transferred by medical devices.

In the field of intubation we realize that the requirements for the reprocessing of **Laryngoscope Handles** are stronger than ever before.

Until now Heine has only allowed the steam sterilization of the outer sheath of our laryngoscope handles. To improve this situation, we tested and modified our laryngoscope handles to allow for sterilization as a complete system. With the incorporation of a new material* for the green ISO marking ring we can now confirm that

Heine Laryngoscope handles, including all components: outer sheath, inner sheath, bulb, alkaline battery / rechargeable battery, and all green ISO marking elements are approved for Sterrad® Sterilizers (NX, 50, 100S, 100NX, 200).

*Heine Laryngoscope handles manufactured from May 2008 on are compatible with STERRAD NX and 100NX (Date code FM and on). Handles with no date code were manufactured before May 2008 can be upgraded for compatibility with STERRAD NX and 100NX sterilizers.

This sterilization procedure, also referred to as Low Temperature Gas Plasma Sterilisation, allows for the sterilization of a wide range of medical devices which are not temperature resistant. The manufacturer of the Sterrad System is Johnson & Johnson.

Our Classic+ Laryngoscope Blades and Laryngoscope handles have been tested in Sterrad system sterilizers. After a detailed assessment of the function and appearance we approve these products and all components for currently available Sterrad® sterilizers (NX, 50, 100S, 100NX, 200).

Please see the attached confirmation and the revised Instruction for Use.

Kind Regards,

HEINE OPTOTECHNIK GmbH & Co. KG
Director Quality Management


Claudia Schwieger