



The following instructions must be followed according to national standards, laws and guidelines. Any such measures must be carried out by qualified personnel.

HEINE Fiber Optic Laryngoscope Reprocessing

MANUAL PRE-CLEANING

Clean immediately after intubation to prevent the drying-on of residues. We recommend wiping with wet cleaning tissues or washing with a SOFT nylon brush and cleaning solution. Cleaning agent: enzymatic or neutral to mildly alkaline (e.g. Neodisher MediClean) After cleaning, rinse blades thoroughly with demineralized water & dry at 65 °C max.

MACHINE CLEANING AND DISINFECTION

For manual cleaning and disinfection, only those products which are approved for use on medical devices made of **stainless steel** and **fiber optics** may be used. The manufacturer's recommendations for use must be followed to avoid material damage / corrosion. After treatment, the instrument must be thoroughly rinsed with demineralized water to avoid surface residues.

Blades can be machine cleaned and disinfected at 93° C. The machine should be loaded correctly so that the cleaning procedure is successful. Rinsing procedures must ensure that no deposits are left. The final rinse should be carried out using demineralized water. Cleaning agent enzymatic or alkaline (e.g. Neodisher MediClean)

CAUTIONS

- Never immerse blades in physiological saline solutions or any cleaning / disinfecting detergents which contain hydrogen peroxide (e. g. Cidex PA, Sporox, Virox 3, Peroxide bleaches) or halide ions (chlorides and iodides) or any other caustic ingredients (e.g. scrub solution).
- Do not sterilize Laryngoscopes in same tray / in close contact with sub-standard stainless steel surgical instruments. Such instruments can rust and cause corrosive damage to blades.
- Flash Sterilization IS NOT an approved method of Sterilization. Blades damaged due to Flash Sterilization will not be covered under warranty. "Flash Sterilization" is described as any cleaning method that rapidly heats and cools the instrument.
- NO Ultrasonic Cleaning.

HIGH LEVEL DISINFECTION

Currently approved Chemical Disinfectants – Cidex and Cidex OPA.

STERILIZATION

Before using the techniques listed below, the instrument must be cleaned and disinfected.

Vacuum or Gravity autoclaving

- Fractionated vacuum procedure (3 times): Sterilization temp.: at least 132°C (max. 134°C) Application time: at least 3 min.; Holding time: at least 3 min.; Drying time: at least 20 min.
- Gravitation procedure (3 times): Sterilization temp.: at least 132°C (max. 134°C) Application time: at least 3 min.; holding time: at least 3 min.; drying time: at least 20 min.

Low temperature **Gas-Plasma-Sterilization** (Sterrad®; Steris®) and Gas Sterilization with **Ethylene oxide** (subject to the usual procedure laid down for anesthetic devices) are permitted for Laryngoscope blades.



HEINE Fiber Optic Laryngoscope Handle Reprocessing

It is our recommendation that the outer sleeve of our Laryngoscope handles be minimally high-level disinfected or sterilized. The inner battery / illumination compartment can be low-level disinfected or in some cases sterilized (see details below).

Recommended procedures below.

OUTER HANDLE SLEEVE

The outer shell of the handles can be processed in the same ways listed for our Blades.

INNER BATTERY / ILLUMINATION COMPARTMENT

Unless utilizing the STERRAD system (see below), all handle insert and / or illumination components may only be low level disinfected (wiped down). The insert is not waterproof, for this reason, **DO NOT IMMERS**E IN ANY SOLUTIONS WHAT-SO-EVER. The insert may be wiped down with an alcohol swab or disinfecting tissue 3 times with a rotating motion in the area of the bulb and 3 times with downward strokes on the handle. Care should be taken not to allow moisture to penetrate the area around the bulb or the base of the handle insert.

COMPLETE HANDLE STERILIZATION USING STERRAD SYSTEMS

The following pertains to all HEINE Xenon Laryngoscope handles manufactured after May 2008*

The entire Xenon bulb illuminated HEINE Laryngoscope handle, including all components: outer sleeve, inner battery sleeve and / or illumination components, **bottom cap**, Xenon bulb, alkaline or rechargeable batteries, and all green ISO marking elements are approved for STERRAD Sterilizers (including NX).

*All handles made after May 2008 have a 2 letter code on the head of the outer handle sleeve.

If your handles do not have a date code, contact your HEINE representative for information on converting your handles to be STERRAD compatible.

LED illumination insert component of a complete handle may not be sterilized in STERRAD or by any other method.

XP DISPOSABLE HANDLE SYSTEM

Customers who choose to utilize our single use XP disposable handle sleeve system need only follow the INNER BATTERY / ILLUMINATION COMPARTMENT cleaning recommendations detailed above for their inserts.

APPLICABLE STANDARDS

DIN EN ISO 7376

IEC60601-1:1988 + A1:1991 + A2:1995; (Medical Electrical Equipment Part1 – General Requirements for Safety)