HEINE QUALITY
MADE IN GERMANY

HEINE F.O. 4 NT/F.O. Laryngoscope Handles

CE

V-200.00.323

HEINE F.O. 4 NT/F.O. Laryngoscope Handles

Please read and follow these instructions for use of and keep them for future reference.

Intended Use
The HEINE internally powered laryngoscope handles are for use with laryngoscope blades according to the "green standard" ISO 7376 for tracheal intubation, determined by medical professionals.

For U.S. only:
Federal law restricts this device to sale by or on the order of a Physician or Practitioner!

Warnings and Safety Information

CAUTION! Indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to moderate extent. (Background color yellow; foreground color black).

NOTE! Indicates valuable advice in terms of installation, operation, maintenance or repair. Notes are important, but not related to hazardous situations.

Setting up

Before first use, sterilize the handle shell (d).

For more information on handle types and components please visit www.heine.com.

❶ ❷ Standard F.O. 4
❸ ❹ Standard F.O. battery handle

Connect the rechargeable battery (c) with the bottom insert (b), so that you hear a distinct clicking sound. Insert the battery (c) into the casing (a) leading with the positive terminal. Screw the bottom insert (b) into casing (a). Finally, screw the casing (a) into the handle shell (d).

If your handle is delivered preassembled, remove the insulation film between the base unit and the rechargeable battery and remove the information band from the handle.

❺ ❻ F.O. 4 SLIM
❼ ❽ Small F.O. battery handle

Insert the rechargeable battery (c) in direction of the arrow into the casing (a) and screw on the bottom insert (b). Finally, screw the casing (a) into the handle shell (d).

❾ ❿ F.O. 4 SHORT

Insert the bulb unit (a) into the handle shell (d). Screw the rechargeable battery (c) into the handle shell.

⓫ ⓬ Short F.O. battery handle

Insert the batterie (c), regarding the markings on the plastic, into the casing (a). Insert the casing with the bulb first into the handle shell (d) and screw on the bottom insert.

⓭ F.O Angled
⓮ F.O. SP

Insert the batterie (c) with the positive terminal first into the handle (d) and screw the bottom insert (b) on.

Operation

Only use laryngoscope blades which comply with the "green standard" ISO 7376 in conjunction with HEINE Laryngoscope handles.

Only trained personnel are allowed to use a laryngoscope for intubation purposes.

The light radiates with high energy from the emission window, which can lead to elevated temperatures. This can lead to degeneration of cellular proteins with temporary loss of function.

HEINE laryngoscopes are designed for short termed use <5 minutes.

In order not to exceed a surface temperature of 41 °C at the application part, keep within the application period.

The maximum temperature of the application part, at an ambient temperature of 35 °C, is 48 °C in continuous operation.

General Operation

Fix the blade into the working position and check the function of the lamp.

Charging of the battery

⚠ If rechargeable batteries are not sufficiently charged before use, the light intensity may be reduced or cut out during operation. We recommend to charge HEINE rechargeable batteries for at least 15 minutes before use in a HEINE charger.

All here described Laryngoscope rechargeable handles are designed for charging with the HEINE® NT4 charger.

Rechargeable handles should not be switched on during the charging process. Please remove the laryngoscope blade before charging.

The HEINE® NT4 is described in a separate instruction manual.

Hygienic Reprocessing

Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines.

Classification according to KRINKO
- Handle shell: semicritical B
- Insert including bottom cap: noncriticalh

Spaulding Classification USA
- Handle shell: semicritical
- Battery insert and bottom insert: noncritical

The following notes must be implemented in the hospital / practice internal rules and guidelines, for example, regarding the implementation of national policies and recommendations, standards and laws. National guidelines and regulations (e. g. regarding CJK / vCJK) and the relevant standards and laws must be put into practise.

⚠ Equipment, where there is a suspicion that they have been in contact with Creutzfeld-Jakob disease (CJD) pathogens or variants thereof, must not be reprocessed under any circumstances.

After each use, carry out hygienic reprocessing.

The described cleaning and disinfection measures do not replace the specific rules applicable for the establishment.

HEINE Optotechnik only approves the cleansing agents and procedures named in these instructions for use.

Observe the instructions of the manufacturer of the reprocessing media.

When using other disinfectants

These must be bactericidal, (including mycobacteria), fungicidal and virucidal.

The disinfection, according to FDA recommendations in the United States, must be at least a high-level disinfection or it must take place after sterilization.

The preparation is to be carried out by persons with adequate hygienic expertise.

A spray disinfection is not permitted!

Before releasing the device for use, check for cleanliness. If necessary, clean the device or dispose of it in the event of non-removable contamination.

When reassembling, avoid recontamination of the sterile parts through non-sterile parts.
(E.g. unsterilized battery cases / inserts, bottom caps and batteries).

Processing

Use only de-mineralised water.

The cases(a), bottom insert (b) and (charging) batteries / units (c) are not suitable for automated machine washing.

When wiping the handles / casings, hold them with the charging contat facing down to prevent the ingress of liquid.

Allow 15 min for the cleaning agent to evaporate before using the handle.

Recommendation: Detailed information regarding hygienic reprocessing (med 0913) is available:

- online as a PDF at http://documents.heine.com/hr/ lary/
- in a paper version which you can request from the address listed below

Handle shell

Either manually (in immersion) or cleaned and disinfected by automated machine.

Recommended agents
Cleaning agent: Neodisher® MediClean
Disinfectant agent: alcoholic (e.g. Rotasept®) or agent ortho-phthalaldehyde (E.g. Cidex® OPA)

Recommended program for mechanical cleaning and disinfection
Vario TD program with disinfection lasting at least 5 min. at 93 °C or an alternative, comparable program.

Recommended sterilization programs
Humid heat: 132–134 °C; 3 min
Fractionated vacuum procedure (ISO 17665) (3 times) or gravity displacement procedure (3 times)

Bottom insert

Clean and disinfect manually (wipe clean and wipe disinfect).

Recommended agents
Cleaning agent: Neodisher® MediClean
Disinfectant agent: alcoholic (e.g. Incides® tissues) or agent ortho-phthalaldehyde (E.g. Cidex® OPA)

Sterilization for the complete handle

Recommended sterilization methods
VHP (Vaporized Hydrogen Peroxide)
Steris® Amsco® V-PRO® 1 Plus / V-Pro Max Non Lumen Cycle or an alternative equivalent program.

⚠ The Hygienic reprocessing only has a minor influence on the product life as this is determined mainly by wear and tear during use. Periodically check the integrity of the device and that the illumination is sufficient!

Maintenance

The LED lights cannot be changed.

Check the correct function of the device after each battery or bulb change.

Routinely inspect the condition of the battery and XHL bulb and replace them if necessary.

Changing the batteries
(For implemetation, see the relevant section)

❶ – ❽ **Standard F.O. and F.O. 4 SLIM / Small F.O.**

Unscrew the bottom insert from the handle shell and then out of the casing and replace the (charging) battery.

❾ ❿ **F.O. 4 SHORT**

Unscrew the charging unit from the handle shell and replace it.

⓫ ⓬ **Short F.O.**

Unscrew the handle head from the handle shell and replace the battery.

⓭ ⓮ **F.O. Angled / F.O. S.P.**

Unscrew the bottom insert and replace the battery.

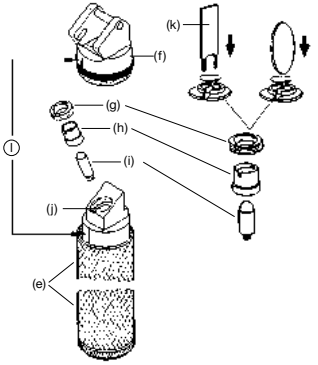
Changing the bulb

❷ ❹ ❻ ❽ ❿ ⓬

To replace the XHL lamp, unscrew it and screw in a new lamp to the end stop.

⓭ F.O. Angled Handle

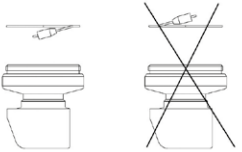
Unscrew the handle head (f) from the handle shell (e). Unscrew the nut (g) using the spanner (k) or a coin. When using a coin, it must be inserted simultaneously into the slot of the nut (g) and socket (h) and pushed down. Completely unscrew the nut (g) and remove the socket (h) and lamp (i) from the fixture. Insert a new bulb into the opening (j) and screw the fixture and nut on again. Place the handle head onto the handle shell so that the markings (l) face each other, and then screw it on tight.



⓮ F.O. SP

Unscrew the handle-head and pull out the bulb.
Push in a new bulb and replace the handle-head.

Please note that when replacing the lamp, the spring does not need to be not be removed. If the spring was removed unintentionally, attention must be payed to the mounting orientation during reassembly. Failure to do so, could cause a malfunction.



Service

HEINE Laryngoscope handles does not require regular service.

General Warnings

⚠ Check the correct operation of the device before use! Do not use the device if there are visible signs of damage.

Do not use the device in fire- or explosive risk area (e.g. oxygen saturated or anaesthetic environments).

This product is not allowed to be entered or used in strong magnetic fields like MRI scanners.

Do not modify the device.

Use only original HEINE parts, spare parts, accessories and power sources.

Repairs shall only be carried out by qualified persons.

Do not shine light directly into the eyes to avoid dazzle, especially if the pupils are dilated. Do not use the laryngoscope for eye reflex testing.

Before commencing a clinical application, the state of the internal electrical power source must be tested by turning on the lamp.

Check the blade before each use for rough surfaces and edges.

We strongly recommend a functional backup of laryngoscopes in an emergency situation.

General Notes

The warranty for the entire product is invalidated if non-genuine HEINE products or non-original parts are used and if repairs or modifications are made to the device by persons not authorized by HEINE. For more information, please visit www.heine.com.

If you don't use the device for a longer period of time, please remove the batteries in advance.

Ensure that moisture does not penetrate the area around the rechargeable battery and the bottom insert.

Check the rechargeable batteries regularly. In case of any abnormalities in the operating or recharging times, replace the rechargeable batteries.

Warning notice for (rechargeable) batteries

Do not put into fire, do not short-circuit, do not modify, do not sterilise, do not drop, do not expose to severe shocks or to direct sunlight.

Dispose of batteries in the event of visible or presumed damage (e.g. leaking liquid, mechanical deformation)

The batteries can be damaged by liquid. They must not be rinsed in running water or submerged under water.

Disposal

The product must be recycled as separated electrical and electronic devices. Please observe the relevant state-specific disposal regulations.

Dispose at your local collection point

Electromagnetic Compatibility

Medical electric devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC). Portable and mobile high frequency communication equipment can affect medical electric devices.

This is a device in the domestic environment, this device may cause radio interference, so that it may be necessary in this case, to take appropriate remedial measures, as e.g. orientation, new arrangement or shielding of the device or restrict the connection to the site.

The use of accessories, converters or cables other than the ones specified by HEINE might lead to increased emission reduced electrical immunity of the medical equipment.

The device may not be stacked directly near or used directly beside other devices. If the device is to be operated in a stack or with other devices, the device should be watched to ensure it operates properly in this location.

The appendix contains following tables

- Guidance and Manufacturer's declaration – Electromagnetic immunity
- Technical specification
- Accessories
- Explanation of the used symbols