

PROACT Hydra Autoclavable Laryngoscope Handles

Instructions for Use

INTENDED USE

The Hydra Laryngoscope Handle is the hand-held segment of a laryngoscope that is used to manipulate the laryngoscope blade for the illumination of the oropharynx and trachea to assist with endotracheal intubation or allow examination of the oral cavity.

- The handle serves as a chamber for the batteries that are used to power the device.
- The handle is available in two configurations, as defined by ISO 7376:2009 Conventional ①②③ (identified by a yellow band), to be used with laryngoscope blades that contain their own bulb or LED, and Green System ④⑤⑥ (identified by a green band), which contain an LED light source, to be used with fibre-optic type laryngoscope blades.
- Three sizes of Hydra handle are available: Adult ①④ Paediatric ②⑤ and Stubby ③⑥. The handles may be used with many different sizes and specifications of laryngoscope blade.
- In addition, PROACT Medical offer a Non-Contact ⑩ variant of all sizes and configurations. These handles are manufactured with an extended top block, designed to stop the laryngoscope blade from folding all the way closed, thereby preventing contact between the handle and tip of the laryngoscope blade. We cannot guarantee compatibility of Non-Contact handles with blades other than those manufactured by PROACT Medical Ltd.

WARNINGS

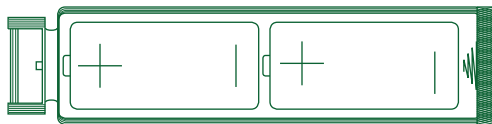
Tracheal intubation requires specialist training. Only competent trained personnel should use this device.

- Power output from rechargeable cells can fall rapidly during use, resulting in sudden failure of illumination. We recommend that rechargeable batteries are not used, with the exception of the PROACT branded Recharge System.
- Use of damaged batteries or the presence of conductive material inside the battery chamber may result in an internal short-circuit, causing the batteries and handle to overheat. In this event, care should be taken when removing the battery cap, as internal components may become hot enough to burn the skin.
- Non-LED lamps, if left illuminated in an exposed position, could generate sufficient heat to burn human tissue.
- Remove batteries from handles when not in use.
- Ensure that used batteries are disposed of in accordance with appropriate national and local laws, regulations and procedures.
- PROACT Medical advocate that intubation is only attempted with a full alternate plan in place in the event of difficult intubation due to equipment failure or physiological complications. This should include the availability of back-up devices and alternative means of ensuring ventilation.
- In the event that one of these devices is involved in a serious clinical incident, please report it to your local competent authority.

PRE-USE CHECKS

Do not use this device unless the following checks have been performed prior to each use

- Check device and batteries for completeness, sharp edges, damage, flaws or loose parts.
- For Green System handles, ensure that LED unit **a** is fully tightened within top block.
- Unscrew cap at base of handle to insert fresh batteries, observing correct polarity.
- Engage and disengage laryngoscope twice prior to use to confirm operation, ensure consistent light when force is exerted on blade tip in all directions.
- Insufficient, flickering or absence of light may indicate that batteries require replacing or a problem with the LED or handle contact.
- In event of pre-use check failure, return product to supplier for inspection.



DIRECTIONS FOR USE

These directions are general guidelines intended for use by a qualified medical personnel. Any instructions and contraindications are not exhaustive and it is the responsibility of the clinician to ensure the safe and correct use of this device.

- Select the appropriately sized device for the patient.
- Attach compatible laryngoscope blade to handle.
- Ensure blade is fitted firmly onto handle and clicked into place.
- To switch on, pull blade up and lock into position. Light will activate automatically.
- Examine / intubate trachea following current accepted medical guidelines.
- To switch off, move blade down. Light will automatically switch off.
- Non-Contact Handles will stop the blade at approximately 45 degrees to the handle.

CLEANING INSTRUCTIONS

Infection from patient to patient can potentially be transmitted by any piece of medical equipment. To prevent this, appropriate measures must be taken to clean, disinfect and sterilise (where appropriate) this device between uses.

- Any handle that is suspected of being exposed to Creutzfeldt-Jakob Disease (CJD) should not be reprocessed under any condition.
- Batteries, LED units ⑦ and battery holders ⑧ MUST be removed prior to reprocessing via washer disinfectant or sterilisation. Water ingress, heat or pressure may damage the function of the LED unit and invalidate warranty. To remove the LED unit unscrew the handle top from the barrel and then unscrew the LED unit, which should be set aside to await reassembly.
- Hydra handles are washer and disinfectant compatible.
- Wash with battery cap removed to ensure disinfection of all areas.
- Observe manufacturer's usage instructions for all cleaning substances.
- Device may be autoclaved up to a maximum of 138°C for periods in compliance with national recommendations or for a maximum of 4 minutes. Do not autoclave LED unit **a**.
- Ensure interior and exterior of handle is dry before replacing batteries and LED unit.
- Do not use any washing agents or substances which leave a residue which could coat the optical parts, or electrical contacts within the handle, or cause moving parts to stick. Issues caused by such residues are not covered by the warranty and may be resolved with maintenance cleaning using appropriate fine brush tool, 70% alcohol wipes and if necessary a very small amount of high temperature PTFE grease or suitable lubricant. Alternatively your supplier will be able to quote for such maintenance to remove the effects of such residues.
- Suitable for sterilisation by Ethylene Oxide (ETO), Steris or Sterrad procedures.
- Ensure all screw connections are tight before use. This may be easier to achieve with a laryngoscope blade attached.
- Do not use abrasive cleaning techniques.
- Update the device's sterilisation record using the unique serial number and date, plus details of washer and sterilisation methods, temperatures and times.

WARRANTY

Hydra laryngoscope Handles are individually serial numbered to ensure effective monitoring of devices through the reprocessing cycle and the maintenance of such a record is required for any warranty claim. Only Green System Handles have an LED Unit.

- PROACT Medical Ltd. offer a warranty period of 4,000 cycles or 5-years (whichever is sooner) for Hydra handles and twelve-months for LED units, battery holders and silicone base and cap seals to be free from manufacturing or materials fault under routine and proper careful use. Contact your distributor for part numbers and prices of spare parts not detailed below.
- The warranty does not cover batteries, failure due to normal wear and tear, misuse, external impact or the use of non original spare parts or damage caused by failure to correctly follow the instructions for use or through unauthorised repairs or modifications of any kind.
- Failure to remove the LED unit from the handle of the fibre-optic type handle (with the Green Band) during reprocessing will invalidate the LED unit warranty.
- PROACT Medical does not place a maximum life on the Hydra Laryngoscope Handle, which may continue to be used indefinitely, provided adequate pre-use inspection is carried out before every use.
- If you encounter any problems with the Hydra laryngoscope handle, please contact your local dealer or PROACT Medical directly via sales@proactmedical.co.uk.

HYDRA LARYNGOSCOPE HANDLES, CONVENTIONAL (YELLOW BAND) FITTING

Part Number ISO 7376:2009	Part Number Non-Contact	Size	Batteries Required	Dimensions (Length x Diameter)
HYCVH001 ①	HYCVHNC1 ⑩	Adult	2 x C	144 x 29mm
HYCVH002 ②	HYCVHNC2 ⑩	Paediatric	2 x AA	144 x 21mm
HYCVH003 ③	HYCVHNC3 ⑩	Stubby	2 x AA	114 x 33mm
HYSP002 ⑥		Battery Insert	2 x AA	To fit ⑤

HYDRA LARYNGOSCOPE HANDLES, FIBRE-OPTIC TYPE (GREEN SYSTEM) FITTING

Part Number ISO 7376:2009	Part Number Non-Contact	Size	Batteries Required	Dimensions (Length x Diameter)
HYGSH001 ④	HYGSHNC1 ⑩	Adult	2 x C	157 x 29mm
HYGSH002 ⑤	HYGSHNC2 ⑩	Paediatric	2 x AA	157 x 21mm
HYGSH003 ⑥	HYGSHNC3 ⑩	Stubby	2 x AA	126 x 33mm
HYSP004 ⑦		LED Unit	N/A	To fit ④ ⑤ ⑥
HYSP002 ⑧		Battery Insert	2 x AA	To fit ⑥
HYSP003 ⑨		Chamber Insert	N/A	To fit ⑤

