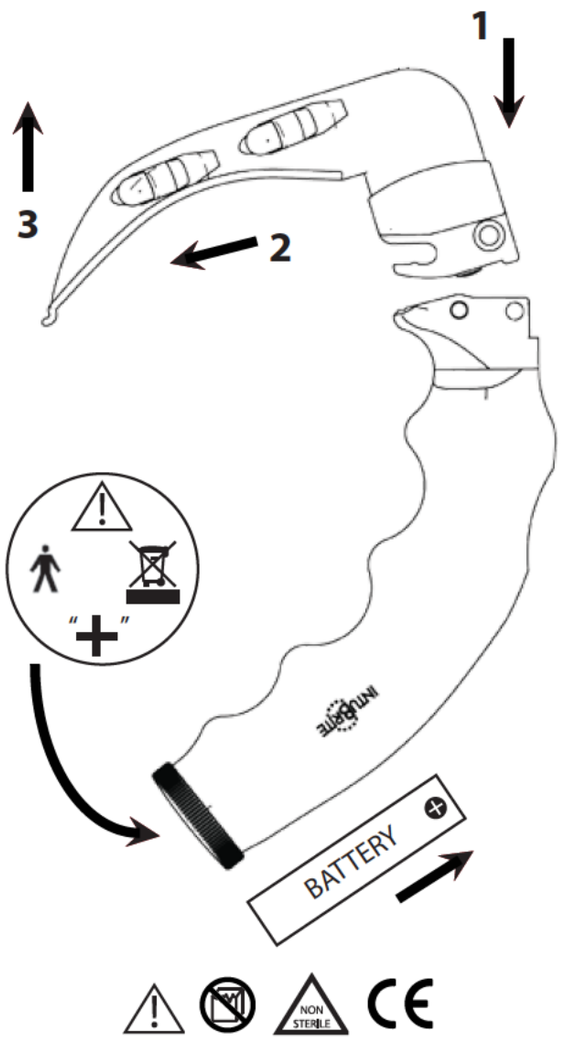
IntuBrite™ Reusable Handles & Blades: Instructions for Use



L016-0211 Rev G & eff 03/2013

IntuBrite™ Reusable Handles and Blades: Instructions for Use

A laryngoscope is used to visualize and examine the upper airway of a patient and to guide placement of the endotracheal tube during intubation procedures. This device must only be used by or on the prescription of a licensed physician or other qualified and licensed healthcare professional. (In the USA and Canada, Federal Law restricts to sale by or on the order of a physician).

HANDLE & BLADE USE:

- Use only with IntuBrite ™ blades and handles.
- Carefully inspect device for burrs, sharp edges, or other visually discernible defects.
- Fit the blade, click into handle to connect.
- Check to see that both bulbs are lit and functioning correctly.
- Ensure that spare blades and handles are always available in case of failure or emergency.

CAUTION:

- Not for use in vicinity of MRI equipment or other intense magnetic fields.
- Batteries for this device are not intended for recharging.
- Repeated testing of this device prior to use may result in a shortened operational time, reducing the life of the product and possibly resulting in operational failure.

POSITIONING AND MOUNTING OF BLADE TO HANDLE:

- Place "hook" on blade-base underneath bar on handle (1).
- Apply downward/forward pressure to seat securely (2).
- Lift the front end of blade until it clicks and locks under the bar (3).
- Verify bulbs are illuminated.
- Reverse the above instructions to remove blade.

NOTE: INCORRECTLY MOUNTING THE BLADE MAY RESULT IN DAMAGE TO BLADE OR LEDS OR MALFUNCTION OF DEVICE.

MAINTENANCE OF HANDLE AND BLADE:

- Test or change battery occasionally.
- Handle and Blade contain no repairable parts.
- Service of all components must be conducted by IntuBrite, LLC.

CLEANING OF HANDLE:

NOTE: Battery must be removed prior to sanitizing with approved decontamination methods.

- Detach blade from handle.
- Remove battery and replace cap of handle.
- Clean externally with a damp cloth or soft brush using warm water, soap, isoprophyl alcohol solution or other disinfectant to remove any deposits.
- Observe manufacturer's usage instructions for all cleaning substances.
- Ensure that fluid does not seep into the electrical contact area.
- Ensure that handle is dry both inside and out prior to continued use or storage.
- Suitable for low temperature sterilization by Steris® or STERRAD® systems NOT to exceed 180° and/or 28 minute cycles.
- To avoid damage, do not soak handles in disinfectant or washing solutions for extended periods.
- Do not use abrasive cleaning techniques.
- Do not ultrasonically clean.

Handles should always be tested after cleaning and prior to use.

INSTALLATION/ REPLACEMENT OF BATTERY:

- Unscrew base of handle and remove.
- Remove battery from handle (if applicable).
- Insert single 3.6/3.7V battery positive terminal end in first.
- Replace base and tighten securely.

CLEANING OF BLADE:

- Detach blade from handle.
- Clean externally with a damp cloth or soft brush using warm water, soap, isoprophyl alcohol solution or other disinfectant to remove any deposits.
- pH neutral cleaning solutions recommended. Avoid caustic ingredients. DO NOT USE CLEANING PRODUCTS THAT CONTAIN AMMONIA, which may cause corrosion of electrical components and shorten the useful life of the blade. Devices tested for functionality with the use of Cidex® disinfectant solutions per manufacturer's instructions.
- Do not use abrasive cleaning techniques.
- Suitable for low temperature sterilization by Steris® or STERRAD® systems NOT to exceed 180° and/or 28 minute cycles.
- Laryngoscope may be autoclaved in accordance with the autoclave manufacturer's instructions. Not to exceed 250 degrees fahrenheit with a maximum PSI of 27 keeping maximum exposure time to under 5 minutes.
- Laryngoscope blades should always be tested after cleaning and prior to use.
- Ensure that laryngoscope blade is dry and fully checked prior to storage.

The above listed cleaning guidelines are intended as suggestions only. They are based on procedures compatible with specific materials.

Sterilization must be performed to approved hospital protocol. IntuBrite cannot guarantee that any of the recommended methods will guarantee sterility. This must be validated by the hospital and/or sterilization equipment manufacturer.

RECOMMENDED OPERATING ENVIRONMENTS:

OPERATING TEMPERATURE	50° F to 104° F
OPERATING HUMIDITY	95% Non-Condensing
TRANSPORT/STORAGE TEMP.	-4° F to 140° F Humidity: Up to 95% Non-Condensing
ALTITUDE	0-13,123 feet (0 - 4,000 meters)
ATMOSPHERIC	50 Kpa to 106 Kpa

WARNING:
Operating your IntuBrite products outside the recommended operating temperature environment may negatively impact device performance, may cause damage to the device and will void the warranty. Those devices suspected of being exposed to Creutzfeldt-Jakob Disease (CJD) or variants shall not be reprocessed under any conditions

For repairs, please contact your supplier, who will return the goods to IntuBrite, LLC or our authorized agent.

Consult accompanying documents.
Consulter la documentation fournie.
Consulte la documentación aneja.
Consultare i documenti forniti con il dispositivo.
Lesen Sie die Begleitdokumente.

Do not use if package has been opened or damaged.
Ne pas utiliser l'article si l'emballage a été ouvert ou endommagé.
No usar si el paquete está dañado o ha sido abierto.
Non utilizzare il dispositivo se la confezione è aperta o danneggiata.
Nicht verwenden, falls die Verpackung geöffnet wurde oder beschädigt ist.

Non sterile.
Non stérile.
No estéril.
Non sterile.
Unsteril.

Do Not Discard. Recycle. Contact the local city or town offices for instructions on proper disposal.

Ne pas jeter. Recyclable. Contacter les autorités locales pour connaitre les modalités appropriées pour vous débarrasser du produit.

No desechar. Reciclar. Consulte a las autoridades pertinentes para informarse sobre cómo deshacerse adecuadamente del aparato.

Non gettare il dispositivo. Riciclare. Contattare gli uffici locali o della propria città per istruzioni sullo smaltimento corretto.

Nicht wegwerfen. Wiederaufbereiten. Wenden Sie sich für Informationen bezüglich der korrekten Entsorgung an die zuständigen Stellen vor Ort.

Type B Equipment: Indicates equipment providing a particular degree of protection against electric shock.

Equipement de type B : indique que l'équipement en question protège dans une certaine mesure contre les chocs électriques.

Equipamiento médico tipo B: indica equipamiento que incluye cierto grado de protección contra descargas eléctricas.

Apparecchiatura di tipo B: indica apparecchiature che offrono un grado particolare di protezione dalle scosse elettriche.

Typ B-Ausrüstung: Bezeichnet Ausrüstungsgegenstände, die einen besonderen Schutz gegen Stromschläge aufweisen.

EC REP

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CE

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