EN

1.0 PRODUCT INFORMATION

MEDICAL DEVICE
Following instructions are for all reusable laryngoscopes blades and handles supplied by Surgicon Medical Instruments, unless stated otherwise with the packaging of the product. These instructions are intended for use only by persons with the required specialist knowledge and training.

PRODUCT DESCRIPTION
Surgicon Laryngoscopes are ideal for physicians for use in Operation Theaters, Trauma Centers and Emergency Services. All Laryngoscopes are made of Medical Grade Stainless Steel. Surgicon Laryngoscopes are ideal for normal, pediatric, neonate, obese and difficult intubations. All Laryngoscopes are made in accordance with ISO 7376:2009.

FIBER OPTIC LARYNGOSCOPE
Surgicon offers light emitting Glass Optical Fiber integrated laryngoscopes. These Laryngoscopes offer cold light on the tip of the blade. The Blades are available in all popular models and sizes. Handles are available in Xenon and LED light source.

CONVENTIONAL LARYNGOSCOPES
Surgicon offers Standard Conventional Laryngoscopes. These laryngoscopes are available in popular models and sizes. Blades are available in vacuum or LED light source. LED Standard Conventional Laryngoscopes offer cold light and 2 times more light output as compared to fiber optic blades.

INTENDED USE
Standard and Fiber Optic Laryngoscopes are used by qualified professionals to lift the glottis and obtain view of the airway and vocal cords for medical purposes.

SIGNIFICANT PHYSICAL AND PERFORMANCE CHARACTERISTICS
During use, the blade should connect to the handle. When in ON position, the blade should emit adequate light on the tip of the blade. The intended performance of the laryngoscope is to slide the tongue and lift glottis and emit light on the airway and vocal cords for visualization.

INDICATIONS
A laryngoscope is a medical instrument used to visualize the larynx (voice box) and surrounding structures. The main indications for using a laryngoscope include:
- Diagnosis and evaluation of upper airway disorders: A laryngoscope can be used to diagnose and evaluate conditions such as vocal cord nodules, polyps, cysts, tumors, laryngitis, and other upper airway disorders.
- Airway management: A laryngoscope is often used to intubate patients who require mechanical ventilation or general anesthesia. The instrument is used to visualize the larynx and guide the insertion of an endotracheal tube or other airway device.
- Swallowing evaluation: A laryngoscope can be used to evaluate a patient's swallowing function by visualizing the larynx and pharynx during swallowing.
- Foreign body removal: A laryngoscope can be used to locate and remove foreign bodies that may be lodged in the upper airway.
- Monitoring and management of chronic conditions: A laryngoscope can be used to monitor and manage chronic conditions such as laryngeal cancer, recurrent respiratory papillomatosis, and vocal cord paralysis.

CONTRA-INDICATIONS
While a laryngoscope is a useful tool for many medical procedures, there are some situations where its use may be contraindicated. Some laryngoscope contraindications include:
- Severe head or neck injury: In cases of severe head or neck injury, a laryngoscope may be contraindicated due to the potential risk of further damage to the airway or surrounding structures.
- Infection or inflammation of the airway: If a patient has an active infection or inflammation of the airway, the use of a laryngoscope may be contraindicated due to the risk of aggravating the condition.
- Coagulopathy: If a patient has a bleeding disorder or is taking anticoagulant medications, the use of a laryngoscope may be contraindicated due to the increased risk of bleeding.
- Limited range of motion in the neck: If a patient has limited range of motion in the neck due to injury or disease, the use of a laryngoscope may be contraindicated due to the potential difficulty in visualizing the airway.
- Allergy or sensitivity to anesthesia or other medications: If a patient has a known allergy or sensitivity to the medications used during laryngoscopy, the procedure may be contraindicated.
- It is important to consult with a healthcare provider before performing laryngoscopy to assess the potential risks and benefits for each individual patient.

INTERACTIONS
No interaction with any Medical Equipment.

PATIENT TARGET GROUP
The target group of patients who may require laryngoscopy includes those with conditions that affect the upper airway and larynx. These conditions may include:
- Upper airway obstruction: Laryngoscopy may be used to diagnose and manage upper airway obstruction due to conditions such as laryngomalacia, tracheomalacia, or sleep apnea.
- Vocal cord disorders: Laryngoscopy may be used to diagnose and manage conditions that affect the vocal cords, such as vocal cord paralysis, polyps, nodules, and tumors.
- Dysphagia: Laryngoscopy may be used to evaluate patients with difficulty swallowing (dysphagia) to identify the cause of the problem.
- Airway management: Laryngoscopy may be used to guide the insertion of an endotracheal tube or other airway device in patients who require mechanical ventilation or general anesthesia.
- Monitoring and management of chronic conditions: Laryngoscopy may be used to monitor and manage chronic conditions such as laryngeal cancer, recurrent respiratory papillomatosis, and vocal cord dysfunction.

USER
A laryngoscope is typically used by a healthcare professional who has been trained in its proper use. The specific type of healthcare professional who may use a laryngoscope can vary depending on the context and the specific procedure being performed. Some examples include:
Anesthesiologists, Otolaryngologists (ENTs), Emergency physicians, Critical care physicians.

CLINICAL BENEFIT
The use of a laryngoscope can provide several clinical benefits in the diagnosis and management of upper airway and laryngeal conditions. Some of the benefits of laryngoscopy include:
- Accurate diagnosis: Laryngoscopy allows for direct visualization of the larynx and surrounding structures, providing a more accurate diagnosis of conditions affecting the upper airway and larynx.
- Treatment planning: Laryngoscopy can provide important information to guide treatment planning, such as the size and location of tumors or the extent of vocal cord dysfunction.
- Airway management: Laryngoscopy is a valuable tool for airway management in patients who require mechanical ventilation or general anesthesia.
- Minimally invasive: Laryngoscopy is a minimally invasive procedure that can be performed on an outpatient basis, reducing the need for more invasive diagnostic or treatment procedures.
- Patient comfort: Laryngoscopy can be performed under local anesthesia, reducing patient discomfort and anxiety during the procedure.
- Safety: Laryngoscopy is a safe procedure when performed by a trained healthcare professional, with low rates of complications or adverse events.
- Overall, the use of a laryngoscope can provide important clinical benefits in the diagnosis and management of a wide range of upper airway and laryngeal conditions.

ADVERSE REACTIONS
Laryngoscopy is a relatively safe procedure. Published scientific literature revealed the potential side effects are rare but may include:
- Allergic reaction to the anesthetic / patient
- Infection
- Bleeding
- Nosebleed
- Vocal cord spasm
- Mouth or throat ulcers
- Injury to tongue, lips or teeth
- Swelling or blockage of the airway
- Inflammation in the throat
- Thinning of the muscle and tissue of the larynx

PRECAUTION
- Test all laryngoscopes before use. Keep spare lamps, batteries, blades and handles available.
- Repeat use of laryngoscope handle result in wear out of the handle head. Overtime, the blade and handle fitting become loose. In case of any loosing and high wear out, replace the handle to avoid Flickering Light.
- Ensure the handle cap threads are clean and free of any foreign debris or else short circuiting will be experienced.
- Ensure the handle cap thread is not close and fits properly with the handle.

WARNING
- The devices supplied by Surgicon are new, cleaned industrially and supplied non-sterile. The device must be cleaned, disinfected and sterilized prior to first time use. While receiving a new product, inspect its surfaces for any sharp edges, burs, dents, pores and Product marking.
- All Blades should be handled with care. Collision could result in lamp damage and/or optical fiber output brightness.
- Storage away from moisture and direct sun light.
- Ensure lamps are securely fastened for conventional blades before immersion in a liquid solution.
- For Fiber Optic Handle, ensure lamp assembly is removed from the handle prior to immersion in a liquid solution.
- Keep Blades always clean and dry to avoid corrosion. Do not Autoclave conventional LED Blades. Autoclave will damage the lamp.
- Ensure all contact points of battery terminal and electrical connectivity are always clean. Presence of any foreign substance will cause short circuiting and Light Flickering.
- Batteries should be removed from the handles prior to cleaning and sterilization.
- During Autoclave do not exceed 138° Centigrade or 280 Fahrenheit.
- Do not use Ultrasonic cleaning method.
- Do not use hydrogen peroxide.
- Test all laryngoscopes before use. Keep spare lamps, batteries, blades and handles available.
- Do not turn on the laryngoscope in ON position for longer duration. Lamp and its surrounding areas tend to get hot. Turn on the laryngoscope only prior to use.
- Do not use device after the expiry.
- Surgicon Reusable Laryngoscopes are compatible with laryngoscope only made as per requirements of ISO 7376. For optimum performance use Surgicon Laryngoscope blades, handles and spares.
- Prior to using the product, visually inspect the product for any sharp edges, burs, dents, or pores. Do not use product with sharp edges or burs.
- While connecting or dis-connecting the blade from the handle, ensure that excessive force is not required. Excessive force could damage the handle head.
- As per ISO 7376 requirement, laryngoscope handle is designed to handle a weight of 150N on the tip of the blade.
- Inserting batteries the wrong way can result in short circuiting, handle heating up, battery chemical leakage, flame, smoke.

NOTE
The user and/or patient are required to report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2.0 CLEANING, DISINFECTION AND STERILIZATION

LIMITATIONS ON REPROCESSING

Repeated autoclaved processing has effects output brightness of optical fiber blades. Life span is normally determined by wear and damage during use.

Product Supplied Sterile or Non-sterile:	Non-sterile
Compatible Sterilization Methods:	Autoclave
Warning	Do not use ultrasonic cleaning, Do not use Hydrogen Peroxide, Remove Battery before sterilization.
Initial Treatment at point of Use:	Remove excess biologic soil from the instruments with a disposable wipe. Place devices in a container of distilled water or cover with damp towels. If instruments cannot be soaked or maintained damp, then they should be cleaned as soon as possible (within 60 minutes is recommended) after use to minimize the potential for drying prior to cleaning.
Preparation before processing	Disengage b***lade from the Handle.*** ***Scrub the device with soft plastic brush to remove any residue.*** All cleaning solutions should be prepared at the dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning solutions. Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (turbid).
Manual Cleaning	Step 1: Prepare a proteolytic enzyme solution according to the manufacturer's instructions. Step 2: Completely submerge instruments in the enzyme solution and gently shake them to remove trapped bubbles. Step 3: Soak instruments for a minimum of 10 minutes. While soaking scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution. Step 4: Remove the instruments from the enzyme solution and rinse in tap water for a minimum of one (1) minute.
Automated Cleaning	Step 1: Prepare a proteolytic enzyme solution according to the manufacturer's instructions. Step 2: Completely submerge instruments in the enzyme solution and gently shake them to remove trapped bubbles. Step 3: Soak instruments for a minimum of 10 minutes. While soaking scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution. Step 4: Remove the instruments from the enzyme solution and rinse in tap water for a minimum of one (1) minute. Step 5: Place instruments in a suitable validated washer/disinfector. Follow the washer/disinfector manufacturer's instructions for loading the instruments for maximum cleaning exposure; e.g. place concave instruments on their side or upside down, use baskets and trays designed for washers, place heavier instruments on the bottom of trays and baskets. If the washer/disinfector is equipped with special racks (e.g. for cannulated instruments) use them according to the manufacturer's instructions. Step 6: Process instruments using a standard washer/disinfector instrument cycle according to the manufacturer's instructions. The following minimum wash cycle parameters are recommended:

Cycle	Description
1	Pre-wash --•-- Cold Softened Tap Water --•-- 2 minutes
2	Enzyme Spray & Soak --•-- Hot Softened Tap Water --•-- 1 minute
3	Rinse --•-- Cold Softened Tap Water
4	Detergent Wash --•-- Hot Tap Water (64-66°C/146-150°F) --•-- 2 minutes
5	Rinse --•-- Hot Purified Water (64-66°C/146-150°F) --•-- 1 minute
6	Hot Air Dry (116°C/240°F) --•-- 7 to 30 minutes

Notes: - The washer/disinfector manufacturer's instructions should be followed. - A washer/disinfector with demonstrated efficacy (e.g. FDA approval, validated to ISO 15883) should be used.
Dry time is shown as a range because it is dependent upon the load size placed into the washer/disinfector.
Many manufacturers pre-program their washer/disinfectors with standard cycles and they may include a thermal low-level disinfection cycle after the detergent wash. The thermal disinfection cycle should be performed to achieve a minimum value A0 = 600 (e.g. 90°C/194°F for 1 minute according to ISO 15883-1).

Disinfection	Instruments must be terminally sterilized prior to use. See sterilization instructions below. Low level disinfection may be used as part of a washer/disinfector cycle, but the devices must also be sterilized before use.
Drying	Dry instruments with a clean, absorbent non-shedding lint free cloth. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas and difficult to access areas.
Inspection and Maintenance	After cleaning, all devices should be thoroughly inspected for residue biologic soil or detergent. If contamination is still present repeat the cleaning process. Visually inspect each device for completeness, damage and excessive wear. If damage or wear is observed that might compromise the function of the device, do not process them further and contact your Symmetry representative for a replacement
Packaging	Instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) general-use perforated tray or case along with other devices under the following conditions: • Arrange all devices to allow access of steam to all surfaces. • The case or tray must be wrapped in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization wrap by following the double wrap method or equivalent (ref: AAMI ST79, AORN Guidelines). • Follow the case/tray manufacturer's recommendations for loading and weight. Total weight of a wrapped case or tray should not exceed 11.4kg/25lbs. Instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) rigid container systems (i.e. those with filters or valves) along with other devices under the following conditions: • The container manufacturer's recommendations should be followed regarding preparation, maintenance and use of the container. • Arrange all devices to allow access of steam to all surfaces. • Follow the container manufacturer's recommendations for loading and weight. Total weight of a filled container system should not exceed 11.4kg/25lbs.
Sterilization	Moist heat/steam sterilization is the recommended method for Symmetry instruments. Use of an approved chemical integrator (class 5) or chemical emulator (class 6) within each sterilization load is recommended. Always consult and follow the sterilizer manufacturer instructions for load configuration and equipment operation. Sterilizing equipment should have demonstrated efficacy (e.g. FDA clearance, EN 13060 or EN 285 compliance). Additionally, the manufacturer's recommendations for installation, validation, and maintenance should be followed. Validated exposure times and temperatures to achieve a 10-6 sterility assurance LCN-204233-0EN/G Page 7 of 8 level (SAL) are listed in the following table.

Cycle Type	Minimum Temperature	Minimum Exposure Time
United States Recommended Parameters		
Pre-vacuum / Vacuum Pulse	132°C/270°F	4 minutes
Cycle Type	Minimum Temperature	Minimum Exposure Time
European Recommended Parameters		
Pre-vacuum / Vacuum Pulse	134°C/273°F	3 minutes

Drying & Cooling
The recommended drying time for single wrapped instruments is 20 minutes unless otherwise noted in device specific instructions.
Drying times for instruments processed in containers and wrapped trays can vary depending upon the type of packaging, type of instruments, type of sterilizer and total load. A minimum dry time of 30 minutes is recommended but to avoid wet packs, extended dry times greater than 30 minutes may be needed for larger loads under certain conditions or if otherwise recommended in accompanying documentation. For large loads verification of dry times by the health care provider is recommended.
A 30-minute minimum cooling time is recommended after drying but longer times may be necessary because of load configuration, ambient temperature and humidity, device design and packaging used.
Note: Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is a concern about TSE/CJD contamination are: 134°C/273°F for 18 minutes.

Storage	Sterile packaged instruments should be stored is a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin and temperature/humidity extremes. Note: Inspect every package before use to ensure that the sterile barrier (e.g. wrap, pouch or filter) is not torn, perforated, shows signs of moisture or appears to be tampered with. If any of those conditions are present then the contents are considered non-sterile and should be re-processed through cleaning, packaging and sterilization.
Transportatio n	Used instruments must be transported to the decontamination area for reprocessing in closed or covered containers to prevent unnecessary contamination risk.

ADDITIONAL INFORMATION
Before disinfection or sterilization process, it is recommended to check manufacturer's data sheet for instructions for use, warnings and concentrations.
All Chemicals to be use for disinfection or sterilization should be compatible with following materials:
Stainless Steel
- Polyamide
- Glass
- Polypropylene (for Handles only)
- Brass Chrome Plated (for Handles only)
- Polycarbonate

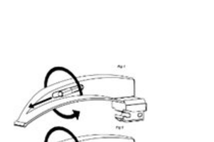
Always use manufacturer supplied lamps for best compatibility and performance. All products come with 5-year warranty against manufacturing defect.
Product Shelf Life: 10 Years.

PRODUCT USE LIFE
- Conventional Blades: 1000 Autoclaves, 1000 Uses or 5 years, whichever comes first.
- Conventional Brass Handles: 500 Autoclaves, 500 Uses or 5 years, whichever comes first.
- Fiber Optic Blades: 200 Autoclaves, 1000 Uses or 5 years, whichever comes first.
- Fiber Optic Brass Handles: 500 Autoclaves, 500 Uses or 5 years, whichever comes first.

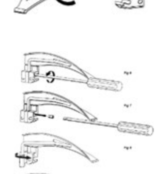
MANUFACTURER'S WARRANTY
All products come with 5 years manufacturer's warranty. Under the warranty all customers enjoy free product repair or replacement. All warranties start from the date of purchase. Any defect caused by user will not be covered under the warranty. To avail warranty, user must follow instructions provided in the IFU and use spares provided by Surgicon. Warranty does not cover lamps and batteries. For replacement, please mail the product to Surgicon with name, address, brief description of the problem and proof of purchase. Claims will be limited to the value of the product.

3.0 USAGE INSTRUCTIONS

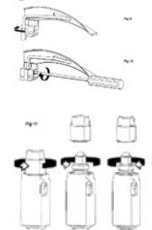
PRE-USE TESTING
Following instructions are to be used for proper usage of laryngoscope blades and handles.
Hold the blade and the handle as shown in ***Fig 1.***
•Engage the hook on the blade with pin on the handle. Apply force till click sound is heard and blade is as shown in the Fig 2.
•To illuminate the light, lift the tip of the blade till click sound is heard. Fig 3 shows the correct position.
•To disengage the blade from the handle, reverse the above-mentioned procedure.
•See handle battery replacement section for instructions on how to insert the batteries.
•Check all edges for any nicks or sharp edges.
•Check the product and packaging for any defects.
•In ON Position, check the light and ensure there is enough illumination for good visibility of Vocal Cords.



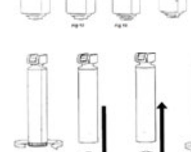
CONVENTIONAL LAMP REPLACEMENT
Following instructions are to be used for replacement of Lamps of Conventional Blades.
•To remove the lamp, with your thumb and index fingers rotate the lamp in counterclockwise direction as shown in Fig 4.
•To fasten the lamp, place the lamp in its socket and rotate in clockwise direction until the lamp is tight as shown in Fig 5.



FIBER OPTIC DETACHABLE BLADE CLEANING
Following instructions are to be used for Fiber Optic Detachable blade cleaning.
•Take flat head screwdriver to rotate the screw in counterclockwise direction as shown in Fig 6.
•Remove the screw as shown in Fig 7.
•Pull the Optical Fiber Bundle out as shown in Fig 8.
•After cleaning of the product, replace the Optical Fiber Bundle back into the blade as shown in Fig 9.
•Fasten the screw in clockwise direction as shown in Fig 10.

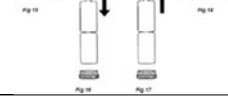


FIBER OPTIC HANDLE LAMP REPLACEMENT
Following instructions are to be used for replacement of lamps of Fiber Optic Handles.
•Unfasten the Lamp cover as shown in Fig 11.
•Unfasten and remove the lamp as shown in Fig 12.
•Securely fasten the Lamp as shown in Fig 13.
•Fasten the lamp cover as shown in Fig 14.



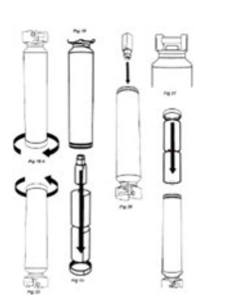
HANDLE BATTERY REPLACEMENT
Following instructions are to be used for replacement of batteries for Handles.
- Unscrew the cap at the bottom of the handle by rotating it in counterclockwise direction as shown in Fig 15.
- Remove/Insert batteries as shown in Fig 16 & Fig 17. (For optimum performance Surgicon recommends alkaline Manganese batteries).
- Fasten the cap by rotating in clockwise direction as shown in Fig 18.

Warning: Inserting batteries in the wrong direction can result in failure of light or short circuiting.



EASY-STERILE FO HANDLE USAGE INSTRUCTIONS
Easy-Sterile FO handle helps avoid contamination of Lamp during and after cleaning and Sterilization of fiber optic handles. Use following instructions.
- Unfasten the bottom Lid as shown in Fig 18 A.
- Slide the batteries and the lamp Capsule out in a clean/non-contaminated tray as shown in Fig 19.
- Fasten the bottom lid as shown in Fig 23. The handle is now ready for sterilization.
- After Sterilization unfasten the bottom lid as shown in Fig. 18 A. Insert the lamp capsule by holding the handle upside down as shown in Fig 20. The lamp capsule should appear as shown in Fig 21. If not, then shake the handle.
- Insert the batteries as shown in Fig 22.
- Fasten the bottom lid as shown in the Fig 23.

Note: If needed, lamp Capsule can be wiped with disinfectant. Do not autoclave or cold soak. Note: Incase lamp capsule does not automatically slide into its position, shake the handle to help the lamp capsule settle in its position. Fasten the bottom lid. Please ensure the bottom lid is securely fastened or else electrical dis-connectivity can occur. Attach handle to the blade and test it twice before use.



MACMOVE CLEANING INSTRUCTIONS
Mac Move blades are designed to help perform difficult intubations.
PRE-USE TESTING
- Press the lever a couple of times and check the movement of the tip.
- Ensure screw connecting lever to the blade is securely fastened.
- Ensure blade is properly cleaned before use.

CLEANING INSTRUCTIONS (MACMOVE BLADE)
- Unfasten the screw holding the lever and the laryngoscope blade and detach the lever from the blade. See Fig 24.
- Use a soft plastic brush to clean the area.
- Attach the lever back to the blade and fasten the screw as shown in Fig 25.

CONVENTIONAL MAX-LED INSTRUCTIONS
WARNING
Do not autoclave Max-LED conventional blades. Do not use dry heat sterilization method. Do not use ultrasonic cleaning method. Do not soak LED lamps for extended period, recommended maximum time is 1 hour. LED lamps are sensitive to shock. Kindly handle them with care.
CLEANING INSTRUCTIONS
Use only soft plastic brush to clean the LED blades.
Note: Surgicon LED lamp are design to require very little maintenance. In case of light flashing, ensure the lamp is tightly screwed. In case of dim light, replace batteries.
STERILIZATION METHODS
Use only Cold Soak, Sterrad, Sterris or ETO process to sterilize LED blades.

TROUBLESHOOTING

In case of low light output, replace the batteries.

CONVENTIONAL LARYNGOSCOPES (IF LAMP IS NOT WORKING)
Ensure the lamp is securely fastened. Change lamp as per conventional lamp replacement instructions. If problem persists, remove the lamp and clean the electrical contact points inside the blade lamp hosing. Replace Handle Batteries.

LED CONVENTIONAL LARYNGOSCOPE
WARNING
Do not autoclave
IF LAMP IS NOT WORKING
Ensure the lamp is securely fastened. Change lamp as per conventional lamp replacement instructions. If problem persists, remove the lamp and clean the conductor pin inside the blade lamp hosing. Replace Handle Batteries.
LED LIGHT FLICKERING
Ensure the lamp is securely fastened. In case the light still flickers, contact manufacturer for free replacement. In case the lamp still does not work, contact manufacturer for more information. Always keep Spare lamps and batteries.

FIBER OPTIC LARYNGOSCOPES
WARNING
Autoclaving Fiber Optic Blades will result in reduction of Light Output.
HANDLE LAMP NOT WORKING
Ensure the lamp is in the correct position and the handle bottom cap is securely fastened. Do not use excessive force to tighten the Cap.
LIGHT FLICKERING
Ensure the bottom cap is securely fastened. In case the light still flickers, contact manufacturer for free replacement. If the Lamp Capsule is dipped in liquid, remove the side screw and clean the contact point. Screw the assembly back and test the handle. Always keep Spare lamps and batteries

4.0 SYMBOLS

	WARNING OR CAUTION-CONSULT ACCOMPANYING DOCUMENTS.READ INSTRUCTIONS BEFORE CONNECTING OR OPERATING		KEEP DRY
NON STERILE	NON-STERILE		HANDLE WITH CARE
	REFER TO THE OPERATIONS & MAINTENANCE MANUAL		THIS WAY UP
	MANUFACTURER		DO NOT USE IF PACKAGE IS DAMAGED
	USE-BY DATE		TYPE BF APPLIED PART
REF	CATALOGUE (PART) NUMBER	DC	DIRECT CURRENT
MD	Medical Device	CE	CE-MARKED IN ACCORDANCE WITH THE MEDICAL DEVICE DIRECTIVE (MDD)
LOT	BATCH CODE		WEE-subject to waste electrical and electronic equipment regulations
	DATE OF EXPIRY	EC REP	EC REP-AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	FRAGILE ITEM, HANDLE CAREFULLY		RECYCLE PRODUCT
	KEEP AWAY FROM DIRECT SUNLIGHT	LATEX	LATEX FREE
Rx	PRESCRIPTION		

5.0 SAFETY

CAUTIONS
- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and operated according to the instructions in this manual. For more information, see the Electromagnetic Compatibility section on page 66. To maintain electromagnetic interference (EMI) within certified limits, the Reusable Laryngoscope must be used with the cables, components, and accessories specified or supplied by Surgicon Medical Instruments. For additional information, see the System Parts & Accessories and Product Specifications sections. The use of accessories or cables other than those specified or supplied may result in increased emissions or decreased immunity of the system. The Reusable Laryngoscope should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used. This device can radiate radio frequency energy and is very unlikely to cause harmful interference with other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. Evidence of interference may include degradation of performance in this device or other devices when operated simultaneously. If this occurs, try to correct the interference by using the following measures: • Turn devices on and off in the vicinity to determine the source of interference • Reorient or relocate this device or other devices Increase the separation between devices • Connect the device to an outlet on a circuit different than the other device(s) • Eliminate or reduce EMI with technical solutions (such as shielding) • Purchase medical devices that comply with IEC 60601-1-2 EMC Standards. Beware that portable and mobile radio frequency communications equipment (cellular phones, etc.) may affect medical electrical equipment; take appropriate precautions during operation.

HAZARDS
- While storing the Laryngoscopes, remove the batteries. Laryngoscope has no hazard, but there are several hazards associated with the battery.
- Read MSDS provided by the battery supplier to all the hazards associated with the battery and safety solutions.
- In case the Laryngoscope handle starts getting hot, immediately unscrew the handle bottom cap and remove the batteries.
- Identification between Standard Conventional and Fiber optic laryngoscope
- All products with a green indicator or green part are Fiber Optic Laryngoscopes.
- All products without any green indicator or green part are Standard Laryngoscopes.

OPERATOR PROFILE
- Surgicon Laryngoscopes are to be used by trained and qualified physicians or Emergency staff who have been provided training by a healthcare institution.
- Minimizing Environmental impact during normal use. Prior to use, do not turn on the laryngoscope for longer duration. This will help conserve the battery power and increase number of medical procedures performed with every lamp.
- Minimizing the environmental impact during its expected service life
- Use care while handling the product. Dropping or any mechanical force can damage the lamp and the product.
- Use correct sterilization methods to avoid damage to the product.
- Minimizing consumption during normal use
- When the laryngoscope is not in use, ensure it is in OFF position. This will help decrease the consumption of batteries and lamps.

Emission during normal use
- During normal use, Laryngoscope emits light and heat.
- Information regarding location within the ME of hazardous substance
- Alkaline batteries are located inside the Laryngoscope Handle. See handle battery replacement instruction on how to remove the batteries. Remove the batteries before disposal of the laryngoscopes.
- Special handling and treatment instructions
- In some areas, Alkaline batteries can be disposed of in regular waste. However, in some areas or commercial organization and institutes cannot disposed of in regular waste. Call your local waste management company on how to dispose of the alkaline batteries.
- Disassembly instructions for removal of hazardous components
- See handle battery replacement instruction on how to remove the batteries.

ELECTROMAGNETIC COMPATIBILITY

Surgicon laryngoscopes are designed to be in compliance with IEC 60601 1 2:2007, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical medical installation. The Surgicon laryngoscope complies with the applicable essential performance requirements specified in IEC 60601 1 and IEC 60601 2 18. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables. For more information about the essential performance of the Surgicon Laryngoscope

ELECTROMAGNETIC EMISSIONS
The Surgicon Reusable Laryngoscope are intended for use in the electromagnetic environment specified below. The customer or the user of the Surgicon Reusable Laryngoscope should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1 Class A	The Surgicon Laryngoscope system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

ELECTROMAGNETIC IMMUNITY
The Surgicon Laryngoscope system is intended for use in the electromagnetic environment specified below. The customer or the user of the Surgicon Reusable Laryngoscope should assure that it is used in such an environment.

EMISSIONS TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	In compliance contact ± 6 kV Air ± 8 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	In compliance 0.3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

ELECTROMAGNETIC IMMUNITY
The Surgicon laryngoscope system is intended for use in the electromagnetic environment specified below. The customer or the user of the Surgicon Reusable Laryngoscope should assure that it is used in such an environment.

EMISSIONS TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	=1.2 √P 80 MHz to 800 MHz d=2.3 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol:

Note: Ut is the AC mains voltage prior to application of the test level. At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Surgicon Reusable Laryngoscope is used exceeds the applicable RF compliance level above, the Surgicon Reusable Laryngoscope should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Surgicon Reusable Laryngoscope.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

RECOMMENDED SEPARATION DISTANCES
Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Surgicon Reusable Laryngoscope: The Surgicon laryngoscope system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Surgicon laryngoscope system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Surgicon laryngoscope system as recommended below, according to the maximum output power of the communications.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (m)		
	150 kHz to 80 MHz d=1.2 √P	80 MHz to 800 MHz d=1.2 √P	800 MHz to 2.5 GHz d=2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance din meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

6.0 ENVIORNMENT

ENVOIRNMENTAL INFORMATION
Installation:
During Installation, ensure the packaging is recycled properly. Test all newly purchased Laryngoscope blade and handle before for functionality before commissioning. Do not turn ON laryngoscope for longer duration. All newly purchased laryngoscope must be cleaned and autoclaved before first use.
Packaging:
Packaging is fully recyclable. Cardboard box is recycled with paper and polythene pouch is recycled with plastics.
During Use:
LED lamps consume less current and last longer. Surgicon recommend customers to use LED products to save battery consumption. Keep product dry and away from sunlight to protect it from rust or contamination. If hospital would like to test laryngoscopes every day, following method is best suited for environment and product life:
Fiber Optic Laryngoscopes:
Use any one blade to test all the Handles. Turn ON the Laryngoscope for no more than 5 seconds. Do not test all blades.
Conventional Laryngoscopes:
Test all blades and handles. Turn on the Handle for no more than 5 seconds.
Consumable:
Laryngoscopes consumable are Lamps and Batteries. Enhance Lamp and battery life by turning ON the Laryngoscope just before use and turning it OFF right after use. During testing, turn on the Laryngoscope for no more than 5 seconds.
Emission:
During Use Laryngoscope emits heat and light from the lamp.
Disposal:
Laryngoscope blade can be disposed of without the need to remove any batteries. Laryngoscope blades contain following materials that can be recycled:
Conventional Blades:
300 Series Non-magnet stainless steel, Copper, Teflon, Polycarbonate, Brass, Glass.
Fiber Optic Blades:
300 Series Non-magnet stainless Steel, Glass, Brass, Nickel, Polycarbonate
Conventional Handles:
Brass, Nickel, Stainless Steel, Polycarbonate
Fiber Optic Handles:
Brass, Nickel, Stainless Steel, Polycarbonate, Glass

In these products highest quantity recovered will be of stainless steel. Before disposal of Laryngoscope handle, it is necessary to remove the batteries. See the battery removal instruction to know how to remove the batteries. Failure to remove the batteries can lead to heat, smoke or fire during the disposal of the laryngoscope handle.

7.0 SPARES CHART

Lamp Replacement Chart

105-100-LB-2E	105-100-7-LB	LB-100-L-4B	LB-100-S-4B	LB-100-L-4A	LB-100-S-4A
105-100-2A 105-100-1A 105-100-4A 105-100-5A 105-100-6A	105-100-2L 105-100-1L 105-100-4L 105-100-5L 105-100-6L	LB-100-1L LB-100-2L LB-100-3L LB-100-4L LB-100-5L LB-200-2L LB-200-3L LB-200-4L LB-100-2MVL LB-100-3MVL LB-100-4MVL	LB-100-0L LB-200-00L LB-200-0L LB-200-1L	LB-100-1 LB-100-2 LB-100-3 LB-100-4 LB-100-5 LB-200-2 LB-200-3 LB-200-4 LB-100-2MV LB-100-3MV LB-100-4MV	LB-100-0 LB-200-00 LB-200-0 LB-200-1

STANDARDS USE IN IFU
ISO 7376:2020, ISO 17664, ISO 20417:2021, ISO 15223-1:2021, IEC 60601-1:2005 + AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010 + AMD1:2013, IEC 60601-1-9:2007 + AMD1:2013

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