Instructions for Use

2658-01-0001 Surgical Light with Zip Strap

2658-01-0002 Surgical Light with Suction

2658-01-0004 Surgical Light with Retractor

BihlerMed, LLC
85 Industrial Drive - Bldg B
Phillipsburg, NJ 08865 USA
P: (908) 329-9123
Bihlermed.com

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Description

The BihlerMed® Surgical Light is an ethylene oxide-sterilized sterile, single-use device designed to provide surgeons with localized brilliant white illumination of the surgical site. Utilizing an internal battery, the device is designed to stay operational for up to three hours of continuous use. The Surgical Light is packaged with one of three accessories: zip straps, suction, or retractor. The zip straps are used to attach the light to another medical instrument. The suction is a Yankauer suction tube with a standard output nozzle. The retractor is a plastic straight retractor with slight curvature.

Indications

The BihlerMed® Surgical Light is intended to provide localized illumination of surgical sites.

The suction is intended to be used while attached to the Surgical Light to aspirate bodily fluid via connection to a suction hose during surgery with localized light.

The retractor is intended to be used while attached to the Surgical Light for light tissue retraction and localized light during general use surgical procedures to allow improved visualization of the surgical site.

The zip strap is intended to attach the device to another surgical instrument.

Contraindications

The Surgical Light and their accessories have no known contraindications intrinsic to the device. No part of the devices should be used in a pulling or tearing action. Neither the light nor its accessories should be in direct contact with the Central Nervous System.

Potential Adverse Effects

Risks possibly associated with the use of the BihlerMed® Surgical Light are similar to those of any light system that could come into contact with the body. The most common risk is tissue necrosis due to excessive heat at a prolonged period of time from the light source.

Disposal

Discard the product according to hospital procedures and in accordance with local, state and federal laws and regulations. When disposing of the product, avoid exposure to bodily substances as contact could lead to infection or disease. Always wear and use proper equipment.

Directions for Use

BihlerMed® Surgical Light

To turn on the light press the “ON/OFF” button located on the top of the handle.

2658-01-0001 Surgical Light with Zip Strap

See Figure 1.

1) Slide Surgical Light onto surgical instrument handle.
2) Pull Zip-Straps tight to secure light to instrument handle.
3) Insert the Surgical Light with the other device into surgical site.
4) Observe general operating room technique.

2658-01-0002 Surgical Light with Suction

See Figure 2.

1) Attach suction hose to output nozzle at end of suction handle.
2) Insert Surgical Light with Suction into surgical site.
3) Observe general operating room technique.

2658-01-0004 Surgical Light with Retractor

See Figure 3.

1) Insert Surgical Light with Retractor into surgical site.
2) Observe general operating room technique.
3) Retractor intended for moderate blunt retraction up to 5 pounds.

Use Environment

The emission and immunity characteristics of the Surgical Light have been tested to Table 4 and Table 9 test levels of the IEC 60601-1-2 International Standard, suitable for use in industrial areas and hospitals (CISPR 11 class A). If the Surgical Lights are used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment away from locations of high intensity electromagnetic disturbances.

Electromagnetic Compatibility

The emissions and immunity characteristics of the BihlerMed® Surgical Lights containing a 3V, 2/3A battery have been tested to the test levels in Tables 2 and 3.

Warnings and Precautions

The following should be considered:

1) Inspect the BihlerMed® Surgical Light prior to use to ensure proper function and working condition. Do not use a device that is damaged.
2) Do not shine the light directly into eyes as it could temporarily impair vision and/or cause harm.
3) This device should never be reused, reprocessed, or resterilized under any circumstances. The device should never be exposed to any cleaning or sterilization methods during or after use. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and create a risk of contamination, which could result in patient injury, illness, or death. Immediately discard after use in surgery.
4) Excessive force on the flexible wand could cause the device to malfunction. Care should be taken when handling the device.
5) The Surgical Light is sterile unless the package is opened or damaged. Inspect the device package before use. Do not use if the package is opened or damaged.
6) Refrain from using the Surgical Light adjacent to or stacked with other equipment to avoid improper operation. If such use is necessary, this equipment and the other equipment shall be observed to verify that they are operating normally.
7) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) shall be used no closer than 30 cm (12 inches) to any part of the light including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment could result.

Product Complaints

Any Health Care Professional who has any complaints or who has experienced dissatisfaction in the product quality, identity, durability, safety, effectiveness, and/or performance should notify the manufacturer at the following:

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Table 1. Explanation of Symbols

	Catalogue Number
	Batch code
	Use-by date
	Sterilized using ethylene oxide
	Single sterile barrier system
	Do not-reuse
	Do not use if package is damaged
	Not made with natural rubber latex
	Consult instructions for use
IPX5	Can resist a sustained, low-pressure water jet spray
	Manufacturer
	Unique device identifier
	Caution

Table 2. Immunity Test Levels

Test	Test Standard	Test Level
Radiated Emissions	CISPR 11	Class A Group 1 30 – 1000 MHz
Electrostatic Discharge	IEC 61000-4-2	8 kV Contact Discharge VCP, HCP ±2 kV, ±4 kV, ±8 kV, ±15 kV Air Discharge
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	3 V/m, 80-2700 MHz 80% AM at 1 kHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m @ 50 Hz or 60 Hz 3 orthogonal orientations
Proximity magnetic fields	IEC 61000-4-39	134.2 kHz @ 2.1 kHz pulse modulation and immunity test level and immunity test level 65 A/m 13.56 MHz @ 50kHz

Table 3. RF Immunity Test Levels

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1,720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1,845				
1,970				
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5,500				