International Marketing Dept.
Kcomy chen
2019-12-3

COMEN

Share with the World

L6

Surgical Light

COMEN

Excellent

L6

★Stability and Safety

★Excellent Color Reproduction

★Surgery environment adaptiveness

Stability and safety

Shadow management system

①Iconic feature of high-end surgical lights

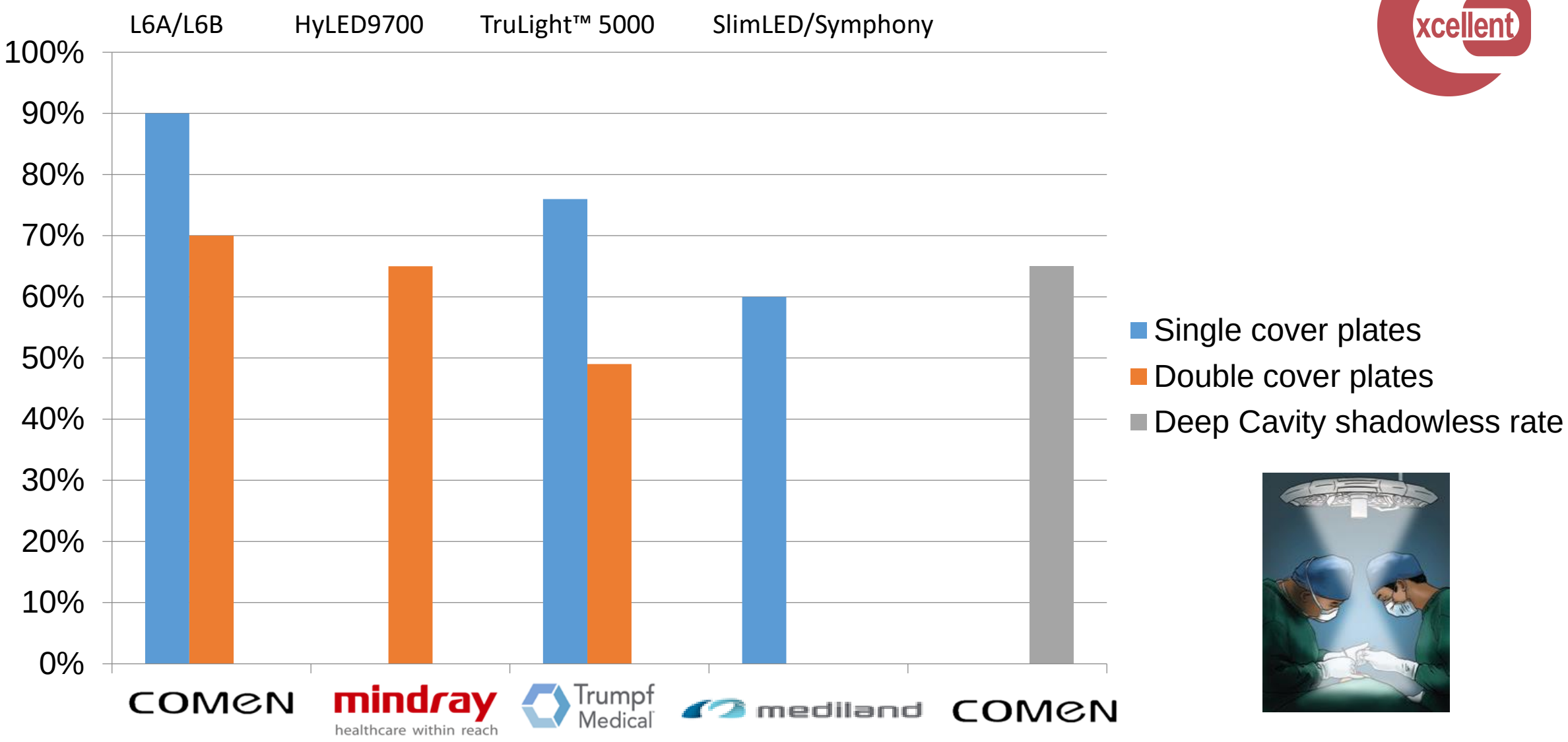
②Maintain stable illumination

③ Decreases the illumination of the surgeon head

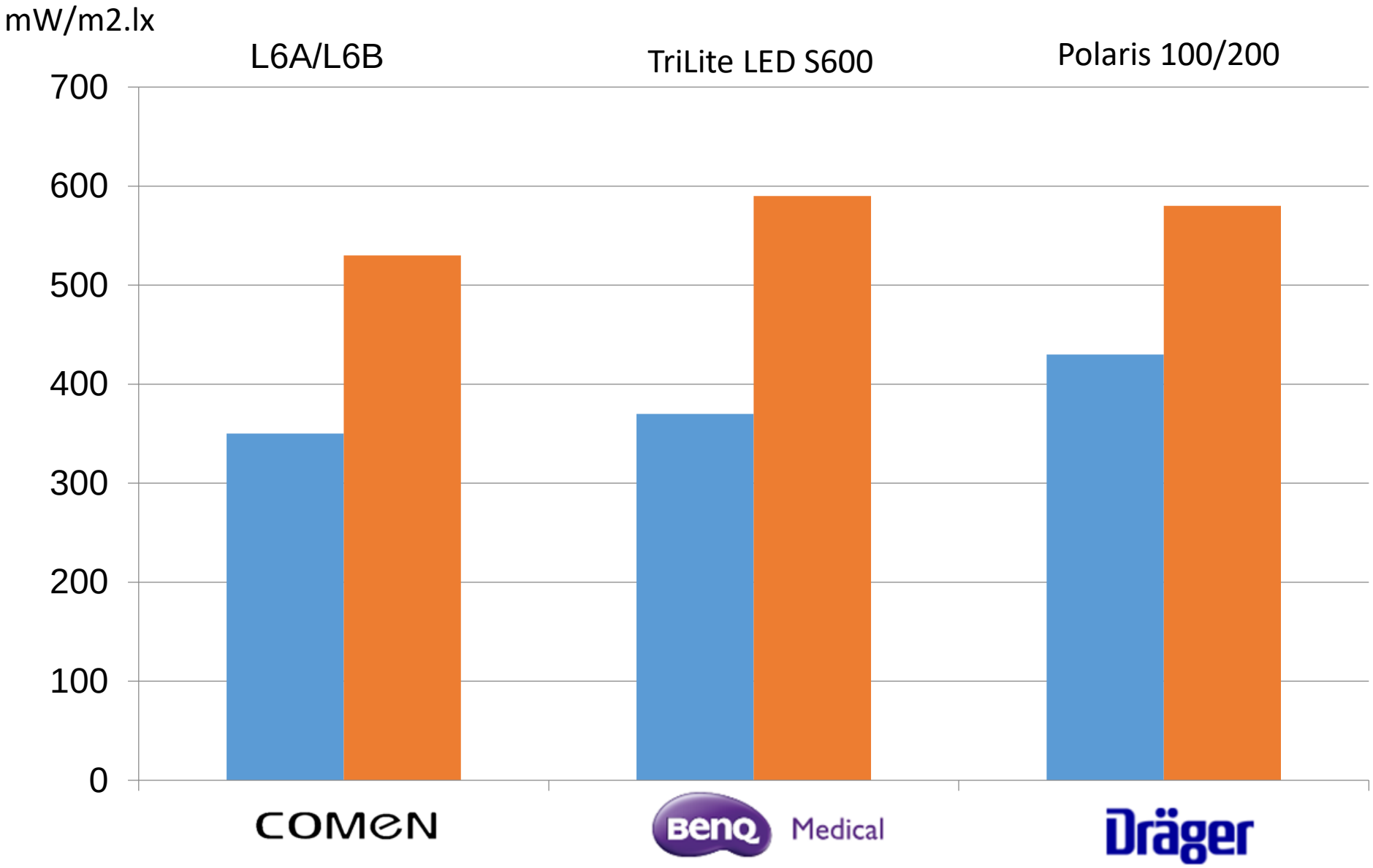
Greatly improve shadow-less rate

Lower irradiance

Shadow management



Lower Irradiance



Overhead temperature increase is ≤ 5℃

Mixed light technology

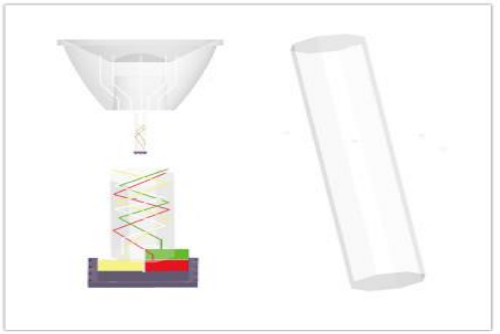
Traditional mixed light

VS

Comen mixed light

- Internal 4-color mixed light beam

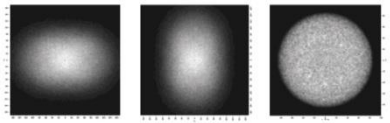
Rainbow

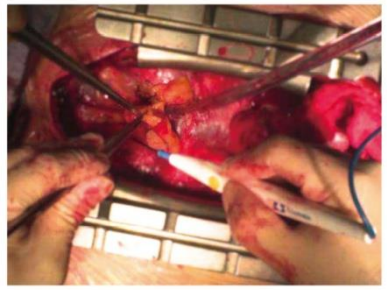


Light beam

Beam component

Elliptical spot





- Suitable for long and narrow wounds
- Avoids the metal reflection of retractor from affecting doctor's vision
- Iconic feature of high-end surgical lights

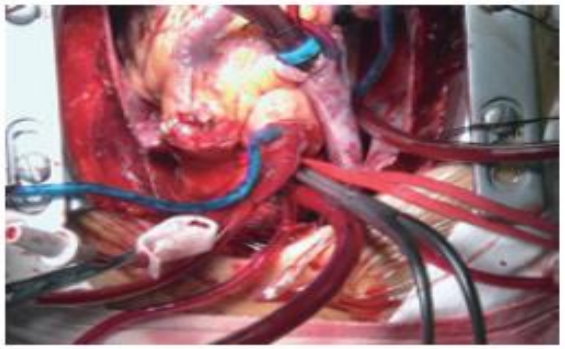
COMEN

Excellent

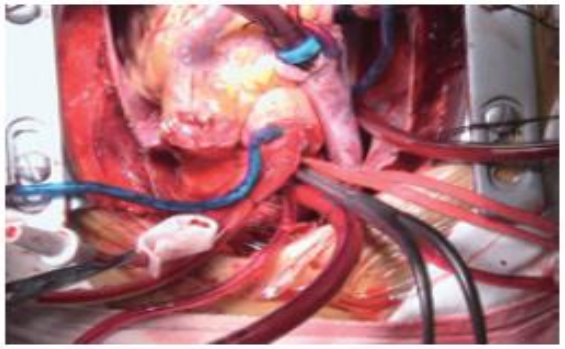
Excellent color reproduction

Color rendering index (CRI) (Ra)

Photographed by L6 LED Surgical Light

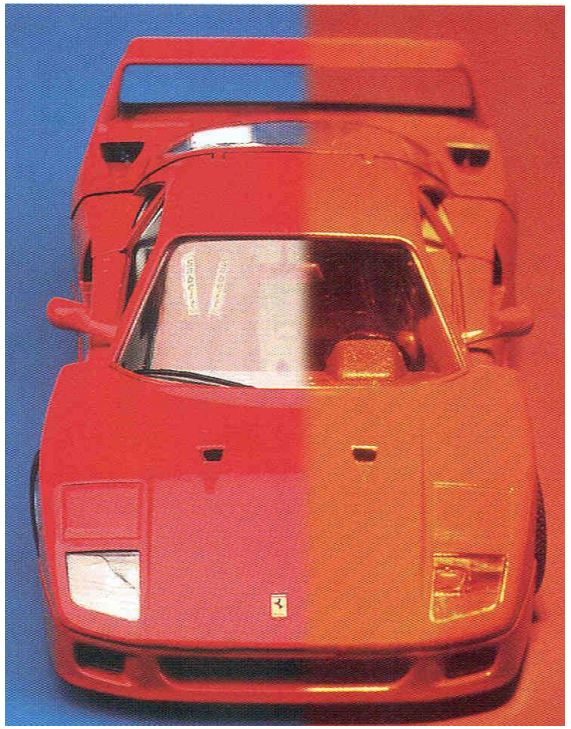


Photographed by traditional surgical light



- Color rendering index (CRI) (Ra):
- Excellent color rending performance
  Ra:95.5±8 (%)
- Excellent red rendering index

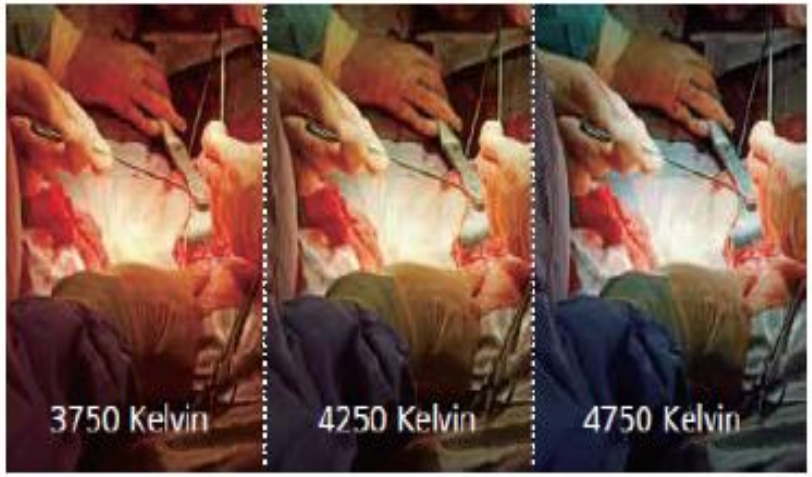
  R9:95Ra:95.5±8 (%)



Reference beam

Test beam

Color temperature



Comen :3800-6200k ,5 positions

An important parameter of high-end surgical light.

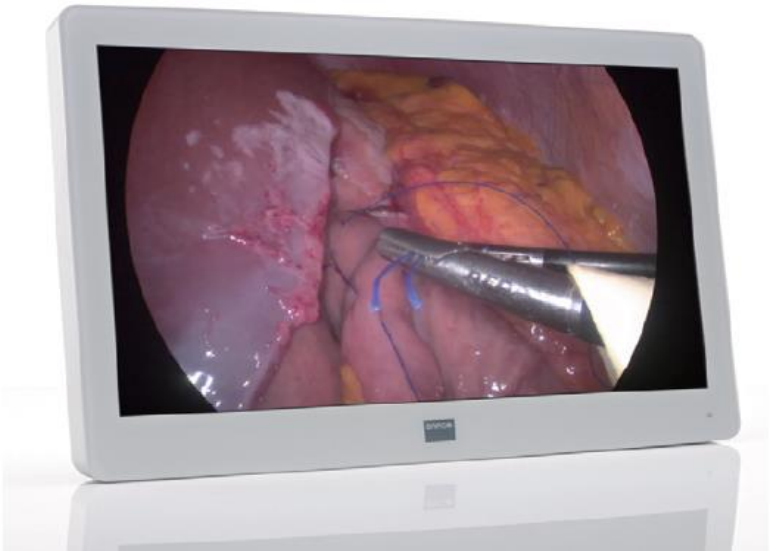
Different surgeries have different lighting requirements, especially different color temperature.

COMEN

Excellent

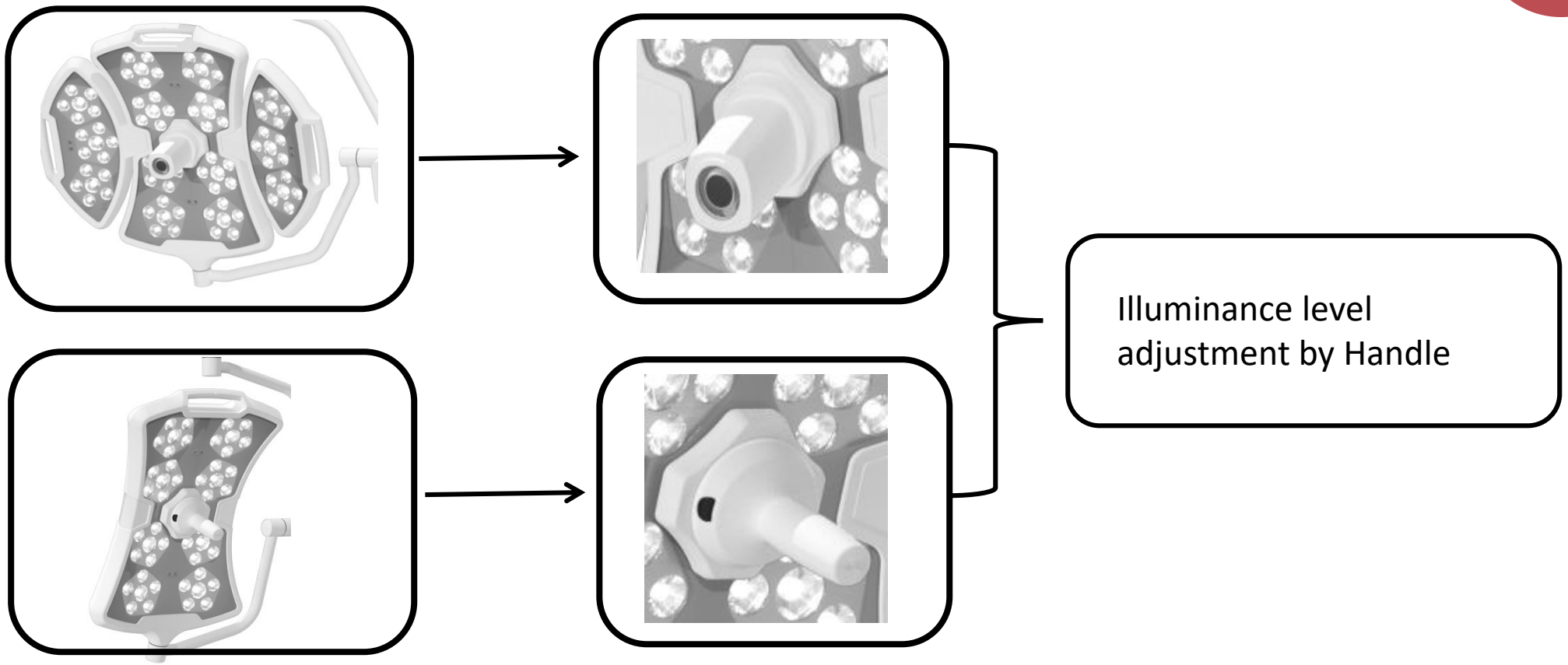
Surgery environment adaptiveness

Endoscopy surgery lighting technology



- Suitable for endoscopic surgery
- It creates a cozy ambient and ensures a clear screen view for doctors.

Multi-function handle



Best reliability

①chip from German OSRAM

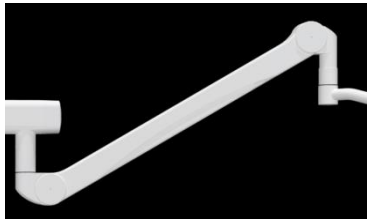
②50000 hours

③Best reliability

①_Sony camera system

② Autofocus system

③ full HD video camera



① arm from German ONDAL

② which sets the standard of its industry with its customer ,

③ covering 70% of operation room worldwide.

① Display from BARCO

② provide accurate and realistic images

To sum up

These are the basic parameters. Our L6 is better than most other similar high level surgical light.

	Illumination (lx)	Light depth	Irradiance (mW/m2.lx)	Deep Cavity shadowless rate(Double)	Color temperature (K)	CRI/R9
Other similar high lever surgical lights	Min: 40,000 - 80,000Lux Max: 120,000 - 160,000Lux	≧900-1200mm	≦3.9 - 6 mW/ (m²·lux)	≥45%	4000-5500K	90-95 / ≤92
L6	40,000 - 160,000Lux	≧1300mm	≦3.65mW/ (m²·lux)	≥65%	3800-6000k	95.5 / 95

MAQUET
GETINGE GROUP

mindray
healthcare within reach

stryker

xcellent

Dräger

Trumpf
Medical

KLS martin
GROUP

BenQ
Medical

mediland

COMEN VS BenQ Medical

COMEN VS BenQ Medical

Surgical Light	COMEN L6	TriLite LED S600-500/700	TriLite LS810-500/700
Mixed light function	4 kinds of colors (internally)	1 color (externally)	2 color (externally)
Color Rendering Index	95.5	95	95
Color Temperature(K)	3800-6200(5 positions)	4200	3500-5000
Temperature increase	≤1℃(head and work field)	<2° (head), <12°(working field)	-
Elliptical Spot	Yes	No	No
Intensity level adjustment by Handle	Yes	No	No
Shadow management system	Yes	No	No

COMEN VS BenQ Medical

Excellent

①4 color lights mixing internally

★COMEN L6:
4 kinds of colors internally mixing

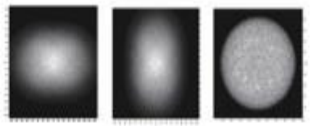
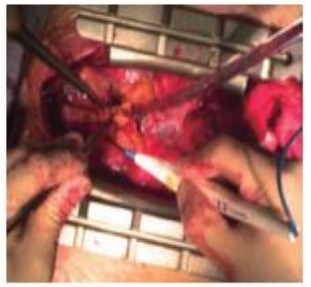
☆TriLite LED S600-500/700：
1 color
☆TriLite LS810-500/700：
2 color

②Shadow management system

★COMEN L6:
Support

☆TriLite LED S600-500/700&TriLite LS810-500/700：
Nonsupport

③Elliptical spot

★COMEN L6:
Support

☆TriLite LED S600-500/700&
TriLite LS810-500/700：
Nonsupport

Comprehensive OR/ICU Solution

COMeN VS mediland

COMEN VS mediland

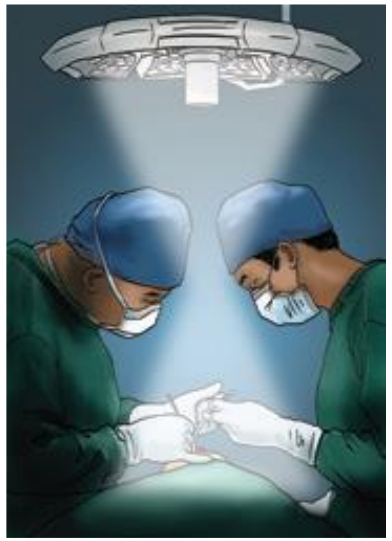
Excellent

	COMEN L6	MediLED Symphony	SlimLED 55
Light source	4 kinds of colors internally	Monochromater (externally)	Monochromater (externally)
Color Rendering Index	95.5	95	95
Color Temperature	3800K≤Tc≤6200K	4300k	4300k
Elliptical Spot	Yes	No	No
Shadow management system	Support	No	No
Shadowless rate	1mask 90%；2 masks 70%	1 mask is 60%	1 mask is 60%
Illumination depth（L1+L2）	1300mm	1400mm	1100mm
Irradiance	Ee: Ec≤3.65mW/(m2·lx)	Ee: Ec=3.3mW/(m2·lx)	Ee: Ec=3.3mW/(m2·lx)

COMEN VS mediland

Excellent

①Shadowless rate



★COMEN L6:
1mask 90%； 2 masks 70%

☆MediLED&SlimLED:
1 mask is 60%.

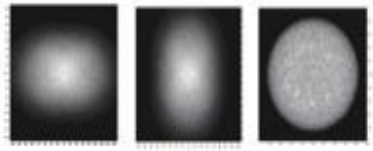
②4 color lights mixing internally

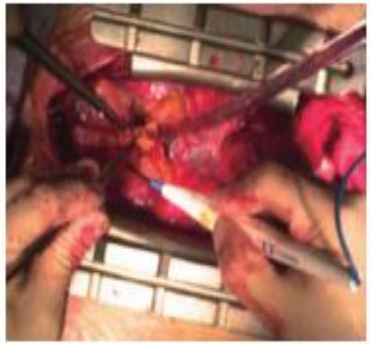
Only 2 companies have this technology

Comen is one of them

L6 offers the most stable vision

③Elliptical spot





★COMEN L6:
Support

☆MediLED&SlimLED:
Nonsupport

Comprehensive OR/ICU Solution

COMEN vs Dräger

COMEN vs Dräger

Excellent

Surgical Light	COMEN L6	Polaris 100/200	Polaris 600
Color Rendering Index	95.5	95	96
Color Temperature(K)	3800k-6200k	4400k,5000k,5600k	3800k,4400k,5000k,5600k
Elliptical Spot	Yes	No	No
Intensity level adjustment by Handle	Yes	No	Yes
Shadow management system	Yes	No	No
R9	95	93	95

COMEN VS Dräger

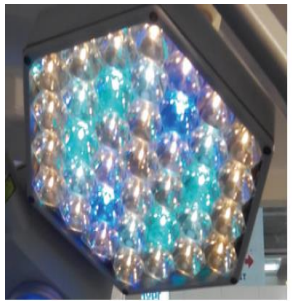
Excellent

①Shadow management system

★COMEN L6:
Support

☆Polaris 100/200&Polaris 600：
Nonsupport

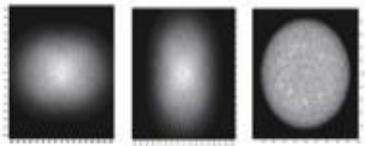
② 4 color lights mixing internally

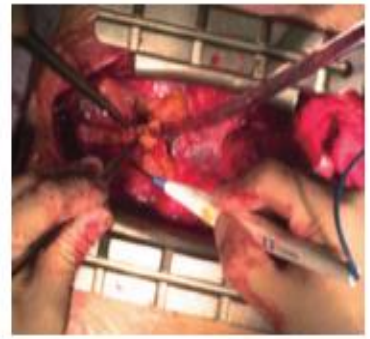


Only 2 companies have this technology

Comen is one of them

③Elliptical spot





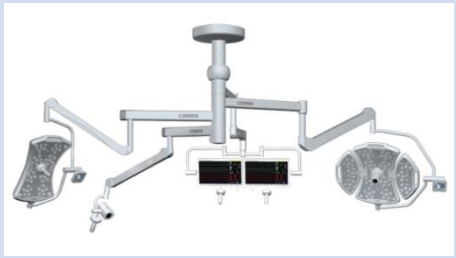
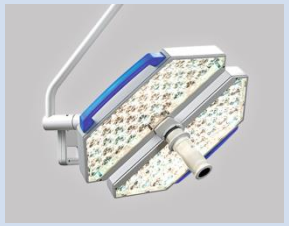
★COMEN L6:
Support

☆Polaris 100/200&Polaris 600：
Nonsupport

Comprehensive OR/ICU Solution

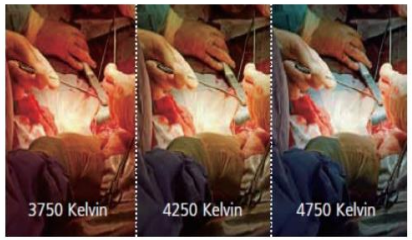
COMEN

VS

	COMEN L6	TruLight™ 5000		iLED™7
				
		5000	5300	
Illumination depth	1300mm	940mm	960mm	1930mm
Shadowless rate	1mask 90%；2 masks 70%	1mask 76%；2 masks 49%	1mask 58%；2masks 43%	1 Mask 92% ; 2 Masks 68%
Ra	95.5	96		97
Color temperature	3800-6200K (5 positions)	3500k-5000k(4 positions)		3500-5000k(4 positions)
Elliptical Spot	Yes	No		No
Shadow management system	Yes	No		Yes

①Optional color temperature

L6 offers the most stable vision

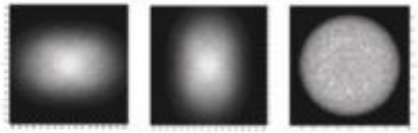


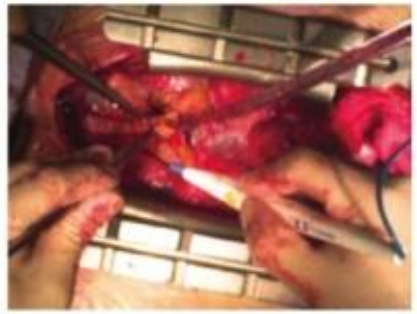
★COMEN L6:
3800k-6200k （5 positions）

☆TruLight™ 5000:
3500k-5000k(4 positions)
☆ iLED™7::
3500k-5000k(4 positions)

②Elliptic spot

More focus less Glare





★COMEN L6:
Support

☆TruLight™ 5000 &iLED™7:
Nonsupport

③Four color LED light mixed light

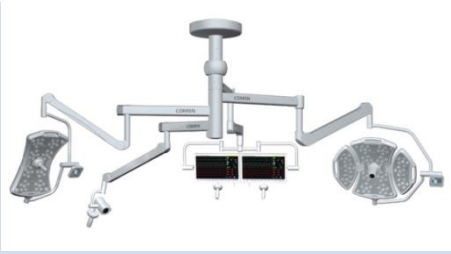
Only 2 company have this technology
Comen is one of them
avoid any color temp change
during the surgery

Comprehensive OR/ICU Solution

COMEN VS KLS martin GROUP

COMEN VS KLS martin GROUP

Excellent

	COMEN L6	marLED V16+V10
		
Illuminance	40,000-160,000 lx	Maximum 160,000 lx
CRI	95.5	95
Color temperature	3,800-6,200 K (5 positions)	3,800-4,800 K (3 positions)
Lifetime of LED	50,000 hours	40,000 hours
Number of bulbs	132	104
Shadow management system	Yes	No
Elliptical Spot	Yes	Unknow
Controller	Control panel and Smart OR	Handle and Control panel

COMEN VS KLS martin GROUP

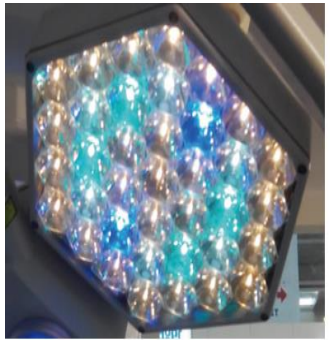
Excellent

①Shadow management system

★COMEN L6:
Support

☆marLED V16+V10：
Nonsupport

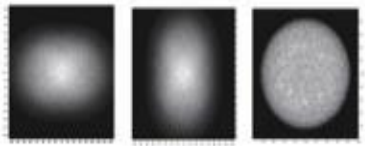
②4 color lights mixing internally

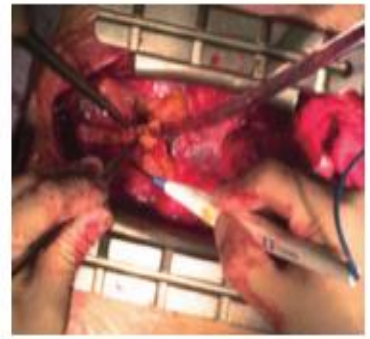


Only 2 companies have this technology

Comen is one of them

③Elliptical spot





★COMEN L6:
Support

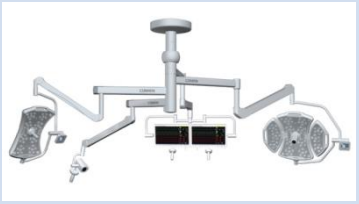
☆marLED V16+V10：
Nonsupport

Comprehensive OR/ICU Solution

COMEN VS MAQUET GETINGE GROUP

COMEN vs MAQUET GETINGE GROUP

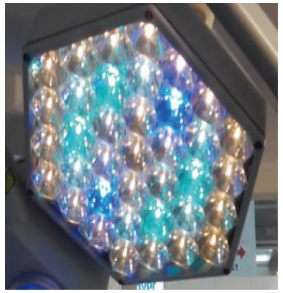
Excellent

Surgical Light	Comen L6	Maquet PowerLED	Maquet Volista
			
Color Rendering Index	95.5	95	95
Red Rendering Index	95	90	-
Color temperature	3800K≤Tc≤6200K	3,800	3,900–4,500–5,100
Illumination depth	1300mm (20%) 750mm (60%)	1200mm (20%)	500mm (60%)
Shadowless	Double cover plates: 70%	Double cover plates: 80%	Double cover plates 66% / 86%
Elliptical Spot	Yes	No	No
Shadow management system	Yes	Yes	Yes

COMEN vs MAQUET GETINGE GROUP

Excellent

①4 color lights mixing internally



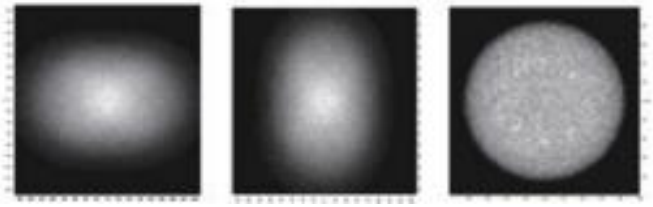
Only 2 companies have this technology

②5-level Color Temperature Adjustment

★COMEN L6:
(3800K≤Tc≤6200K)

☆Maquet PowerLED&Maquet Volista：
Three level adjustable （3900k-4500k-5100k）

③Elliptic Spot



★COMEN L6:
Support

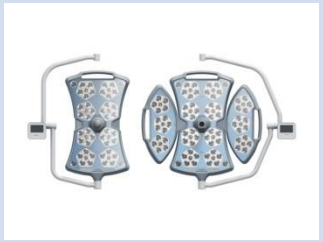
☆Maquet PowerLED&Maquet Volista：
Nonsupport

COMEN VS mindray

healthcare within reach

COMEN VS mindray
healthcare within reach

Excellent

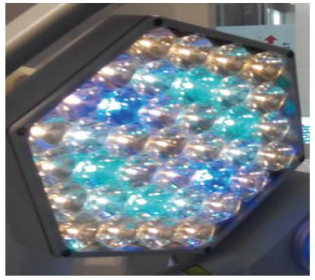
	COMEN L6	Mindray Hyled 9 Series
		
Light source	4 kinds of colors internally mixing	-
Light intensity	160000lux	160000lux
Color Temperature	3800-6200k(5 positions)	3000k-5000k(5 positions)
Elliptical Spot	Support	Nonsupport
Shadow management system	Yes	Yes
Lifetime of LED	50000h	40000h

COMEN VS mindray
healthcare within reach

Excellent

①Four color LED light mixed light

comen L6



Mindray Hyled 9 Series

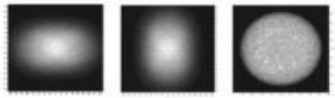
Only 2 companies have this technology

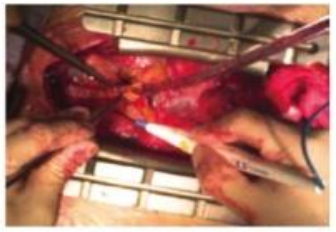
Comen is one of them

②Elliptic spot

★COMEN L6:
Support

☆Mindray Hyled 9 Series:
Nonsupport





More focus less Glare

③More Stable LED

comen L6
50000h

Mindray Hyled 9 Series
40000h

10000h(8h/day ,can use about 3 years)

Recall

Date: 2019.1.24

附件 1

医疗器械召回事件报告表

提交：☑企业所在地省级食品药品监督管理部门　　□器械注册/备案部门

产品名称	LED 手术无影灯 手术辅助移动式手术照明灯	注册证或备案凭证编码	苏食药监械（准）字 2014 第 2541133 号（LED 手术无影灯） 苏械注准 20172540033（LED 手术无影灯） 苏宁械备 20140015 号（手术辅助移动式手术照明灯）
生产企业名称	南京迈瑞生物医疗电子有限公司		
代理人名称	/		
召回单位负责人和联系方式，经办人和联系方式	南京迈瑞生物医疗电子有限公司 联系人：米传同 联系方式：025-66082657，njmrq@mindray.com		
产品的适用范围	LED 手术无影灯：供手术和治疗照明用 手术辅助移动式手术照明灯：用于手术室手术辅助照明		
涉及地区和国家	中国	召回级别	三级
涉及产品生产（中国）批次、数量	1652 台	涉及产品型号、规格	HyLED 系列 LED 手术无影灯 HyLED 系列手术辅助移动式手术照明灯
识别信息（如批号）	设备序列号见附录一受影响产品清单	涉及产品在中国的销售数量	1652 台
召回原因简述	南京迈瑞生物医疗电子有限公司（以下简称“南京迈瑞”）部分批次手术灯消毒手柄组件的手柄芯与手柄盘轴孔配合尺寸不符合公司内控标准，影响产品可靠性。为消除安全隐患，采取主动召回。		
纠正行动简述（包括召回要求和处理方	1.以客户信的形式通知所有受影响的客户，告知其相关信息； 服务人员将联系受影响客户，免费更换消毒手柄组件。		

报告单位：（盖章）南京迈瑞生物医疗电子有限公司

报 告 人：

负 责 人：（签字）

报告日期：2019.1.24

— 1 —

Amount：1652

Reason for recall:
The size of the handle core of the surgical lamp sterilized handle assembly and the shaft hole of the handle disc does not meet the internal control standards

Recall level: Third

Model：HyLED

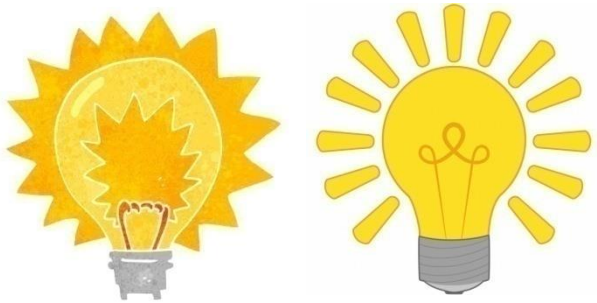
COMEN VS stryker

COMEN VS stryker

Excellent

	COMEN L6	Stryker F Generation
Illuminance	160000 Lux	160000 Lux
R9	95	96
Color temperature	3800K~6200K	3600K~5000K
Irradiance	Main Light: 530W/m2; Satellite Light: 350W/m2	Main Light: 594W/m2; Satellite Light: 460W/m2
Lifetime of LED bulb	50000 hours	40000 hours
Elliptic spot	Support	Nonsupport

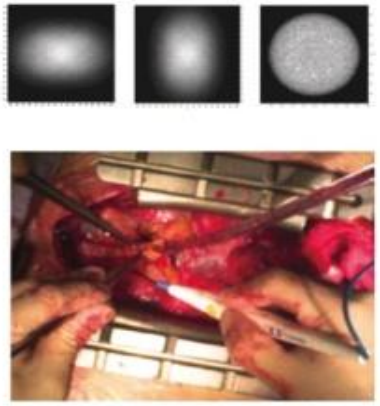
①Low Irradiance



★COMEN L6:
Main Light: 530W/m2;
Satellite Light: 350W/m2

☆Stryker F Generation:
Main Light: 594W/m2;
Satellite Light: 460W/m2

②Elliptic spot



★COMEN L6:
Support

☆Stryker F Generation:
Nonsupport

③More Stable LED

comen L6
50000h

Stryker F Generation
40000h

10000h(8h/day ,can use about 3 years)

FDA recall

Class 2 Device Recall Berchtold Chromophare Ceiling Mounted Surgical Light System

See Related Information

Recalling Firm/ Manufacturer	Stryker Communications 571 Silveron Blvd Flower Mound TX 75028
For Additional Information Contact	Ms. Julie Z. Baker 469-470-4317
Manufacturer Reason for Recall	The device could have a missing spanner nut and snap ring which could potentially result in the equipment falling.
FDA Determined Cause [2]	Employee error
Action	Stryker sent an Urgent Medical Device Correction letters to affected customers. The letter identified the affected product, problem and actions to be taken. The customer is informed a firm representative will be conducting a visual inspection of the equipment. No response form was enclosed. For questions email CommunicationsRA1@stryker.com
Quantity in Commerce	1,162 devices
Distribution	Worldwide Distribution - US Nationwide Distribution and in the countries of Canada.
Total Product Life Cycle	TPLC Device Report

Reason for recall:
The device could have a missing spanner nut and snap ring which could potentially result in the equipment falling.

Date:2018.01.29

Date Initiated by Firm	January 29, 2018
Date Posted	March 01, 2018
Recall Status[1]	Terminated [3]
Recall Number	Z-0828-2018
Recall Event ID	79251
Product Classification	Light, surgical, ceiling mounted - **Product Code** FSY
Product	Berchtold Chromophare Ceiling Mounted Surgical Light System, Catalog #CH13000000. Product Usage: Chromophare surgical lights are medical lights for usage in hospital treatment rooms. They provide localized lighting focused on the patient s body for detecting and treating disease, injury, and disability. The surgical lights may only be used in rooms used for medical purposes that have been equipped in accordance with VDE 0100-710 or IEC 60364-7-10 in accordance with the regulations. The Chromophare surgical lights consist of a ceiling tube, SK Box swivel arm support, and a light head. The light head is mounted on a cardanic suspension unit and can be turned, swiveled and tilted in any direction. The spatial repositioning of the light head makes use of the 360 degree rotating swivel/horizontal arm. The 360 degree rotating spring arm is used to adjust the height. The light can be mounted in several configurations, such as a single/dual ceiling mount, a boom-integrated suspension mount, a wall mount, or a mobile roll stand.

Quanitity:1162 device

COMEN

Excellent

Appreciate for Your Listening!