

ENHANCING SURGICAL OVERHEAD LIGHT PATIENT SAFETY

In the Operating Room (OR), the surgical team relies on overhead lights to illuminate the surgical field. The surgical light can create enhanced visualization of the surgical field, or if substandard, can lead to difficulties and patient safety issues. Medical device manufacturers have designed the surgical light with these things in mind by taking them into consideration throughout the innovation, research, and design phases. This white paper will provide the reader with an in-depth overview of the thought process that goes into safe surgical light development. The paper will also reveal how Baxter medical device manufactures not only design the lights to user's specifications, but ultimately, with patient safety in mind.

LET IT SHINE SAFELY

In the operating room, open surgery occurs daily, an incision is made, and target anatomy is exposed. The surgical team surrounding the incision typically consist of three to four individuals that all need to keep their eyes on the surgical target. Inadvertently, heads are bumped, light is blocked, and shadowing occurs in the surgical field which decreases team visualization. The Baxter engineering team has taken this patient safety issue into consideration with features such as shadow management. The shadow management feature optimizes the light effectiveness by automatically eliminating the shadow caused by the need to see the surgical target by the surgical team.

The brightness of the light is imperative to both surgeon and surgical team alike, often requiring low quality, outdated halogen overhead lights requiring settings at the maximum brightness for visualization, however, visualization can still be an issue. Thus, medical device manufactures have taken the next step in overcoming poor illumination challenges and created the lightemitting diode (LED) solution - semiconductor diode that glows when voltage is applied. The LED surgical light has revolutionized bright light visualization to the surgical world. LED lights and like the ILED surgical light, were introduced in 2005 and has become the preferred light source in the OR¹. Major LED surgical lights typically range in size from 22 to 30 inches

(56 to 76 cm) in diameter and are ceiling- or wall-mounted. ORs will often have two or three lights mounted, with additional support arms for mounting viewing monitors or other devices used by the surgical team¹. Optimal surgical illumination reduces shadow, glare, and distortion, while visualization is maintained. However, brighter illumination is not always better as high intensity directional light increases reflection which decreases the contrast vs contrastability of the microstructures². High intensity can negatively affect the surgical team and manifest itself as eve strain, headache, and in long term use can result in permanent photochemical damage as the eye loses its ability to protect the retina².

PATIENT SAFETY IN SURGICAL ILLUMINATION

Over the years, in the operating room, there have been case reports of iatrogenic patient burns, which are thermal in nature, due to direct heat intensity presented when surgical light heads overlap. Halogen lights posed a risk as higher heat was emitted from the light cones and as the light source got closer to the patient, the patient's surface temperature also increased.

Fortunately, the incidence of iatrogenic burns has decreased since the inception of LED technology, although there is still a risk because they still emit heat. The risk increases when the distance of the operating room light is brought closer to the surgical site and the



convergence of multiple operating lights at a point of focus³. LED lights are constructed so that the focus of the light is at 1m distance. But, due to the LED lights physics, this may not be the point where it is the warmest. The LED heat transmission can be deceiving to the surgical team as LED is a cool light, and intensity can impact the patient at a distance from 120cm to 160cm. Incidence of iatrogenic burns have still been reported in recent years⁴, but the literature is sparce and has stayed hidden to the surgical community.

REQUIREMENTS FROM REGULATORS

In 2022, a Human Factors study was done for the Baxter surgical light that included 25 participants. It was a surprise to the research team that none of the 25 participants were aware of the potential iatrogenic burn risk associated with high heat, overlapping and overhead light heads. The lack of awareness of this potential risk puts the surgical team at a disadvantage in providing safe patient care. Surgical overhead light manufacturers have a responsibility to educate the surgical community of the iatrogenic burn risk that the device poses.

The Food and Drug Administration (FDA) updated the requirements related to surgical overhead light safety in 2021. IEC 60601-2-41:2021 cancels and replaces the second edition that was published in 2009. The requirement update recommends that the manufacturers add exposure limits, test conditions, calculation methods and safety warnings related to photobiological hazards to the instructions for use (IFU). Patient Safety and Quality of Healthcare (PSQH) found that often healthcare professionals do not read the IFU, and at worst do not even know they exist⁵. The lack of IFU access by the healthcare professional can further add to patient risk as overhead surgical light manufacturers are required to identify luminary risk. ECRI, a global, independent authority on healthcare technology and safety, recommends that that surgical light manufacturers should affix a warning diagram or label stating that overlapping light fields at high intensity settings can cause patient burns. These labels should be affixed on a clearly visible surface as well as on any control panels where clinicians will see the label when adjusting the light and was clearly stated in the ECRI exclusive hazard report H0724 on 11/05/21

DECREASING RISK OF THERMAL INJURY

There are simple steps to decrease the risk of thermal injury to the surgical patient no matter what brand of surgical light is being used. Once risk is identified, interventions can be implemented. Some surgical patient populations are at more risk than others, neonates and geriatric patients pose the greatest risk. Patients that take, Antihistamines, Phenothiazines (antiemetics), Sulfonamides, Thiazides and other medications may be at increased risk for thermal injury⁶. By assessing the patient for thermal injury risk, appropriate risk mitigation strategies can be implemented.

OTHER WAYS TO DECREASE THE THERMAL INJURY RISK

that **all manufactured** overhead surgical lights pose include:

- Limiting the time that overhead light heads are crossed and focused on the surgical incision
- Crossing multiple overhead light heads at high intensity on **any brand** of surgical light can pose a thermal risk to the patient.
- Maintaining a light intensity that illuminates the site appropriately at less than 80%
- Knowing the location of both light heads will always decrease the risk of the accidental delivery of light energy to the surgical team and patient.

RAISING THE BAR IN SURGICAL LIGHT SAFETY AWARENESS

Thus far, integrating overhead surgical light risk warnings into manufacturing Instructions for Use (IFU) has not been effective in protecting the patients from the risk of intraoperative burns. The lack of awareness around the issue continues to be a knowledge barrier to the healthcare community. Surgical light manufacturers have become complacent in raising this awareness to the surgical community until now. With this knowledge, it is the utmost importance to review all manufacturing IFU's for patient safety considerations.

The Baxter engineering team recognized the lack of awareness by the healthcare community related to thermal injury risk associated with all overhead surgical lights on the market today. The Baxter surgical light integrates risk mitigation into the technology, keeping the light head 100 cm from the surgical incision in combination with the auto focus feature, ensures that the light, heat, and focus are always at a safe setting.

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