

Wearable Harness Lighting System Using Maneuverable Light Extensions

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Current lighting systems have disadvantages that can adversely impact the performance of surgeons during a procedure. The client for the proposed device is a GI, trauma, and endocrine surgeon. The client expressed frustrations that the current lighting systems are big and bulky, uncomfortable to wear, don't provide enough illumination, fail to provide a clear pathway for the light, and lack a long-lasting battery life. A study that analyzed the effectiveness of current surgical lighting in various fields of surgery, including but not limited to our client's specialty, determined that operating room staff in 13 hospitals all have issues with the usability and lack of illumination ¹. On average, current lighting systems are adjusted every 7.5 minutes, and 74% of the time the surgeons are the ones adjusting the light extending the surgical procedure time ¹. Due to these common issues, a new lighting system is needed and could apply to a broad range of surgeons.

There were four main user needs that our design team focused on when designing this device, these were: comfort, sterility, maneuverability, and adequate lighting. With these criteria in mind, our bioengineering team developed a novel surgical light design that allows for ideal positioning of the light source while fitting more comfortably on the user.

We believe our device could be competitive in the surgical lighting market, due to the low cost of production. Our production cost per unit falls below \$300 while the average price for surgical lighting systems ranges from \$2,000 to \$40,000 per unit. The Center for Devices and Radiological Health will regulate the device because the device uses no chemicals and it's not metabolized by the body. It will be a class 2 medical device that follows the 510(K) pathway. There is freedom-to-operate with the device as there are no patents using this design and application.

1. Indicating shortcomings in surgical lighting systems. Arjan J. Knulst, Rik Mooijweer, Frank W. Jansen, Laurents P. S. Stassen, Jenny Dankelman *Minim Invasive Ther Allied Technol.* 2011 Sep; 20(5): 267–275. Published online 2010 Nov 17. doi: 10.3109/13645706.2010.534169