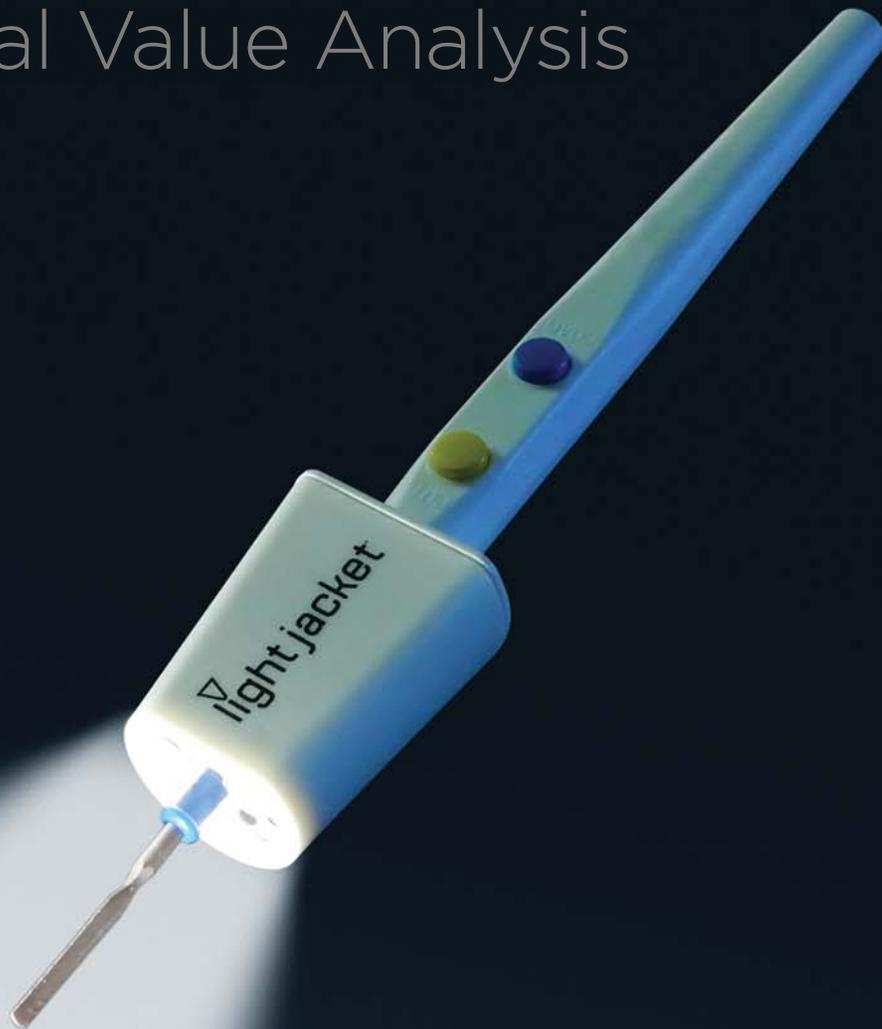


light jacket®

Clinical Value Analysis



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Clinical Value Analysis

Background

Surgical Lighting Basic Requirements

- Center on a surgeon's immediate field
- Illuminate a wide or narrow field with high-intensity light
- Light penetrates into a cavity or under a flap

Currently Available Light Sources

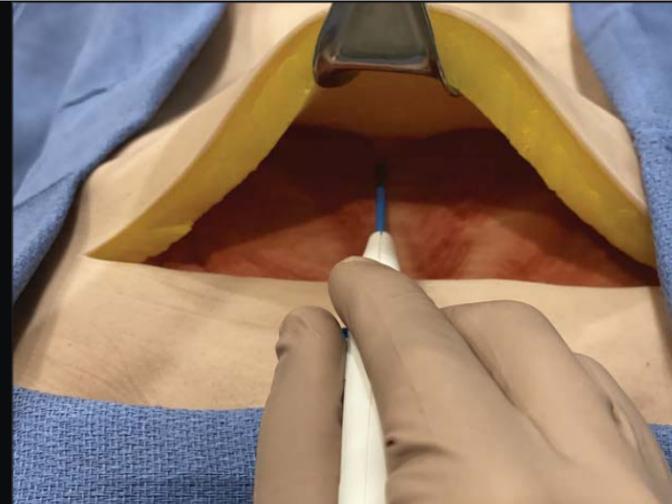
- Overhead surgical lighting systems
- Lighted retractors
- Headlights

light jacket[®]

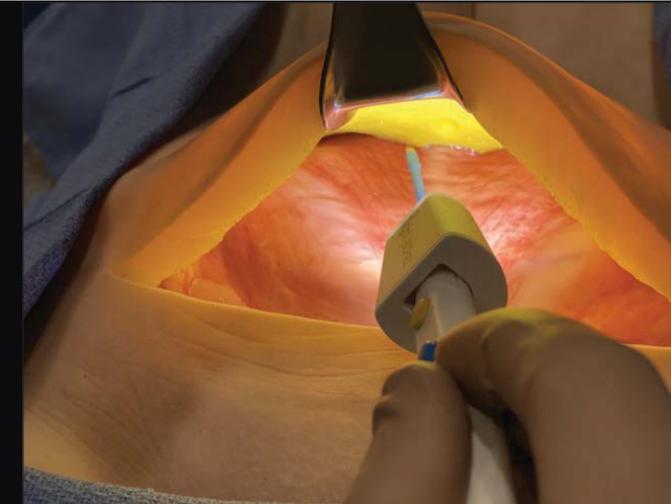
Directs precise illumination at the electrocautery surgical site



WITHOUT LIGHT JACKET[®]



WITH LIGHT JACKET[®]



Problems

Distraction

- Overhead lights provide poor illumination of cavities and require frequent adjustments, on average once every 7.5 minutes¹
- In a recent study, surgeons paused surgery for a lighting adjustment in 97% of cases¹

Contamination

- Up to 50% of previously sterile overhead light handles become colonized with bacterial growth²
- 29.5% of reusable surgical devices have been reported to be bacteriologically positive³
- 66% reduction in surgical infections was seen at one site after introduction of disposable instruments during orthopedic surgery⁴

Patient Burns

- Fiberoptic cables used with lighted retractors can reach 437°F and light cable ends can reach 214°F, serving as sources of burns and surgical fires⁵

Surgeon Health Problems

- Nonergonomic lighting has been associated with surgeon fatigue and musculoskeletal disorders: 68% of high-frequency headlight users reported cervical pain versus 34% of low-frequency users, with 34% developing degenerative cervical disorders⁶

SOLUTION BY PATHY MEDICAL^{® 7}

Potential to Reduce Distractions

- Bright, cordless light source
- Slides onto existing electrocautery pencils in seconds
- Long life: 2 hours of light⁸

Potential to Reduce Contamination

- Sterile, disposable

Reduce Potential for Burns

- Low heat emission

Potential to Reduce Surgeon Fatigue and Physical Strain

- Ergonomic and surgeon-directed light

Cost-Effective

- Less expensive per case than many other light sources when acquisition, maintenance, and resterilization are factored

Cost Analysis

- Inexpensive
- Reduce costs associated with resterilizing reusable light sources
- Substitute more expensive light sources
- Reduce or eliminate cost of maintaining and replacing reusable light sources such as lighted retractors, light cords and bulbs
- Small footprint in the operating room

Cost Comparison (in \$US per Case)			
\$300			
\$200			
\$100			
\$0			
	Reusable Lighted Retractor ⁹	Competing Disposable Lighted Retractor ¹⁰	Light Jacket [®]

■ Acquisition ■ Sterilization ■ Maintenance



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7. Scope of solutions limited to topics listed in the section labeled "Problems".
8. Cumulative runtime; device intended for intermittent use; internal test data on file.
9. Assumes acquisition cost of lighted retractor, cord, and source amortized over 3-year usable life with 200 cases/per year.
10. Compared to Medtronic Radialux lighted retractor.

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