



Document Number  
1094930

Revision Number  
4




TECHNICAL DATA SHEET

Alt. Doc. Number  
N/A

Effective Date  
16Nov2023

LIGHT HANDLE COVERS AND CAMERA COVERS

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<b>Product Family</b>	Light Handle Covers and Camera Covers
<b>Intended Use</b>	<p>Light Handles: are intended to provide a sterile interface between the operating room surgical lamps (non-sterile) and the Surgeon or Nurse (sterile).</p> <p>Camera Covers: intended to provide a sterile interface between the non-sterile surgical camera and the Surgeon</p>
<b>Description</b>	<p>Light Handle Covers: are sterile, single-use devices intended to act as a sterile surface between the non-sterile surgical light and the Surgeon or healthcare professionals during procedures. The devices are available in two main configurations: Rigid Light Handle Cover and Flexible Light Handle Cover</p> <p>Camera Covers: single use universal rigid cover for O.R. cameras, in this case typically attached to an O.R. light. The cover has a transparent material assembled into the distal end to provide a sterile interface while maintaining proper camera visibility</p>
<b>Picture of Device</b>	<p>LIGHT HANDLE COVERS</p>   <p>CAMERA COVERS</p> 



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<b>Manufacturer Name and Address</b>	<p>Aspen Surgical Products, Inc. 6945 Southbelt Dr. SE Caledonia, MI 49316, USA</p> <p>DUN #027680821 Tax ID #383 448 946</p>
<b>Certifications</b>	<p>ISO 13485 CE 612364 MDSAP 690516 MDR 755274 R000</p> <p><a href="https://www.aspensurgical.com/compliance/certificates/">https://www.aspensurgical.com/compliance/certificates/</a></p>
<b>Sterilization Information</b>	<p>Ethylene Oxide (EtO): Sterilization Services of Virginia (SSV) 5674 Eastport Blvd Richmond, Virginia 23231, USA</p>
<b>European Union Classification</b>	<p>Light Handle: MDD - Class I under Rule I per Annex IX Camera Cover: MDD – Class I under Rule I per Annex IX</p> <p>Light Handle: MDR- Class I under Rule I per Annex VIII Camera Cover: MDR- Class I under Rule I per Annex VIII</p>
<b>Authorized Representative of the European Union</b>	<p>Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands</p>
<b>EU Notified Body</b>	<p>BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam Notified Body Number: 2797</p>
<b>Canadian Classification and License Number (If applicable)</b>	<p>Light Handle Cover: Class I, Rule 7 Camera Cover: Class I, Rule 7 Medical Device License: N/A – Both products are a class 1 device in Canada and do not require a medical device license</p>



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**FDA Regulatory Class and Product Code Registration #**

Light Handle Cover: 21 CFR 878.4580 Light, Surgical, Accessories  
Medical Device Listing Number: D359002 Product Code: FTA  
Product Class: Class 2  
510k Submission Type: Exempt

Camera Cover: 21CFR 878.4160 Camera, Surgical and Accessories  
Medical Device Listing Number: D359005  
Product Code: KQM  
Product Class: Class 1  
510k Submission Type: Exempt

**Instruction Insert (IFU)**

1. Disposable Light Handle Cover Sterile IFU: 20190053
2. Disposable Light Handle Cover Non-Sterile IFU: 20190052
3. Flexible Light Handle Cover Sterile IFU: 20200061
4. Camera Cover IFU, Sterile: 20200089
5. Camera Cover IFU, Non-Sterile: 20200088

Provided with product and available on Aspen's website:  
<https://www.aspensurgical.com/education/instructions-for-use/>

**Material Composition**

Rigid Light Handle Cover: Co-Polymer Resin, Polypropylene, Colorant

Flexible Light Handle Cover: Polyethylene, Thermoplastic Elastomer, Colorant, Wood Free Printed Paper

Camera Cover: Polypropylene Co-Polymer, Confidential Copolymer, Colorant,

Configurations do not contain reportable amounts of:

- Natural latex rubber
- Polyvinylchloride (PVC)
- Phthalates
- Bis (2-ethyhexyl) phthalate (DEHP)
- Bisphenol A (BPA)
- Potential contamination by bovine or transmissible spongiform encephalopathies (BSE/TSE).
- Substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR') of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council

**RoHS under DIRECTIVES 2011/65/EU as amended by Directives 2015/863 & 2017/2102**

Not Applicable. This device does not consist of any electrical & electronic equipment



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<b>REACH Regulation 1907/2006</b>	Aspen confirms that to the best of our knowledge that none of these products or product packaging contain any Substances of Very High Concern (SVHC) as noted on the REACH Candidate List in a concentration above 0.1% by weight allowable limit. This list will continue to be monitored for additions or modifications
<b>California Proposition 65</b>	At this time, this product does not contain chemicals listed on California's Safe Drinking Water & Toxic Enforcement Act, commonly known as California Proposition 65. This list will continue to be monitored for additions
<b>Biological/Biocompatibility Report</b>	When used as intended, the Light Handle Covers and Camera Covers are touched by the practitioner with a gloved hand. There is no intended patient or practitioner contact; therefore, biocompatibility testing is not required according to ISO 10993-1  Conclusion: Device poses no biological risk
<b>GMDN Number and EMDN Number, if applicable</b>	GMDN: 44977, Medical equipment handle cover, single-use sterile GMDN: 17977, Medical equipment handle cover, single-use, non-sterile EMDN: T030101 and T030102 Light Handle Cover EMDN: T030202 OR Camera Cover
<b>Shelf Life</b>	5 Years Shelf Life
<b>Country of Origin</b>	USA and China
<b>Tariff Codes</b>	HTS: 9018.90.2000 HS: 9018.90.8000
<b>Radiopaque</b>	N/A - Device is not radiopaque