Aesculap Endoscopic Technology

Instructions for use
LED light source OP940 with sterile adapter OP941

Gebrauchsanweisung
LED-Lichtquelle OP940 mit Steriladapter OP941
Aesculap®
LED light source OP940 with sterile adapter OP941

Legend
1 Power OFF switch
2 Power ON switch
3 Power ON indicator
4 Brightness control with push function
5 Light source test unit with sterile adapter
6 Lock activator for optical cable socket
7 Optical cable socket
8 Communication interfaces
9 Power cord connector
10 Fuse holder
11 Device feet
12 Potential equalization connection
13 Service interfaces

Symbols on product and packages

Caution, general warning symbol
Follow the instructions for use
Type BF applied part
Optical cable connection
Equipotentialization connector
Unlock
Hazardous electrical voltage
Fuse
Alternating current
On/Off switch
Labeling of electrical and electronic devices according to directive 2002/96/EC (WEEE), see Disposal
1. Applicable to

- For item-specific instructions for use and information on material compatibility, see also the Aesculap Extranet at www.extranet.bbraun.com

2. Safe handling

CAUTION

Federal law restricts this device to sale by, or on order of a physician!

- Do not open the product.
- Connect the product only to a grounded power supply.

DANGER

Risk of fatal injury from electric shock!

- Do not open the product.

WARNING

Risk of injury caused by incorrect operation of the product!

- Attend appropriate product training before using the product.
- For information about product training, please contact your national B. Braun/Aesculap agency.

- Prior to use, check that the product is in good working order.
- Observe "Notes on Electromagnetic Compatibility (EMC)", see TA022130.
- To prevent damage caused by improper setup or operation, and in order not to compromise warranty and manufacturer liability:
  - Use the product only according to these instructions for use.
  - Follow the safety and maintenance instructions.
  - Only combine Aesculap products with each other.
- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- Keep the instructions for use accessible for the user.
- Always adhere to applicable standards.
- In the sterile field only use sterile processed sterile adapter OP941.
- Ensure that the electrical facilities in the room in which the device is being used conform to IEC norms.
- Unplug the device by pulling on the plug, and never on the power cord.
- Do not use LED light sources in areas where there is a risk of explosion.
- Make certain that the ambient temperature does not exceed 35° C.
- Make certain that the device's ventilation ducts are not covered.
- Make certain that the following minimum distances from other devices are maintained:
  - on the sides 50 mm
  - from the rear 60 mm
- Make certain that only non-conductive optical cables are used. This applies in particular to products from other manufacturers, in order to meet BF requirements.
3. Product description

3.1 Scope of supply

<table>
<thead>
<tr>
<th>Designation</th>
<th>Art. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>LED light source</td>
<td>OP940</td>
</tr>
<tr>
<td>Sterile adapter</td>
<td>OP941</td>
</tr>
<tr>
<td>Instructions for use</td>
<td>TA013718</td>
</tr>
<tr>
<td>EMC brochure</td>
<td>TA022130</td>
</tr>
</tbody>
</table>

3.2 Components required for operating the LED light source OP940

<table>
<thead>
<tr>
<th>Designation</th>
<th>Art. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>LED light source</td>
<td>OP940</td>
</tr>
<tr>
<td>Sterile adapter</td>
<td>OP941</td>
</tr>
<tr>
<td>Optical cable with an active diameter of 4.8 mm from Aesculap/Storz, Olympus and Wolf</td>
<td>-</td>
</tr>
<tr>
<td>Power cord</td>
<td>-</td>
</tr>
</tbody>
</table>

3.3 Intended use

The LED light source OP940 is used to illuminate the operative field and areas of the body during medical applications.

Indication

The LED light source is used to illuminate the operative field during diagnostic and operative endoscopic procedures.

Contraindication

Due to the universal suitability of the device for endoscopy, no specific contraindication can be stated. The use of the device is considered to be contraindicated if the endoscopic procedure is contraindicated or if its use could pose a risk to the patient.

3.4 Operating principle

The LED lamp is very similar to a point light source. The light is propagated through the optical cable and directed to the field of view (operative field).

Brightness control

The desired brightness can be continuously adjusted with the brightness control 4.

Standby mode

On pressing the brightness control with push function 4, the active light source is put into Standby mode. On pressing the brightness control with push function 4 again, the light source goes back to the previously set value.

Multi optical cable socket

The multi optical cable socket 7 enables different optical tables of type Aesculap/Storz, Olympus and Wolf with an active diameter of 4.8 mm to be plugged in.

Light source test unit with sterile adapter

The optical cable test unit is used in the sterile field with a sterile processed sterile adapter OP941.

Modes shown on the display

<table>
<thead>
<tr>
<th>Display</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiber Connection</td>
<td>Optical cable is not plugged in or not plugged in properly</td>
</tr>
<tr>
<td>Standby</td>
<td>LED of device is off. Circular green light on the brightness control is off.</td>
</tr>
<tr>
<td>Brightness (0 %–100 %)</td>
<td>Percentage of the light output (in increments of 5 %)</td>
</tr>
</tbody>
</table>
4. Preparation and setup

<table>
<thead>
<tr>
<th>DANGER</th>
<th>Danger of explosion from a device that is improperly set up!</th>
</tr>
</thead>
<tbody>
<tr>
<td>►</td>
<td>Do not use the device in explosion-hazard areas.</td>
</tr>
<tr>
<td>►</td>
<td>Make certain that the power plug is connected to the power supply outside of any areas where there is a risk of explosion.</td>
</tr>
<tr>
<td>►</td>
<td>Have ready replacement products/light source.</td>
</tr>
</tbody>
</table>

Non-compliance with the following instructions will preclude all responsibility and liability in this respect on the part of Aesculap.

► When setting up and operating the product, adhere to
  - national regulations for installation and operation,
  - national regulations on fire and explosion protection.

**Note**

For the safety of patients and users it is essential that the mains power cord and, especially, the protective earth connection are intact. In many cases defective or missing protective earth connections are not registered immediately.

**Note**

The connection of electrical devices to a multiple socket creates a system and can lead to a reduced level of safety.

**Note**

If the equipment cart is set up outside of the sterile area, measure the cable length to give enough room for movement so that the sterility is not compromised.

► Connect the device via the potential equalization terminal at the rear panel of the device to the potential equalization system of the room used for medical purposes.

► Ensure that all devices operated in the vicinity meet their relevant EMC requirements.

**Note**

The potential equalization lead can be ordered from the manufacturer as art. no. GK535 (4 m length) or TA008205 (0.8 m length).

4.1 First use

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Risk of injury and/or product malfunction due to incorrect operation of the electromedical system!</th>
</tr>
</thead>
<tbody>
<tr>
<td>►</td>
<td>Adhere to the instructions for use of any medical device.</td>
</tr>
<tr>
<td>►</td>
<td>Do not use the product in a magnetic resonance environment.</td>
</tr>
</tbody>
</table>

4.2 Presetting the correct voltage

The mains voltage must correspond to the voltage indicated on the type plate at the back of the unit.

5. Working with the LED light source

5.1 System set-up

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Risk of burns from excessively high operating temperatures!</th>
</tr>
</thead>
<tbody>
<tr>
<td>►</td>
<td>The optical cable socket and optical cable connections get hot.</td>
</tr>
<tr>
<td>►</td>
<td>Do not situate optical cables near any flammable objects (e.g., drape).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Danger of blinding from light rays!</th>
</tr>
</thead>
<tbody>
<tr>
<td>►</td>
<td>Never look into the open end of an optical cable or endoscope that is connected.</td>
</tr>
</tbody>
</table>

► Set up the device on an even surface in a non-sterile area.
► Make certain that the device support (e.g., table, hanging ceiling light) is sufficiently stable.
► Make certain that the device is safeguarded against vibration during operation.
► Make certain that the rear of the device is accessible at all times.
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LED light source OP940 with sterile adapter OP941

Connecting devices for communication
The communication interfaces 8 connect the light source to a superordinate device. Through these, the light source receives control signals from the connected device.

Connecting the accessories

Risk of injury due to unapproved configuration using additional components!
► For all applied components, ensure that their classification matches that of the application component (e.g. Type BF) of the respective device.

Combinations of accessories that are not mentioned in the present instructions for use may only be employed if they are specifically intended for the respective application, and if they do not compromise the performance and safety characteristics of the products.
Also note that any equipment connected at the interfaces must demonstrably meet the respective IEC standards (e.g. IEC 60950 for data processing equipment, IEC/DIN EN 60601-1 for electromedical devices).
All configurations must comply with basic standard IEC/DIN EN 60601-1. Any individual connecting devices with one another is responsible for such configuration and must ensure compliance with basic standard IEC/DIN EN 60601-1 or applicable national standards.
► Please address your B. Braun/Aesculap partner or Aesculap Technical Service with any inquiries in this respect; for a contact address, see Technical Service.

Connecting the optical cable.
► Plug the optical cable into the optical cable socket 7 until it audibly snaps into place.
► Do not crush or crimp the optical cable or wind it too tightly (minimum diameter 150 mm).

Keep the LED light source separated from the optical cable.
► To unlock the optical cable, turn the activator 6 in the marked direction.

Connecting the sterile adapter
► Before the optical cable test, screw sterile adapter OP941 onto the optical cable test unit 5.
► If necessary, screw on the adapter for connecting the optical cable.

Removing the sterile adapter from the LED light source
► After the optical cable test, unscrew sterile adapter OP941 from the optical cable test unit 5.

Connecting the power supply

Risk of fatal injury from electric shock!
► Connect the product only to a grounded power supply.

► Plug in the power cord into the power cord connector 9 on the rear of the LED light source.
► Plug in the mains plug at a socket of the building mains.
► Turn on the LED light source with the power ON 2 switch.
The power ON 3 indicator lamp shows that the device is activated.
► When operating multiple devices concomitantly, connect the devices to the potential equalization terminal.
5.2 Function checks
► Prior to each use, perform a functionality test for the LED light source.
  Make certain that the self-test runs in accordance with legal regulations.
If the device functions properly, the light will turn on after the device is switched on. After the device is switched on, the power ON 3 indicator lamp lights up on the front of the device.

5.3 Optical cable test
If necessary, carry out an optical cable test:
► Screw sterile adapter OP941 onto the optical cable test unit 5.
► Screw the distal end of the optical cable to be tested onto the sterile adapter.

Note
The optical cable test takes place regardless of the selected light strength (e.g. 80%).
■ The results are displayed:
  - Good (100 %– 66 %)
  - Acceptable (65 %–33 %)
  - Change (32 %–0 %)

5.4 Safe operation

5.5 Ending the operation of the device
► To end the operation of the device, press the power OFF switch 1.
► Remove the optical cable from the sterile adapter 5.
► To completely disconnect the device from the power supply, remove the plug from the power cord connector 9 on the rear of the device.
6. Validated reprocessing procedure

6.1 Disassembling the product before carrying out the reprocessing procedure
► Disassemble the product immediately after use, as described in the respective instructions for use.

6.2 Preparations before cleaning
► Carry out non-fixating/NaCl-free pre-cleaning immediately after use.

6.3 Cleaning/disinfection

Product-specific safety guidelines on the reprocessing procedure

**DANGER**
Risk of electric shock and fire hazard!
► Unplug the device before cleaning.
► Do not use flammable or explosive cleaning or disinfecting solutions.
► Ensure that no fluids will penetrate the product.

**CAUTION**
Damage to, or destruction of the product caused by mechanical cleaning/disinfection!
► Only clean and disinfect the product manually.
► Do not sterilize the product under any circumstances.
► Never clean the product by ultrasound treatment.

**CAUTION**
Risk of damage to the product due to inappropriate cleaning/disinfecting agents!
► Only use cleaning/disinfecting agents approved for surface cleaning. Follow the manufacturer’s instructions for the respective cleaning/disinfecting agent.

**CAUTION**
Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!
► Following the manufacturer’s instructions, use cleaning and disinfecting agents which
  – be approved for plastic material and high-grade steel,
  – do not attack softeners (e.g., in silicone).
► Observe specifications regarding concentration, temperature and exposure time.
► Do not exceed the maximum allowed cleaning temperature.
Validated cleaning and disinfection procedure

Note
Reprocessing may only take place in accordance with the following listed procedures in version V6. These are documented in the Validated Reprocessing Procedures brochure (AVA-V6). You can also find this brochure in the Aesculap extranet at www.extranet.bbraun.com

<table>
<thead>
<tr>
<th>Validated procedure</th>
<th>Specific requirements</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wipe disinfection for electrical devices without sterilization</td>
<td>■ Keep the optical cable interfaces clean.&lt;br&gt;■ Be sure that the optical cable interfaces are not scratched. Rub the optical cable interfaces with a wad of cotton.</td>
<td>Chapter Wipe disinfection for electrical devices without sterilization</td>
</tr>
<tr>
<td>Mechanical alkaline cleaning and thermal disinfection</td>
<td>■ Insert the product in its proper position in the Eccos holder.&lt;br&gt;■ Connect the internal rinsing equipment at the Eccos holder and at the rinsing connector of the rinsing cart.&lt;br&gt;■ Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots).</td>
<td>Chapter Mechanical cleaning/disinfecting and subchapter:</td>
</tr>
</tbody>
</table>

6.4 Inspection, maintenance and checks
► Allow the product to cool down to room temperature.
► Inspect the product after each cleaning and disinfecting cycle to be sure it is: clean, functional, and undamaged.
► Check the product for any damage, abnormal running noise, overheating or excessive vibration.
► Set aside the product if it is damaged.

7. Maintenance
To ensure reliable operation, the product must be maintained at least once a year.
For technical service, please contact your national B. Braun/Aesculap agency, see Technical Service.

8. Troubleshooting list

<table>
<thead>
<tr>
<th>Malfunction</th>
<th>Detection</th>
<th>Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LED light source and fan do not work</td>
<td>Device not powered</td>
<td>The plug is not inserted in the socket</td>
<td>Insert plug in socket</td>
</tr>
<tr>
<td>Indicators not illuminated</td>
<td>Fuses blown</td>
<td>Replace fuses, see Fuse replacement</td>
<td></td>
</tr>
<tr>
<td>Indicator light not illuminated even after change of fuse</td>
<td>Malfunction in power supply unit</td>
<td>Have LED light source repaired by manufacturer</td>
<td></td>
</tr>
<tr>
<td>Fan doesn’t work</td>
<td>No air comes out of the air outlet</td>
<td>Malfunction in fan</td>
<td>Have LED light source repaired by manufacturer</td>
</tr>
<tr>
<td>Brightness significantly lower</td>
<td>The optical cable cannot be removed</td>
<td>Optical cable not completely inserted</td>
<td>Use the correct optical cable connection</td>
</tr>
<tr>
<td>Light source cannot be controlled</td>
<td>Light source does not respond to signals from the camera</td>
<td>Interface cable not correctly plugged in or defective</td>
<td>Check connection or replace cable</td>
</tr>
</tbody>
</table>
8.1 Fuse replacement

DANGER
Risk of fatal injury from electric shock!
► Unplug the device before changing the fuses!

Ask your B. Braun/Aesculap agency about the prescribed fuse set.
► Use a small screwdriver to release the clip on the fuse holder 10.
► Remove fuse holder 10.
► Replace both fuses.
► Reinsert fuse holder 10 so that it audibly snaps into place.

Note
If the fuses burn out frequently, the device is faulty and should be repaired, see Technical Service.

9. Technical Service

WARNING
Risk of injury and/or malfunction!
► Do not modify the product.

► For service and repairs, please contact your national B. Braun/Aesculap agency.

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

Service addresses
Aesculap FLEXIMED GmbH
Robert-Bosch-Strasse 1
79211 Denzlingen / Germany
Phone: +49 7666 9321-0
Fax: +49 7666 9321-580
E-Mail: techserv@aesculap-fleximed.de
Or in the US:
Aesculap Inc.
Attn. Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood
MO, 63042
Aesculap Repair Hotline
Phone: +1 800 214-3392
Fax: +1 314 895-4420
Other service addresses can be obtained from the address indicated above.

10. Accessories/Spare parts

All accessories and spare parts must only be procured from the manufacturer.

10.1 Accessories for sterile adapter

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>OP941</td>
<td>Sterile adapter</td>
</tr>
</tbody>
</table>

10.2 Accessories for power cord

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Approvals</th>
<th>Color</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>TE780</td>
<td>Europe</td>
<td>black</td>
<td>1.5 m</td>
</tr>
<tr>
<td>TE730</td>
<td>Europe</td>
<td>black</td>
<td>5.0 m</td>
</tr>
<tr>
<td>TE734</td>
<td>Great Britain</td>
<td>black</td>
<td>5.0 m</td>
</tr>
<tr>
<td>TE735</td>
<td>USA, Canada, Japan</td>
<td>gray</td>
<td>3.5 m</td>
</tr>
</tbody>
</table>

10.3 Spare part for fuse

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>TA022371</td>
<td>Fuse set</td>
</tr>
</tbody>
</table>
11. Technical Data

Classification acc. to Directive 93/42/EEC

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>OP940</td>
<td>LED light source</td>
<td>I</td>
</tr>
<tr>
<td>OP941</td>
<td>Sterile adapter</td>
<td>I</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Voltage range (current consumption)</th>
<th>100 V — 240 V — (120 VA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>50 Hz to 60 Hz</td>
</tr>
<tr>
<td>Protection class (acc. to IEC/DIN EN 60601-1)</td>
<td>I</td>
</tr>
<tr>
<td>Device protection</td>
<td>T 1.6 A (L)</td>
</tr>
<tr>
<td>Weight</td>
<td>7 kg</td>
</tr>
<tr>
<td>Dimensions L x H x W</td>
<td>305 mm x 125 mm x 305 mm</td>
</tr>
<tr>
<td>EMC</td>
<td>IEC/DIN EN 60601-1-2</td>
</tr>
<tr>
<td>Conforming to standard</td>
<td>IEC/DIN EN 60601-1</td>
</tr>
</tbody>
</table>

12. Ambient conditions

<table>
<thead>
<tr>
<th></th>
<th>Operation</th>
<th>Storage and transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>10 °C</td>
<td>40 °C</td>
</tr>
<tr>
<td></td>
<td>-10 °C</td>
<td>50 °C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>0 %</td>
<td>0 %</td>
</tr>
<tr>
<td></td>
<td>10 %</td>
<td>90 %</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>700 hPa</td>
<td>500 hPa</td>
</tr>
<tr>
<td></td>
<td>1 060 hPa</td>
<td>1 060 hPa</td>
</tr>
</tbody>
</table>

13. Disposal

Note
The user institution is obliged to process the product before its disposal, see Validated reprocessing procedure.

Adhere to national regulations when disposing of or recycling the product, its components and its packaging!
The recycling pass can be downloaded from the Extranet as a PDF document under the respective article number. (The recycling pass includes disassembling instructions for the product, as well as information for proper disposal of components harmful to the environment.)
Products carrying this symbol are subject to separate collection of electrical and electronic devices. Within the European Union, disposal is taken care of by the manufacturer as a free-of-charge service.

14. Distributor in the US/Contact in Canada for product information and complaints

3773 Corporate Parkway
Center Valley, PA, 18034, USA
This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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Meaning: Document signed as Author

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Meaning: Approve Document

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Meaning: Approve Document

UserName: Kasey Sheeran (sheekaus)
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Meaning: Final Release of the Document

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Title: LED LIGHT SOURCE OP90 WITH STERILE ADAPTER OP941 Initiator: Kasey ? Sheeran

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