



Fiber-Optic Light Cable Shield

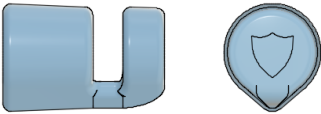
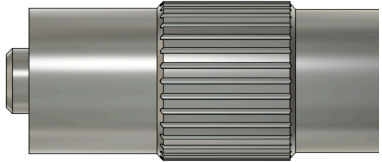
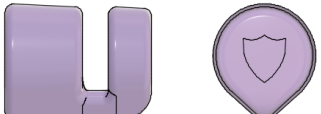
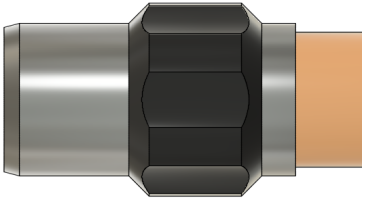
Instructions for Use

DEVICE DESCRIPTION

GloShield® is a single patient use, disposable safety device (not made with natural rubber latex and x-ray detectable) that fits on the scope connector of a fiber-optic light cable. GloShield® shields the majority of the light from the light cable upon scope disconnection, thereby decreasing or reducing the potential for operating room fires and patient burns in the surgery suite.

There are two GloShield® products offered for light cables:

Table 1: GloShield® & Light Cable Compatibility

GloShield® Model	Light Cable Type	Light Cable Connector Profile
<p>Karl Storz® (Color: Sky Blue) Order: REF 16-3001 (Carton) Track: REF 16-3001 (Pouch)</p> 	<p>Karl Storz® (495 Series and similar profile EXCEPT 495 NCSC, NAC, FP, FR, FS, TIP)</p> <p>Stryker® (233-050-064, 233-050-084, and similar profile)</p> <p>Conmed® (1050 with 7453 connector)</p> <p>Intuitive Surgical® (470042 - OEM Schöilly 05.0084I, and similar profile, 05.0088I.ht, and similar profile, and 05-0094I-nir with 05.0108z adapter)</p>	
<p>Olympus® (Color: Orchid) Order: REF 17-3001 (Carton) Track: REF 17-3001 (Pouch)</p> 	<p>Olympus® (WA03200A, WA03210A, WA03310A, and similar profile)</p>	

INTENDED USE/INDICATIONS FOR USE

GloShield® is intended to cover the distal end of a light cable to shield the majority of the light, thereby decreasing or reducing the potential for operating room fires and patient burns by shielding the environment from the light cable. It is indicated for use on patients during minimally invasive surgical procedures that utilize fiber-optic light cables listed in Table 1, above. Examples of procedures include, but are not limited to, arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery), cystoscopy (urological surgery), and endoscopy (general, gastroenterological, and ENT surgery). It is necessary to check each light cable to determine which GloShield® model to use prior to a procedure.

DISCLAIMER:

Device is not intended to replace or substitute safety protocols. Device functions with existing equipment and protocols in the operating room.

WARNINGS

Contents supplied STERILE. Do not use if sterile barrier is damaged. If damage is found, contact your Jackson Medical representative.

For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may have an adverse effect on performance of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

During excessive, consistent use in which exposure of device to light is prolonged, device may be warm to touch. Be cautious when handling any illuminated fiber-optic light cable.

After use, this product and its packaging may be discarded in accordance with hospital and/or administrative policy. Routine disposal is appropriate.

CONTRAINDICATIONS

There are no known contraindications.

CAUTIONS

Federal Law restricts this device to sale by or on the order of a physician.

Do not use this product without reading and understanding the complete instructions enclosed herein. It is necessary to check each light cable to determine which GloShield® model to select prior to use. Usage may result in product warming after extensive, continuous shielding of light. To avoid excessive warming of the product, switch off the light source or set the light source to standby mode whenever the light source is not in use. Consult the Instructions for Use for your specific light cable and light source for additional safety and performance information.

ADVERSE EVENTS

There are no known adverse events.

OPERATIONAL INSTRUCTIONS**Prior to Use**

Caution: Carefully examine the unit to verify that the contents have not been damaged in shipment. DO NOT USE if sterile barrier or product is damaged.

Directions

1. Select proper GloShield® model for type of light cable to be used in surgical procedure (Table 1).
2. Open sterile packaging maintaining sterility.
3. Connect GloShield® onto the distal end of the fiber-optic light cable in the sterile field.
4. Ensure GloShield® is positioned flush with the cable adapter such that the tip of the cable is covered (Figures 1 & 2).
5. Connect light cable to the light source.

6. When required, connect scope to light cable by gently lifting the shield of GloShield® to expose connector.
7. Note: GloShield® can stay on the light cable for the entirety of the procedure. It does not have to be disconnected when attaching a scope to the light cable or reconnected when detaching a scope.
8. Rotate GloShield® to user preference, if necessary.
9. Upon scope disconnection, verify light cable is covered (Figures 1 & 2).
10. At the end of the case, disconnect GloShield® from the light cable.
11. Discard GloShield®. DO NOT REUSE, REPROCESS OR RESTERILIZE.

Twenty (20) separately packaged products are supplied per carton. Newly purchased cartons have affixed tamper-proof seals.

Handling and Storage

Store in a cool, dry place. GloShield® must be in original peel-pouch packaging immediately prior to usage. If placed outside or removed from the sterile field during the surgical procedure, discard and utilize a sterile GloShield®.

IFU ACCESS

An electronic version of this Instructions for Use (IFU) document can be found online at www.jackson-medical.com/eIFU.html

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Conmed is a registered trademark of CONMED CORPORATION

Intuitive Surgical is a registered trademark of INTUITIVE SURGICAL, INC



Manufacturer:

Jackson Medical Group

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Made in USA

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GRAPHIC SYMBOLS IN MEDICAL DEVICE LABELING

 <p>Catalogue number</p>	 <p>Batch code</p>	 <p>Contents (Numeral represents quantity of units inside)</p>
 <p>Do not use if package is damaged</p>	 <p>Manufacturer</p>	 <p>On order of physician only</p>
 <p>Do not re-use</p>	 <p>Caution, consult accompanying documents</p>	 <p>Sterilized using ethylene oxide</p>
 <p>Use by date</p>	 <p>Consult instructions for use</p>	 <p>Not made with natural rubber latex.</p>

INSTALLATION GUIDE

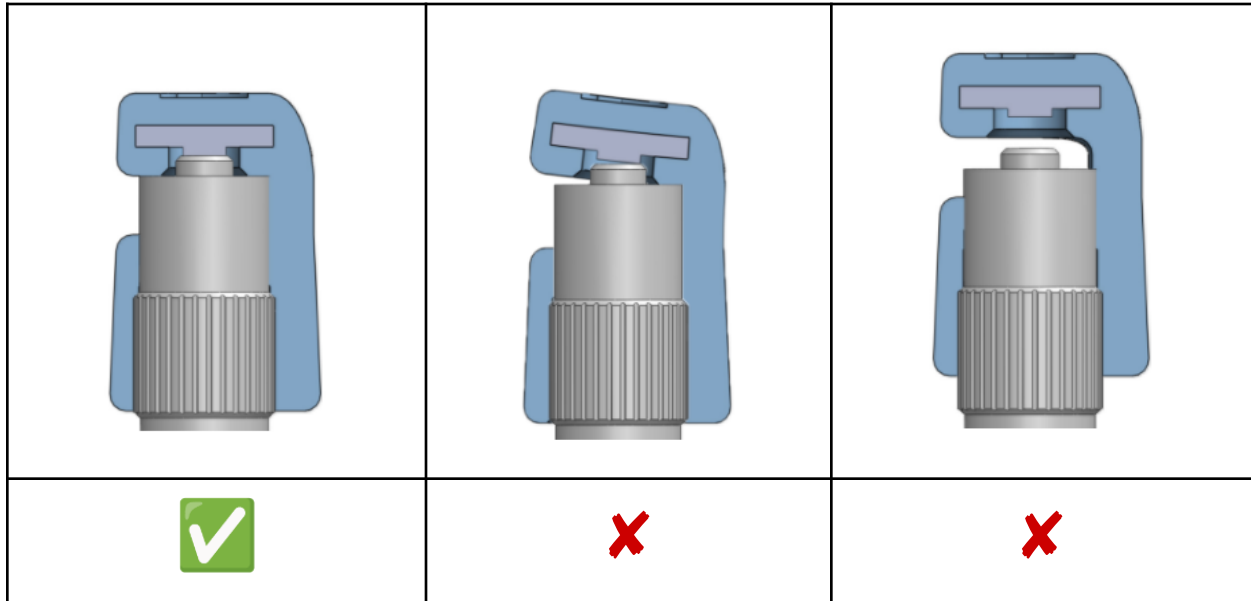


Figure 1: Proper positioning (left) and improper positioning (middle, right) of Sky Blue GloShield® -- REF 16-3001

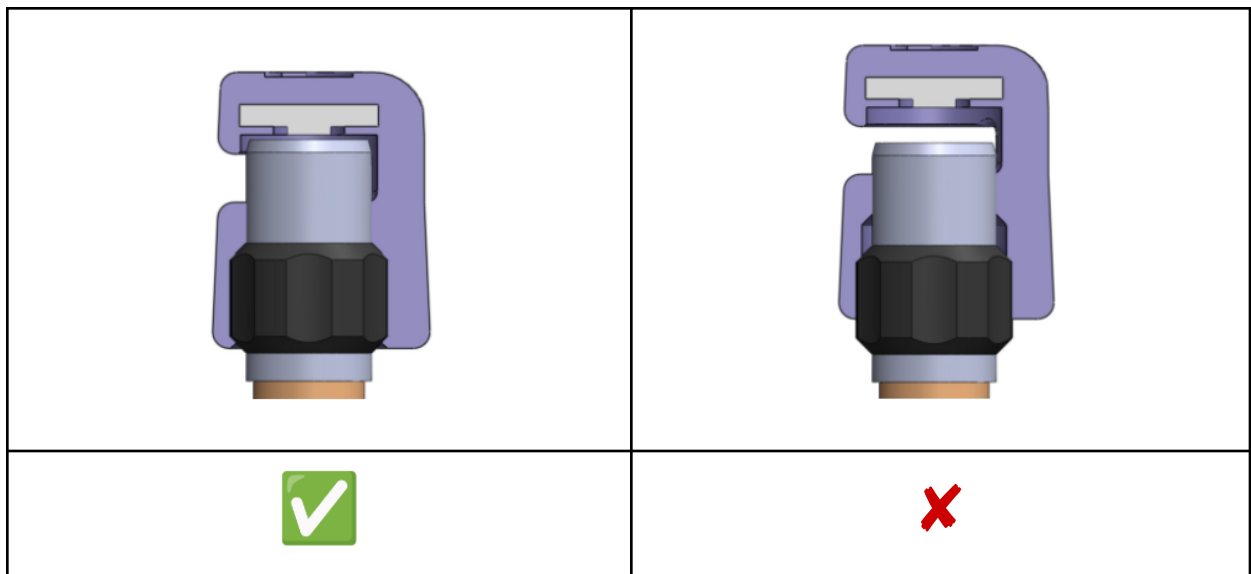


Figure 2: Proper positioning (left) and improper positioning (right) of Orchid GloShield® -- REF 17-3001