

HOLOGIC®

FIBEROPTIC CABLES INSTRUCTIONS FOR USE



83-20-5003	5MM LIGHT GUIDE, BLUE, HOLOGIC
83-20-50031	WOLF LIGHT GUIDE POST ADAPTER, HOLOGIC
83-20-50032	ACMI LIGHT GUIDE POST ADAPTER, HOLOGIC
83-20-50033	STORZ LIGHT GUIDE POST ADAPTER, HOLOGIC



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PLEASE READ BEFORE USE

Failure to follow these instructions could render the device unusable and void any warranty.

Device Description

HOLOGIC® fiberoptic cables are designed to deliver maximum light when coupled to a medical grade light source. HOLOGIC® fiberoptic cables can be used with quartz halogen, metal halide, LED, or xenon light sources. They are compatible with virtually all endoscopes, medical instruments, and microscopes. This guide covers the following products:

83-20-5003 5MM LIGHT GUIDE, BLUE, HOLOGIC
83-20-50031 WOLF LIGHT GUIDE POST ADAPTER, HOLOGIC
83-20-50032 ACMI LIGHT GUIDE POST ADAPTER, HOLOGIC
83-20-50033 STORZ LIGHT GUIDE POST ADAPTER, HOLOGIC

Intended Use

This device is designed to illuminate a surgical site by relaying light from a light source onto the desired site. HOLOGIC® cables are medical grade, high transmittance, peak efficiency.

Contraindications Warnings and Precautions

This device has no contraindications of which we have knowledge.

- HOLOGIC® light cables are provided non-sterile and must be sterilized before use. See instructions for cleaning and sterilization.
- Always inspect cables for any evidence of damage prior to use. Pay particular attention to optical surfaces looking for scratches or dings.
- Use caution to treat HOLOGIC® cables as you would any fine optical device.
- The user of this product should be thoroughly familiar and trained in use and care of the product.
- Match the cable size to the endoscope. Using a larger cable (fiber bundle size) than the endoscope requires will result in overheating the endoscope's proximal end.
- Light loss and warmer than normal instrument temperatures may be encountered if using a light source fiber optic cable with a larger aperture or bundle diameter than the instruments receiving aperture or bundle diameter.
- **FIRE or INJURY HAZARD:** Energy released by illuminators used with fiber optic light guides is retained in the cable and transmitted to a connected instrument through the cable end tip. The output of a connected instrument or end tip left in close proximity or contact with tissue or flammable materials presents a risk of injury or fire. Qualified personnel must determine a safe working distance and intensity setting for each application. The output should never be left on unattended.

Cleaning and Sterilization of Fiberoptic Light Guides Cleaning

Fiberoptic light guides for endoscopes, microscopes, and surgical instruments are high quality optical devices. They require similar care to that taken for any precision optical component. After each use, the light guide should be washed and cleaned of all debris. A soft brush and mild detergent should be used to clean the device. Pay particular attention to any crevices or seams. Avoid any harsh materials or detergents that can scratch or in any way damage the optical surfaces on each end of the light guide. HOLOGIC[®] recommends the following Steam Sterilization (Autoclave) guidelines:

Steam Sterilization (Autoclave)

The cycle selected is dependent on equipment and hospital protocol. General guidelines are:

METHOD	CYCLE	MINIMUM TEMPERATURE	EXPOSURE TIME
<i>Steam (wrapped)</i>	<i>Prevacuum</i>	<i>270 deg. F (132 deg. C)</i>	<i>4 minutes</i>
<i>Steam (wrapped)</i>	<i>Gravity</i>	<i>270 deg. F (132 deg. C)</i>	<i>10 minutes</i>
<i>Steam (wrapped)</i>	<i>Gravity</i>	<i>250 deg. F (121 deg. C)</i>	<i>45 minutes</i>

Chemical Disinfection

It is recommended that the guidelines below published by Advanced Sterilization, a Johnson & Johnson company be followed.

Product	High Level Disinfection Sterilization	Sterilization
<i>Cidex Activated Dialdehyde Solution</i>	<i>45 minutes @ 25 degrees C 77 degrees F</i>	<i>10 Hours</i>
<i>Cidex Plus 28 Day Solution</i>	<i>20 minutes @ 25 degrees C 77 degrees F</i>	<i>NA</i>

Steris Sterilization

Follow Steris Corporation Guidelines

Sterrad Sterilization

Follow Sterrad (a J&J Company) Guidelines

Warranty, Service, and Repair

I. Warranties

Except as otherwise expressly stated in the Hologic customer's agreement, Hologic warrants the light cables to the original Hologic customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment ("Warranty Period"). Hologic does not warrant that use of this product will be uninterrupted or error-free, or that the product will operate with non-Hologic authorized third-party products.















HOLOGIC'S ENTIRE WARRANTY RESPONSIBILITY IS EXPRESSLY LIMITED TO REPAIR OR REPLACEMENT (AT HOLOGIC'S OPTION AND IN THE FORM ORIGINALLY SHIPPED) OF PRODUCT OR CORRECTION OF SERVICE SUBJECT TO ANY CLAIM, OR, AT HOLOGIC'S ELECTION, REPAYMENT OF, OR CREDITING CUSTOMER WITH, AN AMOUNT EQUAL TO THE HOLOGIC PRICE, FEE OR CHARGE THEREFOR. THE FOREGOING WARRANTIES ARE IN LIEU OF AND EXCLUDE ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. SUCH LIMITED WARRANTY IS GIVEN SOLELY TO THE ORIGINAL CUSTOMER AND IS NOT GIVEN TO, NOR MAY IT BE RELIED UPON BY, ANY THIRD PARTY INCLUDING, WITHOUT LIMITATION, CUSTOMERS OF CUSTOMER. THIS WARRANTY IS VOID UPON TRANSFER OF PRODUCT BY CUSTOMER TO ANY ENTITY WHO IS NOT AN AFFILIATE OF CUSTOMER. SOME STATES DO NOT ALLOW THE EXCLUSION OF IMPLIED WARRANTIES SO THE ABOVE EXCLUSIONS MAY NOT APPLY TO CUSTOMER. CUSTOMER MAY ALSO HAVE OTHER RIGHTS, WHICH VARY, FROM STATE TO STATE.

This warranty does not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

II. Technical Support and Product Return Information

Contact Hologic Technical Support if the light cable fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number. Return the light cable according to the instructions provided by Technical Support. Be sure to clean and sterilize the product before returning it and include all accessories in the box with the returned unit.

Chart of medical device symbols used

	<i>Manufacturer</i>
	<i>Date of manufacture (YYYY-MM-DD)</i>
	<i>Distributor</i>
	<i>Caution, consult accompanying documents</i>
	<i>Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner</i>
	<i>Keep product dry</i>
	<i>Batch code / lot number</i>
	<i>Consult Instructions for Use</i>
	<i>CE mark</i>
	<i>Nonsterile</i>
	<i>Catalog, reorder or reference number</i>
	<i>Do not use if package is damaged</i>
	<i>EC Representative</i>
	<i>Medical Device</i>