



DISPOSABLE LIGHT FIBERS AND CHANDELIER

Indications for Use

Vitreoq Disposable Laser Probes, 90° Directional Laser Probes and (90°) Directional Illuminated Laser Probes are intended for use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments at operating wavelengths of 500nm to 900nm.

The (90°) Directional Illuminated Laser Probes, Light Fibers and Chandelier are for illumination during ophthalmic surgery and should only be used with the light wavelength range of 425nm to 700nm.

Instructions for Use

The Light Fibers are intended to be connected to an ophthalmic light source to conduct a field of cold light to the posterior segment of the eye during vitrectomy surgery. Please verify that the Light Fiber is compatible with the ophthalmic light source. The following Light Source Adaptors are available to make the Vitreoq Light Fibers compatible with your ophthalmic light source:

Reference	Article Name	Equipment designation	Light technology
LF00.R01	Constellation® Light Source Adaptor	Alcon Accurus Alcon Constellation DORC Associate 2500	Xenon
LF00.R02	Stellaris® Light Source Adaptor	Bausch & Lomb Stellaris	Xenon / Mercury
LF00.R03	Geuder® Light Source Adaptor	Geuder megaTRON S4(HPS)	Xenon
LF00.R04	Ruck® Light Source Adaptor	Fritz Ruck Pentasys2 Fritz Ruck QUBE PRO	Xenon
LF00.R05	DORC® Light Source Adaptor	DORC Xenon BrightStar	Xenon
		DORC Associate 6000 DORC LEDStar DORC EVA surgical system	LED
The Vitreoq light fibers can be connected directly to Synergetics® ophthalmic light sources.		Synergetics PI Photon	Xenon
		Synergetics PII Photon	Mercury

CAUTION: -Rx only: “Federal law restricts this device to sale by or on order of a licensed physician.”

CAUTION: - The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity (100% setting) will exceed the recommended maximum exposure (RME) of 2.2 J/cm², unless additional action is taken by the user to minimize exposure, after 2 min for a Mercury light source and 4.2 min for Xenon and LED light sources. The risk of retinal injury at an exposure of 2.2 J/cm² is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than 9 min for a Mercury light source and 19 min for Xenon and LED light sources.

Packaging

The Light Fibers are supplied sterile. The Light Fibers are ethylene oxide gas sterilized and guaranteed to be sterile until the expiration date stated on the product label. Each Light Fiber is packaged in a peel pouch for ease of introduction into the sterile field.

Preparation

- Please visually inspect the packaging of the sterile Light Fiber for possible damages and expiration date. Fibers from previously opened or damaged packaging must be deemed unsterile.
- Unpack the Light Fiber for introduction into a sterile environment.
- Remove Light Fiber from protection tray and uncoil with care.
- Insert the light fiber connector into the receptor port of the ophthalmic light source (adapter).



Directions for Use

Insert the Light Fiber in the posterior segment of the eye through the entry port or incision.
Please follow the instructions for use of your ophthalmic light source.

Maximum exposure guidelines for Mercury light sources according to ISO 15752:2010 (water-filled values)

Endoilluminator light guide type	Field angle	Recommended working distance	Time to reach maximum exposure guideline				
			without retinal protection means at maximum light output		without retinal protection means at 50% of maximum light output		
			US standard ANSI Z80.36 [minutes]	EU standard ISO 15004-2 [minutes]	US standard ANSI Z80.36 [minutes]	EU standard ISO 15004-2 [minutes]	
LF20.D01	45	15	2	9	4	18	
LF23.D01	45	15	2	9	4	18	
LF25.D01	45	15	2.6	11.9	5.2	23.8	
LF27.D01	45	15	5.5	25	11	50	
Directional illuminated laser probes	23G	45	15	17	77	34	Max 120
	25G	45	15	13.5	61	27	Max 120
LF20.D02	180	18	14.9	68	29.8	Max 120	
LF23.D02	180	18	14.9	68	29.8	Max 120	
LF25.D02	180	18	15.2	69	30.4	Max 120	
LF27.D02	180	18	17.4	79	34.8	Max 120	
LF29.D02	180	18	17.4	79	34.8	Max 120	
LF20.D03	135	18	8	36	16	72	
LF23.D03	135	18	8	36	16	72	
LF25.D03	135	18	8.9	40	17.8	80	
LF27.D03	135	18	16.7	76	33.4	Max 120	
NOTE 1 Maximum exposure times are for cumulative retinal exposure with a stationary distal tip of the light guide positioned at the specified distances from the retina. Changing the distance of the endoilluminator light guide from the retina will also significantly affect the risk factor.							
NOTE 2 Lower intensities increase the maximum exposure times in direct proportion to the decrease in intensities.							
NOTE 3 Movement of the light guide increases safe exposure time.							
NOTE 4 Maximum exposure times are given for clear media. Vitreous haemorrhage will increase these times.							
Maximum exposure times may be significantly reduced for field angles smaller than those shown. The light emitted from this instrument is potentially hazardous. See Notes 1 to 4.							

**Maximum exposure guidelines for Xenon and LED light sources according to ISO 15752:2010
(water-filled values)**

Endoilluminator light guide type	Field angle	Recommended working distance	Time to reach maximum exposure guideline				
			without retinal protection means at maximum light output		without retinal protection means at 50% of maximum light output		
			US standard ANSI Z80.36 [minutes]	EU standard ISO 15004-2 [minutes]	US standard ANSI Z80.36 [minutes]	EU standard ISO 15004-2 [minutes]	
LF20.D01	45	15	4.2	19	8.5	38	
LF23.D01	45	15	4.2	19	8.5	38	
LF25.D01	45	15	7	31	14	63	
LF27.D01	45	15	10.7	48	21.3	97	
Directional illuminated laser probes	23G	45	15	20	91	39.9	Max 120
	25G	45	15	57.5	Max 120	105.8	Max 120
LF20.D02	180	18	25.2	114	50.1	Max 120	
LF23.D02	180	18	25.2	114	50.1	Max 120	
LF25.D02	180	18	43.5	Max 120	86	Max 120	
LF27.D02	180	18	34.4	Max 120	67.9	Max 120	
LF29.D02	180	18	34.4	Max 120	67.9	Max 120	
LF20.D03	135	18	17.4	79	34.4	Max 120	
LF23.D03	135	18	17.4	79	34.4	Max 120	
LF25.D03	135	18	18.8	85	37.3	Max 120	
LF27.D03	135	18	31.2	Max 120	61.6	Max 120	
NOTE 1 Maximum exposure times are for cumulative retinal exposure with a stationary distal tip of the light guide positioned at the specified distances from the retina. Changing the distance of the endoilluminator light guide from the retina will also significantly affect the risk factor.							
NOTE 2 Lower intensities increase the maximum exposure times in direct proportion to the decrease in intensities.							
NOTE 3 Movement of the light guide increases safe exposure time.							
NOTE 4 Maximum exposure times are given for clear media. Vitreous haemorrhage will increase these times.							
Maximum exposure times may be significantly reduced for field angles smaller than those shown. The light emitted from this instrument is potentially hazardous. See Notes 1 to 4.							

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. Ophthalmic light sources should be used with filters that eliminate UV radiation and short-wave blue light (<420nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

Known complications

- Phototoxicity

Occurrence of this complication is statistically rare. The user is adequately trained in the use of vitrectomy surgery and in the treatment of the known complication.

Contraindications

- Use of this product if package integrity has been breached or compromised;
- Use of the product after the expiration date.

Vitreo a company of:



Warnings

Do not apply excessive stress to the Light Fiber as to avoid product damage.

Please avoid contamination of the Light Fiber tip before and during use of the Light Fiber. Contamination will affect performance considerably and may result in a deformation of the Light Fiber tip.

Do not re-use

The design and the materials used do not allow cleaning and re-sterilization of the Vitreo Light Fibers. Reprocessing will decrease the performance of the device and correct function and sterility cannot be guaranteed.

Symbols



Do not re-use



Use-by date YYYY-MM-DD



Batch code



Sterilized using ethylene oxide



Catalogue number



Store at temperature range 15° to 30°C
(59° to 86°F)



Keep away from heat



Keep dry



Manufacturer



Do not use if pack is damaged



Consult instructions for use

Liability statement

Vitreo makes no warranty, neither expressed nor implied, relating to sales of Light Fibers and disclaims warranty liability with regard to merchantability or suitability of use. Vitreo will not be liable for injury or damage resulting from surgeon's method or technique.

Vitreo will not be liable for injury or damage resulting from selection and use of any Light Fiber for any particular patient or any patient's condition.

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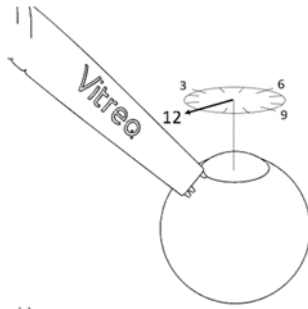


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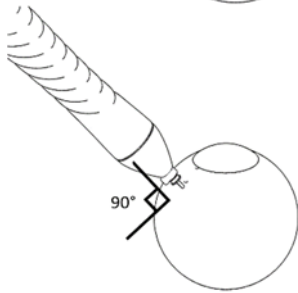
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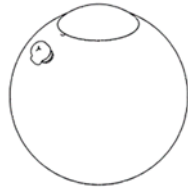
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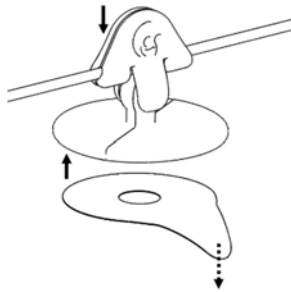
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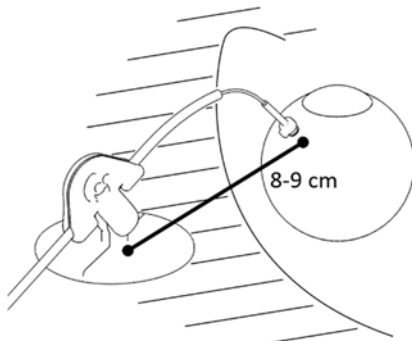
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4



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**29G Spotlight,
Directional
Chandelier**

LF29.D02



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