



Gemini Universal Light Cable
Instructions for Use - English

Gemini 通用光导纤维光缆
使用说明 - 简体中文

Gemini Universal Light Cable

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(Model Number 7205180)

Instructions for Use - English



Rx only

Cautions

WHEN THE LIGHT SOURCE IS TURNED ON, DO NOT HOLD THE SHUTTER OPEN WITHOUT A LIGHT CABLE IN PLACE. THE LIGHT SOURCE MUST ALWAYS BE TURNED OFF BEFORE THE GEMINI UNIVERSAL LIGHT CABLE IS DISCONNECTED FROM THE ENDOSCOPE. FAILURE TO OBSERVE THESE PRECAUTIONS MAY RESULT IN BURNS TO SKIN, CLOTHING OR OTHER MATERIAL INADVERTENTLY PLACED IN FRONT OF THE LIGHT PORT OR CABLE.

THE METAL TIP OF THE LIGHT CABLE MAY BE HOT WHEN IT IS REMOVED FROM THE LIGHT SOURCE. TO AVOID INJURY DURING REMOVAL, GRASP THE CABLE ONLY BY THE SOURCE END VERSITIP ADAPTOR USED TO SECURE THE CABLE TO THE LIGHT SOURCE.

CUTS OR SLICES IN THE SILICONE JACKET MAY EXPOSE AND/OR DAMAGE GLASS FIBERS. EXPOSURE TO GLASS FIBERS WHILE THE LIGHT SOURCE IS ON MAY CAUSE BURNS TO SKIN, CLOTHING OR OTHER MATERIAL.

Compatibility

Gemini Universal Light Cables are designed for use with metal halide and xenon arc lamp light sources.

Gemini Universal Light Cables are secured to the light source and to the Illuminator via the Versitip Adaptor.

Operation Instructions

NOTE: These guidelines assume concurrent use of a Gemini Universal Light Cable with the TRIVEX light source.

- Connect the light source end (proximal end) of the Gemini Universal Light Cable to the LeMaitre Vascular Source End Versitip Adaptor. Connect the illuminator end (distal end) of the Gemini Universal Light Cable to the Instrument End Versitip Adaptor.
- Secure the instrument end of the Gemini Universal Light Cable to the light post on the illuminator via the Instrument End Versitip Adaptor.
- Depress the button above the light guide input connector to open the shutter and allow smooth insertion of the Adaptor into the light source.
- When the Adaptor is fully inserted, release the shutter button to lock the Light Cable in place and turn on the light source.
- At completion of the endoscopic procedure, turn off the light source and remove the instrument end of the Gemini Light Cable from the endoscope.
- Remove the Gemini Universal Light Cable from the light source: Depress the shutter button, grasp the Source End Versitip Adaptor and pull outward. When the proximal end of the Adaptor is fully removed, release the shutter button.

Maintenance

Keep Gemini Universal Light Cables loosely coiled until needed.

IMPORTANT: Gemini Universal Light Cables are constructed of glass fibers. To avoid damage, the Cable should not be coiled tightly, bent at sharp angles, knotted or stretched.

Inspect the Light Cable before each use for darkened ends, broken fibers, cuts in the silicone jacket or other damage. Regularly clean the proximal and distal ends of the Light Cable. This will prevent residue build-up from cleaning solutions which may permanently discolor the glass fiber ends.

Sterilization/Disinfection

Prior to sterilization, the instruments should be cleaned and inspected for damage and debris. Place instruments in a sterilization container, ensuring all mechanical parts are in the open position to allow complete sterilization of all surfaces.

Steam Sterilization (Wrapped):

- Pre-Vacuum Sterilizer: 270-275°F (132-135°C) for
- 4 minutes, 27-30 Psig (2.1 kg/cm²)

Gravity Displacement:

- 270-275°F (132-135°C),
- 10 minutes, 27-30 Psi (2.1 kg/cm²)

EtO-Sterilization:

- 126-136°F (52-57°C)
- Relative Humidity: 35-70%
- Gas Concentration: 736 mg/l
- Exposure Time: 120 minutes
- Post Vacuum: 24 ±2 Hg - two times
- Aeration: 11 hours minimum

Disinfectant: Follow manufacturer's recommendations. Disinfection is not a substitute for sterilization.

NOTE: These are suggested parameters only. The chosen sterility method must be validated with chemical or biological indicators to ensure sterility.

Limited Product Warranty; Limitation of Remedies

LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. LeMaitre Vascular makes no representation regarding the suitability for any particular treatment in which this device is used, which determination is the sole responsibility of the purchaser. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be repair or replacement of this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the date that is three months from the date of invoice for such device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US\$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

Gemini 通用光导纤维光缆

(型号 7205180)

使用说明 - 简体中文



小心

打亮光源时,如果未安装光缆,请勿让光源盖保持打开状态。在 GEMINI 通用光缆从照明棒取下之前必须关灭光源。不遵守这些注意事项可能导致皮肤烧伤,以及烧坏衣服或无意中放在光端口或光缆前面的其他材料。

光缆的金属端从光源中取出时可能会热。为了避免在取出过程中发生伤害,只能抓住光缆上用于将光缆固定到光源的光源端 VERSITIP 适配器。

硅胶套上的切口或损坏可能会暴露和/或损坏玻璃纤维。打开电源时暴露的玻璃纤维可能导致皮肤烧伤,以及烧坏衣服或其他材料。

兼容性

Gemini 通用光缆旨在与金属卤化物和氙弧灯光源结合使用。

Gemini 通用光缆通过 Versitip 适配器固定到光源和照明棒上。

操作说明

注意: 这些指南假定同时使用 Gemini 通用光缆和 TRIVEX 光源。

- 将 Gemini 通用光缆的光源端(近端)连接到 Versitip 适配器的光源端。将 Gemini 通用光缆的照明棒端(远端)连接到 Versitip 适配器的器械端。
- 通过 Versitip 适配器器械端将 Gemini 通用光缆的器械端固定到照明棒上的接口。
- 按下光纤输入连接器上方的按钮可打开光源盖,使适配器顺利插入光源。
- 适配器完全插入时,松开光源盖按钮将光缆锁定到位并点亮光源。
- 完成手术后,关灭光源并从照明棒上的接口处取下 Gemini 光缆的器械端。
- 从光源中取出 Gemini 通用光缆: 按下光源盖按钮,抓住光源端 Versitip 适配器并向外拉。当适配器的近端完全退出时,松开光源盖按钮。

维护

在不使用时,请将 Gemini 通用光缆松散盘绕储存。

重要事项: Gemini 通用光缆由玻璃纤维构成。为了避免损坏,不得将光缆盘绕太紧、弯成锐角、打结或拉伸。

在每次使用之前检查光缆是否存在末端变黑、纤维破损、硅胶套上有切口或其他损坏。定期清洗光缆的近端和远端。这将防止洗涤剂残留堆积,可能使玻璃纤维端永久变色。

灭菌/消毒

在灭菌之前,应清洗器械并检查是否存在损坏和碎片。将器械放在灭菌容器中,确保所有机械零件都处于打开状态,从而对所有表面进行完全灭菌。

蒸汽灭菌(包裹):

- 预真空灭菌器: 132-135°C (270-275°F)
- 4 分钟,压力2.1 千克/平方厘米 (27-30 磅/平方英寸)
重力置换
- 132-135°C (270-275°F)
- 10 分钟,压力2.1 千克/平方厘米 (27-30 磅/平方英寸)

环氧乙烷灭菌:

- 52-57°C (126-136°F)
- 相对湿度: 35-70%
- 环氧乙烷气体浓度: 736 毫克/升
- 暴露时间: 120 分钟
- 过程后真空: 24 ± 2 Hg - 两次
- 散气: 最少 11 小时

消毒剂: 请遵循制造商的建议使用。消毒不能代替灭菌。

注意：这些只是建议参数。您选择的无菌方法必须使用化学或生物指示剂进行验证，以确保无菌性。

有限产品质保：有限产品赔偿

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这些说明的修订或发布日期包含在使用说明的最后一页，以供参考。如果使用本产品时距此日期已超过二十四（24）个月，则用户应联系 LeMaitre Vascular，了解是否有更多产品信息。

Symbol Legend

English	Symbol Legend		Rx only
简体中文	符号图例	Distributed By 经销商	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician. 小心：根据美国联邦法律规定，该设备需由医师销售或在医师的指导下进行销售。



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