

Gemini Universal Light Cable

(Model Number 7205180)

Instructions for Use - English



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.

Symbol Legend

			
English Symbol Legend	Distributed By		Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.



LeMaitre Vascular, Inc.
Customer Service:
Tel: 781 221-2266
Fax: 781 221-2223

LeMaitre Vascular GK
1F Kubodera Twin Tower Bldg.
2-9-4 Kudan-minami, Chiyoda-ku
Tokyo 102-0074, Japan
Tel: +81-(0)3-5215-5681

LeMaitre Vascular ULC
5915 Airport Road, Suite 608
Mississauga, Ontario
Canada L4V 1T1
Tel: +1 905 673-2266



LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts., Germany
Tel: +49-(0)6196-659230



LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803

