




DI120A-EN (Rev L)	MARS™ (MINIMAL ACCESS RETRACTOR SYSTEM)	
<p>04/2025</p>  <p>GLOBUS MEDICAL</p> <p>GLOBUS MEDICAL, INC. Valley Forge Business Center 2560 General Armistead Avenue Audubon, PA 19403 USA Customer Service: Phone 1-866-GLOBUS1 (OR) 1-866-456-2871 Fax 1-866-GLOBUS3 (OR) 1-866-456-2873</p>	<p>IMPORTANT INFORMATION ON MARS™</p> <p>[EC]REPI: AJW Technology Consulting GmbH Breite Straße 3 40213 Düsseldorf, Germany</p> <p>[CH]REPI: AJW Technology Consulting GmbH Kreuzplatz 2, 8032 Zurich, Switzerland</p>	<p>AUSTRALIA SPONSOR: GLOBUS MEDICAL AUSTRALIA PTY LIMITED, Unit 9/5-7 Inglewood Place Baukham Hills NSW 2153, Australia</p> <p> 0297 </p>

For symbols glossary, please refer to www.globusmedical.com/eIFU

ENGLISH

IMPORTANT INFORMATION ON MARS™

DESCRIPTION

MARS™ (Minimal Access Retractor System) [MARS™, MARS™ ACDP, MARS™ Anterior, MARS™ Midline, MARS™ Auxiliary, MARS™3V, MARS™3VL] is a comprehensive retractor, ports and instrument system that provides efficient access to the spine. MARS™ consists of retractor frames, blades, disposable ports, silicone sleeves, light cables and associated manual surgical instruments. The blades and ports are available in several designs to accommodate individual patient anatomy.

MARS™ instruments are made from titanium, aluminum, or stainless steel as specified in ASTM F67, B221, and F899. The ports are made from radiolucent polymer (PEEK) as specified in ASTM F2026.

CLEANING

Cleaning instructions by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

1. Clear any corners or recesses of all debris. (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
2. Remove all traces of blood and other such residues immediately. Do not allow these to dry.
3. The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Infraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
6. Dry instruments immediately after cleaning.

STERILIZATION

Instruments that are provided STERILE should be considered sterile unless the packaging has been opened or damaged.

For instruments that are supplied NONSTERILE, sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Gravity (Wrapped)	132°C (270°F)	25 Minutes	45 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132°C (270°F)	15 Minutes	30 Minutes

Cycles should be performed on tray with devices opened for maximum steam penetration.

These parameters are validated to sterilize only these instruments. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

The following information is provided by LumitexMD, Inc. for MARS™ Light cable distributed by Globus Medical, Inc.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

MARS™ LIGHT CABLE

INFORMATION FOR USE FOR THE MARS™ LIGHT CABLE DESCRIPTION

The MARS™ Light Cable is a sterile, single use, latex free, plastic fiber optic device intended to bring cool area lighting into deep surgical sites. The MARS™ Light Cable is intended for use with a 300 watt xenon illuminator, using a 4mm fiber optic cable with a female ACMI connector. For best results use a Globus cable by LumitexMD.

INDICATIONS FOR USE

The MARS™ Light Cable is intended for the illumination of surgical procedures, particularly where deep cavities or adjacent tissues limit outside light in the surgical field. It is designed for use in less invasive spinal surgery.

CONTRAINDICATIONS

The MARS™ Light Cable presents no contraindication. However, the user should be familiar with the use of light sources and cables and should take precautions accordingly.

WARNINGS

The MARS™ Light Cable is designed for use with 300 watt xenon illuminators, using a 4mm fiber optic cable. **Do not use light sources rated higher than 300 watts, or cables with fiber optic bundles of more than 4mm diameter. Use of higher watt sources or larger diameter cables could result in overheating; causing product failure and patient injury.**

Should the MARS™ Light Cable become cut, collect fluid inside, appear broken or damaged in any manner, it should be replaced to minimize risk to the patient.

Do not operate the light source and cable without the MARS™ Light Cable attached. Without the MARS™ Light Cable, the output from the fiberoptic cable is extremely bright, hot and may cause burns, ignite drapes/gowns, or temporarily blind vision.

PRECAUTIONS

Light sources vary widely in emission of visible and infrared energy. As a precautionary measure, we recommend occasionally monitoring connector temperature during first time use with a new light source or lamp; thereafter if needed. As is common with fiber optic equipment, metal portion of connector can become hot to the touch. Use plastic grip as handle. Do not place the metal ring portion of connector directly on the patient's skin.

Because light energy can be absorbed as heat, the entire lit portion (distal end) of the MARS™ Light Cable should not be continuously embedded (i.e. lit surface should not be completely buried) in tissue and held fixed for more than a few minutes at one time.

Each MARS™ Light Cable package contains one MARS™ Light Cable assembly with an integrated adhesive strip and two double-sided adhesive strips. Each adhesive strip includes two paper release liners. Prior to closing the surgical site, all components must be accounted for.

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

DIRECTIONS FOR USE

Attach the MARS™ Light Cable to the Globus Medical MARS™ retractor using the integrated stainless steel clip located on the back of each MARS™ Light Cable.

The MARS™ Light Cable connects to a light source used for head lamps or endoscopes. A fiber optic cable attaches the light source and MARS™ Light Cable. Make sure the MARS™ Light Cable connector is securely attached to the cable. The cable should be in good repair with clean optics. Dirty optics or cables in need of repair can cause excessive heat at the connectors.

Turning down overhead lighting may improve visualization within the surgical site.

Body fluids or debris collecting on the surface of the MARS™ Light Cable may be irrigated or wiped away.

Sterile unless package is opened or damaged. Do not use if package is opened or damaged.

LIMITED WARRANTY

LumitexMD warrants the material conformity of the MARS™ Light Cable to specifications in the product labeling until the earlier of 12 months from shipment to customer or the expiration date of the product, and will repair or replace at LumitexMD option and expense any LumitexMD product that does not meet specifications in all material respects. LUMITEXMD LIABILITY TO CUSTOMER, USER, OR PATIENT IS EXPRESSLY LIMITED TO REPAIR OR REPLACEMENT. LumitexMD expressly disclaims all other warranties, express or implied, including, without limitation, merchantability or fitness for a particular purpose. Please direct any inquires to Globus Medical.

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