

AcuBlade™ D Micromanipulator- Digital AcuBlade™

Prescriptive Information

Refer to the device user manual for complete instructions on device use.

Intended Use/Indications for Use

This delivery system is indicated for a variety of surgical uses including, but not limited to, ablation, coagulation, incision, excision, and vaporization. This device may be used in the medical specialties or procedures for which the compatible laser has received regulatory clearance. Refer to the laser operator's manual, Indications for Use section.

Contraindications

See the user manual for your laser system for a list of contraindications by specialty.

Warnings and Precautions

- Lasers generate a highly concentrated beam of light which may cause injury if improperly used. To protect the patient and operating personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
- Never look directly into the gimbaled mirror or laser articulated arm while the laser system is energized - severe eye damage could occur. Turn off the laser and close the manual safety shutter, if applicable, before inspecting the micromanipulator lenses.
- Failure to set the microscope eyepieces to the correct refraction will result in a mismatch of visual and laser beam focus, which may cause an abnormally large spot size at the smallest setting on the micromanipulator. In addition, the treatment beam could actually become smaller as the operator uses the focusing knob to enlarge the laser beam, delivering higher energy and power densities than intended, and possibly resulting in over-treatment of tissue. The treatment beam is in optimum focus when the microscope is optimally focused. Do not rely on the size of the aiming beam for focusing purposes.
- To prevent unintentional defocusing of the treatment beam when using Digital AcuBlade, ensure that the preset defocus limiter on the micromanipulator is always set to FOCUS.
- Beam alignment checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call your Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.
- The working distance displayed on the control screen must match the working distance settings of both the microscope and the micromanipulator. Mismatched working distance settings may result in incorrect spot sizes and unintended tissue effect.
- The ablation depth of multiple passes is deeper than that of a single pass. It is recommended that the lowest practical settings be used until thoroughly familiar with the biological interaction of the laser energy with the tissue. The surgeon must clinically assess the depth of ablation throughout the procedure.
- Serious tissue damage can occur as a result of incorrect power settings. Use the lowest acceptable settings until you understand the biological interaction between the laser power and tissue.
- The power shown on the power display indicates the power delivered at the end of the articulated arm, not necessarily the power delivered to the treatment site. See Specifications in the Maintenance chapter of this manual to determine the approximate reduction of laser power at the treatment site.
- Except during actual treatment, the system must always be in Standby mode. Keeping the system in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before setting the laser to Ready mode.

- To avoid unintended tissue effect, pay attention to changes in power settings when toggling between scan and non-scan modes while operating.
- The working distance displayed on the control screen must match the working distance settings of both the microscope and the micromanipulator. Mismatched working distance settings may result in incorrect spot sizes and unintended tissue effect.
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- The power shown on the power display indicates the power delivered at the end of the articulated arm, not necessarily the power delivered to the treatment site. See Specifications in the Maintenance chapter of this manual to determine the approximate reduction of laser power at the treatment site.
- To avoid unintended tissue effect, pay attention to changes in power settings when toggling between scan and non-scan modes while operating.
- Verify that all persons in the treatment room are wearing appropriate laser safety eyewear before setting the laser to Ready mode.
- Do not use the micromanipulator until the problem [Troubleshooting 2.1.6- Micromanipulator Slips Out of Place on the Operating Microscope] is corrected.
- Do not use the laser until the problem [Troubleshooting 2.1.8- The Burn Spot Falls Outside of the Area of the Aiming Beam] is corrected, as the laser may be misaligned. Contact your Lumenis representative.
- Do not use the micromanipulator until the problem [Troubleshooting 2.1.15- A Secondary Satellite Burn, in the Shape of a Crescent, Appears near the Treatment Burn] is corrected.
- Beam alignment checks are extremely important for the safe operation of your laser. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call your Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.
- Do not perform the beam alignment check near or in-line with the patient, operating personnel, or flammable material. Laser energy can penetrate a tongue depressor and ignite underlying flammable material, causing possible injury. It may be desirable to place energy-absorbing material behind a target area.
- Always disconnect the delivery system from the laser before inspection. Never look directly into the device while it is connected to the laser. Accidental laser exposure can cause severe eye damage.
- Failure to clean, or improperly cleaning the micro-manipulator, can cause irreversible damage to the micro-manipulator optics, adversely altering the efficiency of the delivery system.
- Do not touch any optical lens; finger oils may damage the delicate optical coatings.
- Irreversible damage could occur if disinfectant comes into contact with any of the micromanipulator's internal surfaces or optics. Therefore do not spray or pour cleaning agents directly on the device, and do not wipe the inside surface.
- Do not soak, steam sterilize, or autoclave the micro-manipulator. The optics will be irreversibly damaged.
- Do not use any solutions other than those specified. Doing so may permanently damage the lens and adversely alter the delivered laser power.
- Do not attempt to clean lenses that are not readily accessible.
- Do not use any solutions other than those specified. Doing so may permanently damage the mirror and adversely alter the delivered laser power.
- Do not touch the mirror top or bottom surface with your fingers. Fingerprints can permanently damage the mirror coating.
- Do not use dry material, such as gauze, to clean the mirror.
- Do not sterilize the micromanipulator, scanner or thread adapter. Sterilization may irreparably damage the optics and internal electronic circuitry.

- Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.
- Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.
- Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- Never look directly into any optical lens, optical fiber, handpiece, probe, laser articulated arm, or laser system aperture while the laser is energized. Severe eye damage could occur. Turn off the laser and disconnect the delivery system before inspecting any delivery system or laser components.
- Spot size and laser energy are independently controlled. If the operator changes to a delivery system with a smaller spot size during a procedure, the operator must remember that the energy or power density will increase.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- Incision/excision ideally should be performed with small laser spot sizes and appropriate power/energy densities. At the highest power densities, avoid prolonged exposure to limit depth of incision.
- Plastic instruments such as speculums or eye shields can melt when impacted by the laser beam, possibly resulting in chemical burns or noxious gases. Therefore, use only stainless steel surgical instruments designed specifically for laser use.
- Carbon dioxide light can be reflected off of smooth metallic surfaces, even though they may be blackened.
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.
- When using carbon dioxide as a purge gas, the treatment room must be adequately ventilated. Uncontrolled carbon dioxide gas flow can cause suffocation in a confined area.
- Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, volatile surgical preparation solutions and similar substances. An explosion or fire could occur.
- The area around the target site can be protected with wet towels or gauze sponges. If allowed to dry, these protective towels and sponges can increase the potential fire hazard.
- When procedures are performed in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.
- Never use oxygen as a purge gas. When used with lasers, combustible gases, such as oxygen, increase the potential fire hazard, and may cause patient injury.
- Laser treatment of adipose tissue may cause cellular fat to liquefy and accumulate into lipid pools. Pooled lipids are flammable and can be ignited by laser radiation, resulting in fire and potential patient injury.
- Laser plume may contain viable tissue particulates.
- The laser plume obscures the operative field and is noxious to those who come into contact with it. The plume presents a possible biologic and pollution hazard and should be effectively evacuated.
- Care should be taken to prevent the introduction of laser plume into the lungs during the treatment of patients with Recurrent Respiratory Papillomatosis (RRP) to prevent the spread of the papillomas virus to the lungs.
- Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, and exposure duration and power settings that

are effective for the intended application should be used until familiar with the instrument's capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.

- Except during actual treatment, the system must always be in Standby mode. Maintaining the system in the Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Only the person directing the aim of the laser beam should have access to the laser footswitch. Use caution pressing the laser footswitch when it is in proximity to footswitches for other equipment. Make sure the footswitch pressed is the correct one to avoid unintended laser exposure.
- Beam alignment checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call your local Lumenis service representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.
- Never place hands or other objects in the path of the laser beam. Severe burns could occur.
- Backstops exposed to continuous CO₂ laser energy may become excessively hot. Do not allow a hot backstop to touch tissue or any flammable materials. Doing so may cause possible injury or fire.
- Activate the laser only when the aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.
- Never discharge the laser without a target to absorb it and without consideration given to what lies behind the target. Place energy-absorbing material behind the target tissue when aiming the laser at an oblique target.
- To prevent unintended laser discharge, always turn off the laser before connecting a delivery system.
- Use caution when performing the laser beam alignment check, as instructed in the delivery device operator's manual. Care should be taken to ensure that the alignment procedure is not performed in line with the patient or operating room personnel or materials.
- Metal instruments used behind the area of treatment, such as tongue depressors or laser backstops, must be anodized or ebonized matte-finished to avoid reflection.
- Never open the laser console's protective covers. Opening the covers will expose personnel to high voltage components, the laser resonator, and possible laser radiation. Only Lumenis-certified service technicians are qualified to work inside the console.
- To avoid electrical shock, the area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.

Adverse Events/Complications

Refer to the Laser Console User Manual for adverse events/complications that may be specific to each surgical specialty.

Precautions can be found in the product labeling supplied with each device.

Boston Scientific acquired the global surgical business of Lumenis Ltd.

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URO-1225004-AA JAN 2022

AcuSpot™ Micromanipulators- AcuSpot 712, AcuSpot 712-L, AcuSpot 712-Z

Prescriptive Information

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Intended Use/Indications for Use

This delivery system is indicated for a variety of surgical uses including, but not limited to, ablation, coagulation, incision, excision, and vaporization. This device may be used in the medical specialties or procedures for which the compatible laser has received regulatory clearance. Refer to the laser operator's manual, Indications for Use section.

Contraindications

See the user manual for your laser system for a list of contraindications by specialty.

Warnings and Precautions

- Lasers generate a highly concentrated beam of light which may cause injury if improperly used. To protect the patient and operating personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
- The AcuSpot's gimbaled mirror (see Figure 4) is very fragile and has a very fine optical coating. Exercise extreme caution when handling the AcuSpot so as not to damage the mirror, its optical coating or its rotating mechanism.
- Remove the plastic window in the drape's plastic connector; otherwise the laser beam will burn a hole through the window.
- Smoke evacuation of approximately 15 lps (32 cfm), or more, is highly recommended with the use of this product. If smoke evacuation is not used, laser plume debris may accumulate on the optical components, causing lens damage, decreased energy transmission, or unintended, adverse tissue effect.
- Beam alignment checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.
- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before setting the laser to Ready mode.
- Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, exposure duration, or power settings that are effective for the intended application should be used until familiar with the instrument's capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.
- Do not use the laser or delivery system if the aiming and treatment beams are not aligned or if the test burn is unacceptable; contact your local Lumenis service representative. Misalignment may result in laser exposure to non-target tissues and possible injury.
- Do not perform the beam alignment check near or in-line with the patient, operating personnel, or flammable material. Laser energy can penetrate a tongue depressor and ignite underlying flammable material, causing possible injury. It may be desirable to place energy-absorbing material behind a target area.
- Always disconnect the delivery system from the laser before inspection. Never look directly into the device while it is connected to the laser. Accidental laser exposure can cause severe eye damage.
- Failure to clean, or improperly cleaning the micro-manipulator, can cause irreversible damage to the micro-manipulator optics, adversely altering the efficiency of the delivery system.

- Irreversible damage could occur if disinfectant comes into contact with any of the micromanipulator's internal surfaces or optics. Therefore do not spray or pour cleaning agents directly on the device, and do not wipe the inside surface.
- Do not soak, steam sterilize, or autoclave the micro-manipulator. The optics will be irreversibly damaged.
- Do not use any solutions other than those specified. Doing so may permanently damage the lens and adversely alter the delivered laser power.
- Isopropyl 70% alcohol contains a large amount of water and therefore should not be used.
- Do not use dry material, such as gauze, to clean the mirror.
- Should the mirror come in contact with water, carefully wipe it dry and clean according to the above instructions.
- Select the appropriate laser safety eyewear for the specific laser in use, by verifying that the above specifications are indicated on the laser safety eyewear that is at your disposal
- Always provide eye protection for the patient. Wet thick cloths or wet gauze 4 x 4's can be used together with the patient's protective eyewear to reduce patient inconvenience. Never use them to replace protective goggles.
- For periorbital treatment, always protect the patient with dulled metal eye shields, as severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam.
- Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.
- Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.
- Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- Never look directly into any optical lens, optical fiber, handpiece, probe, laser articulated arm, or laser system aperture while the laser is energized. Severe eye damage could occur. Turn off the laser and disconnect the delivery system before inspecting any delivery system or laser components.
- Depending on the procedure, the physician must protect the patient's eyes with either laser safety eyewear or one of the following items moistened with a nonflammable solution: thick cloth, eye pads, or gauze 4 x 4's.
- Use of the laser in the presence of oxygen increases potential fire hazard. When performing a laser procedure, the surgeon and anesthesiologist should carefully consider airway management. Oxygen concentrations should be as low as clinically permissible during airway laser procedures. Anesthetic gases should be least supportive of combustion.
- When choosing endotracheal tubes, consider the by-product complications of tube combustion, ensuring that it is least hazardous to the patient. Laser-resistant, cuffed, and flexible stainless steel endotracheal tubes are commercially available. Red rubber or silicone endotracheal tubes wrapped with FDA-approved, laser-resistant wrapping are also used. The endotracheal tube cuff may be inflated with saline to protect it from inadvertent penetration and the saline may be dyed with methylene blue so evidence of cuff penetration by the laser will readily appear on surrounding gauze sponges. The endotracheal tube may be further protected by strategic placement of wet sponges to absorb accidental or stray laser energy. Ensure that the sponges do not dry and increase the overall fire hazard.
- Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently depressed.

- To prevent accidental laser discharge, always turn off the laser before connecting the delivery system.
- Never place hands or other objects in the path of the laser beam. Severe burns could occur.
- Never discharge the laser without a target to absorb it and without consideration given to what lies behind the target. Place energy-absorbing material behind the target tissue when aiming the laser at an oblique target.
- Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, certain surgical preparation solutions, and similar substances. An explosion and/or fire could occur.
- The treatment beam can ignite most nonmetallic materials. Use fire retardant drapes and gowns. The area around the treatment site can be protected with towels or gauze sponges moistened with sterile saline solution or sterile water. If allowed to dry, protective towels and sponges can increase the potential fire hazard. A UL-approved fire extinguisher and water should be readily available.
- Never open the laser console protective covers. Opening the covers will expose the user to high voltage components, the laser resonator, and possible laser radiation. Only Lumenis-certified service technicians shall work inside the console.
- The area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- Carbon dioxide light can be reflected off of smooth metallic surfaces, even though they may be blackened
- Laser plume may contain viable tissue particulates.
- The laser plume obscures the operative field and is noxious to those who come into contact with it. The plume presents a possible biologic and pollution hazard and should be effectively evacuated.

Adverse Events/Complications

Refer to the Laser Console User Manual for adverse events/complications that may be specific to each surgical specialty.

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Boston Scientific acquired the global surgical business of Lumenis Ltd.

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URO-1226605-AA JAN 2022