Operating Microscope Adapter

Operator Manual

Operating Microscope Adapter Operator Manual
13106-EN Rev E 2019 06

1
Introduction

The Operating Microscope Adapter (OMA), when connected to an IRIDEX laser, adds the therapeutic capability of retinal photocoagulation to an operating microscope. The eye safety filter protects your eyes while providing a clear view of the target area.

Indications for Use

The OMA is indicated for retinal photocoagulation. Qualified physicians should review the available literature presented in clinical papers before using the delivery device.

Contraindications

- Any situation where the target tissue cannot be adequately visualized or stabilized.
- Do not treat albino patients who have no pigmentation.

⚠ Clinical Warnings

- Excessive treatment power may result in retinal hole and retinal hemorrhage.
- Excessive power delivered at short pulse durations may result in choroidal hemorrhage.

Recommended Procedures

Power and duration

If uncertain of tissue response, start with the lower power settings and increase the power until satisfactory clinical lesions are observed.

Red aiming and treatment beams

Since the red aiming beam and the treatment beam come to focus at the same optical point, ensure that the aiming beam is always in sharp focus during laser delivery. An out-of-focus spot may not produce a clinically satisfactory lesion.

Warnings and Cautions

WARNINGS:

Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the operating personnel, the entire laser and the appropriate delivery system operator manuals should be carefully read and comprehended before operation.

Never look directly into the aiming or treatment beam apertures or the fiber-optic cables that deliver the laser beams, with or without laser safety eyewear.

Never look directly into the laser light source or at laser light scattered from bright reflective surfaces. Avoid directing the treatment beam at highly reflective surfaces such as metal instruments.

Ensure that all personnel in the treatment room are wearing the appropriate laser safety eyewear. Never substitute prescription eyewear for laser safety eyewear.

If you are using a beam splitter, you must install the fixed eye safety filter for the 810 nm wavelength before installing the beam splitter.

The relationship between spot size and resultant power density is not linear. Halving the spot size quadruples the power density. The physician must understand the relationship among spot size, laser power, power density, and laser/tissue interaction before using the OMA.

Always inspect the fiber-optic cable before connecting it to the laser to ensure that it has not been damaged. A damaged fiber-optic cable could cause accidental laser exposure or injury to yourself, your patient, or others in the treatment room.

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.

Do not use the delivery device with any laser system other than an IRIDEX laser. Such use may void product warranties and jeopardize the safety of the patient, yourself, and others in the treatment room.

Tissue absorption is directly dependent upon presence of pigmentation; therefore, dark pigmented eyes will require lower energies to obtain equivalent results as compared to light pigmented eyes.

CAUTIONS:

US federal law restricts this device to sale by or on the order of a healthcare practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Use of controls or adjustments or performing of procedures other than those specified herein may result in hazardous radiation exposure.

Do not operate the equipment in the presence of flammables or explosives, such as volatile anesthetics, alcohol, and surgical preparation solutions.

Turn off the laser before inspecting any delivery device components.

Always handle the fiber-optic cables with extreme care. Do not coil the cable into a diameter less than 15 cm (6 in).

Keep the protective cap over the fiber-optic connector when the delivery device is not in use.

IRIDEX Corporation Contact Information

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, California 94043-1824 USA

Telephone:	(650) 940-4700 (800) 388-4747 (US only)
Fax:	(650) 962-0486
Technical Support:	(650) 962-8100 techsupport@iridex.com

EC REP Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Warranty and Service. This device carries a standard factory warranty. This warranty is void if service is attempted by anyone other than certified IRIDEX service personnel.

NOTE: *This Warranty and Service statement is subject to the Disclaimer of Warranties, Limitation of Remedy, and Limitation of Liability contained in IRIDEX's Terms and Conditions.*

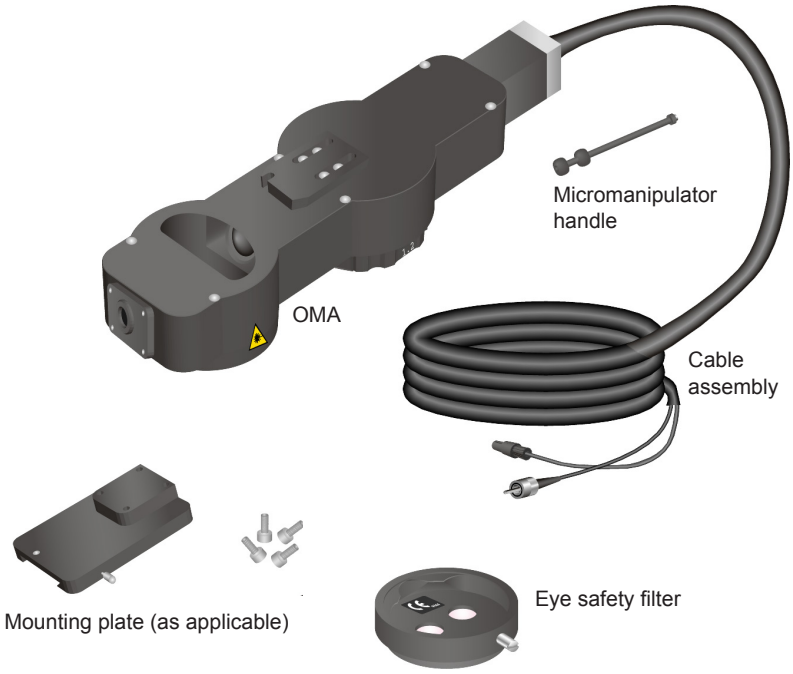
Should you require assistance, please contact your local IRIDEX Technical Support representative or our corporate headquarters.

WEEE Guidance. Contact IRIDEX or your distributor for disposal information.

2
Operation

About the Components

After unpacking the contents of the Operating Microscope Adapter (OMA), ensure that you have all of the ordered components. Check the components carefully before use to ensure that no damage occurred during transit. Along with this manual, you should have the OMA and a micromanipulator. You may also have mounting brackets, hardware, tools, and an eye safety filter.

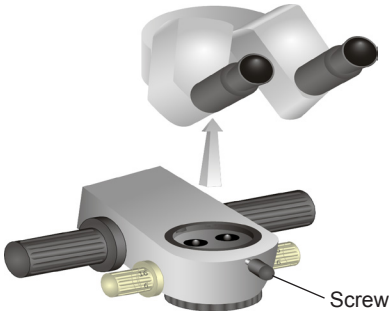


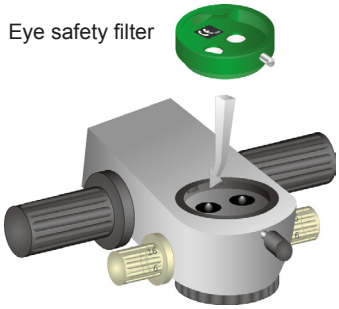
Component	Description
Fiber-optic cable	Transmits laser light
SmartKey™	Communicates spot size
Micromanipulator	Allows beam steering capabilities
Fixed eye safety filter for the 810 nm wavelength	Protects against 810 nm wavelength
Mounting accessories	As necessary, depending on microscope model

Connecting the Components

Install the Eye Safety Filter

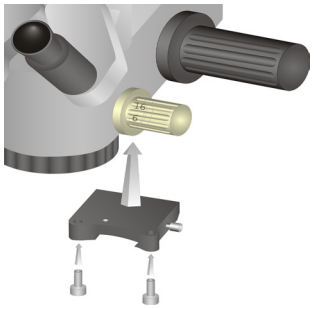
1. Loosen the screw, and carefully lift off the binocular tube.
2. Install the eye safety filter, then remount the binocular tube.





Install the OMA

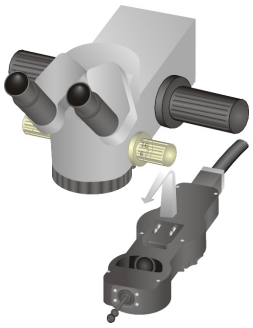
Remove any accessories that are mounted to the underside of the microscope. If applicable, install the mounting plate and spacer.

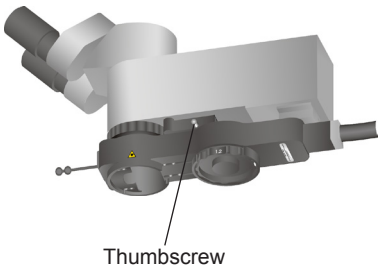


Mount the OMA

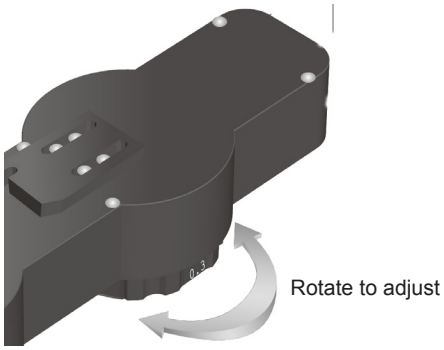
1. Loosen the thumbscrew and slide the OMA into the mount.

2. Tighten the thumbscrew.





Select the Spot Size



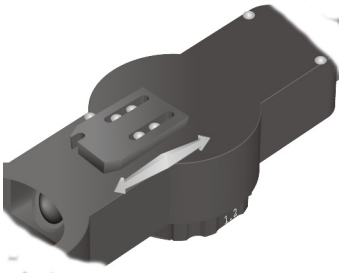
Verify the Focus

The OMA is preset for use with 175 mm focal-length objective lenses.

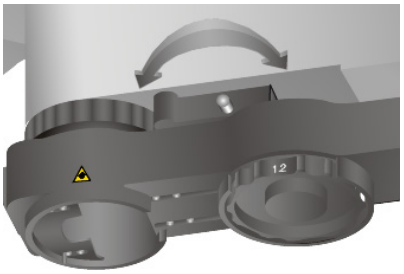
1. Focus the microscope.
2. Set spot size to 0.3 and turn on the aiming beam.
3. Verify that the aiming beam is in focus with the microscope. Adjust as necessary.

Adjust the OMA

You may have to remove the OMA before making adjustments.

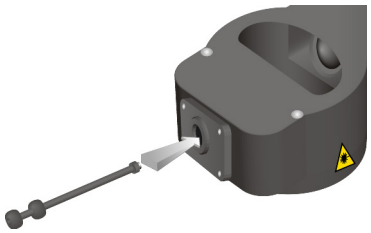


Forward and backward adjustments on OMA mounting plate

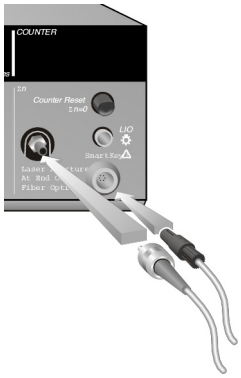


Slide lever to adjust OMA from side to side

Attach the Micromanipulator Handle



Connect the Fiber Optic and the SmartKey to the Laser Console



Treating Patients

Before treating a patient:

- Ensure that the eye safety filter (as appropriate) is properly installed and that the SmartKey®, if used, is selected.
- Ensure that the laser components and delivery device(s) are properly connected.
- Post the laser warning sign outside the treatment room door.

NOTE: *Refer to Chapter 5, "Safety and Compliance," and your delivery device manual(s) for important information about laser safety eyewear and eye safety filters.*

To treat a patient:

1. Turn on the laser.
2. Reset the counter.
3. Set the treatment parameters.
4. Position the patient.
5. If required, select an appropriate contact lens for the treatment.
6. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
7. Select Treat mode.
8. Position the aiming beam on the treatment site.
9. Focus or adjust the delivery device as applicable.
10. Press the footswitch to deliver the treatment beam.

To conclude patient treatment:

1. Select Standby mode.
2. Record the number of exposures and any other treatment parameters.
3. Turn off the laser and remove the key.
4. Collect the safety eyewear.
5. Remove the warning sign from the treatment room door.
6. Disconnect the delivery device(s).
7. Disconnect the SmartKey, if used.
8. If the delivery device is single-use, dispose of it properly. Otherwise, inspect and clean the delivery device(s) as instructed in your delivery device manual(s).
9. If a contact lens was used, handle the lens according to the manufacturer's instructions.

3
Troubleshooting

General Problems

Problem	User Action(s)
No display	• Verify that the keyswitch is on. • Verify that the components are properly connected. • Verify that the electrical service is on. • Inspect the fuses. If there is still no display, contact your local IRIDEX Technical Support representative.
Inadequate or no aiming beam	• Verify that the delivery device is properly connected. • Verify that the console is in Treat mode. • Turn the aiming beam control fully clockwise. • Verify that the fiber-optic connector is not damaged. • If possible, connect another IRIDEX delivery device and place the console in Treat mode. If the aiming beam is still not visible, contact your local IRIDEX Technical Support representative.
No treatment beam	• Verify that the remote interlock has not been activated. • Verify that the aiming beam is visible. • Verify that the fiber switch is in the correct position for the laser system and wavelength you are using. • Verify that the eye safety filter is in the closed position. If there is still no treatment beam, contact your local IRIDEX Technical Support representative.

4
Maintenance

To provide routine care:

- Do not kink or bend the fiber-optic cable.
- When connected to the laser, the fiber-optic cable must be located away from high traffic areas.
- Do not bend the probe needle during use or storage.
- Do not strike the tip against hard surfaces.
- Keep the optical components free of fingerprints.
- Keep the SLA attached to the slit lamp, except when you need to move it or attach it to another delivery device.
- When not in use, cover the slit lamp with the provided cover to keep the slit lamp free of dust, and store all accessories in suitable storage boxes.

Cleaning Optical Components

1. Wrap a lens tissue around one end of a cotton-tipped swab.
2. Place several drops of 100% ethanol, 100% methanol, or high-grade acetone on the tissue.
3. Wipe the lens gently with the swab to remove all dust and debris.
4. If the surface is still not clean, put a clean lens tissue around the end of the swab and gently wipe it again.

Cleaning the External Surfaces

Remove accumulated dust with a very soft cloth. When necessary, wipe the external non-optical surfaces with a soft cloth dampened with a mild detergent.

5
Safety and Compliance

To ensure safe operation and prevent hazards and unintended exposure to the laser beams, read and follow these instructions:

- To prevent exposure to laser energy, except as a therapeutic application from either direct or diffusely reflected laser beams, always review and observe the safety precautions outlined in the operator manuals before using the device.
- This device is intended for use only by a qualified physician. The applicability of the equipment and treatment techniques selected is your sole responsibility.
- Do not use any device if you think it is not functioning properly.
- Laser beams reflected from specular surfaces can harm your eyes, the patient's eyes, or others' eyes. Any mirror or metal object that reflects the laser beam can constitute a reflection hazard. Be sure to remove all reflection hazards near the laser. Use non-reflecting instruments whenever possible. Be careful not to direct the laser beam at unintended objects.

CAUTION: *Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.*

Protection for the Physician

Eye safety filters protect the physician from backscattered treatment laser light. Integral eye safety filters are permanently installed in every compatible Slit Lamp Adapter (SLA) and Laser Indirect Ophthalmoscope (LIO). For endophotocoagulation or for Operating Microscope Adapter (OMA) use, a separate discrete eye safety filter assembly must be installed into each viewing path of the operating microscope. All eye safety filters have an optical density (OD) at the laser wavelength sufficient to permit long-term viewing of diffuse laser light at Class I levels. When using handpieces, always wear the appropriate laser safety eyewear.

Always wear appropriate laser safety eye wear when performing or observing laser treatments with the unaided eye. Refer to laser console Operator Manual for laser safety eye wear minimum OD, it is specific per each laser console wavelength and maximum power output.

Protection for All Treatment Room Personnel

The Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Ocular Hazard Area (NOHA), and Nominal Ocular Hazard Distance (NOHD) for each of the delivery devices used with the laser system, as well as the configuration of the treatment room. For additional information, refer to ANSI Z136.1, ANSI Z136.3, or European Standard IEC 60825-1.

Safety Compliance

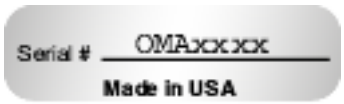
Complies with FDA performance standards for laser products, except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

CE-marked devices comply with all requirements of the European Medical Device Directive MDD 93/42/EEC.

Feature	Function
Eye safety filter	The eye safety filter ensures that all laser radiation returned to the physician and any co-observers is below Class I limits.
Safety interlock	The delivery device's protective housing and the laser fiber connector cannot be opened without the use of special tools. The delivery device is also safety-interlocked at the fiber-optic port on the laser.

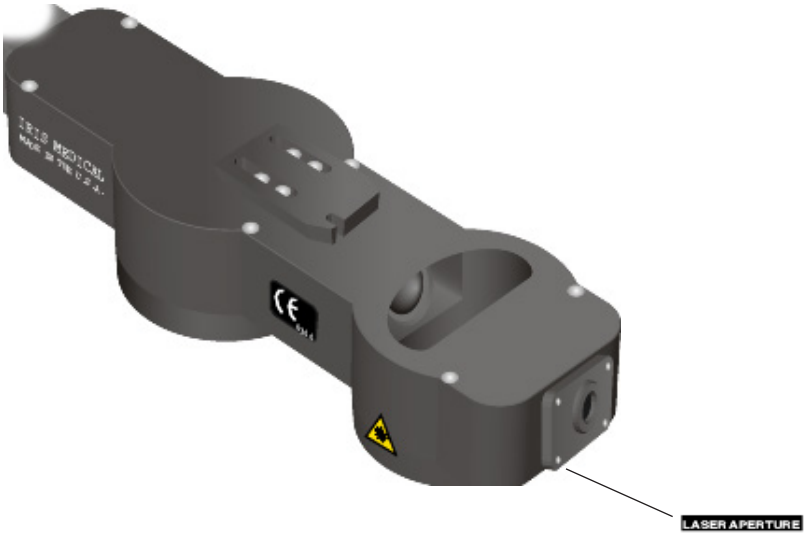
Labels

Serial Number Label



OR

Laser Aperture Label



Symbols (As Applicable)

	Aiming Beam		Angle		Aspirating Probe
	Caution		Audible Signal		CE Mark
	Connector Type		Do Not Use if Package is Damaged		Duration
	Duration with MicroPulse		Emergency Stop		ETL Mark
	EtO Sterile		EU Authorized Representative		Expiration Date
	Footswitch		Footswitch In		Footswitch Out
	Fuse		Gauge		Protective Earth (Ground)
	Illuminating Probe		Decrease/Increase		Interval
	Interval with MicroPulse		Laser Aperture at End of Fiber		Laser Warning
	Illumination		LOT		Manufacturer
	Date of manufacture		Off		On
	Part Number		Power		Pulse Count
	Pulse Count Reset		No-ionizing Electromagnetic Radiation		Read Information
	Remote Control		Remote Interlock		Serial Number
	Single Use		Standby		Treat
	Type B Equipment		Waste Electrical and Electronic Equipment (WEEE)		Pattern is Activated

	Temperature Limitations	**IPX4**	Protections Against Splash Water Coming from all Directions	**IPX8**	Protections Against Continuous Immersion
	Refer to Instruction Manual/Booklet (in blue)		Initial Power (PowerStep)		Interval between Groups
	Number of Pulses (Group)		Number of Steps (PowerStep)		Power (MicroPulse)
	Power Increment		Power Increment (PowerStep)		Parameter is Locked
	USB		Port Indicators		Laser Firing
	Laser Preparing		Speaker		Screen
	System Brightness		Latex Free		Prescription
	Warning, Replace with fuses as indicated				

OMA Specifications

Specification	Definition
Laser compatibility	OcuLight SL OcuLight SLx IQ 810
Spot sizes	0.3 mm 0.5 mm 0.8 mm 1.2 mm 3 mm
Eye filter	810 nm