EndoProbe® and OtoProbe Operator Manual

IRIDEX

13103-EN
Revision F

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Contents

Introduction

About the EndoProbe and ENT Probe

The IRIDEX EndoProbe is used to perform a variety of ophthalmic laser treatments.

The EndoProbe is offered in straight or angled styles and features a low cone angle to allow a comfortable working distance from the retina and a more reproducible endpoint. The aspiration feature removes unwanted eye fluid that is causing refraction or scattering of the laser beam from the intended treatment site. The illumination feature illuminates the interior of the eye.

The ENT Probe is used to perform otolaryngological procedures, and is offered in short- and long-angled styles. The OtoProbe is a member of the ENT Probe family.

The EndoProbe handpieces come with a universal SMA connector that allows them to be used with validated compatible laser systems.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

WARNING

Surgical lasers generate a highly concentrated beam of light, which may cause injury if improperly used. Be sure to operate the console and the probe in accordance with the procedures described in your console manual and this manual. Failure to do so may harm yourself, your patient, or others.

EndoProbe Specifications

Probe models

Standard and specialty EndoProbe and ENT probe handpieces are available.

Sterile condition

The probes are single-use devices that have been factory pre-sterilized using Ethylene Oxide (EtO) gas and are shipped in double-pouched, sterile bags, ready for clinical use.

Illuminating EndoProbe specifications

In accordance with ISO 15752, Section 6.2 the following information specific to the illumination capability of this device is provided:

EndoIlluminator effective aperture

0.6 mm

EndoIlluminator numerical aperture

0.5

EndoIlluminator light guide materials

PMMA acrylic plastic polymer or fused silica

Illumination testing

In accordance with ISO 15752, Section 4.4.2 the following information specific to the illumination capability of this device is provided:

Measurement of the aphakic weighted irradiance of an illuminating EndoProbe may be made under sterile conditions by using the means provided for this purpose by the manufacturer of your EndoIlluminator light source together with the use of a means to temporarily grip the EndoProbe during measurement. This may be accomplished by draping the EndoProbe handpiece with a sterile sleeve or alternatively by gripping the EndoProbe with a sterile clamp, forceps, or gloves during measurement. Be careful not to compromise the sterile tip of the EndoProbe during fixturing or measurement.

Warranty and Service

Warranty

The probes are single-use devices that are warranted against manufacturing defects.

Service and technical support

IRIDEX has established an efficient process to support its installations worldwide. Should you require assistance, please contact your local IRIDEX Technical Support representative or our corporate headquarters.

NOTE

The probes are intended for single-use only.

WARNING

If these single-use devices are reused, performance, safety, and efficacy cannot be guaranteed.

Operation

About the Components

After unpacking the contents of the package, ensure that you have received all of the components ordered. Check the components carefully before use to ensure that no damage occurred during transit. If you ordered an EndoProbe Starter Kit, please refer to the appropriate section below:

EndoProbe Starter Kit components for the OcuLight GL/GLx/TX/OR

Along with this manual, you should have the EndoProbe style(s) you ordered, an IRIDEX fixed or two-position eye safety filter labeled for use at the 532 nm wavelength, four pairs of safety glasses, and a SmartKey®, (if applicable).

EndoProbe Starter Kit components for the OcuLight SL/SLx or IQ810

Along with this manual, you should have the EndoProbe style(s) you ordered, an IRIDEX fixed eye safety filter labeled for use at the 810 nm wavelength, and four pairs of safety glasses, (if applicable).

Component descriptions

EndoProbe

Each EndoProbe delivers the treatment and aiming laser beams from the console to the patient's eye and consists of a blunt intraocular needle that comes in straight and angled models, a handle, a fiber-optic cable, and, on some models, an illumination fiber or aspiration tube. The angled EndoProbe needles allow for more effective treatment of the peripheral retina.

ENT Probe

Each ENT Probe delivers the treatment and aiming beams from the console to the tissue and consists of a tapered needle that comes in two varieties of angulation, a handle, and a fiber-optic cable.

NOTE

Should you notice problems with your order, please contact your local IRIDEX Customer Service representative immediately.

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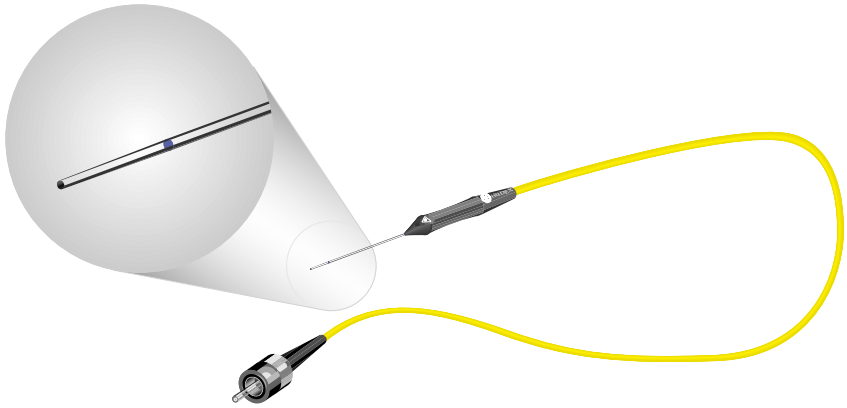
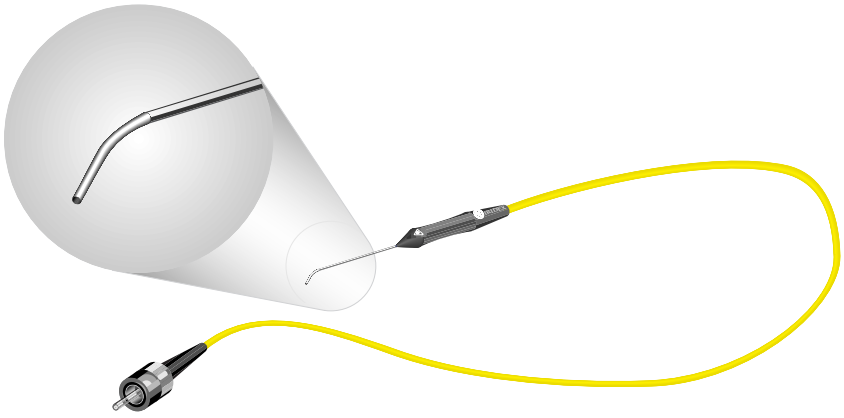
Standard

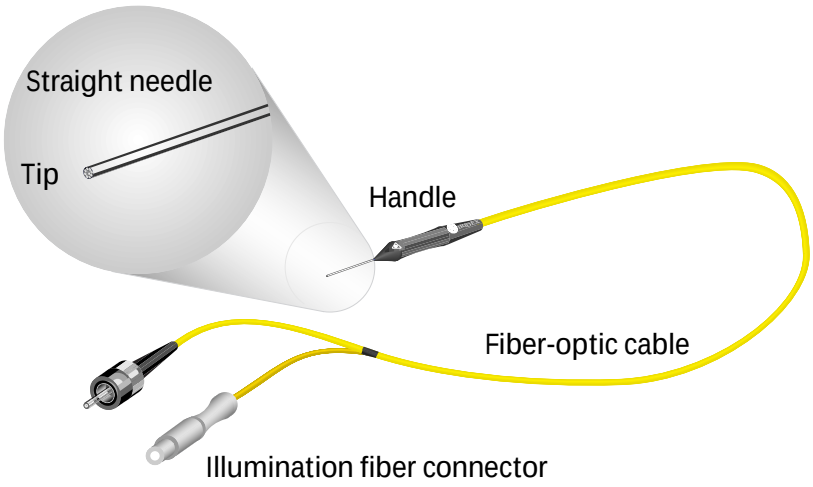
The tapered EndoProbe makes it easier to insert and extract at the sclerostomy site.

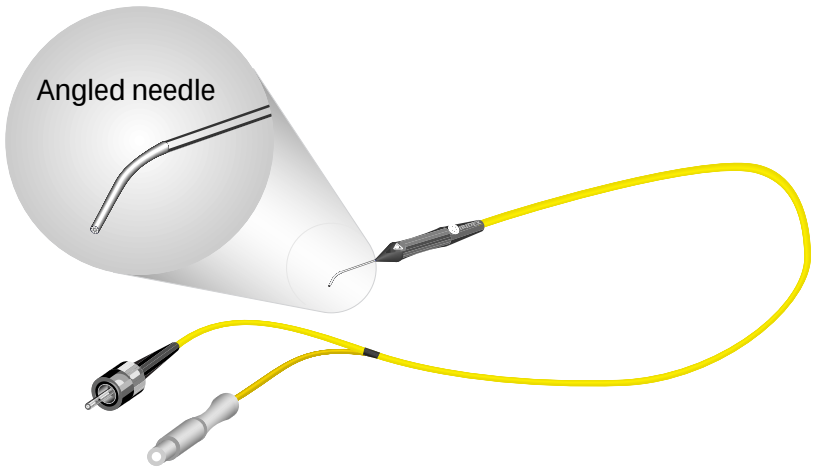




Illuminating

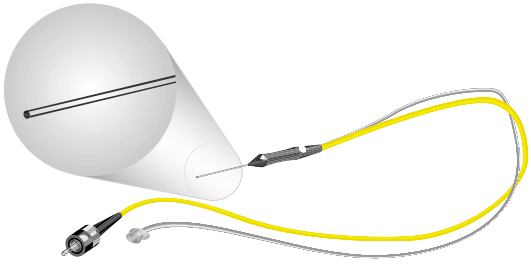
An illuminating EndoProbe permits simultaneous white light illumination and laser photocoagulation from the same needle. The illumination connector allows you to use the EndoProbe with a variety of ophthalmic light sources, such as Bausch & Lomb® and Alcon®. An adapter may be required for use with some illuminating light sources. Contact IRIDEX customer service for additional information.

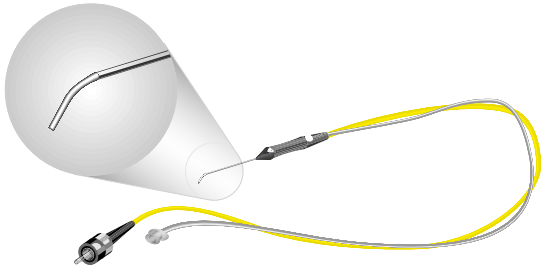




Active Aspirating

The active aspirating EndoProbe (available in straight and angled models) allows for aspiration (ventilation) of unwanted fluid from the eye. The aspiration is originated from the vitrectomy port on the vitrectomy system console and is regulated through depression of the vitrectomy system foot pedal.





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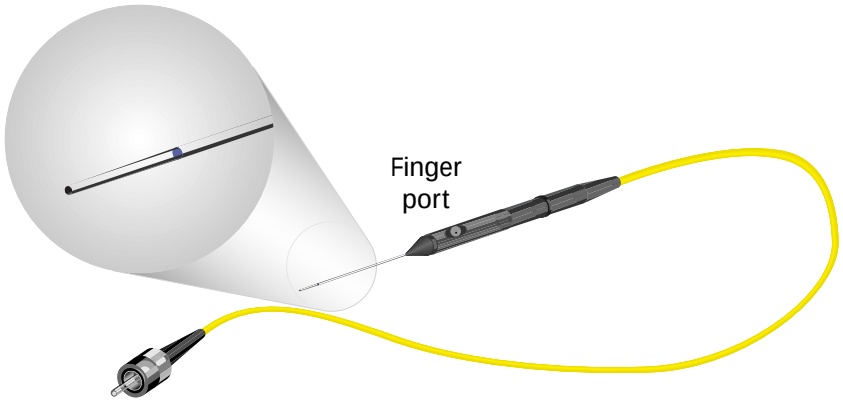
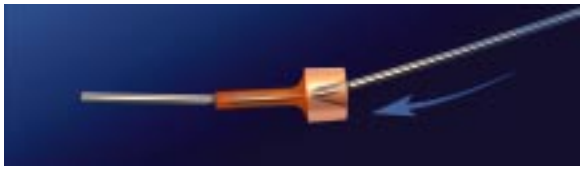
Fluted Aspirating

The fluted EndoProbe allows for aspiration (ventilation) of unwanted fluid from the eye. By removing your finger from the opening (finger port) on the probe handle, you can control the amount of fluid that is aspirated. Aspiration occurs through the positive pressure within the eye.



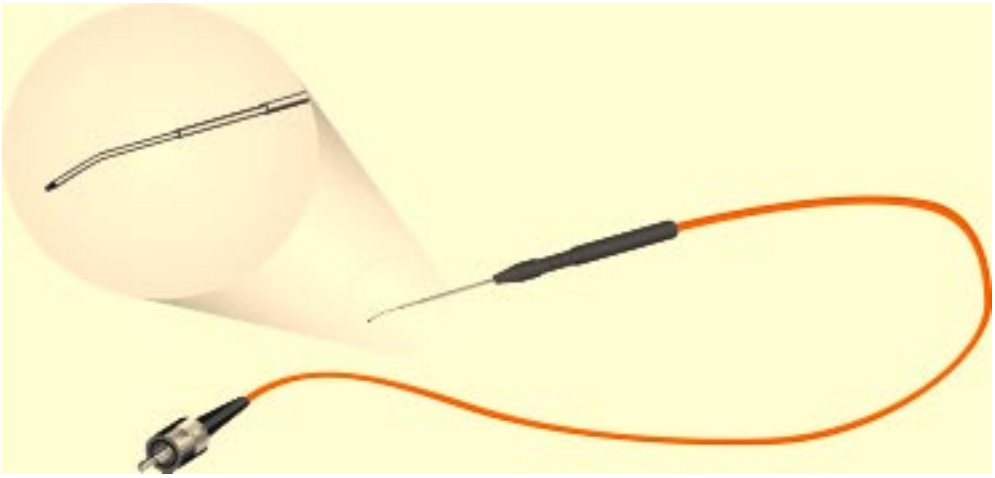
Stepped 45° Angled

The stepped EndoProbe handpieces offer a smooth, gently tapered needle which permits the angled 45° tip to be inserted through straight cannulas for full coverage of the peripheral retina.



ENT Probes

The short-angled OtoProbe offers better visibility when viewing the tissue around the needle tip.



The long-angled OtoProbe offers a longer, straight needle for easier tissue applanation.

IRIDEX eye safety filter styles and accessories

The IRIDEX eye safety filters have optics which protect your eyes from backscattered laser reflections during laser surgery while using the probe with an operating microscope.

Two eye safety filter styles for the 532 nm wavelength are available for the OcuLight GL/GLx/TX and OR consoles: the fixed eye safety filter and the two-position eye safety filter.

The fixed eye safety filter for the 810 nm wavelength is available for the OcuLight SL/SLx and IQ 810™ consoles.

Fixed eye safety filter (available for all OcuLight consoles)

The fixed eye safety filter is silent and non-moving and has specially coated lenses that allow for a clear, unobstructed view of the retina.

SmartKey emulation plug (available for OcuLight GL/GLx/OR consoles)

The SmartKey emulation plug, which comes with the fixed eye safety filter for the 532 nm wavelength, must be inserted into the corresponding port on the console to place the laser in Treat mode. The OcuLight TX laser does not require a SmartKey emulation plug.

Fixed eye safety filter

SmartKey emulation plug

(For OcuLight 532 nm consoles, excluding the TX)

WARNING

When using an IRIDEX probe with a non-IRIDEX laser console, ensure that the proper eye safety filter is installed for the specific non-IRIDEX laser console being used. Refer to your laser operator manual for specific eye safety filter information.

CAUTION

Use the ENT probes only with the OcuLight GLx/TX or OcuLight OR console.

WARNING

The IRIDEX two-position eye safety filter protects from backscattered laser light in the closed filter positions only when used with the IRIDEX 532 nm lasers. The two-position eye safety filter should not be used with any other laser photocoagulator consoles, including other 532 nm lasers.

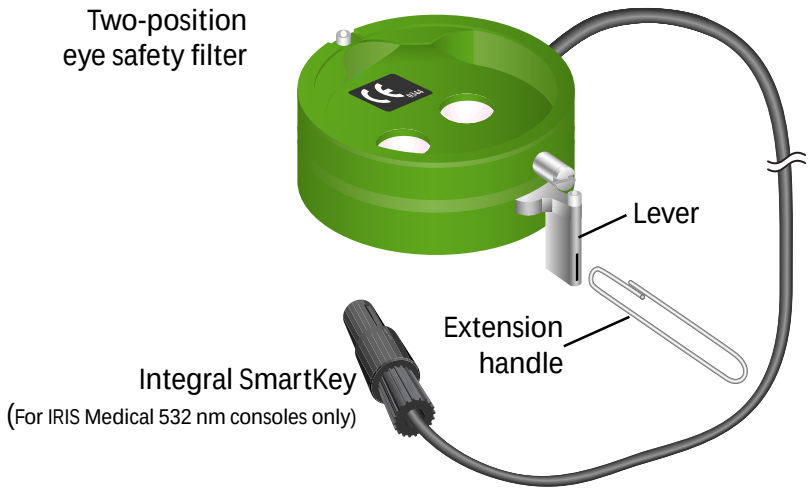
Two-position eye safety filter (available only for the 532 nm consoles)

The two-position eye safety filter has specially coated UltraView™ lenses which enable you to see objects in their true colors and in heightened detail.

A manual lever allows you to open or close the filter when you are not performing photocoagulation. During photocoagulation, the filter must be in the viewing path to enable laser activation.

The integral SmartKey that is attached to the two-position eye safety filter provides electronic communication from the eye safety filter to the console, indicating when the filter is in the viewing path and when it is not.

The extension handle provides easier access to the eye safety filter lever in the event that access to the lever is obstructed by microscope accessories (such as binoculars, a beamsplitter, etc.)



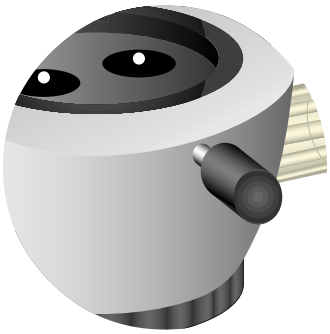
Connecting the Components

Install the appropriate IRIDEX eye safety filter

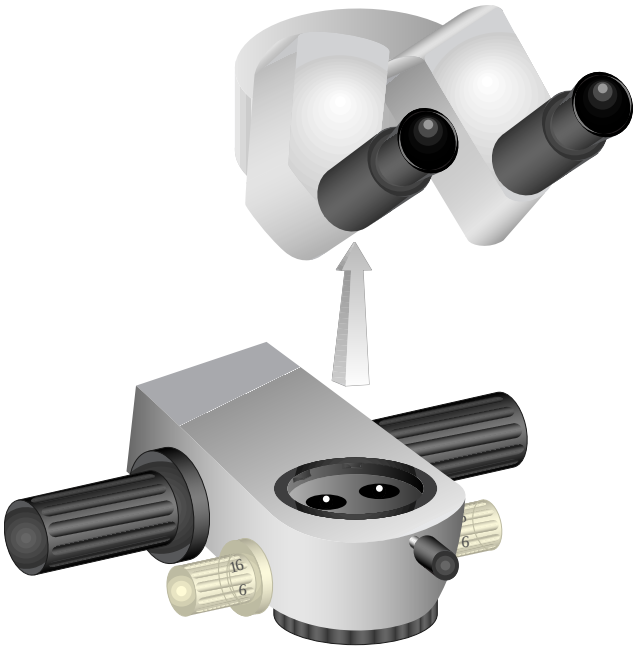
When using the OcuLight SL/SLx or IQ 810 console, install the IRIDEX 810 nm eye safety filter into your microscope. When using the OcuLight GL/GLx/TX or OcuLight OR console, install the 532 nm eye safety filter into your microscope. For simultaneous protection from 810 nm and 532 nm laser light, install both IRIDEX eye safety filters into your microscope.

Remove the binocular tube from the operating microscope

Loosen the thumbscrew that holds the binocular tube onto the operating microscope.



Carefully lift the binocular tube off of the microscope.



NOTE

Fixed eye safety filters for both 810 nm and 532 nm IRIDEX laser systems are available for the Leica M84X surgical microscope. Please contact your local IRIDEX representative for further information.

WARNING

The two-position eye safety filter is not compatible with OcuLight GL/GLx firmware versions 1.02, 1.03, 1.04, or 1.06.

Installing a two-position eye safety filter

OcuLight GL/GLx console

The two-position eye safety filter is compatible with firmware versions 1.05, 1.1, and higher. When installing this type of filter, first configure your console:

1. Activate the diagnostic mode to determine which firmware version you have by pressing the Counter Reset and Treat/Standby buttons simultaneously for three seconds or until you hear a beep. The Treat and Standby lights illuminate.
2. Simultaneously press and hold the Counter Reset button while rotating the Repeat Interval control clockwise until you see #7 in the Counter display. Release the Counter Reset button. Your version of firmware is shown in the status display.
3. If you have a compatible version of firmware, turn the Repeat Interval control until #8 is shown in the Counter display. Press the Treat/ Standby button to scroll to Movable.
4. Press the Mode button to activate your selection and exit diagnostic mode.

OcuLight OR

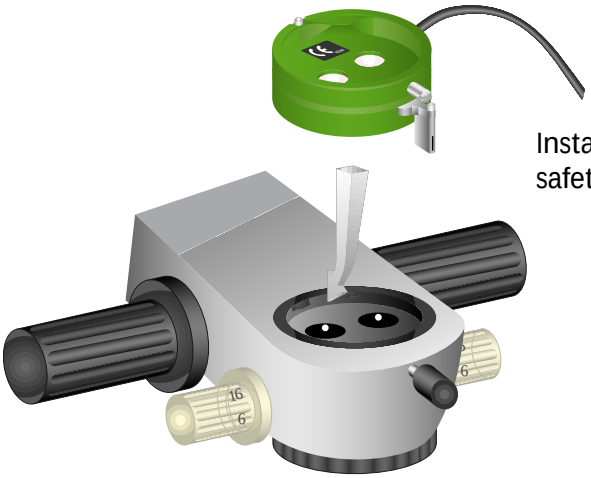
1. Refer to “Setting Up for an Endo Procedure” in the OcuLight OR Operator Manual.

OcuLight TX

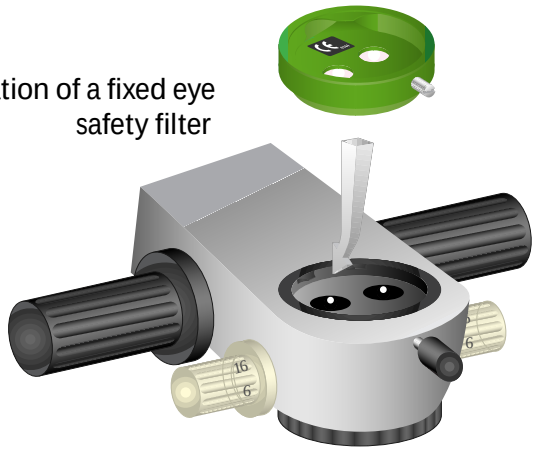
1. Simply connect the SmartKey to the laser.. No changes to laser preference setting required. The OcuLight TX is designed to recognize a twp-position filter.

Install the eye safety filter

Install the eye safety filter on the microscope and tighten the thumbscrew to secure.



Installation of a two-position eye safety filter



Installation of a fixed eye safety filter

Remount the binocular tube on the microscope

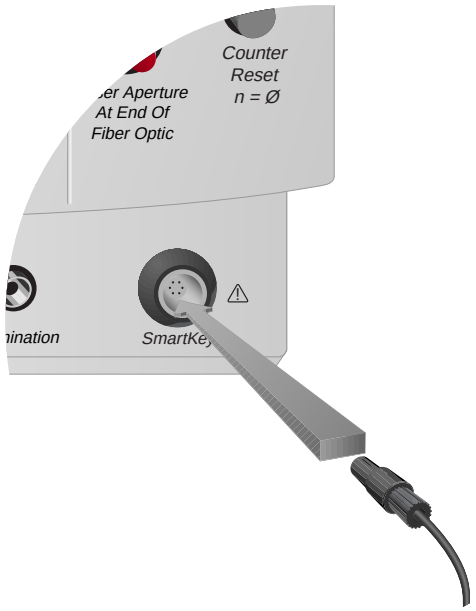
Remount the binocular tube into the top of the eye safety filter or beam splitter and tighten the screw to secure.

WARNING

If you are using a beam splitter on your operating microscope, you must install the fixed eye safety filter before installing the beam splitter.

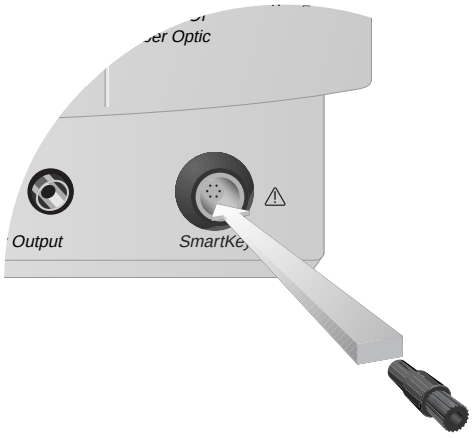
If using a two-position eye safety filter, insert the SmartKey

Insert the SmartKey into the SmartKey port on the OcuLight GL/GLx/TX or OR console.



If using an OcuLight GL/GLx or OcuLight OR console and a fixed eye safety filter, insert the SmartKey emulation plug

Insert the SmartKey emulation plug into the laser console SmartKey port.



WARNING

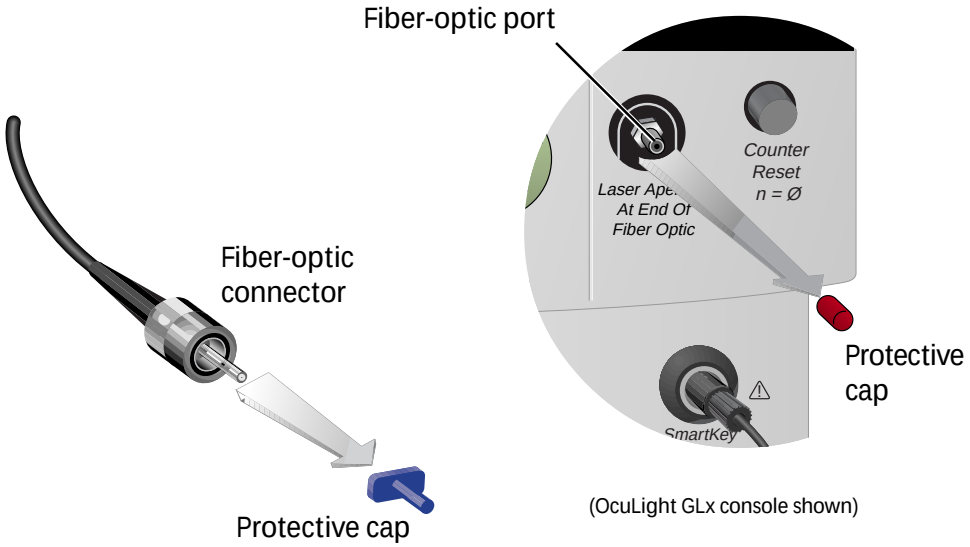
Always inspect the fiber-optic cable before connecting it to the console to ensure that it has not been damaged. A damaged fiber-optic cable could cause accidental laser exposure or injury to yourself, your patient, or others in the treatment room.

Connect the fiber-optic

When performing these steps, ensure sterility of the probe by following your hospital's aseptic procedures for removal and connection of delivery systems in a sterile environment.

Remove the probe from the sterile pouch and inspect the fiber-optic cable for damage. Remove the protective cap from the probe's fiber-optic connector.

Do not use a probe whose pouch was delivered damaged or open.



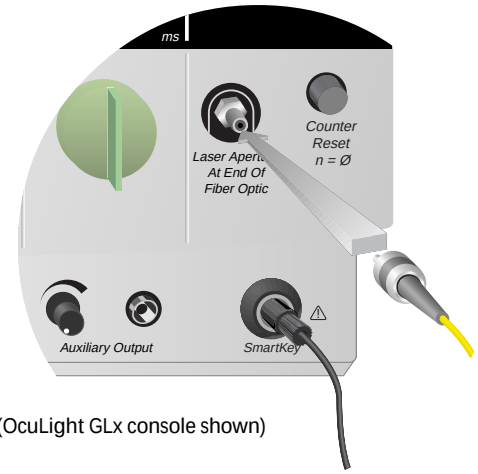
(OcuLight GLx console shown)

To IRIDEX lasers

Remove the protective caps from the console fiber-optic port.

Carefully insert and finger-tighten the connector into the console fiber-optic port until secure.

If the probe is properly connected, when you turn on the console, EndoProbe displays on the console status panel.



(OcuLight GLx console shown)

To non-IRIDEX lasers

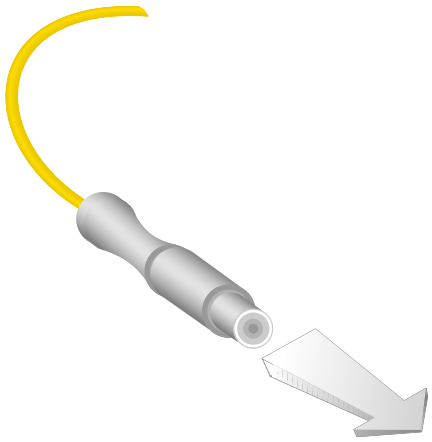
Remove the protective cap from the console fiber-optic port and connect the fiber optic connector to your laser, as described in your laser operator manual.

CAUTION

Gently finger-tighten the fiber-optic connector and do not overtighten to avoid undue damage to the connector port.

If applicable, connect the EndoProbe to an illumination source

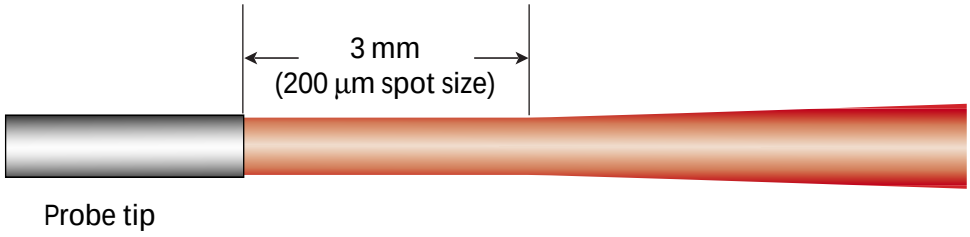
If using the illuminating EndoProbe, insert the illumination fiber connector into the appropriate light source port. An illumination source adapter accessory is available for use with certain light sources, such as Grieshaber®. For a complete list of adapters and compatible light sources, please contact your local IRIDEX representative.



To light source

Controlling the Size of the Laser Spot

Laser spot size is controlled by positioning the probe tip near the tissue to be treated. The probe has a spot size of 200 µm 3 mm from the probe tip. To change the spot size, move the probe farther from or closer to the target.



WARNING

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 between spot size, laser power, power density, and laser/tissue interaction.

WARNING

Excessive power settings can result in retinal holes and hemorrhages. Excessive power with short pulse durations may result in choroidal hemorrhage.

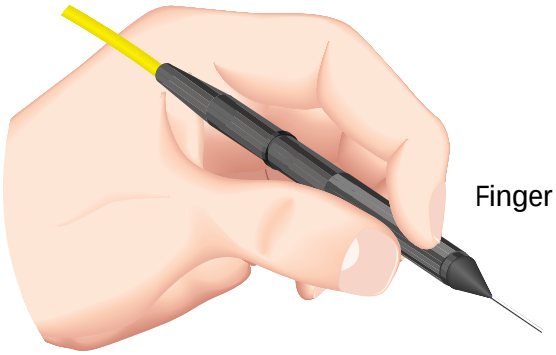
CAUTION

If you are uncertain of tissue response, always start with the lowest power settings and gradually increase the power until you observe satisfactory clinical lesions.

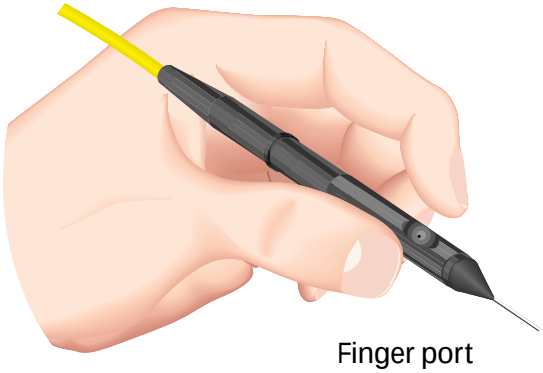
Controlling the Aspiration

Passive

During normal operation, cover the hole on the handle with your finger. To aspirate, lift your finger off of the hole.



Finger port covered



Finger port uncovered

Active

Regulate the aspiration by depressing the vitrectomy system foot pedal.

Using the Two-Position Eye Safety Filter

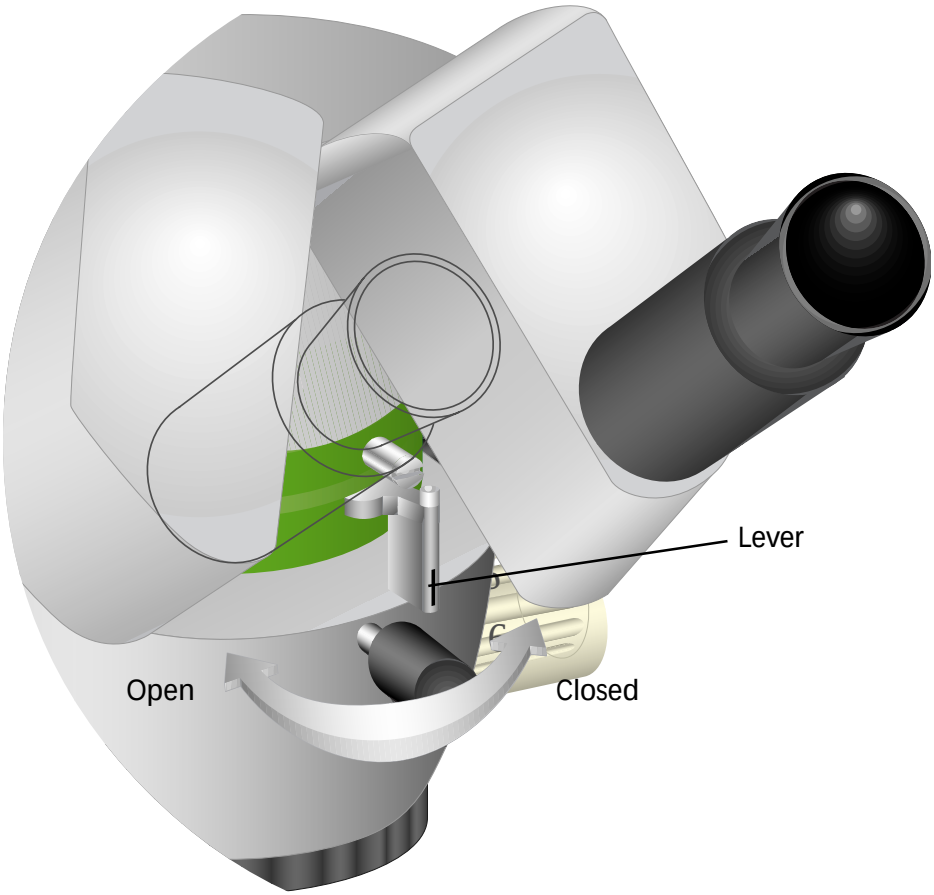
Closing the filter

When the filter is closed, the filter moves into your visual path and your eyes are protected from laser radiation above regulatory requirements.

Before beginning treatment, close the filter using the lever on the two-position eye safety filter. EndoProbe displays on the OcuLight GL/GLx console status panel when the filter is closed; ENT Probe displays on the OcuLight OR.

Opening the filter

When the two-position eye safety filter is open, the filter moves out of your visual path and you cannot activate the laser. Green Safety Filter? displays on the OcuLight GL/GLx and Two-Position Safety Filter? on OcuLight OR consoles status panel when the filter is open and the yellow Standby light flashes.



Before Treating Patients

REFERENCE

Read the **Clinical and Safety** sections of your console manual and this manual before using the probe.

REFERENCE

See the **Connecting Components** sections of your console manual and this manual for connection instructions.

REFERENCE

See the **Using the Control Panel** section of your console manual for instructions on using the treatment controls and displays.

WARNING

Do not use a probe whose pouch arrived opened or damaged.

1. Ensure that the appropriate eye safety filter is installed.
2. Ensure that the console and the probe are properly connected and set up.
3. Ensure that the microscope is adjusted, as instructed by your microscope manufacturer.
4. Post the laser warning sign outside the treatment room door.

Treating a Patient

1. Set the treatment parameters.
2. Position the patient.
3. If used, close the two-position eye safety filter.
4. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
5. Select Treat mode.
6. Position the aiming beam on the treatment site.
7. If desired, adjust the intensity of the red aiming beam.
8. Press the footswitch to deliver the treatment beam.
9. When you do not require the treatment beam, remove your foot from the footswitch and place the console in Standby mode.

REFERENCE

See **Using the Two-Position Eye Safety Filter** in this manual for instructions on closing the filter.

REFERENCE

See the **Clinical and Safety** sections of your console manual and this manual for important laser safety eyewear information.

WARNING

Always keep the console in Standby mode when you are not treating a patient. Maintaining the console in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.

REFERENCE

See the **Inspecting and Cleaning** sections of your console manual and this manual for cleaning and storage instructions.

Concluding Patient Treatment

1. Place the console in Standby mode.
2. If desired, record the number of exposures and any other treatment parameters.
3. Turn off the console and remove the key to prevent unauthorized use.
4. Disconnect the probe fiber-optic connector from the console fiber-optic port. Cover the fiber-optic port with the protective cap.
5. Cut the probe in half with scissors so it cannot be used again. Discard both probe pieces in accordance with your hospital's procedures for disposing of hazardous materials.
6. If using a SmartKey, remove it from the console and store it.
7. Disconnect the eye safety filter from the operating microscope and store it.
8. If desired, clean and store the console.
9. If desired, remove the laser warning sign from the treatment room door.

Troubleshooting

Reporting problems

Should you experience problems with your probe when using it with an IRIDEX laser, refer to the suggestions in this section. If you continue to experience problems, write down the error message, product name, serial number of the console, and lot number of the probe before contacting your local IRIDEX Technical Support representative.

Problem	Action
Inadequate or no aiming beam	• Ensure that the probe is properly connected to the console. • Ensure that the console is in Treat mode. • Turn the Aiming Beam control fully clockwise. • Ensure that the fiber-optic connector is not damaged. • If possible, connect another IRIS Medical 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	• Ensure that the remote interlock has not been activated. • Ensure that the aiming beam is present and bright. • If you still have no treatment beam, contact your local IRIDEX Technical Support representative. • If used, ensure that the two-position eye safety filter is in the closed position.

REFERENCE

Should you experience problems with your probe when using it with a non-IRIDEX laser, refer to the **Troubleshooting** section of your laser operator manual.

For connection instructions, see the **Operation** sections of your console manual and this manual.

Problem	Action
The Status panel reads:	
Connect Fiber	• Ensure that the probe is properly connected.
Connect SmartKey	• Ensure that the SmartKey is properly inserted.
Eye Safety Filter	• Ensure that the IRIS Medical eye safety filter is properly installed.
Green Safety Filter?	• Close the eye safety filter to permit laser delivery.
532nm Safety Filter?	• Close the eye safety filter to permit laser delivery.
Two-Position Safety Filter?	• Close the eye safety filter to permit laser delivery.

Maintenance

Disposing of the Probe

The probe is a single-use, disposable delivery device. When finished with a procedure, dispose of the probe; do not reuse or resterilize it.

CAUTION

Follow standard facility procedures for the handling of biohazardous material after each probe use.

Inspecting and Cleaning

CAUTION

Always handle the fiber-optic cable with extreme care. **Do not wrap the cable in a diameter less than 15 cm (6 in)**. Damage to the fiber can impair light transmission through the fiber-optic and reduce power.

CAUTION

Turn off the console before inspecting any delivery device components.

CAUTION

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

Routine care

- Do not tightly kink or bend the fiber-optic.
- When connected to the console, ensure that the fiber-optic is located away from high traffic areas.
- Keep the fiber tip free of fingerprints.
- Do not bend the probe needle during use or storage.
- Do not strike the tip against hard surfaces.
- Keep the eye safety filter free of fingerprints.

Inspect the eye safety filter

Frequently inspect the eye safety filter for dirt, debris, and damage.

Clean the eye safety filter

To clean the eye safety filter:

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.

Clinical Applications

Indications for clinical use

The EndoProbe is indicated for use in performing ophthalmic laser treatments to deliver laser energy to the treatment area inside the eye. The EndoProbe is cleared for use for the particular indications of the laser system to which it is attached.

The IRIDEX OtoProbe is intended for delivering laser energy during ENT procedures. Indications include, but are not limited to, incision, excision, coagulation and vaporization of soft and fibrous tissue including osseous tissue.

The IRIDEX OtoProbe is indicated for ENT surgery and cleared for use for the particular indications of the laser system to which it is attached.

Warnings

Ophthalmic

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

ENT

- Excessive treatment may cause swelling (edema) in the area treated by the laser.

WARNING

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 relationships between spot size, laser power, power density, and laser/tissue interaction before using the probe.

Precautions

Protect fiber-optic tip from damage. If damage is suspected to the fiber tip, discard the probe.

Recommended procedure for clinical use

This section contains general guidelines and is not intended to suggest treatment techniques. Qualified physicians should review the available literature presented in clinical papers before using the probe delivery device. A reference catalog of clinical papers and presentations is available through IRIDEX Marketing.

Power density and spot size

Tissue response to laser light is primarily determined by power density. Power density (watts/cm^2) is laser power divided by the area of the illuminated spot; therefore, you can increase power density either by increasing the laser power or by decreasing the spot size.

Power and duration

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

Shorter pulse durations require higher power densities to create a burn; however, very short pulse durations can be potentially dangerous. Longer pulse durations may be safer to use with the probe.

Safety

Preventing unintended exposure of laser energy

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 this manual and the console operator manual before using the probe.

Preventing unauthorized use of the system

This device is intended for use only by you, the qualified physician. The applicability of the equipment and treatment techniques selected is your sole responsibility.

Ensuring safe operation

Do not use the probe or eye safety filter if you suspect it is not functioning properly.

Preventing reflection hazards

Laser beams reflected from specular surfaces can harm your eyes, the patient's eyes, or others' eyes. Any mirror or metal object which reflects the laser beam can constitute a reflection hazard. Make 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.

Preventing fire and explosion hazards

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

CAUTION

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

WARNING

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

WARNING

Always verify that the probe is properly connected to the console. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.

WARNING

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.

WARNING

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

WARNING

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

REFERENCE

See your console manual for more information about the formula used to calculate the worst case NOHD for the console in use.

REFERENCE

For further information, you may refer to: IEC 60825-1 and ANSI Z136.1.

Ensuring ocular protection

Protection for the physician

To protect your eyes from laser radiation when using an operating microscope with the probe, install the appropriate eye safety filter(s).

Protection for all persons in the treatment room — laser safety eyewear requirements

When using the console with a probe, a Laser Safety Officer should determine the need for safety eyewear for others in the treatment room based on the MPE, Nominal Ocular Hazard Area (NOHA), and Nominal Ocular Hazard Distance (NOHD) for the probe and the console used and the configuration of the treatment room.

Regulatory compliance safety features for IRIS Medical lasers

The laser probes, and IRIDEX eye safety filters comply with 21 CFR subchapter J as administered by the Center for Devices and Radiological Health of the Food and Drug Administration (FDA).

CE-labeled devices comply with appropriate performance standards as specified in Annex II of the Medical Device Directive MDD 93/42/EEC.

Eye safety filter

The eye safety filter ensures that all laser radiation returned to the physician and any co-observers is below the Class I limit.

Laser emission indicator

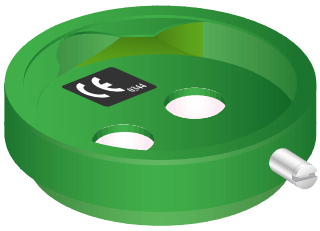
Illumination of the green Treat light on the console provides a visible warning that laser radiation may be emitted from the probe.

Safety interlocks

The probe is safety interlocked at the console fiber-optic receptacle to prevent inadvertent laser emission when the probe is not fully connected.

Location of regulatory compliance and other system labels

CE 0344



CE label

REFERENCE

Refer to your laser operator manual for regulatory compliance safety features specific to your laser.

Sterile pouch label

WARNING

Do not use if package is damaged.

Sample of an EndoProbe sterile pouch label

QTY 6

23-27 Gauge; Stepped Angled 45°

For use with IRIS Medical laser systems and other laser systems validated for use with the IRIS Medical family of EndoProbe handpieces. Consult your local IRIDEX representative for compatibility details.

Caution: This device must be used with appropriate laser safety filter. U.S. Federal law restricts this device to sale by or on the order of a physician.

This product protected by U.S. patent 5395492 and other patent pending

Intraokularsonde: 23-27 G; mit gebogener 45° Spitze

Zur Verwendung mit Lasersystemen von IRIS Medical und anderen Lasersystemen, die zur Verwendung mit den EndoProbe-Handstücken von IRIS Medical zugelassen sind. Bei Kompatibilitäts-fragen den zuständigen IRIDEX-Vertreter konsultieren.

Achtung: Dieses Gerät darf nur mit einem geeigneten Laserschutzfilter verwendet werden.

Sonde intra-oculaire: 23-27 G; coudée 45°

À utiliser avec les systèmes laser IRIS Medical et autres systèmes laser agréés pour les pièces à main EndoProbe de la gamme IRIS Medical. Vérifier les conditions de compatibilité auprès de votre représentant IRIDEX.

Attention! Ce dispositif doit être utilisé avec un filtre de sécurité laser adapté.

Sonda intraoculare: calibro 23-27; angolata a 45°

Da usarsi con i sistemi laser della IRIS Medical ed altri convalidati per l'uso assieme alla serie di manipoli EndoProbe della IRIS Medical. Verificare le condizioni Di compatibilità con il distributore IRIDEX ufficiale.

Attenzione: Il presente dispositivo deve essere utilizzato con un filtro di protezione laser adeguato.

Sonda intraocular: calibre 23-27; ángulo de 45°

Indicada para sistemas láser de IRIS Medical y otros sistemas láser homologados para la serie de piezas de mano EndoProbe de IRIS Medical. Para obtener información más detallada sobre compatibilidades, consulte con un representante local de IRIDEX.

Advertencia: este dispositivo debe utilizarse con un filtro de seguridad de láser apropiado.

Sonda Intra-Ocular: Calibre 23-27; Ângulo de 45°

Para uso com sistemas de laser da IRIS Medical e outros sistemas a laser validados para uso com a família IRIS Medical de Peça de Mão EndoProbe. Consulte seu repre-sentante local IRIDEX para detalhes de compatibilidade.

Atenção: Esse dispositivo deve ser usado com filtro de segurança para laser.

IRIDEX

1212 Terra Bella Avenue
Mountain View, CA 94043 USA
Tel: 650-962-8100
Fax: 650-962-0486
www.iridex.com

IRIS Medical®
EndoProbe® Handpiece

REF 14400

CE 0344

EC REP

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STERILE EO

LOT 012345

15-JAN-2006

Label p.n. 14389-0 rev. A

Sample of an ENT sterile pouch label

QTY 6

OtoProbe,™ Long Angle

For use with the OcuLight OR and other 532 nm laser systems validated for use with this product. Consult your local IRIDEX representative for compatibility details.

Caution: This device must be used with appropriate laser safety filter. U.S. Federal law restricts this device to sale by or on the order of a physician.

Otolaryngologie-Sonde, Winkelstück, lang

Zur Benutzung mit dem OcuLight OR und anderen 532-nm-Lasersystemen, die zur Benutzung mit diesem Produkt zugelassen sind. Bei Kompatibilitäts-fragen den zuständigen IRIDEX-Vertreter konsultieren.

Achtung: Dieses Gerät darf nur mit einem geeigneten Laserschutzfilter verwendet werden.

Sonde d'otolaryngologie, pièce angulaire longue

Conçu pour être utilisé avec le système OcuLight OR et tout autre système laser à 532 nm indiqué pour être utilisé avec ce produit. Vérifier les conditions de compatibilité auprès de votre représentant IRIDEX.

Attention! Ce dispositif doit être utilisé avec un filtre de sécurité laser adapté.

Sonda otolaringoiatrica, angolatura lunga

Utilizzare solo con OcuLight OR ed altri sistemi laser da 532 nm validati per l'uso con questo prodotto. Verificare le condizioni di compatibilità con il distributore IRIDEX ufficiale.

Attenzione: Il presente dispositivo deve essere utilizzato con un filtro di protezione laser adeguato.

Sonda para otorrinolaringologia, Ángulo largo

Para usar con el OcuLight OR y con otros sistemas de láser de 532 nm validados para el uso con este producto. Para obtener información más detallada sobre compatibilidades, consulte con un representante local de IRIDEX.

Advertencia: este dispositivo debe utilizarse con un filtro de seguridad de láser apropiado.

Sonda para Otorrinolaringologia, ângulo aberto

Para uso com o OcuLight OR e outros sistemas de laser de 532 nm aprovados para uso com este produto. Consulte seu repre-sentante local IRIDEX para detalhes de compatibilidade.

Atenção: Esse dispositivo deve ser usado com filtro de segurança para laser.

IRIDEX

1212 Terra Bella Avenue
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Tel: 650-962-8100
Fax: 650-962-0486
www.iridex.com

ENT Probe
Handpiece

REF 14310

CE

0344

EC REP

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Fax: +49 (0)76 (0)0

STERILE EO

LOT 012345

15-JAN-2006

Label p.n. 14381-0 rev. A