



Fluoresce HD Dual LED Coupler Operator Manual - US Version

REF 13568

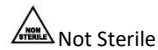
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Manufacturer:
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Chico, CA 95973 USA

EU REP
MDSS Schiffgraben 41, 30175 Hannover, Germany

Lares Research hopes that you will benefit greatly from working with your new Lares Fluoresce HD Dual LED coupler. Please observe the following notes to assure continued trouble-free and safe product operation:

1.0 Technical Data



Lares Fluoresce HD LED Coupler

Connection: ISO-Type 3 (6 pin)

Weight: 20-30 grams

Pressure: maximum drive air and water pressure is 40 psi (275 KPa).

Voltage: LED Lamp operating voltage: 3.6 to 4.2 volts DC

Fluoresce HD Dual LED Lamp: Violetlight (405 nm wavelength) and white light with a color temperature of 4500 to 5000K.

IEC 62471 Risk Group Classifications		
Actinic UV (200 nm - 400 nm)	Es	Exempt group
Near UV (315 nm - 400 nm)	Euva	Exempt group
Blue Light (300 nm - 700 nm)	La	Moderate, Risk group 2
Retinal Thermal (380 nm - 1400 nm)	La	Exempt group
IR radiation, eye (780 nm - 3000 nm)	Er	Exempt group
Skin Thermal (380 nm - 3000 nm)	Er	Exempt group

Filter Glasses: Amber color, 99.9% UVA and UVB blockage; alternate specification: Optical Density (OD) > 5 for 190 -410 nm wavelengths; > 50% visible light transmission (vlt).

2.0 Introduction

The Fluoresce HD Dual LED coupler has white and 405nm wavelength light sources built in. The integral coupler switch can be activated to change from white light to 405nm light. The Fluoresce HD Dual LED coupler Dual LED is used to help visualize dental decay, healthy tooth, and dental filling materials.

As shown in the illustration figure 1, the tooth is illuminated with a blue-violet light (405 nm). Carious tooth material and healthy dentin is excited to fluorescence. The operator views the oral cavity through filter

glasses. Shorter wavelengths are filtered out, in particular the violet excitation light. Light with higher wavelengths remains visible through the filter, so that the red-fluorescent sections of a caries can be visualized. The 405nm light causes healthy enamel & dentin to fluoresce with a green color. The contrasting colors of the viewable prepared surfaces can be used to help visualize dental decay, healthy tooth, and dental filling materials.

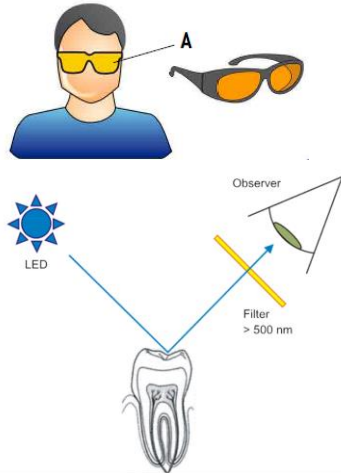


Figure 1.

3.0 Indications for use

The Lares Fluoresce HD Dual LED system is intended to be used by qualified physicians in dentistry to help visualize dental decay, healthy tooth, and dental filling materials.

- Fluoresce HD Dual LED Coupler is a dental device intended to provide a 360-degree swivel connection for air powered dental handpieces that are KaVo MULTIFlex® compatible.

4.0 Cautions

4.1 Regulations require that the Lares Fluoresce HD Dual LED coupler only be used by a competent person for the described application and following:

- Valid regulations on work safety.
- Valid accident prevention measures.
- These operating instructions.

4.2 The user must:

- Only use Fluoresce HD Dual LED Coupler to help visualize dental decay, healthy tooth, and dental filling materials.
- Do not use Fluoresce HD Dual LED Coupler 405 nm light if you have red-green color vision deficiency or similar visual impairment.
- Use only devices in good working order (no damage).
- Do not use parts from other sources and/or not make any type of modification. Both may result in damage or injury.
- Use Fluoresce HD Dual LED coupler only with handpieces having clean undamaged

optics (solid optic handpieces recommended).

- Protect patients and third parties from all dangers.
 - Do not look directly at the lamp (light) when energized.
 - Do not use Fluoresce HD Dual LED Coupler in conjunction with caries detection dyes.
- 4.4 When the Lares Fluoresce HD Dual LED Coupler will not be used for an extended period of time it should be removed from the hose, cleaned, maintained and stored in a dry place.
- 4.5 Any waste which is generated must be recycled or disposed of in a manner which is safe, both for people and for the environment. This must be done in strict compliance with all applicable national regulations. Questions on proper disposal of the Lares product can be answered by Technical Services.
- 4.6 In case of any malfunction or problem stop product use immediately. Contact Lares Research Technical Service or your account representative.

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5.0 Putting Into Operation (Installation)

5.1 Connection to hose

- ⚠ **Warning:** When connecting Lares Fluoresce HD Dual LED coupler make sure the power source is compliant with IEC 60601-1.
- ⚠ **Caution:** A supply of dry, clean, compressed and uncontaminated air must be provided.

5.1.1 Screw the Lares Fluoresce HD Dual LED coupler to the dental unit hose and tighten firmly with the enclosed wrench.

5.1.2 Lightly spray the exposed o-rings with Lares One-Step Handpiece Conditioner. Remove excess with a towel. The coupler remains connected to the hose during normal use & maintenance.

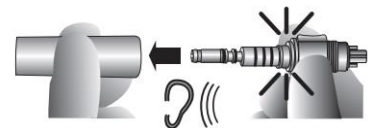
5.1.3 To remove from the hose use the wrench.

5.2 Changing the swivel handpiece

All Lares MX Swivel handpieces and Kavo MULTIFlex® connection handpieces may be connected to the Fluoresce HD Dual LED coupler.

5.2.1 Insert the Fluoresce HD Dual LED coupler into the backend of the handpiece and push until it clicks audibly into place.

5.2.2 Pull to remove.



5.3 Verify LED Operation

- ⚠ **Caution:** Do not look directly at the Lamp (light) when energized.

- Activate lamp by pressing foot switch rheostat.
- Activate coupler rocker switch to activate alternate wavelength LED light source.

⚠ Caution:

Avoid external bright sources of light to maximize the distinction (contrast) between red and green fluorescence. Turn the operatory or head lamp lights away from the oral cavity or switch them off while using Fluoresce HD Dual LED Coupler in 405nm mode.

6.0 Troubleshooting

6.1 No Light? - Replace the Dual LED Lamp

⚠ Caution: Allow to cool for five (5) minutes after use before changing lamp. Sleeve and lamp may be hot!

Unscrew the lamp guard by turning it counterclockwise. Pull the lamp out of the coupler and discard. Remove any fluid or debris from the sleeve and coupler socket with gauze or cotton swab and isopropyl alcohol. Carefully insert the new Dual LED Lamp into the sleeve. Align and insert the Dual LED lamp pins into the sockets in the coupler.

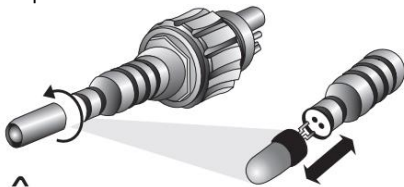


Figure 2.

Caution: Be sure that the two contact pins align with the two sockets in the coupler.

⚠ Caution: Do not look directly at the Lamp (Light) when energized.

6.2 Leaks? - Replace the o-rings

If the coupler leaks, replace the o-rings. Press the defective o-ring(s) to one side between two fingers until a loop is formed and then slide the rings to the front and remove them. Insert new o-ring(s) in the recesses and apply Lares One-Step conditioner.

⚠ Caution: Do not use Vaseline or any other type of grease on O-rings. It may result in handpiece or coupler damage.

6.3 Intermittent Light Operation?

If the lamp flashes or switch loses function in one position, clean the coupler in an ultrasonic cleaner in a mild cleaning solution for 5 minutes twice, once in each switch position, to remove any debris from the switch contacts. Spray the coupler with handpiece conditioner to lubricate the o-rings and preclude corrosion. Wipe the

excess handpiece conditioner off with a lint free wipe.

7.0 Care Instructions

Cleaning Exterior

The Lares Fluoresce HD Dual LED coupler can be cleaned on the outside with an isopropyl alcohol solution.

7.1 Maintenance at the site of use (chair side)

⚠ WARNING

Hazard from non-sterile products.

There is a risk of infection from contaminated couplers and accessories.

► Take suitable personal protective measures (i.e. exam gloves, eye protection, 5 µm particulate filter mask).

- Remove all residual cement, composite or blood without delay.
- Clean and maintain the coupler as soon as possible after treatment.
- Remove the coupler from the dental unit hose.
- The coupler must be dry when transported for cleaning and sterilizing.

7.2 Cleaning

7.2.1 Cleaning: Manual cleaning - external

Accessories required:

- Warm tap water 40 °C ± 5 °C (104 °F ± 10 °F)
- Brush, e.g. medium-hard toothbrush or comparable nylon-bristled dental instrument cleaning brush.

Manual cleaning process:

Coupler disassembly not required.

- Rinse product under warm flowing tap water to remove gross soil.
- Brush off while rinsing under flowing warm tap water for 30 to 45 seconds to remove all soil. Brush in a direction parallel to the o-ring grooves and completely around the coupler.
- Use filtered pressurized air to completely dry coupler. If soil is still visible when dry, repeat the cleaning steps.
- Apply Lares One-Step Handpiece Conditioner to the exterior of the coupler. Spray the conditioner for two seconds over a towel or sink.
- Remove excess conditioner from the exterior of coupler with a towel.

7.3 Disinfection

⚠ CAUTION

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine.

Coupler damage may result.

- Never disinfect in a thermo-disinfector.

7.3.1 Disinfection: Manual disinfection - external

The Lares Fluoresce HD Dual LED coupler can be disinfected on the outside with chemical disinfectants (spray disinfectant or wipe clean disinfectants). The coupler should not be immersed in any disinfecting solutions.

7.4 Drying

7.4.1 Manual Drying

- Blow off the outside and inside with compressed air until water drops are no longer visible.

7.5 Care products and systems - Servicing

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.

Reduced product life.

- Perform proper care regularly.

Note

Lares Research only guarantees that its products will function properly when the care products used are those listed as accessories, as they were tested for proper use on our products.

7.5.2 Visual inspection:

Fluoresce HD Dual LED Couplers: Visually inspect for damage and wear.

Service or Discard damaged couplers.

7.6 Packaging prior to autoclaving

Note

The autoclave bag must be large enough for the coupler so that the bag is not stretched. The quality and use of the autoclave bag must satisfy applicable standards, be cleared to market and be suitable for the autoclave procedure.

- Seal each coupler individually in an autoclave bag.

7.7 Autoclaving

Process couplers in a steam sterilizer (autoclave).

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.

Reduced product life.

► Before each autoclave cycle, service the coupler with Lares One-Step Handpiece Conditioner.

CAUTION

Contact corrosion due to moisture.

Leaving coupler in autoclave after cycle has finished may damage the coupler.

► Immediately remove the product from the steam sterilizer after the sterilization cycle to reduce condensation!

CAUTION

Do not use Flash Sterilization Techniques.

These techniques are not validated for efficacy and damage to the coupler may result.

The Lares Research Fluoresce HD Dual LED Coupler has a maximum temperature resistance up to 135 °C (275 °F).

Autoclave with gravitation process for at least 15 minutes at 132 °C ± 1 °C (270 °F ± 1.8 °F)

Drying time: 30 minutes minimum.

When autoclaving multiple couplers in one autoclave cycle ensure that the autoclave's maximum load is not exceeded. Follow the autoclave manufacturer's Instructions for Use.

7.8 Handling and storage after autoclaving

- Keep couplers in the autoclave bag until next use.
- Cleaned and autoclaved couplers should be stored protected from dust with minimum exposure to germs in a dry, dark and cool space.

Note

The reprocessing instructions provided have been validated by Lares Research as being CAPABLE of preparing a Fluoresce HD Dual LED Coupler for re-use. It remains the responsibility of the practitioner to ensure that the processing was actually performed using equipment, materials and personnel in the practitioner's facility to achieve the desired result. Use only FDA cleared equipment and materials for autoclaving and routine monitoring of the autoclaving process.

WARNING

Hazard from cross infection.

There is a risk of cross infection from patient to patient or patient to dental staff contaminated couplers.

► Do not deviate from the specified coupler reprocessing steps (i.e. cleaning, autoclaving and storage).

8.0 Accessories

Replacement Parts

Description	Part ID
Wrench	10363
Gasket	10905
Dual LED Lamp	11553
O-ring Kit	10074
Bulb Sleeve	11459
Handpiece Conditioner	10083

9.0 Limited Warranty:

Each Lares Fluoresce HD Dual LED Coupler (and LED lamp assembly) is warranted against defects in materials and workmanship for a period of 1 year from the date of purchase.

Any use that is not described in this manual as correct usage is considered incorrect usage. Lares Research is not to be held liable for any damage caused as a result of incorrect use. The dental practitioner bears all risks.

9.1 Additional Conditions of Warranty:

1. Warranty registration is automatic as of shipping date (Outside the US warranty registration may be required).
2. The Fluoresce HD Dual LED coupler must be operated and maintained in accordance with procedures outlined in these instructions.
3. The Fluoresce HD Dual LED coupler must not be subjected to abuse or neglect.
4. The Fluoresce HD Dual LED coupler must not be repaired or disassembled by anyone other than Lares Research or your authorized Lares distributor. Lares Research will repair or replace, at its discretion, without charge any defective parts covered by this warranty provided the swivel coupler is returned to the factory, transportation prepaid. (Outside the US return to your authorized Lares distributor.) Lares Research makes no other warranties expressed or implied.

10.0 Patents:

This product is covered by one or more of the following patents:

US United States: 6,769,911 / 9,028,251 **AU**

Australia: 2010/300079

NZ New Zealand: 599177.

