

Lares MAX Power LED MX Coupler Operator Manual

REF 10567, 10568

CE
1639

Manufacturer:

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EC REP

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

Technical Data

Not Sterile

Lares MAX Power LED MX Coupler

ISO-Type 3 (6 pin) connection

Weight 20-30 grams

Adjustable spray control ring (optional)

Safe maximum drive air and water

pressure is 40 psi (275 KPa).

LED Lamp operating voltage: 3.2-4.2 vdc

Power of the LED Lamp: max. 2.5 Watts

Cautions

Lares MAX Power LED MX Coupler

- Only intended for dental treatment in the area of dental medicine.
- Intended to connect to Air Driven dental handpiece instruments.
- An accessory to an active medical device according to the applicable regulatory requirements.

Regulations require that the Lares MAX Power LED MX 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.

The user must:

- Use only devices in good working order (no damage).
- Ensure that it is used for the correct purpose.
- Protect patients and third parties from all dangers.
- Not use parts from other sources and/or not make any type of modification. Both may result in damage or injury.

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

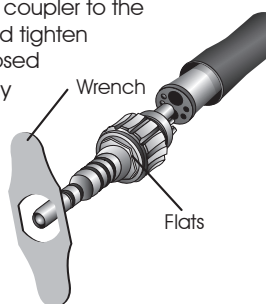
Putting Into Operation (Installation)

Connection to hose

Warning: When connecting Lares MX coupler make sure the power source is a Lares Apollo power supply or other device labeled "medical grade" and compliant with IEC 60601-1.

Caution: A supply of dry, clean, compressed and uncontaminated air must be provided.

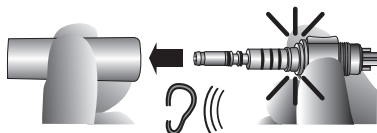
Screw the Lares MX coupler to the dental unit hose and tighten firmly with the enclosed wrench. Lightly spray the exposed o-rings with **Lares One-Step Handpiece Conditioner**. The coupler remains connected to the hose during normal use & maintenance. To remove from the hose use the wrench.



Caution: Do not hold on to the spray adjustment ring when securing the coupler to the hose since this may result in malfunction.

Changing the swivel handpiece

All Lares MX swivel handpieces and Kavo MULTiflex® connection handpieces may be connected to the MAX Power LED MX coupler. Insert the MAX Power LED MX coupler into the backend of the handpiece and push until it clicks audibly into place. Pull to remove.



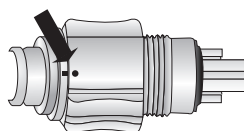
Verify LED Operation

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

- Activate lamp
- If LED lamp does not light, remove sleeve, pull lamp out & rotate 180°. reinstall sleeve.

Adjusting the spray (optional feature)

By turning the spray ring on the Lares MAX Power MX coupler in clockwise direction, the water content of the spray can be reduced by means of different adjustments. Maximum water flow is achieved when the marks on the ring and coupler are aligned.



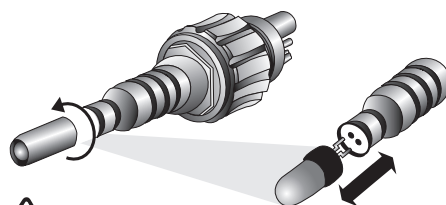
Caution: To increase the water content of the spray turn the ring in the counter-clockwise direction.

Troubleshooting

No Light? - Replace the LED Lamp

Caution: Allow to cool for five (5) minutes after use before changing lamp. Sleeve and lamp may be hot! Unscrew the sleeve by turning it counter-clockwise. 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. Carefully insert the new LED Lamp.

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).

- Activate light source.
- If LED lamp does not light, remove sleeve, pull lamp out & rotate 180°.
- Reinstall Sleeve.

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.

7.0 Care Instructions

7.1 Cleaning Exterior

The Lares MAX Power LED Coupler can be cleaned on the outside with an isopropyl alcohol solution.

Caution: Do not place the Lares MAX Power LED Coupler in an ultrasonic cleaner since this may result in malfunction.



WARNING

Hazard from non-sterile products.

There is a risk of infection from contaminated handpieces 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.
- ▶ Do not submerge or place it in any solution.

7.2 Cleaning

CAUTION

Malfunctions from cleaning in the ultrasonic unit.

Ultrasonic cleaning may cause severe damage to the product.

- ▶ Only clean manually.

7.2.1 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 oil.
- ▶ 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 all the cleaning steps.
- ▶ Apply Lares One-Step Handpiece Conditioner to the exterior of the coupler. Spray the conditioner over the coupler into a towel or sink.
- ▶ Remove excess conditioner from the exterior of coupler with a towel.

7.2.2 Automated External Cleaning

Not applicable.

7.2.3 Manual Cleaning of the Inside

Not applicable.

7.2.4 Automated Internal Cleaning

Not applicable.

7.3 Disinfection

CAUTION

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine.

Handpiece damage may result.

- ▶ Never disinfect in a thermo-disinfector.

7.3.1 Manual Disinfection - External

The Lares MAX Power 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.

7.3.2 Manual Disinfection - Internal

Not applicable.

7.3.3 Machine Disinfection - External & Internal

Not applicable.

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7.4 Drying

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

7.4.1 Automatic Drying

Not applicable

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.

7.5.1 Care Products & Systems - Servicing:
Care with Lares One-Step Handpiece Conditioner

Lares Research recommends applying handpiece conditioner after each time it is used, i.e. after each cleaning and before each sterilization.

7.5.2 Inspection & Function Testing

MAX Power LED MX Couplers: Visually inspect for damage and wear. Service or discard damaged couplers.

7.5.3 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!

7.5.4 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 MAX Power 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: 15 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.

7.5.5 Handling & 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 MAX Power 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. This requires validation and routine monitoring of the process as specified by the autoclave manufacturer. Use only FDA cleared to market 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 to dental staff from contaminated couplers.

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

Accessories
Replacement Parts

Description	Part ID
Wrench	10363
Gasket	10905
Replacement LED Lamp	11377
O-ring Kit	10074
Bulb Sleeve	10111

Cautions for Use
and Safety

When the Lares MAX Power LED MX 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. 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. In case of any malfunction or problem stop use immediately. Contact you Lares Research technical service or account representative.

Safety note: If a serious event should occur during the use of this device it should be reported to Lares Research. It should also be reported to the regulatory authorities of the marketing region where the user/patient is established.

Toll Free 1-888-333-8440

Limited Warranty:

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

Additional Conditions of
Warranty:

1. Warranty registration is automatic as of shipping date (Outside the US warranty registration may be required).
2. The swivel coupler must be operated and maintained in accordance with procedures outlined in these instructions.
3. The swivel coupler must not be subjected to abuse or neglect.
4. The swivel 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.

Symbol Description

REF

Catalog Number

SN

Serial Number

EU

REP

EU Representative

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Consult Accompanying Documents

UDI

Unique Device Identifier

⚠

Caution

🏭

Manufacturer

YYYY-MM

Manufacture Date

134°C

Steam autoclave

CE

Conformity Marking

1639