



RizyCure[®]

Curing Light Device

CORDED

INSTRUCTIONS FOR USE

Please read these instructions carefully before application.

RizyCure[®]

Curing Light Device - Corded

GENERAL DESCRIPTION

Corded RizyCure developed by OrthoHeal, is light device which emits high intensity blue light, especially designed to cure FlexiOH – light cured polymer immobilizer.

KEY FEATURES



INTENDED USE / INDICATION

RizyCure - is used to cure FlexiOH with high intensity uniform blue light, which gives deep and smooth curing.

CONTRAINDICATIONS

None known.

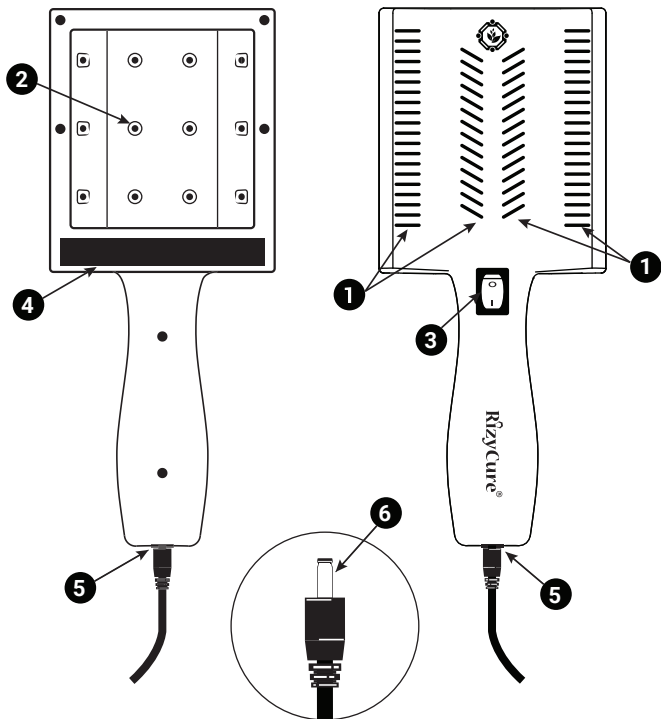
PATIENT POPULATION

Patients undergoing fracture immobilization treatment using FlexiOH - Light Cured Polymer Immobilizer.

INTENDED USERS

A healthcare professional (HCP) such as an orthopedic surgeon, emergency room doctor, physician assistant, orthopedic technician, or nurse practitioner.

CONFIGURATION AND DIAGRAMS



- | | |
|------------------|------------------------------|
| 1. Air Vent | 2. LED |
| 3. ON/OFF Switch | 4. Product Label Information |
| 5. Power Port | 6. Power Pin |

TECHNICAL SPECIFICATIONS

Weight of light	250 gms
Medical Equipment class	Class I
Output Power	~ 48 Watt
Light intensity	~ 27 - 30 mW/cm ² 185,000 - 200,000 Lux
Power Input	110V-240VAC, 50Hz / 60Hz
Power Output	DC 12V-5Amp (max)
Protection from shock	Type B 
IP Rating	IP20
Operating and Storage temperature	Temperature- 0 to 104°F (0° to 40°C) Relative humidity - 10% to 85% (non-condensing) Atmospheric pressure - 0.5atm to 1.0atm (500-hPa to 1060-hPa)

APPLICATION PROCESS

STEP 1 : Select the appropriate plug and attach with the adapter.

STEP 2 : Connect the adapter DC pin with the RizyCure light device.

STEP 3 : Plug-in and switch on the RizyCure light device.

STEP 4 : Expose the uncured region of FlexiOH keeping RizyCure at ~10 cm distance from the surface of FlexiOH.

STEP 5 : Hold and wait for the buzzer sound, move RizyCure position after every beep.

STEP 6 : Switch off the RizyCure after each use.

WARNINGS AND PRECAUTIONS

- If you determine that the RizyCure becomes hot or you observe change in color or shape, stop using the device immediately, as it needs to be replaced. Contact 'OrthoHeal Customer Care' at 'care@orthoheal.com' for further guidance.
- Do not open/ modify the RizyCure curing light device or adapter.
- Keep away from children / Do not allow children to play with RizyCure.
- Use goggles provided with the product while using RizyCure to avoid eye fatigue.
- Do not use RizyCure light device, if light is blinking while using.
- Do not use RizyCure light device with wet hand.
- Voltage fluctuation may impact the light intensity or lead to device failure.
- RizyCure light device is for Professional use only.
- Maximum safe run time for RizyCure light device is about 10 minutes.
- RizyCure device cool down itself in 10 minutes at $25 \pm 2^{\circ}\text{C}$.
(It is recommended to cool down the device after every use.)
- Do not keep RizyCure on any surface which can catch fire when device is switched-on for longer duration.

SAFETY GUIDELINE

- Before switching "ON" light, put on yellow colour goggles which are provided with the RizyCure curing light device (These goggles provide eye comfort during curing process).
- Do not see the light directly without wearing goggles as it may create slight discomfort and blurring of vision for a few minutes. It is recommended to use the provided goggles or Z87 +EN166 standard (yellow colour) goggles.

WARRANTY

- The Rizycure corded light device is covered under manufacturer's warranty for 1 year from the date of issue.
- The warranty covers manufacturing defects only.
- All components of the light device are covered under the one year warranty.
- Power adapter is covered under a three months warranty from the date of issue.
- Damage from operator misuse or any attempt to disassemble the light voids the warranty.
- In case of malfunction of Rizycure corded light device, do not disassemble the hand piece or attempt to repair as this will void the warranty.
- Use only provided adapter with RizyCure curing light device - corded.

ADVERSE EFFECTS:

None known.

STORAGE CONDITIONS

0 to 104°F (0° to 40°C) 10% to 85% relative humidity (non-condensing) 0.5 atm to 1.0 atm (500-hPa to 1060-hPa) atmospheric pressure.

EM COMPATIBILITY

RizyCure curing light device - corded is electromagnetic compatible.

REPORTING OF ADVERSE EVENTS

In case of any event please notify to 'care@orthoheal.com' or to the respective country regulatory authority.

CLEANING GUIDELINE

Clean the RizyCure curing light device as per manufacturer instruction for Cleaning "W/QAC/05"

DISPOSAL

To dispose of RizyCure curing light devices, refer to local regulation guidelines.

SYMBOL GLOSSARY



Medical Device



Do not use if package is damaged and consult instructions for use



Consult instructions for use.



Manufacturer



Date of Manufacture



Use-by Date



Catalogue Number / Reference code



Batch code / Lot Number



Serial Number



Unique device identifier



Authorised representative in the European Union



CAUTION: Hot area

Copy of the design or technology may infringe IP rights.



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