Directions For Use

Symbols	Symbol Meaning
	Manufacturer
LOT	Batch number
\triangle	Caution: See instructions for use
R _X ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
C UL US	Product has been tested by UL to nationally recognized safety and sustainability standards
7	Keep Dry
	Protected Earth



Glass Bead Mirror Warmer

A Convenient Method of Chairside Mirror Warming

Meeting the needs of the ENT clinician for improved laryngeal examinations. Offering these advantages!

- · Modern, space-saving design
- Hinged lid for convenient use
- Rapid warm-up for greater efficiency
- Outside surface remains cool and safe to the touch
- Thermostatically controlled to maintain required temperature







Intended Use: A sterile laryngeal mirror inserted into heated bead well is warmed through heat conduction to prevent condensation fogging to aid in examination

Device Description: Premier* Glass Bead Mirror Warmer consists of a stainless steel well, which is encircled by a 75-watt heating element. The heating element is activated through a preset thermostat that maintains the desired temperature range of 200° - 250°F. A built-in thermal cutoff switch interrupts the heater current in the unlikely event of thermostat failure.

Contraindications:

Glass Bead Mirror Warmer should not be used under following conditions -

- · Patient's sensitivity to heat.
- · A contaminated laryngeal mirror inserted into stainless steel bead well.
- · Glass beads soiled or contaminated.

PRECAUTIONS:

- Only sterile mirrors should be inserted into bead well. Do not insert soiled or contaminated mirrors.
- · Discard soiled or contaminated glass beads.
- · Inspect device for electrical malfunctions prior to each use.
- Inspect device for any breaks, cracks and/or fractures to the housing, electrical cord or inside well prior to each use.
- During operation, avoid direct contact with hinged-lid surface by using knob on the lid.
- Do not allow sterile mirror to rest in the heated bead well longer than recommended time of 3-5 seconds.
- · Prescription device, Rx only.

WARNINGS:

- At the end of day, always disconnect the plug from the electrical outlet and allow unit to cool down.
- Do not attempt to disassemble the unit. Doing so will void our warranty and could damage the unit or cause personal injury.
- Extra care should be taken while handling aggressive and/or caustic solutions around electrical equipment.

Adverse Events:

• During examination, overheated mirror may lead to thermal burns.

Contents and Setup:

Item No.	Product/Device
1006131	Glass Bead Mirror Warmer (110V)
1006132	Glass Bead Mirror Warmer (220V)
1006105	Replacement Glass Beads

Materials:

Components	Materials used
Unit outer walls	ASTM A582 – 303 Stainless steel
Hinged lid or Top plate	ASTM A582 – 303 Stainless steel
Bead well	ASTM A582 – 303 Stainless steel
Unit platform	0.046 Aluminum Sheet Zinc Plated

Directions for Use:

- Fill the stainless steel well with the clean Glass Beads provided.
- Plug the device into an electrical outlet. Recommended to use three-wire grounded receptacle to avoid electrical hazard.
- Turn ON-OFF switch located on device front panel to ON position.
- Glowing light of ON-OFF switch indicates that device is energized.
- Cover the bead well with hinged lid to ensure minimum heat loss during warm-up.
- A heating element warms the stainless steel well filled with glass beads. Thermostat helps to regulate the intended temperature required.
- After the device is energized, recommended to allow 18-20 minutes for the stainless steel bead well to reach intended temperature.
- A sterile laryngeal mirror should be immersed into heated bead well for 3-5 seconds in order to warm the intended mirror surface.
- After brief cool-down period of 5 seconds, the mirror is ready for patient examination. Any concern of fogging and occluded visualization will be eliminated.

Cleaning:

- Ensure the unit is unplugged from electrical outlet and bead well is empty, prior to cleaning. DO NOT REUSE BEADS.
- Empty bead well can be wiped down with isopropyl alcohol, when required.
- · Use clean dry cloth to wipe the outside walls of device.

Sterilization/Reprocessing: Premier® Glass Bead Mirror Warmer not intended to be sterilized and does not require sterilization.

Storage:

- Device storage and handling temperature should not exceed (37.7° C) 100° F.
- Extra care should be taken while handling and avoid the device from coming in contact with aggressive and/or caustic solutions.

Shelf Life: Premier® Glass Bead Mirror Warmer have indefinite shelf life. Device long-term durability based on usage.

Disposal: Dispose contaminated glass beads as biohazardous medical waste in accordance to facility or institutional guidelines/procedures.

Warranty: Premier* Glass Bead Mirror Warmer warranted for three (3) years from date of purchase against defects in workmanship or components. Warranty is void if the unit is subjected to improper use or damage and unauthorized repairs.

To register your Glass Bead Mirror Warmer online, go to: premiermedicalco.com/medwarranty or contact Premier Customer Experience for assistance at 1-888-670-6100

For Further Information: Please visit premier medical co.com