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**LUMORA - MOULDABLE CUSTOMIZED BOLUS**

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**INSTRUCTIONS FOR USE**

# LUMORA - MOULDABLE CUSTOMIZED BOLUS

## 1. DEVICE DESCRIPTION

LUMORA™ is a translucent, soft, and flexible radiotherapy bolus designed to be heat-activated and molded at the point of care to conform to external patient anatomy.

LUMORA™ is supplied as a flat sheet in predefined sizes and thicknesses intended to support standardized clinical workflows.

## 2. INTENDED USE

LUMORA™ is intended for use as a patient-specific radiotherapy bolus and positioning aid to during external beam radiation therapy.

Rx Only

Caution: United States Federal law restricts this device to use by or on the order of a physician.

## 3. INTENDED USE AND USERS

LUMORA™ The device referred to in this instructions for use is used for bolus and or patient positioning in imaging and Radiation therapy.

LUMORA™ is intended for use by trained healthcare professionals, including but not limited to:

- Radiation Therapists
- Medical Physicists
- Radiation Oncologists

## 4. INDICATIONS FOR USE

LUMORA™ is indicated for use during external beam radiotherapy procedures where a conformable bolus is required to adapt to patient anatomy.

## 5. CONTRAINDICATIONS

- Do not use LUMORA™ on broken or compromised skin unless clinically justified.
- Do not use LUMORA™ on patients other than the originally assigned patient.

## 6. WARNINGS

- LUMORA™ is intended for single-patient use only. Do not reuse on multiple patients.
- LUMORA™ is supplied non-sterile.
- LUMORA™ must be heat-activated prior to molding.
  - Heated LUMORA™ may cause burns if applied to the patient without appropriate temperature assessment
  - Do not exceed recommended heating temperatures or heating times
  - Smaller or trimmed pieces may heat faster and require reduced heating time
  - Heating conditions may vary depending on the equipment used
- Do not use the device if it is damaged or visibly degraded

LUMORA™ exhibits surface tackiness when heated, which may aid positioning. In applications where adhesion to skin, thermoplastic masks, or other surfaces is undesirable, mitigation steps must be employed.

## 7. PRECAUTIONS

- Use appropriate personal protective equipment when handling heated materials.
- Always assess device temperature prior to patient contact.
- Do not place any objects on the LUMORA™ sheet or molded bolus at any time. Permanent deformation may occur.
- Ensure proper conformity of the bolus to patient anatomy prior to treatment.
- Ensure the bolus remains securely in place during use and does not slip or detach from the treatment site.
- Follow all packaging, handling, and storage instructions.
- LUMORA™ does not replace clinical judgment or established treatment protocols.

## 8. STORAGE AND HANDLING

- Store LUMORA™ at room temperature when not in use.
- Store in a clean & dry environment
- Avoid Exposure to direct sunlight or heat sources
- Do not stack objects on top of the sheet or molded bolus.
- Store the molded bolus in a manner that preserves its shape.

### 8.1 SHELF LIFE

The device has a shelf life of two (2) years from the Date of Manufacture indicated on the product label. The device must not be used more than two (2) years after the Date of Manufacture. This shelf life applies only when the device is stored in accordance with the specified storage conditions in sections: 10.

## 9. INSTRUCTIONS FOR USE

### 9.1 FIRST TIME USE

1. Determine the appropriate LUMORA™ thickness based on the treatment area and the radiation therapy plan.
2. Open the packaging only when the product is ready to be used.
3. Inspect the product for shape, integrity, and cleanliness. Do not use the product if damage or contamination is observed. Mark and trim the bolus to the required shape, if needed.
4. Heat the product according to the Heating Guide until the edges begin to turn transparent.
5. To prevent adhesion of the heated bolus to the skin, hair, or to a thermoplastic mask, cover the application area with a medical disposable sheet or equivalent.
6. After heating, place the bolus on the application area and gently mold it for approximately 1–2 minutes, mould in a manner that maintains uniform thickness.
7. Ensure the bolus is in full contact with the surface without air gaps.
8. Allow the bolus to cool, set, and dry completely for 10–15 minutes, or until it solidifies and returns to its original appearance.
9. After use, carefully remove the bolus from the patient and store it in the designated storage area.
10. If the product becomes contaminated or unusable during or after use, discard it and prepare a new bolus by following the steps above.

### 9.2 HEATING PARAMETERS

METHOD	TEMP	THICKNESS	TIME
DRY HEAT (OVEN)	75 ± 2 °C (167 ± 4 °F)	3 mm	3–5 minutes
DRY HEAT (OVEN)	75 ± 2 °C (167 ± 4 °F)	5 mm	5–10 minutes
WATER BATH	75 ± 2 °C (167 ± 4 °F)	3 mm	3–5 minutes
WATER BATH	75 ± 2 °C (167 ± 4 °F)	5 mm	3–6 minutes

\* Excessive heating temperature or duration may result in material degradation, increased surface adhesion, or patient injury. Users are responsible for verifying both temperature and heating time prior to application.

\*Heating performance may vary based on equipment type, load size, water circulation, and trimmed material dimensions. Smaller or modified pieces may reach activation temperature more rapidly and require reduced heating time.

### **9.3 REUSE (SAME PATIENT ONLY)**

- Inspect the bolus for signs of damage, deformation, or contamination prior to use.
- Do Not reuse the bolus if there is any surface damage, deformation, or if hygiene cannot be ensured.
- Fit the previously shaped bolus on the treatment area and secure if needed.
- Reuse beyond the intended course of treatment or outside the recommended service life is not advised.

### **10. POST-USE HANDLING AND STORAGE**

- LUMORA™ may be reused for the same patient throughout the full course of treatment.
- Avoid exposure to direct sunlight, heat sources or hard sharp objects.
- Store in a cool, dry place at **15–25 °C (59–77 °F)** when not in use.

### **11. CLEANING AND DISINFECTION**

This device is supplied non-sterile.

#### **PREPARATION**

- Wash hands and wear appropriate personal protective equipment (PPE).

#### **SURFACE CLEANING**

- Wipe the device surface with a soft cloth dampened with a mild detergent solution (e.g., Dawn® dish soap diluted 1:10 with water).

#### **DISINFECTION**

- After surface cleaning, apply an intermediate-level disinfectant suitable for non-critical medical devices.
- Approved agents include:
  - Low-alcohol disinfectant towelettes
  - CaviCide® wipes or equivalent
  - Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes or equivalent

#### **CAUTION**

Aggressive or repeated use of hydrogen peroxide-based disinfectants may cause discoloration of the device. Mild discoloration does not indicate a loss of functional performance.

- Allow the disinfectant to air-dry completely or follow the manufacturer's recommended contact time

#### **RINSING (SAME PATIENT ONLY)**

- If hydrogen peroxide-based disinfectants are used, rinse thoroughly with clean water to remove residual chemicals.








## 12. PHYSICAL AND RADIOLOGICAL PROPERTIES

Property	Value
Mass Density	0.971 g/cm <sup>3</sup>
Hounsfield Unit *(HU)	0 +/- 50
Effective Atomic Number (Z <sup>off</sup> )	6.05
Available Thicknesses	3mm, 5mm

## 13. DISPOSAL

- Dispose of LUMORA™ in accordance with local, state, and institutional medical waste regulations once treatment is complete or if the device becomes damaged or unusable.

## 14. SYMBOLS

Indication	Symbol
Non-Sterile	
Single Patient Use	
Consultant Instructions for Use	
Rx Only	
Manufacturer	
Date of Manufacture	
Authorized Representative in European Community	

## RECOMMENDED PRODUCTS

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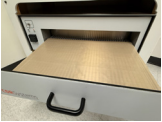
**WB-LRG-3**  
Digital Water Bath



**DHCO-01**  
Dry Heat Convection



**SC-01**  
Muscle Shears. Bent design, stainless steel blades.



**DHCO-TL**  
Dry Heat Oven -  
Teflon Liner

*\*CDR systems offers a full compliment of related patient positioning devices, positioning aids, and consumables. Contact your sales rep for more information.*



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**Corporate Headquarters:**

4334 110 Ave SE | Calgary AB, Canada  
T2C0J6+1.855.856.7035 | local: +403.850.7035

[www.cdrpositioning.com](http://www.cdrpositioning.com) | [info@cdrsys.ca](mailto:info@cdrsys.ca)

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Advena Ltd |  
TOWER BUSINESS CENTRE, 2ND FL  
TOWER STREET, SWATAR, BKR 4013  
CV34 6WE, UK  
Ph: +44 (0) 1926 800153

