

CLEARLIGHT BOLUS INSTRUCTIONS FOR USE



25833 Feather Ridge Lane
Sorrento, FL 32776

Product Information:

| Item Number | Description |
|-------------|---|
| B-03-18-01 | Clearsight Bolus, 0.3cm water eq. thickness, Clear, 30cm x 30cm |
| B-05-18-01 | Clearsight Bolus, 0.5cm water eq. thickness, Clear, 30cm x 30cm |
| B-11-18-01 | Clearsight Bolus, 1.0cm water eq. thickness, Clear, 30cm x 30cm |
| B-03-20-01 | Clearsight Bolus, 0.3cm water eq. thickness, Clear, 40cm x 40cm |
| B-05-20-01 | Clearsight Bolus, 0.5cm water eq. thickness, Clear, 40cm x 40cm |
| B-11-20-01 | Clearsight Bolus, 1.0cm water eq. thickness, Clear, 40cm x 40cm |

Intended Purpose:

The intended purpose of Clearsight Bolus is to (i) level uneven areas of the patient, (ii) to make up for missing tissue, or (iii) to provide build-up of dose to the skin surface for patients undergoing external beam radiation treatment. This product is available by prescription only, and the intended users are licensed radiation oncologists, radiation therapists, medical physicists, and dosimetrists.

Instructions for Use:

1. Select desired thickness/size of Clearsight bolus as prescribed by the physician. Label the outer clamshell shipping case with the patient name and identification number.
2. Remove Clearsight Bolus from clamshell container and separate from inner, protective mylar layer. Cut Clearsight Bolus to the appropriate size as prescribed by the physician.
3. Place Clearsight Bolus on the patient as prescribed by the physician.
4. Ensure there are no air gaps between Clearsight Bolus and the surface of the patient's skin.
5. Administer external beam radiation.
6. Remove Clearsight Bolus from the patient, replace mylar sheets and place protected bolus in clamshell case. Store flat in a cool, dry place.

Features/Clinical Benefits/Performance Characteristics:

- Conforms to surface
- High transparency for visualization through bolus of light field, crosshairs, and adherence to surface
- Uniform density throughout
- Flexible to conform to anatomical contour
- Strong enough to avoid breaking during routine clinical use
- End user is able to modify the geometry of the material using scissors
- Nominal water equivalent thickness of each bolus can be used with negligible change to electron and photon depth dose
- Not made with PVC, latex, or phthalate plasticizers
- Hypo-allergenic

Shelf Life:

4 years from date of manufacture

Attenuation:

Due to the density being slightly less than water (mass density 0.85g/cm³), the bolus is manufactured in sheets that are slightly thicker than the intended water equivalent thickness. The “water equivalent” thickness is the product of physical thickness and bolus / water density ratio. “Water equivalent” thickness should be utilized when electron density is not accounted for in the dose calculation.

Storage, Care and Cleaning:

Store flat (not folded) in original packaging in a cool, dry environment. Ensure inner mylar sheets are removed from bolus before each use. Paper and other oil absorbing materials may become stained with prolonged contact & alter bolus transparency. If needed, gently wash with soap and water. Rinse thoroughly with water to remove residue and air dry fully. Do not attempt to clean if there are visible cracks or tears on the surface.

Disposal:




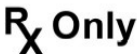



No special disposal considerations exist for ClearSight Bolus.







Warnings & Contraindications:

Restricted to professional users. Product is non-sterile and single patient use. The following characteristics and technical factors could pose a risk if the device were to be re-used: Possible patient cross-contamination; bolus cut with scissors to meet the anatomical and/or treatment contour of one patient would pose a risk of not meeting the anatomical and/or treatment contour should it be reused on another patient.

Any serious incident that has occurred in relation to ClearSight Bolus should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Definitions from Label:

| Symbol | Definition |
|---|----------------------|
|  | Date of manufacture |
|  | Batch code |
|  | Catalog number |
|  | Prescription only |
|  | Place of manufacture |
|  | Use-by date |
|  | Do not re-use |

| Symbol | Definition |
|---|------------------------------|
|  | Non-sterile |
|  | Consult instructions for use |
|  | Single patient multiple use |
|  | Medical device |
|  | EC Rep |
|  | Unique device identifier |