

Care and Use Guide Bolx-I Radiation Bolus

Products are designed as bolus materials for use in radiation therapy, diagnostic x-ray, and ultrasound imaging procedures. Product quality is closely controlled for uniformity of thickness, and its chemical composition inherently maintains a physical density of approximately 1.02 g/cc. Additional technical information may be found at www.actionproducts.com/Moyer.

CAUTION – To avoid serious injury:

- Product is to be used by a trained radiological professional
- Do not place in direct contact with broken skin, or open wounds
- Consult your individual facility's guidelines and standards of practice related to the use of bolus materials
- Follow established radiological practice parameters established by professional organizations such as ACR.org or ARRT.org
- Visit www.actionproducts.com/Moyer for additional technical information

Prior to Initial Use:

- Remove pad from its packaging
- Inspect for any visual damage and discard if observed
- Clean and disinfect product prior to first use
- Read this Care and Use Guide
- Save Guide for future reference

General Product Information

- Product has physical density of approximately 1.02 g/cc \pm 0.01 g/cc
- Do not tear, puncture, gouge, or compromise homogeneity of product
- Bolx-I features a polyurethane film, or "skin"
- Product is polyurethane that is hypoallergenic and is not made with natural rubber latex
- Do not expose product to UV rays, direct or indirect sunlight as it may compromise product performance (hardening, discoloring, decreased flexibility)
- Pads may be safely exposed to temperature range of 0°F to 115°F or -17°C to 46°C

BOLX-I Specific Guidelines

General Use

- Clean, disinfect and inspect product before each use. Discard product if film or polymer is damaged: torn, punctured, gouged, cracked or is excessively wrinkled, or has deep creases

Storage

- Store in clean, dry environment protected from UV exposure
- Product best stored flat. Avoid stacking, bending, piling to avoid wrinkling of film cover during storage

Cleaning and Disinfecting

- Thoroughly clean, disinfect, rinse, and dry product before each use
- Use warm, soapy water or a 1:10 solution of bleach and water to clean and disinfect the product. If blood has been in contact with the product, use the 1:10 solution of bleach and water to clean and disinfect the product. Always rinse with clear water to remove any cleaning residuals. (*Bleach is a 5-10% solution of Sodium Hypochlorite*)
- Avoid alcohol-based cleaners and other strong, undiluted disinfectants as they may damage flexible film cover
- Do not soak product in any type of cleaning or disinfecting agent
- Do not autoclave or gas sterilize product, as it will compromise product integrity
- Do not machine wash or machine dry product
- Failure to properly clean product may result in:
 - Risk of infection
 - Chemical changes to the material that could alter functionality and performance
 - Chemical residues that could cause irritation or sensitization

Warranty

- Product is warranted to be free of defective materials and workmanship at the time of initial purchase only
- Direct specific warranty questions to your authorized distributor
- Call 800-228-7763 or email service@actionproducts.com if you require assistance identifying your authorized distributor

Disposal

- Follow your facility's protocol for disposal of biohazardous waste to dispose of product after use

Adverse Event/ Complaint Reporting

- In case of an adverse reaction or injury suspected to have been caused by an Action® product, immediately notify the Manufacturer. If an adverse event or injury occurs within the European Union, immediately notify the Manufacturer and the competent authority of the Member State in which you are established.
 - Within the European Union contact the Authorized Representative (Regulatory affairs only):
 - Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
 - Tel: (31) (0) 70 345-8570 Email: EmergoEurope@ul.com
 - Within the UK contact the UK Responsible Person (Regulatory affairs only):
 - Emergo Consulting (UK) Limited, c/o Cr360 – UL International, Compass House, Vision Park Histon, Cambridge CB24 9BZ, United Kingdom Tel: +44 (0) 1223 772 671 Email: UKRPvigilance@ul.com
 - Within Switzerland contact the Swiss Authorized Representative (Regulatory affairs only):
 - MedEnvoy Switzerland, Gotthardstrasse 28, 6302 Zug, Switzerland Email: EmergoVigilance@ul.com

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