CARE AND USE GUIDE

Action[®] O.R. Support Surfaces and Patient Positioners

CAUTION- To avoid serious injury:

- Product is to be used by a trained medical professional.
- Do not place in direct contact with broken skin, or open wounds.
- Follow medically recognized patient positioning practices and standards such as those published by the Association of Operating Room Nurses (AORN).
- Follow guidelines and standards of practice established by your institution.
- Consult your individual institution's guidelines for assessing the risk of each individual patient as it pertains to patient positioning and pressure injury prevention.

Prior to initial use:

- Remove the pad from its packaging.
- Inspect for any visual damage and contact Manufacturer or authorized distributor if observed.
- Clean and disinfect product prior to first use following this Care and Use Guide.
- Read this Care and Use Guide.
- Save Care and Use Guide for future reference.

General Product Information

- Prevent contact with any sharp objects, items, or edges likely to cut, tear, puncture, pinch or otherwise compromise the product.
- Do not expose product to UV rays, direct or indirect sunlight as it may compromise product performance.
- Products may be safely exposed to temperature range of 0°F to 115°F or -17°C to 46°C.
- Products are hypoallergenic and are not made with natural rubber latex or phthalates.
- Patient may be placed directly on the Akton[®] polymer surface to enhance shear reduction and pressure distribution. A loosely fitting 100% unstarched cotton sheet or approved cover may be placed between the patient and the product if indicated. Ensure that sheet or cover is free of wrinkles and folds when placed beneath the patient.
- For products sold with loose hook and loop fasteners to provide secure product-to-hardware placement, the hook (hard) part is to be applied to the stationary equipment or the existing equipment padding. The loop (soft) part is to be applied to the Action[®] product. Allow the hook and loop adhesive to rest for at least two (2) hours after initial placement before first use. After installation, place the product at its desired position by matching hook and loop fasteners and pressing with moderate force to ensure connection.

General Use

- Inspect, clean, and disinfect product before each use.
- Discard any product featuring foam or fabric that is or becomes damaged.
- Any polymer product with tears, gouges, large cracks, bubbles, or excessively deep creases should be removed from service, discarded, and replaced. Review "Resurfacing" section below for guidance on when and how to resurface.
- Inspect hardware and hook/ loop attachments prior to each use to ensure they are properly assembled and secure.

Storage

- Products should be stored in a clean, dry environment protected from UV exposure.
- Table pads and patient positioners are best stored flat. Overlays not containing foam may be rolled for space efficiency and ease of transport.
- Store away from sharp objects, edges or other items that may damage the product.
- Products may be safely exposed to temperature range of 0°F to 115°F or -17°C to 46°C.

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 defined here as an 8.25% solution of Sodium Hypochlorite*)
- Avoid cleaners containing alcohol, hydrogen peroxide or any strong, undiluted disinfectants as they may damage flexible film cover.
- Do not soak product in any type of cleaning or disinfecting agent.

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- 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 skin irritation or sensitization.

Transport and Handling

- Handle Action[®] pads carefully to maintain product integrity and maximize product longevity.
- Fully support products using two hands or a cradling method during placement and transport.
- Bulky and heavier items are best transported using a cart.
- Avoid lifting or carrying product by corners or edges to prevent damage of flexible film surface.
- Large, non-foam overlays may be rolled for easier transport; carry cradled in arms or on cart.

Heating and Cooling

- Consult your institution's protocol for recommended heating/ cooling ranges identified for safe patient use. Use extreme caution when heating products to temperatures above normal body temperature of 98.6°F (37°C).
- Action[®] pads and positioners may be safely exposed to a 0°F to 115°F or -17°C to 46°C temperature range while maintaining its pliability.
- Action[®] table pads with polymer and foam may be warmed with a hypo/ hyperthermia unit placed atop the fabric or polymer surface.
- Action[®] products not containing foam may be heated in a blanket warming cabinet, in hot water or used in conjunction with a hypo/hyperthermia unit placed beneath the product or may be cooled in a refrigerator, a cold ice water bath or with the use of ice packs.

Special Consideration

X-Ray

Action[®] pads are radiolucent. To prevent an increase in radiation to the patient, place Action[®] pad between the X-ray source and patient. Check the radiation effect on the x-ray equipment to ensure proper dosage levels prior to use.

Electrosurgery

• Consult your institution's guidelines and ensure a risk assessment is carried out by relevant competent personnel before using Action[®] pads and positioners with electrosurgery devices.

Resurfacing

- Consult your individual facility's protocol for resurface or repair of any product.
- Products with foam and fabric are not recommended for resurfacing. If damaged, we recommend they be removed from service, discarded, and replaced immediately.
- Polymer products may be resurfaced if they have minor cuts or light abrasions only. Multiple attempts to resurface a single product are not recommended. Presence of tears, gouges, large cracks, bubbles, or excessively deep creases indicates a product should be removed from service, discarded, and replaced.
- Inspect any resurfaced product before each use to ensure the film resurfacing tape remains secure and clean. There should be no loose edges or presence of debris.

Resurfacing Guidance:

- Clean and disinfect product according to this Guide prior to resurfacing the product.
- If necessary, cut film tape to proper size, allowing a 0.25 0.5" (0.6 1.3cm) border of film to ensure damaged area is fully encased beneath the film.
- Carefully peel back one-half of release paper and crease it. Carefully adhere exposed portion of film tape to damaged surface, pushing out any air bubbles that may become trapped beneath the film tape.
- Continue to apply tape while slowly removing the release paper until film tape is firmly secured to the product surface.
- Clean and disinfect product before placing it back into service.

Warranty

• Support surfaces and patient positioners are warranted to be free of defective materials and workmanship at the time of purchase and are serviceable for a period of two years excepting misuse, negligence, abuse, or failure to follow the Care and Use instructions provided herein.

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- Accessories are warranted to be free of defective materials and workmanship at the time of initial purchase only.
 - Direct specific warranty questions to Customer Service (see below) or to your authorized distributor.
 - Call: 800.228.7763 or +1 301.797.1414 or Email: <u>service@actionproducts.com</u>

Disposal

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

Terms and Policies

- All returns require prior authorization through assignment of an RMA number by Customer Service.
- Returns are subject to a 20% restocking fee.
- Action Products reserves the right to determine if a product has suffered misuse, negligence, or abuse.
- Customer accepts full cost of return shipping charges.

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: <u>UKRPvigilance@ul.com</u>
 - Within Switzerland contact the Swiss Authorized Representative (Regulatory affairs only):
 - MedEnvoy Switzerland, Gotthardstrasse 28, 6302 Zug, Switzerland Email: EmergoVigilance@ul.com
 - OR Table Replacement Pads, Disposable Covers, and Stool Covers not included



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