CARE AND USE GUIDE

Action® DME (Durable Medical Equipment) Pads

Risk Assessment:

The risk of an individual developing pressure related injury due to immobility can be minimized by the correct use of ACTION Pads in combination with good nursing practices, like regular repositioning of an immobilized person. A person's predisposition to pressure injury is based on many factors including general health, vascular health, existing diabetic condition, age, weight, medication, etc. Consult your physician, physical or occupational therapist, medical advisor or caregiver for personal risk assessment and information about pressure injury prevention.

CAUTION: To avoid serious injury:

- For best results, consult a trained medical professional or caregiver prior to first product use.
- Do not place product in direct contact with broken skin or open wounds.
- Follow medically recognized practices and standards related to pressure injury prevention such as those published by the NPIAP (National Pressure Injury Advisory Panel) or RESNA (Rehabilitation Engineering and Assistive Technology Society of North America).
- Follow guidelines and standards of practice established by your institution, if applicable.
- Use extreme caution if pad is allowed to reach temperatures above normal body temperature of 98.6°F or 37°C as burns could occur if
 product becomes too hot. Polymer pad will assume the ambient temperature of its environment.
- Products are not intended to be used in a wet environment without a cover due to risk of slips or falls.

Prior to Initial Use:

- Remove pad from its packaging.
- Inspect for any visible damage and contact Manufacturer or authorized Importer, Distributor or Dealer 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 polymer pads to UV rays, direct or indirect sunlight as it may compromise product performance.
- Pads may be safely exposed to temperature range of 0°F to 115°F or -17°C to 46°C.
- Use extreme caution if pad is allowed to reach temperatures above normal body temperature of 98.6°F or 37°C as burns could occur if product becomes too hot. Polymer pad will assume the ambient temperature of its environment.
- Products sold with a cover are intended to be used with the cover. If product is sold without a cover, user may be placed directly on the
 Akton® polymer surface. A loosely fitting unstarched cotton sheet may be placed between the user and the product if indicated or
 desired. Ensure that sheet is free of wrinkles and folds when placed beneath the user.
- Failure to properly clean Action® DME Pads (wheelchair cushions, mattress overlays, covers, etc.) 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.

General Use

- Inspect, clean, and disinfect product before each use.
- Discard any product with foam that has become damaged (e.g., exposed foam).
- Any polymer product or surface with tears, gouges, large cracks, bubbles, or excessively deep creases should be removed from use, discarded, and replaced. Review "Resurfacing" section within this Care and Use Guide for guidance on when and how to resurface.
- Inspect hook and loop attachments, straps, buckles, and hardware prior to each use to ensure they are properly assembled and secured.

Storage

- Pads should be stored in a clean, dry environment protected from UV exposure.
- Pads should be stored in a flat, unfolded position. Large mattress overlays can be rolled for efficient storage.
- Store away from sharp objects, edges or other items that may damage product.
- Products may be safely stored in temperature range of 0°F to 115°F or -17°C to 46°C.

Transport and Handling:

- Handle Action® pads carefully to maintain product integrity and maximize product longevity.
- Avoid lifting or carrying product by corners or edges to prevent damage.
- Large mattress overlays may be rolled for easier transport. Carry cradled in arms.

Cleaning: Wheelchair pads, mattress overlays, commode pads, heel/ elbow protectors, lap tray pads and adaptive pads:

- Thoroughly clean, disinfect, rinse, and dry pad before each use.
- Use warm, soapy water or a 1:10 solution of bleach and water to clean and disinfect pad. If blood has been in contact with pad, only use the 1:10 solution of bleach and water to clean and disinfect the pad. 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 disinfectant as they may damage the pad surface.

- 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 pads.

Cleaning: Wheelchair Covers

- If pad is encased in a clear film bag do not remove or damage the bag because it can expose the interior foam to contaminants that may result in user harm or product deterioration.
- Follow cleaning instructions printed on the cushion cover label. Always rinse with clear water to remove any cleaning residuals. For best results ensure covers are thoroughly dried before replacing on the cushion.
- Incontinent covers should be air-dried or towel-dried inside and out before replacing on cushion
- Use care when removing and replacing cover on pad. Keep corners of film covering and edges of pad away from cover zipper.
- Always ensure cover is properly fit to the cushion before placing it back in use.
 - For Xact® series wheelchair covers, align cover zipper with flat, bottom edge of cushion for proper fit.
 - o For Xact® LP2 covers with clear windows, match cover windows to the green "Correct" labels on the cushion for proper fit.

Resurfacing:

- If product is being used in a healthcare facility, consult your facility's protocol for resurface or repair of any product.
- Twister® Wheelchair Backs and products with foam are not recommended for resurfacing. If damaged, we recommend the pad be removed from use, discarded, and replaced immediately.
- Polymer products may be resurfaced if they have minor cuts or light abrasions only. Product should not be resurfaced more than once.
 Presence of tears, gouges, large cracks, bubbles, or excessively deep creases indicates a product should be removed from use, 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.
- o If necessary, cut the 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 the product before placing it back in use.

Twister® Back

Action recommends this product be installed by a trained individual. Product is designed to function as a 2-piece set. Pieces should not be used individually. The hook and loop strap system designed to position the patient, is the component that attaches to the wheelchair cane posts. The padded fabric overlay that is placed over the hook and loop strap system is designed to comfortably protect and support the user at the product interface.

Inspect product at regular intervals to ensure:

- Hook and loop strap system is properly attached to wheelchair cane posts.
- Hook and loop strap system is properly attached to the padded fabric overlay component.
- User is properly and comfortably positioned by installed product.

Installation and Adjustment:

- Remove existing wheelchair back upholstery in manner best suited for the wheelchair style.
- Install hook and loop strap system on existing wheelchair cane posts.
- Reinstall screws into eyelets of the cane posts to securely affix the strap system to the wheelchair.
- Increase or decrease tension of the hook and loop straps to the user's comfort level and positioning requirements to achieve optimal fit and performance.
- Place padded overlay component of product over hook and loop strap system and secure vertical hook and loop strips on both front and back of the overlay component to mated hook and loop strips of installed strap system.
- Face the padded, ribbed fabric portion of the overlay towards the user/ front of the wheelchair to create an overlay to user interface.
- Secure mated hook and loop strips at bottom of overlay and tuck bottom flap of overlay component beneath wheelchair cushion. Mated hook strips are enclosed to place on wheelchair seat to additionally secure overlay component directly to the wheelchair.
- Ensure hook and loop strap system is secured to overlay component. Regularly inspect straps to ensure they are properly secured.

Cleaning: Twister® Back

- Fabric covering of padded overlay component and strap system base may be lightly cleaned with a microfiber cloth dampened with a
 solution of warm, soapy water. Always rinse with clear water to remove any cleaning residuals. Allow to air dry.
- Do not machine wash, machine dry, or dry-clean this product.

WARRANTY INFORMATION

Action® DME Pads are warranted to be free of defective materials and workmanship when first purchased for use and are serviceable for the period of time noted below provided the product is not subject to misuse, negligence, accident, or abuse.

- Action® Wheelchair and Mattress Overlays: five (5) years
- Shear Smart® Pads and Lap Tray Pads: two (2) years
- Action® Xact® Wheelchair Cushions and Twister® Wheelchair Backs: two (2) years
- Action® Adaptive Cube Pads, Adaptive Flat Pads, Commode Pads, Heel and Elbow Pads and Covers: At time of initial purchase only

Direct specific warranty questions to Customer Service (see below) or to your authorized Importer, Distributor or Dealer.

Call: 800.228.7763 or +1 301.797.1414
 Email: service@actionproducts.com

Disposal:

- Follow your local guidelines for disposal of product in a domestic setting.
- Follow your facility's protocol for disposal of biohazardous waste to dispose of product after use.
- Action® DME Pads should not be recycled.

Terms and Policies

- All returns require prior authorization through assignment of an RMA number by Customer Service (contact info above).
- 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 Action® DME Pads, 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.
 - o Within the European Union contact the Authorized Representative (Regulatory affairs only):
 - Emergo Europe, B.V., Prinsessegracht 20, 2514 AP The Hague, The Netherlands
 - Tel: (31) (0) 70 345-8570 Email: EmergoVigilance@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>



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