

INSTRUCTIONS FOR USE

# RIK Fluid Overlay





## **WARNING**

**To avoid injury, always read this Instructions For Use and accompanied documents before using the product.**



**Mandatory to read the Instructions For Use.**

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## The RIK Fluid Overlay

The RIK™ Fluid Overlay has been designed to provide pressure redistribution, low shear, comfort and stability. To ensure proper use of the RIK Fluid Overlay, please read these instructions and save them for future reference.

Features include:

- Attaches easily to most hospital mattresses
- Eliminates noise, heat and power consumption
- Self-adjusting during patient repositioning

## Indication

- The RIK Fluid Overlay is indicated for patients at high risk of pressure ulcers.

## Contraindications

- Unstable cervical, thoracic and / or lumbar fracture
- Cervical traction

## Risks and Precautions

- **Transfer** - Precaution should be taken during patient transfer.
- **Side Rails and Restraints - WARNING:** Use or non-use of restraints, including side rails, can be critical to patient safety. Serious or fatal injury can result from the use (potential entrapment) or non-use (potential patient falls) of side rails or other restraints. See related **Safety Information**.
- **Patient Migration** - Specialty surfaces have different shear and support characteristics than conventional surfaces and may increase the risk of patient movement, sinking and / or migration into hazardous positions of entrapment and / or inadvertent bed exit. Monitor patients frequently to guard against patient entrapment.
- **Skeletal Traction or Unstable Fracture (if not contraindicated)** - With skeletal traction, unstable pelvic fracture or any other unstable fracture (to the extent not contraindicated), maintain physician-directed angle of articulation and guard against risks of patient migration.

## Safety Information

### Serious Incident

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

### Side Rails / Patient Restraints

Whether and how to use side rails or restraints is a decision that should be based on each patient's needs and should be made by the patient and the patient's family, physician and caregivers, with facility protocols in mind. Caregivers should assess risks and benefits of side rail / restraint use (including entrapment and patient falls from bed) in conjunction with individual patient needs, and should discuss use or non-use with patient and / or family. Consider not only the clinical and other needs of the patient but also the risks of fatal or serious injury from falling out of bed and from patient entrapment in or around the side rails, restraints or other accessories. In the US, for a description of entrapment hazards, vulnerable patient profile and guidance to further reduce entrapment risks, refer to FDA's

Hospital Bed System Dimensional and Assessment Guidance To Reduce Entrapment. Outside the US, consult the local Competent Authority or Government Agency for Medical Device Safety for specific local guidance. Consult a caregiver and carefully consider the use of bolsters, positioning aids or floor pads, especially with confused, restless or agitated patients. It is recommended that side rails (if used) be locked in the full upright position when the patient is unattended. Make sure a capable patient knows how to get out of bed safely (and, if necessary, how to release the side rails) in case of fire or other emergency. Monitor patients frequently to guard against patient entrapment.

**When selecting a standard mattress, ensure the distance between top of side rails (if used) and top of mattress (without compression) is at least 8.66 in (220 mm) to help prevent inadvertent bed exit or falls. Consider individual patient size, position (relative to the top of the side rail) and patient condition in assessing fall risk.**

### **Bed Frame**

Always use a standard health care bed frame with safeguards or protocols that may be appropriate. It is recommended that bed and side rails (if used) comply with the Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment, March 2006 (see [www.fda.gov/CDRH/Beds/Guidance/1537.pdf](http://www.fda.gov/CDRH/Beds/Guidance/1537.pdf)). Frame and side rails must be properly sized relative to the mattress to help minimize any gaps that might entrap a patient's head or body.

### **Bed Height**

To minimize risk of falls or injury, the bed should always be in the lowest practical position when the patient is unattended.

### **Brakes**

Caster brakes should always be locked once the bed is in position. Verify wheels are locked before any patient transfer to or from the bed.

### **Head of Bed Elevation**

Keep head of bed as low as possible to help prevent patient migration.

### **Patient Entrance / Exit**

Caregiver should always aid patient in exiting the bed. Make sure a capable patient knows how to get out of bed safely (and, if necessary, how to release the side rails) in case of fire or other emergency.

### **Skin Care**

Monitor skin conditions regularly and consider adjunct or alternative therapies for high acuity patients. Give extra attention to any possible pressure points and locations where moisture or incontinence may occur or collect. Early intervention may be essential to preventing skin breakdown.

### **No Smoking in Bed**

Smoking in bed can be dangerous. To avoid the risk of fire, smoking in bed should never be allowed.

## Patient Weight

The maximum recommended patient weight for this system is 350 lb (159 kg). Consult individual bed frame manufacturer for total safe working load.

## General Protocols

Follow all applicable safety rules and institution protocols concerning patient and caregiver safety.

## End of Life Disposal

- Fabric material used on the mattresses or any other textiles, polymers or plastic materials etc. should be sorted as combustible waste.
- Mattresses at the end of life should be disposed of as waste according to the national or local requirements which may be landfill or combustion.

## Assembly of the *RIK Fluid Overlay* (if needed)

The *RIK Fluid Overlay* is made of five main components:

- Three fluid pads consisting of two blue bottom end pads and one black bottom center pad
  - One bottom panel
  - One top cover
1. Lay out the bottom panel over the bed mattress with the end labeled HEAD at the appropriate end.
  2. Attach the elastic corner straps around each corner of the bed mattress to secure the bottom panel (**Figure 1**). These straps are adjustable to accommodate different mattress sizes.

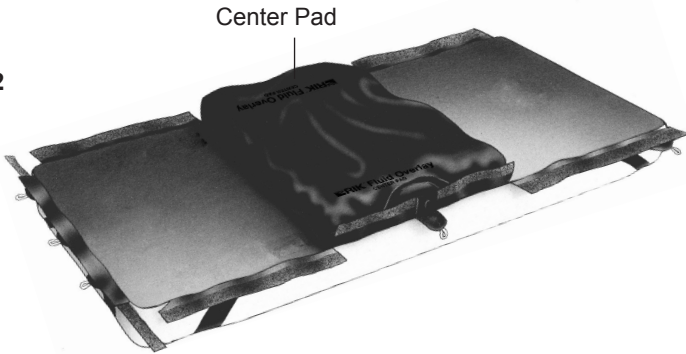
**Figure 1**



### Assembly of the RIK Fluid Overlay (continued)

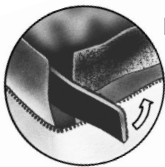
3. Place the black bottom center pad on the center of the bottom panel. Align the nylon hook and loop material sides of the center pad with the black side wings of the bottom panel and fold the wings upward on each side so that the nylon hook and loop material connects (**Figure 2**).

Figure 2



4. Repeat the previous procedure with each blue bottom end pad so that all three pads are attached to the bottom panel (**Figure 3**). Ensure that the blue bottom end pads sit snugly against the black bottom center pad. Fold the wing at the HEAD end of the bottom panel upward, and tightly fasten the nylon hook and loop straps on each side to the adjacent side wings (**Figure 3** magnified view).

Figure 3



Magnified view of corner



## Assembly of the *RIK Fluid Overlay* (continued)

5. Zip top cover onto bottom panel ensuring HEAD and FOOT ends are properly aligned (**Figure 4**). Note the seven magnet flaps must detach from the wings so that the top cover zips between each flap and wing.

**Figure 4**



### Top Cover

The top cover is made of a nylon fabric with a moisture vapor permeable backing and is designed to fit loosely on the overlay.

### Sheet Magnets

Specially designed magnets allow for a flat linen sheet to be placed loosely on the overlay while still being held securely. Sheets should remain loose to avoid the increased pressure that occurs with tight fitting sheets. Wrinkles in the sheets are not of concern, as the fluid design of the overlay helps prevent increased pressure on the skin at the area of the wrinkle.

### Overlay Positioning

The overlay is designed to fit on most standard hospital mattresses.

### Patient Ingress and Egress

The *RIK Fluid Overlay* has a firm foam edge of support along each side. It provides support during patient ingress and egress.

### *RIK Fluid Overlay* Covers

Use only the *RIK Fluid Overlay* covers, as the use of improper covers may adversely affect the performance of the *RIK Fluid Overlay*. A standard flat sheet, incontinence pad or turn-and-draw sheet may be used as long as they are kept loose and not tucked under the overlay edge. Do not use any additional padding on the overlay surface.



## Cleaning

Arjo recommends the use of approved hospital disinfectants provided the manufacturer's instructions are followed.

**NOTE:** Always wear personal protective equipment as outlined by facility protocol. The RIK Fluid Overlay can be cleaned using a two-step procedure.

Using a soft cloth wipe the entire surface of the overlay with warm soapy water or approved hospital disinfectant diluted according to manufacturer's instructions. Do not use abrasive cleaning agents or phenolics.

1. Wipe off excess solution.
2. Rinse the cover thoroughly using plain water.
3. Allow to air dry.
4. Examine the cover for any tears that may have allowed contaminants to penetrate the cover.

**If the top cover is heavily soiled** or if penetration of the top cover is suspected, use the following process for cleaning.

1. Unzip the top cover and remove.

**NOTE:** The top cover can be laundered using low temperatures up to <70°F (21°C) with chemicals suitable for low temperature washings and prepared in recommended dilutions. Allow to air dry. Ensure cover is completely dry before storage.

2. After top cover is removed, wipe down all visible surfaces with approved hospital disinfectant mixed according to manufacturer's instructions.
3. Wipe off excess solution.
4. Wipe entire surface a second time with the hospital grade disinfectant mixed to manufacturer's recommendations.
5. Rinse the surface thoroughly using plain water.
6. Allow to air dry.
7. Examine the three individual section covers for any tears that may have allowed-contamination to penetrate this layer.
8. If any of these section covers are breached, remove the cover and disinfect the surface below it using the two-step process noted above.
9. Allow to air dry.
10. Replace any torn covers with new ones.

## Repairs

It is recommended that any maintenance or repairs beyond those described in this guide be performed by Arjo authorized personnel.

## Product Specifications\*\*

### The *RIK Fluid Overlay*

Dimensions	78 in L x 33 in W x 5.5 in H (198 cm x 83 cm x 13.9 cm)
Weight	99 lb (45 kg)
Top Cover Material	Nylon fabric with a moisture vapor permeable backing

### Supplemental Mattress

Dimensions	78 in L x 33 in. W x 2.5 in H (198 cm x 83 cm x 6.4 cm)
Weight	10 lb (4.5 kg)

### Part Numbers

Complete Assembly	VL22000
Supplemental Mattress	MS22000

### Replacement Parts

Top Cover	TC22000
End Pad	ES22000
Center Pad	CS22000
Bottom Panel	BC22000

\*\*Specifications subject to change without notice.

## Definition of Symbols Used



Manufacturer



Chlorine bleach



Reorder number



Do not iron



CE marking indicating conformity with European Community harmonised legislation.



Do not dry clean



Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745.



Do not launder



Consult instructions for use



Head End



Wash using cold water



Foot End



Drip dry

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Address page - REV 24: 04/2019

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