Reusable rapid deployment limb restraint
(QTY 1 per package) Latex FREE

IMPORTANT INFORMATION, PLEASE READ BEFORE USE

Rx Only

CAUTION:
Federal law restricts this device to sale by or on the order of a Physician or Licensed Prescriber / Provider.

WARNING:

SERIOUS INJURY OR DEATH MAY RESULT IF THIS DEVICE IS NOT PROPERLY APPLIED OR IF THERE IS NOT SUFFICIENT MONITORING BEFORE AND AFTER APPLICATION. KEEP OUT OF REACH OF CHILDREN. NOT FOR HOME USE.

ADVERSE REACTIONS: Severe emotional, psychological, and physical problems may occur when a patient's movement is severely limited. If the device is uncomfortable or severely limits the patient's movement, the patient may become injured, restless, or agitated. Consider all treatment options before application.

The following complications have been reported on restraints when the correct restraint or size was not chosen, properly applied or there was insufficient patient monitoring: **death, strangulation, infection, chafing, burns, bedsores, impaired circulation, falls, fractures, and psychological disorders**.

VIPER Emergency Medical Restraints should only be used when necessary and only by trained personnel. This device should only be used under strict medical supervision and or approval of Medical Direction or department administration. Prior to use, all options should be considered including de-escalation.

Post application peripheral circulation monitoring:

Regularly assess the restrained limb (s) for proper circulation and any changes such as:

- Color changes (pallor or cyanosis).
- Temperature changes (coldness).
- Swelling or excessive redness.
- Loss of sensation or tingling.

Adjustments During Struggling: If the patient is actively struggling, tension on the restraint system could inadvertently increase.

Train staff to anticipate and mitigate this by adjusting the tension and readjusting the soft cuff restraint portion as needed, but never attempt during periods of combative behavior. Do not compromising safety of the patient or provider to restore any signs of diminished circulation in restrained extremity until safe to do so. As VIPER is a rapidly deployable soft restraint, it is recommended for temporary immediate limb control during periods of agitation requiring restraint application.

VIPER Emergency Medical Restraints LLC.
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VIPERemr.com

Registration: 10088172

Prolonged compression can lead to nerve damage, compartment syndrome, or limb ischemia if not addressed promptly.

Implement protocols for quick removal or repositioning of the restraint in the event there are signs of circulatory compromise.

If overtightening should occur as evident by the afore mentioned assessment of impaired circulation, loosen tension on the restraint webbing. Depress the CAM thumb latch to release tension on restraint known as "Burping" the restraint. This will release all tension and alleviate the overtightening without having to remove the restraint.

Ensure providers assess circulation of restrained limb (s) as part of their regular reassessment and after any strain has been applied by the patient against the restraint which may have caused tightening of the cuff.

INTENDED USE: VIPER Emergency Medical Restraints are intended to be used to prevent a patient or subject during a medical / psychological emergency from moving their limbs beyond the desired limits following local and state guidelines. The device is **NOT** intended nor has been evaluated for long term patient use.

This device is not a substitute for good clinical practice.

INDICATIONS:

- This device is intended for use in gaining immediate and temporary limb control of combative, agitated, or assaultive behavior that could otherwise cause the patient to further harm themselves or others if care is not rendered.
- For the safety of the patient and provider when rendering immediate lifesaving care and therapy, to aid in extrication or transport and not intended to replace good clinical judgment.
- Patients have been assessed to be at risk of pulling, preventing, or removing lifesaving therapies such as but not limited to; intravenous therapy, breathing tubes or removal of safety belts.

CONTRAINDICATIONS:

Contraindications include but not limited to the following conditions:

- Known or suspected injury to limb to be restrained due to fracture, dislocation or pain.
- Absence of behavior consistent with assaultive, perceive. assaultive behavior or escalating agitation that places the patient, caregiver, or greater public at risk.
- Any condition where application may cause harm to patient or provider.
- Application to a limb where the restraint could dislodge a medical device and lifesaving equipment.

NOT FOR HOME USE. PATIENTS SHOULD BE MONITORED FREQUENTLY PER DEPARTMENT, FACILITY OR OGANIZATION POLICY

TRAINING:

Staff must have ongoing training in accordance with department policy and following VIPER Emergency Medical Restraints LLC guidelines and instructions for use.
Staff who use the VIPER Emergency Medical Restraints should thoroughly read the attached instructions to become familiar with the device application, removal, and limitations, contraindications, and possible hazards. Further references can be found on the web at VIPERemr.com.
BEFORE APPLYING ANY RESTRAINT:
• A complete medical assessment exam should be performed prior to restraint application, including all vital signs.
• All other least restrictive options must be attempted prior to restraint application unless credible fear that delaying application may cause or pose greater risk than applying device.

Restraint choice should be based on the least restrictive manner possible and be in accordance with state and local guidelines.

Patients should be constantly reassessed. All vital signs assessed for wellbeing, injury, device integrity, proper location and deployment and appropriateness of restraint use. If there is any concern of patient harm, device damage, integrity, or applicability of the restraint, stop use at once.

DO NOT:
Alter or repair this product. VIPER Emergency Medical Restraints products should ALWAYS be inspected before use. Any product defects should prompt discontinuation of use and filing of proper department forms.
Secured to a movable part of a chair or stretcher unless believed to be in the best interest of the patient and caregiver for **temporary** control of aggressive or violent behavior and or prevent worsening injuries. Once the crisis has been mitigated, place restraint clip on non-movable frame as per instructions.
DO NOT USE if product is damaged or concerns for functionality from earlier applications apply. Not following these guidelines can result in significant injury or death.
NEVER place restraint devices around neck or impede the patient's ability to breathe.

- Never secure to any other device such as car seat, furniture, toilet, etc.
- Never exposed to open flame, fire, smoking materials, or high heat sources, or corrosive materials.
- Never use if frayed or broken.
- Alter device from original form.

LAUNDERING INSTRUCTIONS:

• VIPER Emergency Medical Restraints can be machine washed (Delicate) in cold or warm water and dried on a low setting in an approved laundry wash bag so as not to damage components, fabric, and plastic clips.
• Use of Chlorine bleach is not advised, as it may weaken fabric and stitching and shorten the life of the product.
• Use medical bio wipes per product instructions.
• Hand wash with warm soap and water and allow airdrying. Avoid excessive heat as this may cause shrinkage.
• To reduce the risk of damage during wash and dry cycles, ensure all buckles are fastened.

DO NOT: place VIPER Emergency Medical Restraints through extractors, dryer or autoclave. For maximum life, launder in a laundry bag or hand wash if soiled.

STORAGE AND HANDLING:

This device may be stored in ambient warehouse temperatures at normal humidity levels. Avoid excess moisture or high humidity that may damage product materials. Products that are too small or large may compromise patient comfort and could result in severe injury or death.

MATERAL COMPOSITION AND FABRICS USED:
(LATEX FREE) (BPA FREE) (PFAS FREE)
Polypropylene webbing $C_{22}H_{42}O_3$ / Molecular Weight 354.6 Neoprene:

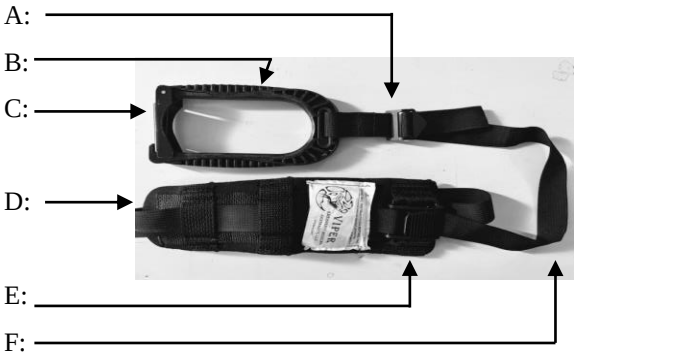
Gate clip, buckle, and springs: 17/7 stainless steel.

Webbing. Mil-Spec Nylon webbing

Plastic components. Injection molded, Plastic, glass, resin.

Warranty: Information can be found @ VIPERemr.com.

Disposal: If soiled or damaged beyond usage dispose of it in a proper manner as determined by department policy and procedures.



Device reference Key

A: Belt tensioner
B: Universal stretcher clip / horseshoe
C: Gate clip
D: Soft restraint cuff
E: CAM
F: Webbing