DeRoyal®

SECURITY CUFF WITH TRI-CLIP BUCKLE

	SINGLE PATIENT USE
NON STERILE	NON-STERILE
LATEX	NOT MADE WITH NATURAL RUBBER LATEX
RX ONLY	FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO SALE OR USE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

IMPORTANT INFORMATION

Please read all instructions, warnings and cautions before use. Correct application is essential for proper functioning of the device. Use only on the patient it was prescribed for by a licensed prescriber and only for the use it was intended.

INTENDED USE

The Security Cuffs with Tri-Clip Buckle are to be prescribed by a licensed prescriber and are intended to protect the patient from harming themselves, other patients, family members and/or staff.

CONTRAINDICATIONS

Never use on a patient if an I.V. or wound site could be compromised by the device.

⚠ WARNINGS

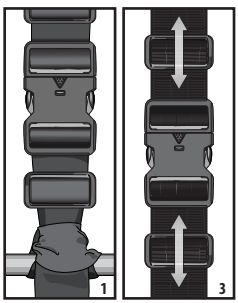
- Improper application or use of any restraint device may result in serious injury or death. Determination of whether device remains appropriate for use must be made by a qualified healthcare provider based on the patient's level of agitation and overall clinical condition. Reassess use if patient's agitation or behavior results in excessive force on the device or potential risk of injury.
- Inspect device for damage, missing components, or contamination before use. Ensure that all hook and loop and buckle closures function properly. Discard and replace if device is damaged, contaminated, missing components, or not functioning properly. Never alter or repair device.
- Always follow facility's policies and procedures. Always secure straps to the portion of the bed or gurney that moves with the patient. Do not secure straps to bed siderails, headboard, or footboard.
- Check the patient regularly per facility's policies and procedures to ensure circulation is not compromised.
- After device is placed on the patient, ensure that all three buttons of the tri-clip buckle are engaged. Incorrect insertion of the buckle may allow a patient to unintentionally exit the device.

CAUTIONS

- Ensure straps are not twisted or knotted during application.
- This device is to be prescribed by a licensed prescriber who is familiar with the purpose for which it is intended. The prescriber is responsible for providing application instructions and cautions to other healthcare providers involved in the patient's care.
- Consult licensed prescriber immediately if patient experiences sensation changes, unusual reactions, swelling or increased pain while using this device.
- Always follow facility's policies and procedures for patient monitoring and frequency. Failure to follow facility policies and procedures can result in harm to patient, family members, and/or staff.

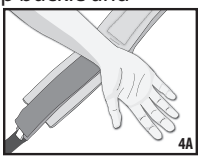
INSTRUCTIONS FOR USE

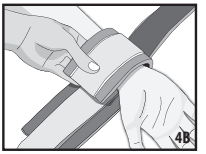
1. To secure the attachment strap to the bed or gurney, release the female end of the buckle and wrap the strap around the anchor. Pull the female portion through the looped portion of the strap.
2. Connect the male and female ends of the buckle until an audible click is heard. Ensure the buckle is securely engaged. Pull the excess strap to tighten.
3. Once straps are adjusted to the desired



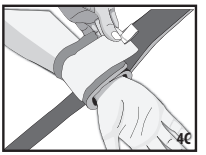
length, position the slide buckles flush against both sides of the tri-clip buckle to secure and prevent slippage. **NOTE:** For additional security, excess straps may be tied in a knot behind the buckle. Secure straps out of patient's reach.

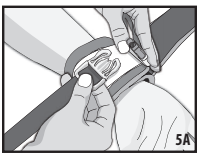
4. To secure the cuff on the patient, open the cuff by releasing the tri-clip buckle and hook and loop, utilizing the small white tabs. Wrap the cuff around the patient's wrist or ankle with the soft foam side touching the patient's skin, followed by the loop side to secure it to the hook. Attach the outermost hook tab to the loop.

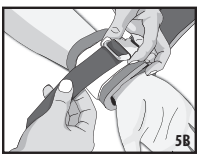




5. To secure the tri-clip buckle around the cuff, insert the male end into the female end of the buckle. Pull excess strap to tighten and secure the hook tab to the foam cuff, ensuring hook does not touch patient's skin. **NOTE:** The tri-clip buckle will release only when pressure is applied to all three buttons simultaneously.







DISPOSAL

Dispose of any used device according to local, state, and federal laws and regulations. For safe disposal of devices, follow facility's policies and procedures.

STORAGE AND TRANSPORT CONDITIONS

	KEEP DRY
	KEEP AWAY FROM SUNLIGHT

In addition to the competent authority in the country where the patient resides, serious incidents must be reported to DeRoyal Industries, Inc.

WARRANTY

DeRoyal® products are warranted for ninety (90) days from the date of shipment from DeRoyal as to product quality and workmanship. **DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

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