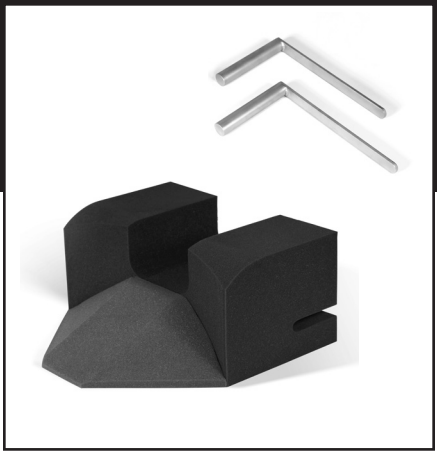
DeRoyal®



STEEP-T® APX™ PATIENT POSITIONING SYSTEM

	SINGLE PATIENT USE
MD	MEDICAL DEVICE
	NON-STERILE
	DO NOT USE IF PACKAGE IS DAMAGED
	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 product.

This product requires wide-body OR table rail clamps which accept flat mounting blades. STEEP-T® APX™ Patient Positioning System requires rail clamps rated for at least 550lbs.

Inspect hardware prior to use. **DO NOT** use if the securement bars appear to be damaged.

INTENDED USE

The STEEP-T APX Patient Positioning System is intended to help prevent unwanted movement when patients are in Trendelenburg positions while helping protect patients from nerve injuries, potential pressure injuries, and/or tissue breakdown.

INTENDED USERS

The STEEP-T APX Patient Positioning System is intended to be used by a licensed practitioner or healthcare professionals trained in steep-angled patient positioning.

PATIENT TARGET GROUP(S)

The STEEP-T APX Patient Positioning System is intended for pediatric and adult patients weighing 80 - 550lbs and undergoing procedures which utilize Trendelenburg positioning.

PRODUCT DESCRIPTION

The STEEP-T APX Patient Positioning System consists of a foam support pillow, two securement bars, and a chest strap with optional additional components such as a lift sheet or arm protectors.

CONTRAINDICATIONS

- **DO NOT** use on patients over 550lbs.
- This product may not be appropriate for patients who have severe kyphosis, have obstructions preventing direct contact with the neck, may not present with a discernible cervical notch, or have any other known conditions that would prevent them from proper positioning on the ramp and head opening.

⚠ WARNINGS

- **DO NOT** fold or compress the patient's ears when positioning the head in the cutout to reduce the risk of pressure injury or skin irritation.
- **DO NOT** exceed 40° Trendelenburg when using this product.
- Additional positioning equipment is required when the OR table is laterally tilted. Special attention should be given to the patient's head position to prevent hyper extending the neck.
- **DO NOT** attach the rail clamps and bars to the removable headrest / head section of the OR table.
- Additional positioning equipment is required when Reverse Trendelenburg positioning is used.
- Prior to use, inspect the kit components for damaged, missing, or contaminated components.
- Use only as directed.
- Confirm that rail clamps are free of defects and in good working order.
- Ensure securement bars are clean, dry, and in good working order.
- **DO NOT** use the kit without all components included in the kit. Both securement bars must be used at all times.
- Ensure kit components are installed correctly and the patient is properly positioned on the device to prevent movement and reduce the possibility of pressure injuries.
- Discontinue use if skin reaction occurs.
- **DO NOT** reuse single-use components.

ADVERSE REACTIONS

While adverse reactions are rare, the following are potential adverse reactions associated with the use of foam surgical positioners while the device is in use or associated with improperly cleaned reusable components:

- infection/sepsis
- allergic reaction to materials
- pressure injury

CAUTIONS

- Lift and support the patient when repositioning the positioning pillow and/or per facility protocol.
- All tests performed on this system utilized only original manufacturer components for the system - use of outside components could alter proper performance.
- Ensure the positioning pillow is clean and free of residue, and is attached securely to the OR table by fully tightening the rail clamps.
- Follow hospital's policies and procedures for patient monitoring.
- Discontinue use if device does not properly support patient.

DIRECTIONS FOR USE

1. Mount standard rail clamps to the side rails of the torso/back portion of the surgical table.
2. Insert the flat portion of the securement bars into the standard rail clamps, with the cylinder portion of the bar extending across the OR table. For ease of adjustment, **DO NOT** tighten the clamps at this step.
3. Place the positioning pillow on the OR table and insert the securement bars fully into the channels on the back of the pillow.
4. If included, place the lift sheet across the OR table. **DO NOT** place directly over the top of the ramp. If needed based on the patient positioning, the lift sheet can be placed underneath the ramp.
5. Transfer the patient onto the OR table. Move the pillow up or down the table to reposition.
6. Ensure patient is positioned with head in center cutout and that there is no more than a hands-width (0.25 in | 0.75 cm) gap between pillow and patient's shoulder. Visually confirm that the ramp is secure under the patient. If the product is not properly positioned, lift the head and slide the product forward to support the patient.
7. Once patient is properly positioned, ensure the securement bars are still fully in the channels on the back of the pillow and then secure the product to the OR table by fully tightening the rail clamps to the securement bars.
8. If included, secure the patient's arms using the lift sheet or foam arm protectors.
9. Place the chest strap across the patient and secure to the bed railing tautly.
10. Before procedure begins, do an assessment to ensure the patient is securely positioned, and that the surgical team is in agreement with the final patient positioning, or as per facility protocol.

CLEANING INSTRUCTIONS FOR SECUREMENT BARS

- Securement bars are reusable
- Follow hospital protocol for cleaning and disinfecting table accessories.
- The securement bars have not been evaluated for heat sterilization. Heat sterilization is not recommended for the securement bars.
- DeRoyal has validated that the following cleaning agents/solutions, or their equivalents, are acceptable for cleaning:
  - **a.** Oxivir® Tb Disinfectant
  - **b.** Dispatch® Hospital Cleaner Disinfectant
  - **c.** Super Sani-Cloth® Germicidal Wipes
  - **d.** Cavi-Wipes® Disinfecting Towelettes
  - **e.** 70% Isopropyl Alcohol Solution

DISPOSAL

The positioning pillow, chest strap, lift sheet (if used), and arm protectors (if used) are single patient use disposable. Dispose of any used components according to local, state, and federal laws and regulations. For safe disposal of devices, follow your facility's protocol.

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.**

Manufactured for:
DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849 USA
888.938.7828 or (001) 865.938.7828
www.deroyal.com

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